ESCO MEDICAL

CE

USER MANUAL

Multi-zone ART Workstation

Rev. 11.0
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Rx only

CERTIFIED INCUBATION

Esco Medical Technologies, UAB
Gamybos g. 2 • Ramuciai, Kauno r., 54468 Lithuania
Tel +370 37 470 000
www.esco-medical.com • support-medical@escolifesciences.com

For Technical Service, contact:

Europe
Esco Medical Technologies, UAB
Gamybos g. 2 • Ramuciai, Kauno r., 54468 Lithuania
Tel +370 37 470 000
www.esco-medical.com • support-medical@escolifesciences.com

North America
Esco Technologies, Inc.
903 Sheehy Drive, Suite F, Horsham, PA 19044, USA
Tel 215-441-9661 • Fax 484-698-7757
www.escolifesciences.us • eti.admin@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.escolifesciences.com • mail@escolifesciences.com

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 medical device. Check the shipping carton for damage. If the damage is found, stop unpacking the medical device. Notify the freight carrier and ask for an agent to be present while the medical device is unpacked. There are no special unpacking instructions, but be careful not to damage the medical device when unpacking it. Inspect the medical device 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 medical device 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 Technologies, UAB 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 Technologies, UAB 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 medical device has been thoroughly tested/inspected and found to meet Esco Medical Technologies, UAB manufacturing specifications when shipped from the factory.

Calibration measurements and testing are traceable and done according to Esco Medical Technologies, UAB ISO certification.

Warranty and Product Support

Esco Medical Technologies, UAB warrants this medical device to be free from defects in materials and workmanship under regular use and service for two (2) years from the original purchase date, provided the medical device is calibrated and maintained following this manual. During the warranty period, Esco Medical Technologies, UAB 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 Technologies, UAB. 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 Technologies, UAB.

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

Only CultureCoin® 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 medical device per Esco Medical Technologies, UAB specifications.

When you return the medical device to Esco Medical Technologies, UAB 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 medical device 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 medical device.

Esco Medical Technologies, UAB will not be responsible for lost shipments or medical devices 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 Technologies, UAB to obtain an RMA number and receive help with shipping/customs documentation.

Re-calibration of the medical device, which has a recommended annual calibration frequency, is not covered under warranty.

Warranty Disclaimer

If your medical device is serviced and/or calibrated by someone other than Esco Medical Technologies, UAB 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 medical device warranty. In an event where the seal must be broken to gain internal access to the medical device, you must first contact Esco Medical Technologies, UAB.

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

WARNING

Unauthorized user modifications or applications beyond the published specifications may result in an electrical shock hazard or improper operation. Esco Medical Technologies, UAB will not be responsible for any injury sustained due to unauthorized equipment modifications.

ESCO MEDICAL TECHNOLOGIES, UAB 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 MEDICAL DEVICE COVER SHALL VOID THIS AND ALL OTHER EXPRESSED OR IMPLIED WARRANTIES.

Table of contents

1 How to use this manual

The manual is designed to be read by sections and not ideally from cover to cover. It means that if the manual is read from start to finish, there will be some repetition and overlap. We recommend the following method for going through the manual: first, familiarize yourself with the safety instructions; then, proceed to the essential user functions that are needed for operating the equipment on a day-to-day basis; then, review the alarm functions. The menu functions of the user interface detail information that is required only for advanced users. All parts must be read before the device is taken into use. The validation guide is described in detail in sections 29 – 32. The maintenance guide is described in detail in section 33. The installation procedures are described in detail in section 34.

☞ **Digital versions of the English user manual and all translated versions are available on our website www.esco-medical.com.**

To locate the user manual, simply follow these steps:

1. Click on the "Products" tab in the navigation menu.
2. Scroll down and select "Multi-Zone ART Workstation".
3. Continue scrolling further down to find the "Literature & Resources" section.
4. Click on the "Information for Users" tab.

2 Safety warning

- Only personnel operating this equipment must read the user manual. Failure to read, understand and follow the instructions given in this documentation may result in damage to the device, injury to the operating personnel and/or poor equipment performance.
- Any internal adjustment, modification or maintenance to this equipment must be undertaken by qualified service personnel.
- If the equipment must be relocated, make sure it is appropriately fixed on a support stand or base and move it on a flat surface. When necessary, move the equipment and the support stand/base separately.
- The use of any hazardous materials in this equipment must be monitored by an industrial hygienist, safety officer or other suitably qualified individuals.
- Before you proceed, you must thoroughly read and understand the installation procedures and adhere to environmental/electrical requirements.
- If the equipment is used in a manner not specified by this manual, the protection provided by this equipment may be impaired.

- 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.

3 Intended purpose/use

The Multi-zone ART Workstation is a laminar flow workstation intended to work with gametes and/or embryos at or near body temperature during in vitro fertilization (IVF)/assisted reproduction technology (ART) procedures. The workstation also provides humidified gas to maintain gametes and embryos in the working environment.

4 About the product

The Multi-zone ART Workstation is a laminar flow workstation intended to work with gametes and/or embryos at or near body temperature during *in vitro* fertilization (IVF)/assisted reproduction technology (ART) procedures. The workstation also provides humidified gas to maintain gametes and embryos in the working environment.

The 12-zone heating system (8 x table plate and 4 x chambers) gives ideal temperature conditions compared to conventional layouts.

The system has 12 separate temperature controllers for maximum performance, controlling and regulating each zone's temperature.

The workstation has been primarily developed and designed to provide short-term tissue, gametes and embryos with an overlay of either Paraffin or mineral oil, incubation storage conditions.

If open culture is used, the user can utilize the humidified gas system built into the tabletop. The dish is placed under the gas hood where the pH conditions in a buffered media without oil overlay can be maintained.

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

An integral part of the Multi-zone ART Workstation is the All-in-one PC, which runs with the Workstation logger software. The software functions as a constant surveillance system that will give the user early warnings if any parameter drifts beyond safe limits.

The software includes data logging, data storage and report functions for ISO quality management compliance. The All-in-one PC can also be used for microscope camera imaging. Using a microscope camera will still warn the user by bringing an alarm notification to the screen while working with the microscope camera imaging.

Multi-zone ART Workstations are stationary devices. The term refers to equipment that, once installed and placed into service, is not intended to be moved from one place to another.

Only individuals with formal education in healthcare or medical discipline may work with Esco Medical MIRI® family's multiroom IVF incubators.

Esco Medical Multi-zone ART Workstations are used for *in vitro* fertilization (IVF) patients. Patients are women in their reproductive years who have fertility health issues. The intended target group indication is IVF treatment. There are no intended target group contraindications.

The device is manufactured under a full EU certified 13485 ISO quality management system.

This product fulfills EN60601-1 3rd edition standards as a Class I type B equivalent device suited for continuous operation. It also conforms to the EU Council directive's 2017/745 requirements concerning medical devices and is classified as a Class I device under annex VIII rule 13.

Personal Protective Equipment (89/686/EEC) and Machine Directive (2006/42/EC) is not applicable for Multi-zone ART Workstation. Also, the Multi-zone ART Workstation does not contain or incorporate: a medical substance, including a human blood or plasma derivate; tissues or cells, or their derivates, of human origin; or tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No. 722/2012.

5 Transport, Storage and Disposal

5.1 Transport

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

A visual inspection should be done if there is any damage. If there was no damage found, the Multi-Zone ART Workstation is prepared to be transported.

These labels should be glued on the box:

- Label with handling symbols and the marked packing date.

5.2 Storage and operation environment requirements

5.2.1 Storage requirements

The device may only be store under the following conditions:

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

⚠ **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.**

5.2.2 Operation environment requirements

The device may only be used under the following conditions:

- Operating humidity: 5 – 95% RH (Non-Condensing).
- Operating altitude – up to 2000 meters (6560 feet or 80kPa – 106kPa).
- Non-operating altitude – more than 2000 meters (6560 feet or more than 80kPa – 106kPa).
- Environmental temperature: 18 – 30 °C.
- Away from direct sunlight.
- Kept dry.
- For indoor use only.

⚠ **The device should not be installed or operated near windows.**

5.3 Disposal

Information on the handling of the device as per the WEEE Directive (Waste Electrical and Electronic Equipment).

⚠ **The device may have been used for treating and processing infectious substances. Therefore, the device and device components may be contaminated. Device must be disinfected or decontaminated prior to disposal.**

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

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

6 Supplied service parts and accessories

Service parts provided with the device are listed below:

- 1 × 0.22 µm HEPA filter for input gas supply (2 × 0.22 µm HEPA filters for models with built-in gas mixer).
- 1 × USB stick containing PDF version of the English version of the user manual and all available translations.
- 1 × gas hood for models without chambers or 2 for 6 ft DUAL model.
- 1 × carry tray for models without chambers or 2 for models with chambers. 1 carry tray per chamber.
- 1 × humidification bottle for 3 ft, 4 ft, 6ft single, 6ft MP and all gas mixing models or 2 for 6 ft DUAL model (premix model).
- 2 × medical grade power cords for 3 ft, 4 ft models or 3 for 6 ft DUAL model.
- 2 × heating optimization plates for models with chambers or 3 for 6 ft DUAL model.

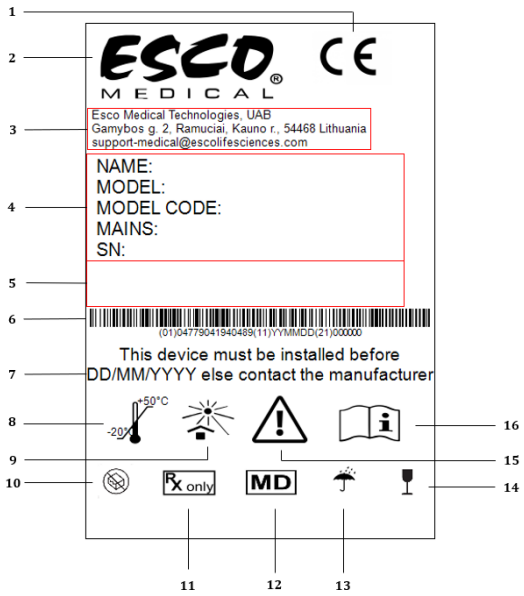
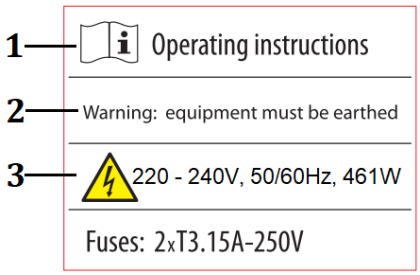
⚠ **Included service parts vary depending on the configuration of the device. For the exact part list, please refer to the Packing List document provided together with the device.**

Accessories do not apply with the Multi-zone ART Workstation.

7 Safety symbols and labels

Several user labels on the surface of the Multi-zone ART Workstation guide the user. User labels are shown below.

Table 7.1 Packing box and electrical safety labels

Description	Image
Packing box label for the Multi-zone ART Workstation: 1. CE mark. 2. Logo. 3. Manufacturer`s contact information. 4. Information about packed medical device (name, model, mains, serial number (SN), included dish type). 5. Free space for additional information. 6. UDI-DI code. 7. If stored longer than the shelf life, the device must be returned to the manufacturer for a new release test[1]. 8. Shipping temperature between -20 °C and +50 °C. 9. Keep away from direct sunlight. 10. Do not use it if the packing material is damaged. 11. Rx only. 12. Medical Device. 13. Keep dry. 14. Fragile. 15. 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. 16. Consult instructions for proper use of the device.	
1. View the instructions for use. 2. Warning on the back of the device indicates that an earth connection is needed and the mains information and an “ON/OFF” push button. 3. “Lightning bolt” indicates the potential risk of electrical shock (never remove any cover).	

[1] Applicable for MAW models with integrated gas-mixers only.

Table 7.2 Device label

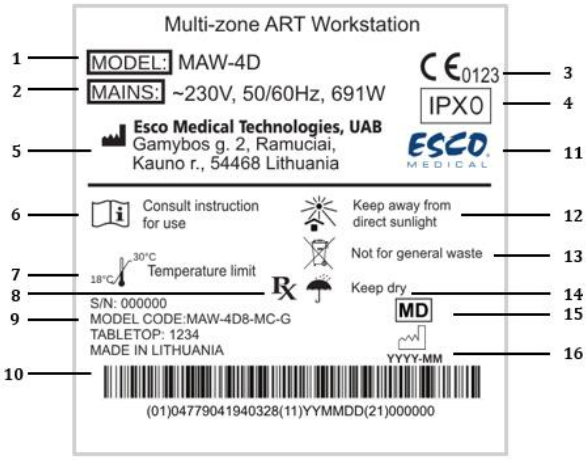
Description	Image
1. Model. 2. Mains power rating. 3. CE mark. 4. Not protected against the ingress of water. 5. Manufacturer's address and country of origin. 6. View instruction for use. 7. Upper limit of temperature. 8. Rx only. 9. Serial number, model code, tabletop and place of manufacture. 10. UDI-DI code. 11. Logo. 12. Keep away from direct sunlight. 13. Observe WEEE. 14. Keep dry. 15. Medical Device. 16. Year of manufacture.	

Table 7.3 Labels on the Multi-zone ART Workstation

Description	Image
PT 1000 validation sensors	
Gas sample ports	
PC on/off button	
Chambers numbers are indicated in the top corner of the lid with a label (only Multi-zone ART Workstation with chambers)	
Gas inlet on table plate (only Multi-zone ART Workstation without chambers)	
CO_2[2] and N_2 gas inlets (only for Multi-zone ART Workstation with a gas mixer).	
Ethernet	

The connected external device to signal input/output connections should be compliant with the appropriate safety standard for medical equipment EN 60601-1. It applies to USB and Ethernet connections.

[2] The user should connect the premix gas container to this inlet when intending to use the premix gas mode.

8 Important safety instructions and warnings

8.1 Before installation

1. Do not use the product if the package is damaged. Contact Esco Medical Technologies, UAB or the local Representative.
2. Read the User manual thoroughly before use.
3. Always keep these instructions easily accessible near the device.
4. Do not try to lift heavy equipment alone.
5. If a forklift is used, only lift on the custom-built pallet. The tabletop itself cannot withstand any lifting in the middle. Permanent damage will occur. Warranty void if this happens.
6. The electronics box under the tabletop is not flush with the rest of the underside. Any blows can result in permanent damage. Warranty void if this happens.

8.2 During installation

1. Never place this device on top of other equipment that might heat it.
2. Place this device on a flat, hard and stable surface.
3. Never place the device on a carpet or similar surfaces.
4. Do not defy 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. Always use an external HEPA filter to input CO_2 or premixed gases.
10. Do not use this product at temperatures exceeding 30°C.
11. Place this device 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.
12. This device is intended for indoor purposes only.

8.3 Post-installation

1. Refer all servicing to qualified service personnel.
2. Servicing is required according to the service manual and when the device 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 Multi-zone ART Workstation contains high voltage components that may be hazardous.

3. Unplug this device during lightning storms or when unused for an extended period of time.
4. Protect the power cord from being walked on or pinched, particularly at the plug, the socket and the point where it exits from the device.
5. Perform temperature and gas calibration at the intervals described in the manuals.
6. NEVER block gas supply holes in the tabletop.
7. Ensure that CO_2 or premixed gas supply pressures are kept stable between 0.4 – 0.6 bar (5.80 – 8.70 PSI).

9 Getting started

⚠ **The Multi-zone ART Workstation must be installed by authorized and trained personnel only!**

1. Follow the guidelines in the safety instructions and warnings section.
2. Connect the medical grade power cord to the top of the Workstation for the fan device to work.
3. Connect the medical grade power cord to the tabletop's underside for the PC and tabletop heating system to work.
4. Connect the gas lines.
5. Set gas pressure on the external gas regulator between 0.4 – 0.6 bar (5.80 – 8.70 PSI).
6. Switch on the Multi-zone ART Workstation with the switch under the tabletop (next to the medical grade power cord).
7. Power up the PC by pressing the button in the middle of the inner wall work area.
8. Observe for standard functionality.
9. Let the device warm up and stabilize for 20 min.
10. Follow the guidelines in the validation guide (refer to the “29 Validation guide” section of the User Manual).
11. Complete user training (instructions must be read prior to setting up the device).
12. After a burn-in phase of 24-hours, the device is ready to be used IF testing is **successful**.

☞ **Clean and disinfect the device before use. It is not delivered sterile or in a clinically acceptable clean state. Refer to the "20 Cleaning instructions" section of the User Manual for the manufacturer's recommended guidelines!**

10 Mains connection

The Multi-zone ART Workstation comes with a detachable medical grade power cord. The power cord is prepared for the country in which the device is intended to be used.

The ON/OFF switch provides the user with means to isolate the Multi-zone ART Workstation from the main power source.

⚠ **Do not defy the safety purpose of the grounding-type plug! A grounding-type plug has two blades and a prong, which is provided for your safety. If the provided plug does not fit into your outlet, consult an electrician to replace the outlet.**

The power requirement is 230V 50Hz OR 115V 60Hz. The built-in power supply has a switch-mode that automatically adjusts to the correct mains power between 100V-240V AC 50-60 Hz.

Figure 10.1 Power supply

11 Gas connection and the humidification system

Under the SINGLE type tabletop, one single gas input (black and blue) is located, whereas, under the DUAL type tabletop, two single gas inputs are located.

Figure 11.1 Gas inlet under Single tabletop

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

The N_2 inlet should be connected to 100% concentration N_2 if low oxygen conditions are required. The O_2 control in the chambers is available in the range from 5.0% – 20.0%. O_2 concentration control is achieved by infusing N_2 to push out excess O_2 in the gas system.

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

⚠ **Be wary of the Multi-Zone ART Workstation's type (premix or premix/gas mix) before connecting the gas supply.**

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

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

Figure 11.2 Pressure regulator

Connect the CO_2 gas to the CO_2 inlet with a suitable silicone tube. Ensure that the tube is fastened with a clip so that it does not accidentally loosen itself during sudden pressure fluctuation. Use the supplied 0.22µm HEPA filter on the gas line just before the inlet on the Multi-zone ART Workstation. Notice the direction.

Connect the N_2 inlet to the nitrogen gas canister in a similar way.

Figure 11.3 0.22µm external HEPA filter for incoming CO_2 / N_2 gas

The CO_2 inlet should be connected to a 5.0% or 6.0% premixed CO_2.

The gas flow can be controlled digitally with the keys on the back wall (only for models without the built-in gas mixer).

⚠ **Before turning on the flow, the valve in the gas canister must be opened!**

The gas will pass through the humidification system.

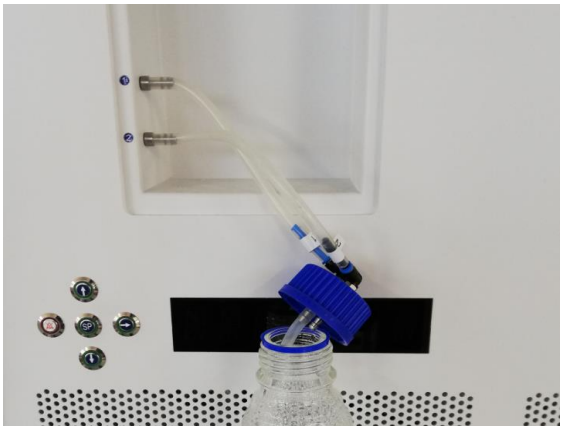


Figure 11.4 Humidification flask

Humidification flask tubes are marked with the number 1 and 2. Both outlets are marked in the same way. Flask tubes must be connected to outlets according to their number (number "1" tube should connect to the outlet marked with the same number).

Figure 11.5 Tubes connected to the flask

⚠ **If no humidification is required or wanted, an empty bottle without water should still be installed in Multi-zone ART Workstation models with a built-in gas mixer.**

Fill the flask with sterile water.

☞ **One-third of the humidification bottle should be filled with sterile water in order for the Multi-zone ART Workstation to work properly and maintain the required humidity in the system.**

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

11.1 Multi-zone ART Workstation without chambers

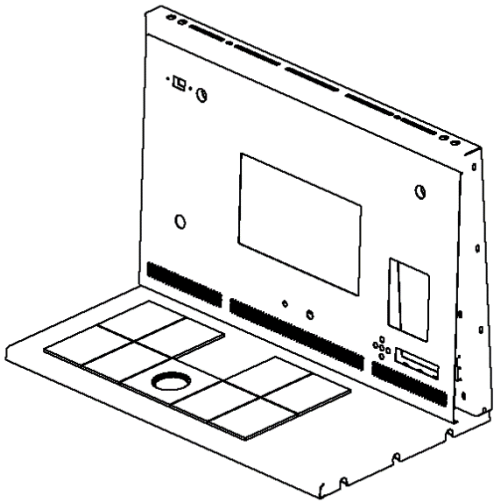


Figure 11.6 Multi-Zone ART Workstation without chambers

The gas will flow through the nozzle in the tabletop work area.

Figure 11.7 Gas nozzle in tabletop

A gas hood must be placed over the outlet. The constant flow will flush the environment so that the correct CO_2 concentration can be kept and thus, no pH drift will occur.

Figure 11.8 Gas hood placed over the gas nozzle

Keep the lids on the dishes when they are placed under the gas hood. The dishes can be placed directly on the warmed surface. A heating optimization plate can also be used. With the Carry Tray, several dishes can be conveniently transported between a CO_2 incubator and the Multi-zone ART Workstation.

Figure 11.9 Carry Tray

11.2 Multi-zone ART Workstation with chambers

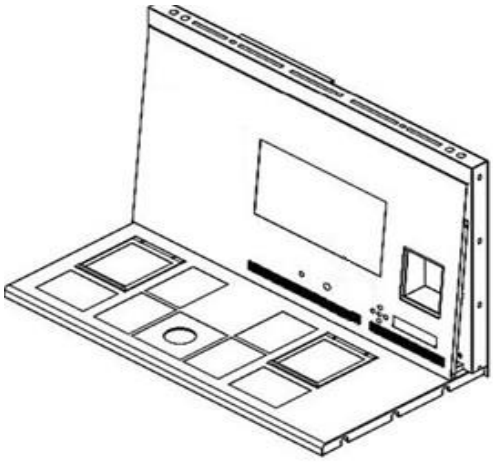


Figure 11.10 Multi-zone ART Workstation with chambers

The gas will flow through and will be circuited in both chambers by the internal FAN. The FAN will automatically start when the flow is set.

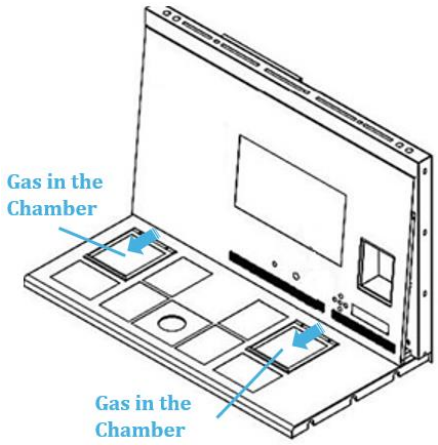


Figure 11.11 Gas flow in the chambers

Gas system overview

Required input gas type: premixed CO_2 gas. Check medium types for the correct mixture and validate the mixture with a gas analyzer before use.

Required input gas pressure: gas pressure on the external source should be 0.4 – 0.6 bar (5.80 – 8.70 PSI) and must be kept stable.

If the pressure falls below 0.3 bar (4.40 PSI) or rises above 0.7 bar (10.20 PSI), it will trigger the gas pressure alarm. If there is an alarm, remove the sample to a safe CO_2 incubator and investigate the alarm's cause.

The gas flow setpoint can be adjusted in the range from 0 l/h to 40 l/h (by increments of 1 l/h).

When the gas flow is active, the user can turn on the "Purge" function by pressing the up (⇧) key when the status in the menu shows the "FLW 1". The gas flow of 40 l/h will be switched on for 5 min.

The correct flow rate is a balanced with the intention of maintaining the correct pH level while at the same time minimizing the gas usage and improving economy. With the increased flow rate, it is easier to maintain correct gas concentration and provide rapid gas recovery. However, it also increases gas consumption. So, the flow rate can be adjusted to a level where the medium's pH is still maintained, and the gas consumption is as low as possible. Only a validation test locally can decide this for the specific medium. Also, be sure to check the medium manufacturer's recommendations before adjusting the flow rate in your Multi-zone ART Workstation.

11.3 Multi-zone ART Workstation with chambers and a built-in gas mixer

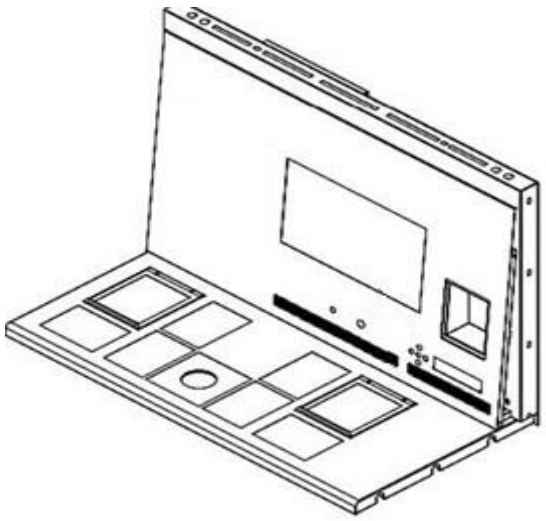


Figure 11.12 Multi-zone ART Workstation with chambers and a built-in gas mixer

The gas will flow through and will be circuited in both chambers by the internal FAN. CO_2 and O_2 sensors will provide gas concentration control.

Gas system overview

Required input gas type: pure CO_2 and N_2 gas. Also, there is a possibility to use premixed CO_2 gas.

Required input gas pressure: gas pressure on the external source should be 0.4 – 0.6 bar (5.80 – 8.70 PSI) and must be kept stable.

If the pressure falls below 0.3 bar (4.40 PSI) or rises above 0.7 bar (10.20 PSI), it will trigger the gas pressure alarm. If there is an alarm, remove the sample to a safe CO_2 incubator and investigate the alarm's cause.

The CO_2 gas concentration setpoint can be adjusted from 3.0% to 10.0% (by increments of 0.1 %). The N_2 gas concentration setpoint can be adjusted from 5.0% to 20.0%. An audible alarm will start when the gas concentration in chambers differ ± 1% from the setpoint.

☞ **If premixed gas is intended to be used instead of pure gas, refer to trained personnel for help!**

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

⚠ **O_2 control TURNS OFF when premix mode is activated.**

☞ **Be advised that premixed gas consumption will be significantly higher compared to pure gas. Also, recovery to the setpoint will be longer.**

12 User interface

The main keys and their purpose are presented in Table 12.1.

Table 12.1 The main keys and their purpose

Description	Image
Main keys	
ON/OFF keys Located in the REAR of the device	
Alarm button It is used to mute an audible alarm and visually indicate the alarm condition by a flashing red backlight. 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 device. The display consists of 7 x high brightness 16 segment LEDs. The 1st LED is red, which indicates a user warning. The other 6 LEDs are blue and used to display normal running conditions.	
Setpoint key It is used to select items on the menu to change their status. It is also used to change the temperature and gas setpoints	
Arrow keys up, down & right They are used to navigate through the menu and change the values for temperature and gas concentrations	

12.1 Activating heat and gas controls

The main controls are activated using the “ON/OFF” switch under the tabletop.

12.2 System menu

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

Navigate in menu using:

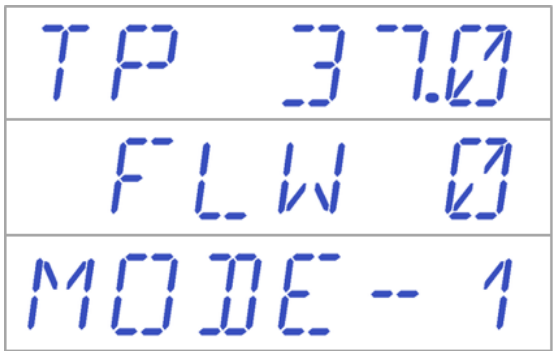
- Arrow right (⇨) key = enter.
- Up (⇧) and Down (⇩) arrow keys = previous OR next.
- SP/Enter key = change OR accept.

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

12.3 Status

12.3.1 Models without a built-in gas mixer

Soon after system activation, the main display will alternate the reading between the following parameters. Scroll between the parameters with the (⇨) key.



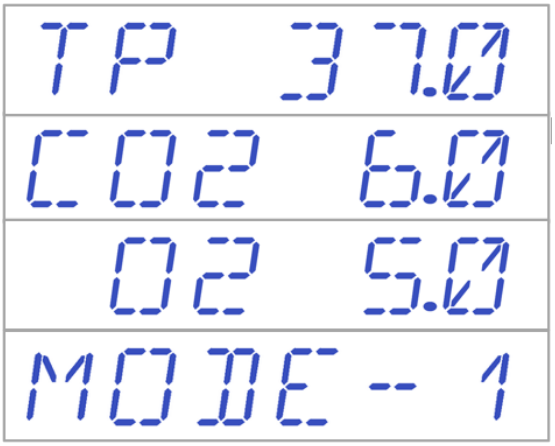
There is an additional culture mode parameter in the Multi-zone ART Workstation and models with chambers. The display shows:

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

If the Multi-zone ART Workstation has chambers, after the display shows “TP 37.0”, the user can see the chamber's temperature (CP) by pressing the (⇧) key. Then the display will show:

12.3.2 Models with a built-in gas mixer

Soon after system activation, the main display will alternate the reading between the following parameters. Scroll between the parameters with the (⇨) key.



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

If the Multi-zone ART Workstation has chambers, there is an additional culture mode parameter:

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

If the Multi-zone ART Workstation has chambers, after the display shows “TP 37.0”, the user can see the chamber's temperature by pressing the (⇧) key. Then the display shows:

12.4 Main menu

There are two main menus in the Multi-zone ART Workstation **depending on whether it has a built-in gas mixer or not**.

12.4.1 Main menu (only for models without a built-in gas mixer)

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

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

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

12.4.2 Main menu (only for models with a built-in gas mixer)

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

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

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

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

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

12.5 Sub-menus

12.5.1 Temperature sub-menu

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

Calibrate the temperature by holding down the SP key and using (⇧) and (⇩) keys to adjust the setpoint values. The first item in the temperature sub-menu is T1 sensor calibration:

Use (⇩) or (⇧) keys to move between the sub-menu items. You can also go back to the main menu by pressing the (⇧) key when the menu shows "T1 CAL".

Example – how to calibrate the temperature:

During calibration, the temperature must 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, press and hold the SP key. The display should show:

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

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

⚠ **Calibration value change procedure should only be done with a calibrated device and by a trained user or the technician, according to specific measurements.**

Exit the menu by pressing the (⇧) key.

12.5.2 CO_2 sub-menu (only for models with a built-in gas mixer)

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

Calibrate the CO_2 by holding down the SP key and using (⇧) and (⇩) keys to adjust the setpoint value. Use (⇩) or (⇧) keys to move between the sub-menu items. You can also go back to the main menu by pressing the (⇧) key when the menu shows "CO2.CAL".

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

The default status for the CO_2 control is OFF.

Press the (⇩) key to move to the next item in the CO_2 sub-menu. Here you can see the CO_2 flow rate display (the flow rate cannot be adjusted):

It shows the present flow of CO_2 gas through the flow sensor. The volume is shown in liters/hour. It will usually change depending on the current concentration of CO_2 in the system.

Press the (⇩) key to move to the next item in the CO_2 sub-menu. Here you can see the CO_2 internal pressure (it cannot be adjusted on the Multi-Zone ART Workstation. It is adjusted on the external gas regulator):

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

Example – how to calibrate CO_2:

CO_2 gas concertation must 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. Every port is suitable for this purpose.

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

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

☞ **CO_2 gas recovery to 5% is less than 3 minutes while inflating 100% CO_2 gas.**

☞ **Calibration is performed by adjusting the CO_2 concentration according to the gas sampling outlet's measurement by an external reliable CO_2 measurement device.**

⚠ **Calibration value change procedure should only be done with a calibrated device and by a trained user or the technician, according to specific measurements.**

Exit the menu by pressing the (⇧) key.

12.5.3 O_2 sub-menu (only for models with a built-in gas mixer)

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

Calibrate O_2 by holding down the SP key and using (⇧) and (⇩) keys to adjust the setpoint value. Use (⇩) or (⇧) keys to move between the sub-menu items. You can also go back to the main menu by pressing the (⇧) key when the menu shows "O2 CAL".

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

The Default status for the O_2 control is OFF.

Press the (⇩) key to move to the next item in the CO_2 sub-menu. Here you can see the N_2 flow rate display (the flow rate cannot be adjusted):

It shows the present flow of N_2 gas through the flow sensor. The volume is shown in liters/hour. It will usually change depending on the current concentration of O_2 in the system.

Press (⇩) key to move to the next item in the O_2 sub-menu.

Here you can see the O_2 internal pressure (it cannot be adjusted on Multi-Zone ART Workstation. It is adjusted on the external gas regulator):

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

Example – how to calibrate the O_2:

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

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

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

Calibration is performed by adjusting the O_2 concentration according to the gas

sampling outlet's measurement by an external reliable O_2 measurement device.

Calibration value change procedure should only be done with a calibrated device and by a trained user or the technician, according to specific measurements.

Exit the menu by pressing the (⇧) key.

12.5.4 Service sub-menu

Press the (⇨) key on the service menu to enter the service sub-menu.
The service sub-menu is locked as default.

If the right (⇨) arrow key is pressed for longer than 10 sec., the service menu will be unlocked, and the display will show the current firmware version number:

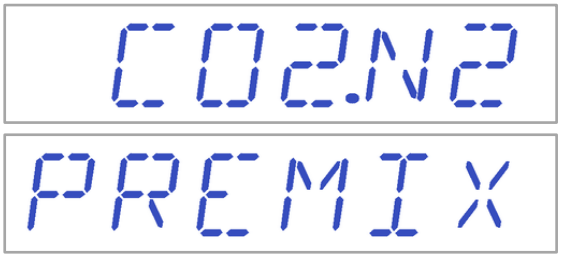
Ver 2.0 is only shown as an EXAMPLE. Please refer to the "17 Firmware" section of the User Manual for the latest firmware version.

Use (⇩) or (⇧) keys to move between the sub-menu items.

The display will show the "GAS" function:

Press the (⇨) key to enter and press (⇩) or (⇧) keys to choose "PREMIX" or "CO_2/N_2" options. When the desired gas mode is shown, press the SP key and select between the "PREMIX" or "CO_2/N_2" gas modes by pressing (⇩) or (⇧) keys. Let go of the SP key when the desired gas mode is displayed. It will be now stored.

When choosing the gas mode, screen will alternate between:



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

O_2 control TURNS OFF when premix mode is activated.

Exit the menu by pressing the (⇧) key.

13 Alarms

In the case of an alarm condition, alarm button and an audible alarm signal will turn on while the corresponding alarm(s) will be visible on the segment display matrix. An audio signal can be muted by pressing the alarm button once (muted ON/OFF for 5-minutes). A red “A” will be displayed on the LED matrix, followed by an alarm cause and an arrow pointing up or down (depending on the nature of the alarm condition) and the value of the alarm cause. For example: if temperature is too low in chamber 1, the display will show "A1↓ 36.3". The alarm button backlight will pulse if at least one error condition is present in the system.

Figure 15.1 Alarm button that indicates the alarm condition

The audio pattern is 3 and 2 short beeps separated by a 1-second pause. All alarms have the same audio pattern. The audio sound pressure level is 61.1 dB(A).

Make sure that the ambient sound pressure level does not exceed 62 dB(A) because the user will not hear the alarm!

13.1 Temperature alarms

All 12 heating zones can trigger a temperature alarm if their temperature varies over ±0.5

°C from the setpoint.

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

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

Temperature is too high in heating zone 3:

Temperature is too low in heating zone 1:

The display will indicate the errors only while the audible alarm is on. If the audible alarm is muted using the alarm button, the alarm menu will be turned off and the user menu will be available. The audible alarm will restart after 5 minutes, and the display will show the alarm menu again until the alarm button is pressed. The mute alarm button will still show the alarm condition by blinking red while the alarm is muted.

Please refer to the "26 Emergency procedure" section of the User Manual on how to behave when there is a temperature alarm.

The zone layout and sensor placement are described in the section “15 Surface temperatures and measuring temperature”.
If a temperature sensor malfunctions, it will be indicated by the following warning:

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

13.2 Gas concentration alarms (only for models with a built-in gas mixer)

13.2.1 CO_2 alarms

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

Remember that changing the setpoint more than ± 1% from the current gas concentration will result in a gas concentration 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 button 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 button will still show the alarm condition by blinking red while the alarm is muted.

Please refer to the "25 Emergency procedure" section of the User Manual on how to behave when there is a CO_2 concentration alarm.

13.2.2 O_2 alarms

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

Remember that changing the setpoint more than ±1% from the current gas concentration will result in a gas concentration 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 button 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 button will still show the alarm condition by blinking red while the alarm is muted.

Please refer to the "25 Emergency procedure" section on how to behave when there is an O_2 concentration alarm.

13.3 Gas pressure alarms

13.3.1 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, Multi-zone ART Workstation will go into CO_2 pressure alarm mode. The display will show “CO2 P”, which indicates an incorrect incoming gas pressure. If the pressure falls below 0.3 bar (4.40 PSI) or rises above 0.7 bar (10.20 PSI), it will trigger the alarm.

“P” stands for pressure.

The display will lock on the alarm condition and will stop alternating between the standard status messages. If the mute button 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 button will still show the alarm condition by blinking red while the alarm is muted.

Please refer to the "25 Emergency procedure" section of the User Manual on how to behave when there is a CO_2 pressure alarm.

13.3.2 N_2 pressure alarm (only for models with built-in gas mixer)

If the N_2 gas supply is not attached correctly or incorrect N_2 gas pressure is applied to the system, Multi-zone ART Workstation will go into N_2 pressure alarm mode. The display will show “N2 P”, which indicates an incorrect incoming gas pressure. If the pressure falls below 0.3 bar (4.40 PSI) or rises above 0.7 bar (10.20 PSI), it will trigger the alarm.

“P” stands for pressure.

The display will lock on the alarm condition and will stop alternating between the standard status messages. If the mute button 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 button will still show the alarm condition by blinking red while the alarm is muted.

Please refer to the "25 Emergency procedure" section of the User Manual on how to behave when there is an N_2 pressure alarm.

13.4 Multiple alarms

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

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

Please refer to the "25 Emergency procedures" section on how to behave when there is a multiple alarm.

13.5 Summary of alarms

In the table below, there is a list of every possible alarm in the Multi-zone ART Workstation.

Table 13.1 Every possible alarm in the Multi-zone ART Workstation

Alarm name	Conditions	How it is determined	Alarm group	Alarm priority
Low-temperature alarm	If the temperature falls below 0.5 °C from the SP. It is applicable for all chamber's bottom temperature	Each temperature zone sensor reading	Technical	High priority alarm
High-temperature alarm	If the temperature rises above 0.5 °C from the SP. It is applicable for all chamber's bottom temperature			
Low CO_2 concentration[3]	When the CO_2 concentration drops by 1% from the SP, after 3 min the alarm will turn on	CO_2 sensor reading		
High CO_2 concentration[3]	When the CO_2 concentration rises by 1% from the SP, after 3 min the alarm will turn on			
Low O_2 concentration[3]	When the O_2 concentration drops by 1% from the SP, after 5 min the alarm will turn on	O_2 sensor reading		
High O_2 concentration[3]	When the O_2 concentration rises by 1% from the SP, after 5 min the alarm will turn on			
Low incoming CO_2 pressure	If the pressure falls below 0.3 bar	Pressure sensor reading		
High internal CO_2 pressure	If the pressure rises above 0.7 bar			
Low incoming N_2 pressure[3]	If the pressure falls below 0.3 bar			
High internal N_2 pressure[3]	If the pressure rises above 0.7 bar			

[3] Only for Multi-zone ART Workstation models with a built-in gas mixer

13.6 Alarm verification

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

Table 13.2 Alarm verification in the Multi-zone ART Workstation

Alarm name	How to verify an alarm	When to verify an alarm
High-temperature alarm	Decrease the setpoint value by 3.0 °C from the current setpoint	If you have a suspicion that alarms are malfunctioning
Low-temperature alarm	Put cold metal part in the middle of the heating zone	
High CO_2 concentration	Decrease the setpoint value by 3.0% from the current setpoint	
Low O_2 concentration[4]	Increase the setpoint value by 3.0% from the current setpoint	
High O_2 concentration[4]	Open the lid and leave it open for 5 min	
Low CO_2 concentration	Open the lid and leave it open for 3 min	
Low incoming CO_2 pressure	Disconnect the incoming CO_2 gas	
Low incoming N_2 pressure[4]	Disconnect the incoming N_2 gas	

14 Changing the setpoints and the heating mode

14.1 Temperature setpoint

The temperature setpoint can be adjusted in the range from 25 °C to 40.0 °C.

☞ **The default temperature setpoint is 37.0 °C.**

To change the temperature setpoint, follow these instructions:

1. When the display shows the current temperature:

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

If the display does not show the current temperature reading, the (⇨) key will toggle between temperature, gas flow setpoint and heating mode.

[4] Only for Multi-zone ART Workstation models with a built-in gas mixer

14.2 Gas flow setpoint (only for models without a built-in gas mixer)

The gas flow setpoint can be adjusted in the range from 0 l/h to 40 l/h.

To change the gas flow setpoint, follow these instructions:

1. When the display shows the current gas flow:

2. Hold down the SP key and use (⇧) and (⇩) keys to adjust the setpoint: one keypress corresponds to a 1 l/h change.
3. After changing the gas flow, let go of the SP key. The value is now stored.

If the display does not show the current gas flow setpoint reading, the (⇨) key will toggle between temperature, gas flow setpoint and heating mode.

14.3 CO_2 gas concentration setpoint (only for models with a built-in gas mixer)

The CO_2 concentration can be adjusted in the range between 3.0% to 10%.

The default CO_2 setpoint is 6.0%.

To change the CO_2 concentration setpoint, follow these instructions:

1. When the display shows the CO_2 gas concentration:

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

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

14.4 O_2 gas concentration setpoint (only for models with a built-in gas mixer)

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

The default O_2 setpoint is 5.0%.

To change the O_2 concentration setpoint, follow these instructions:

1. When the display shows the O_2 concentration:

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

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

14.5 Heating mode

The table plate has 4 heating modes.

To change heating mode, follow these instructions:

1. When the display shows the current heating mode:

2. Hold down the SP key and use (⇧) and (⇩) keys to adjust the heating mode.
3. After changing the heating mode, let go of the SP key. The mode is now stored.

Mode 1:

All zones and chambers (depending on the configuration) are “ON” and controlled. The zones are heated up to the temperature setpoint.

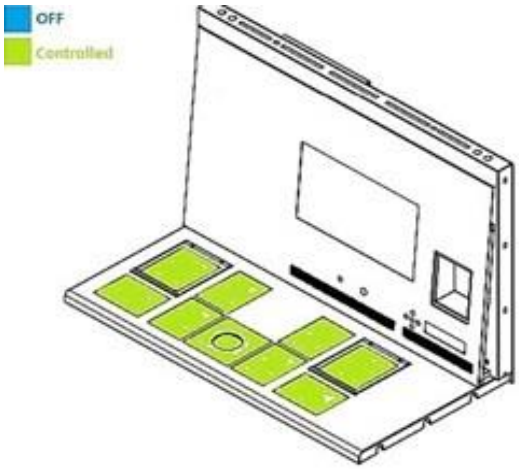


Figure 14.1 Mode 1

Mode 2:

Both chambers are “ON” and controlled.

The left side and the middle zone are “ON” and controlled.

The right side of the area is “OFF”; as shown in the picture below, all other zones are heated up to the temperature setpoint.

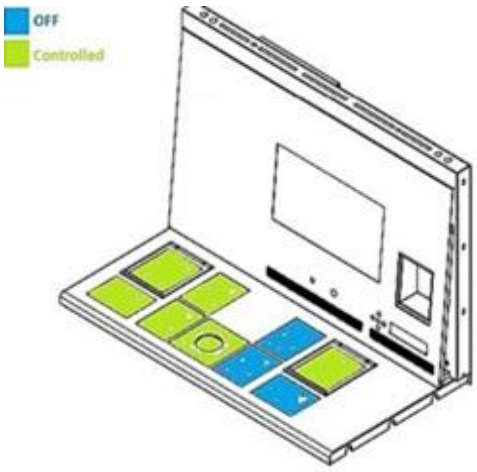


Figure 14.2 Mode 2

Mode 3:

Both chambers (depending on the configuration) and the left side of the table plate are "ON" and controlled.

The middle zone and right-side area are "OFF", as shown in the picture below.

All other zones are heated up to the temperature setpoint.

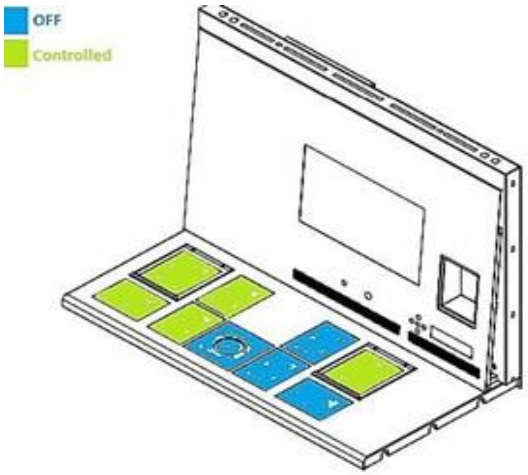


Figure 14.3 Mode 3

Mode 4:

Both chambers (depending on the configuration) are "ON" and controlled.

The rest of the table plate is "OFF," as shown in the picture below.

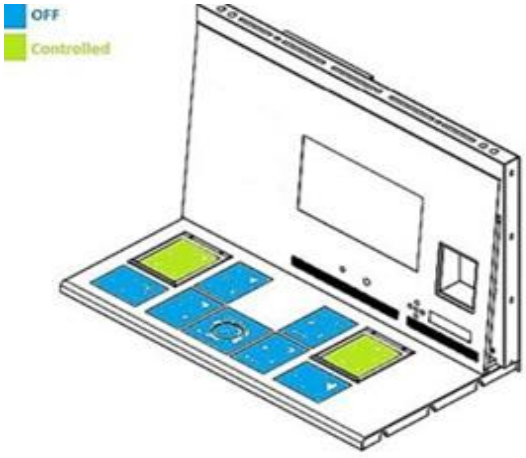


Figure 14.4 Mode 4

15 Surface temperatures and measuring temperature

In this section, the Multi-zone ART Workstation temperature control system is described in more detail.

Multi-zone ART Workstation is equipped with 12 completely separate PID controllers for temperature measurement. Each controller is responsible for controlling the temperature of a separate area.

Each of the 12 available areas is equipped with a separate temperature sensor and heater, allowing the user to adjust the temperature in every area separately, thus achieving higher precision.

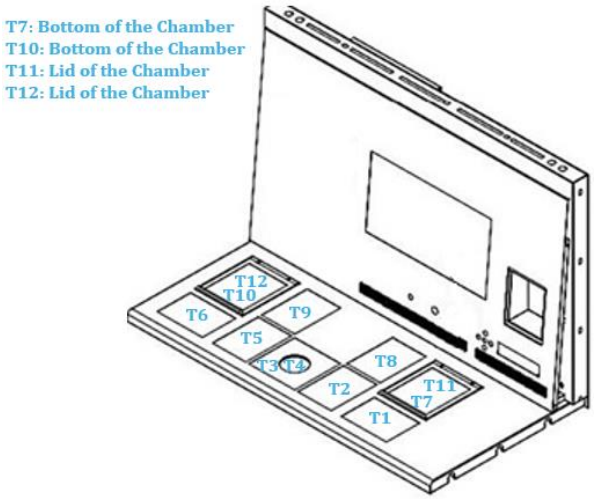


Figure 15.1 PID controllers on the table plate

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

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.

Esco Medical Technologies, UAB recommends using only a suitable and calibrated device with a precision of at least 0.1 °C.

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

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

☞ **Tape the calibrated thermometer sensor to the middle of the zone. It may be necessary to do iterations before the zone is thoroughly calibrated.**

☞ **Heating modes do not affect the chambers.**

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 12 zones when adjusted to temperatures within 0.5 °C. At more considerable temperature differences, the hotter zone will affect the colder zone.**

☞ **How to calibrate the temperature at the T1 area can be found in the "12.5.1 Temperature sub-menu" section the User Manual.**

16 Pressure

16.1 CO_2 gas pressure

The CO_2 pressure can be viewed in the CO_2 sub-menu:

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

☞ **There is a pressure alarm set for pressure limits. The alarm goes off when pressure falls below 0.3 bar or rises above 0.7 bar (4.40 - 10.20 PSI).**

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

16.2 N_2 gas pressure

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

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

There is a pressure alarm set for pressure limits. The alarm goes off when pressure falls below 0.3 bar or rises above 0.7 bar (4.40 - 10.20 PSI).

The internal pressure sensor cannot be calibrated by the user. Under normal circumstances, the pressure sensor is replaced every 2 years in accordance with the maintenance plan.

17 Firmware

The firmware installed on your Multi-zone ART Workstation 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 device:

1. Press the (⇨) key on the service menu to enter the service sub-menu.
   The service sub-menu is locked as default.

2. If the right (⇨) arrow key is pressed for longer than 10 sec., the service menu will be unlocked, and the display will show the current firmware version number:

Ver 2.0 is only shown as an **example**.

The current 4-ft Multi-zone ART Workstation's with a built-in gas mixer firmware version is **3.0.3**; 6-ft DUAL Multi-zone ART Workstation's with a built-in gas mixer firmware version on the right side is – **3.0.5** and on left side is **3.0.1**; all Multi-zone ART Workstations without a built-in gas mixer (premix only) has the firmware version **3.1.1**.

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

18 The Laminar Flow

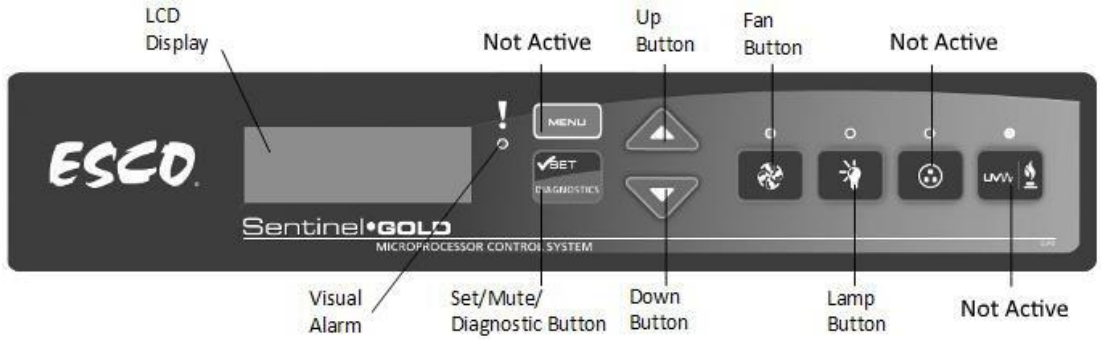


Figure 18.1 Main keys

- "Fan" button – turns on and turns off the fan. It activates standby mode.
- "Lamp" button – turns on and turns off the fluorescent lamps.
- "Socket" button – not active for the user.
- "UV/Gas" button – not active for the user.
- "Menu" button – enters the menu. It works like the "Back" button as well.
- "Set/Mute/Diagnostic" button – select folder/enter the parameter button.
- "UP/Down" buttons – scroll through the menu.

There are only 3 user functions available: turning the laminar airflow "ON/OFF", activating standby flow mode, and turning the interior light "ON/OFF".

19 Cleaning instructions

19.1 Considerations about a sterile device

Multi-zone ART Workstation is not a sterile device. It is not delivered in a 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 and not contaminate the key components.

These cleaning instructions are for general-purpose use and have not been validated for sufficiency to cover all possible usage aspects and all imaginable use scenarios.

The design features intended to provide cleanliness are:

- A ULPA filtered laminar airflow.
- A flush stainless-steel work surface.
- Use of parts that withstand cleaning well.

19.2 Manufacturer's 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 using alcohol-free detergents is recommended for event-related concerns such as media spills, visual accumulation of soil and/or other evidence of contamination. It is also recommended to clean and disinfect the Multi-Zone ART Workstations immediately after any media spills.

Periodic cleaning of the device (with no embryos inside)

Wearing gloves and GLP (good laboratory practice) techniques are essential to the successful cleaning of the device.

1. Clean the incubator with a suitable detergent that does not contain alcohol, i.e. benzyl-alkyldimethyl chloride. Wipe external device surfaces with wipes and repeat the process until the wipes are no longer discolored.
2. After cleaning leave the device for some time to ensure that all detergent fumes have evaporated.
3. Change your gloves and after 10 minutes of contact time, spray sterile water on the surfaces and wipe them with a sterile wipe.
4. Once it is visually clean, it is ready to be used again.

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

19.3 Manufacturer's recommended disinfection procedure

Disinfection of the device (with no embryos inside)

Wearing gloves and GLP (good laboratory practice) techniques are essential to the successful disinfection of the device.

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 Multi-zone ART Workstation (underside panel).
2. Open the lids (in Multi-zone ART Workstation with chambers).
3. Use the required disinfectant that does not contain alcohol, i.e. benzyl-alkyldimethyl chloride, to disinfect the internal surface and a glass plate on the lid's top. Use sterile wipes to apply the disinfectant.
4. Wipe all internal surfaces and the top of the lid with wipes and repeat the process until the wipes are no longer discolored.
5. Change your gloves, and after 10 minutes of contact time, spray sterile water on the surfaces and wipe them with a sterile wipe.
6. Inspect the device – if it is visually clean, consider it ready for use. If the device is visually not clean, go to step 3 and repeat the procedure.
7. Turn on the Multi-zone ART Workstation (underside panel).

20 Heating optimization plates/Carry Trays

The heating optimization plate and carry tray will ensure full contact with the dish. It generally means much more stable temperature conditions for the cells. The carry tray fits the area under the gas hood. The heating optimization plate is used inside MIRI® chambers. Both plates can be taken out for cleaning and serve as a convenient way to carry several dishes between the CO_2 incubator and the Multi-zone ART Workstation.

⚠ **Do not autoclave the heating optimization plates and carry tray. It will damage the plates as high temperature bends them out of shape.**

Place the dish where it fits the pattern. There are carry trays for Nunc™ or Falcon® dishes, while heat optimization plates – Nunc™, Falcon®, Oosafe®, Vitrolife® and BIRR® dishes. Additionally, there is a plain version of the heating optimization plate.

☞ **Use only the correct type of heating optimization plate/carry tray heating optimization plates for your dishes.**

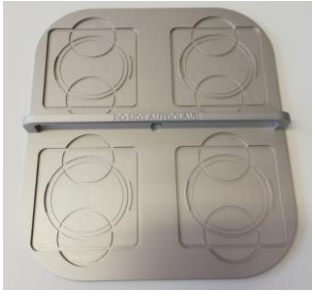


Figure 20.1 Carry Tray

21 Humidification

If the Multi-zone ART Workstation is used for open culture conditions, humidification and gas hood are recommended.

If the Multi-zone ART Workstation is used for culturing with a mineral overlay, it is unnecessary to use the humidification system.

The Multi-zone ART Workstation design does not allow active control of humidity levels in circulated gas. The humidification method used in the Multi-zone ART Workstation increases circulating gas' humidity, which will decrease evaporation risks in the media of Petri dishes placed in the chambers. Usually one should expect that the humidification level in the Multi-zone ART Workstation chambers would stabilize around 45 – 50%.

☞ **One-third of the humidification bottle should be filled with sterile water for the Multi-zone ART Workstation to work properly and maintain the required humidity in the system.**

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

☞ **The humidification bottle can be autoclaved. We recommend sterilizing the bottle as a monthly routine procedure in your lab to avoid microorganism contamination.**

22 Temperature validation

The single 3 ft and 4 ft Multi-zone ART Workstation has 5 PT-1000 Class B sensors, whereas the dual 6ft Multi-zone ART Workstation has 9. 5 sensors are on the left side of the table plate and 4 are on the table plate's right side.

Each zone has an extra sensor for validation (zone 1, 2, 3, 5, 6). These sensors are not connected to any of the electronics on the device. The user can connect an external device to validate the temperature readings.

PT-1000 Class B sensors are located in the central positions of the bottom zones and are connected to a connector inside of the table plate as shown:

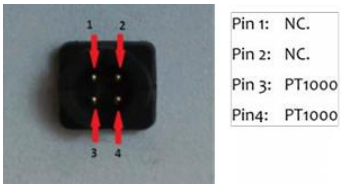


Figure 22.1 Pin

Esco Medical Technologies, UAB or your distributor can supply a connector and wire.

The zones' temperature conditions can be logged continuously externally through the connectors without compromising the device's performance. Any logging system that uses standard PT-1000 sensors can be used.

Esco Medical Technologies, UAB can supply an external logging system for the sensors.

23 All-in-one PC

The single Multi-zone ART Workstation is equipped with one powerful touch-enabled AIO PC, whereas dual Multi-zone ART Workstation has 2 AIO PCs. To power your PC, simply press the button located below the screen. This button can be used to turn the PC ON or OFF.

Figure 23.1 The AIO PC screen in Multi-zone ART Workstation

The initial step is to turn on the PC, which will then load the Windows operating system. The workstation logger surveillance software will automatically generate parameters, and warnings that will be shown on the screen.

23.1 Data Logger Software

Under normal working conditions, on the PC display, the user should see these numeric values:

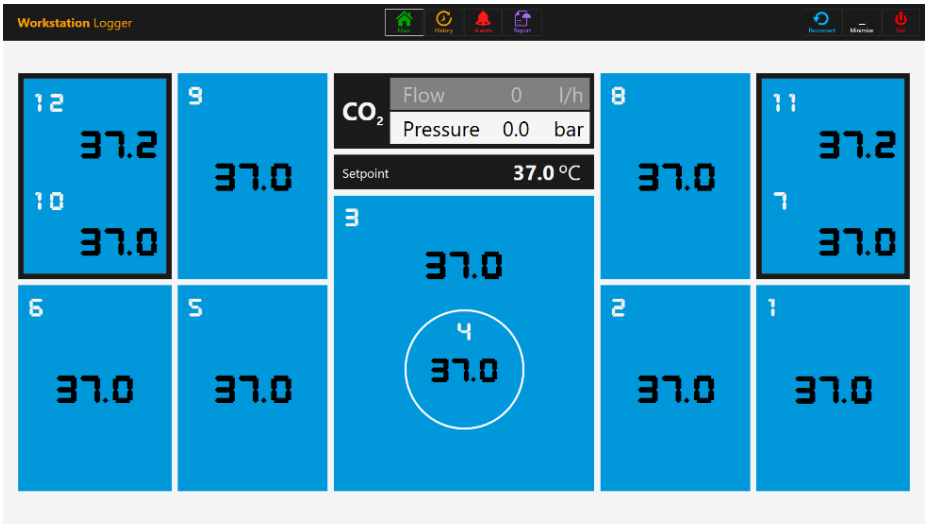


Figure 23.2 The Workstation Logger view under normal working conditions (without a gas mixer)

For Multi-zone ART Workstation models with a built-in gas mixer, the main display also shows the CO_2 concentration, CO_2 flow, CO_2 pressure, O_2 concentration, N_2 flow, N_2 pressure, CO_2 and O_2 setpoints, active gas mode (mix or premix) and culture mode (under oil culture or open culture).

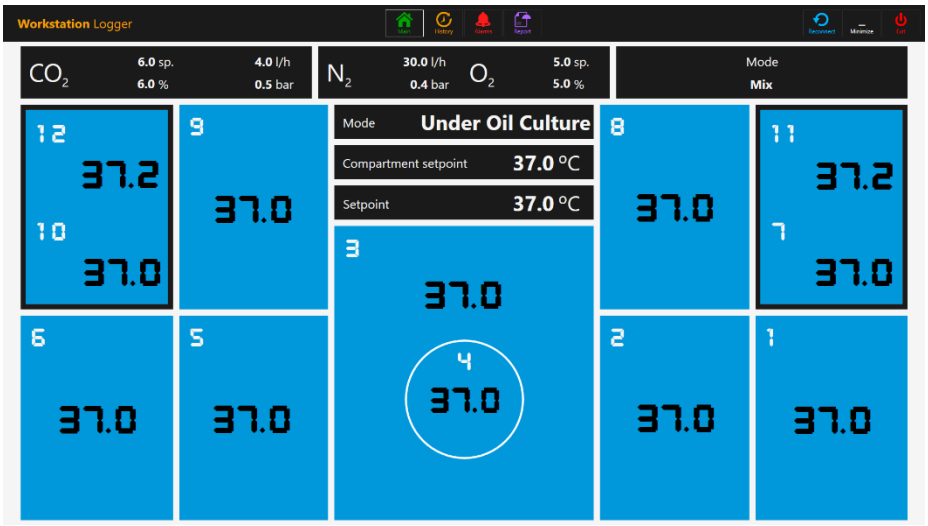


Figure 23.3 The Workstation Logger view under normal working conditions (with a gas mixer)

There is also a second display, which only shows culture mode, chamber setpoint and temperature setpoint.

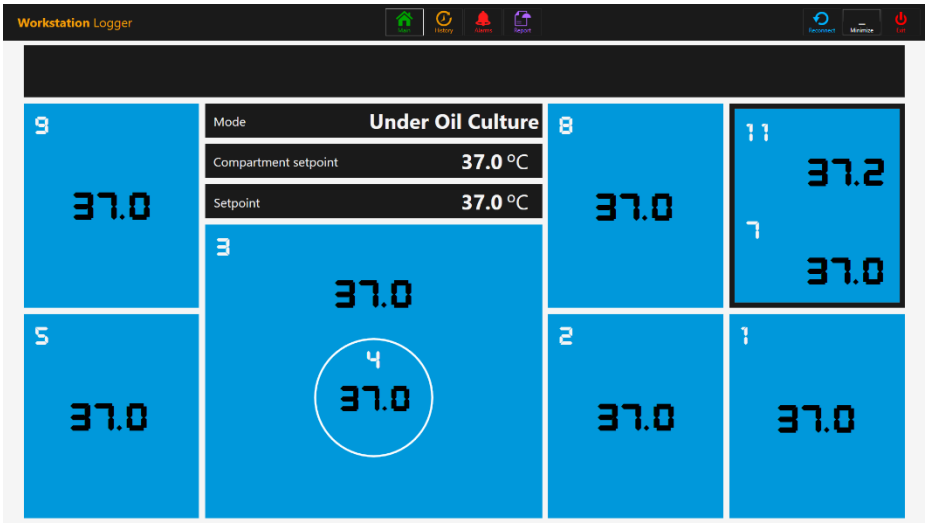


Figure 23.4 The Workstation Logger 2nd display view under normal working conditions (with a gas mixer)

If the signal is lost, dotted lines will appear instead of numeric values.

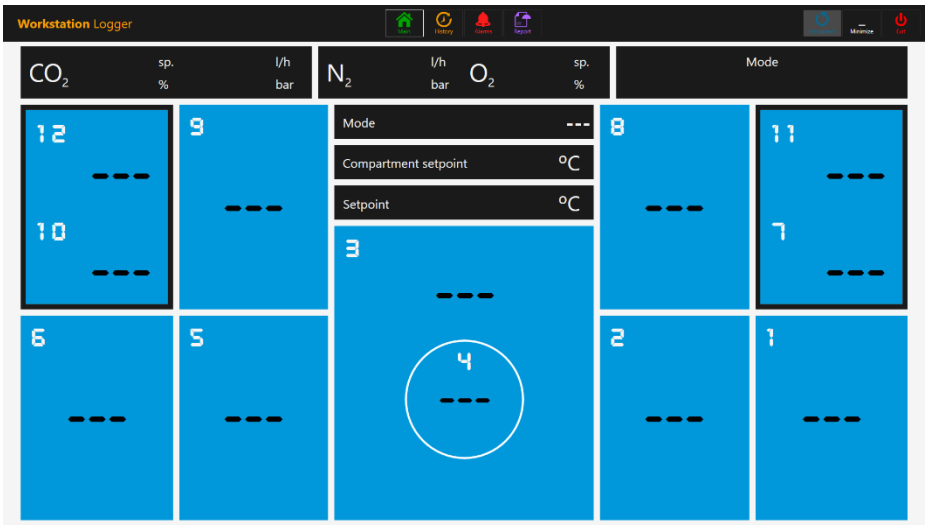


Figure 23.5 The Workstation Logger main view when the signal is lost

Once the signal is established, numeric values will be shown again.

The blue color signifies that the zone is in normal operation mode. If there is an alarm, the color will shift to red on the relevant zone.

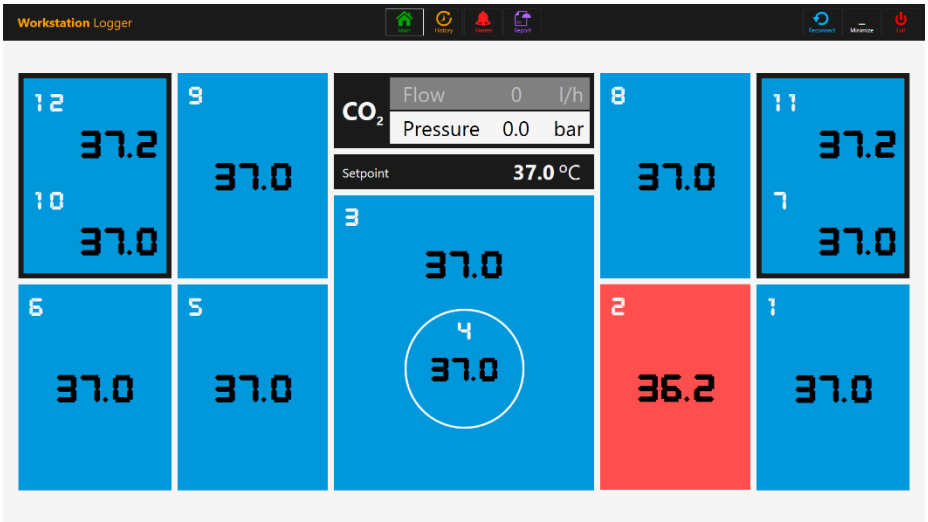


Figure 23.6 The Workstation Logger main view when there is a low-temperature alarm in the T2 heating area

In this way, the user will always have a clear visual indication of the regular operation and an easy way to identify and respond to a malfunction.

This is a unique safety feature of the Multi-zone ART workstation, which cannot be found on any comparable system.

Some models of Multi-zone Workstations contain chambers. In this case, the zone will have a black border and two temperature values (bottom and lid).

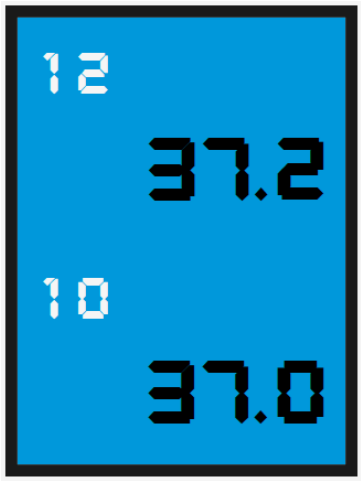


Figure 23.7 Chamber view in the Workstation Logger

At the top of the screen, 4 navigation buttons are placed in the middle and 3 actions buttons in the right-hand corner of the screen.

The “MAIN” button brings up the main view (shown in the Figures 24.2 and 24.3 above).

The “HISTORY” button toggles the graph view, where graphs can be shown for all the parameters. It is useful to document the stability of the system and identify any erratic behavior.

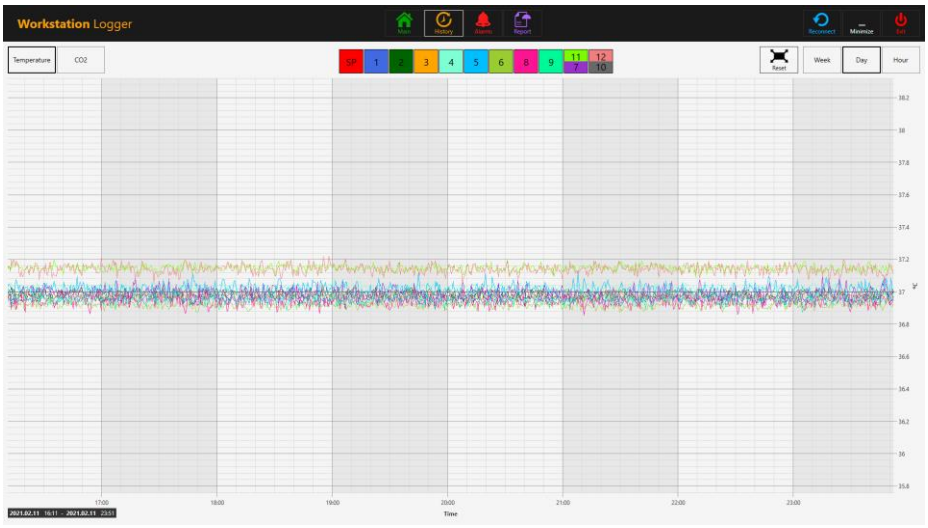


Figure 23.8 The “History” temperature data view

Several extra buttons appear in the graph view. By pressing the colored square button with the number for the zone, the user can see temperatures and toggle “ON/OFF” graphs for each zone in the view.

For Multi-zone Workstation with chambers, some buttons will contain two values wherein two separate temperature curves will be shown.

Figure 23.9 Chambers with two temperature values

A zoom function is available by touching the screen and swiping the finger left over the area that should be zoomed.

Pressing the “Reset” button the menu will jump back to full view.

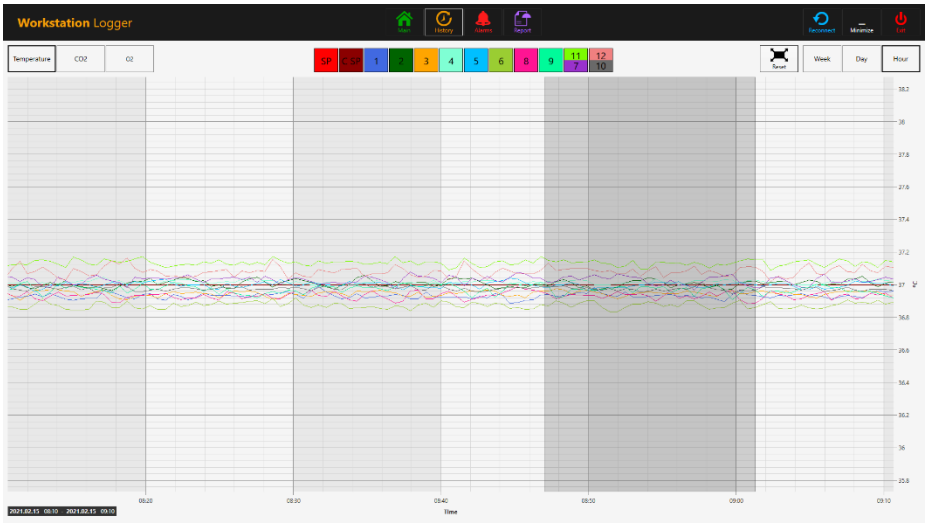


Figure 23.10 The zoom-in graph view

If there are data accumulated, it is possible to shift between a “Week”, “Day” and “Hour” view.

Pressing the CO_2 button the view will shift from the temperature data view to the CO_2 gas data view. In Multi-zone ART Workstation models without a built-in gas mixer, the user can only see the flow and pressure's historical CO_2 data.

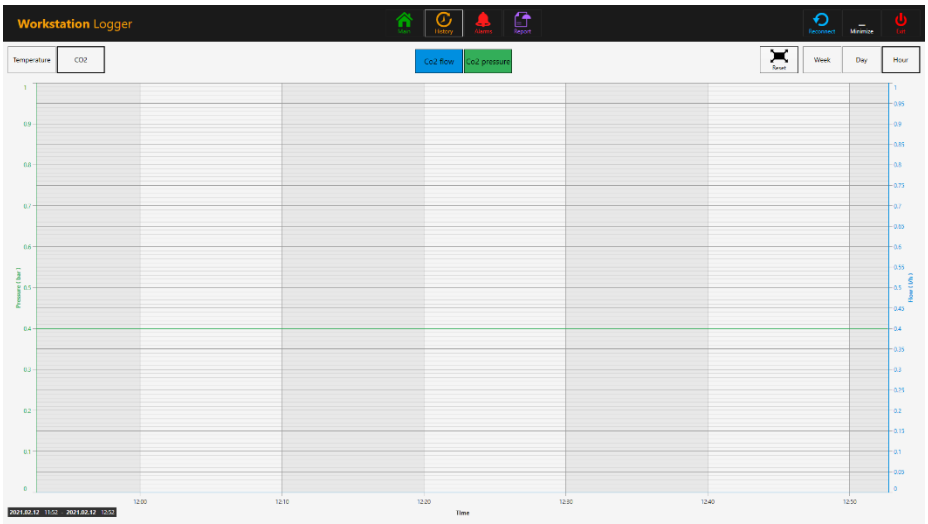


Figure 23.11 The “History” CO_2 data view

In Multi-zone ART Workstation models with a built-in gas mixer, the user can see the historical data of CO_2 gas concentration setpoint, concentration, flow and pressure.

Pressing the O_2 button will shift from the CO_2 gas data view to the O_2 gas data view. This function is only available in Multi-zone ART Workstation models with a built-in gas mixer.

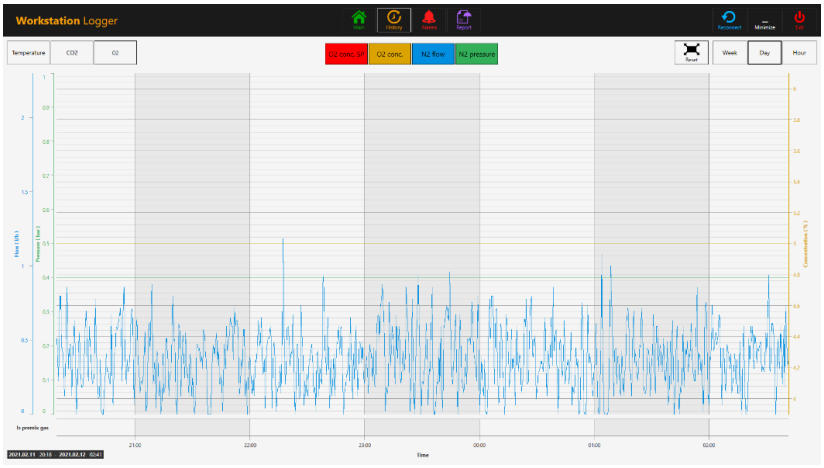


Figure 23.12 The "History" O_2 data view

The user can see historical data of O_2 gas concentration setpoint, concentration, N_2 gas flow and pressure.

The "Alarm" button will bring up the graphical alarm view. Alarm conditions for the parameters are shown as red on the timeline, thus making easy identification possible.

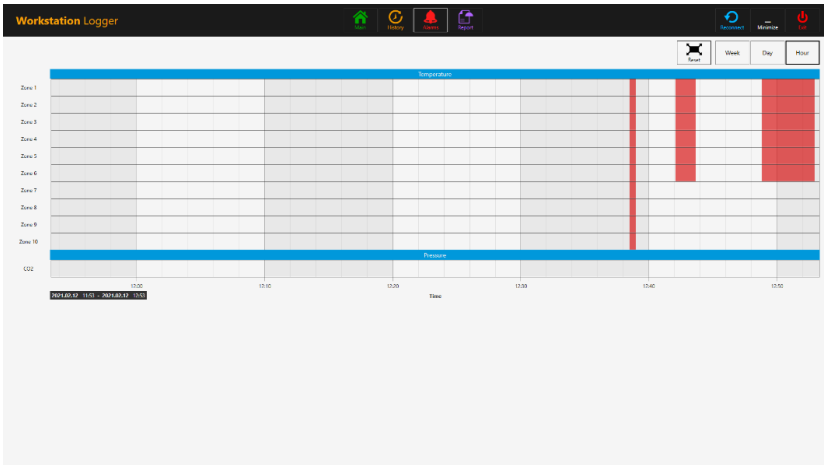


Figure 23.13 The graphical "Alarm" view (without a gas mixer)

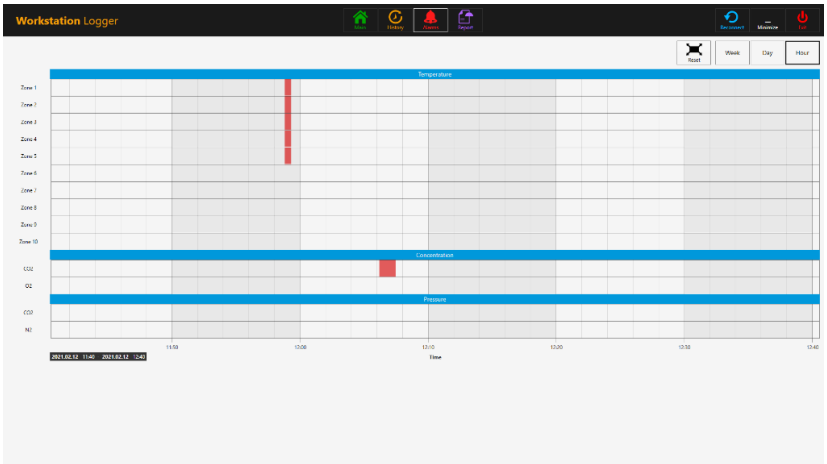


Figure 23.14 The graphical "Alarm" view (with a gas mixer)

The “Report” button will bring up the report mode. All the Multi-zone ART workstation's running parameters can easily be documented and printed as a report or exported in PDF, Excel or Word for convenient ISO quality management compliance.

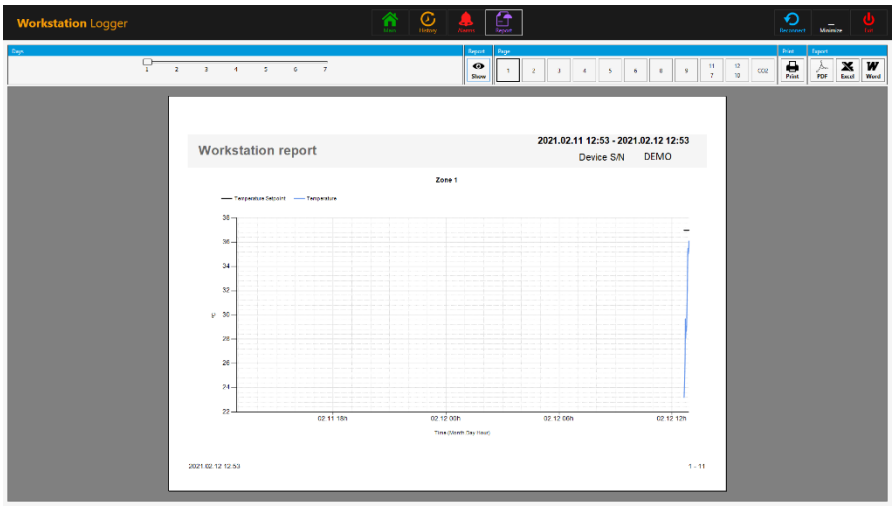


Figure 23.15 The “Report” mode view (without a gas mixer)

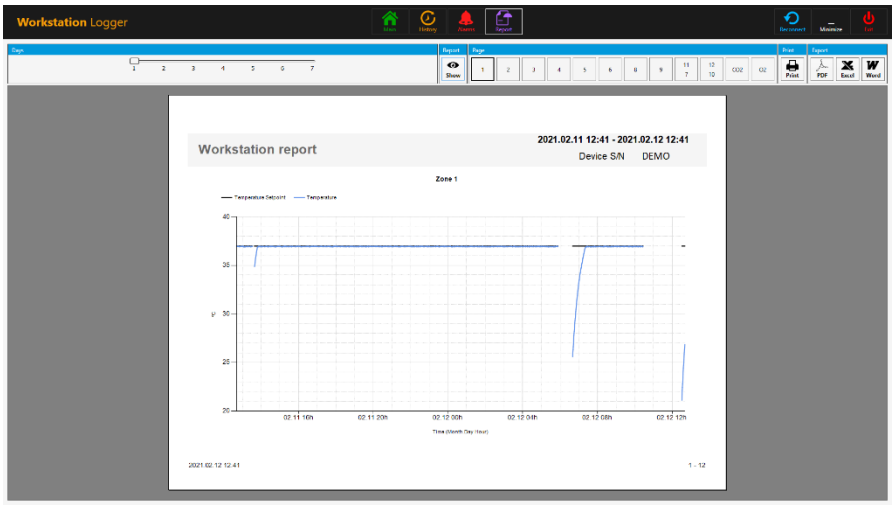


Figure 23.16 The “Report” mode view (with a gas mixer)

The 3 action buttons are located on the right-hand side:

- The “Reconnect” button allows the system to reconnect with the sensors (in case of data loss due to USB connection issues).
- The “Minimize” button toggles the full-screen format off for the Workstation Logger.
- The “Exit” button shuts down the Workstation Logger software.

No data will be stored and all safety surveillance functions will not be operative if the Workstation Logger is shut down.

The AIO PC can easily be used to display an image from any USB-type microscope camera.

A standard USB socket is located on the front panel. It can be used to load the microscope camera drivers or other software onto the AIO PC. When the software is set up, the microscope camera can be connected to the USB socket and the image shown on the screen.

⚠ **The access to the USB socket (located on the backwall of Multi-zone ART Workstation) should be limited to authorized personnel only. Unauthorized USB access could compromise the safety and performance of the medical device.**

☞ **A force function is built into the Workstation Logger. When the microscope camera image uses the full screen on the AIO PC, the system will visually alert the user to any alarm conditions and make a rapid shift to the Workstation Logger's full view possible.**

The current Multi-zone ART Workstation Data Logger software version is 1.6.0.0.

24 Maintenance

The Multi-zone ART Workstation is designed to be easy to use, but the reliable and safe operation of this equipment is based on the following conditions:

1. Correct calibration of temperature and gas concentration, using high-precision equipment in the intervals prescribed based on clinical practice at the laboratory, where Multi-zone ART Workstation is used. The manufacturer recommends that the period between validation should be no longer than 14 days.
2. In-line HEPA filters must be replaced yearly during annual maintenance.
3. According to the clinical practice intervals, suitable cleaning procedures must be employed in the laboratory where the Multi-zone ART Workstation is used. The manufacturer does not recommend periods longer than 14 days between cleaning.

⚠ **It is essential to perform the inspection and service at the intervals indicated in the "33 Maintenance guide" section of the User Manual. Failure to do so can have serious adverse outcomes, causing the device to stop performing as expected and cause damage to samples, patients or users.**

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

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

25 Emergency Procedures

Total loss of power to or on the device:

- Remove all the samples and place them in an alternative or backup device that is not affected by the problem.
- The Multi-zone ART Workstation will lose its temperature below a safe level in around 5 minutes.
- The CO_2 concentration will remain within 1% of the setpoint for 30 minutes if the lids remain closed.

If a single temperature alarm turns ON:

- Remove all the samples and place them in an alternative or backup device that is not affected by the problem;
- The Multi-zone ART Workstation will lose its temperature below a safe level in around 5 minutes;
- Remove the samples from the affected zone. They can be relocated to the other zones. Each zone is separate so that the other zones will stay safe.

If multiple temperature alarms turn ON:

- Remove the samples from the affected zones. They can be relocated to either of the other zones. Each zone is separate so that the others will stay safe.

If the CO_2 concentration alarm turns ON (not applicable to models without the built-in gas mixer):

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

If the O_2 concentration alarm turns ON (not applicable to models without the built-in gas mixer):

- 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 turns ON (not applicable to models without the built-in gas mixer):

- Inspect the external gas supply and gas supply lines. If the problem is external and not readily fixed, follow the guidelines under the section "13.3.1 CO_2 pressure alarm".

If the N_2 pressure alarm turns ON (not applicable to models without the built-in gas mixer):

- Inspect the external gas supply and gas supply lines. If the problem is external and not readily fixed, follow the guidelines under the "13.3.2 N_2 pressure alarm" section.

26 User troubleshooting

Table 26.1 Heating system

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

Table 26.2 CO_2 gas regulator (for models without a built-in gas mixer)

Symptom	Cause	Action
“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 between 0.4 - 0.6 bar (5.80 – 8.70 PSI)

Table 26.3 CO_2 gas regulator (not applicable for models without a built-in gas mixer and MIRI® chambers)

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

Table 26.4 O_2 gas regulator (not applicable for models without a built-in gas mixer and MIRI® chambers)

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

Table 26.5 Data Logger

Symptom	Cause	Action
No data is sent to 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 device
	Data logger software/USB driver not correctly installed	Please refer to the software installation guide

Table 26.6 Display

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

Table 26.7 Keyboard

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

27 Specifications

Table 27.1 Multi-zone ART Workstations' general specifications

Technical specifications	MAW-3D	MAW-4D	MAW-6D MONO	MAW-6D DUAL	MAW-6D MP
Work area dimensions (W×D×H)	950 × 500 × 710 mm	1260 × 500 × 710 mm	1870 × 500 × 710 mm		1870 × 490 × 780 mm
External dimensions without support stand (W×D×H)	1035 × 640 × 1300 mm	1340 × 640 × 1300 mm	1950 × 640 × 1300 mm		1950 × 647 × 1360 mm
External dimension with "B" type support stand (W×D×H)	1050 × 640 × 2160 mm	1340 × 640 × 2160 mm	1950 × 640 × 2160 mm		1950 × 647 × 2220 mm
Laminar airflow velocity		Average of 0,21 m/s or 41 fpm (± 20%)			
Filter efficiency	>99.999% for particle size between 0.1 to 0.3 microns per IEST-RP-CC001.3 / H14 per EN 1822				
Noise level (per NSF 49)	47 dBA		52 dBA		
Pre-filter	Disposable and non-washable polyester fibers with 85% arrestance, EU3 rated.				
Heating system	Smart power injection electrical heating, (7+1) zones.	Smart power injection electrical heating, (9+1) zones.		Smart power injection electrical heating, 2 x (9+1) zones.	Smart power injection electrical heating, (9+1) zones.
Temperature accuracy	± 0.2 °C				
Temperature uniformity	± 0.2 °C				
Operating altitude	Up to 2000 meters (6560 feet or 80kPa – 106kPa)				
Included advanced features	• Integrated humidification system HS-1 • Surveillance system with data logger • AIO PC • Heated glass stage • Transmitted light source SC-1 (with bulb) • 5 × PT1000 validation ports			• Dual Integrated humidification system HS-1 • Surveillance system with data logger • AIO PC • 2 × Heated glass stage • 2 × Transmitted light source SC-1 (with bulb) • 9 × PT1000 validation ports	• Dual Integrated humidification system HS-1 • Surveillance system with data logger • AIO PC • Heated glass stage • Transmitted light source SC-1 (with bulb) • 5 × PT1000 validation ports
Included accessories	• 1 × water bottle for HS-1, including tubing • 1 × sample carry tray • 1 × humidified gas plastic cover			• 2 × water bottle for HS-1, including tubing • 2 × carry tray • 2 × humidified gas plastic cover	• 1 × water bottle for HS-1, including tubing • 1 × carry tray • 1 × humidified gas plastic cover
Microscope provision	Provision for 1 microscope			Provision for 2 microscopes	Provision for 1 microscope and 1 inverted microscope

Table 27.2 Multi-zone ART Workstations' with MIRI® chambers general specifications

Technical specifications	MAW-4D MC	MAW-6D MONO-MC	MAW-6D DUAL-MC	MAW-6D MP-MC
Work area dimensions (W×D×H)	1260 × 500 × 710 mm	1870 × 500 × 710 mm		1870 × 490 × 780 mm
External dimensions without support stand (W×D×H)	1340 × 640 × 1300 mm	1950 × 640 × 1300 mm		1950 × 647 × 1360 mm
External dimension with "B" type support stand (W×D×H)	1340 × 640 × 2160 mm	1950 × 640 × 2160 mm		1950 × 647 × 2220 mm
Laminar airflow velocity	Average of 0,21 m/s or 41 fpm (± 20%)			
Filter efficiency	>99.999% for particle size between 0.1 to 0.3 microns per IEST-RP-CC001.3 / H14 per EN 1822			
Noise level (As per IEST)	47 dBA	52 dBA		
Pre-filter	Disposable and non-washable polyester fibers with 85% arrestance, EU3 rated.			
Heating system	Smart power injection electrical heating, (7+1) zones.		Smart power injection electrical heating, 2 x (7+1) zones.	Smart power injection electrical heating, (7+1) zones.
Number of MIRI® chambers	2		3	2
Temperature accuracy	± 0.2 °C			
Temperature uniformity	± 0.2 °C			
Operating altitude	Up to 2000 meters (6560 feet or 80kPa – 106kPa)			
Included advanced features	• Integrated humidification system HS-1 • Surveillance system with data logger • AIO PC • Heated glass stage • Transmitted light source SC-1 (with bulb) • 5 × PT1000 validation ports		• Dual Integrated humidification system HS-1 • Surveillance system with data logger • AIO PC • 2 × Heated glass stage • 2 × Transmitted light source SC-1 (with bulb) • 9 × PT1000 validation ports	• Dual Integrated humidification system HS-1 • Surveillance system with data logger • AIO PC • Heated glass stage • Transmitted light source SC-1 (with bulb) • 5 × PT1000 validation ports
Included accessories	• 1 × water bottle for HS-1, including tubing • 2 × sample carry tray • 1 × humidified gas plastic cover		• 2 × water bottle for HS-1, including tubing • 3 × carry tray • 2 × humidified gas plastic cover	• 1 × water bottle for HS-1, including tubing • 2 × sample tray • 1 × humidified gas plastic cover
Microscope provision	Provision for 1 microscope		Provision for 2 microscopes	Provision for 1 microscope and 1 inverted microscope

Table 27.3 Multi-zone ART Workstations with integrated AVT table

Technical specifications	MAW-6D-MP
Float size	540 × 340
Recommended load weight	15 – 75 kg
Damping coefficient (6 Hz)	~ 0.1
Amplitude (6 Hz)	< 1 µm
Vibration criteria	VC-B*
Frequency Range of Isolation	1 Hz – 100 Hz
Vertical Natural Frequency	2 Hz – 5 Hz
Horizontal Natural Frequency	1 Hz – 3Hz
Damping Ratio	0.1 – 0.3

* VC-B: Sensitive equipment requiring low vibration levels (25 µm/s). It is appropriate for optical microscopes up to 1000× and inspection and lithography equipment (including steppers) down to 3-micron line widths.

Table 27.4 Multi-zone ART Workstations temperature and gas system technical specifications

Technical specifications	MAW-6D-MP
Temperature control range	25.0 – 40.0 °C
Temperature deviation from the setpoint	± 0.1 °C
Premixed gas consumption	In purge < 40 liters per hour In a normal run, adjustable from 1 to 40 liters per hour
Gas consumption (CO_2)	< 4 liters per hour
Gas consumption (N_2)	< 12 liters per hour
CO_2 range	3.0 – 10.0 %
O_2 range	5.0 – 20.0 %
CO_2 and O_2 concentration deviation from the setpoint	± 0.2 %
Gas pressure premix (input)	0.4 – 0.6 bar (5.80 – 8.70 PSI)
Gas pressure CO_2 (input)	0.4 – 0.6 bar (5.80 – 8.70 PSI)
Gas pressure N_2 (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.
Operating altitude	Up to 2000 meters (6560 feet or 80kPa – 106kPa)
Shelf life	1 year

28 Electromagnetic compatibility

Table 28.1 Electromagnetic emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
The Multi-zone ART Workstation is intended for use in the electromagnetic environment specified below. The customer or the Multi-zone ART Workstation user should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Multi-zone ART Workstation 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 Multi-zone ART Workstation 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	Class A	

Table 28.2 Electromagnetic immunity

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

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

Table 28.3 Recommended separation distances

Recommended separation distances between portable and mobile RF communication equipment and the Multi-zone ART Workstation			
The Multi-zone ART Workstation is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the Multi-zone ART Workstation user, can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Multi-zone ART Workstation as recommended below according to the maximum output power of the communications equipment.			
The rated maximum output power of the transmitter W	**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 2.5 GHz d=2.3√P**
0.01	0.1 m	0.1 m	0.2 m
0.1	0.4 m	0.4 m	0.7 m
1	1.2 m	1.2 m	2.3 m
10	3.7 m	3.7 m	7.4 m
100	11.7 m	11.7 m	23.3 m
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.			

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 Multi-zone ART workstation product comply with the medical electromagnetic compatibility standard and to check before use that no interference is evident or possible. If interference is suspected or possible, switching off the offending device is the usual solution required in aircraft and medical facilities.

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

29 Validation guide

29.1 Product release criteria

The Esco Medical Multi-zone ART Workstation undergoes a strict quality and performance testing before being released for sale.

29.1.1 Performance

Each component used in the Multi-zone ART Workstation is tested during the manufacturing process to ensure a defect-free device.

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

Pass I: Internal sensor temperature variation from setpoint within ± 0.1 °C absolute.

The below list is only applicable for Multi-zone ART Workstation with a built-in gas mixer

Pass II: Internal sensor CO_2 concentration variation from setpoint within ± 0.2% absolute.
Pass III: Internal sensor N_2 concentration variation from setpoint within ± 0.2% absolute.
Pass IV: Gas flow of CO_2 is less than 2 l/h
Pass V: Gas flow of N_2 is less than 8 l/h

29.1.2 Electrical safety

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

29.1.3 Communication & data logging

Each device has a built-in AIO PC running the Multi-zone ART Workstation data logging software. Gas is supplied to the device, and the system is activated. The data received by the PC program is analyzed to ensure communication between the Multi-zone ART Workstation and the PC.

29.1.4 Gas concentration and consumption (only for models with a built-in gas mixer)

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

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

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

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

The gas flow under regular operation is less than 8 liters per hour. The average should be below 8 liters.

29.1.5 Visual inspection

Make sure, that:

- There is no misalignment in the heated glass stage.
- Stainless-steel tabletop surface is prepared for visual indication of heated zones.
- There aren't scratches or missing paint on the cabinet.
- Overall presentable as a high-quality item.

30 Validation on-site

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

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

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

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

30.1 Mandatory equipment

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

- A thermometer with a suitable sensor for measuring in a droplet of media covered with Paraffin oil with a minimum resolution of 0.1 °C.
- A thermometer with a suitable sensor for measuring on an aluminum surface with

a minimum resolution of 0.1 °C.
- A Pressure tester with a minimum range of 0.0 – 1.0 bar.
- A Multimeter.

Additional equipment only needed for Multi-zone ART Workstation with a built-in gas mixer:

- A CO_2 analyzer with a minimum range of 0.0 – 10.0%.
- An O_2 analyzer with a minimum range of 0.0 – 20.0%.

30.2 Recommended additional equipment

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

- A VOC meter able to measure the most common volatile organic compounds at least at the ppm level.
- Particle counters can measure a laser particle counter that can sample a volume of 0.1 CFM and at least at the 0.3-micron particle size level.

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

31 Testing

31.1 Gas supply premixed CO_2/O_2

☞ **Multi-zone ART Workstation, without a built-in gas mixer, can only use premixed CO_2/O_2 gas. Multi-zone ART Workstation, with a built-in gas mixer, can use either premixed CO_2/O_2 or pure CO_2 and O_2 gas.**

A humidified gassing system is provided to avoid evaporation and maintain a safe pH level in open culture bicarbonate buffered culture media while working in the Multi-zone ART Workstation.

If the media is covered with oil, the humidification part of the gassing system can be omitted, but the gas part is still essential to keep the pH levels safe.

☞ **If a HEPES buffered culture media is used, the gas system must not be utilized.**

The gassing system must be connected to a premixed gas supply at around 0.4 – 0.6 bar pressure. The gas mixture, for example, can be 5.0% CO_2, 5.0% O_2 and 90% N_2 or whatever mixture that is suitable for the type of media used.

Connect the gas bottle and adjust the pressure. Fill up the humidification bottle with sterile water and connect the tubes. Put the gas hood on the tabletop over the gas outlet. Measure the CO_2 concentration with a gas analyzer inside the gas hood.

PASS: CO_2 concentration measured must correspond to the Premixed gas.

⚠ **The use of premixed CO_2/O_2 gas with moisture will damage the flow sensors. Moisture level must be verified on the gas manufacturer's certificate: only 0.0 ppm v/v Max is permissible.**

31.2 Gas supply CO_2 (only for models with a built-in gas mixer)

For the regulation system to maintain the correct CO_2 concentration in the Multi-zone ART Workstation MIRI® chambers, the device must be connected to a stable source of 100% CO_2 at 0.4 – 0.6 bar (5.80 – 8.70 PSI) of pressure.

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

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

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

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

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

31.2.1 About CO_2

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

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

⚠ **A high concentration of carbon dioxide (10.0% or more) in the surrounding atmosphere can cause rapid asphyxiation.**

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

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

31.3 Gas supply N_2 (only for models with a built-in gas mixer)

For the regulation and maintenance of the correct O_2 concentration in the Multi-zone ART Workstation MIRI® chambers, the device must be connected to a stable source of 100% N_2 at 0.4 – 0.6 bar (5.80 – 8.70 PSI) of pressure.

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

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

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

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

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

31.3.1 About N_2

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

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

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

- Research Grade 99.9995%.
- Contaminant.
- Argon (Ar) 5.0 ppm.
- Carbon Dioxide (CO_2) 1.0 ppm.
- Carbon Monoxide (CO) 1.0 ppm.
- Hydrogen (H_2) 0.5 ppm.
- Methane 0.5 ppm.
- Oxygen (O_2) 0.5 ppm.
- Water (H_2O) 0.5 ppm.

31.4 Premix gas pressure check

The Multi-zone ART Workstation, with and/or without a built-in gas mixer, requires a pressure of 0.4 – 0.6 bar (5.80 – 8.70 PSI) on the input gas line. Therefore, the gas pressure must be held stable at all times.

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

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

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

PASS: The value must be 0.4 – 0.6 bar.

31.5 CO_2 gas pressure check (only for models with a built-in gas mixer)

The Multi-zone ART Workstation requires a pressure of 0.4 – 0.6 bar (5.80 – 8.70 PSI) on the input gas line. This gas pressure must always be held stable.

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

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

PASS: The value must be 0.4 – 0.6 bar.

Please refer to the "16.1 CO_2 Pressure" section of the User Manual for more information.

31.6 N_2 gas pressure check (only for models with a built-in gas mixer)

The Multi-zone ART Workstation requires a pressure of 0.4 – 0.6 bar (5.80 – 8.70 PSI) on the input gas line. This gas pressure must always be held stable.

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

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

PASS: The value must be 0.4 – 0.6 bar.

Please refer to the "16.2 N_2 Pressure" section of the User Manual for more information.

31.7 Voltage supply

The voltage on-site must be verified.

Measure the output plug on the UPS that the Multi-zone ART Workstation will be connected to. Also, check that the UPS is attached to a properly grounded mains outlet.

Use a multimeter set for AC.

PASS: 230V ± 10.0%
115V ± 10.0%

31.8 Temperature check: heating zones

The temperature validation is performed using a thermometer with a sensor suitable for measuring temperature on a stainless steel surface with a resolution of 0.1 °C as a minimum. Tape the sensor is placed in the middle position of the heating zone. Make sure that the tape keeps the sensor in complete contact with the surface area.

☞ **Taping the sensors on the heating zones is not an optimal procedure as the tape itself will insulate the sensor from the airflow and thus a perfect picture will not be represented. It is, however, a usable compromise if the size of the taped area is kept small and the tape used is strong, thin and light.**

Place the sensor on each zone and verify the temperature. For temperature validation in the MIRI® chambers, tape the sensor in the middle of the chamber and/or lid.

PASS: all temperatures measured on the bottom of the chambers where the dishes are located must not deviate more than ± 0.2 °C from the setpoint.

If calibration is needed, please refer to the "12.5.1 Temperature sub-menu" section for more information on how to perform the temperature calibration.

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

31.9 6-hour stability test

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

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

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

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

Pass I: Internal sensor temperature variation from set point is within ± 0.2 °C absolute.
Pass II: if gas is attached, monitor that the gas pressure stays within ± 0.1 bar of 0.5 bar

The below list is only applicable for Multi-zone ART Workstation with a built-in gas mixer:

Pass III Internal sensor CO_2 concentration variation from setpoint within ± 0.2% absolute.
Pass IV: Internal sensor N_2 concentration variation from setpoint within ± 0.2% absolute.
Pass V: Gas flow of CO_2 is less than 2 l/h.
Pass VI: Gas flow of N_2 is less than 8 l/h.

31.10 Cleaning

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

After the testing has been conducted successfully, it should be cleaned again before the device is taken into clinical use (for cleaning instructions refer to the "19 Cleaning instructions" section of the User Manual).

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

31.11 Test documentation form

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

31.12 Recommended additional testing

31.12.1 A VOC meter

A sample should be taken in the room in front of the Multi-zone ART Workstation with the VOC meter. The reading should be noted down as the background VOC level. Then inside the work area, a sample should be made. A sample should also be made from under the gas hood with the gas system running.

Pass: 0.0 ppm VOC

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

31.12.2 A laser particle counter

A sample should be taken in front of the Multi-zone ART Workstation with the laser particle counter. The reading should be noted down as the background particle level. Then with the fan switched on, a sample should be taken inside the work area with the

sample opening pointing towards the side of the work area (either left or right).

Pass: 0.3-micron < 100 ppm.

Ensure that the sample lines do not contain any particles.

32 Clinical use

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

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

Do not attempt to run Multi-zone ART Workstation for clinical purposes without access to high-grade quality control validation equipment.

Table 33.1 Validation intervals

Task	Every day	Every week
Temperature check		×
Premixed, CO_2 and O_2 gas concentration check	×	
Check log for anomalies		×
Premixed, CO_2 and N_2 gas pressure check	×	

32.1 Temperature check

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

Please refer to the "12.5.1 Temperature sub-menu" section for more information on how to perform the temperature calibration.

PASS:

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

32.2 Premixed, CO_2 and O_2 gas concentration check

The gas concentration is checked for deviations. For Multi-zone ART Workstation, without MIRI® chambers, the sample is taken from under the gas hood with the gassing system running. For Multi-zone ART Workstation, with MIRI® chambers, the sample is taken from one of the sample ports located in the back of the device.

It is essential to have a high-precision gas analyzer for CO_2 and O_2 available to do the test.

Please follow these simple rules while testing gas concentration in MIRI® chambers:

- Check the CO_2/O_2 gas setpoint.
- Check the actual CO_2/O_2 gas concentration to ensure that the setpoint is reached and gas concentration is stabilized around the setpoint.
- Remember not to open the lid for at least 10 min, before starting the test or during the testing itself.

Please refer to the "12.5.2 CO_2 sub-menu (only for models with a built-in gas mixer)" / "12.5.3 O_2 sub-menu (only for models with a built-in gas mixer)" section for more information on how to perform the CO_2/O_2 gas calibration.

PASS:

- **The concentration measured must not deviate more than ± 0.3% from the concentration given on the premixed gas bottle label.**
- **CO_2 concentration measured must not deviate more than ± 0.2% from the setpoint.**
- **O_2 concentration measured must not deviate more than ± 0.2% from the setpoint.**

32.3 Premixed, CO_2 and O_2 gas pressure check

The Multi-zone ART Workstation requires a pressure of 0.4 – 0.6 bar on the input gas line. This gas pressure must always be held stable.

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

It is recommended to check the gas pressure in the Multi-zone ART Workstation data logger.

PASS: The value must be 0.4 – 0.6 bar.

Please refer to the “16 Pressure” section of the User Manual for more information.

33 Maintenance guide

The Multi-zone ART Workstation from Esco Medical Technologies, UAB contains high precision quality components. These components are chosen to ensure the high durability and performance of the equipment.

However, continual validation of the performance is necessary.

User validation should be done as a minimum according to instructions given in the "29 Validation guide" section of the User Manual.

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

However, to sustain the high-performance level and avoid system errors, the owner is responsible for having a certified technician who performs components replacements, according to table 33.1.

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

⚠ **Warranty void if service intervals are not followed according to table 33.1.**

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

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

Table 33.1 Service interval plan

Component name	Every 3 months	Every year	Every 2 years	Every 3 years	Every 4 years
External 0.22µm HEPA filter for incoming premixed gas[5]		×			
External 0.22µm HEPA filter for incoming CO_2 and N_2 gas[6]		×			
O_2 sensor[6]		×			
CO_2 sensor[6]					×
Pump module[5]			×		
Internal gas pump[6]			×		
Proportional valves				×	
Gas lines				×	
Flow sensors			×		
Pressure regulators					×
Pre-filter (cabinet hood)	×				
Internal in-line 0.2µm HEPA filter for incoming premix gas[5]		×			
Internal in-line 0.2µm HEPA filter for incoming CO_2 and N_2 gas[6]		×			
A firmware update (if a new version has been released)		×			

33.1 External 0.22µm HEPA filter for premixed gas (only for models without a built-in gas mixer)

The bigger 64mm round-shape external 0.22µm HEPA filter for premixed gas removes any particles found in the incoming gas. Failure to use the HEPA filter may cause damage to the high precision flow sensor or compromise the gas flow system.

Please follow these safety precautions when changing the filter:

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

Please refer to the service manual for replacement instructions.

[5] Only for Multi-zone ART Workstation models without a built-in gas mixer.
[6] Only for Multi-zone ART Workstation models with a built-in gas mixer.

33.2 External 0.22µm HEPA filter for CO_2 and N_2 gas (only for models with a built-in gas mixer)

The bigger 64mm round-shape external 0.22µm HEPA filter for CO_2 and N_2 gas removes any particles found in the incoming gas. Failure to use the HEPA filter may cause damage to the high precision flow sensor or compromise the CO_2/N_2 regulation system.

Please follow these safety precautions when changing the filter:

- Always use the original filter (contact Esco Medical Technologies, UAB or your local distributor for more details or ordering).
- Change the filter once every year.
- Failure to change the filter on time will result in low/no cleaning of incoming CO_2/N_2 gas.
- Warranty void if wrong/non-original filter is used.

Please refer to the service manual for replacement instructions.

33.3 O_2 sensor (only for models with a built-in gas mixer)

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

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

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

The User will see when this sensor was installed in the Multi-zone ART Workstation "Installation report" form. This date must be used to calculate the date for the following O_2 sensor change.

Please follow these safety precautions when changing sensor:

- Always use an original O_2 sensor (contact Esco Medical Technologies, UAB or your local distributor for more details or ordering).
- Change the O_2 sensor within 1 year from the date of the previous sensor installation.

- Failure to change the oxygen sensor on time will result in low/no regulation of O_2 concentration.
- Warranty void if wrong/non-original sensor is used.

Please refer to the service manual for replacement instructions.

33.4 CO_2 sensor (only for models with a built-in gas mixer)

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

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

Please follow these safety precautions when changing the sensor:

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

Please refer to the service manual for replacement instructions.

33.5 Pump module (only for models without a built-in gas mixer)

The pump module is used only in the Multi-zone ART Workstation without a built-in gas mixer. It is needed to ensure internal gas circulation in the system.

Therefore, the pump module must be replaced once every 2 years to maintain proper gas circulation in the system.

Please follow these safety precautions when changing the pump module:

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

Please refer to the service manual for replacement instructions.

33.6 Internal gas pump (only for models with a built-in gas mixer)

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

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

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

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

Please refer to the service manual for replacement instructions.

33.7 Proportional valves

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

Please follow these safety precautions when changing valves:

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

Please refer to the service manual for replacement instructions.

33.8 Gas lines

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

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

Please follow these safety precautions when changing gas lines:

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

Please refer to the service manual for replacement instructions.

33.9 Flow sensors

The digital gas humidification system uses flow sensors for the premixed gas.

The flow sensors are used by the CO_2/N_2 regulations and for logging the device's gas consumption (applicable in the Multi-zone ART Workstation with a built-in gas mixer).

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

Please follow these safety precautions when changing sensors:

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

Please refer to the service manual for replacement instructions.

33.10 Pressure regulators

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

Please follow these safety precautions when changing regulators:

- Always use original pressure regulators (contact Esco Medical Technologies, UAB or your local distributor for more details or ordering).
- Change the regulators within 4 years from the date of installation.
- Failure to change the regulators may cause breakdowns.

- Warranty void if wrong/non-original regulators are used.

Please refer to the service manual for replacement instructions.

33.11 Pre-filter (cabinet hood)

The rectangular pre-filter is used for cleaning the room air, drawn in from the top of the cabinet where it traps larger particles and prolongs the life of the main HEPA filter.

⚠ **Failure to use the pre-filter may cause damage to the main filter, which would affect the airflow through the device.**

Please follow these safety precautions when changing the pre-filter:

- Always use the original pre-filter (contact Esco Medical Technologies, UAB or your local distributor for more details or ordering).
- Change the pre-filter every three months.
- Failure to change the pre-filter on time will result in low/no cleaning of room air and possible breakdown of main HEPA filter's functions.
- Warranty void if wrong/non-original pre-filter is used.

Please refer to the service manual for replacement instructions.

33.12 Internal in-line 0.2µm HEPA filter for incoming premix gas

The smaller 33mm round-shape internal in-line 0.2µm HEPA filter for premix gas further acts to remove any particles left in the incoming gas that have passed through the external HEPA filter. Failure to use the internal HEPA filter may cause damage to the high precision flow sensor or compromise the premix regulation system.

Please follow these safety precautions when changing the filter:

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

Please refer to the service manual for replacement instructions.

33.13 Internal in-line 0.2µm HEPA filter for incoming CO_2 and N_2 gas

The smaller 33mm round-shape internal in-line 0.2µm HEPA filter for CO_2 and N_2 gas further acts to remove any particles left in the incoming gas that have passed through the external HEPA filter. Failure to use the internal HEPA filter may cause damage to the high precision flow sensor or compromise the CO_2/N_2 regulation system.

Please follow these safety precautions when changing the filter:

- Always use the original filter (contact Esco Medical Technologies, UAB or your local distributor for more details or ordering).
- Change the filter once every year.
- Failure to change the filter on time will result in low/no cleaning of incoming CO_2/N_2 gas.
- Warranty void if wrong/non-original filter is used.

Please refer to the service manual for replacement instructions.

33.14 Firmware update

If Esco Medical Technologies, UAB has released a newer version of the firmware, this should be installed on the Multi-zone ART Workstation during the scheduled maintenance yearly.

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

34 Installation guide

This document describes when and how to install Multi-zone ART Workstation in the IVF clinic.

34.1 Responsibilities

All technicians or embryologists installing the Multi-zone ART Workstation must identify problems and perform any necessary calibrations, adjustments and maintenance.

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

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

34.2 Before installation

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

The released Multi-zone ART Workstation must be sent 1 – 3 weeks before installation, depending on the clinic location. Check with shippers about local customs regulations and delays that could arise from that.

The clinic must be informed about the site requirements before installation and should have signed the customer requirement checklist:

1. The lab must have an open and flat lab floor space for standing operation.
2. The weight of the 3-ft Multi-zone ART Workstation is 200 kg, 4-ft is 225 kg, and the 6-ft is 345 kg.
3. The required space for placement is provided in the "27 Specifications" section tables.
4. Temperature control should be able to maintain a stable temperature, never exceeding 30 °C.
5. Uninterrupted power supply (UPS) with 115 or 230 V, minimum 120 W.
6. Proper grounding.
7. Premixed and CO_2 gas outlet with 0.6 – 1.0 atm above ambient.
8. N_2 gas outlet with 0.6 – 1.0 atm above ambient if the clinic uses reduced oxygen levels.
9. Tubes that fit 4 mm hose end and HEPA filter.
10. Access to a PC with USB for the data logging.

34.3 Preparing for installation

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

34.4 Bring the following to the installation site

- "Installation report" form.
- Service manual for the Multi-zone ART Workstation.

- Updated service tool kit.
- Memory stick with the latest released firmware & software.
- High precision thermometer with a resolution not less than 0.1 °C.
- Calibrated gas analyzer with precision at least 0.1% for CO_2 and O_2.
- Extension cable for USB connection.

34.5 Installation procedure at the site

For the correct installation procedure please refer to the "9 Getting started" section of the User Manual.

34.6 User training

1. Mains switch on/off.
2. Explain the essential function of Multi-zone ART Workstation with room facility for storing the samples.
3. Explain the temperature control in the Multi-zone ART Workstation (direct heat transfer with heated lids).
4. Gas regulation on/off.
5. Setpoint for temperature, CO_2 and O_2.
6. Alarm turn-off procedure (temperature, CO_2, O_2 or Premix gas) and revert times.
7. Insertion and removal of heating optimization plates
8. Emergency procedures (can be found in the "25 Emergency Procedures" section of the User Manual).
9. Explain how to clean the device and heating optimization plates.
10. External measurement and calibration of temperature.
11. External measurement and calibration of gas concentration.
12. How to add and remove a sample.
13. Data logger functionality, how to establish a connection and re-connection.

34.7 After the installation

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

Suppose the Multi-zone ART Workstation user or owner inquiries about a written "Installation report". The completed and signed "Installation report" form must be sent to the clinic. Any deviations/complaints/suggestions from the Installation visit are reported in the CAPA system. If a critical error has occurred, information about this will be reported directly to QC or QA.

⚠ **If the Multi-zone ART Workstation fails any of the "Installation report" form acceptance criteria, or it in any way suffer from a severe error and incubation parameters are compromised, the Multi-zone ART Workstation must be taken out of service until it is repaired/exchanged, or a new test approves the Multi-zone ART Workstation. The User and owner must be informed about this and arrangements to solve the problems must be initiated.**

35 Other countries

35.1 Switzerland

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

Figure 35.1 Swiss Authorised Representative

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

36 Reporting on serious incidents

In case of any serious incidents that have occurred in relation to the device should be reported to Esco Medical Technologies, UAB by contacts, written on the contact information page, and the Authorised Representative in which the user and/or patient is established.

For contacting Authorised Representative, please refer to the “Other countries” section according to your country.