





USER MANUAL

MAW, Multi-Zone ART Workstation®

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

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

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

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Refunds & Credits

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

Return Procedure

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

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

Certification

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

Warranty and Product Support

Esco Medical warrants this instrument to be free from defects in materials and workmanship under normal use, and service for two (2) years from the date of original purchase, provided the instrument is calibrated and maintained in accordance with this manual. During the warranty period Esco Medical will, at our option, either repair or replace a product that proves to be defective at no charge, provided you return the product (shipping, duty, brokerage and taxes prepaid) to Esco Medical. Any and all transportation charges incurred are the responsibility of the purchaser and are not included within this warranty. This warranty extends only to the original purchaser and does not cover damage from abuse, neglect, accident or misuse, or as the result of service or modification by parties other than Esco Medical.

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

- Power failure, surges, or spikes
- Damage in transit or when moving the instrument
- Improper power supply such as low voltage, incorrect voltage, defective wiring or inadequate fuses
- Accident, alteration, abuse or misuse of the instrument
- Fire, water damage, theft, war, riot, hostility, acts of God such as hurricanes, floods, etc. Only serialized products (those items bearing a distinct serial number tag) and their accessory items are covered under this warranty.

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

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

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

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

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

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

Warranty Disclaimer

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

In all cases, breaking the tamper-resistant Quality Seal should be avoided at all cost, as this seal is key to your original instrument warranty. In an event where the seal must be broken to gain internal access to the instrument, you must first contact Esco Medical Ltd. You will be required to provide us with the serial number for your instrument, as well as a valid reason for breaking the Quality Seal. You should break this seal only after you have received factory authorization. Do not break the Quality Seal before you have contacted us! Following these steps will help ensure that you will retain the original warranty on your instrument without interruption.

WARNING

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

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THIS PRODUCT CONTAINS NO USER-SERVICEABLE COMPONENTS.

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

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1 How to use this manual

The manual is designed to be read by sections, and not ideally cover to cover. This means that if the manual is read, from start to finish, there will be some repetition and overlap. We recommend the following method to go through the manual: first, familiarize yourself with the safety instructions; then proceed to the basic user functions that are needed for operating the equipment on a day to day basis; then review the alarm functions. The menu function of the user interface details information that is needed for the advanced level of users only. All parts must be read before the device is taken into use.

2 Safety warning

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



NOTE

Used to direct attention to a specific item.



WARNING

Use caution

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

3 Indication for use

The MAW, Multi-zone ART Workstation is a laminar flow workstation that is intended for working 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 MAW, Multi-zone ART Workstation is a laminar flow workstation that is intended for working 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 compartments) gives superior temperature conditions in comparison to conventional layouts.

For maximum performance, the system has 12 separate temperature controllers, controlling and regulating the temperature in each zone.

The workstation has been primarily developed and optimized for tissue culturing with an overlay of either Paraffin or Mineral oil.

If open culture is used the user can utilize the humidified gas system that built into the table top. 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 ART Workstation is the All-in-one PC that is running 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 monitor can be used for a microscope camera image, as any warning will still be brought to the attention of the user and an easy possibility to toggle the modes presented. The software includes data logging, data storage and report functions for ISO quality management compliance.

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

This product fulfils the requirements of EN60601-1 3rd edition standards as a Class I type B equivalent device suited for continuous operation. It also conforms to the requirements of the EU Council directive 93/42/EEC concerning medical devices and is classified as a Class I device under rule XII.

Personal Protective Equipment (89/686/EEC) and Machine Directive (2006/42/EC) is not applicable for MAW, Multi-zone ART Workstation.

5 transport, Storage and Disposal

5.1 Transport

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

Visual inspection should be done if there is any damage and then the Multi-Zone ART Workstation is prepared to be transported.

These labels should be glued on the box:

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

5.2 Storage

The device may only be used under the following conditions:

- The unit can be in store for one year
- If stored longer than one year, the unit must be returned to the manufacturer for a new release test
- Shipping temperature between -20 °C and + 50 °C temperature limits
- Keep away from direct sunlight
- Caution consult the accompanying documents for important safety-related information such as warnings and precautions that cannot, for a variety of reasons, be presented on the device itself
- Do not use if the packing material is damaged
- Keep dry

5.3 Disposal

The unit contains reusable materials. All components (with the exception of the HEPA filter) can be discarded after having been cleaned and disinfected.

Please not that the HEPA filters must be discarded in accordance with the applicable national regulations for special solid waste.

The device may have been used for treating and processing infectious substances. Therefore, the device and device components may have been contaminated.

Prior to disposal, all device components must be decontaminated.

Clean the device components thoroughly and either disinfect or decontaminate them.

6 Accessories supplied

- 1 HEPA filters for input gas supply
- 1 USB stick containing Esco Medical Data logger software and PDF versions of the manuals
- 1 gas hood
- 1 carry tray
- 1 humidification flask
- 1 medical grade mains cord (for the table top)

7 Manuals supplied

The MAW, Multi-zone ART Workstation ® comes with 3 manuals as standard:

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

Each manual has a specific purpose.

7.1 The user manual

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

The user manual cannot stand alone nor replace user training.

7.2 The validation manual

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

7.3 The maintenance manual

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

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

8 Safety symbols and labels

There are several user labels on the surfaces of the MAW, Multi-zone ART Workstation® to guide the user. User labels are shown below.

Table 7.1 Labels

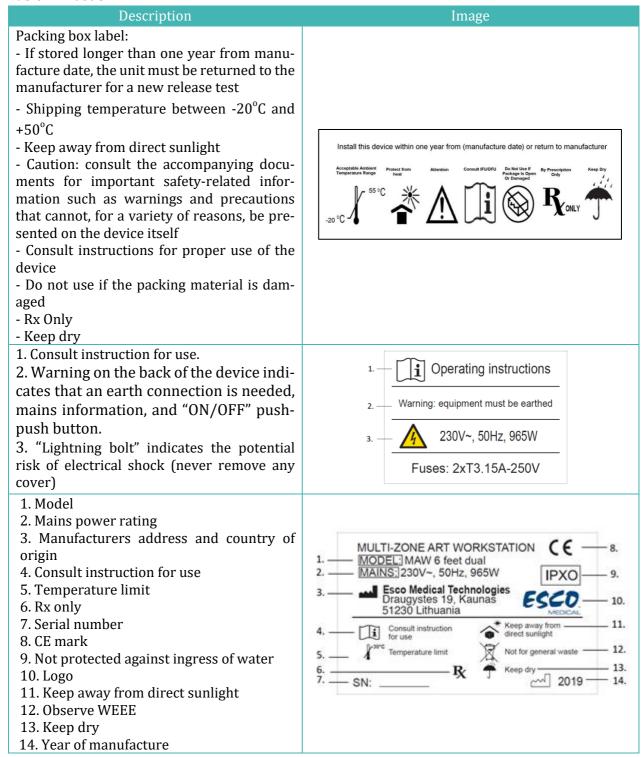


Table 7.2 Labels on the front side of MAW, Multi-zone ART Workstation®

Description	Image
USB communication port	USB communication port
Compartments numbers are indicated in the top corner of the lid with a label	123

9 Important safety instructions and warnings

9.1 Before installation

- 1. Do not use the product if the package is damaged.
- 2. Read the user manual completely before use
- 3. Always keep these instructions easily accessible near the device
- 4. The MAW, Multi-zone ART Workstation® is heavy and can present a life-threatening danger if it tips over or drops during installation
- 5. Use sample personal for any manual lift.
- 6. If a forklift is used only lift on the custom-built pallet. The table top itself cannot withstand any lifting in the middle. Permanent damage will occur. Warranty void if this happens
- 7. Electronics box under the table top is not flush with the rest of the underside. Any blows can result in permanent damage. Warranty void if this happens.

9.2 During installation

- 1. Never place this unit on top of other equipment that might heat it up
- 2. Place this unit on a flat, hard and stable surface
- 3. Never place the unit on a carpet or similar surfaces
- 4. Do not defeat the safety purpose of the grounding-type (earthing) plug
- 5. A grounding-type (earthing) plug has two blades and a third prong is provided for your safety. If the provided plug does not fit into your outlet, consult an electrician to replace the outlet
- 6. Always connect the power cord to a properly grounded outlet and only use the cord that came with the device
- 7. Do not install near any heat sources such as radiators, heat registers, stoves or other apparatus that produce heat
- 8. Do not use this device near water
- 9. Always use external HEPA filter for input CO₂ gas
- 10. Do not use this product at temperatures exceeding 30°C
- 11. Place this unit in a location with adequate ventilation to prevent internal heat build-up. Allow at least 10 cm clearance from the rear, 30 cm from the top and 20 cm from left and right to prevent overheating
- 12. This unit is intended for indoor purposes only
- 13. Read the section about EMC in this IFU on section 27 and heed the warnings

9.3 Post installation

- 1. Refer all servicing to qualified service personnel
- 2. Servicing is required according to the service manual, or if the apparatus has been damaged in any way, e.g. if the apparatus has been dropped, exposed to rain or moisture, or does not operate normally. The MAW, Multi-zone ART Workstation® contains high voltage components that may be hazardous
- 3. Unplug this apparatus during lightning storms or when unused for a long period of time
- 4. Protect the power cord from being walked on or pinched, particularly at the plug, convenience receptacles, and the point where it exits from the apparatus
- 5. Perform temperature and gas calibration at the intervals described in the manuals
- 6. NEVER block gas supply holes in table top
- 7. Make sure that CO₂ gas supply pressures are kept stable at 0.6 bar (8.70 PSI)

10 Getting started

The MAW, 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 mains cable to the top of the Workstation for the fan unit work
- 3. Connect the mains cable to the underside of the table top for the PC and table top heating system to work
- 4. Connect the gas line for the CO₂ 5 or 6% premixed gas
- 5. Set the gas pressure on the external gas regulator at 0.6 bar (8.70 PSI)
- 6. Switch on the MAW, Multi-zone ART Workstation® on with the on/off switch under the table top (next to the mains cable)
- 7. Power up the PC by pressing the button in the middle of the inner wall work area
- 8. Observe for normal function
- 9. Let the unit warm up and stabilize for 20 min
- 10. Follow the guidelines in the validation guide
- 11. Complete user training and instructions
- 12. After a burn-in phase of 24-hours, the unit is ready for use IF the testing is successful

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

11 Mains connection

The MAW, Multi-zone ART Workstation® comes with a detachable mains power cord. The power cord is prepared for the country in which the unit is intended to be used.

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

The power requirement is 115V 60 Hz OR 230V 50Hz.



Figure 11.1 Power supply

12 Gas connection and the humidification system

Under the table top one single gas input (black and blue) is located.



Figure 12.1 Gas inlet

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

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



Figure 12.2 Pressure regulator

Connect the CO_2 gas to the CO_2 inlet with a suitable silicone tube. Make sure the tube is fastened with a clip, so that it does not accidentally loosen itself during sudden pressure fluctuation. Use the supplied 0.2μ HEPA filter on the gas line just before the inlet on the MAW, Multi-zone ART Workstation®. Notice the flow direction marked on the filter.



Figure 12.3 Gas filter

The CO₂ intel should be connected to a 5 or 6% Premixed CO₂.

The gas flow can be controlled digitally with the keys on the table top.

The gas will pass through the humidification system.

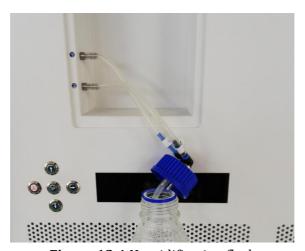


Figure 12.4 Humidification flask

Connect the tube between the port marked "Outlet" and the connector in the lid of the flask with the long silicone tube on the inside. The connector without the long tube must be connected to the port under the port marked "Outlet".



Figure 12.5 Tubes connected to the flask

If no humidification is required/wanted a U-looped silicone tube must be put from the port marked "Outlet" to the port below.

Fill the flask to the bottle mark with sterile water.

12.1 MAW without compartments

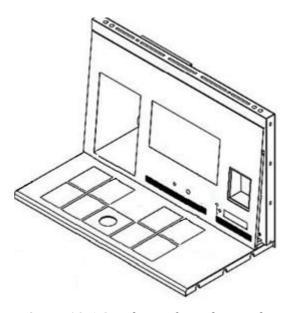


Figure 12.6 Gas choose from the nozzle

The gas will flow through the nozzle in the table top work are.



Figure 12.7 Gas nozzle in table top

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



Figure 12.8 Gas hood placed over gas nozzle

Keep the lids on the dishes when they are placed under the gas hood. The dished can be placed directly on the warmed surface but a Carry Tray.

Heating optimization plate can also be used. With the Carry Tray, several dishes can be conveniently being transported between a CO₂ incubator and the Workstation.



Figure 12.9 Carry Tray

12.2 MAW with compartments

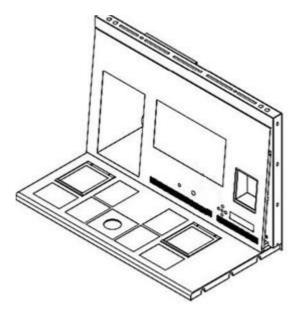


Figure 12.10 Maw with compartments

The gas will flow through and circuit in both compartments by the internal FAN. The FAN will automatically start when the flow is set.

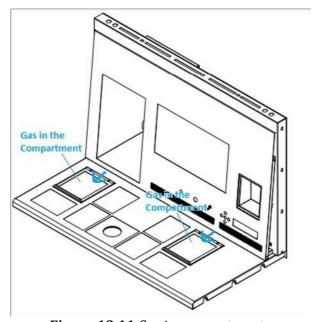


Figure 12.11 Gas in compartments

Gas system over view

Required input gas type: Premixed CO₂. Check medium types for the correct mixture and validate the mixture with a gas analyzer prior to use.

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

Gas alarm; the alarm level < 0.2 bar and > 0.8 bar. In case of an alarm remove the sample to safe CO_2 incubator and investigate the cause of the alarm.

The gas flow set point can be adjusted in the range from 0 l/h to 40 l/h. 1 l/h increments.

The correct flow is a balance towards maintaining the pH level in the medium and economy of the gas usage. With increased flow there is an increased likely hood of correct gas level and fast gas recovery. But also increased gas cost. So the flow can be adjusted down to a level where the pH in the medium 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 check the medium manufactures recommendations.

13 User interface

The table 13.1 shows the main keys and their purpose.

Table 13.1 Main keys and their purpose

Description	Image
Main keys	
On/off In the REAR of the unit	
Alarm key – Is used to mute an audible alarm and indicates the alarm condition visually by a flashing red circle of light. The audio alarm will automatically come back on after 5 min; it can be muted again	
Display panel - Shows the information on the current status of the unit. The display consists of 7 x high brightness 16 segment LEDs. The first one is red, to indicate a user warning. The other 6 are blue and used to display normal running conditions	AB A B B B

Set point

- Is used to select items on the menu to change their status. It is also used to change the temperature and gas set points



Arrow keys up, down & right

- Are used to navigate through the menu, and changing values for temperature and gas concentrations



13.1 Activating the heat and gas flow controls

The heat and gas controls are activated using the on/off switch under the table top.

Soon after system activation the main display will show the actual temperature.



Change the display reading to gas flow, press key right

13.1.1 Temperature sub-menu

The temperature set point can be adjusted in the range from ambient to 40.0 °C.

The default temperature set point is 37.0 °C.

Changing the set point for the temperature, flow these instructions:

When the display show the current temperature:



Press and hold the SP key.

Now the set point can be adjusted up or down with the arrow up or arrow down key.

One key press corresponds to a 0.1 °C change.

If the display does not show the current temperature reading press the arrow right key.

13.1.2 Gas flow set point

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

Changing the set point for the gas flow, follow these instructions:

When the display show the gas flow:



Press and hold the SP key.

Now the set point can be adjusted up or down with the arrow up or arrow down key.

One key press corresponds to a 1 l/h change.

If the display does not show the current gas flow reading the arrow right key will toggle between the temperature and gas flow readings.

13.1.3 Heated Mode

Table plate has four heated mode. It possible to heated area.

To adjust Heated mode, press right key unit the mode function is shown on the display.

Changing the Heat mode, follow these instructions.

When the display show the gas flow:



Press and hold the SP key.

Now the Mode can be adjusted up or down with the arrow up or arrow down key.

Mode 1:

All zones are on and controlled, all zones are heated up to the set point.

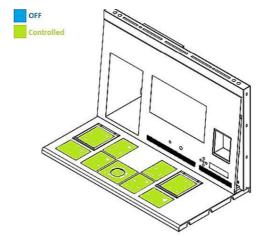


Figure 13.1 Mode 1

Model 2:

Both compartments are on and controlled.

Right side and the middle zone are on and controlled

Left side of the area is off, as shown, all other zones are heated up to set point.

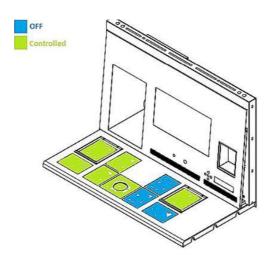


Figure 13.2 Mode 2

Mode 3:

Both compartments and the right side of the plate are on and controlled.

The middle zone and left side area are off; as shown.

All other zones are heated up to set point.

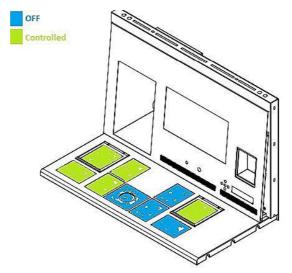


Figure 13.3 Mode 3

Mode 4:

Both compartments are on and controlled, rest of the table plate is off as shown.

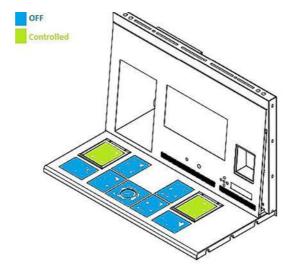


Figure 13.4 Mode 4

13.2 Surface temperatures

There are 12 separate PID controls for the temperature on the table plate. Each controller is responsible for controlling the temperature of a separate zones.

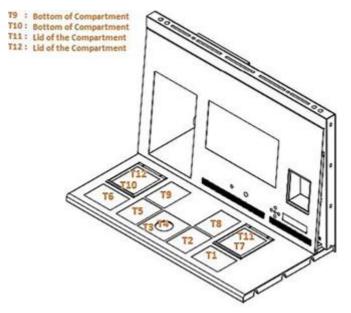


Figure 13.5 PID

Each of the 12 available zones is equipped with its own separate temperature sensor and heater, allowing the user to adjust the temperature within every zone separately and achieving higher precision.

Each zone can be calibrated separately using the item that corresponds to the respective zone in the menu.

These items are placed in the menu and they are named: T1, T2, T3, T4, T5, T6, T7, T8, T9 and T10, 11, 12.

To adjust/calibrate the temperature of the zone please find the item called 'tx' (where x is the zone number) and adjust it based on a measurement taken using a high precision thermometer.

Esco Medical recommends ONLY the YSI 4610 equipped with a 4611 probe.

To achieve precision, the measurement device must be both fast in response and accurate.

Calibration of temperature is done by adjusting the tx according to a measurement done on a spot.

After temperature adjustment allow at least 15 minutes for the temperature to stabilize, use the thermometer to verify correct temperature on each zone.

Tape the 4611 sensors to the middle of the zone. It may be necessary to do iterations before the zone is completely calibrated.

Be careful when changing the calibration settings to only change the value corresponding to the place where the measurement is done. Give the system time to adjust.

There is virtually no cross over heating between the 12 zones when they are adjusted to temperatures within $0.5\,^{0}$ C. At larger temperature differences the hotter zone will affect the colder zone.

Example: How to calibrate the temperature

Note: (the procedure is the same for T1-T12)

After measuring with a quality thermometer, it has been noted that T1 is 37.4 °C. locate T1 in the sub menu:



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



Adjust the temperature by pressing the arrow up key 4 times while holding the SP key down.

The display will show the steps from 37.1, 37.2, 37.3 and 37.4. let go of the SP key and the value is now stored and calibration value for the T1 area temperature has been modified.

Press the arrow up to exit back into the menu.

13.3 Menu Options

Press and hold arrow up and down – 3 seconds – to access menu:

Navigate in menu using:

- Arrow right (in)
- Up and down (previous next)
- SP/Enter (change accept)
- Pressing and holding arrow up and down for 3 seconds will exit from any stage in the menu.

13.3.1 Main Menu



Arrow up – leave menu Arrow right – enter menu



Arrow down scroll further down in menu, arrow up on stage back and right arrow chose the Temp category:



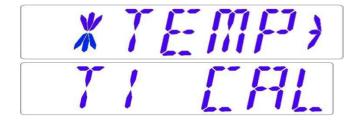
Arrow up on stage back and right arrow chose the Service category

13.3.2 Sub-menu

All Sub-menu are described in the next passage.

13.3.2 Temperature sub-menu

Choose arrow right under temp to enter the temperature sub-menu:



Calibrate holding down the SP key and using up and down arrow to adjust:

Move to the next sub-menu item with arrow down or one step up with arrow up.



Calibrate holding down the SP key and using up and down arrow to adjust:

Move to the next sub-menu item with arrow down or one step up with arrow up.



Calibrate holding down the SP key and using up and down arrow to adjust: Move to the next sub menu item with arrow down or one step up with arrow up.



Calibrate holding down the SP key and using up and down arrow to adjust: Move to the next sub menu item with arrow down or one step up with arrow up.



Calibrate holding down the SP key and using up and down arrow to adjust: Move to the next sub menu item with arrow down or one step up with arrow up.



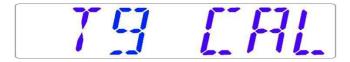
Calibrate holding down the SP key and using up and down arrow to adjust: Move to the next sub menu item with arrow down or one step up with arrow up.



Calibrate holding down the SP key and using up and down arrow to adjust: Move to the next sub menu item with arrow down or one step up with arrow up.



Calibrate holding down the SP key and using up and down arrow to adjust: Move to the next sub menu item with arrow down or one step up with arrow up.



Calibrate holding down the SP key and using up and down arrow to adjust: Move to the next sub menu item with arrow down or one step up with arrow up.



Calibrate holding down the SP key and using up and down arrow to adjust: Move one step up with arrow up.



Calibrate holding down the SP key and using up and down arrow to adjust: Move to the next sub menu item with arrow down or one step up with arrow up.



Calibrate holding down the SP key and using up and down arrow to adjust: Move one step up with arrow up

13.3.3 Service sub-menu

Choose arrow right under Serv to enter the Service sub menu:



The service sub menu is locked as default: The display will show:



Press SP to read the currently installed firmware version:



Press the arrow up to exit back into the main menu.

14 Alarms

On single fault condition, the display will show a red "A" along with the status message of the affected parameter. There will be an audio signal that can be muted by pressing the alarm key once (toggled on/off, for a period of 5-minutes). There will also be an arrow indicating if the alarm is triggered due to too high or too low values, and the audio on/off key will blink red:





Figure 14.1 Alarm key which indicate the alarm condition

The audio pattern is 3 short beeps followed by a 3-second pause. All alarms have the same audio pattern.

14.1 Temperature alarms

All 10 compartments can trigger a temperature alarm if their temperature varies over $\pm 0.5^{\circ}\text{C}$ from the set point.

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



Temperature is too high in compartment 3. The display will lock-on the alarm condition and will stop alternating between the normal status messages.

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

The zone triggering the alarm will be indicated by the number following "A".

The zone layout and sensor placement are described in section 167



Temperature is too low in compartment 4.

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



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

14.2 Gas pressure alarms

If the CO_2 gas supply is not attached correctly or a wrong CO_2 gas pressure is applied to the system, the MAW, Multi-zone ART Workstation® will go into CO_2 pressure alarm mode. " CO_2 P" will be displayed, indicating wrong incoming gas pressure. The alarm level is < 0.2 and > 0.8 bar.





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

14.3 Multiple alarms

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



The flow will be forced according to the alarms. The temperature alarms have 1^{st} priority. gas level alarms 2^{nd} .

14.4 Loss of power alarm

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





Figure 14.2 Alarm key which indicate the alarm condition

15 Changing the set points

The CO₂ pressure rate can only be seen in the workstation logger view on the PC. The value is in bar. External pressure must be 0.6 bar always. It cannot be adjusted on the MAW, Multizone ART Workstation®, only on the external gas regulator.

Remember there is a pressure alarm on the pressure limits if the fall below 0.2 bar or rise above 0.8 bar.

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

16 Firmware

The firmware installed on your ART Workstation is upgradeable. Whenever an important update is available it will be distributed to our distributors around the world who will make sure that your incubator runs with the newest available logic firmware. This can be done by a service technician during the scheduled yearly service.

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

In the menu locate the Service sub menu "Serv".

Choose arrow right under "Serv" to enter the Service sub menu:



The service sub menu is locked as default:

The display will alternate between:



And the currently installed firmware version:



Press the arrow up to exit back into the menu

17 The Laminar Flow

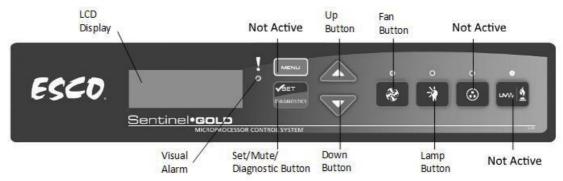


Figure 17.1 Main keys

Fan Button - Turns on and turns off the fan. 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 Not active for the User.

Only 3 functions are available for the user. Switching on/off the laminar airflow, activating the standby flow mode and Switching on/off the interior light.

18 Cleaning instructions

18.1 Considerations about a sterile device

The MAW, Multi-zone ART Workstation[®] is not a sterile device: It is not delivered sterile, and it is not assumed to be possible to keep it sterile when in use.

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

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

The design features intended to provide cleanliness are:

- An ULPA filtered laminar air flow
- A flush stainless-steel work surface
- Use of parts that withstand cleaning well

18.2 Manufacturer recommended cleaning procedure

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

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

Periodic cleaning of the device (with no embryos in)

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

- 1. Power off the MAW, Multi-zone ART Workstation® (underside panel)
- 2. It is recommended that the unit is cleaned with aqueous 70% isopropyl alcohol: Moisten a sterile wipe (Gamma Wipe® 300) and clean all internal and external surfaces of the device by rubbing the wipe on the surfaces
- 3. Following cleaning leave the lids of the device open to allow sufficient time to ensure that all alcohol fumes have dissipated
- 4. Finally, purified or sterile water is used to wipe the device surfaces
- 5. Inspect the device: If visually clean, the device is ready for use
- 6. Turn on the MAW, Multi-zone ART Workstation® (underside panel)

If not visually clean, repeat process from step 2.

18.3 Manufacturer recommended disinfection procedure

Disinfection of the device (with no embryos in)

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

Proceed with the following steps (This procedure has been demonstrated during the on-site training program as part of the installation protocol):

- 1. Complete the full cleaning procedure except step 6
- 2. Open the lids
- 3. Disinfect the internal surfaces, the heating inserts plus the glass plate on the top of the lid with EcaFlo® Anolyte. Apply EcaFlo® Anolyte using sterile wipes (Gamma Wipe® 300)
 - Wipe all internal surfaces and the top of the lid with at least three wipes. Repeat until the wipes are no longer discolored
- 4. Change the gloves and after a 10-minute contact time spray sterile water and wipe with a sterile wipe (Gamma Wipe® 300)
- 5. Inspect the device and if visually clean the device is ready for use. If not visually clean go to step 3 and repeat the procedure
- 6. Turn on the MAW, Multi-zone ART Workstation® (rear panel)

19 Heat optimization plates.

The Carry Tray heat optimization plate will ensure full contact with the dish. This generally means much more stable temperature conditions for the cells. The plate fits the area under the gas hood. The plate can be taken out for cleaning and serves as a convenient way to carry several dishes between the CO2 incubator and the ART Workstation.

Do not autoclave at the Carry Tray. This will damage it, as the high temperature will make it bend out of shape.

Place the dish where it fits the pattern. There is a Carry Trays for Nunc® and for Falcon® dishes.

Only use the correct type for your dishes.



Figure 19.1 Carry Tray

20 Humidification

If the MAW, Multi-zone ART Workstation® is used for open culture conditions the use of the humidification system and gas hood is recommended.

If the MAW, Multi-zone ART Workstation® is used for culture with a mineral overlay it is not necessary to use the humidification system

21 Temperature validation

The MAW, Multi-zone ART Workstation® is equipped with 5 PT-1000 Class B sensors

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 unit.

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

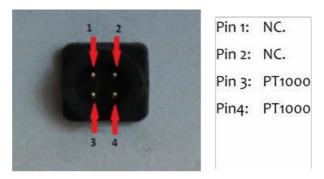


Figure 21.1 Pin

A connector and wire can be supplied by Esco Medical or your distributor.

Through the connectors the temperature conditions in the zones can be logged continually externally without compromising any performance of the unit. Any logging system that uses standard PT-1000 sensors can be used.

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

22 All in one PC

The ART workstation is equipped with a powerful touch enabled AIO PC. Switch on the PC by pressing the button below the screen.



Figure 22.1 The screen

AIO PC with on/off button under the screen

The PC will start and load the Windows operating system first. After that the workstation logger surveillance software will load automatically and the parameters and warnings will be shown on the screen.

The main view shows the 10 zones (numbered). When there are no signal 3 lines are displayed instead of the value. When the sensor signal is received, this will shift to a numeric value.

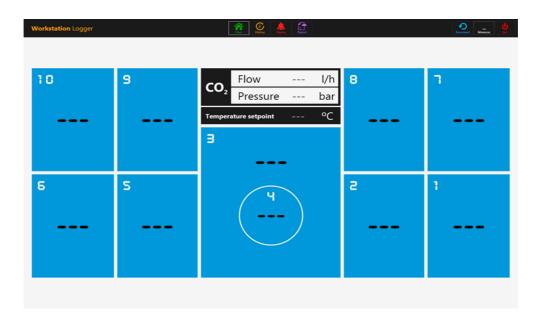


Figure 22.2 The main view

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.

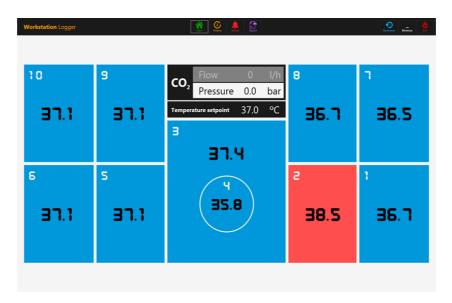


Figure 22.3 The zone operation mode

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

This is unique safety feature of the ART workstation which cannot be found on any comparable system.

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

The greenhouse "Main" brings up the main view (as shown in the pictures above). The orange button "History" toggles the graph view, where graphs can be shown for all the parameters. This is useful for documentation of the systems stability and to identify errant behavior.

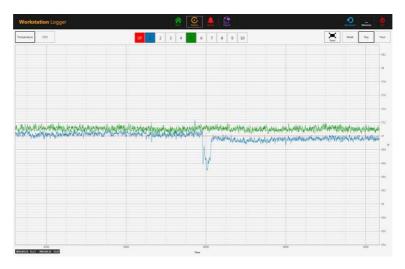


Figure 22.4 The greenhouse "Main" brings up the main view

Several extra buttons appear in the graph view. The user can see the temperatures and toggle on/off the graph for each zone in the view by pressing the button with the number for the zone.



Figure 22.5 The graph view

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 will jump back to full view.

If there are data accumulated it is possible to shift between a "week", "day" or "hour" view.

Pressing the CO_2 button will shift from the temperature view to the CO_2 gas view. Here the user can see the historical data for the flow and pressure.

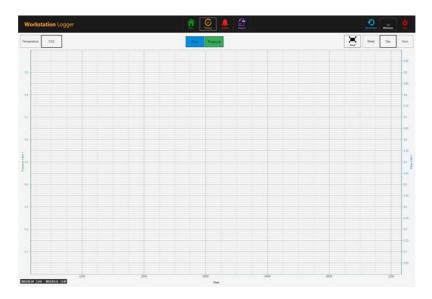


Figure 22.6 The historical data

Pressing the red "Alarm" button in the top will bring up the graphical alarm view. Alarm conditions for the parameters are shown as red on the time line, thus making easy identification possible.

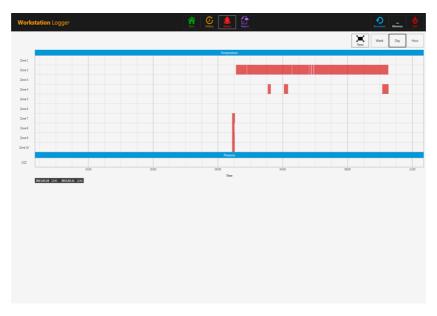


Figure 22.7 The graphical alarm view

Pressing the magenta "report" button will bring up the report mode.

This is for convenient ISO quality management compliance as all the running parameters of the ART workstation can easily be documented and printed as a report or exported in either PDF, Excel or Word.

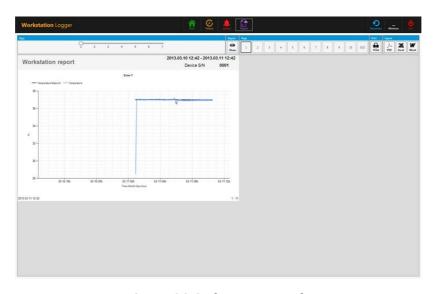


Figure 22.8 The report mode

The 3 action buttons in the right-hand side. The button "reconnect" allows the system to reconnect with the sensors (in case of data loss due to USB connection issues). The button "minimizes" - toggles the full screen format off for the workstation logger. The button

"exit" - shuts down the workstation logger software.

No data will be stored and all safety surveillance functions will be operative if the data logger is shut down.

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



Figure 22.9 The gas humidification bottle

A standard USB socket is located under the humidification system. This 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.

A force function is built into the workstation logger, so even though the full screen on the AIO PC is being use by the microscope camera image, the system will visually alert the user to any alarm conditions and make a rapid shift to the full view of the workstation logger possible.

23 Maintenance

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

- 1. Correct calibration of temperature and gas using high precision equipment per the intervals prescribed by clinical practice at the laboratory where the MAW, Multi-zone ART Workstation [®] is in use. Intervals longer than 14-days between validation are not recommended by the manufacturer
- 2. Replacement of in-line HEPA filter in correct intervals. Once at every changeover of gas bottle

3. Suitable cleaning according to the intervals prescribed by the clinical practice in the laboratory where the MAW, Multi-zone ART Workstation ® is in use. Intervals longer than 14-days between cleaning are not recommended by the manufacturer.

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



Warranty voids if service and maintenance are not followed.

 Δ Warranty voids if service and maintenance are not done by trained and authorized personnel.

24 Emergency Procedures

Total loss of power to or on the unit:

- Remove all the samples and place them in an alternative or backup device that is not affected by the problem.
- The MAW, Multi-zone ART Workstation® will lose its temperature below a safe level in around 5 minutes.

In case of a single temperature alarm on the unit:

- Remove all the samples and place them in an alternative or backup device that is not affected by the problem.
- The MAW, Multi-zone ART Workstation® will lose its temperature below a safe level in around 5 minutes

In case of a single temperature alarm on the unit:

• Remove the samples from the affected zone. They can be relocated to either of the 9 other zones. Each zone is separate so the 9 others will stay safe.

In case of a single temperature alarm on the unit:

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

In case of a CO₂ pressure alarm on the unit:

• Inspect the external gas supply and the gas supply lines. If the problem is external and not readily amendable it normally will not be necessary to perform any emergency procedures other than stop using the humidification system.

25 User Troubleshooting

Table 25.1 Heating system

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

Table 25.2 CO₂ gas

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 at 0.6 bar (8.70 PSI)	

Table 25.3 Data logger

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

Table 25.4 Display

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

Table 25.5 Keyboard

Symptom	Cause	Action	
Absent or erratic function of	Failure in the keys	Contact your Esco Medical Dis-	
keys	ranure in the keys	tributor to replace the keys	

26 Specifications

Table 26.1 MAW, Multi-zone ART Workstation® specifications

Technical specifications	MAW-4D	MAW-6D	MAW-6D DUAL	MAW-6D MP
Work area dimensions (WxDxH)	1260 x 500 x 710 mm	1	1870 x 500 x 710 mm	
External dimensions without support stand (WxDxH)	1340 x 640 x 1300 mm 1950 x 640 x 1300 mm			
External dimension with "B" type support stand (WxDxH)	1340 x 640 x 2160 mm	1	950 x 640 x 2160 mm	
Laminar airflow velocity	Av	verage of 0,21 m/s or	41 fpm (± 20%)	
Filter efficiency	>99.999% for particle siz	e between 0.1 to 0.3 i EN 182	-	C001.3 / H14 per
Noise level (As per IEST)	≤ 47 dB		≤ 48 d	
Per-filter	Disposable and non-w	ashable polyester fib		•
Heating system	Smart power injection ele 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		
Included advanced features	 Integrated humidificati Surveillance system wit AIO PC Heated glass stage Transmitted light source 5 x PT1000 validation p 	th data logger	 Dual Integrated humidification system HS-1 Surveillance system with data logger AIO PC 2 x Heated glass stage 2 x Transmitted light source SC-1 (with bulb) 10 x PT1000 validation ports 	 Dual Integrated humidification system HS-1 Surveillance system with data logger AIO PC 2 x heated glass stage 2 x transmitted light source SC-1 (with bulb) 5 x PT1000 validation ports
Included accessories	 1 x water bottle for HS-1, including tubing 1 x sample carry tray 1 x humidified gas plastic cover 2 x water bottle for HS-1, tubing 2 x sample carry tray 2 x sample carry tray 2 x humidified gas plastic 		ray s plastic cover	
Microscope provision	Provision for 1 microscope		Provision for 2 microscopes	Provision for 1 microscope and 1 inverted mi- croscope

27 Electromagnetic compatibility

Guidance and manufacturer's declaration - electromagnetic emissions

The MAW, Multi-zone ART Workstation[®] is intended for use in the electromagnetic environment specified below. The customer or the user of MAW, Multi-zone ART Workstation [®] should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The MAW, 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 MAW, Multi-zone ART Workstation [®] is suitable
Harmonic emissions IEC 61000-3-2	Class A	for use in a hospital environment
Voltage fluctuations/ flicker emissions	Class A	It is not for domestic establishments

Guidance and manufacturer's declaration - electromagnetic immunity

The MAW, Multi-zone ART Workstation [®] is intended for use in the electromagnetic environment specified below. The customer or the user of the MAW, Multi-zone ART Workstation [®] should assure that it is used in such an environment.

Immunity tost	IEC 60601	Compli-	Electromagnetic environ-
Immunity test	Test level	ance level	ment- guidance
Electrostatic discharge (ESD)	±6 kV contact	±6 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic
IEC 61000-4-2	±8 kV air	±8 kV air	material, the relative humidity should be at least 30%
Electrical fast	±2 kV for power supply lines		
transient/burst	±1 kV for input/		
IEC 61000-4-4	output lines		
Surge	±1kV differential mode ±2kV		
IEC 61000-4-5	common mode		
Voltage dips, short interruptions and voltage variations on power supply input lines	<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		
IEC 61000-4-11	100V) for 5 sec		
Power frequency		Perfor-	Power frequency magnetic
(50/60 Hz)	3 A/m	mance	fields should be at levels
magnetic field		A	neras snoura se acreveis

	characteristic of a typical loca-
IEC 61000-4-8	tion in a typical commercial or
	hospital environment.

Guidance and manufacturer's declaration - electromagnetic immunity

The MAW, Multi-zone ART Workstation [®] is intended for use in the electromagnetic environment specified below. The customer or the user of the MAW, Multi-zone ART Workstation [®] should assure that it is used in such an environment.

Immunity test	IEC 60601	Compli-	Electromagnetic environ-
immunity test	Test level	ance level	ment- 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 MAW, Multizone ART Workstation® including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d=0.35 P d=0.35 P 80MHz to 800 MHz d=0.7 P 800MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur near

Recommended separation distances between portable and mobile RF communication equipment and the MAW, Multi-zone ART Workstation®

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

Rated maximum	Separation distance according to frequency of transmitter (m)			
output power of transmitter W	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 metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (w) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations.

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 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 normal solution, as is required in aircraft and medical facilities.

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