

USER MANUAL

K-MINC-1000

Benchtop Incubator

FROM SERIAL NO. A803560

Please familiarise yourself with
the safety instructions
before using the device.
Accessories and devices may
be used only by physicians
and medical assistants with the
appropriate technical qualification.

C € 0123

COOK®

GENERAL INFORMATION



WARNING:
READ THIS MANUAL.
Please familiarise yourself with the contents of the manual before using the device. Failure to comply with these instructions may result in damage to device, device contents, and/or patient or user injury. This device should only be used by qualified personnel.



WARNING:
ELECTRIC SHOCK HAZARD.
The equipment is to be used only with electrical systems complying with all IEC, CEC and NEC requirements!



CAUTION:
Any adjustment, modification or repairs to the equipment should be carried out by persons authorised to perform them.



Disposal of this product must be undertaken with regard to the WEEE directive (2002/96/EC).

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The symbol to the left indicates that this product may not be treated as municipal waste. Please ensure that this product is properly disposed as inappropriate waste handling of this product may cause potential hazards to the environment and human health. For more detailed information about disposal of this product, please contact your local city office or Cook representative.

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Document No. IFU-MINC-2.

Service address:

Please refer to your local Cook distributor or representative for details of your nearest authorised service agent.

WARNING - CONFIDENTIAL PROPRIETARY PROPERTY







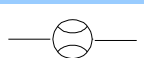





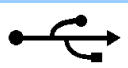







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EXPLANATION OF PICTOGRAMS

The following pictograms appear on the device

	Before connection, read the manual!
	Standby/Active
	Start / Stop
	Increase Decrease Set-Point
	Heater
	Gas Flow Status
	Gas Flow Meter
	Temperature
	Outlet
	Gas Cylinder
	Inlet
	Contacts
	USB Connections
	Symbol for type B equipment
	C – Tick Approval
	CE – Mark Approval
IP31	Degree of enclosure protection from solid objects and liquids
	Dispose in accordance with WEEE directive (2002/96/EC)
	Manufacturer
	EC Representative
	North American Representative

HOW TO USE THIS MANUAL

Warnings, Cautions, and Important Notes

Throughout this manual, blocks of text may be accompanied by a pictogram and/or printed in bold type. These blocks are WARNINGS, CAUTIONS, and IMPORTANT NOTES and they are used as follows:



WARNING: The personal safety of the patient may be involved. Disregarding this information could result in injury to the patient, operator or the device!



WARNING: Biological hazard



WARNING: Electric shock hazard



WARNING: Explosion hazard



CAUTION: These instructions point out special service procedures or precautions that you must follow to avoid damaging the device!



IMPORTANT NOTE: This provides special information that facilitates maintenance or clarifies important instructions. Please pay particular attention to the section Safety Instructions.

Manual Structure

This manual has a table of contents (page i) to locate section titles quickly. Additionally, an index can be found on page 32.

A list of error messages and warning indications can be found on page 16 and a troubleshooting guide on page 29.

1. SAFETY INSTRUCTIONS



WARNING: Please familiarise yourself with the safety instructions before using the device.

This manual describes the operation and intended use of the device and the accessories.

It is essential to use this manual to familiarise yourself with the functions and the operation of the device before use.

Not following these instructions can result in damage or breakdown of the device and accessories.



WARNING:
Electric shock hazard!

Internal circuitry is energised whenever the device is connected to mains power, irrespective of whether or not the displays are illuminated. Always disconnect the device from mains power before cord replacement or cleaning. Should any power cord or plug associated with the incubator become cracked, frayed, broken or damaged it must be replaced immediately.



WARNING: No user serviceable parts inside.

To reduce the risk of electric shock, do not remove covers. Please refer all servicing to the manufacturer's authorised service agent.



WARNING: This device should only be operated by appropriately qualified personnel.

Protect the device from being splashed by liquid. Should any liquid enter the device, discontinue use immediately.



WARNING:
Device can cause explosion in presence of flammable gases.

Do not use in an area where flammable gases are present.



WARNING: Use the correct gas connecting hose.

Use only the Braided PTFE lined gas connecting hose supplied with the K-MINC-1000 to connect it to a gas supply. The use of another tubing type may result in the loss of desired gas concentrations.



WARNING: Use only original disposables.

For your own safety, use only original disposables (see § 7).

2. ABOUT THE K-MINC-1000

2.1 Intended Use

The K-MINC-1000 is a microprocessor controlled, gassed, humidified, incubator intended for use in cell culture.

2.2 Device Description

The device is designed to maintain temperature accurately at a user specified temperature within the range of 35 to 40°C, and to maintain accurate gas flow at a user specified flow rate within the range of 15 to 25 ml/min.

The device utilises premixed gas to maintain optimum culture conditions within the incubation chambers.

All components in contact with the gas flow, including external and internal gas lines, have undergone rigorous testing to ensure a toxin free environment.

The device has the ability to accept NUNC® four well culture dishes, or NUNC® and FALCON® 35mm and 60mm single round culture dishes in two separate chambers. The two chambers have individual temperature control whilst the single gas flow control applies commonly to both chambers.

The heater blocks under each culture dish are in direct contact with the bottom surface of the dish. Whenever the chamber lid is opened and closed, a rapid purge with the gas mix occurs to re-establish the required environment.

The device enhances safety by continuously monitoring the critical functions. Deviation from normal operation is immediately detected and the user is alerted to the detected fault. The device can be connected to an external remote alarm to alert staff out of normal working hours to any problems that the device is unable to self-correct in the allotted time.

2.3 Precautions for Device Use

Should any electrical or mechanical fault occur while using the K-MINC-1000, stop using the device until it has been checked by an authorised service agent.

3. INSTALLATION AND SET-UP



IMPORTANT

NOTE: To reduce the risk of damage to the device, the use of an Uninterruptible Power Supply (UPS) with power conditioning capabilities is strongly recommended.

Furthermore, to ensure uninterrupted device functionality, the use of the following is also strongly recommended:

- An automatic gas cylinder changeover unit that can maintain a minimum pressure of 135kPa.
- A remote alarm to alert staff to any failures in the gas or power supply.



IMPORTANT

NOTE: It is important to retain packaging for future use. (Refer to §6.5 - Return Procedure)



IMPORTANT

NOTE: This device has been certified by an independent testing authority for use with USB and Remote Alarm Cables of less than 3 metres in length.



WARNING: If connecting the K-MINC-1000 Benchtop Incubator to the External Electrical System via the USB cable, ensure that the External Electrical System complies with the IEC 60601-1 safety standard or equivalent.

An installation and set-up checklist has been included in the rear of the manual (see § 4). This may be used to help ensure correct set up.

3.1 Unpacking

Please find the following items supplied:



Description

- | | |
|---|--|
| 1 | User Manual |
| 2 | K-MINC-1000 Device |
| 3 | Patient Identification Plates (8 plates) |
| 4 | K-MINC-CTS-S Disposable Humidification Flask |
| 5 | Medical Grade Mains Power Cord |
| 6 | External Alarm Connector (on rear of device) |
| 7 | K-MINC-BCT-10-300 Braided Connecting Hose (3 metre length) |
| 8 | USB A-B Cable (2 metre length) |

Check the device and all accessories immediately upon receipt to make sure the contents are complete and that nothing is damaged. The manufacturer will only honour claims for compensation which are forwarded immediately to your Cook representative or authorised service agent.

Remove all items from plastic covers except the Disposable Humidification Flask, which needs to be handled under sterile conditions (refer to § 3.8)

**IMPORTANT**











NOTE: Items required but not supplied are listed here.

3.2 You Need to Supply

- A clean source of mains power to supply the device. We strongly recommend the use of a UPS with power conditioning capabilities suitable for your local power supply system.
- Premixed medical grade gas cylinders. All gas concentrations should be within $\pm 0.2\%$ and cylinders should be supplied with a certificate of analysis, refer to § 3.7.1.
- A single stage high purity gas regulator capable of supplying the gas listed above at 150kPa (1.5 bar, 22psi) to the device inlet, refer to § 3.7.2.
- Automatic gas cylinder change over unit. We strongly recommend the use of automatic change over units to ensure continuity of gas supply.
- A source of sterile distilled water.
- A pressure manometer (to measure the device input gas supply). This item is not required if the regulator has gas output display gauges.
- A 9/16" spanner.
- If a longer connecting hose is required, refer to § 7.

3.3 Front of the Device



Symbol	Description
1	 Standby Touch-Pad Toggles the device between Active and Standby State.
2	 Power Indicator Green = Indicates the power is connected to the device, Off = Power is disconnected.
3	 Temperature Display (Heater Chambers)
4	 Heating Status Indicator (Heater Chambers) Flashing Orange = Below Set point, Solid Green = Set Point Reached, Flashing Red = Above Set Point.
5	 Temperature Selection Touch-Pads (Heater Chambers) Adjust Set Point from 35.0 to 40.0°C.
6	 Heating Start/Stop Touch-Pad (Heater Chambers)
7	 Gas Flow Rate Display
8	 Gas Flow Status Indicator Flashing Orange = Purge Cycle, Flashing Red = Outside Set Point, Solid Green = Set Point Reached.
9	 Gas Flow Rate Selection Touch-Pads Adjust Set Point from 15 to 25 ml/min.
10	 Gas Flow Start/Stop Touch-Pad Activates Gas Flow when one or both heater chambers are active.
11	- Gas Vent Holes
12	- Patient Identification Plates

3.4 Rear of the Device



	Description
1	Mains Power Inlet Connect the appropriate power cord to this point.
2	Gas Inlet Connect Gas Supply to this point.
3	Gas Outlet Blanking plug shown.
4	External Alarm Contacts Connect to external alarm if required.
5	USB Connector Type B socket provided.

External Alarm Connection:

Use only with suitable alarm transmitters activated by means of contact closure. Battery or Safety Extra Low Voltage powered alarm equipment, not exceeding stated contact ratings may be connected to the external alarm terminals. Refer to Technical Specifications (§8) for alarm contact rating.

USB connection:

Use only with Laptop or Desktop PC standard USB connections (USB1.1 and USB2.0 compliant).

Gas connections:

Refer to Gas Supply (§ 3.7) for details



WARNING:
ELECTRIC SHOCK
HAZARD.

Determine if the available voltage corresponds to the device. Connecting to the wrong voltage will cause the device to malfunction or may permanently damage the device!

The power cord must be equipped with a safety plug. Use the enclosed power cord for the connection between the power plug and the device socket!

WITHIN CANADA & U.S.A
– Use only a listed detachable power supply cable, type SJT, minimum 18AWGx30, 3 conductors, one end configured for NEMA 5-15, other end for IEC 320/CEE22!

Grounding will only be reliable if the equipment is connected to a corresponding hospital grade socket!



WARNING: The K-MINC-1000 should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.



WARNING:
EXPLOSION HAZARD. Do not use the device in the presence of flammable gases!



WARNING:
ELECTRIC SHOCK
HAZARD. Do not immerse the device!

3.5 Electromagnetic Compatibility

The K-MINC-1000 Benchtop Incubator has been tested and found to comply with the electromagnetic compatibility (EMC) limits for medical devices as specified by IEC 60601-1-2:2001. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

Medical electrical equipment requires special precautions regarding EMC and must be installed and operated according to these instructions. It is possible that high levels of radiated or conducted radio-frequency electromagnetic interference (EMI) from portable and mobile RF communications equipment or other strong or nearby radio-frequency sources could result in performance disruption of the Benchtop Incubator. Evidence of disruption may include erratic readings, equipment ceasing to operate, or other incorrect functioning. If this occurs cease using the Benchtop Incubator and contact your Cook authorised service agent.

For guidance and manufacturer's declaration on electromagnetic emissions and immunity of the K-MINC-1000 Benchtop Incubator, refer to § 8.

3.6 Device Placement

The device should be placed on a level secure surface, away from heaters, coolers, air-conditioning outlets, mists, splashes and exposure to direct sunlight. It must not be placed in the presence of flammable gases. Position device such that quick and easy disconnection of the power supply plug is not impeded.

The ambient temperature range should be between +20°C and +28°C to maintain a device set point between the ranges of 35°C to 40°C. At a device set point of 37°C, the ambient temperature range can be extended from +18°C to +32°C.



WARNING: Ensure that the appropriate high purity gas mixture is selected to suit the altitude above sea level of use and the culture media being used!



IMPORTANT NOTE: When using the Cook Culture System at sea level a 6% CO₂, 5% O₂, and 89% N₂ blend high purity gas mixture is recommended.

3.7 Gas Supply

3.7.1 Gas Mixture Required

To maintain the correct operating pH of 7.2 to 7.4 in bicarbonate buffered media the concentration of CO₂ in the atmosphere in contact with the media must be strictly controlled.

The concentration of CO₂ (expressed as a percentage) required to maintain the correct operating pH is dependant on the chemical composition and concentration of the media, the altitude at which the device is being operated and the humidification status of the atmosphere in contact with the media.

The correct percentage CO₂ for the desired pH can be determined from the graph provided.

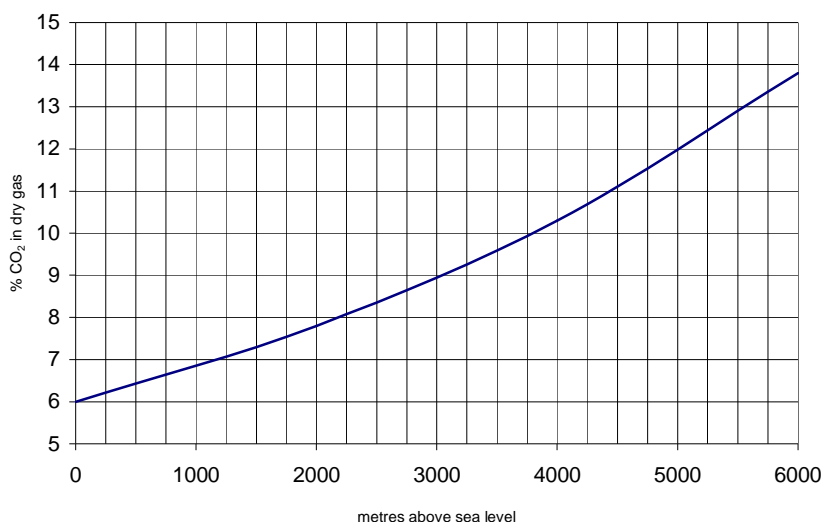
At sea level, the Cook Culture System range of media will give an approximate pH of 7.4 if 5.0% CO₂ is used and 7.3 if 6.0% CO₂ is used in the gas mixture.

Cook recommends the use of 6.0% CO₂ as it promotes a more rapid recovery to an acceptable pH.

Cook recommends a reduced oxygen concentration from the normal atmospheric concentration, to a more physiological value of 5-8% in the atmosphere in contact with the media, as this may reduce reactive oxygen species formation.

If using the device at other than sea level, the following graph may be used to find the approximate CO₂ percentage to achieve a pH of 7.3.

%CO₂ required to maintain pH 7.3 vs Altitude



If a different medium is used or a different pH is required, then the end user will need to determine the appropriate gas mix for connection to the device.



WARNING: The gas inlet must be connected to a regulated pressure source set to 150kPa (tolerance of $\pm 15\text{kPa}$) at the device to operate correctly!



IMPORTANT NOTE:

Cook strongly recommends the use of automatic gas cylinder change over units to ensure continuity of gas supply.

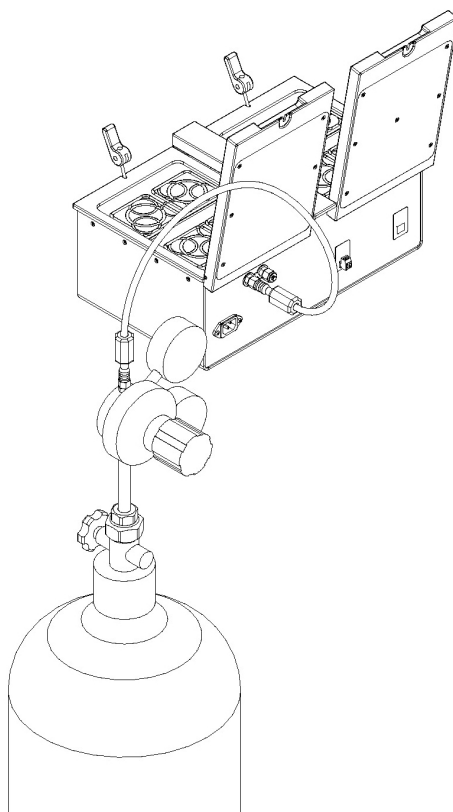
3.7.2 Gas Cylinder Regulator Recommendations

The following information is a recommended guide for the selection of a gas cylinder regulator used with the K-MINC-1000. Following these guidelines will provide a reliable gas connection between a gas cylinder and the K-MINC-1000.

The gas regulator chosen in conjunction with the K-MINC-1000 is an important part of the gas delivery system and must be designed and manufactured to carry medical gases. As the gas specified to be used with the K-MINC-1000 is of high purity and accuracy it is important that the regulator used does not contaminate the gas stream.

Please specify the information below when ordering your gas regulator:

- Single stage high purity regulator.
- Metal to metal diaphragm seal.
- Stainless Steel diaphragm, which doesn't contaminate high purity gas streams.
- Dual scale gauges (optional).
- Fully configured for a special blend medical grade gas cylinder.
- Delivery pressure of 150kPa $\pm 15\text{kPa}$ at the device inlet.
- A minimum flow (without undue supply pressure sag) capability of 350ml/min per K-MINC-1000 is required during the purge cycle.
- The outlet fitting of the regulator is to be a Swagelok® SS-400-1-4RT fitting to fit the connecting hose supplied with the K-MINC-1000.





CAUTION: Use only a suitable medical gas grade pressure regulator set to a nominal 150kPa. Do not use flow restrictors or flow regulators in the gas stream



WARNING: Silicone tubing must not be used in the connection between gas cylinder and the K-MINC-1000, or in series connections of multiple devices.



IMPORTANT NOTE: Firmly tighten the connecting hose(s) to the K-MINC-1000 fitting and ensure that the blanking plug is also firmly tightened (if used).

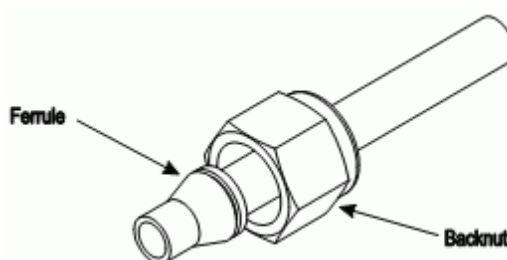
3.7.3 Connection to Gas Cylinder

Connection of the device to gas cylinder is achieved by use of the supplied braided connecting hose. It has a non-toxic, low permeability PTFE lining which prevents the loss of CO₂ content associated with high pressure use of more permeable materials such as silicone and PVC. Silicone tubing is relatively porous to pressurised CO₂ and must not be used anywhere in the connection from the gas cylinder as the correct gas concentrations may not reach the K-MINC-1000 chambers.

The K-MINC-1000 and connecting hose are fitted with Swagelok® ¼" series tube fittings. The standard hose length is 3 meters. Alternative lengths are available – refer to Disposables § 7.

A pressure regulator with these fittings should also be used.

These fittings use a tapered ferrule to provide a leak-free seal upon connection.



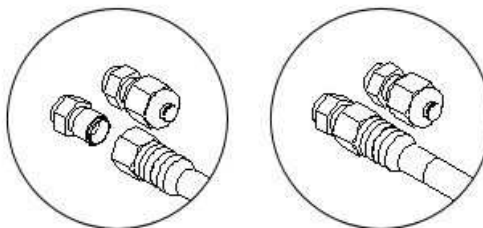
The ferrules on the connecting hose have been pre-swaged before shipping. Therefore, any ferrule and backnut on the cylinder mounted regulator will be surplus to requirements.

It will be necessary to connect the hose to the regulator outlet fitting and also to the device inlet fitting. The instructions below must therefore be performed on each end of the connecting hose. Following these instructions should ensure a reliable leak-proof seal every time the connection is made.

To connect the hose to a fitting:

1. Ensure that the fitting body, tube end and ferrules are free of any foreign materials.
2. Insert the tube adaptor with pre-swaged ferrules into the fitting body until the front ferrule seats.
3. Tighten the backnut firmly by hand. Using a 9/16" spanner tighten the nut slightly (usually 1/8 turn or less).

Check the seal is gas tight by covering with soapy water and looking for the presence of bubbles. If bubbles are observed, disconnect and repeat from step 1, tightening the nut further if no foreign material is found in the fitting.



The blanking plug, shown above, must be tightened onto the unused gas connection.

**IMPORTANT**

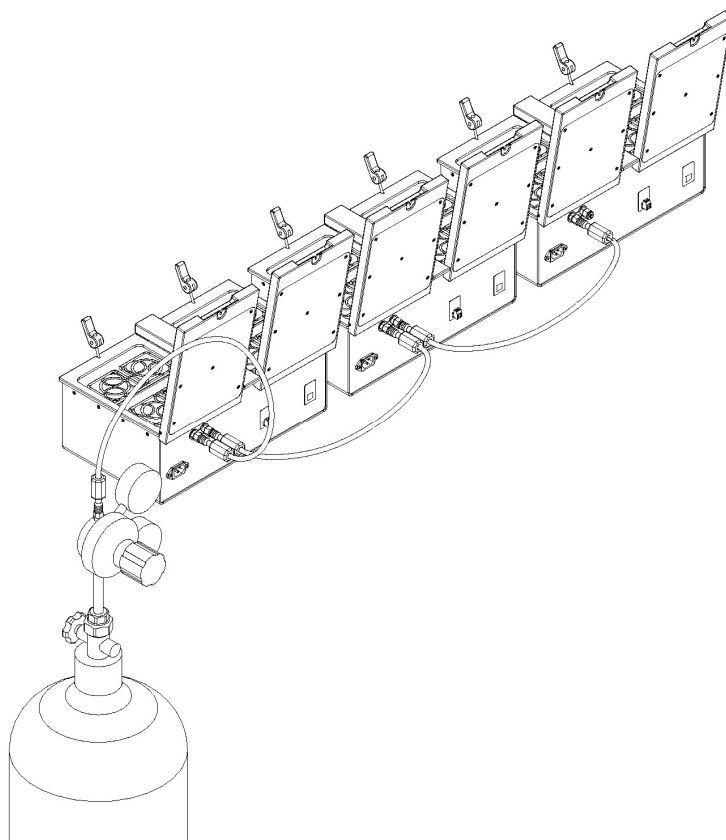
NOTE: Keep your unused blanking plugs securely stored in the event that independent operation of the units is required in the future.

Ensure that your pressure regulator is capable of flowing sufficiently for your needs. If in doubt, check the regulated pressure is still a nominal 150kPa with all series connected devices purging.

Silicone tubing must not be used in the connections of multiple devices.

3.7.4 Series Connection of Devices

In situations where multiple K-MINC-1000 devices are to be operated from a single gas supply point, sequential connection of the units is possible.



To connect units in series:

1. Remove the blanking plugs from the second gas connection point of all but the last unit in the sequence.
2. Connect the hose of the last unit to the second gas connection point of the previous unit.
3. Repeat step 2 until all units are linked.

The gas connecting hose can be ordered in different lengths to suit individual installation requirements. Contact your Cook Representative for further details.

3.7.5 Other Gas Connections

For other gas connections or existing gas delivery systems, (e.g. gas cylinder change-over units or permanently installed gas supply systems) it is recommended that the user contact the relevant gas equipment supply centre for installation advice, e.g. BOC Gases or Air Liquide. For gas connection information, contact your Swagelok® distributor (www.swagelok.com).



**WARNING:
BIOLOGICAL HAZARD.**

Do not use a contaminated humidification flask in the device. It is recommended that the sterile humidification flask be replaced regularly with a maximum period of use being 4 weeks.

The humidification flask, gas lines, and filter set are for single use only. Used sets are classed as infectious waste. All infectious waste must be disposed of in a suitable biohazard container or bag. No sharps shall be placed into biohazard bags. All sharps should be disposed of in suitable puncture proof containers.



IMPORTANT

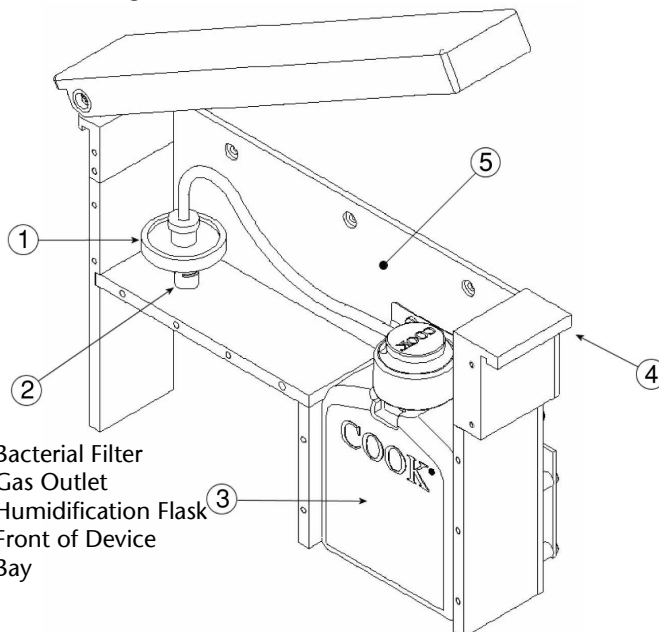
NOTE: During the filling process do not overfill the flask above the limit line and ensure that no water gets through to the bacterial filter. If this occurs, the filter will be blocked and no CO₂ flow will be possible. In such case replace the whole humidification flask assembly (K-MINC-CTS-S)

To avoid bacterial filter blockage and/or spillage of water inside the unit, remove the humidification flask assembly from the bay before moving the device.

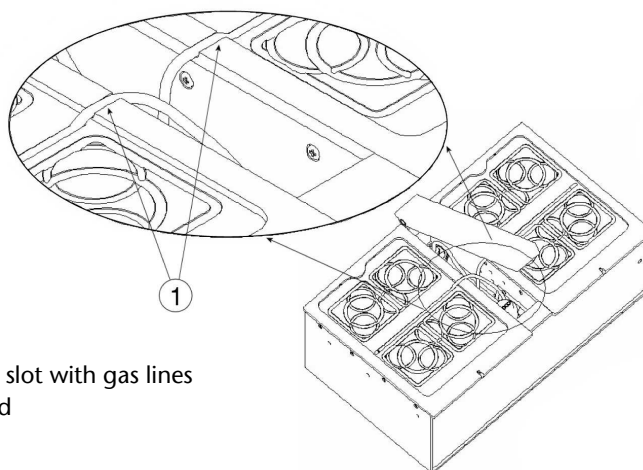
3.8 Humidification Flask

The K-MINC-1000 uses a disposable humidification flask, gas line and filter set (re-order code K-MINC-CTS-S). To prepare and install the humidification flask:-

1. Under laminar flow conditions and using aseptic techniques, fill the humidification flask with 170ml of sterile water. Ensure the flask cap is pushed on in the correct orientation. Failure to seal the cap may result in loss of gas flow to the chambers.



2. Insert the flask into the appropriate position in the bay. The tubing exiting the flask should face the rear of the device. Connect the filter with the Luer fitting to the gas outlet as shown below. Rotate the filter and tubing anticlockwise 180° before pressing onto the Luer fitting and rotating clockwise to lock the filter in place. This will ensure no kinking or twisting of the tubing occurs.
3. Insert the gas lines into the centre slots on each side of the bay as per the diagram below. Check to ensure that the gas lines are not kinked and are seated correctly into the slots to ensure they are not crimped when the lid is closed.



1. Centre slot with gas lines inserted



**WARNING:
ELECTRIC SHOCK
HAZARD.**

Internal circuitry is energised whenever the device is connected to mains power irrespective of whether the device is on or in standby.



IMPORTANT

NOTE: *Ensure that gas supply is available to the device.*



IMPORTANT

NOTE: *For the gas flow to be active, one or both of the chambers must be active.*

3.9 Activating the Device

- Connect the power cord to the mains power inlet and switch power on at the mains.
- The device serial number should be displayed in the left and right temperature displays for approximately 2 seconds.
- The gas flow rate display should display the software version number for approximately 2 seconds
- The device performs a self-test.
- The device will then return to its last mains powered state, either in standby or normal operation.
- If the device was active before the mains power was disconnected then the device will then recommence operation, using the previous temperature and gas flow rate settings.

When either lid is opened and closed or gas flow is started, the chambers are automatically purged to re-establish the appropriate gaseous environment quickly. The automatic purge flow rate is preset and operates independently of the set flow rate.

When the device has just been turned on or when the temperature has been adjusted, the temperature alarm is deactivated for 120 minutes to allow the device to reach stable conditions without constantly alarming.

The device will not be interrupted by a temporary loss of mains power. The device can be placed in standby mode by pressing the standby touch-pad.

3.10 Chamber Temperature Selection

When first turned on, the device will default to a temperature of 37.0°C.

The front panel displays will show actual temperatures of each chamber in degrees Celsius (°C).

3.10.1 Turn the Chamber On or Off

- Press and release the heating start/stop touch-pad.
- This will turn the chamber on or off depending on the current state.

3.10.2 Display the Temperature Set Point

- Press and release one of the temperature selection touch-pads.
- The device will beep and display the temperature set point for that chamber.
- After approximately one second, the temperature display will revert to the actual chamber temperature status.

3.10.3 Adjust the Temperature Set Point

- Press and hold one of the temperature selection touch-pads. The device will beep.
- The temperature will adjust in 0.1°C increments, from 35°C to 40°C.
- The selected value appears in the temperature display for that chamber.
- When the desired temperature setting is reached release the touch-pad

**IMPORTANT**

NOTE: For the device to maintain an appropriate environment in the chambers, the lid must be securely latched when it is closed.

- After approximately one second, the device will beep and the temperature display will revert to the actual chamber temperature. The new temperature set point will be saved.

3.10.4 Open Lid

- Opening the lid will cause the temperature display for that chamber to display **Lid** instead of the chamber temperature. A 'beep' will be emitted from the device approximately every 30 seconds to alert the user to an open lid.
- Closing the lid will cause the temperature display to revert to the actual chamber temperature and the 'beep' will cease.

3.11 Gas Flow Rate Selection

When first turned on the device will default to a gas flow set point of 15ml/min per chamber.

The front panel display will show actual gas flow per chamber in millilitres per minute (ml/min).

**IMPORTANT NOTE:**

For the gas flow to be active, one or both of the chambers must be active. (See §3.10.1)

3.11.1 Turn the Gas Flow On

- Press and release the gas flow start/stop touch-pad.
- The device will begin purging for approximately 3 minutes and then go into normal flow operation.

3.11.2 Turn the Gas Flow Off

- Press and release the gas flow start/stop touch-pad.
- The gas flow will turn off.

3.11.3 Display the Gas Flow Rate Set Point.

- Press and release one of the gas flow rate selection touch-pads.
- The device will beep and display the gas flow rate set point.
- After approximately one second, the gas flow rate display will revert to show the gas flow status.

**IMPORTANT**

NOTE: Follow these steps the first time the device is used to ensure reliable performance.

3.11.4 Adjust the Gas Flow Rate Set Point.

- Press and hold one of the gas flow rate selection touch-pads, the device will beep.
- The gas flow rate will adjust in 5ml/min increments, from 15 to 25 ml/min.
- The selected value appears in the gas flow rate display.
- When the desired gas flow rate setting is reached release the touch-pad.
- After approximately one second, the device will beep and the gas flow rate display will switch back to show the gas flow rate. The new gas flow rate set point will be saved.

3.12 First Time Use

Leave the device to operate with both chambers at 37°C and gas flow at 15ml/min for a minimum of 24 hours to ensure that any residual out-gassing of components is complete.

Test each chamber for pH maintenance using culture media containing phenol red indicator (15µg/ml). Adjust the gas flow to 15ml/min and place the culture media in culture wells in both incubation chambers. After overnight incubation observe that the phenol red indicator is the correct colour (salmon pink).

The device is now successfully installed and commissioned.

3.13 Alarm Conditions

3.13.1 External Alarm

The device has the facility to connect to an external alarm monitor that will alert staff of activated alarms out-of-hours. This external alarm is normally an "open circuit" and can "close" under the following conditions:

- Loss of mains power
- Low inlet pressure
- No gas flow or gas flow out of range
- Temperature out of range

See § 8 Technical Data for the alarm contact rating.

Customer requirements for the external alarm monitor should be referred to a company that specialises in this type of equipment.

3.13.2 Loss of Mains Power

- If the device is switched on and one or both heater chambers are active, loss of mains power will cause the external alarm to activate if the power is still off after 2 minutes.
- If mains power is restored within the 2 minutes, the external alarm will not activate and the device will recommence normal operation.
- If mains power is restored after the 2 minutes, the external alarm will deactivate and the device will recommence normal operation.
- Also if the gas flow was active before the power was lost then the device will restart the flow sequence in purge mode when power is restored.

3.13.3 Low Inlet Pressure

The image shows the text "CO2" in a green, digital-style font, representing the display on the device when low inlet pressure is detected.

The gas flow display will show a "CO2" display and emit an audible alarm if the gas inlet pressure is too low to maintain flow, the nominal inlet pressure to trigger this alarm is >60kPa.

The external alarm contacts will close 15 minutes later if the correct inlet pressure is not restored.

3.13.4 No Gas Flow or Gas Flow Out of Range

The image shows the text "Err" in a green, digital-style font, representing the display on the device when there is no gas flow or gas flow out of range.

The gas flow display will show an "Err" display and emit an audible alarm if the gas flow differs from the set point by greater than 4ml/min (including no gas flow) for longer than 10 minutes.

The external alarm contacts will close 5 minutes later.

3.13.5 Temperature Out of Range

Err

When the device has just been turned on or the set temperature has been adjusted, the temperature alarm is deactivated for 120 minutes to allow the incubator to reach stable conditions without constantly alarming.

After this time the temperature display will show "Err", emit an audible alarm and the external alarm will be activated if the set temperature differs by greater than $\pm 0.2^{\circ}\text{C}$, for longer than 2 minutes.

4. INSTALLATION AND SET-UP CHECKLIST

Check the following:

- ☐ All items have been supplied.
- ☐ The packaging has been safely stored for future use.
- ☐ All non-sterile items have been removed from plastic covers.
- ☐ The power cord is correct for your region.
- ☐ The device has been placed in a suitable location.
- ☐ The appropriate gas mixture has been determined.
- ☐ An appropriate gas regulator has been sourced.
- ☐ The gas regulator has been set to 150kPa.
- ☐ The gas connections have been made and checked.
- ☐ The humidification flask has been filled and fitted.
- ☐ The device has been activated.
- ☐ The chamber temperatures and flow rate have been adjusted to desired values.
- ☐ The device has been left to operate for 24 hours to ensure any residual out-gassing of components is complete.

5. OPERATION OF THE DEVICE



WARNING: To guarantee safe operation, it is necessary to carry out proper care and maintenance of the device and disposables.

Regular checks to confirm correct functioning of the device are recommended!

New and repaired products must be prepared and tested according to the manual instructions before use.



WARNING: BIOLOGICAL HAZARD. Do not use a contaminated humidification flask in the device. It is recommended that the sterile humidification flask be replaced each time the sterile water needs refilling in order to avoid bacterial contamination of contents.

This section provides general information about the use of the device. Only the clinician/embryologist can evaluate the clinical factors involved with each patient and determine if the use of this device is indicated. The clinician/embryologist must decide on the specific technique and procedure that will accomplish the desired outcome.

5.1 Before Use

- Use the temperature selection touch-pads to select the desired chamber temperature.
- Install the humidification flask as detailed in § 6.1.
- Activate the required chambers.
- Use the gas flow selection touch-pads to select the desired gas flow.
- Activate the gas flow.
- Wait a minimum of 4 hours before using to allow for equilibration.

5.2 Insertion of the Culture Dishes

The K-MINC-1000 has been designed to be used with NUNC® four-well dishes, or NUNC® and FALCON® 35mm and 60mm single round culture dishes.

Four-well dishes or single round dishes may be placed on the chamber base. Ensure that they sit securely in the grooves designed to accept them. There should be direct contact between the base of the dish and the surface of the chamber base.

5.3 Patient Identification Plates

Use the magnetic Patient Identification Plates on the chamber lids to record culture dish contents with a marking pen. Pen markings can be removed using an alcohol solution.

6. SERVICE AND MAINTENANCE


WARNING:

To guarantee safe operation, it is necessary to carry out proper care and maintenance of the device and disposables. Regular checks to confirm correct functioning of the device are recommended!

New and repaired products must be prepared and tested according to the user manual before use.


WARNING:
BIOLOGICAL HAZARD.

Do not use a contaminated humidification flask in the device. It is recommended that the sterile humidification flask be replaced each time the sterile water needs refilling in order to avoid bacterial contamination of contents.


WARNING:
ELECTRIC SHOCK HAZARD.

Do not immerse the incubator!

6.1 Changing Internal Filter, Gas Lines & Humidification Flask

Proper service, maintenance and storage must be provided to preserve the device and ensure its proper functioning. To protect the patient from infection, all disposable items that come into contact with human tissue (such as test tubes and tubing) must be sterile. Disposables must be discarded after each patient use.

To change the internal filter, gas lines and humidification flask:

1. Ensure the gas flow is turned off.
2. Lift both heater chamber lids, and the centre chamber lid. Detach and remove the old filter, gas lines and humidification flask.
3. It is recommended to clean the entire device prior to installing a new filter, gas line and humidification flask. Refer to § 6.2.
4. Prepare and insert a new flask as detailed in § 3.8.
5. To recommence operation of the incubator:
 - a. Turn the gas flow on.
 - b. Check that bubbles can be observed in the humidification flask.
 - c. Check that the gas line supplying each chamber is not kinked or pinched.
 - d. Close the lid of the centre chamber and adjust the flow rate if required.
6. Allow 4 hours for the water to heat and saturate with CO₂.

This process can be accelerated by:

1. Pre-heating the aseptically prepared humidification flask to 35°C in step 4, and
2. Purging the system at least 3 times in quick succession as in step 5.

This will allow immediate use of the device.

6.2 Cleaning the Device

Before periodic cleaning of the device, remove:

- The mains power cord
- The humidification flask
- The contents of the incubation chambers

It is recommended that the unit be cleaned with aqueous 70% alcohol (ethanol or isopropyl). Moisten a cloth and wipe all internal and external surfaces of the device.

Do not immerse the device in the cleaning solution.

Clean the gas vents located in the centre of the front of the chamber lids by scrubbing the hole with a small "pipe-cleaner" wetted with the aqueous 70% alcohol solution.

**IMPORTANT**

NOTE: This functionality testing must be performed every six months.

Following cleaning, leave the lids of the unit open to allow sufficient time to ensure that all alcohol fumes have dissipated.

Purified water may be used to wipe device surfaces at times when the use of alcohol solution is not appropriate.

6.3 Biannual Functionality Testing

In order to preserve the device and maintain its safety, regular inspections are necessary for early detection of possible malfunctions.

Regulations stipulate that the user or a qualified technician must regularly test the device to assess its functionality and electrical safety.

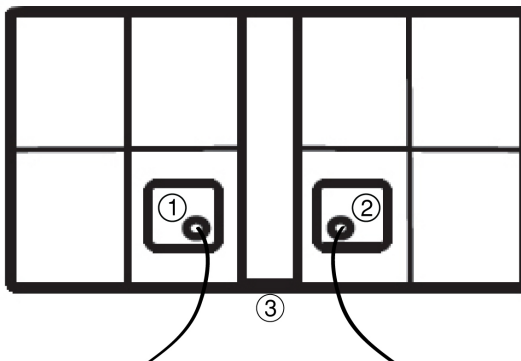
The following must be tested on a biannual basis:

- Temperature
- Gas Flow Rate
- External Alarm Contacts

6.3.1 Temperature

Set each chamber temperature to 37 °C. Place a NUNC® four-well dish into the front inner corner of each chamber. Fill the front inner well of each dish with 2ml of media culture and thermally equilibrate.

To measure the temperature, immerse the tips of calibrated thermocouples into the culture media as shown below, ensuring that the each thermocouple tip sits on the bottom of each well. Close the chamber lid and allow enough time for the thermocouples to thermally equilibrate.



1. Left chamber thermocouple well position
2. Right chamber thermocouple well position
3. Front of device

The temperatures measured will be the user set temperature $\pm 0.2^{\circ}\text{C}$.

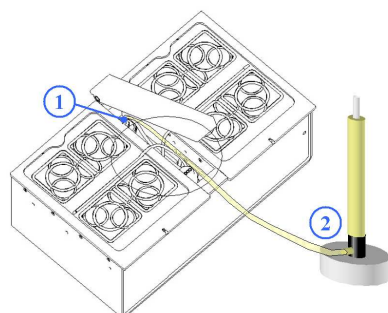
If the measured temperatures are more than $\pm 0.2^{\circ}\text{C}$ from the user set temperature for more than two minutes, contact your Cook representative.

**IMPORTANT**

NOTE: This functionality testing must be performed every six months.

6.3.2 Gas Flow Rate

To test flow rate, use an air calibrated gas flow meter connected to the Luer lock outlet beneath the bacterial filter as shown below.



1. Luer Lock Outlet
2. Flow Meter

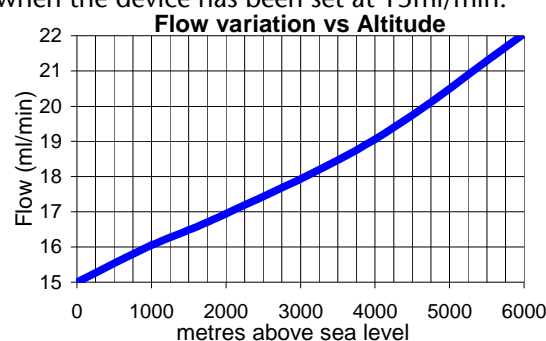
The gas flow meter should have no further restriction on the outlet and be open to atmospheric pressure. Start the gas flowing. The gas flow meter should indicate twice the user set point value $\pm 15\%$. Twice the user set point is observed because the display shows gas flow rate per chamber.

At each of the following set points, check that the measured flow rate is within the corresponding acceptable range:

Flow Rate Set Point (ml/min)	Measured Flow Rate Range (ml/min)
15	25.5 to 34.5
20	34 to 46
25	42.5 to 57.5

If measurements lie outside the acceptable ranges then contact your Cook representative. Gas flow rates for the K-MINC-1000 are calibrated at 22°C at sea level.

Temperature and atmospheric pressure must be taken into account when calculating the expected gas flow. The table below shows the flow obtained with altitude when the device has been set at 15ml/min.

**6.3.3 External Alarm Contacts**

To test the external alarm contacts, ensure at least one heater chamber is active and then disconnect the device from mains power. The contacts should close approximately 2 minutes later. Once the contacts close reconnect the device to mains power and allow to operate for 1 hour.

Open an active chamber lid and mist the chamber with cold water. During this period the temperature display should display "Lid" and a 'beep' should be emitted from the device approximately every 30 seconds. The contacts should close approximately 2 minutes later. If the contacts fail to close then contact your Cook representative.



WARNING: No
user serviceable parts
inside!

6.4 Inspection by an Authorised Service Technician

Inspections at least once a year:	For ongoing operational safety of the device, an authorised service technician must maintain the device annually.
Authorised service technicians:	All services such as alterations, repairs, calibrations etc., may only be performed by the manufacturer or by service technicians who are authorised by the manufacturer.
Liability:	The manufacturer is free from all liability for the operational safety of the device if the device has been wilfully opened and unauthorised persons have performed repairs or alterations on it during the warranty period.
Certification:	The device owner will receive a signed certificate from the service technician for all inspections or repairs. This certificate states the type and scope of the services rendered, the service date, and the name of the service company.
Technical documentation:	If the manufacturer provides technical documentation, this does not authorise the user to perform repairs, adjustments or alterations to the device or accessories.

**WARNING:
BIOLOGICAL HAZARD.**

The returned product must be clearly marked with a contamination warning and should be sealed in a plastic bag and sealed within a second plastic bag.

When shipping the K-MINC-1000 ensure that the humidification flask and all chamber contents are removed prior to transport.

**IMPORTANT**

NOTE: *When returning goods, use the original packaging. The manufacturer does not take responsibility for damage that has occurred during transportation if the damage was caused by inadequate transport packaging.*


6.5 Return Procedure

All devices or disposables that are returned must be prepared as described below for the protection of the service personnel and for safety during transportation.

1. Clean as detailed in § 6.2.
2. Seal in a plastic bag and seal within a second plastic bag.
3. Place in the original packaging.
4. Enclose the following information:
 - Owner's name
 - Owner's address
 - Model type
 - Serial number of the equipment (see identification plate)
 - Description of the damage

The manufacturer or service agent has the right to refuse to carry out repairs if the products it receives are contaminated.

7. DISPOSABLES

 **IMPORTANT**
NOTE: For optimal functioning of the incubator, use only original disposables.

Order No.	Description
K-MINC-CTS-S	Disposable humidification flask, gas tubing and filter set supplied.

8. TECHNICAL DATA

Classification according to IEC 60601-1

Type of protection against electric shock: Class 1 equipment

Degree of protection against electric shock: Type B

Degree of protection against harmful ingress of solids and water: IP31

Specifications

Power supply: 100 – 240VAC

Frequency: 50 – 60 Hz

Maximum current: 1.0A (115V)
0.5A (240V)

Maximum power consumption: 120VA

Alarm contact rating: 2A/30VDC

Environmental operating conditions: +18°C to +32°C

Storage and transport directions: Store in a cool dry place

Manufactured and tested to the following standards: IEC 60601-1:1988+A1:1991+A2:1995
IEC 60601-1-2:2001+Ammendment 2004
EN 60601-1:1990+A1:1992+A2:1995+A13:1995
IEC61010-1:2001 2nd Ed
EN61010-1:2001 2nd Ed
AS/NZS 3200.1.0:1998
UL60601-1:2003

Dimensions: Door closed: 405mm wide x 190mm high x 265mm deep
Door opened: 405mm wide x 400mm high x 315mm deep

Weight: 11kg (24.3lb)

Gas supply type: Blend of 6% CO₂, 5% O₂, 89% N₂ (Cook Culture System at sea-level) or high purity 6% CO₂ in air (recommended tolerances ±0.2%)

Gas supply pressure: 150kPa ±15kPa (21.8psi ±2.2psi) (1500mbar ±150mbar)

Gas flow rate capability : 15ml/min to 25ml/min per chamber in 5ml/min increments.
Purge at 175ml/min per chamber for 3 minutes.

Gas flow rate accuracy: ±15% of flow per chamber (normal flow)
±18 ml/min per chamber (purge)

Chamber temperature capability: 35.0°C to 40.0°C in 0.1°C increments in an ambient temperature range of +20°C to +28°C. At set point of 37°C, the ambient temperature range is extended to +18°C to +32°C

Chamber temperature accuracy: ±0.2°C at calibration point

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The K-MINC-1000 Benchtop Incubator is intended for use in the electromagnetic environment specified below. The customer or the end user of the K-MINC-1000 Benchtop Incubator should assure that it is used in such an environment.

<i>Emissions Test</i>	<i>Compliance</i>	<i>Electromagnetic Environment Guidance</i>
RF emissions CISPR 11	Group 1	The K-MINC-1000 Benchtop Incubator uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. The K-MINC-1000 Benchtop Incubator is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flick er emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The K-MINC-1000 Benchtop Incubator is intended for use in the electromagnetic environment specified below. The customer or the end user of the K-MINC-1000 Benchtop Incubator should assure that it is used in such an environment.

<i>Immunity Test</i>	<i>IEC 60601 Test Level</i>	<i>Compliance Level</i>	<i>Electromagnetic Environment Guidance</i>
Electrostatic discharge (ESD) IEC 61000-4-2	± 6kV contact ± 8kV air	± 6kV contact ± 8kV 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	± 2kV for power supply lines ± 1kV for input/output lines	± 2kV for power supply lines ± 1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV differential mode ± 2kV common mode	± 1kV differential mode ± 2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5%U _T (>95% dip in U _T) for 0.5 cycles 40%U _T (60% dip in U _T) for 0.5 cycles 70%U _T (30% dip in U _T) for 25 cycles <5%U _T (95% dip in U _T) for 5 seconds	<5%U _T (>95% dip in U _T) for 0.5 cycles 40%U _T (60% dip in U _T) for 0.5 cycles 70%U _T (30% dip in U _T) for 25 cycles <5%U _T (95% dip in U _T) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the K-MINC-1000 Benchtop Incubator requires continued operation during power mains interruptions, it is recommended that the K-MINC-1000 Benchtop Incubator be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-5	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

9. TROUBLESHOOTING



IMPORTANT NOTE: Should any errors persist, contact your Cook representative.

Error and Alarm Indicator	Source of Error	Elimination of Error
Unit will not turn on. Displays do not illuminate.	Power supply cord is not connected. Mains power is not turned on.	Check the power supply connection. Turn on the mains power. (Refer to §3.9)
	The device is in standby.	Check that the Standby Indicator is illuminated green. Press the Standby touch-pad. (Refer to §3.9)
Incubator will not heat to correct temperature. 'Temperature out of range' alarm, "Err" displayed.	Temperature settings not entered correctly.	Enter correct temperature settings. (Refer to §3.10.3)
	Set temperature not achieved in time.	Turn heater bay off and on again. (Refer to §3.10.1)
	Lids open for extended periods.	Do not leave lids open for extended periods. Turn heater bay off and on again. (Refer to §3.10.1)
	Device is not operating in functional environmental conditions.	Evaluate device placement. (Refer to §3.6)
'Low inlet pressure' alarm. "CO2" displayed.	Gas supply not connected.	Check gas supply connection. (Refer to §3.7.3)
		The gas flow should recommence in purge mode when the gas supply is reconnected.
	Gas supply empty.	Check available remaining volume.
		The gas flow should recommence in purge mode when the gas supply is re-connected.
	Gas lines are kinked.	Check that gas lines are not obstructed.
		The gas flow should recommence in purge mode when the gas supply is reconnected.
	Gas cylinder change over unit incompatible with the K-MINC-1000.	Ensure that the inlet pressure to the K-MINC-1000 does not fall below 135kPa.
		The gas flow should recommence in purge mode when the gas supply is reconnected.
	Resistance to gas flow from series connection of multiple devices is too high to allow multi-unit purging.	Check the regulated pressure is still a nominal 150kPa with all series connected devices purging. (Refer to § 3.7.4)

Error and Alarm Indicator	Source of Error	Elimination of Error
'No gas flow or gas flow out of range' alarm. "Err" displayed.	Disposable gas lines, flask and filter are incorrectly connected or occluded.	Check connections to Luer fitting in central chamber and check that disposable lines are not kinked (Refer to § 3.8). Turn flow off and on again. (Refer to § 3.11.1)
	Disposable filter occlusion due to moisture.	Replace the disposable humidification flask, gas tubing and filter set - K-MINC-CTS-S. (Refer to § 3.8) Turn flow off and on again. (Refer to § 3.11.1)
	Disposable gas lines are kinked or blocked.	Check that gas lines are not kinked or obstructed (Refer to § 3.8). Turn flow off and on again. (Refer to § 3.11.1)
Low or no gas flow from disposable gas lines without alarm present.	Disposable flask and filter are incorrectly connected.	Check connections to Luer fitting in central chamber. (Refer to § 3.8)
	Disposable flask lid seal.	Check lid is tight and flask is not cracked or damaged. (Refer to § 3.8)
Excessive gas consumption.	High supply pressure.	Ensure that the inlet pressure to the K-MINC-1000 does not rise above 165kPa.
	Gas connections not secure or damaged.	Ensure all gas fittings from the cylinder to the K-MINC-1000 gas inlet are tight. If error persists, inspect all fittings for damage to seal surfaces, and replace as necessary.
	Gas line damaged.	Replace the gas line.
"Lid" displayed and device emitting beep every 30 seconds.	A lid is opened.	Close the lid, this feature is provided to help prevent the chamber from being left open for longer than is required. (Refer to § 3.10.4)

10. LIMITED WARRANTY

William A Cook Australia Pty Ltd warrants to the purchasers of this device that at time of manufacture, the product was prepared and tested in accordance with good manufacturing practices and guidelines specified by the Australian Therapeutic Goods Administration or relevant competent authority.

In the event of product failure under normal use, due to defects in material or workmanship, within a period of one (1) year from the date of purchase, the product will be repaired, or at William A Cook Australia Pty Ltd's option, replaced, at no charge. This limited warranty does not apply to products subjected to abnormal use or conditions, improper storage, damaged by accident, misuse or abuse, improper line voltage or to products altered or serviced by anyone other than William A Cook Australia Pty Ltd or its authorised agent.

The foregoing limited warranty is exclusive and in lieu of all other warranties whether written, oral, expressed or implied. In particular, William A Cook Australia Pty Ltd does not warrant that the product is suitable for the needs of the purchaser and there are no warranties given as to merchantability or fitness for a particular purpose. William A Cook Australia Pty Ltd's representations concerning fitness for purpose or suitability for use by any purchaser does not extend beyond those representations set out in the William A Cook Australia Pty Ltd literature that accompanies the product. William A Cook Australia Pty Ltd assumes that the purchaser is experienced in the use of this device and is able to judge from his/her own expertise the suitability or otherwise of the product for the intended use. William A Cook Australia Pty Ltd conducts a technical advisory service, which can be consulted by a purchaser or intended purchaser on an advisory basis.

After one (1) year from the date of purchase, this device will be repaired for a repair charge equal to the cost of parts, labour and transport.

Before returning a product for any reason, please contact your nearest William A Cook Australia Pty Ltd representative for assistance and instructions.

William A Cook Australia Pty Ltd reserves the right to change or discontinue this product without notice.

10.1 Liability

Because William A Cook Australia Pty Ltd has no control or influence over the conditions under which this device is used, over its method of use or administration, or on handling of the product after it leaves its possession, William A Cook Australia Pty Ltd takes no responsibility for the results, use and/or performance of the product. William A Cook Australia Pty Ltd expects that use of the product will be confined to trained and expert users.

In no event will William A Cook Australia Pty Ltd be liable for any direct or indirect damages including incidental, consequential or special damages, arising out of or in connection with the use or performance of the product.

If the manufacturer provides you with technical documentation, this does not authorise you to perform repairs, adjustments or alterations on the device or accessories.

No representative of William A Cook Australia Pty Ltd and no vendor or leaser of the product is authorised to change any of the foregoing terms and conditions, and the purchaser accepts the product subject to all terms and conditions herein, subject always to any contrary provisions which are necessarily implied by statute or law notwithstanding the within terms and conditions.

10.2 Life of Product

The life of this product is deemed to be seven (7) years. After this time William A Cook Australia Pty Ltd will no longer be responsible for this product. The local service provider may still perform repairs or maintenance.

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NOTES

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PRODUCT MANUFACTURED BY:

WILLIAM A. COOK AUSTRALIA PTY LTD

12 Electronics St
Brisbane Technology Park
Eight Mile Plains
Queensland 4113 AUSTRALIA
Telephone: +61 7 3841 1188
Fax: +61 7 3841 1288

EC REPRESENTATIVE:

COOK IRELAND LTD

O'Halloran Road
National Technology Park
Limerick IRELAND
Telephone: +353 61 33 4440
Fax: +353 61 33 4441

NORTH AMERICAN REPRESENTATIVE:

COOK OB/GYN

1100 West Morgan Street
Spencer Indiana 47460 USA
Toll Free: 800 541 5591
Telephone +1 812 829 4981
Fax: +1 812 829 2022

www.cookmedical.com

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