MINC™

BENCHTOP INCUBATOR

INCUBATION 37°C

K-MINC-1000

From Serial No. A803560

User Manual

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

CE 0123

COOK MEDICAL

www.cookmedical.com

Language Index

General information

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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.*

WARNING: *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).

Copyright

Some of the parts and equipment referred to in this manual bear registered trademarks but are not identified as such. It should therefore not be assumed that the absence of the trademark indicates that any given designation is not subject to trademark protection.

Users of William A. Cook Australia Pty. Ltd. products should not hesitate to contact us if there are any unclear points or ambiguities in this manual.

This symbol indicates that this product may not be treated as municipal waste. Please ensure that this product is properly disposed of 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 Medical Representative.

Cook fulfills its legal obligations with regards to WEEE and Waste Packaging compliance through our own takeback initiatives and through national takeback schemes.

Please see **http://www.cookmedical.com/businessPractice.do?id=Environmental_Recycling** for details on how to properly recycle WEEE or waste packaging in your country.

Document No: IFU-MINC2/9

Service address:
Please refer to your local Cook Medical distributor for details of your nearest authorised service agent.

Table of contents

Explanation of pictograms

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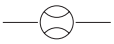
The following pictograms appear on the MINC Benchtop Incubator and the Sterile Disposable Humidification Flask packaging

	Before connection, read the manual!
	Consult the operating instructions for information needed for the proper use of the device
	Standby/On
	Start/Stop
	Increase/Decrease Set-Point
	Heater
	Gas Flow Status
	Gas Flow Meter
	Temperature
	Outlet
	Gas Cylinder
	Inlet
	Contacts
	USB Connections

	CE – Mark Approval
IP31	Degree of enclosure protection from solid objects and liquids
	UL – Approval Marking
	RoHS Compliance Mark
	Dispose of in accordance with WEEE directive (2002/96/EC)
	Manufacturer
EC REP	EC Representative
REF	Catalogue Code
SN	Serial Number
(1) 	Do not use if packaging is damaged
(1) 	Keep away from sunlight
(1) 	Keep dry
(1) LOT	Batch code

Note (1): Symbols are on Sterile Disposable Humidification Flask packaging only.

How to use this manual

Warnings and Important Notes

Throughout these Instructions for Use, blocks of text may be accompanied by a pictogram and/or printed in bold type. These blocks are WARNINGS 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 operator, device or the contents!
	WARNING: Biological hazard
	WARNING: Electric shock hazard
	WARNING: Explosion hazard
	WARNING: Radio Frequency Interference
	IMPORTANT NOTE: This provides special information that facilitates maintenance or clarifies important instructions. Please pay particular attention to the Safety Instructions (see §1).

Manual Structure

This manual has a table of contents (page 2) to help you find section titles quickly. Additionally, an index can be found on page 27. A list of error messages and warning indications can be found on page 14 and there is a trouble-shooting guide on page 25.

1. Safety instructions

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

WARNING: ELECTRIC SHOCK HAZARD.

***WARNING:** Do not sterilise the device.*

***WARNING:** No user serviceable parts inside.*

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

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

***WARNING:** Use the correct gas connecting hose.*

***WARNING:** Use only original disposables.*

This manual describes the operation and intended use of the MINC Benchtop Incubator (MINC) for devices with serial numbers from A803560 onwards.

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

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

Internal circuitry is energised whenever the MINC 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.

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

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

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

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

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

2. About the MINC Benchtop Incubator

2.1 Intended use

The MINC Benchtop Incubator (MINC) is a microprocessor controlled, gassed, humidified, incubator intended for use in cell culture.

2.2 Device description

The MINC 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 MINC 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 MINC has the ability to accept NUNC® four well culture dishes, or NUNC® and FALCON® 35 mm and 60 mm 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 MINC 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.

The K-MINC-1000 Logger Software is a PC based program that is used to continuously record the operating state of up to 10 devices. The software monitors the behaviour of the MINC, but will not control the device. This software can only be used with MINC's with serial numbers from A803560 onward.

2.3 Precautions for device use

Should any electrical or mechanical fault occur while using the MINC, 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 MINC, 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 135 kPa.*
- *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 MINC 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.*

IMPORTANT NOTE: *Items required but not supplied are listed here.*

IMPORTANT NOTE: *A non-powered USB hub is suitable to connect multiple devices.*

An installation and set-up checklist has been included at the end of this section (see §4). This may be used to help ensure correct preparation.

3.1 Unpacking

Please find the following items supplied:

1. **User manual**
2. **MINC Benchtop Incubator**
3. **Patient identification plates** (8 plates)
4. **Disposable Humidification Flask (K-MINC-CTS-S)**
5. **Medical grade mains power cord**
6. **External alarm connector** (on rear of device)
7. **Braided Connecting Hose** (3 metre length) **(K-MINC-BCT-10-300)**
8. **USB A-B cable** (2 metre length)
9. **K-MINC-1000 Benchtop Incubator Logger Software installation CD**
10. **MINC Introduction DVD**

Check the MINC and all items 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 the sales representative or the 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).

3.2 You need to supply

- A clean source of mains power to supply the MINC. Cook Medical strongly recommends 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 ±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 150 kPa (1.5 bar, 22 psi) to the MINC inlet, refer to § 3.7.2.
- Automatic gas cylinder change over unit. Cook Medical strongly recommends 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 pressure). This item is not required if the regulator has gas output display gauges.
- A 9/16" spanner.
- If a longer gas connecting hose is required, contact your Cook Medical representative.
- A computer suitable to install and run the K-MINC-1000 Logger Software on.
- A USB hub for connecting multiple (up to a maximum of 10) MINC's to a single computer.

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°C 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.**

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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 (USB 1.1 and USB 2.0 compliant).

Gas connections:
Refer to Gas Supply (§ 3.7) for details.

3.5 Electromagnetic compatibility

The MINC Benchtop Incubator has been tested and found to comply with the electromagnetic compatibility (EMC) limits for medical devices as specified by IEC 60601-1-2:2007. 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 MINC. Evidence of disruption may include erratic readings, equipment ceasing to operate, or other incorrect functioning. If this occurs cease using the MINC and contact your Cook Medical authorised service agent.

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

⚠ ***WARNING: ELECTRIC SHOCK HAZARD.*** *Determine if the available voltage corresponds to the device. Connecting to the wrong voltage will cause the MINC 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!

To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

WARNING: *The MINC should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be monitored 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!*

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% CO_2, 5% O_2, and 89% N_2 blend high purity gas mixture is recommended.*

3.6 Device placement

The MINC 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 the MINC such that quick and easy disconnection of the power supply plug is not impeded.

It is recommended to allow a reasonable amount of space around each MINC to allow for natural air circulation. A clearance of at least 10 cm is recommended around each device.

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.

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 CO_2 in the atmosphere in contact with the media must be strictly controlled.

The concentration of CO_2 (expressed as a percentage) required to maintain the correct operating pH is dependent on the chemical composition and concentration of the media, the altitude at which the MINC is being operated and the humidification status of the atmosphere in contact with the media.

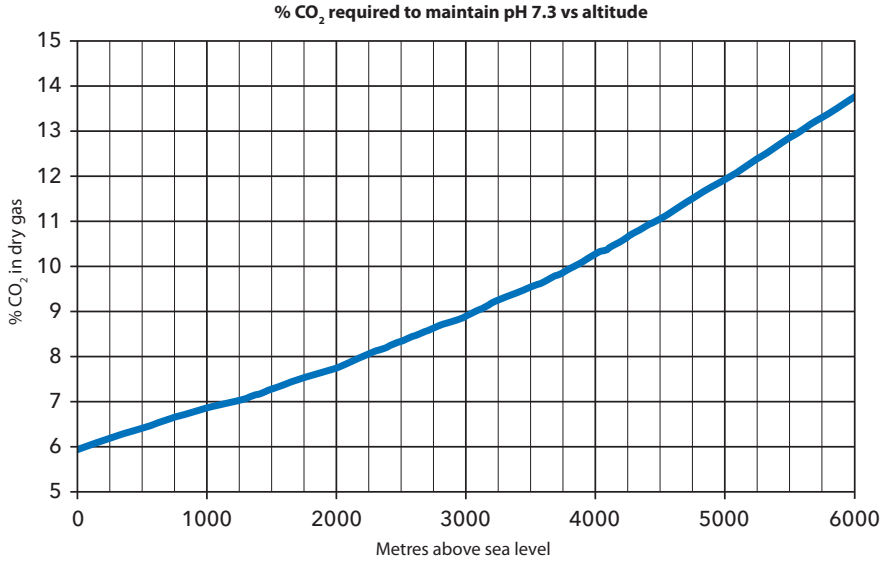
The correct percentage CO_2 for the desired pH can be determined from the graph provided.

At sea level, the Cook Culture System range of media will give an approximate pH of 7.4 if 5.0% CO_2 is used and 7.3 if 6.0% CO_2 is used in the gas mixture.

Cook Medical recommends the use of 6.0% CO_2 as it promotes a more rapid recovery to an acceptable pH.

Cook Medical 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 MINC at an altitude other than sea level, the following graph may be used to find the approximate CO_2 percentage to achieve a pH of 7.3.



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 MINC.

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⚠ ***WARNING:*** *The gas inlet must be connected to a regulated pressure source set to 150 kPa (tolerance of ±15 kPa) at the MINC to operate correctly!*

IMPORTANT NOTE: *Cook Medical strongly recommends the use of automatic gas cylinder change over units to ensure continuity of gas supply.*

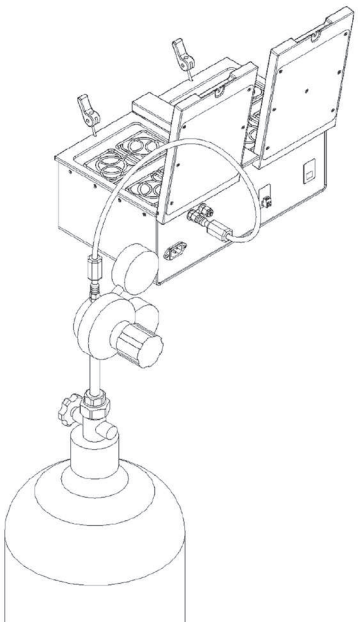
3.7.2 Gas cylinder regulator recommendations

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

The gas regulator chosen in conjunction with the MINC 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 MINC 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 150 kPa ± 15 kPa at the MINC gas inlet.
- A minimum flow (without undue supply pressure sag) capability of 350 mL/min per MINC 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 MINC.



3.7.3 Connection to gas cylinder

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

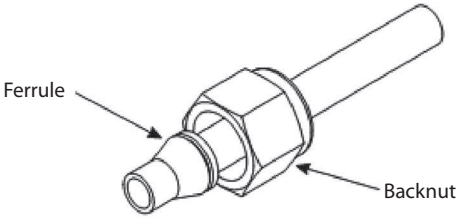
⚠ ***WARNING:*** *Silicone tubing must not be used in the connection between gas cylinder and the MINC , or in series connections of multiple devices.*

Connection of the MINC 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 CO_2 content associated with high pressure use of more permeable materials such as silicone and PVC. Silicone tubing is relatively porous to pressurised CO_2 and must not be used anywhere in the connection from the gas cylinder as the correct gas concentrations may not reach the MINC chambers.

The MINC and connecting hose are fitted with Swagelok® ¼" series tube fittings. The standard hose length is 3 meters. Alternative lengths are available in 60 cm, 100 cm, 6 m, 10 m or 20 m. A union fitting is available to connect gas hoses. Refer to your local Cook Medical representative for more information.

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.

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

It will be necessary to connect the hose to the regulator outlet fitting and also to the MINC 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.

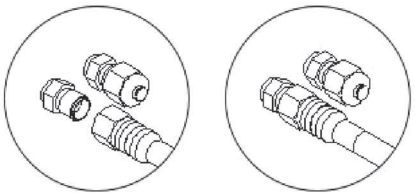
To connect the hose to a fitting:

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.

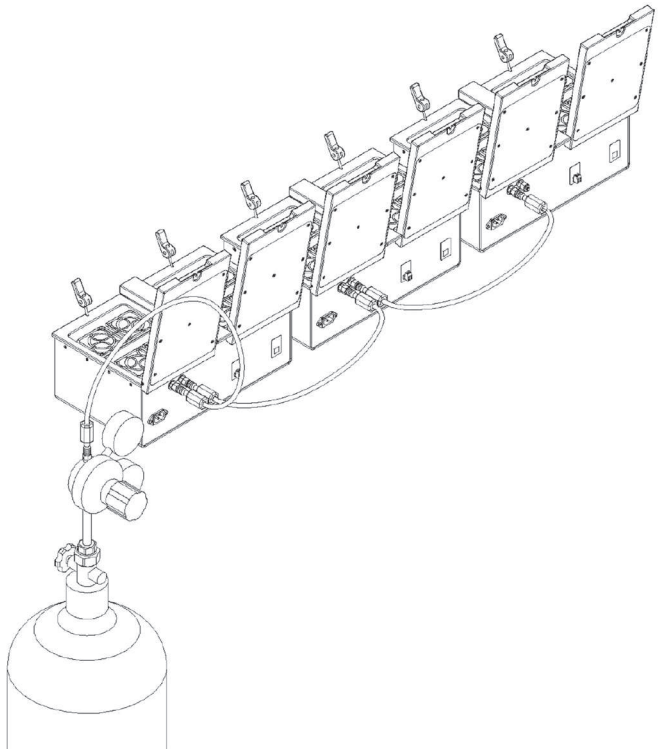
IMPORTANT NOTE: *Keep your unused blanking plugs securely stored in the event that independent operation of the units is required in the future.*

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

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

3.7.4 Series connection of devices

In situations where multiple MINCs 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 Medical 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).

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WARNING: BIOLOGICAL HAZARD. *Do not use a contaminated humidification flask in the MINC. It is recommended that the sterile humidification flask be replaced each time the sterile water needs replacing, or regularly with a maximum period of use being 4 weeks.*

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.

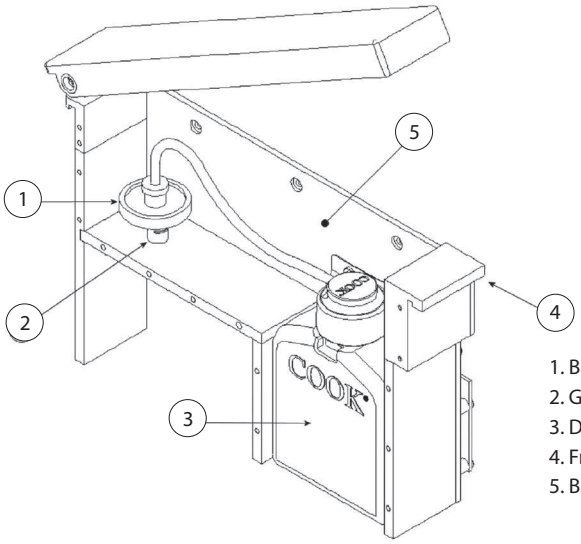
IMPORTANT NOTE: *During the filling process do not overfill the flask above the limit line and ensure that no water gets through to the bacterial filter. If this occurs, the filter will be blocked and no CO_2 flow will be possible. In such case replace the whole humidification flask assembly (K-MINC-CTS-S).*

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

3.8 Humidification flask

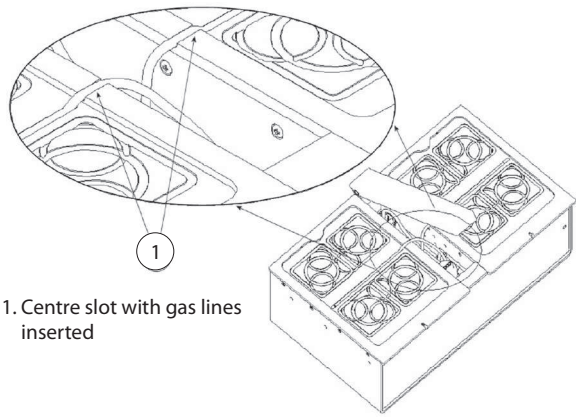
The MINC uses a disposable humidification flask, gas line and filter set (re-order code K-MINC-CTS-S). To prepare and install the humidification flask:-

1. Under laminar flow conditions and using aseptic techniques, fill the humidification flask with 170 mL 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.



1. Bacterial filter
2. Gas outlet
3. Disposable Humidification Flask
4. Front of device
5. Bay

2. Insert the flask into the appropriate position in the bay. The tubing exiting the flask should face the rear of the MINC. Connect the filter with the Luer fitting to the gas outlet as shown above. 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

3.9 K-MINC-1000 Benchtop Incubator Logger Software

The K-MINC-1000 Benchtop Incubator Logger Software is a PC based program that monitors the operating state of up to 10 MINC incubators. You may use this software to monitor the behaviour of the MINC over the incubation period. The software cannot be used to control the device and does not affect the normal operation of the MINC.

Key features are:

- Regular 5 minute logging of: actual temperature, temperature set-points, actual gas flow and gas set-point.
- Immediate logging of events and errors such as: lid opening and closing events, set point changes, activation of chambers and gas flow, activation of the device, gas flow/supply errors and temperature errors.
- Graphical presentation of all data on-screen
- Data is logged to a CSV file for easy analysis with spreadsheet packages.
- Ability to hot-swap connections of up to 10 MINC's.
- Ability to name individual devices for easy identification.

IMPORTANT NOTE: *Refer to § 5.5 for limitations when running Windows 2000 operating system.*

IMPORTANT NOTE: *Users must have Administrator privileges to install software.*

3.9.1 Software installation

Note: The Logger Software and drivers should be installed before connecting the MINC to the PC.

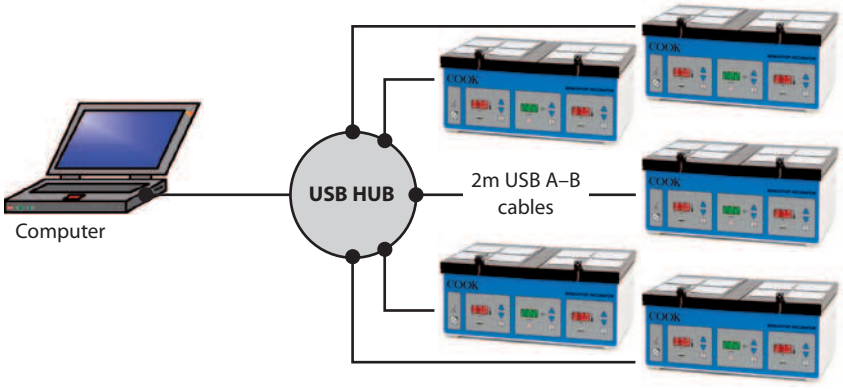
To install this software:

1. Insert the CD marked "K-MINC-1000 Benchtop Incubator Logger Software".
2. Run KMINC1000-setup.exe from the root directory of the CD. For installation on Windows 2000, use KMINC1000-Legacy-setup.exe, located in the "Legacy Installer" directory.

Follow the instructions on-screen to complete the installation.

3.9.2 Connecting USB cables

For connection of multiple MINC's, it is recommended that a USB hub be used (not supplied).



Once connected, the software will automatically detect the connected MINCs.

The MINC does not consume any power from the USB port, so un-powered USB hubs are suitable for connecting up to 10 devices. Daisy chaining of USB hubs is not recommended. Each hub should be connected to a separate USB port on the computer.

The MINC has been successfully tested with the following USB Hubs:

Make	Model	Description
D-Link	DUB-H7	7-Port USB 2.0 Hub
Belkin	FSU407	Hi-Speed USB 2.0 4-Port Ultra-Mini Hub

WARNING: ELECTRIC SHOCK HAZARD. *Internal circuitry is energised whenever the MINC 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 MINC.*

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

3.10 Activating the device

- Connect the power cord to the mains power inlet and switch power on at the mains.
- The MINC's 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 MINC 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 MINC 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 MINC 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.

3.11 Chamber temperature selection

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

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

3.11.1 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.

3.11.2 Display the temperature set point

- Press and release one of the temperature selection touch-pads.
- The MINC 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.

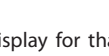
1

3.11.3 Adjust the temperature set point

- Press and hold one of the temperature selection touch-pads. The MINC 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.
- 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.

3.11.4 Open lid

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

- Opening the lid will cause the temperature display for that chamber to display  instead of the chamber temperature. A 'beep' will be emitted from the MINC 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 beeping will cease.

3.12 Gas flow rate selection

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

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

3.12.1 Turn the gas flow on

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

3.12.2 Turn the gas flow off

IMPORTANT NOTE: *For the gas flow to be active, one or both of the chambers must be active (See §3.11.1).*

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

3.12.3 Display the gas flow rate set point

- Press and release one of the gas flow rate selection touch-pads.
- The MINC 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.

3.12.4 Adjust the gas flow rate set point

IMPORTANT NOTE: *Follow these steps the first time the MINC is used to ensure reliable performance.*

- Press and hold one of the gas flow rate selection touch-pads, the MINC will beep.
- The gas flow rate will adjust in 5 mL/min increments, from 15 mL/min 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 MINC 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.

3.13 First time use

Leave the MINC to operate with both heater chambers at 37°C and gas flow at 15 mL/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 (15 µg/mL). Adjust the gas flow to 15 mL/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 MINC is now successfully installed and commissioned.

3.14 Alarm conditions

3.14.1 External alarm

The MINC 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" that can "close" under the following conditions:

- Loss of mains power
- Low inlet gas 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.

3.14.2 Loss of mains power

- If the MINC 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 MINC will recommence normal operation.
- If mains power is restored after the 2 minutes, the external alarm will deactivate and the MINC will recommence normal operation.
- Also if the gas flow was active before the power was lost then the MINC will restart the flow sequence in purge mode when power is restored.

3.14.3 Low inlet pressure

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 <50 kPa.

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

The alarm will reset when a gas inlet pressure >60 kPa is restored.

3.14.4 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 4 mL/min (including no gas flow) for longer than 10 minutes.

The external alarm contacts will close 5 minutes later.

To reset alarm, after rectification of cause of alarm condition, toggle the gas flow start/stop touch pad. Allow at least 3 seconds between toggled off then on again.

3.14.5 Temperature out of range

When the MINC has just been turned on or the set temperature has been adjusted, the temperature alarm is deactivated for 120 minutes to allow the device 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 ±0.4°C, for longer than 2 minutes.

To reset alarm, toggle heater chamber start/stop touch pad.
Note: This will deactivate alarm for 120 minutes.

If any alarm condition is unable to be rectified, contact your local Cook Medical representative or authorised service agent.

4. Installation and set-up checklist

Check the following for installation of the MINC:-

- ❑ 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 MINC 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 150 kPa.
- ❑ The gas connections have been made and checked.
- ❑ The Humidification Flask has been filled and fitted.
- ❑ The MINC has been activated.
- ❑ The chamber temperatures and flow rate have been adjusted to desired values.
- ❑ The MINC has been left to operate for 24 hours to ensure any residual out-gassing of components is complete.

Check the following for installing the K-MINC-1000 Logger Software (optional):-

- ❑ The installation CD and USB cable has been supplied.
- ❑ A computer with the the appropriate specification is available to run the Logger application on.
- ❑ The Logger Software has been installed.
- ❑ The USB connections have been made and checked using USB hubs where required for multiple MINC connections.
- ❑ The MINC's have been activated.

5. Operation of the device

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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.

IMPORTANT NOTE: *The MINC measures gas flow internally prior to the gas entering the humidification bay. There is no mechanism to verify correct gas flow into each chamber. The user must visually ensure the correct installation of the humidification flask and gas lines to ensure unobstructed delivery of gas to each chamber.*

WARNING: BIOLOGICAL HAZARD. *Do not use a contaminated humidification flask in the MINC. It is recommended that the sterile humidification flask be replaced each time the sterile water needs refilling, or replaced regularly with a maximum period of use being 4 weeks, in order to avoid bacterial contamination of contents.*

This section provides general information about the use of the MINC and Logger Software. 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

Prior to commencing the culturing procedure, carry out the following steps:

- Use the temperature selection touch-pads to select the desired chamber temperature (see § 3.11.3).
- Install the humidification flask filled with sterile water as detailed in § 6.1.
- Confirm humidification flask and gas lines are correctly installed.
- Activate the required chambers as per § 3.11.1.
- Use the gas flow selection touch-pads to select the desired gas flow (see § 3.12.4).
- Activate the gas flow (see § 3.12.1). Ensure that gas bubbles are observed in the flask during both the purge cycle and normal flow.
- Wait a minimum of 4 hours before using to allow for equilibration.

5.2 Insertion of the culture dishes

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

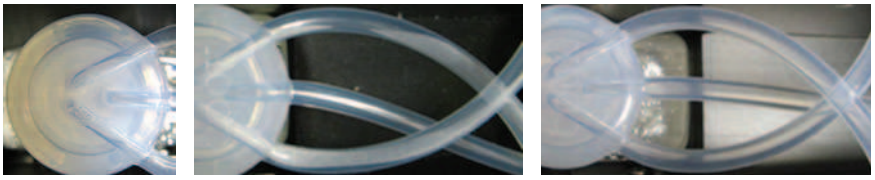
Four-well dishes or single round dishes may be placed on the chamber base. Ensure that they sit securely in the grooves designed to accept them. There should be direct contact between the base of the dish and the surface of the chamber base.

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.

5.4 Possible condensate formation

During the normal usage of the humidification flask, some condensation may naturally form in the tubing.

Normal	
Excessive	
Blockage	

There are several factors that can cause the formation of condensation:

- Repeated opening and closing of the humidifier chamber lid.
- Leaving the humidifier chamber lid open.
- Fluctuating ambient conditions.
- Draughts.

It is not recommended to obstruct any tubing in any manner.

IMPORTANT NOTE: *It is recommended that no other applications be running while the Logger Software is being used. Other processor or memory intensive applications may prevent the proper operation of the Logger Software.*

5.5 Starting the Logger Software

Once the software has been installed, it can be run from the K-MINC-1000 Logger icon on the desktop:

The program can also be started from the Start Menu under – Program Files › Cook Australia › K-MINC-1000 Logger.

After starting the Logger Software, any MINC that is connected to the USB ports will be identified, after a short delay, then logging will commence.

The program continuously scans the USB port for connected devices. The MINCs can be connected at any time.

Note: For users running Windows 2000, the logger software must be closed before disconnecting any of the devices from the USB port. Failure to do so may result in a system crash due to deficiencies in the way Windows 2000 handles USB devices. For users running Windows XP, Vista, 7 or 8, the devices may be disconnected and reconnected at any time. It is recommended to upgrade to Windows XP, Vista, 7 or 8, if the selected computer is running Windows 2000.

5.6 Using the Logger Software

5.6.1 Logger working screen

When the Logger Software detects a connected MINC, three graphs will be shown for each device. The first and last graph displays the left and right hand chamber temperatures respectively while the middle graph shows the gas flow.

The graph data is continuously updated approximately once a second and both the actual measurement and the set-point are displayed.

The graphs will rescale as new data is collected. A maximum of 3 days of logging information can be displayed on the screen. After this, the old data will be truncated from the end of the graph and cannot be viewed again in the Logger program. All data logged may be reviewed via the CSV file - refer to § 5.6.3

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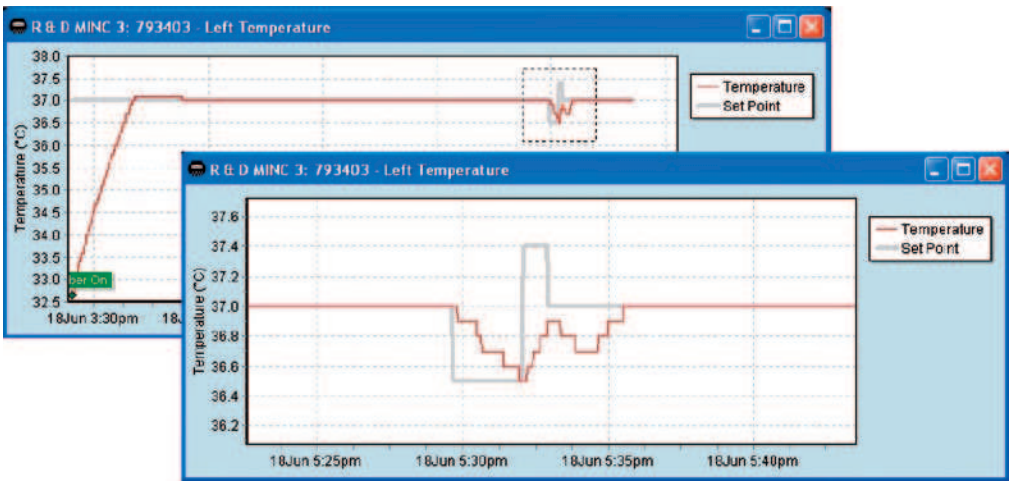
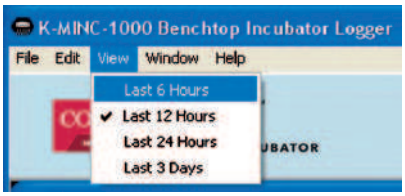
An area of the graph can be zoomed in by clicking and dragging a rectangular region using the left mouse button.



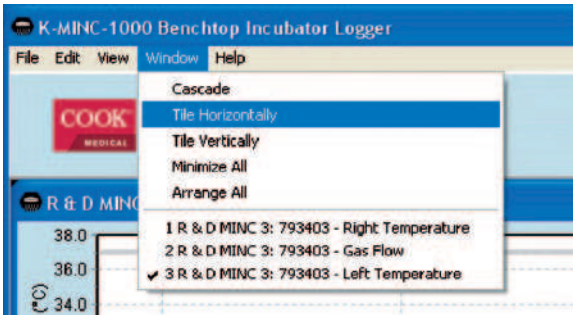
Holding the right mouse button will pan the graph around. To return to the original graph scale, double click the left mouse button.

Use the View menu to select the timescale of the graphs.



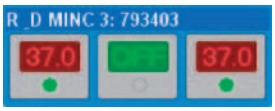
There is a choice of displaying the last 6 hours, 12 hours, 24 hours or 3 days of data on the scrolling graphs. The last 12 hours of data will be shown by default.

The items in the Window menu can be used to arrange the graph windows as desired. The program will first arrange the graphs by tiling them horizontally. If the application window is resized, select this option again to refit the graphs to the main window.



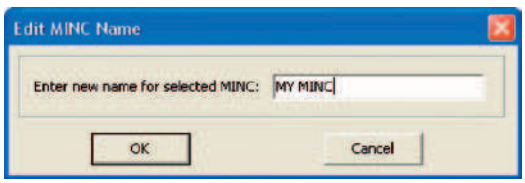
5.6.2 Selecting and naming devices

If there is more than one MINC connected, the set of graphs for a specific device can be displayed by choosing the desired device icon, shown below, located in the banner area along the top of the window.



Only one MINC can be selected at a time. The icons are arranged in alphabetical order according to their name.

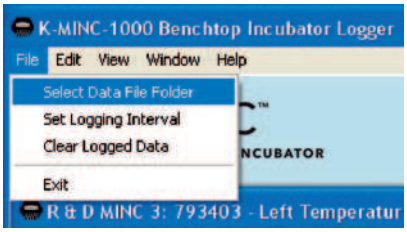
To (re)name the selected MINC, select "MINC Name" from the Edit menu.

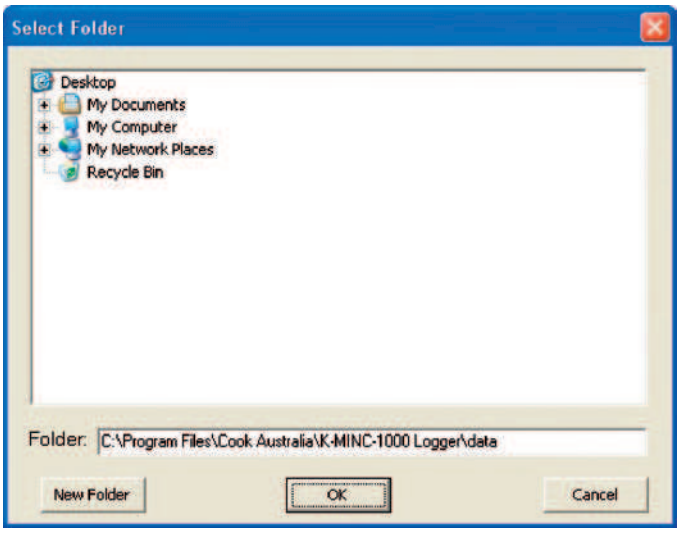


The name must be less than 128 characters and must not contain: \ / : * ? " < > or |. The MINC's name is used to construct the CSV filename so it must contain valid filename characters.

5.6.3 Logging data

Logging of the data to a CSV file begins as soon as a MINC is detected. The logging function cannot be turned off. A separate data file is written for each connected device and these files are created in the data file folder. To view the current folder, choose "Select Data File Folder" from the File menu.



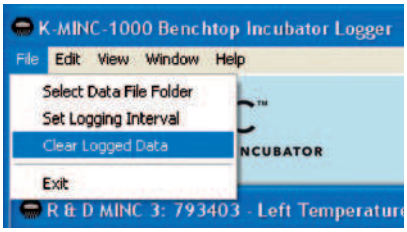


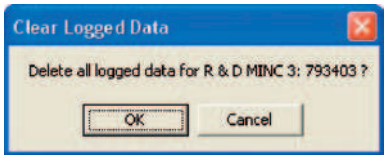
From here, a new data file folder may be selected or created.

The files are named with the MINC's name followed by its serial number. The data in these files is appended so that they may contain data from several different runs. To clear the data, select "Clear Logged Data" from the File menu. Data is cleared only from the actively displayed MINC.

If data files are to be kept for individual cycles, it is recommended to copy the specific MINC data file to an archiving area and rename the copied file prior to clearing logged data files.

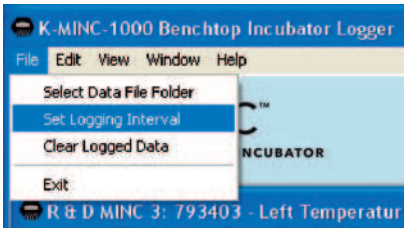
The copied file will contain all logged data from start-up, or the last time the file was cleared, to the time the file was copied. If the MINC is not disconnected, and the logged data is cleared, subsequent data will continue to be written to the cleared file.

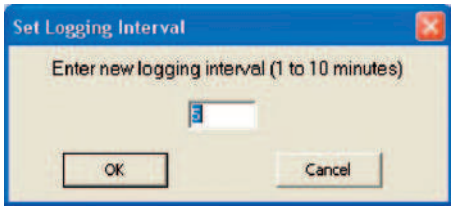




The files may also be deleted or renamed with the Windows File Manager.

By default, measurements are logged to file at an interval of 5 minutes. Each line of the file is time and date stamped. Alarms and other events are logged immediately. The logging interval may be set from 1 to 10 minutes by selecting "Set Logging Interval" from the File menu.





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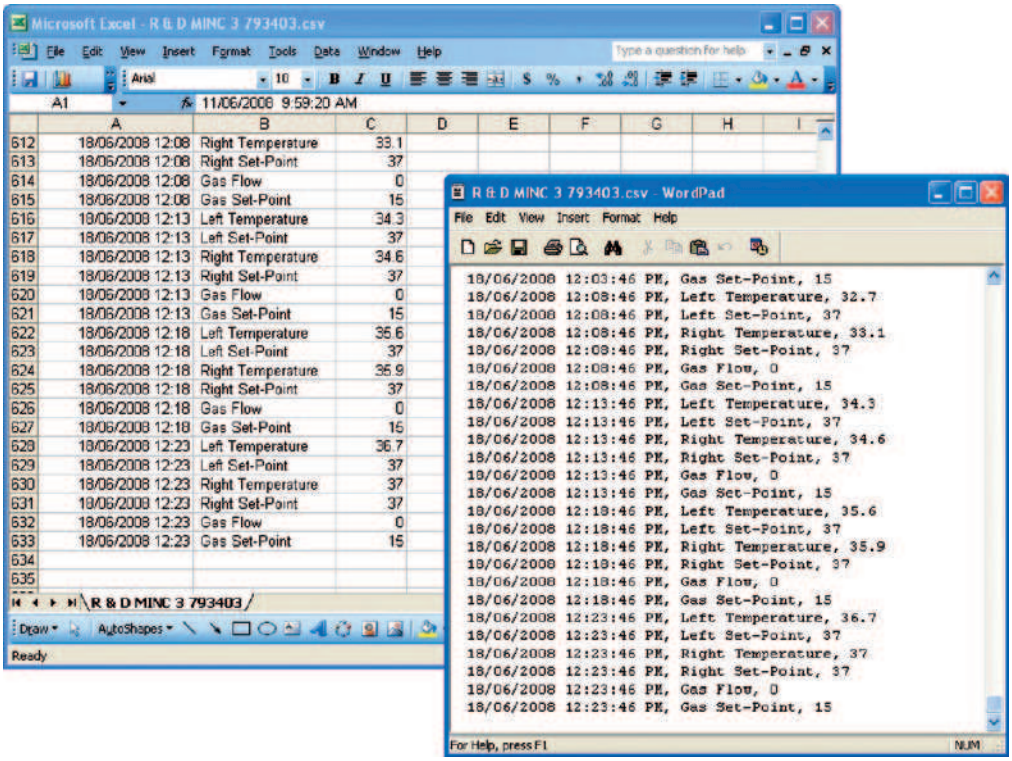
The CSV data files may be opened in any text editor or in Microsoft Excel. The log files may also be opened in read only mode while logging is in progress but might not have the most recent data. Disconnect the MINC and close the Logger to flush and close the log files.



IMPORTANT NOTE: *User will require Administrator privileges to remove programs.*

5.6.4 Un-installation of Logger Software

- Select the relevant program management application to uninstall the software.
- In the list of currently installed programs, select "K-MINC-1000 Benchtop Incubator Logger" and then click the appropriate icon to uninstall and follow the instructions.

5.7 After Use

1. Use the Standby Touch-Pad to place the MINC in standby mode.
2. Remove the humidification flask, gas supply and power cord.

6. Service and maintenance

WARNING: *To guarantee safe operation, it is necessary to carry out proper care and maintenance of the MINC 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 MINC. It is recommended that the sterile humidification flask be replaced each time the sterile water needs refilling, or replaced regularly with a maximum period of use being 4 weeks, in order to avoid bacterial contamination of contents.*

WARNING: ELECTRIC SHOCK HAZARD. *Do not immerse the MINC!*

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

6.1 Changing filter, gas lines & humidification flask

Proper service, maintenance and storage must be provided to preserve the MINC 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 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 MINC:
   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 CO_2.

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 MINC, remove the contents of the incubation chambers.

Shut down device. Refer to § 5.7.

It is recommended that the MINC 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.

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 MINC and maintain its safety, regular inspections are necessary for early detection of possible malfunctions.

The user or a qualified technician must regularly test the device to assess its functionality.

The following must be tested on a biannual basis:

- Temperature
- Gas Flow Rate
- External Alarm Contacts

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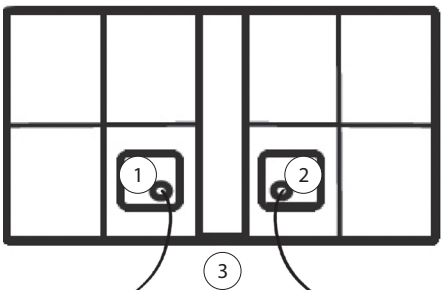
6.3.1 Temperature

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 0.8 mL 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.



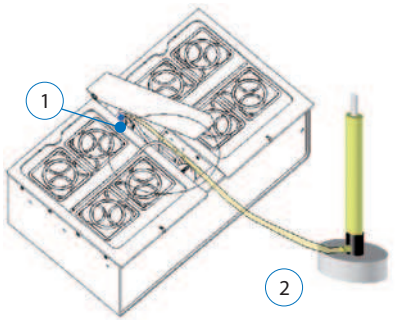
1. Left chamber thermocouple well position
2. Right chamber thermocouple well position
3. Front of MINC

The temperatures measured will be the user set temperature ±0.2°C.

6.3.2 Gas flow rate

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

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

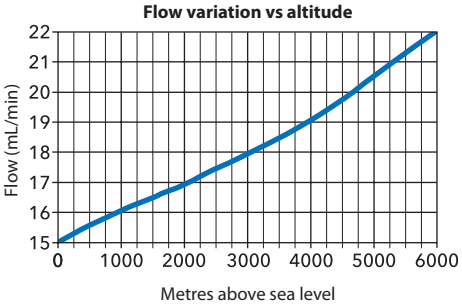
The gas flow meter should have no further restriction on the outlet and be open to atmospheric pressure. Start the gas flowing. The gas flow meter should indicate twice the user set point value ± 15%. Twice the user set point is observed because the display shows gas flow rate per chamber.

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 Medical representative. Gas flow rates for the MINC 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 MINC has been set at 15 mL/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 MINC 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 150 minutes.

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 MINC 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 agent

Inspections at least once a year	For ongoing operational safety of the MINC, an authorised service agent must maintain the device annually as per Service Manual SMA30002. The service agent will asses the operational functionality of the gas and temperature control systems and external alarm contacts.
Authorised service agents	All services such as alterations, repairs, calibrations etc., may only be performed by the manufacturer or by service agents who are authorised by the manufacturer as per Service Manual SMA30002.
Liability	The manufacturer is free from all liability for the operational safety of the MINC if the device has been wilfully opened and unauthorised persons have performed repairs or alterations on it during the warranty period.
Certification	The MINC owner will receive a signed certificate from the service agent 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 MINC or disposables.

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 MINC ensure that the humidification flask and all chamber contents are removed prior to transport.

6.5 Return procedure

All devices or disposables that are returned must be prepared as described below for the protection of the service agent 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 or fault.

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

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.*

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 I equipment
Degree of protection against harmful ingress of solids and water:	IP31
General specifications	
Power Supply:	100 - 240 VAC
Frequency:	50 - 60 Hz
Maximum power consumption:	140 VA
Alarm contact rating:	2 A / 30 VDC
Environmental operating conditions:	+18°C to +32°C 5% to 85% RH 700 hPa to 1060 hPa
Storage and transport directions:	+5°C to +40°C 10% to 75% RH
Manufactured and tested to the following standards:	IEC 60601-1: 1988 + A1: 1991 + A2: 1995 IEC 60601-1: 2005 IEC 60601-1-2: 2007 IEC 61010-1: 2001, EN 61010-2: 010: 2003 UL 61010-1 2ED CSA C22.2 No. 61010-1 2ED CSA C22.2 No. 61010-2-010 2ED
Dimensions:	Door closed: 405 mm wide x 190 mm high x 265 mm deep Door opened: 405 mm wide x 400 mm high x 315 mm deep
Weight:	11 kg (24.3 lb)
Gas supply type:	Blend of 6% CO_2, 5% O_2, 89% N_2 (Cook Culture System at sea-level) or high purity 6% CO_2 in air (recommended tolerances ±0.2%)
Gas supply pressure:	150 kPa ± 15 kPa (21.8 psi ± 2.2 psi) (1500 mbar ± 150 mbar)
Gas flow rate capability :	15 mL/min to 25 mL/min per chamber in 5 mL/min increments Purge at 175 mL/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
Computer requirements for K-MINC-1000 Benchtop Incubator Logger Software	
Operating system	Windows Vista, Windows XP, Windows NT, Windows 7, Windows 8 or Windows 2000 *(1)*
RAM	256 Mb minimum
Free hard disc space	10 Gb minimum
Processor	Pentium 4, 1.6 GHz or better
Display	1024 x 768, 256 colour or better
I/O ports:	USB port, 1.1 or 2.0 compliant
K-MINC-1000 Benchtop Incubator logger software specifications	
Maximum connected MINC's	10
Logging interval range	Adjustable from 1 to 10 minutes
Maximum logging time period	Only limited by free disc space
Log file format	Comma-Separated Values (CSV)
Graph Update Interval	1 second
Maximum displayed time period on screen	3 days
Temperature resolution	0.1 deg. C
Gas flow resolution	5 mL/min

Note (1): Not recommended

Guidance and manufacturer's declaration – electromagnetic emissions

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

Emissions Test	*Compliance*	*Electromagnetic Environment Guidance*
RF emissions CISPR 11	Group 1	The MINC 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.
RF emissions CISPR 11	Class B	The MINC 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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity

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

Immunity Test	*IEC 60601 Test Level*	*Compliance Level*	*Electromagnetic Environment Guidance*
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV 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% UT (>95% dip in UT) for 0.5 cycles 40% UT (60% dip in UT) for 0.5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (95% dip in UT) for 5 seconds	<5% UT (>95% dip in UT) for 0.5 cycles 40% UT (60% dip in UT) for 0.5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (95% dip in UT) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the MINC Benchtop Incubator requires continued operation during power mains interruptions, it is recommended that the MINC 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.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the MINC Benchtop Incubator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommend separation distance** $d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	**Recommend separation distance** $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz 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 metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

Note: At 80 MHz and 800 MHz, the higher frequency range applies.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the MINC Benchtop Incubator is used exceeds the applicable RF compliance level above, the MINC Benchtop Incubator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the MINC Benchtop Incubator.

[b] Over the frequency range 150 kHz to 80MHz, field strengths should be less than 3 V/m.

Recommended separation distance between portable and mobile RF communications equipment and the MINC Benchtop Incubator

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

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people

9. Troubleshooting

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

Error and alarm indicator	Source of error	Elimination of error
MINC will not turn on.	Power supply cord is not connected. Mains power is not turned on.	Check the power supply connection. Turn on the mains power. (Refer to §3.10).
Displays do not illuminate.	The device is in standby.	Check that the Standby Indicator is illuminated green. Press the Standby touch-pad. (Refer to §3.10).
MINC will not heat to correct temperature.	Temperature settings not entered correctly.	Enter correct temperature settings. (Refer to §3.11.3).
'Temperature out of range' alarm.	Set temperature not achieved in time.	Turn heater bay off and on again. (Refer to §3.11.1).
"Err" displayed.	Lids open for extended periods.	Do not leave lids open for extended periods. Turn heater bay off and on again. (Refer to §3.11.1).
	Device is not operating in functional environmental conditions.	Evaluate device placement. (Refer to §3.6).
'Low inlet pressure' alarm.	Gas supply not connected.	Check gas supply connection. (Refer to §3.7.3).
"CO_2" displayed.		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 MINC.	Ensure that the inlet pressure to the MINC does not fall below 135 kPa.
		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).
'No gas flow or gas flow out of range' alarm.	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).
"Err" displayed.		Turn flow off and on again. (Refer to § 3.12.1).
	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 § 3.12.1).
	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 § 3.12.1).

Error and alarm indicator	Source of error	Elimination of error
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 flask 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 MINC does not rise above 165 kPa.
	Gas connections not secure or damaged.	Ensure all gas fittings from the cylinder to the MINC 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 § 3.11.4).
Logger software fails to recognise a device.	MINC is not powered.	Ensure that the MINC has mains power present.
	MINC is not connected.	Connect the MINC to the PC using the supplied USB cable. If connecting multiple devices use the approved USB hubs. Start by connecting one MINC at a time to isolate the fault. If the USB drivers have installed correctly, the MINC will appear in Windows Device Manager under "Universal Serial Bus controllers" as "USBXpress Device" when connected.
No logged data.	Invalid filename.	Ensure the file name of the MINC is a valid filename. (Refer to §5.6.2).
	Incorrect or invalid log directory.	Check that the log file directory is correct. (Refer to §5.6.3).
	Name recently changed.	If the name of the MINC is changed, the data is not logged to the new filename until the software is started again.
	Disc full.	Free up some disc space by deleting unnecessary files.
Obscured event labels or graph trace.	Many events or errors occurring in a short period.	Zoom in to spread the labels apart. (Refer to §5.6.1). Alternately, load the CSV file and scroll down to the time in question. (Refer to §5.6.3).
Data extends beyond normal range of graph.	Gas purge event.	Pan the graph up using the right mouse button. The flow axis is scaled to give satisfactory viewing of normal flow rates. (Refer to §5.6.1).
	Extended logging period.	Pan the graph sideways using the right mouse button or use a longer time period on the 'View' menu. (Refer to §5.6.1).
"File Open Error! Cannot Open: *filename.csv*" message.	The log directory is invalid or does not exists.	Create the directory if it doesn't already exist. (Refer to §5.6.3).
	The file is already open in another application.	Close the other application and start the logger again.
	The user doesn't have sufficient privileges to append to a file that was created by another user.	Change the logging directory to begin writing a new log file. (Refer to §5.6.3).
"Invalid MINC Name! The MINC's name cannot contain \ / : * ? " < > or |" message.	The name of the MINC is used as part of the log filename so none of these characters can be used.	Remove the offending characters from the MINC name. (Refer to §5.6.1).
"File: *filename.csv* exceeds 10 MB. Consider archiving and deleting" message.	The specified log file is greater than 10 MB in size. Large log files can slow the system down.	Archive the specified log file and move it to another folder. (Refer to §5.6.3).

10. Limited warranty

Cook Australia 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 Cook'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 Cook Australia 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, Cook Australia 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. Cook Australia's representations concerning fitness for purpose or suitability for use by any purchaser does not extend beyond those representations set out in the Cook Australia literature that accompanies the product. Cook Australia 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. Cook Australia 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 Cook distributor for assistance and instructions.

Cook Australia reserves the right to change or discontinue this product without notice.

10.1 Liability

Because Cook Australia 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, Cook Australia takes no responsibility for the results, use and/or performance of the product. Cook Australia expects that use of the product will be confined to trained and expert users.

In no event will Cook Australia 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 disposables.

No representative of Cook Australia and no vendor or lessor 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 stature 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 Cook Australia will no longer be responsible for this product.

11. Index

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