BT37 Mark II
(Model Number: BT37M-02)
INSTRUCTIONS FOR USE

Original Instructions

Nexpring Health™

PLANER
Powered by Nexpring Health

Introduction

1 Introduction

This manual only applies to the following models: BT37M-02

UDI **B199INCUBATORG2

This guide has been designed to help you install and use the BT37M-02. The guide includes important information regarding safe use of the equipment and it is important that you familiarise yourself with this document before attempting to install or operate the equipment.

1.1 Notices

INSTRUCTIONS FOR USE: BT37M-02

Issue: 9.0.50 2025-12-08

Original Instructions

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CE 1639 UKCA 0120

EU REP

Advena Ltd. Tower Business Centre, 2nd Flr, Tower Street, Swatar, BKR 4013, Malta

CH REP

TS Q&E GmbH, Theilerstrasse 7, 6300, Zug, Suisse

1.2 Intended use

The BT37M-02 is intended to be used to provide an environment with controlled temperature at or near body temperature, carbon dioxide, oxygen and nitrogen gases,

and elevated humidity for the development of gametes and embryos during in vitro fertilization (IVF) / assisted reproductive technology (ART) treatments.

The BT37M-02 is intended to be used by laboratory trained personnel and not a lay person.

The BT37M-02 is intended to be used within an IVF laboratory with access to mains electricity and 6% CO^2.

Installation and service of The BT37M-02 is to be performed by suitably trained service personnel.

The patient target group is anyone wishing to pursue IVF/ART treatment.

USA: Caution

By prescription only. **Rx only**. Caution: Federal law restricts this device to sale by or on the order of a physician or a practitioner trained in its use.

1.3 Residual risks/Contraindications/Undesirable side effects

There are no residual risks associated with the use of this device.

There are no contraindications for this device.

There are no undesirable side-effects.

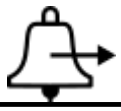
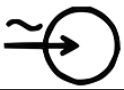
1.4 Symbols

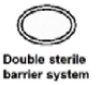
1.4.1 Symbols used in this manual

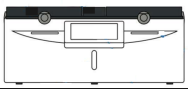
	This symbol shows information or instructions that are related to safety. Failure to follow these instructions may result in personal or third-party injury.
	This symbol is used to introduce important information or instructions related to use of the product. Failure to follow these instructions may result in damage to the equipment, samples or data.
	The light bulb symbol is used to highlight information and tips that may help you get the best from your product.

1.4.2 Symbols used on the equipment

	Refer to these instructions. Failure to follow these instructions may result in personal or third-party injury.

 *eIFU indicator*	Consult instructions for use. Electronic instructions can be accessed from the **eIFU indicator** web address.
	Alternating current (AC).
	Ethernet connection.
RST	Reset switch. Only press if the system becomes unresponsive.
	Alarm output connector.
	Premixed gas inlet.
	Premixed gas outlet.
	AC mains input
	Sterilized using irradiation
	Do not reuse.
	Do not use if packaging is broken.
	Do not resterilize.
	Batch code.
	Use by date.

	Do not dispose of with general waste.
	Model number.
	The equipment must be serviced only by qualified personnel. This device must not be serviced by the user.
	Disconnect mains plug from electrical outlet.
	Unique device identifier
	CE mark
	UKCA mark
	Device Catalogue number
	Manufacturer
	Manufactured in Great Britain / Date of manufacture
	Email
	Internet
	Once opened use the bottle within 30 days.
	Min - Max temperature
	Min - Max relative humidity
	Double sterile barrier system

	BT37 Mark II
	Humidification bottle
	Bottle filter
	Keep out of light
	Keep dry
	Store at room temperature (15 - 25°C for bottles only)
	Packaging Quantity (X defines the quantity)

Rx only	USA: Caution: Federal law restricts this device to sale by or on the order of a physician or a practitioner trained in its use.
MD REF	Medical Device Catalogue number
EU REP	European Representative
CH REP	Swiss Representative

1.5 Safety

1.5.1 Warnings

- Operating the equipment in a manner not specified within this manual or under conditions outside of the equipment specifications, may result in the protection offered by the equipment being impaired.
- Use in well ventilated areas. Risk of asphyxiation from carbon dioxide released from the equipment. Additional ventilation may be required. Consider carbon dioxide alarms in confined spaces. Refer to the Gas supply 61 topic for gas release rates.
- Never connect to flammable or oxidising gas mixtures.
- Do not connect to a gas supply with a pressure exceeding 1.65 bar.
- Do not attempt to charge the battery externally. The BT37M-02 contains a sealed lead acid battery. Over-charging can result in the release of dangerous gases. Refer to the Internal battery 60 topic for details.
- Equipment must be earthed. Class 1.
- Supply power via a residual current circuit breaker (RCCB) operating at a differential of 30 mA.
- To avoid risk of fire, fuses must always be replaced with the same type and rating.
  - Fuses should only be replaced by suitably trained service personnel.
  - Fuses should only be replaced after the cause of the original failure has been determined and corrected as appropriate.

1.5.2 Precautions

- Ensure the equipment and mains cords are regularly checked by a competent person, using a Portable Appliance Tester or similar equipment, to ensure adequate earth bonding.
- Ensure the earth continuity of the mains installation is regularly inspected by a competent person.
- Check the voltage requirements of the equipment, shown on the rating label, match the local mains supply.
- The mains lead to the power supply is the main disconnect device. If power needs to be disconnected immediately, disconnect the mains lead from the power supply or switch off at the mains power outlet.
- Ensure the equipment is positioned so that the mains lead can be easily disconnected.
- Connected devices must comply with EN60950 or its equivalent.
- To ensure you can respond to alarm conditions when the laboratory is unattended, the equipment should be connected to an independent, external alarm system.
- The alarm output must not be used in safety-critical applications.
  - Any circuit connected to the alarm output must meet the requirements for an accessible part as defined in EN 61010-1 or its equivalent.
- Do not connect to Ethernet local area networks (LAN) external to the building.
- User servicing is limited to cleaning and calibration.

- Ensure cables do not cause a trip hazard.
- Take care when lifting. Uneven load: 17 kg.
- Keep the humidifier lid closed during normal operation.
- Operating parameters should only be modified by qualified service personnel or under their guidance. Entering incorrect values may impair the performance of the product.
- The internal battery can only support the incubator for up to 2 hours if mains power fails. This time is dependent on the battery condition and operating conditions.

1.5.3 Electromagnetic compatibility (EMC)

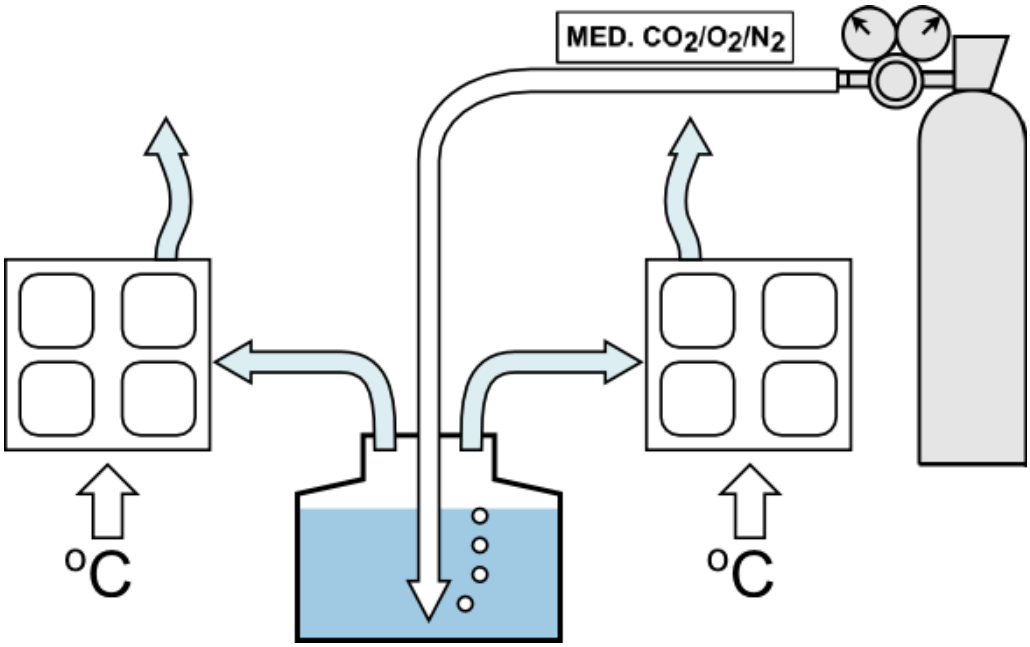
The equipment is intended for use in a basic electromagnetic environment, characterised by being supplied directly at low voltage from the public mains network.

- All connections via the External alarm connection 58 must use fully screened cable no longer than 2 m.
- Take care to avoid placing the BT37M-02 in environments influenced by sources of electromagnetic interference, such as large transformers for example.

1.6 About the equipment

1.6.1 Theory of operation

The basic principle of operation is illustrated in the diagram below.



Samples are placed in dishes in the left and right chambers which are heated to maintain a constant temperature. Pre-mixed gas is supplied from a pressurised

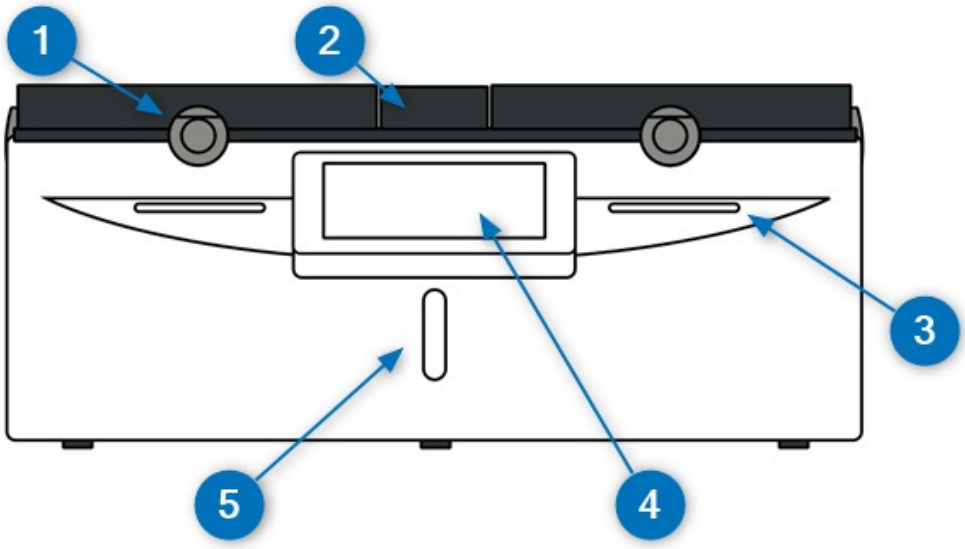
cylinder, bubbled through water contained in the humidifier bottle, and then passed to the left and right chambers. This results in the samples being maintained at a controlled temperature and within a controlled atmosphere.

If the lids are opened and then shut again, gas is provided at an increased flow rate to reduce the time taken to restore the chambers back to the required gas concentration.

The BT37M-02 can be in one of three modes: Standby, Run and Bottle change.

Mode	Heaters	Gas	Note
Standby	Off	Off	The system is inactive and ready to be switched off.
Bottle change	On	Off	The system is waiting for the humidifier to be changed.
Run	Controlled	Controlled	This is the normal operating state.

1.6.2 Front view



1. Chamber lid and catch.
2. Humidifier lid.
3. Status indicators.
4. Touchscreen display.
5. Liquid level indicator.

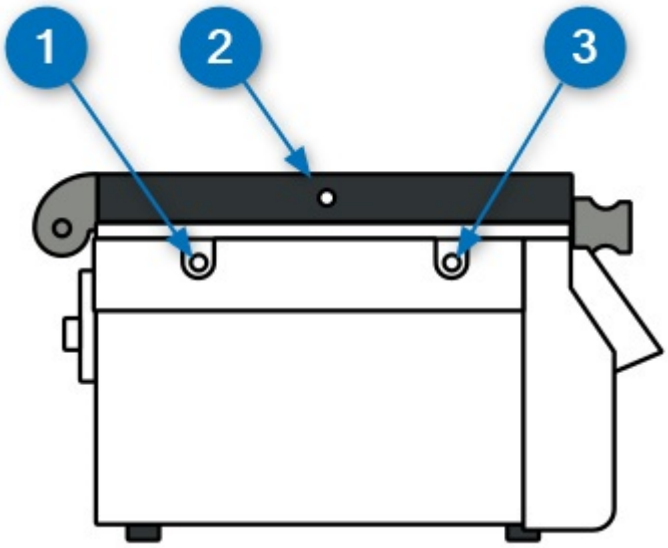
The lids are fitted with rotary catches.

1. To open a lid, rotate the knob anticlockwise and lift the lid.
2. To close a lid, ensure the knob is rotated anticlockwise so it can engage with the pin on the main body.

3. Gently lower the lid, and when it is fully closed, rotate the knob clockwise until it is felt to latch.

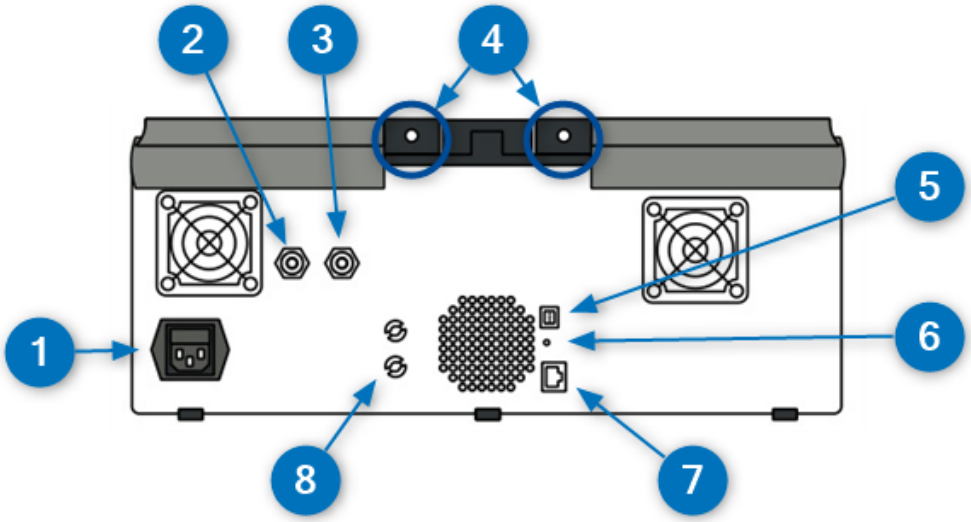
The BT37M-02 will not regard a lid as being shut until it is both closed and the knob rotated clockwise into its locked position.

1.6.3 Side view



1. Rear of base monitoring port for independent temperature probes.
2. Lid monitoring port for independent temperature probes.
3. Front of base monitoring port for independent temperature probes.

1.6.4 Rear view

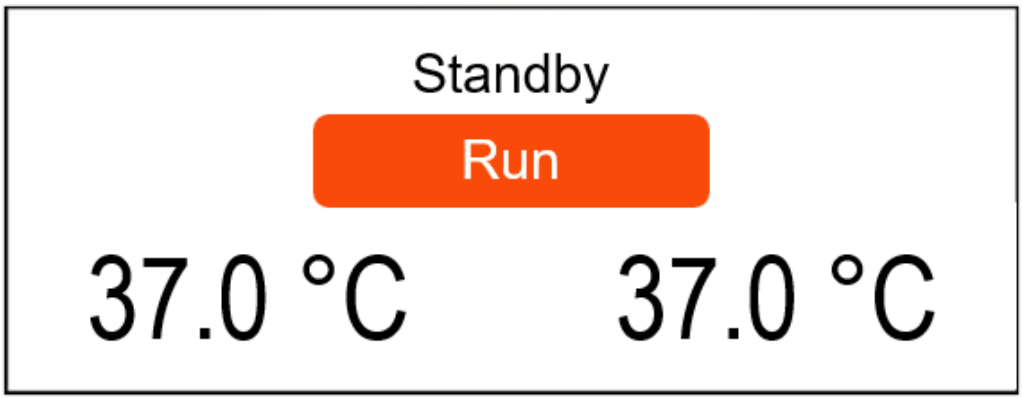


1. Mains inlet.
2. Premixed gas inlet
3. Daisy-chain gas outlet
4. Gas vents
5. Alarm output.
6. Reset switch.
7. Ethernet output.
8. Access ports for pH monitoring; for use by service personnel only.

1.6.5 User interface

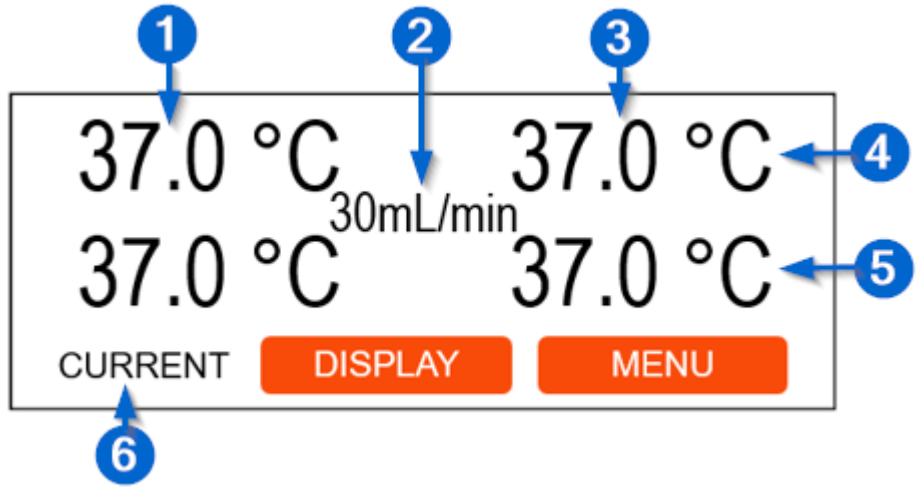
The BT37M-02 is provided with a resistive touchscreen interface.

When the system is idle, the standby screen is shown.



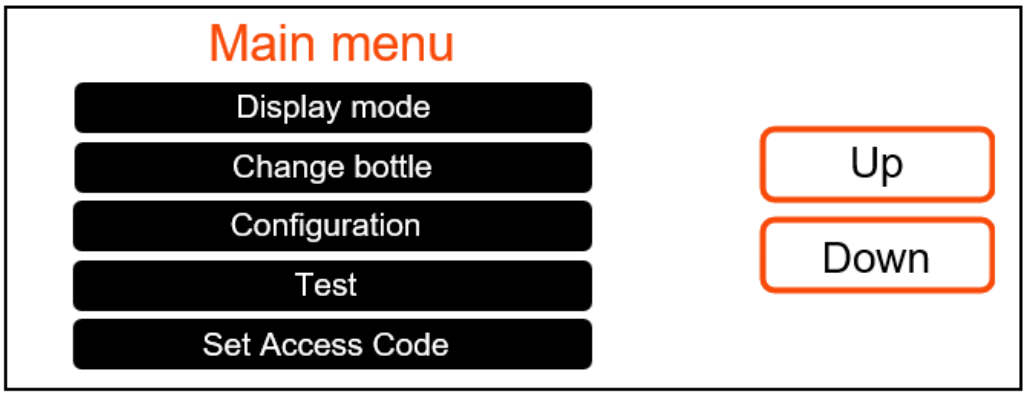
Pressing the **Run** button, moves the BT37M-02 out of standby and into its normal operating mode.

In normal operation, the display shows the current status of the incubator. Pressing the **Display** button cycles through different screens, each of which shows different information about the state of incubator. An example is shown below.



1. Left-hand chamber readings are shown on the left of the display
2. Humidification chamber readings are shown in the middle of the display.
3. Right-hand chamber readings are shown on the right of the display
4. Lid temperatures are shown at the top of the display above the humidification chamber readings.
5. Base temperatures are shown at the bottom of the display below the humidification chamber readings.
6. The current temperature readings are identified by the label CURRENT. If the setpoints are displayed, the values are displayed in a yellow font and identified by the label SETPOINT.

Other options can be found by selecting the **MENU** option, which will open the main menu shown below.



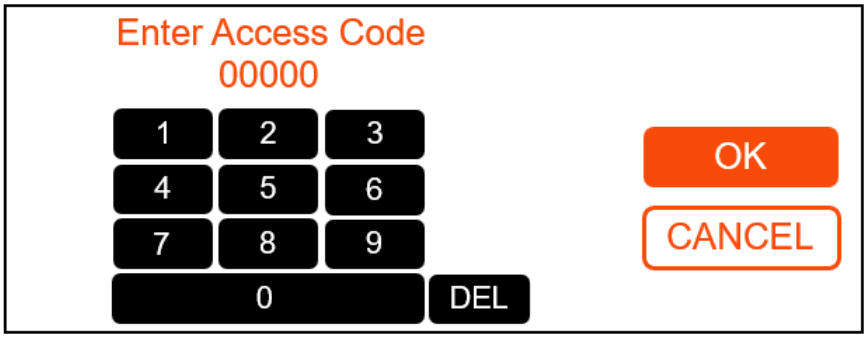
To return to the main display, select **Display mode**.

All menus operate in the same way, with a set of options and **UP** and **DOWN** buttons which can be used to scroll up and down if there are more options to display.

Sub-menus also contain a **BACK** button which will take you back to the previous menu.

1.6.5.1 Numeric entry

Some screens require a numeric entry to be entered. At these screens a keypad appropriate to the required entry will be displayed. The screen for an access code entry is shown below.



1. Use the keypad to enter the required number.
2. Use **DEL** to erase an invalid entry.
3. Press **OK** to submit the entry or **CANCEL** to exit the menu option.

1.6.5.2 Menus

All menu options are shown below:

- **Display mode**: Press to toggle through different presentations of the current incubator readings and setpoints.
- **Change bottle**: Select to change the humidifier. See the Installing the humidifier 29 section.
- **Configuration**: Select to change the control settings or calibration settings. Calibration settings should only be adjusted by trained service personnel.
  - **Control settings**: Select to adjust the main incubator settings. See the Changing the control settings 27 section.
  - **Calibration offsets**: Select to adjust the calibration settings. Calibration settings should only be adjusted by trained service personnel. See the Calibration and servicing 47 section.
- **Test**: Select to run the in-built tests. See the Testing the alarms 49 section.
- **Set access code**: Select to set the access code. See the Setting the access code 27 section.
- **Reset access code**: Select to reset the access code if it has been forgotten. See the Resetting the access code 54 section.
- **Security**: Select to allow the incubator settings to be temporarily modified via the network. See the Network security 58 section.
- **Standby**: Select to place the incubator into standby mode. See the Theory of operation 12 and Switching off 41 sections.

1.6.6 Status and alarm indicators

The status indicators on the front of the BT37M-02 show the current state of the system. These are used along with an internal buzzer and the external alarm. The state of the indicators, buzzer and external alarm in various states are shown below.

State	Status indicators	Buzzer	External alarm	Display
Standby	Steady orange	Off	Off	Standby
Normal	Steady green	Off	Off	Normal display
Unacknowledged alarm	Flashing red	On	Off	Alarm message
Unacknowledged alarm for longer than 5 minutes	Flashing red	On	On	Alarm message
Acknowledged alarm	Steady red	Off	Off	Normal display
Temperatures not ready.	Steady orange	Off	Off	Normal display

1.6.6.1 Acknowledging an alarm

When an alarm occurs, an alarm message is shown. An example is shown below:

1. To silence the alarm, press **SILENCE**.
2. To acknowledge the alarm, press **OK**. This will close the alarm message.

Installation

2 Installation

Caution

- Installation and completion of the installation qualification must only be undertaken by suitably trained personnel.
- All updates and upgrades must be applied prior to completion of the Installation Qualification.
- Ensure the equipment is positioned so that the mains lead can be easily disconnected.
- Ensure cables do not cause a trip hazard.
- Take care when lifting. Uneven load: 17 kg.

Important

- Keep away from hot or cold temperature sources such heaters or air-conditioning units.
- Keep away from sources of electromagnetic interference such as large transformers.
- Maintain clear space around the incubator: 150 mm at the rear and at least 25 mm at the front and sides.

Note

- The location of the connectors is shown in the Rear view 15 section.

1. Carefully unpack the equipment.
2. Install on a flat, level and stable surface.
3. Connect the gas supply; see Connecting the gas supply 21.
4. If the local area network is to be used to collect data, connect now; see External data collection 22.
5. If an external alarm is to be used, connect now; see Connecting the external alarm 22.
6. Clean and disinfect before use; see Cleaning and disinfecting the chamber 45.
7. Install the humidifier; see Installing the humidifier 29.
8. Connect the mains supply; see Connecting to the mains supply 22.
9. Press the **Run** button to leave standby mode and enter the normal run mode.
10. Ensure both status indicators turn green within 30 minutes.
11. Check bubbles can be seen flowing through the bottle; see Checking the liquid level indicator 46.

12. From the main display, click **Menu**.
13. Select **Standby**. This will switch off the gas supply and stop heating the chambers.

2.1 Connecting the gas supply

Warning

- The supply pressure must not exceed 1.65 bar.
- Never connect to flammable or oxidising gas mixtures.

1. Consult your media supplier for the appropriate gas concentrations. The concentration may need to be adjusted for local air pressure.
2. Only use medical-grade premixed gas, or medical-grade gases supplied via a gas mixer.
3. Gas should be supplied at or around the normal lab temperature where the incubator is being operated.
4. Any tubing used to connect the gas supply should be made of a material that is impermeable to the premixed gas supply.
5. Clean tube fittings and blow through pipes with medical grade gas to clear any foreign bodies before assembly.
6. Gas should be provided via a high purity gas regulator. The regulator will require a SWAGELOK® SS-400-1-4RT fitting to match the hose supplied with the BT37M-02.
7. It is recommended that a volatile organic compound (VOC) filter is fitted in the line.
8. Any pipework must be designed to supply at least 360 mL/min per incubator.
9. When tightening the hose fittings, assemble finger tight. Then using a 14.29 mm (9/16 ") spanner, tighten a further 60 degrees. Do not over-tighten.
10. Connect the hose to the gas supply.
11. Connect the hose to the gas inlet of the incubator.
12. If daisy-chaining incubators:
    a. Remove the blanking plug from the gas outlet of the first incubator.
    b. Connect a hose from the gas outlet of the first incubator to the gas inlet of the second.
    c. A maximum of 10 incubators can be connected in series.
13. Use soapy water over the joints to check for leaks. If any bubbles are seen, gently tighten the joint. If bubbles continue, switch off the gas supply, disconnect the hose and check the fitting for any debris before reconnecting.

2.2 External data collection

The Ethernet connection on the rear of the BT37M-02 can be used to collect data via the local area network. Contact your distributor for details.

2.3 Connecting the external alarm

Caution

- To ensure you can respond to alarm conditions when the laboratory is unattended, the equipment should be connected to an independent, external alarm system.

If you are using an external alarm, you should now connect the external alarm connector to the alarm system. Details of the connector are given in the External alarm connection 58 section.

Details of how to connect the external alarm output to your alarm system will depend upon the characteristics of your external alarm system.

2.4 Connecting to the mains supply

Caution

- Check the voltage requirements of the equipment, shown on the rating label, match the local mains supply.
- The plug-in power supply is the main disconnect device. In the event of a fault occurring that requires the power to be disconnected immediately, switch off the mains wall power outlet or disconnect the power supply from the outlet.
- Ensure the equipment is positioned so that the power supply can be easily disconnected.
- Only use the power supply provided with the equipment.

1. Connect the cable to the mains inlet at the rear of the BT37M-02; see the Rear view 15 section.
2. Connect the power supply to a suitable mains power outlet.
3. The BT37M-02 will normally start in standby mode.

2.5 EMC

2.5.1 Emissions Tests

Emission Tests

This testing has been performed in accordance with the limits, the methods of measurement and the provisions of EN55011:2009 +A1:2010.

Based on the stated operation and intended environment, the equipment has been classified as Group 1, Class B.

TEST STANDARD	TEST	COMMENT
EN 55016-2-1:2014 +A1:2017	Mains terminal disturbance voltages	Pass
EN 55016-2-3:2017	Electromagnetic radiation disturbances – Magnetic field	Note b)
EN 55016-2-3:2017	Electromagnetic radiation disturbances – Electric field	Pass
EN 61000-3-2:2014	Harmonic current emissions	Pass
EN 61000-3-3:2013	Voltage fluctuations and flicker	Pass

Notes:

a) As only one product was tested it is the manufacturer's responsibility to comply with clause 12.1 of EN55011:2009 +A1:2010.

b) This test is not applicable as the EUT is a Group 1 device

2.5.2 Immunity Tests

Immunity Tests

Test levels have been applied for an industrial electromagnetic environment.

TEST STANDARD	TEST	COMMENT
EN 61000-4-2:2009	Electrostatic discharge	Pass
EN 61000-4-3:2006 +A1: 2008 +A2:2010	Electromagnetic field	Pass
EN 61000-4-4:2012	Electrical fast transient / Burst	Pass
EN 61000-4-5:2014	Surge	Pass
EN 61000-4-6:2014	Conducted RF	Pass
EN 61000-4-8:2010	Power frequency magnetic field	Pass
EN 61000-4-11:2004	Voltage dips and short interruptions	Pass

2.5.2.1 Equipment under tests

Description

The EUT is a 100-240Vac 50/60Hz incubator to grow and maintain gametes / embryos in IVF applications. The EUT has a touch screen display for user input / status and has an Ethernet port for remote monitoring.

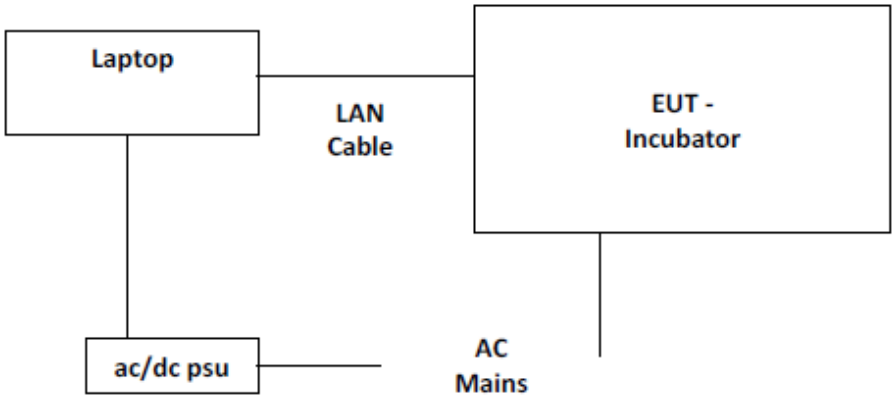
The EUT was tested as received with no external visible signs of damage and was of production build quality.

Modes of Operation

Emissions & Immunity:

Mode 1 – Maintaining a temperature of 37°C and sending its temperature status to the support laptop via the LAN cable.

Configuration diagram



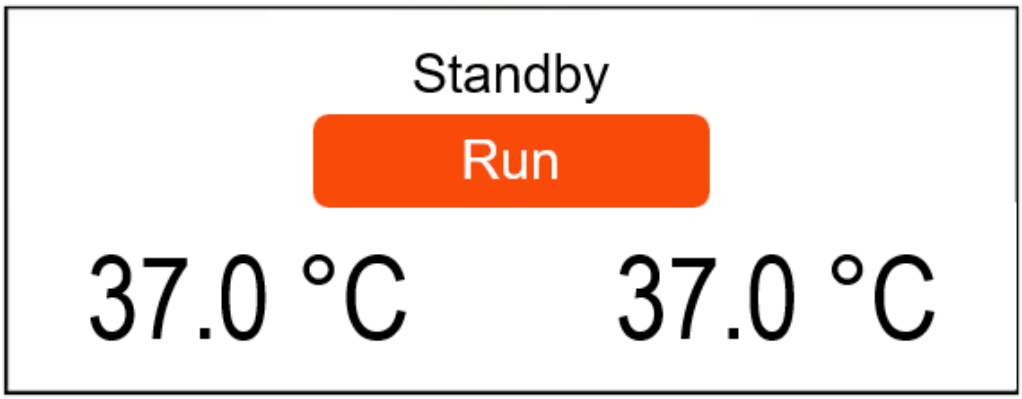
Operation

3 Operation

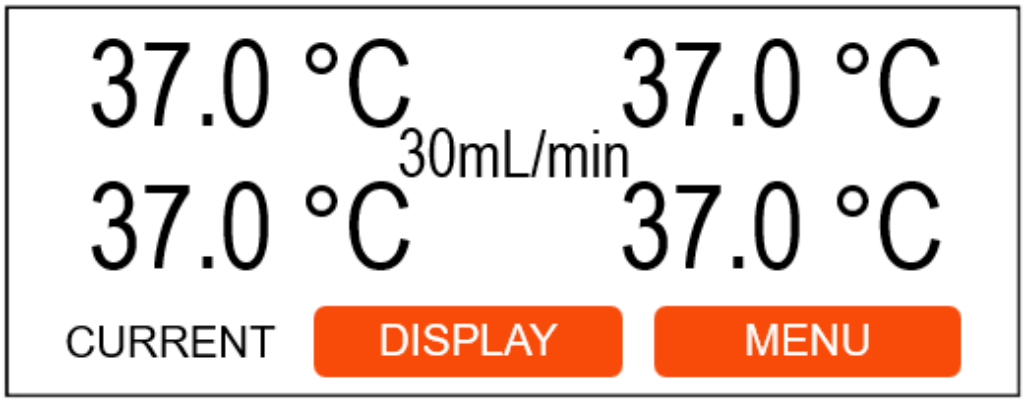
Caution

- Do not operate until the Installation Qualification has been completed.
- If a fault occurs while using the BT37M-02, stop using the device and report it to Planer Limited or local distributor. Move samples to another benchtop incubator.

1. Switch on the mains supply to the BT37M-02.
2. When the system powers on, it will normally enter standby mode; see Theory of operation 12. In this mode, no gas is supplied to the chambers and the lid and base are not heated.



3. Press the **Run** button to leave standby mode and enter the normal run mode. For more details refer to the Theory of operation 12 and User interface 15 sections.



4. If this is the first time the BT37M-02, has been used follow the steps below:
   a. Set the access code to restrict access. See Setting the Access code 27.
   b. Check the configuration. See Changing the control settings 27.
   c. Install the humidifier. See Installing the humidifier 29.
   d. Wait one day before adding samples.
   e. In normal run mode, disconnect power and confirm the unit can run from the battery for 30 minutes. Note the available hold-up time following the test will have been reduced and it may take up to 24 hours for full capacity to be restored.

f. Check the gas supply to the chambers by using culture medium containing phenol red indicator.

   i. Place the medium in culture dishes and leave them in both the left and right chambers overnight.

   ii. Next day, check the phenol red indicator has changed to the expected salmon pink colour.

3.1 Setting the access code

Access to the BT37M-02 settings requires an access code to be entered. This is a 5 digit number used to control access to the menus. This can be changed as follows:

1. From the main display, click **Menu**.
2. Select **Set access code**.
3. When prompted, enter the current access code. The default is **00000**.
4. At the **Enter access code** screen, enter the new access code.
5. Select **Display mode** to return to the main screen.

3.2 Changing the control settings

The control settings will normally only need to be adjusted when the BT37M-02 is first installed. The default chamber temperature is 37.0 °C. The flow rates should not normally be adjusted from their default settings.

1. From the main display, click **Menu**.
2. Select **Configuration**.
3. When prompted, enter your access code.
4. At the **Select group to adjust** screen, select **Control settings**.
5. Select from the following options to change the control settings:

Left temp C	Adjust the left-hand chamber temperature. Default 37.0 °C.
Right temp C	Adjust the right-hand chamber temperature. Default 37.0 °C.
Bleed on time s	See Gas flow 28 for details of these settings.
Bleed off time s	See Gas flow 28 for details of these settings.
Purge duration s	See Gas flow 28 for details of these settings.
Extended purge duration s	See Gas flow 28 for details of these settings.
Non-pulsed flow mL/min	See Gas flow 28 for details of these settings.

Important

- After changing any parameters, use the main display to check the setpoints are correct. From the main screen you can keep pressing **Display** until the setpoints are displayed.

3.2.1 Gas flow

The gas flow to the chamber can be in one of four states: off, bleed flow, purge flow, extended purge.

- The gas flow is only off when in standby or bottle change mode.
- Bleed flow is the default flow condition and provides the background gas flow required to maintain the gas concentration in the chambers. Bleed flow provides gas at a low background rate but can operate in two modes: non-pulsed 28 and pulsed 29.
- Purge flow provides gas at a higher rate, factory set to 360 mL/min, for a length of time defined by the **Purge duration s** setting. The default duration is 180 seconds. Purge flow only occurs when both lids are shut and starts when the lids are closed. The flow then returns to bleed flow.
- Extended purge flow provides gas at the same flow as the normal purge flow but for an extended duration defined by the **Extended purge duration s** setting. The default duration is 540 seconds. Extended purge flow only occurs when both lids are shut and starts when the user exits standby or bottle change mode. The flow then returns to bleed flow.

3.2.1.1 Non-pulsed bleed flow

In non-pulsed mode, gas is provided at a steady rate defined by the **Non-pulsed flow mL/min** setting. This is the default and recommended mode.

3.2.1.2 Pulsed bleed flow

In pulsed mode, the flow alternates between a low and high bleed flow rate. This requires the **Bleed off time s** setting to be set to a non-zero value, otherwise non-pulsed flow will be provided. In pulsed mode the flow is held at a low bleed rate for a duration defined by the **Bleed off time s** and then at a high bleed rate for the **Bleed on time s** duration. The low bleed rate is factory set to 20 mL/min and the high bleed rate to 60 mL/min.

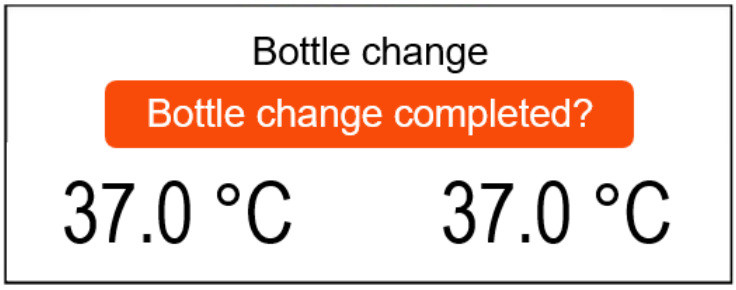
3.3 Installing the humidifier

Caution

- Use aseptic technique.
- Do not re-use the bottles.
- Do not use if packaging is broken or unintentionally opened before use.
- Do not resterilize.
- Do not refill the bottle.

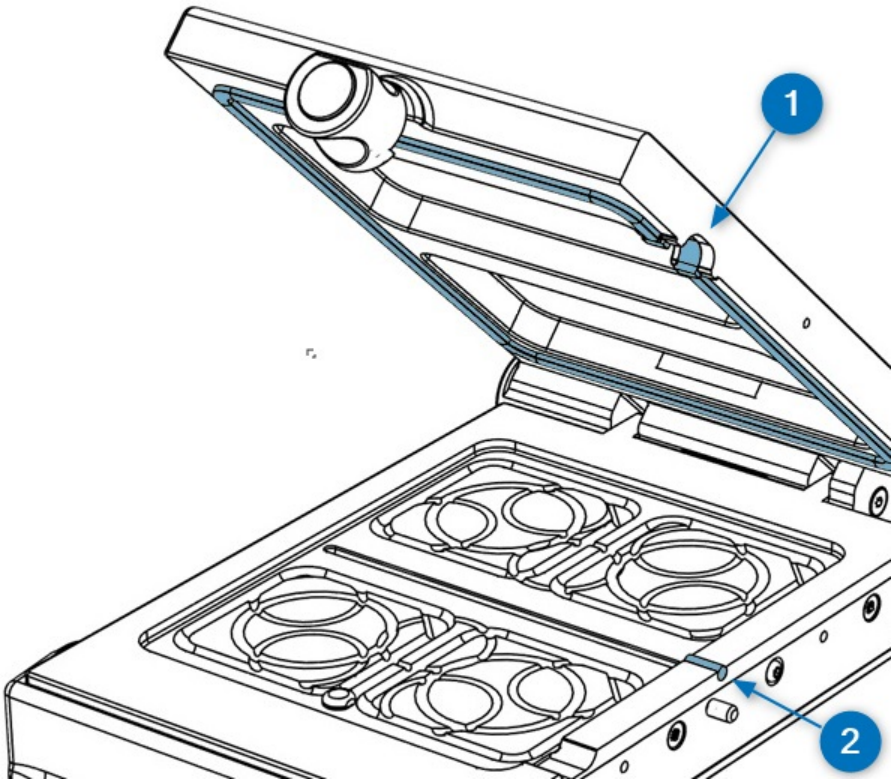
The humidifier comprises a bottle, tube set and filter. A new humidifier will need to be installed when the BT37M-02 is first installed. The humidifier must be replaced every **30 days** to avoid the growth of mould and bacteria that may occur as a result of the warm humid environment.

1. If there are samples in the BT37M-02, transfer them to another unit.
2. From the main display, click **Menu**.
3. Select **Bottle change**. This will switch off the gas supply to the chambers.
4. The bottle change screen will be displayed along with the base temperatures.

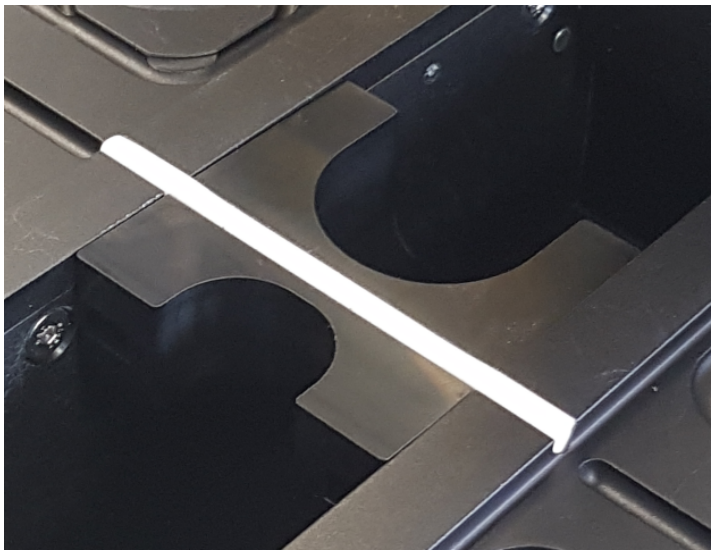


5. Remove the existing bottle if fitted.
6. Install a new bottle.

Single tube system



1. The single tube system has a seal that **does not** cover the large opening towards the front of the chamber lid.
2. The single tube system also includes a small cylindrical seal that seals the tube entry towards the centre of the chamber base.
3. On later incubators the seal has been integrated in to a modified heater block.



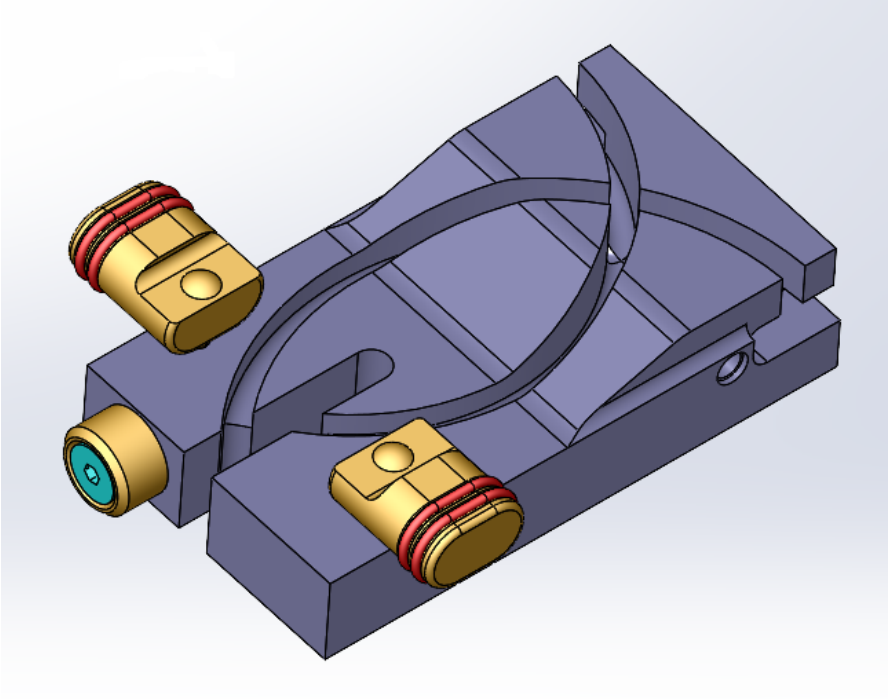
Refer to the Single tube bottle humidifier 32 section for details on how to change the bottle.

Three tube system

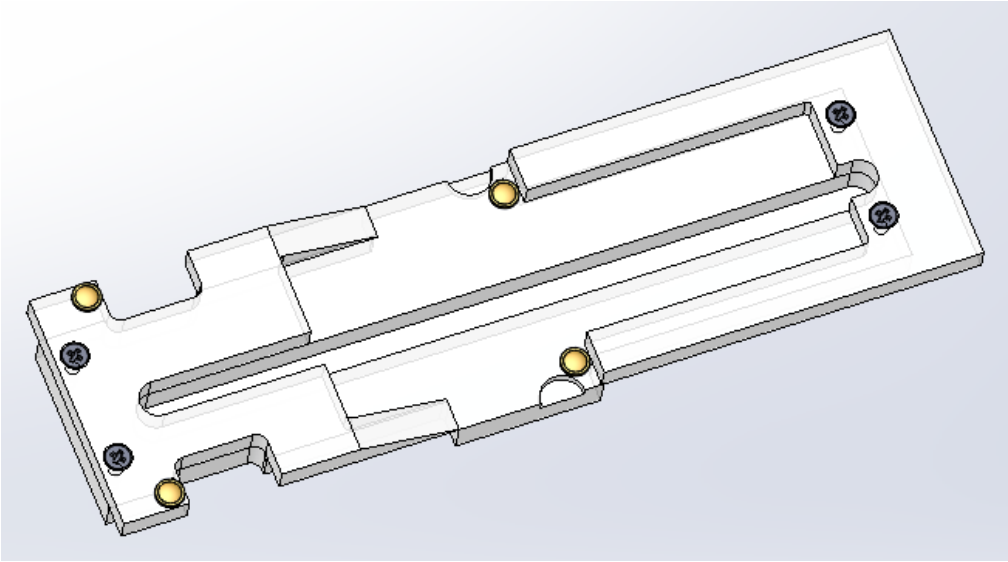
1. The three tube system uses an adapted tube block that seals the large opening towards the front of the chamber lid.
2. To enable the three tube bottle to be used you will need to fit the BT37 Mark II three tube bottle humidifier kit AY200288.

The kits consists of:

Heater block with sealing plugs



Translucent humidifier lid assembly



Refer to the Three tube bottle humidifier 36 section for details on how to change the bottle.

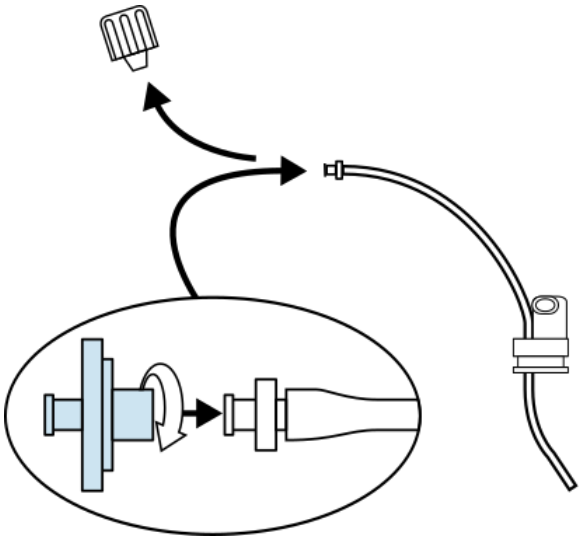
7. Select **Bottle change completed?** when the new humidifier has been installed.
8. Look through the liquid level indicator and ensure bubbles can be seen when the bleed flow of 31mL/min is active following the purge flow of 360mL/min. See Checking the liquid level indicator 46.
9. Ensure both status indicators are green.
10. If you removed any samples, you can now replace them.

Important

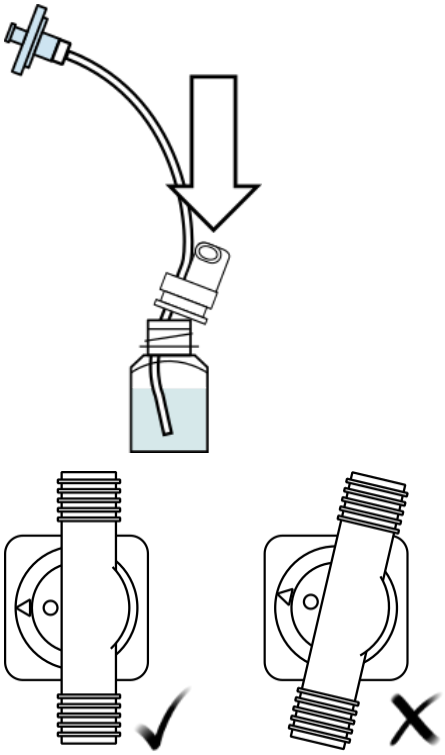
- Keep the humidifier lid shut during normal operation.

3.3.1 Single tube bottle humidifier

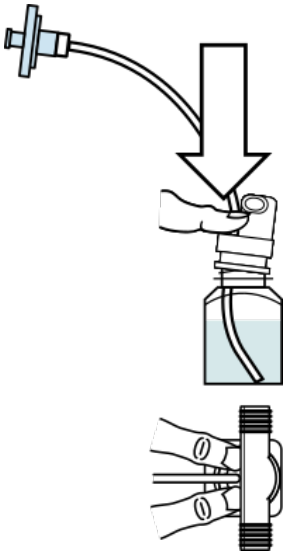
1. Inspect the bottle and tubing. Do not use if the tubing is kinked or damaged.
2. Fill the bottle with 125 mL of sterile, distilled water.
3. Remove the cap from the luer fitting on the inlet tube and replace with the filter.



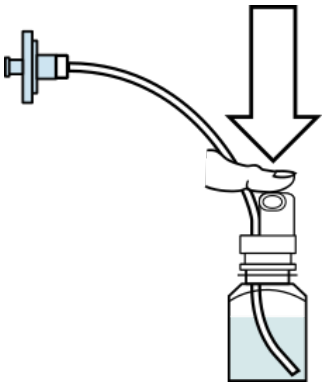
4. Fit the bottle cap to the bottle by first pushing the rear of the cap down. Ensure the tubes are correctly aligned with the bottle.



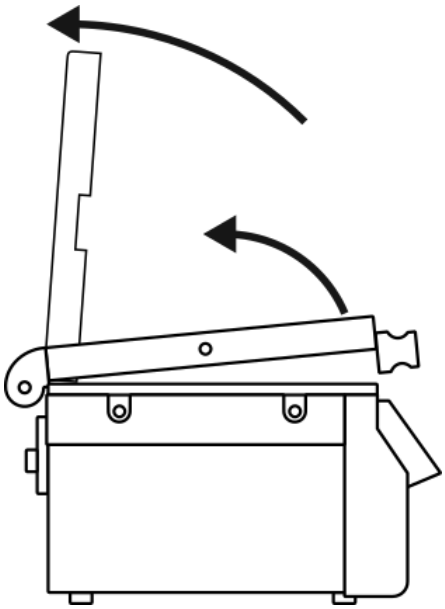
5. Then push the front down with your thumbs using equal pressure on either side of the inlet tube.



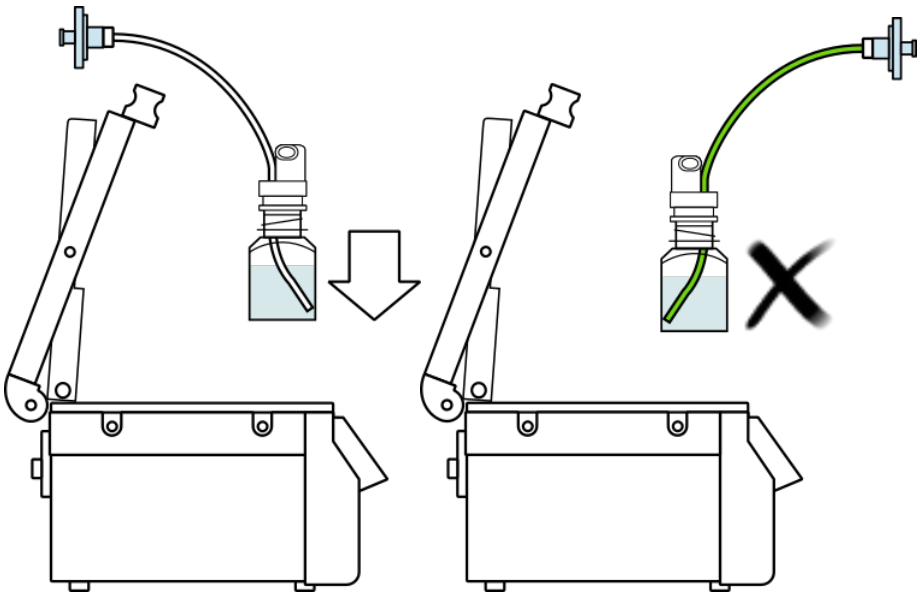
6. Finally, press down on the top of the bottle cap to make sure it is inserted fully.



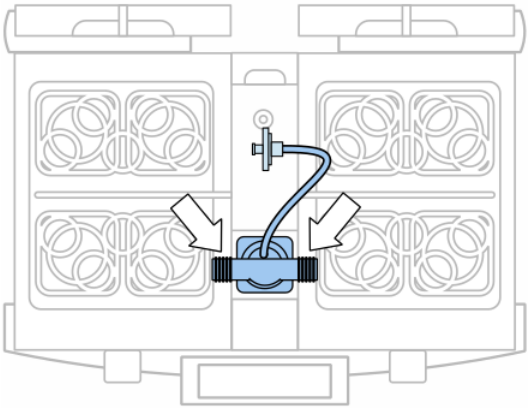
7. Open the humidifier and the left and right-hand chamber lids.



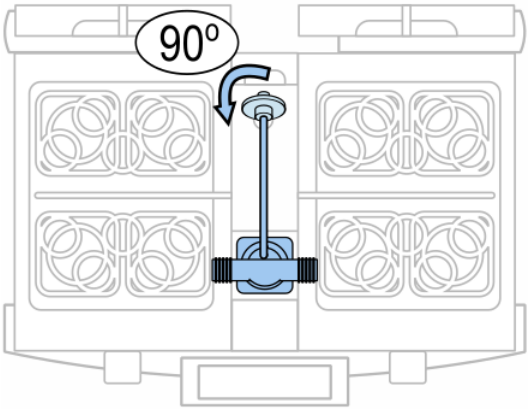
8. Fit the bottle. Press in firmly and ensure the orientation is correct



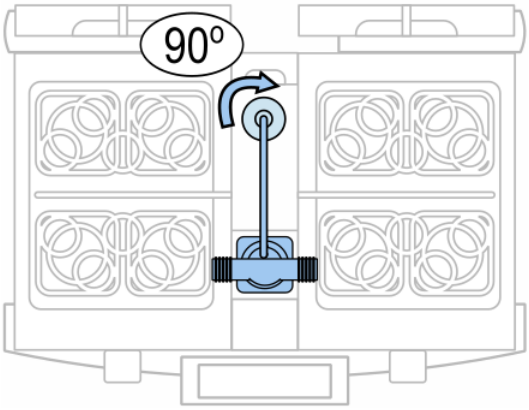
9. Ensure the bottle arms are seated correctly in the base of the left and right-hand chambers.



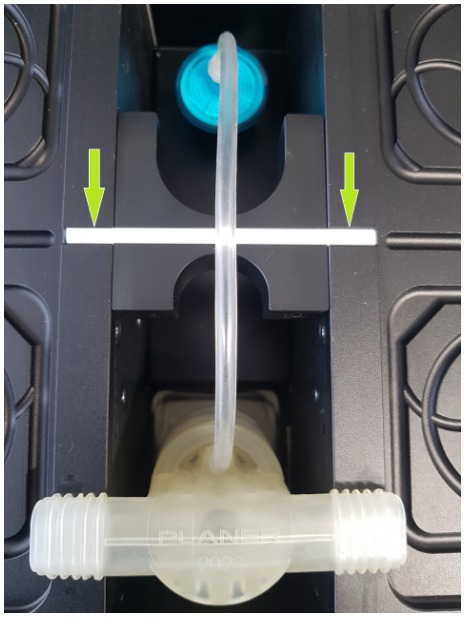
10. Rotate the rear tube and filter anticlockwise.



11. Fit the filter to the gas inlet.



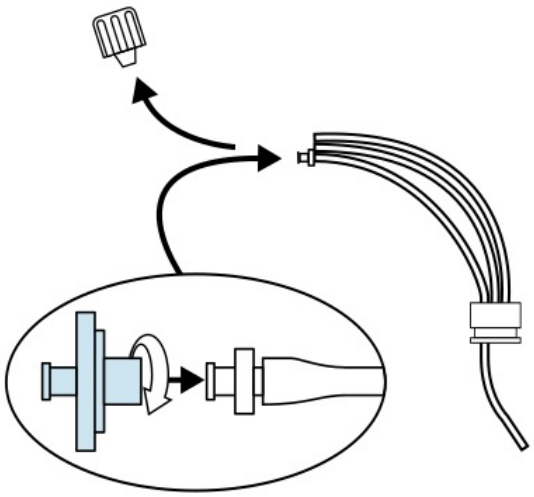
12. Make sure the filter is correctly fitted to the gas inlet and is not misaligned.
13. Check the tube. Ensure there are no kinks.
14. Ensure the plug recess retainer and recess seal are in place. These are not normally removed or replaced and should already be in position.



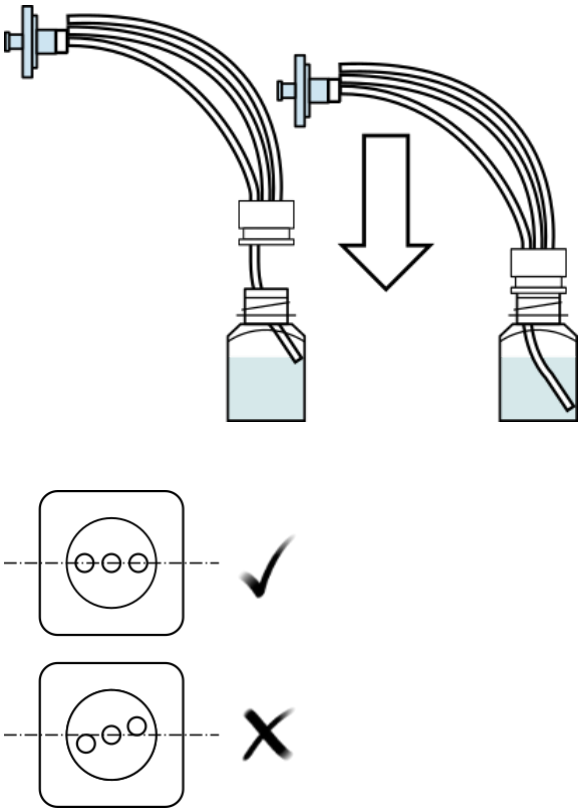
15. Close the humidifier and chamber lids.

3.3.2 Three tube bottle humidifier

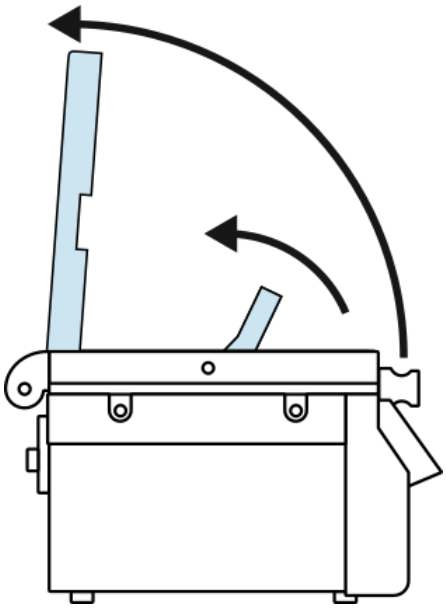
1. Inspect the bottle. Do not use if the tubing is kinked or damaged.
2. Fill the bottle with 125 mL of sterile, distilled water.
3. Remove the cap from the luer fitting on the inlet tube and replace with the filter.



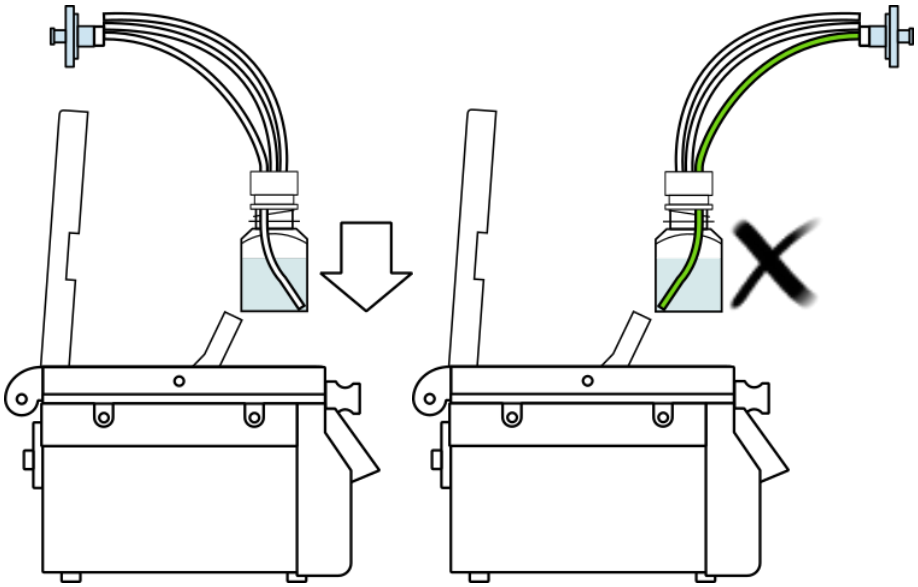
4. Press the bottle cap onto the bottle. Ensure the tubes are aligned with the bottle.



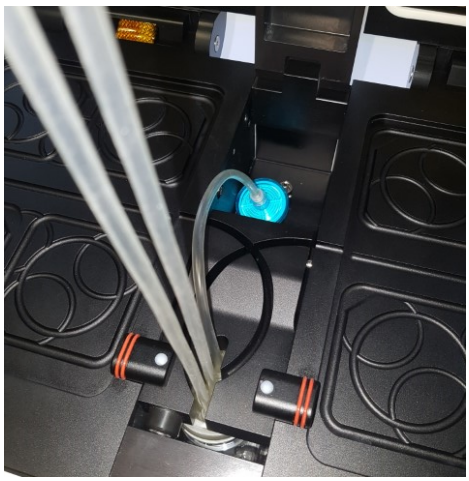
5. Open the humidifier lid and rotate the tube guide to its back position.



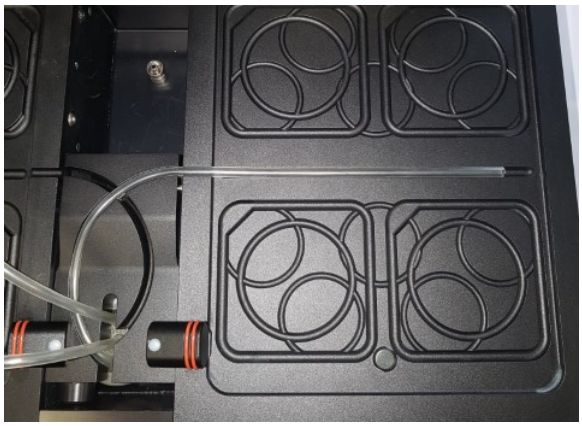
6. Fit the bottle. Press in firmly and ensure the orientation is correct.



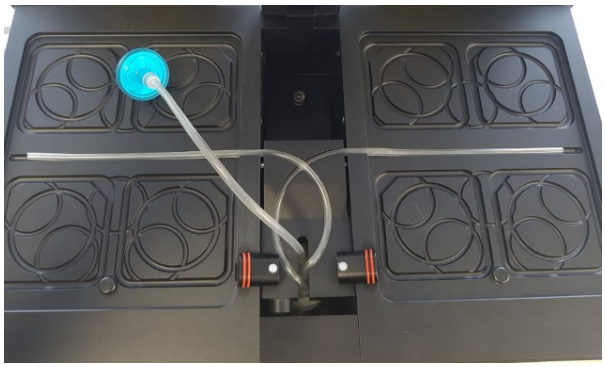
7. Close the tube guide. Ensure all three tubes pass through the slot in the guide and are not pinched.



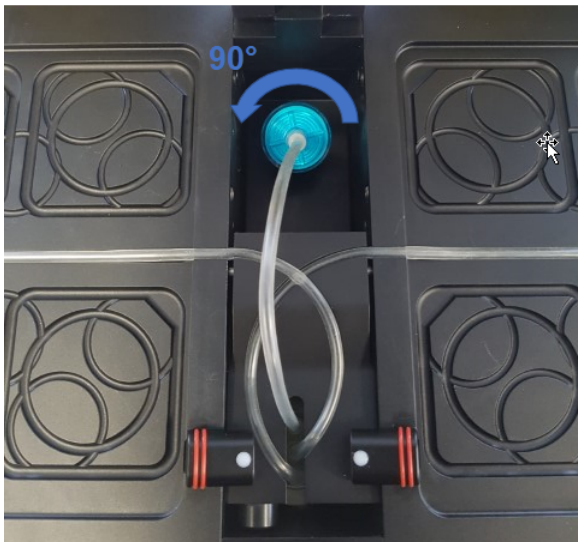
8. Route the front tube to the right-hand chamber.



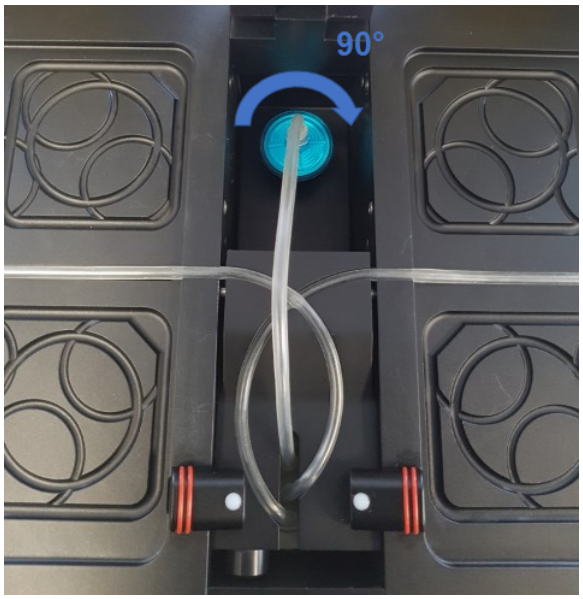
9. Route the middle tube to the left-hand chamber.



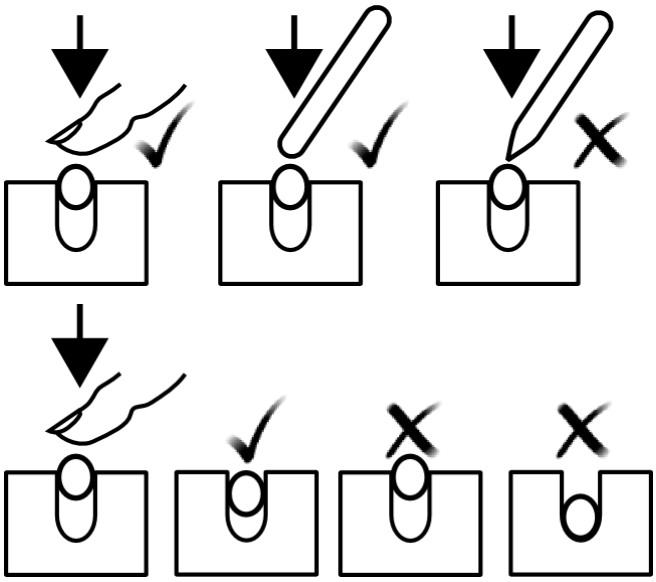
10. Rotate the rear tube and filter anticlockwise.



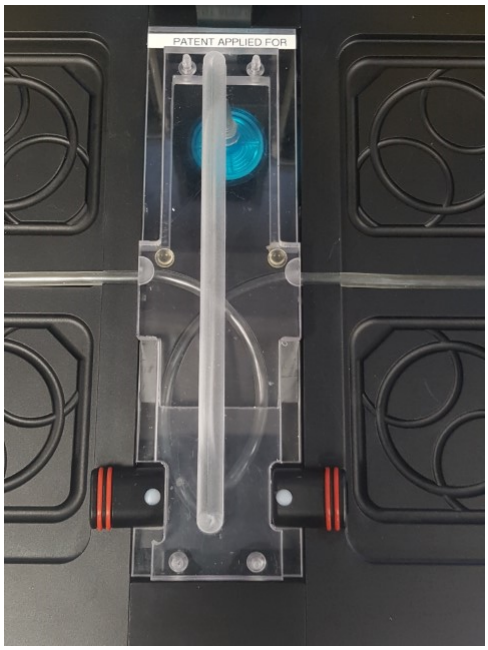
11. Fit the filter to the gas inlet.



12. Press the tubes into the grooves. Do not use sharp objects.



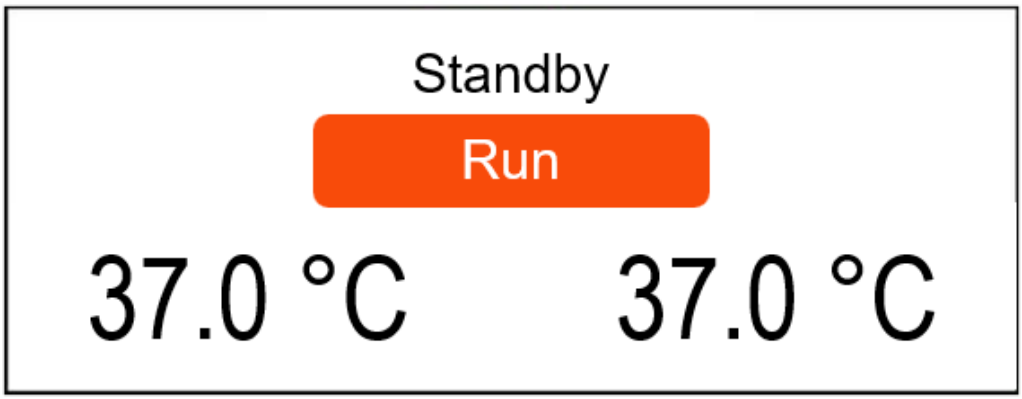
13. Check the tubes. Ensure there are no kinks.
14. Lay the clear cover gently over the tubes. The cover does not clip in place.



15. Ensure the clear cover is correctly orientated as shown.
16. Ensure the central tube from the gas filter lies in the channel in the clear cover.
17. Close the humidifier lid.

3.4 Switching off

1. From the main display, click **Menu**.
2. Select **Standby**. This will switch off the gas supply and stop heating the chambers.
3. The standby screen will be displayed.



4. You can now switch off the mains display and disconnect the power cord from the mains inlet.

Routine maintenance and troubleshooting

4 Routine maintenance and troubleshooting

4.1 Regular checks

Daily	• Check bubbles can be seen through the liquid level indicator. • See Checking the liquid level indicator 46. If there is insufficient water to cover the dip tube in the bottle, replace the humidifier. • Check the humidifier tubing to ensure there is no build up of condensation. If you have a three tube bottle humidifier, do not remove the clear cover during this check. If condensation is forming in the tubes, refer to the Condensation 53 section.
When samples are added or removed.	Check the humidifier tubing to ensure there is no build up of condensation. If you have a three tube bottle humidifier, do not remove the clear cover during this check. If condensation is forming in the tubes, refer to the Condensation 53 section.
Every 4 months	Check the battery. See Checking the battery 46.
Annually	Calibrate and service the BT37M-02. See Calibration and servicing 47.

4.2 General cleaning

Warning

- Bleaches are corrosive and may damage sensitive components and metal surfaces within the chamber.
- Switch off the BT37M-02 and disconnect the mains supply before cleaning. See Switching off 41.
- Always allow the unit to dry fully before reconnecting the mains supply.
- Note that disinfectants are potentially hazardous to health. Ensure that you obtain a material safety data sheet (MSDS) before use and follow the instructions contained therein.

Caution

- The person responsible for the equipment must ensure that:
  - the unit is decontaminated if hazardous material is split onto or into the equipment.
  - only cleaning and disinfecting materials compatible with the equipment are used. Incompatible materials may cause a hazard by reacting with the equipment or materials contained within.

These instructions are for the exterior of the device only.

1. Clean the BT37M-02 periodically with a damp cloth and sterile water or 70% isopropyl alcohol.
2. Clear the gas vent at the end of the incubation chamber using a clean miniature bottle brush wetted with sterile water or 70% isopropyl alcohol. Always push the brush from the inside of the chamber through to the exterior to avoid introducing contamination into the chambers. If in doubt, clean and disinfect the chambers after clearing the ports; see Cleaning and disinfecting the chamber 45.
3. Clean the external monitoring ports using a miniature bottle brush wetted with sterile water or 70% isopropyl alcohol. See the Side view 14 section.
4. Allow the unit to dry fully before reconnecting the mains supply.

4.3 Cleaning and disinfecting the chamber

Warning

- Switch off the BT37M-02 and disconnect the mains supply before cleaning. See Switching off 41.
- Always allow the unit to dry fully before reconnecting the mains supply.
- Note that disinfectants are potentially hazardous to health. Ensure that you obtain a material safety data sheet (MSDS) before use and follow the instructions contained therein.

Caution

- The person responsible for the equipment must ensure that:
  - the unit is decontaminated if hazardous material is split onto or into the equipment.
  - only cleaning and disinfecting materials compatible with the equipment are used. Incompatible materials may cause a hazard by reacting with the equipment or materials contained within.
  - if there is any doubt about the compatibility of a cleaning or disinfection agent, please contact Planer Limited or your distributor.

Cleaning

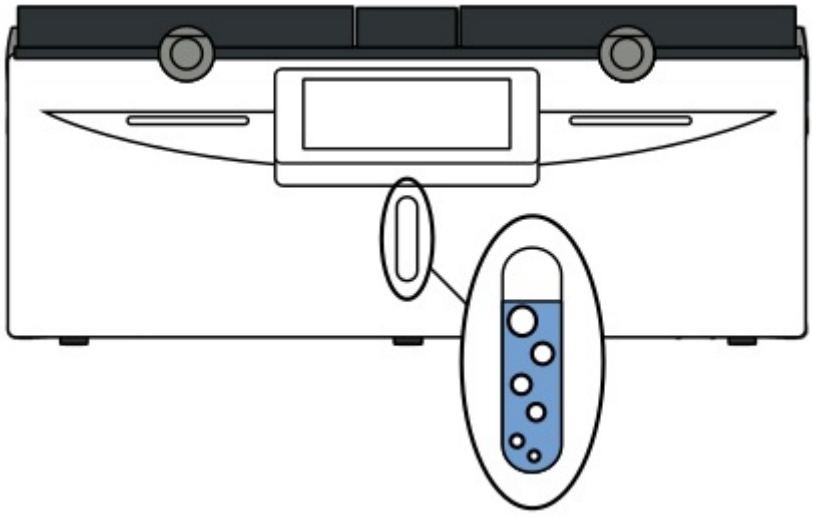
1. Remove gross spills by wiping with a disposable wipe. Discard used wipe safely.
2. Spray the surface with sterile water.
3. Allow to soak for 2 minutes at room temperature to soften any material that has dried on the surface.
4. Remove the water with a clean lint-free cloth (gauze). Use cotton buds or swabs where necessary to ensure contact is made with all grooves and corners of the surface plate.
5. Repeat steps 2, 3 and 4, three more times.
6. Visually inspect the surface to ensure that all visible soil has been removed.

Disinfection

1. Prior to disinfection, the incubator chamber must first be cleaned by following the cleaning procedure above.
2. Spray the surface with isopropyl alcohol at 70% v/v dilution.
3. Allow to soak for 15 minutes at room temperature.
4. Remove the disinfectant with a clean non-linting cloth (gauze). Use cotton buds or swabs where necessary to ensure contact is made with all grooves and corners of the surface plate.
5. Repeat steps 2, 3 and 4 one more time.
6. Wipe the surface over with sterile water and a clean non-lint cloth to remove any residual fluids. Use cotton buds or swabs where necessary to ensure contact is made with all grooves and corners of the surface plate.
7. Leave the unit to dry until all residual cleaning fluids have evaporated.

4.4 Checking the liquid level indicator

1. Look through the liquid level indicator and ensure bubbles can be seen.



2. With three tube bottle humidifiers (see Installing the humidifier 29), lift the humidifier lid and check the tubes to ensure there is no build up of condensation. Do not remove the clear cover during this check. If condensation appears to be forming, refer to the Condensation 53 section.

4.5 Checking the battery

1. Ensure the BT37M-02 has been running for at least 24 hours.
2. In normal run mode, disconnect power.
3. Acknowledge the power fail alarm.
4. Confirm the unit can run from the battery for 30 minutes.

5. Reconnect the mains supply.
6. Following the test, the available backup time will have been reduced and it may take up to 24 hours for full capacity to be restored.

4.6 Calibration and servicing

The BT37M-02 should be calibrated and serviced annually. Contact your service provider.

Caution

- Operating parameters should only be modified by qualified service personnel or under their guidance. Entering incorrect values may impair the performance of the product.
- The following information is provided for reference only.

The calibration offsets can be adjusted as follows.

1. From the main display, click **Menu**.
2. Select **Configuration**.
3. When prompted, enter your access code.
4. At the **Select group to adjust** screen, select **Calibration offsets**.
5. The following calibration settings can then be adjusted:

Cal offset top left temp C	Calibration offset for the left-hand lid temperature in °C.
Cal offset top right temp C	Calibration offset for the right-hand lid temperature in °C.
Cal offset bottom left temp C	Calibration offset for the left-hand base temperature in °C.
Cal offset bottom right temp C	Calibration offset for the right-hand base temperature in °C.
Cal offset humidifier temp C	Calibration offset for the humidification chamber in °C.
Low flow cal at mL/min	Flow rate for the low flow calibration point in mL/min. The default value is 20 mL/min.
Cal offset Low flow mL/min	Calibration offset at the low flow calibration point in mL/min.
Mid flow cal at mL/min	Flow rate for the middle flow calibration point in mL/min. The default value is 60 mL/min.
Cal offset Mid flow mL/min	Calibration offset at the middle flow calibration point in mL/min.
High flow cal at mL/min	Flow rate for the high flow calibration point in mL/min. The default value is 360 mL/min.
Cal offset High flow mL/min	Calibration offset at the high flow calibration point in mL/min.

4.7 Safety testing

Warning

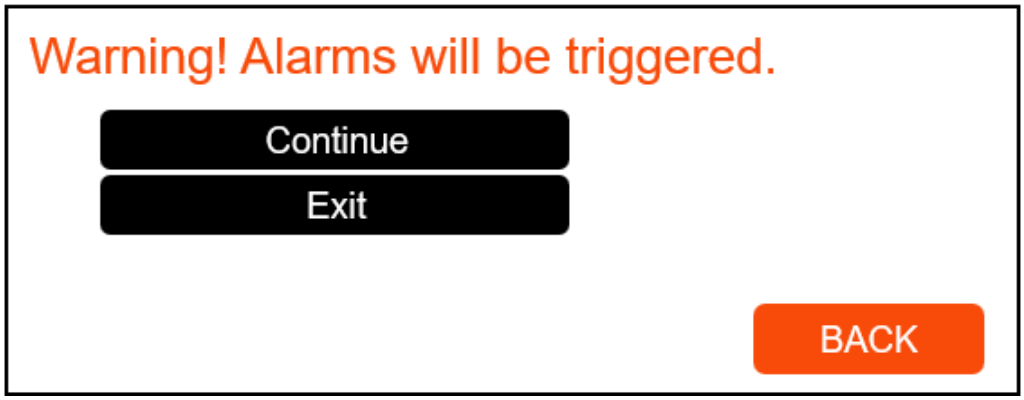
- The BT37M-02 is classified as electrical Class 1 equipment and must be earthed for safe operation.
- Repetition of potentially damaging high-voltage flash tests should be avoided.

1. The BT37M-02 and the mains connecting cord should be regularly checked by suitably trained personnel using a Portable Appliance Tester or similar equipment, to ensure adequate earth bonding.
2. The earth continuity of the mains installation must also be regularly inspected by the person responsible for the installation.
3. All mains leads should be checked for signs of damage and replaced if necessary.

4. All gas joints should be checked for leaks by using soapy-water and looking any sign of any bubbles. Leaking joints should be corrected as described in the section, Connecting the gas supply 21.

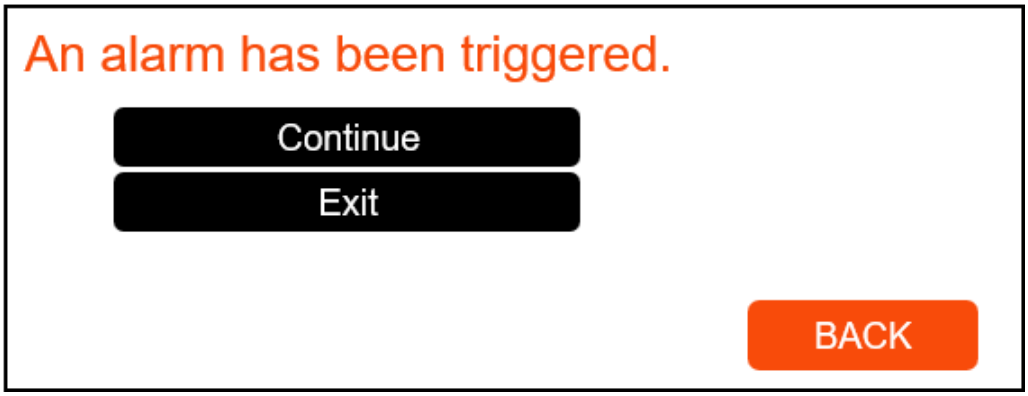
4.8 Testing the alarms

1. From the main display, click **Menu**.
2. Select **Test**.
3. The alarm test screen will be displayed.



4. Press **Continue** to switch on the alarms.
5. An alarm showing that the alarms are being tested will be displayed.

6. Press **OK** to acknowledge.
7. The alarms will be switched off and a message that an alarm was triggered will be displayed.



8. Press **Back** to end the tests and return to the normal display. If you press **Continue**, you will be taken to an EMC test screen. This is for use by service engineers only and should not be run.

4.9 Troubleshooting

Should any problem persist, please contact your service provider for assistance. Should a serious incident occur involving the loss of patient samples or injury to the user, you must inform Planer Limited and if within the EU, the competent authority for your country.

4.9.1 Normal messages

Message	Fault	Possible cause	Action
Ensure bubbles can be seen flowing through bottle!	None	This is a warning to check the gas flow through the humidifier.	See Checking the liquid level indicator 46.
In bottle change mode for too long!	The system has been left in bottle change mode too long.	User has forgotten to exit bottle change mode.	See Installing the humidifier 29.
One of the lids is open or unlocked!	The lids have not been closed or locked.	The BT37M-02 will not regard a lid as being shut until it is both closed and the knob rotated clockwise into its locked position.	Check the lids are closed correctly.
Network write enabled!	None	This is a warning that the network can be used to write to the system.	See Network security 58.
Unexpected reset: press any key to continue.	The system has restarted unexpectedly.	• The incubator was left running without power until the battery ran out. • The reset switch was depressed.	Always shut down the system correctly. See Switching off 41.

4.9.2 Control errors

Message	Fault	Possible cause	Action
Alarm. Left lid at xxx °C	Left lid at incorrect temperature.	• Room ambient temperature is too close to the setpoint. • Setpoint has just been adjusted by a large value. • Setpoint is outside specification.	• Check the room temperature. • Ensure the equipment is not influenced by sources of hot or cold air such as air conditioning units. • Check the setpoints. See Changing the control settings 27. • Check the setpoints against the specification. See Control 59.
Alarm. Left base at xxx °C	Left base at incorrect temperature.		
Alarm. Right lid at xxx °C	Right lid at incorrect temperature.		
Alarm. Right base at xxx °C	Right base at incorrect temperature.		
Alarm. Humidifier at xxx °C	Humidifier chamber at incorrect temperature.		
Alarm. Bleed flow at xxx °C	Gas flow during bleed mode incorrect.	• Gas pressure incorrect. • Humidifier bottle tubes kinked. • Inlet filter on humidifier gas inlet is wet. • Setpoint has just been adjusted by a large value. • Setpoint is outside specification.	• Check the gas pressure. • Check the setpoints. See Changing the control settings 27. • Check the setpoints against the specification. See Control 59.
Alarm. Purge flow at xxx °C	Gas flow during purge mode incorrect.		

Temperature alarm trigger point

An alarm will be triggered when the chamber temperature deviates more than 0.2 °C from the setpoint.

An alarm will be triggered when the humidifier temperature deviates more than 1.0 °C from the setpoint.

Flow alarm trigger point

An alarm will be triggered when the bleed flow deviates more than 9 mL/min from the setpoint.

An alarm will be triggered when the purge flow deviates more than 54 mL/min from the setpoint.

4.9.3 Battery errors

Message	Fault	Possible cause	Action
Mains failure: running on battery.	The mains power supply has failed.	• Mains power to the BT37M-02 has failed. • The mains cord is unplugged.	Check the mains power supply connections.
Mains failure: running on low battery.	The mains power supply has failed and the battery has almost run out.	• The BT37M-02 has been running from its battery for too long. • The battery has not been given time to recharge after a mains power failure.	• Check the mains power supply connections. • Allow time for the battery to recharge once mains power is available.
Faulty low battery: no mains backup.	The internal battery is faulty.	The battery requires replacement.	Contact your service provider.
Faulty battery charger: contact service.	Battery voltage is too high.	Faulty charging circuit.	Contact your service provider.

4.9.4 Miscellaneous errors

Message	Fault	Possible cause	Action
Call service: xxxxxxxxxxxx	Internal fault.	Electronics failure.	Contact your service provider.
Diagnostics ADC error	Unexpected measurement recorded.	Electronics failure.	Contact your service provider.
Memory write error x	Unable to write to the internal memory.	Electronics failure.	Contact your service provider.

4.9.5 Condensation

The following questions can be used to identify causes of condensation in the humidifier tubing.

Has the bottle just been changed?

Condensation may appear immediately after a bottle change. This should slowly clear.

Is the rear fan operating correctly?

The fan can be checked by holding a thin piece of tissue paper over the fan inlet; the fan inlet is located at the rear of the incubator in the centre. The paper should be seen to be drawn very gently towards the unit. Note that the fan may be running in pulsed mode; in this mode you should see the tissue moving every minute. If the fan is not operating, contact your service provider.

Is the air flow restricted?

Ensure that the rear of the incubator is not placed up against a wall or other equipment as this will restrict the air flow.

Is the incubator positioned so that it is drawing-in warm air for cooling?

Ensure that the incubator is not positioned so that it is drawing in warm air from other devices such as incubators or computers for example.

Is the incubator being affected by other sources of heat or cold?

Other devices, such as air conditioning units, can produce localised hot and cold areas. The incubator must be positioned to avoid these.

Is the environment too warm?

Check that the local environment is within the specification given in this manual; see the Control 59 section.

4.9.6 Resetting the access code

The access code can be reset if it has been forgotten.

1. From the main display, click **Menu**.
2. Select **Reset access code**.
3. A reset code will be displayed at the top of the screen.
4. Contact the service department at Planer Limited, who will be able to provide you with a new access code.
5. Enter the new access code.
6. You can change the new code later as normal. See Setting the access code 27.

4.9.7 Resetting the system

The BT37M-02 includes an internal watchdog so if the controller should stop running for any reason, it will automatically restart. In the unlikely event that it is necessary to reset the processor, follow the steps below:

1. Locate the **RST** hole at the back of the BT37M-02; see Rear view 15.
2. Depress the switch using the tip of a ball-point pen or similar object.
3. Keep it depressed for 1 second and then release. The BT37M-02 will then restart.

4.10 Returning for service

Should the system need to be sent back to Planer Limited for repair, or if the unit is to be inspected, maintained or repaired on-site by Planer Limited, a Declaration of Decontamination must be completed. This can be downloaded from http://planer.com/support/service/decontamination-certificate.html.

4.11 Disposal

- Do not dispose of with general waste.
- Ensure the system has been cleaned as necessary to ensure it is safe to handle and service and is free from any biohazard or toxic materials. See Cleaning and disinfecting the system 45.
- Dispose of humidification bottles in accordance with your laboratory standard operating procedure.

Additional information

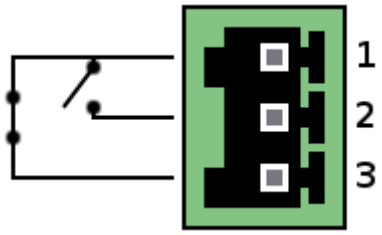
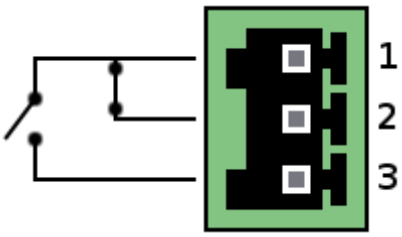
5 Additional information

5.1 External alarm connection

Caution

- Any circuit connected to the alarm output must be within the limits stated below.
- Any circuit connected to the alarm output must meet the requirements for an accessible part as defined in EN 61010-1 or its equivalent.
- The alarm output must not be used in safety critical applications.
- External alarm connections should only be made by trained service personnel.

The system is fitted with a connector for fitting to an external alarm. The alarm connector has three volt-free (dry) terminals which provide normally-open and normally-closed contacts as shown in the diagrams below.

Connector type	Phoenix 3 way horizontal PCB header. Manufacturer's part number 1181451
Maximum voltage	30 V DC
Maximum current	1 A
Access code connections in normal operating mode	
Access code connections in alarm mode or power disconnected	

5.2 Network security

In normal operation, the BT37M-02 only allows data to be read via the network connection. Follow the steps below to enable data to be written via the network. This is normally only required by service personnel.

1. From the main menu, select **Security**.
2. From the **Modbus** screen, select **Network write**.

3. The screen will show that data can now be written via the network.
4. Press **OK** to return to read-only mode.

5.3 Specifications

5.3.1 System

Dimensions	435 mm wide x 330 mm deep x 185 mm high
Weight	17 kg
Storage temperature	-10 °C to +50 °C
Storage humidity	5% to 95% relative humidity non-condensing
Storage special instructions	Recharge every 4 months by connecting to the mains power supply for 24 hours.
Operating environment	For indoor use only
Operating temperature	+5 °C to +40 °C for safe operation See Control 59 table for control limitations.
Operating humidity	20 % to 80 % relative humidity non-condensing decreasing linearly to 50 % relative humidity at 40 ° C.
Altitude	up to 2000 m
Pollution degree	Pollution degree 2 (BS EN61010-1)

5.3.2 Control

Temperature control range	(ambient + 5 °C) to (ambient + 20 °C) 40 °C max.
Temperature measurement accuracy	± 0.2 °C
Temperature control accuracy	± 0.1 °C measured after any transient effects due to set-point changes have subsided.
Flow control range	0 ml/minute to 900 mL/minute Normalised to 0 C , 50% RH and 1 bar.
Flow accuracy	The greater of ± 10% or ± 3 ml/minute
Flow control accuracy	The greater of ± 5% or ± 2 ml/minute measured after any transient effects due to set-point changes have subsided.
Accuracies apply at the calibration points. The system is factory calibrated for an operating temperature of 37°C, nominal bleed flow of 30 mL/min and a purge at 360mL/min.	

5.3.3 Capacity

Dishes per chamber	4 x NUNC 4 well dishes, 4 x NUNC 60 mm Petri dishes 10 x NUNC 35 mm Petri dishes 4 x MINITUBE 5 well dishes 4 x FALCON 60 mm Petri dishes

5.3.4 Power

Power requirements	100 - 240 V~ (± 10%) 50/60Hz (± 5%) 2 A

Note. The BT37M-02 system is designed to be plug connected to the normal building wiring.

5.3.4.1 Internal battery

Warning

- The internal battery is not user-replaceable and may only be replaced by persons trained in the servicing of this equipment.
- The battery must only be replaced with a battery of the same type and rating..

Internal battery backup	Gelled sealed lead acid battery 12 V x 12 A.h
Weight	4 kg
Composition w/w	Pb 57%, PbO2 22%, H2SO4 14%

Gases released:

Operating condition	Gases released
Normal	None
Over-charging Excessive temperatures	SO_2,SO_3, H_2, CO, H_2SO_4 mist

5.3.5 Humidifier bottle and filter

Item	Description	Manufacturer	Part number
Bottle: single tube system	Sterilized bottle assembly	Planer Limited	CN200115
Filter	Syringe filter. 0.2 µm, Supor membrane, 32 mm	PALL Corporation	HP4642 Planer ordering code: CN101517
Bottle: three tube system	Sterilized bottle assembly	Planer Limited	CN101568-1

5.3.6 Gas supply

Gas supply	Premixed gas. Typically 6% CO2, 5% O_2, 89% N2
Supply pressure	1.5 ± 0.15 bar
Connectors	SWAGELOK 1/4" tube fitting

Using default settings, the supplied gas is released to the room at the following rates:

Operating condition	Gases released
Normal	Gas mix. 31 mL/min.
After lid closure	Gas mix. 360 mL/min for 3 minutes.
After bottle change	Gas mix. 360 mL/min for 9 minutes.

5.3.7 Monitoring

Feature	Controller
Local area network (LAN)	10 Base T Ethernet - RJ45 shielded. Modbus-TCP-IP protocol.
Independent temperature monitoring	Independent sensors can be fitted to the monitoring ports; see Side view 14 section. Recommended sensor type: PT100 Class A to EN60751. Maximum diameter: 2.51 mm.

Contact your service provider for more details and available options.

5.3.8 Fuses

Warning

- To avoid risk of fire, fuses must always be replaced with the same type and rating.
  - Fuses should only be replaced by suitably trained service personnel.
  - Fuses should only be replaced after the cause of the original failure has been determined and corrected as appropriate.

Fuse	Location	Type
F1, F2	Mains inlet	T 3.15A L 250V 5 x 20 mm

- A -

- B -

- C -

- D -

- E -

- F -

- G -

- H -

- I -

- L -

- W -

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