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

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1. Int	roduction	5
1.1	Notices	6
1.2	Intended use	6
1.3	Symbols	7
1.3.1	Symbols used in this manual	7
1.3.2	Symbols used on the equipment	7
1.4	Safety	
1.4.1	Warnings	8
1.4.2	Precautions	9
1.4.3	Electromagnetic compatibility (EMC)	10
1.5	About the equipment	10
1.5.1	Theory of operation	10
1.5.2	Front view	11
1.5.3	Side view	12
1.5.4	Rear view	
1.5.5	User interface	
1.5. 1.5.		
1.5.	Status and alarm indicators	
1.5.		
2. Ins	tallation	17
2.1	Connecting the gas supply	19
2.2	External data collection	
2.3	Connecting the external alarm	
2.4	Connecting to the mains supply	
3. Op	eration	21
3.1	Setting the access code	23
3.2	Changing the control settings	
3.2.1	Gas flow	
3.2.		
3.2.	1.2 Pulsed bleed flow	
3.3	Installing the humidifier	25
3.3.1	Single tube bottle humidifier	27
3.4	Switching off	30
4. Ro	utine maintenance and troubleshooting	33
4.1	Regular checks	34
4.2	General cleaning	34
4.3	Cleaning and disinfecting the chamber	35
4.4	Checking the liquid level indicator	36

4.5	Checking the battery	
4.6	Calibration and servicing	37
4.7	Safety testing	
4.8	Testing the alarms	39
4.9	Troubleshooting	40
4.9.1	Normal messages	41
4.9.2	Control errors	42
4.9.3	Battery errors	43
4.9.4	Miscellaneous errors	43
4.9.5	Condensation	43
4.9.6	Resetting the access code	44
4.9.7	Resetting the system	44
4.10	Returning for service	45
4.11	Disposal	45
5. Add	ditional information	47
5.1	External alarm connection	48
5.1 5.2	External alarm connection	
-		48
5.2	Network security	48 49
5.2 5.3	Network security Specifications	 48 49 49
5.2 5.3 5.3.1	Network security Specifications System	 48 49 49 49
5.2 5.3 5.3.1 5.3.2	Network security Specifications System Control	48 49 49 49 50
5.2 5.3 5.3.1 5.3.2 5.3.3	Network security Specifications System Control Capacity Power	48 49 49 49 50 50
5.2 5.3 5.3.1 5.3.2 5.3.3 5.3.4	Network security Specifications System Control Capacity Power	48 49 49 49 50 50 50
5.2 5.3 5.3.1 5.3.2 5.3.3 5.3.4 5.3.4	Network security	48 49 49 49 50 50 50 50 50
5.2 5.3 5.3.1 5.3.2 5.3.3 5.3.4 5.3.4 5.3.5	Network security Specifications System Control Capacity Power 4.1 Internal battery Humidifier bottle and filter	48 49 49 49 50 50 50 50 50 51
5.2 5.3 5.3.1 5.3.2 5.3.3 5.3.4 5.3.4 5.3.5 5.3.6	Network security Specifications System Control Capacity Power 4.1 Internal battery Humidifier bottle and filter Gas supply	48 49 49 49 50 50 50 50 50 51 51 51
5.2 5.3 5.3.1 5.3.2 5.3.3 5.3.4 5.3.5 5.3.6 5.3.6 5.3.7	Network security Specifications	48 49 49 49 50 50 50 50 51 51 51 51 52

Introduction

1 Introduction

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

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

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Original Instructions



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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.

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 Symbols

1.3.1 Symbols used in this manual

\land	This symbol shows information or instructions that are related to safety. Failure to follow these instructions may result in personal or third-party injury.
2	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.

1.3.2 Symbols used on the equipment

\triangle	Refer to these instructions. Failure to follow these instructions may result in personal or third-party injury.
elFU indicator	Consult instructions for use. Electronic instructions can be accessed from the eIFU indicator web address.
\sim	Alternating current (AC).
~• >	Ethernet connection.
RST	Reset switch. Only press if the system becomes unresponsive.
Ĺ ↓	Alarm output connector.
$ \Rightarrow $	Premixed gas inlet.
\bigcirc	Premixed gas outlet.
STERILE R	Sterilized using irradiation

\otimes	Do not reuse.
8	Do not use if packaging is broken.
STERNIZE	Do not resterilize.
LOT	Batch code.
Σ	Use by date.
X	Do not dispose of with general waste.

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.

1.4 Safety

1.4.1 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 <u>Gas supply</u> [51] 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.
- Take care when handling samples. Samples may present other biological hazards. Refer to the person responsible for the equipment.

- 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 [50] 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.
 - o 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.

1.4.2 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.

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 <u>External alarm connection</u> [48] 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.

1.5 About the equipment

1.5.1 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.

1.5.2 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.

Introduction

1.5.3 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.

Introduction

1.5.4 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.

1.5.5 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.
- 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.

1.5.5.1 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.

1.5.5.2 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 <u>Installing the humidifier</u> [25] 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 <u>Changing</u> the control settings 23 section.
 - Calibration offsets: Select to adjust the calibration settings. Calibration settings should only be adjusted by trained service personnel. See the <u>Calibration and</u> <u>servicing</u> 37 section.
- Test: Select to run the in-built tests. See the <u>Testing the alarms</u> section.
- Set access code: Select to set the access code. See the <u>Setting the access</u> code 23 section.
- **Reset access code**: Select to reset the access code if it has been forgotten. See the <u>Resetting the access code</u> 44 section.
- Security: Select to allow the incubator settings to be temporarily modified via the network. See the <u>Network security</u> [48] section.
- **Standby**: Select to place the incubator into standby mode. See the <u>Theory of</u> <u>operation</u> and <u>Switching off</u> 30 sections.

1.5.6 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

1.5.6.1 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



- 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.



- The location of the connectors is shown in the Rear view 13 section.
- 1. Carefully unpack the equipment.
- 2. Install on a flat, level and stable surface.
- 3. Connect the gas supply; see <u>Connecting the gas supply</u> 19.
- 4. If the local area network is to be used to collect data, connect now; see <u>External</u> <u>data collection</u> 19.
- 5. If an external alarm is to be used, connect now; see <u>Connecting the external</u> <u>alarm</u> 20.
- 6. Clean and disinfect before use; see <u>Cleaning and disinfecting the chamber</u> 351.
- 7. Install the humidifier; see Installing the humidifier 25.
- 8. Connect the mains supply; see <u>Connecting to the mains supply</u> 201.
- 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 <u>Checking the liquid level</u> indicator 36.
- 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

- 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



• 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 <u>External alarm</u> <u>connection</u> [48] 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

- 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 <u>Rear</u> <u>view</u> 13 section.
- 2. Connect the power supply to a suitable mains power outlet.
- 3. The BT37M-02 will normally start in standby mode.

Operation

3 Operation

- 1. Switch on the mains supply to the BT37M-02.
- 2. When the system powers on, it will normally enter standby mode; see <u>Theory of</u> <u>operation</u> 10. 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 <u>Theory of operation</u> 10 and <u>User interface</u> 13 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 23.
 - b. Check the configuration. See Changing the control settings 23.
 - c. Install the humidifier. See Installing the humidifier 251.
 - 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 <u>Gas flow</u> ²⁴ for details of these settings.
Bleed off time s	See <u>Gas flow</u> ²⁴ for details of these settings.
Purge duration s	See <u>Gas flow</u> 24 for details of these settings.
Extended purge duration s	See <u>Gas flow</u> ²⁴ for details of these settings.
Non-pulsed flow mL/min	See <u>Gas flow</u> ^[24] for details of these settings.



 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: <u>non-pulsed</u> 24 and <u>pulsed</u> 24.
- 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

- Use aseptic technique.
- Do not re-use the bottles.
- Do not use if packaging is broken.
- 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.

- 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.

Bottle change		
Bottle change completed?		
37.0 °C	37.0 °C	

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



- 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.

Refer to the <u>Single tube bottle humidifier</u> 27 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. See <u>Checking the liquid level indicator</u> 36.
- 9. Ensure both status indicators are green.
- 10. If you removed any samples, you can now replace them.



• 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 centre groove seals are in place. These are not normally removed or replaced and should already be in position.



15. Close the humidifier and chamber lids.

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 <u>Checking the liquid level indicator</u> ³⁶. 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 condensation is forming in the tubes, refer to the <u>Condensation</u> [43] section.
When samples are added or removed.	Check the humidifier tubing to ensure there is no build up of condensation. If condensation is forming in the tubes, refer to the <u>Condensation</u> 43 section.
Every 4 months	Check the battery. See <u>Checking the battery</u> िउ6ी.
Annually	Calibrate and service the BT37M-02. See <u>Calibration and servicing</u> 37.

4.2 General cleaning



- 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 <u>Switching off</u> 30.
- 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.



- 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.
- 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 <u>Cleaning and disinfecting the chamber</u> ³⁵.
- Clean the external monitoring ports using a miniature bottle brush wetted with sterile water_or 70% isopropyl alcohol. See the <u>Side view</u> 12 section.
- 4. Allow the unit to dry fully before reconnecting the mains supply.

4.3 Cleaning and disinfecting the chamber

Marning

- Switch off the BT37M-02 and disconnect the mains supply before cleaning. See <u>Switching off</u> 301.
- 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.



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.

- 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



- 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.
- 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, <u>Connecting the gas supply</u> 19.

4.8 Testing the alarms

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

Warning	g! Alarms will be triggered
Back	Continue

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

Testing the alarm.	
ок	SILENCE

- 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 <u>Checking the</u> <u>liquid level</u> <u>indicator 36</u> 1.
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 <u>Installing the</u> <u>humidifier [25]</u>
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 <u>Network</u> <u>security</u> 4िहो.
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 <u>Switching off</u> उणे.

4.9.2 Control errors

Message	Fault	Possible cause	Action
Alarm. Left lid at xxx °C Alarm. Left base at xxx °C Alarm. Right lid at xxx °C	Left lid at incorrect temperature. Left base at incorrect temperature. Right lid at incorrect	 Room ambient temperature is too close to the setpoint. Setpoint has just been adjusted by a large value. Setpoint is outside 	 Check the room temperature. Ensure the equipment is not influenced by sources of hot or cold air such as air conditioning units.
Alarm. Right base at xxx °C Alarm. Humidifier at xxx °C	temperature. Right base at incorrect temperature. Humidifier chamber at incorrect temperature.	specification.	 Check the setpoints. See <u>Changing the</u> <u>control settings</u> 23. Check the setpoints against the specification. See <u>Control</u> 49.
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. 	 Check the gas pressure. Check the setpoints. See <u>Changing the</u> <u>control settings</u> ^[23]. Check the setpoints against the
Alarm. Purge flow at xxx °C	Gas flow during purge mode incorrect.	 Setpoint has just been adjusted by a large value. Setpoint is outside specification. 	against the specification. See <u>Control</u> 4ि9ो.

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 battery: no mains backup.	The internal battery is faulty.	The battery requires replacement.	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 <u>Control</u> 49 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 <u>Setting the access code</u> 23.

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 13.
- 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 <u>Cleaning and</u> <u>disinfecting the system</u> 35.

Additional information

5 Additional information

5.1 External alarm connection



- 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 <u>Control</u> 49 table for control limitations.
Operating humidity	20 % to 80 % relative humidity non-condensing decreasing linearly to 50 % relative humidity at 40 $^\circ$ C.
Altitude	up to 2000 m
Pollution degree	Pollution degree 2 (BS EN61010-1)
IP rating	IP31

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	\pm 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 \pm 10% or \pm 3 ml/minute
Flow control accuracy	The greater of \pm 5% or \pm 2 ml/minute measured after any transient effects due to set-point changes have subsided.
Accuracies apply at the calibration The system is factory calibrated flow of 30 mL/min and a purge at	for an operating temperature of 37°C, nominal bleed

5.3.3 Capacity

4 x NUNC 4 well dishes, 4 x NUNC 60 mm Petri dishes 10 x NUNC 30 mm Petri dishes
4 x MINITUB 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
	273

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

5.3.4.1 Internal battery

- 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	SO ₂ ,SO ₃ , H ₂ , CO, H ₂ SO ₄ mist
Excessive temperatures	

5.3.5 Humidifier bottle and filter

ltem	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

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. 30 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 External alarm connections

Output	Volt free
Connector type	PHOENIX 3 way horizontal PCB header. # 1181451
Maximum voltage	30 V DC
Maximum current	1 A
Normal operating mode	
Alarm mode & power disconnected	

5.3.8 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 <u>Side view</u> 12] section. Recommended sensor type: PT100 Class A to EN60751. Maximum diameter: 2.51 mm.

Contact your service provider for more details and available options.

5.3.9 Fuses



- To avoid risk of fire, fuses must always be replaced with the same type and rating.
 - $\,\circ\,$ 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	Туре
F1, F2	Mains inlet	T 3.15A L 250V 5 x 20 mm

Index

- A -

access code 15, 23 resetting 44 alarm acknowledging 16 connecting 48 connecting external 20 external 51 alarm indicators 16 alarms testing 39 annually 34

- B -

battery 50 check 34 checking 36 bleed flow 24 bottle 51 BT37M-02 specification 49 bubbles 36

- C -

calibrate 34 calibration 37 capacity 50 check gas joints 38 checking battery 36 checks 34 cleaning 35 general 34 condensation 43 connecting gas 19 connections alarm 51 control specification 49

- D -

daily checks 34 decontamination 45

dishes 50 disinfecting 35 disposal 45

- E -

electromagnetic compatibility 10 errors battery 43 control 42 miscellaneous 43 ethernet 19 expected temperature graph 39 external alarm connecting 20 external alarm 48

- F -

filter 51 front view 11 fuses 52

- G -

gas connecting 19 specification 51 gas check 38 gas flow 24 groove seals 27

- H -

host failure test 39 humidifier 51 installing 25 single tube 27

- | -

indicators 16 installation 18 installing humidiifer 25 intended use 6 IO failure test 39

Index

- L -

LAN 52 liquid level 36 local area network 19,52

- M -

mains supply connecting 20 maintenance 6 menus 15 messages battery errors 43 control errors 42 miscellaneous errors 43 normal 41 monitoring 52

- N -

network 48 non-pulsed bleed flow 24 notices 6 numeric entry 15

- 0 -

operating theory 10 operation 22

- P -

portable appliance testing 38 power 50 power supply 20 precautions 9 EMC 10 pulsed bleed flow 24 purge duration 24 purge flow 24

- R -

rear view 13 regular checks 34 reset 44 resetting access code access code 44 returning for service 45 run 22 running 10

- S -

safety testing 38 security 48 service returning 45 servicing 37 setpoints 42 side view 12 silence 16 specification 51 battery 50 bottle 51 BT37M-02 49 capacity 50 control 49 filter 51 fuses 52 humidifier 51 network 52 power 50 standby 10, 30 status indicators 16 switching off 30 symbols equipment 7 manual 7

- T -

testing 39 theory of operation 10 trademarks 6 troubleshooting 40

- U -

unpacking 18 user interface 13

- V -

view front 11 rear 13

Index

view side 12

- W -

warnings 8 warranty 6

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