User Manual

RI WITNESS™

Embryology Heated Plate

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CE 0120 Rx only

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CONTENTS

SECTION 1 - PREFACE 1

SECTION 2 - INTRODUCTION TO RI WITNESS 2

Indications for Use for RI Witness Embryology Heated Plate 2
Applicable Part Numbers 2
Related Documents 2
Compatibility 2
Installation 2

SECTION 3 - SAFETY WARNINGS 3

Guidance and Manufacturer's Declaration (Part 15 of FCC)
— Electromagnetic Emissions 4
Guidance and Manufacturer's Declaration (IEC 60601-1-2)
— Electromagnetic Emissions 4
— Electromagnetic Immunity 5
— Electromagnetic Immunity 6
Safety/Information Symbols 7
Safety and Reliability 8
Temperature Safety 8
RFID Reader Environment 8
Startup / Shutdown Procedure 8

SECTION 4 - PRODUCT OVERVIEW 9

Embryology Heated Plate 9
RI Witness Embryology Heated Plate Specification Table 10

SECTION 5 - RI WITNESS BASIC OPERATION 11

Startup Procedure 11
Shutdown Procedure 11
Connecting to the Software 11
User Interface 11
Achieving the Correct Sample Temperature 12
Changing the Temperature Setpoint Using the Device 13
Changing the Temperature Setpoint using a PC and RI Witness Work Area software 13

CONTENTS

Temperature Calibration 14
ITO Glass Window Calibration Using Built-In User Interface 14
Full 5-channel Calibration Using PC and RI Witness Work Area Software 15
Tube Reader Antenna Accessory 16

SECTION 6 - TROUBLESHOOTING 17

Alarms and System Status 18
Audible Alarms 18
Alarm Conditions Codes 19

SECTION 7- CARE AND MAINTENANCE 23

Cleaning 23

SECTION 8 - REPAIRS AND RETURNS 24

Reuse Statement 24
RI Repairs System 24
Product Disposal (European Union) 24
RI Returns System 24
Contact Details 24
Obligation to Inform 24
Feedback 24

1

SECTION 1 - PREFACE

Thank you for choosing RI Witness.

This manual provides all necessary information to use RI Witness Embryology Heated Plate and should be read in conjunction with any manuals provided with other RI Witness hardware or software components that you are using. The system should be operated by trained personnel only. All sections of this manual should be read and understood fully before any operation of the system. Please see the Intended Use for more information.

If the operator is unsure of any of the information contained in this manual they should contact Research Instruments or an appointed representative before attempting to use this equipment.

In no event does Research Instruments Ltd (RI) assume the liability for any technical or editorial errors of commission, or omission; nor is RI liable for direct, indirect, incidental, or consequential damages arising out of the use or inability to use this manual.

The information in this manual is current at the time of publication. Our commitment to product improvement requires that we reserve the right to change equipment, procedures and specifications at any time. The latest version of the User Manual can be downloaded from software.research-instruments.com. The RI Witness manual belongs with the RI Witness system and should be passed on with the system if relocated to another clinic.

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This indicates cautionary text which should be followed to avoid injury to users or damage to samples.

The system should be operated by qualified and trained personnel only.

SECTION 2 - INTRODUCTION TO RI WITNESS

Indications for Use for RI Witness Embryology Heated Plate

To maintain the temperature of human reproductive tissue such as oocytes and embryos through an assited reproduction (AR) cycle.

CE 0120 Rx only

Applicable indications for use are subject to the regulations of the country into which the device is sold. Availability of RI Witness for clinical use is dependent on the regulatory approval status of RI Witness within the country the device is intended to be sold into.

Applicable Part Numbers

Part Number	Description
6-70-807*	RI Witness Embryology Heated Plate
6-70-809	RI Witness Tube Reader

** 6-70-807 can be supplied in several configurations depending on the required mounting type eg flush fitted or sit on top.*

Related Documents

6-7-121UM RI Witness Software Manual

Compatibility

RI Witness is used in conjunction with the following:

- Essential medical devices, eg dishes and tubes, maybe AR or non-AR specific.
- Non-essential medical devices, eg safety cabinets, incubators, micromanipulators, lasers.
- Non medical devices (general laboratory equipment), eg work benches, microscopes, PCs.

This device is not intended to be exposed to known sources of electromagnetic Interference (EMI) with medical devices such as diathermy, and electromagnetic security systems e.g., metal detectors and electronic article surveillance system.

Installation

Installations of the RI Witness Embryology Heated plate should be carried out by a RI technician or other RI authorised personnel. Incorrect installation could result in overall poor performance.

SECTION 3 - SAFETY WARNINGS

This symbol indicates cautionary text which should be followed to avoid injury to users or damage to samples.

The system should be operated by qualified and trained personnel only.

DO NOT disassemble or modify any part of the RI Witness Embryology Heated plate, or substitute any component for any other. Doing so may result in damage to samples. This voids the warranty and/or service contract.

ONLY use the power cable and power supply adaptor supplied with the system.

The cable to the power supply is the 'disconnect device' for this equipment. To remove all electrical power from this product, disconnect the power cable from the electrical outlet. Equipment should be positioned so as to allow easy access to the power cable. The appliance coupler or mains plug is used as the disconnect and must remain readily operable.

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

WARNING Not to be used in a patient environment.

Guidance and Manufacturer's Declaration (Part 15 of FCC) — Electromagnetic Emissions

Note: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the Federal Communications Commision (FCC) Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at their own expense.

Note: This device complies with Industry Canada's licence-exempt RSSs. Operation is subject to the following two conditions:

1. This device may not cause interference.
2. This device must accept any interference, including interference that may cause undesired operation of the device.

Guidance and Manufacturer's Declaration (IEC 60601-1-2) — Electromagnetic Emissions

RI Witness is intended for use in the electromagnetic environment specified below. The customer or the user of RI Witness should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment guidance
RF emissions CISPR 11	Group 2	RI Witness must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	RI Witness is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

USA Only

Compliance with the emissions requirements of CISPR 22 Class A requires the following warning: "This is a class A product. In a domestic environment this product may cause radio interference in which case the user may be required to take adequate measures."

3 Guidance and Manufacturer's Declaration — Electromagnetic Immunity

IMMUNITY Test	IEC 60601 Test level	Compliance level	Electro magnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/ output Lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV differential Mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5s	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5s	Mains power quality should be that of a typical commercial or hospital environment. If the user of RI Witness requires continued operation during power mains interruptions, it is recommended that RI Witness be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: *UT* is the a.c. mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration — Electromagnetic Immunity

IMMUNITY Test	IEC 60601 Test level	Compliance level	Electro magnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of RI Witness, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = [3.5/V_1] \sqrt{p}$ $d = [3.5/V_1] \sqrt{p}$ *80MHz to 800MHz* $d = [3.5/V_1 \sqrt{p}$ *800MHz to 2.5GHz* where *p* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Note 3: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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

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

3

Safety/Information Symbols

Symbol	Meaning
	Indicates instruction for disposal of goods.
CE 0120	In accordance with Annex II of the European Medical Device Directive 93/42/EEC, as amended by Directive 2007/47/EC under the supervision of notified body No.0120, SGS, UK Ltd.
CE	In accordance with the European Directive for R&TTE, Directive 1999/5/EC
	Indicates the medical device manufacturer.
	Indicates the date of manufacture.
	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Consult instructions for use.
SN	The four digit number is a unique identifier assigned to the product.
Rx Only	Caution: US Federal law restricts this device for sale to or on the order of a licensed healthcare practitioner.

Safety and Reliability

Please read this manual carefully and follow the instructions to ensure that the system will work safely and reliably.

Temperature Safety

Safety is the responsibility of the laboratory. Risk assessment and working practices should comply with local regulatory policies.

A warning triangle will be displayed on the work area touch screen and the status LED on the device user interface will display a yellow status alarm if the currently selected temperature cannot be maintained.

Gently place your hand on the heated surface to verify that the temperature is appropriate for use.

As with all heating systems, it is advisable to perform a periodic check of temperatures using a calibrated thermocouple thermometer.

RFID Reader Environment

An RI Witness system uses Radio Frequency Identification (RFID) readers to monitor a work area. Readers detect RFID tagged containers that are placed in the work area.

The performance of RFID tag detection may be compromised by repositioning the reader and by the proximity of metal objects or electrical equipment that were not present during installation and tuning. If the device is relocated ensure that the autotuning procedure documented in the RI Witness Software Manual (6-7-121UM) is followed to ensure optimum level of performance.

For cleaning the reader may be lifted and returned to the same position. See “Cleaning” on page 23 for more cleaning details.

Do not place metal objects near reader.

Do not place electrical equipment near reader.

Do not disconnect reader.

Do follow the startup/shutdown procedures.

Startup / Shutdown Procedure

RI Witness hardware may be damaged by incorrect startup and shutdown procedures.

“Section 5 - RI Witness Basic Operation” on page 11 describes the recommended startup and shutdown procedure for the RI Witness Embryology Heated Plate.

SECTION 4 - PRODUCT OVERVIEW

RI Witness is a system which operates within an assisted reproduction (AR) clinic setting and provides a method of identifying human samples throughout an AR cycle (from egg and sperm collection to embryo transfer). The system is intended to minimise the risks associated with traditional/manual double-checking and provides the essential controls necessary to ensure eggs, sperm and embryos are correctly matched and treated during the AR process.

The RI Witness system comprises hardware, firmware and software components, which can be configured depending on the treatment activities, number of AR cycles conducted, size and layout of the AR clinic.

RFID (radio frequency identification) technology provides the means of identifying the containers (dishes, tubes) in which eggs, sperm and embryos are transferred and stored. The containers are labelled by a clinician with a special RFID tag which has been assigned a unique identifier. The unique identifier is linked to a patient/couple (specific parentage).

As samples are processed as part of an AR cycle, RFID readers (both heated and non-heated) read the tags on the container and their identity and status is confirmed on-screen. If containers containing samples of incompatible origin come into contact at any stage of this process, the system activates an alarm and prompts the clinician to respond.

This manual is specifically for the Embryology Heated Plate (and associated Tube Reader accessory) in both its flush fitted and sit on top configuration.

Other devices in the RI Witness range have their own manuals, as does the software.

Embryology Heated Plate

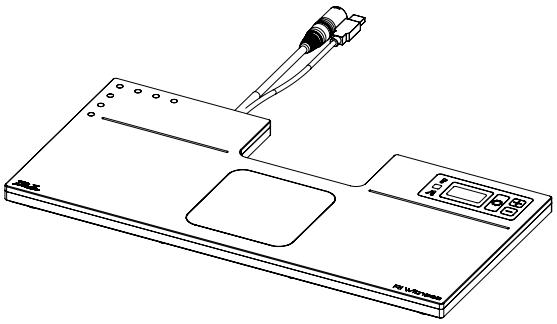

Figure 4-1 Sit on Top Heated Reader

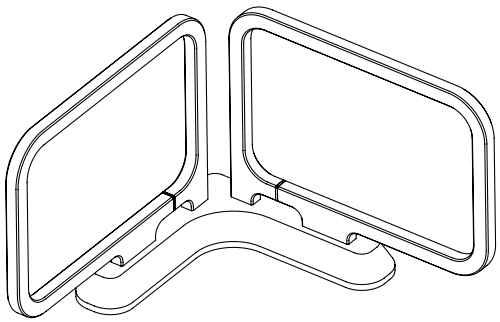

Figure 4-2 Tube Reader Accessory

RI Witness Embryology Heated Plate Specification Table

Part	Description
Temperature Sensor	5 x PT1000 (1 per Channel)
Temperature Control	Electrical heating is controlled by a built-in 5-channel PWM temperature controller: • Channel 1-4: Work surface surrounding the ITO glass window is divided into quarters • Channel 5: ITO glass window Temperature controller accuracy: better than ±0.2°C when calibrated against a known reference. Displayed resolution: 0.1°C Setpoint temperature range: 30-45°C
Displays	3 x 7-segment LED display shows the temperature reading from the ITO glass window temperature sensor.
Connectivity	USB plug type A
Power Supply	Input: 85-264VAC (100-240VAC Nominal), 47-63Hz, <3A , Class I Output: 48VDC, Max 4.6A (220W)
Operating Conditions	Temperature: 15˚C (59˚F) to 40˚C (104˚F). Ambient temperature must be > 5°C below setpoint. Humidity: 15% to 85% RH (Non Condensing)
RFID Antennas	Embryology Heated Plate: 3 Antennas Tube Reader Accessory: 2 Antennas (5 Total)
RFID	50Ω Load at 13.56Mhz, 1W Max
Dimensions	Width: 460mm Depth: 220mm 6-70-807 Thickness: 20mm 6-70-807-A/-B Thickness: 34mm
Mass	6-70-807: 3.0kg (plus Power Supply 1.0kg) 6-70-807-A/-B: 5.0kg (plus Power Supply 1.0kg)

SECTION 5 - RI WITNESS BASIC OPERATION

Startup Procedure

To turn the device on, plug the power cable from the device into the power supply in-line connector ensuring it is fully inserted. Then plug the power supply into the wall power outlet.

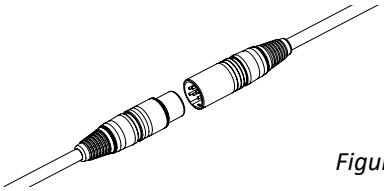

Figure 5-1 Power Supply In-Line Connector

Once the device is plugged in, it will display the current measured temperature on the display. The status LED will remain off until the temperature has stabilised at the specified setpoint. The time to reach this will vary according to the ambient temperature, but will generally be within 15-30 minutes.

Once the temperature has stabilised, the green status light will illuminate (see “Alarms and System Status” on page 18 for more information).

RI suggests that you keep the RI Witness computers and work areas (including the Embryology Heated Plate) switched on. This means that the heating and monitoring is constant.

Shutdown Procedure

To shutdown the device remove all electrical power by disconnecting the cable from the electrical outlet.

Connecting to the Software

Plug the device into the tablet or PC (or attached USB hub) using the USB A cable that protrudes from the device. Once the Windows operating system has recognised the devices within the Embryology Heated Plate, open the RI Witness Work Area software. To verify that the RI Witness Work Area software can communicate successfully, navigate to the Work Area Status window (click the yellow triangle or press the **(i)** icon). This will bring up the Work Area Status window where the ‘Embryology Reader’ and ‘Temperature Control’ should be listed in the Connected Devices section with a green tick next to them. For more detailed set up information, refer to the RI Witness software manual (6-70-121UM).

User Interface

The Embryology Heated Plate contains a built in user interface which allows access to basic temperature setpoint and calibration adjustment. A complete set of calibration options can only be accessed through the RI Witness Work Area software.

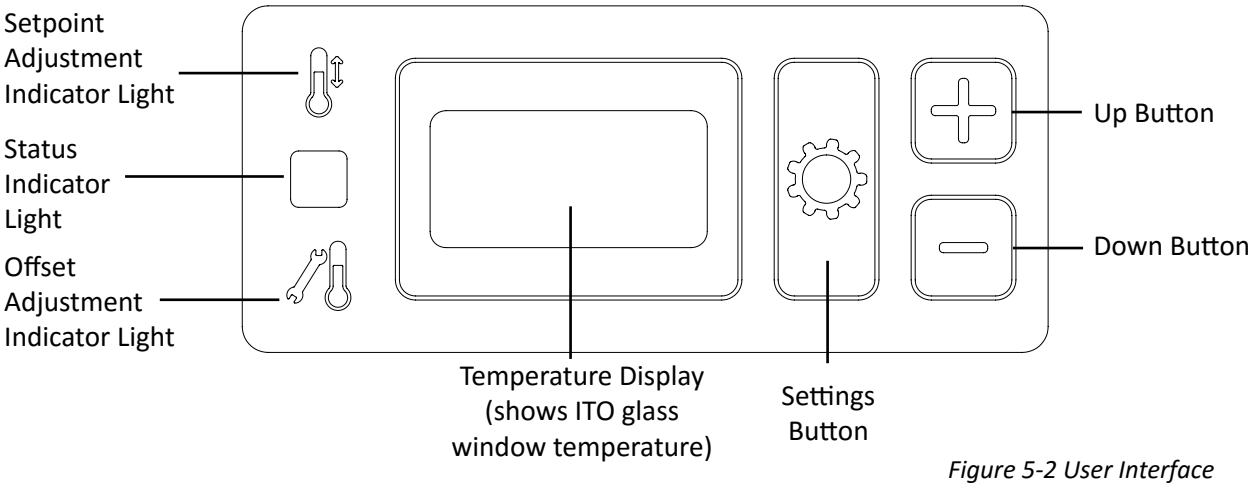

Figure 5-2 User Interface

Achieving the Correct Sample Temperature

The heated plate is divided into 5 areas for calibration purposes. In order to achieve the correct sample temperature place the sample on top of the heated areas shown below. Do not place samples on top of the User Interface.

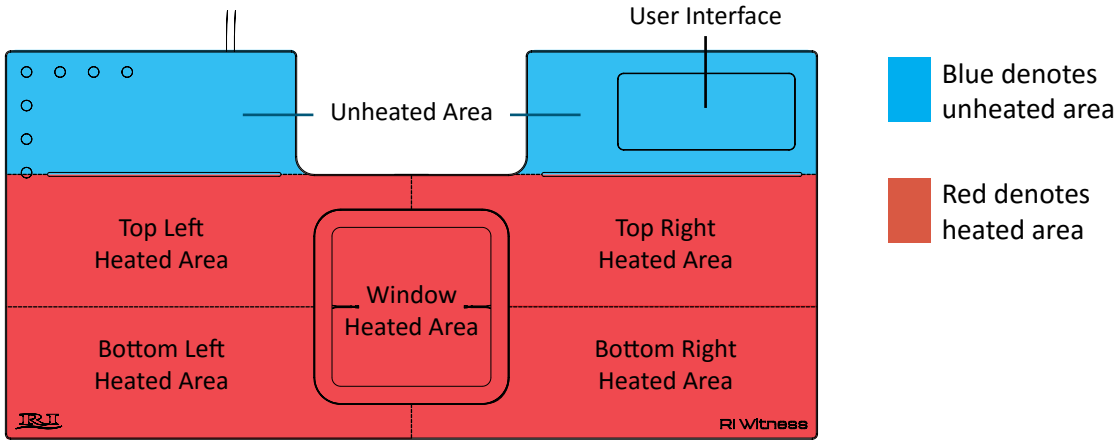

Figure 5-3 Embryology Heated Plate Heated Areas

When working with multiple samples on the heated plate, it is recommended that only one sample is placed on the window heated area at a time.

Temperatures within the Petri dish are adjusted by changing the setpoint temperature as described on the next page. The temperature inside a Petri dish will normally be slightly lower than the heated plate, depending on ambient conditions, type of Petri dish and the sample preparation. After the system has been installed in its operating location, the temperature of the heated plate should be adjusted to allow for this difference.

We recommend using a thermometer calibrated to 37°C fitted with a small thermocouple probe, such as the RI IVF Thermometer to measure the temperature inside the Petri dish.

Prepare a Petri dish that mimics your normal Petri dish preparation and place it on the heated surface in its normal position. Place the probe of the thermometer in the centre of the dish against the bottom of the dish and allow the temperature reading to stabilise. Adjust the setpoint temperature until the desired temperature in the dish is reached, allowing 20 minutes (or as long as required) in between each setpoint change to allow the Petri dish temperatures to stabilise.

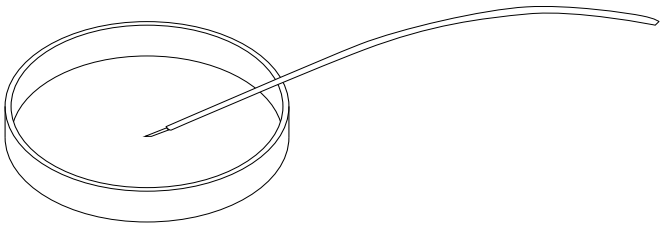

Figure 5-4 Thermometer Probe Positioned in a Petri Dish

Functions of the built-in user interface are shown below.

Changing the Temperature Setpoint Using the Device

The temperature setpoint is applied to all heating channels and is set using the following procedure, or from within the RI Witness Work Area software. Refer to the RI Witness Software Manual (6-70-121UM) for further information.

1. Press and hold the Settings button for 3 seconds.
2. The Setpoint Adjustment Indicator light will flash. The Temperature Display will now show the current setpoint (not the current temperature).
3. Adjust the value shown on the Temperature Display using the Up and Down buttons until the desired setpoint is shown.
4. Save the temperature by pressing and holding the Settings button for 3 seconds. A beep will be heard.
5. The Setpoint Adjustment Indicator light will go out and the Temperature Display will now show the current temperature. Once the temperature has stabilised at the setpoint, the green Status Indicator Light will illuminate.

Note: To exit the setpoint adjustment mode without saving changes, do not press any buttons for a short time and the device will return to normal operation (the Setpoint Adjustment Indicator light will go out).

Changing the Temperature Setpoint using a PC and RI Witness Work Area software

To change the setpoint using the RI Witness WorkArea software, click on the temperature displayed at the bottom right hand side of the screen. This will bring up a pop up box with up and down arrows which can be used to adjust the setpoint temperature. The temperature controller will then begin controlling using the new settings .

After adjusting the setpoint temperature, check sample temperature inside the Petri dish.

Temperature Calibration

Note: It is only possible to calibrate the temperature of the ITO glass window using the built-in user interface on the Embryology Heated Plate. To perform a full calibration of all 5 heated areas, this must be done from within the RI Witness Work Area software.

Perform calibration only if the displayed temperature is different to the actual surface temperature of any of the 5 heated areas. The process of calibration allows the user to manually adjust the temperature so that the displayed temperatures match the temperature of the surface.

Before temperature calibration can be performed the device must be in the same conditions that it will be in during normal operation. The temperature calibration is affected by ambient conditions.

Place the probe of a calibrated thermometer in good thermal contact with the surface.

Note: Simply touching the probe on the surface is not adequate. Use a purpose-made surface probe and use thermal transfer paste. Products sold for computer heatsinks are suitable, and RI can also supply suitable materials. Wait at least 30 minutes to allow the temperature to stabilise before calibrating.

Heated areas are divided as shown below, with the '**X**' denoting recommended thermocouple positions for calibration:

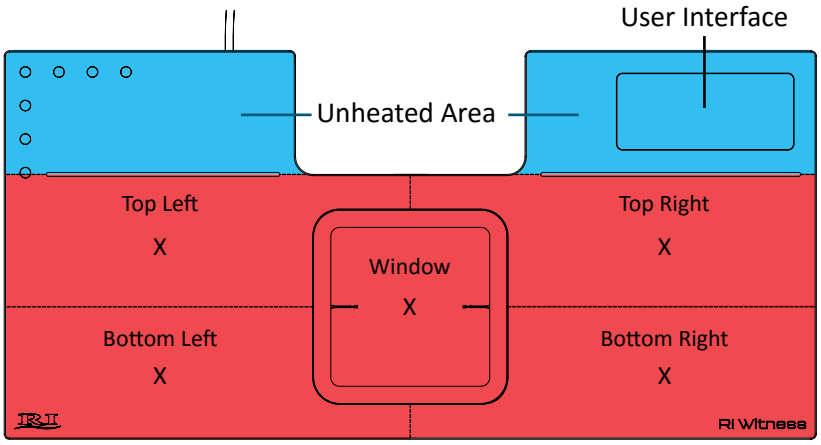

Figure 5-5 Recommended Thermocouple Positions for Temperature Calibration

ITO Glass Window Calibration Using Built-In User Interface

During calibration using the built-in user interface close the RI Witness Work Area software to prevent interference with the thermometer reading.

1. Position the thermocouple probe on the Window in the location shown above.
2. Press and hold the Settings and + buttons simultaneously for 3 seconds. The Offset Adjustment Adjustment Indicator light will flash. The Temperature Display will now show the current temperature (which may be a moving value).
3. Adjust the value shown on the Temperature Display using the Up + and Down − buttons until the temperature matches that shown on the external thermometer.
4. Save the calibration by pressing and holding the Settings button for 3 seconds. A beep will be heard.
5. The Offset Adjustment Adjustment Indicator light will go out and the Temperature Display will now show the current temperature with applied calibration. Leave the probe in position

and once the temperature has stabilised at the setpoint, check that the calibration is accurate. Repeat the calibration process if necessary. The green Status Indicator Light will illuminate once temperatures have stabilised.

6. After adjusting calibration check sample temperatures and adjust the setpoint temperature if required.

Note: To exit the window calibration mode without saving changes, do not press any buttons for a short time and the device will return to normal operation. The Offset Adjustment Indicator light will go out.

Full 5-channel Calibration Using PC and RI Witness Work Area Software

Full calibration of the 5 heated areas requires that each of the areas is calibrated in turn.

1. Open the RI Witness Work Area software and navigate to the WorkArea Status window.
2. Click on the yellow triangle or the **(i)** icon then click **Workarea Settings**, then **Connected Devices**, then **Temperature Controller,** then **Check Calibration**. The screen will now show the current temperature and calibration offsets of the five different heated areas.
   Note: RF will be switched off automiatically when on the Temperature Control screen.
3. Each heated area is independent so the order of calibration is not important. Position the thermocouple probe in one of the positions shown above.
4. Allow the reading to stabilise, then compare the temperature shown in the Work Area software with the thermometer reading.
5. A difference within ± 0.2°C is acceptable. If the readings are outside this increase the offset to increase the reading displayed by the software, or decrease the offset to decrease the reading displayed by the software.

Allow a small delay for the offset change to register. When changing the offset, the temperature controller will then begin controlling using the new settings, so the surface temperature of that heated area may take a short time to re-stabilise.

6. Repeat this process for all 5 heated areas.
7. Once calibration is complete it is advisable to verify the temperature of each heated area to check that temperature calibration has been carried out effectively. After adjusting calibration, check sample temperatures and adjust the setpoint temperature if required.

Tube Reader Antenna Accessory

The Tube Reader Antenna is an accessory for the Embryology Heated Plate that allows tags to be read in a vertical orientation. It is specifically designed to read tags placed on tubes in the RI Tube Holder. The Tube Reader Antenna is a passive device that only becomes powered when attached to the Embryology Heated Plate. The correct mounting orientation position is shown below in Figure 5-6.

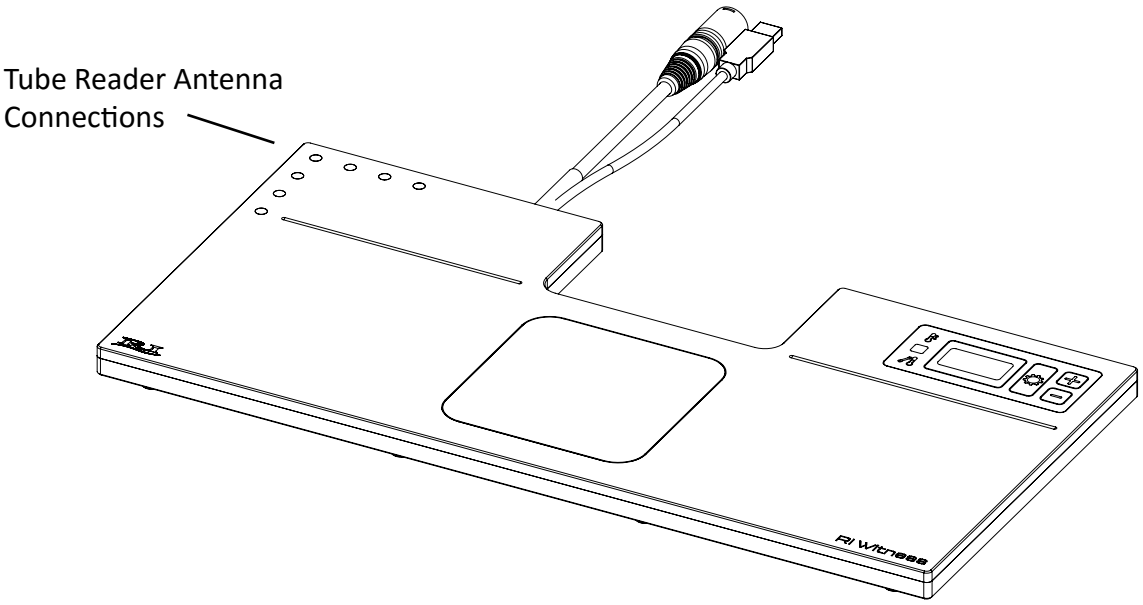

Figure 5-6 Tube Reader Connections on the Embryology Heated Plate

Refer to “Section 7- Care and Maintenance” on page 23 for cleaning precautions relating to the Tube Reader Antenna.

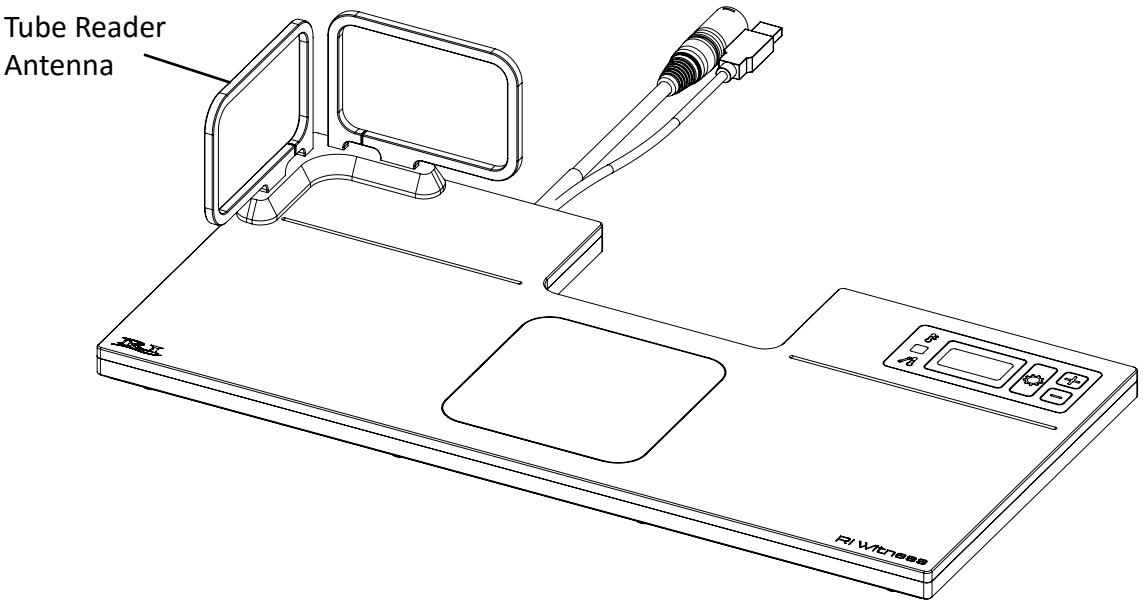

Figure 5-7 Tube Reader Correctly Mounted on the Embryology Heated Plate

SECTION 6 - TROUBLESHOOTING

Problem	Possible Cause	Solution
Tags Reading Intermittently or Only in Certain Areas	Loose connection	Check security of USB and power cable connections.
	Antenna not tuned properly	Navigate to the **Workarea Settings** screen, then click **Connected Devices** , then **Embryology Reader**, then **RFID Tuning**, then **Auto tune**.
	RF Noise/interference	Other devices in the lab can cause RF noise/ interference, contact an RI service representative.
	Faulty Device	Contact an RI Service representative.
Tags Not Reading	Broken tag	Check the tag on another device.
	Poor/no connection or no power.	Check security of USB and power cable connections. Verify that the light on the power supply is illuminated.
	Tag not encrypted	Navigate to the **Workarea Settings** screen, then click **Connected Devices** , then **Embryology Reader,** then click the down arrow next to Tags. Non encrypted tags are shown as **Not Valid**.
	WorkArea configuration	Navigate to the **Workarea Settings** screen, then click **Connected Devices** , then **Embryology Reader**, then **RFID Tuning**, to check that the number of antennas (channels) is 5 for the Embryology Reader with the Tube Reader Antenna Accessory.
	Antenna not tuned	Navigate to the **Workarea Settings** screen, then click **Connected Devices** , then **Embryology Reader**, then **RFID Tuning**, then **Auto tune**.
	Faulty Device	Contact RI or an RI Service Representative.

Alarms and System Status

The status of the temperature control system is shown by the Status Indicator Light positioned on the user interface of the device.

Status Indicator Light Colour	Meaning / Priority
On	**Please wait** Initial power up/setpoint/mode/calibration changed. The light will be off until temperature of all heating systems is within ±1°C of setpoint.
Green	**Ready for use** Temperature of all heating systems within ±1°C of setpoint.
Yellow constantly on	**Low Priority Alarm** Built-in user interface and RI Witness WorkArea software will show current window temperature. Press the − or + buttons to cycle through the Alarm Condition Codes. Refer to tables on the following pages for details of each code. Alarm Condition Codes can be cleared by holding the − and + buttons simultaneously for 3 seconds. A beep will be heard to confirm codes have been cleared. If the alarm sounds, finish the current procedure and promptly investigate the cause of the alarm.
Yellow flashing	**Medium Priority Alarm** Built-in user interface and RI Witness WorkArea software will show current window temperature. Press the − or + buttons to cycle through the Alarm Condition Codes. Refer to the tables on the following pages for details of each code. Alarm Condition Codes can be cleared by holding the − and + buttons simultaneously for 3 seconds. A beep will be heard to confirm codes have been cleared.

When multiple alarms are active, the icon on the RI Witness WorkArea Software on the device and Status Indicator Light for the highest priority alarm will be shown.

Note: For a full list of possible faults relating to each alarm condition and applicability of each alarm condition, refer to the tables on the following pages.

Audible Alarms

Audible alarms are sounded to indicate Low and Medium Priority Alarms, as described above. When an alarm sounds, the alarm can be muted by pressing the − or + buttons, which also cycles through the Alarm Condition Codes. The alarm audio is automatically un-muted each time a new alarm becomes active.

When multiple alarms are active, the audio for the highest priority alarm will be sounded. The alarm volume is not adjustable. Low and medium priority alarms are sounded at the same level.

Alarm Conditions Codes

Alarm Code	Fault Condition	Priority	Fault Description	Alarm Actions	Solution
E01	ITO Window Heating Failure	Low	Heating system is not able to heat the specified heating channel. Alarm will be activated 2 minutes after power on if there is less than 1.5˚C temperature rise between 1 and 2 minutes after power on. If the temperature at 1 minute is already within ± 2.5˚C from the setpoint the test is omitted.	Heating controller power is set to 0% for that heating channel until device is restarted.	Restart the device by removing mains power then re-connecting.
E02	Bottom Right Heating Channel Failure				
E03	Bottom Left Heating Channel Failure				
E04	Top Right Heating Channel Failure				
E05	Top Left Heating Channel Failure Failure Channel				
E06	ITO Window Sensor Failure (either main sensor or overheat protection sensor)	Low/ Medium Low priority alarm is activated if the fault occurs when system is switched on. After this time a medium priority alarm is activated	No signal/out of range signal from temperature sensor. Alarm activates at any time if the sensor circuit fails to read a valid temperature.	Heating power is set to 0% for that heating channel until a valid temperature is read. If the ITO Window main sensor fails the temperature display will shown --.-˚C **Note:** If the ITO overheat protection sensor is faulty, the display will still show the current temperature.	Possible sensor, cable or controller fault.
E07	Bottom Right Sensor Failure				
E08	Bottom Left Sensor Failure				
E09	Top Right Sensor Failure				
E10	Top Left Sensor Failure				

Alarm Code	Fault Condition	Priority	Fault Description	Alarm Actions	Solution
E11	ITO Window Heating Channel Over Temperature	Low / Medium If fault occurs when the system is switched on	Heating channel has exceeded the maximum allowable setpoint temperature. Alarm activated at any time if the temperature sensor exceeds 50˚C.	Temperature controller power is set to 0% until temperature falls to below 50˚C. **Note:** If the temperature continues to rise past this point, over temperature protection built in to the device will shut down the heating. (See E27)	Possible heater or controller fault.
E12	Bottom Right Heating Channel Over Temperature				
E13	Bottom Left Heating Channel Over Temperature				
E14	Top Right Heating Channel Over Temperature				
E15	Top Left Heating Channel Over Temperature				
E16	ITO Window Heating Channel Temperature outside ± 1°C	Medium	Heating channel has deviated by more than 1˚C from the setpoint temperature. Alarm enabled 5 minutes after the temperature reaches ±2.5˚C from the setpoint temperature.	The temperature controller continues to operate to bring back within the allowable limits.	This may be caused by placing either hot or cold objects on the device, in particular the ITO Window. In this case either remove the object or wait a short time for the setpoint temperature to be reached. Sudden air movements or temperature change can also cause minor temperature fluctuations. In this case wait a short while for the temperature controller to respond.
E17	Bottom Right Heating Channel Temperature outside ± 1°C				
E18	Bottom Left Heating Channel Temperature outside ± 1°C				
E19	Top Right Heating Channel Temperature outside ± 1°C				
E20	Top Left Heating Channel Temperature outside ± 1°C				

Alarm Code	Fault Condition	Priority	Fault Description	Alarm Actions	Solution
E21	ITO Window Heating Channel Temperature outside ± 2.5°C	Medium	Heating channel has deviated by more than 2.5˚C from the setpoint temperature. Alarm enabled 5 minutes after the temperature reaches ±2.5˚C from the setpoint temperature.	The temperature controller continues to operate to bring back within the allowable limits.	This may be caused by placing either hot or cold objects on the device, in particular the ITO Window. In this case either remove the object or wait a short time for the setpoint temperature to be reached. Sudden air movements or temperature change can also cause minor temperature fluctuations. In this case wait a short while for the temperature controller to respond.
E22	Bottom Right Heating Channel Temperature outside ± 2.5°C				
E23	Bottom Left Heating Channel Temperature outside ± 2.5°C				
E24	Top Right Heating Channel Temperature outside ± 2.5°C				
E25	Top Left Heating Channel Temperature outside ± 2.5°C				
E26	ITO Window Heating Channel Low Heating Rate	Medium	Heating controller did not achieve a temperature within 2.5˚C of the setpoint in 15 minutes from power on.	Temperature controller continues to operate.	If the device is operated in an environment where the ambient temperature is colder than the specified operating conditions or if there is a large amount of cold airflow over the device, then this alarm may triggered routinely. If neither of these conditions are present, restart the device. If the fault reoccurs contact an RI Service personnel.
E27	Bottom Right Heating Channel Low Heating Rate				
E28	Bottom Left Heating Channel Low Heating Rate				
E29	Top Right Heating Channel Low Heating Rate				
E30	Top Left Heating Channel Low Heating Rate				

Alarm Code	Fault Condition	Priority	Fault Description	Alarm Actions	Solution
E31	Memory Fault	Low	Memory/controller fault. During normal use controller has failed to save data. When power is switched off and then on all values will be returned to factory defaults.	System continues to operate until power is removed. When power is returned the screen will show the uncalibrated temperature.	Recalibrate device. If the problem persists after re-calibration then there may be a fault with the controller. If the problem is resolved by recalibrating then the memory may have been corrupted during saving of values, eg if the device loses power whilst saving values.
E32	Main Over Temperature Protection	Medium	Main over temperature protection is triggered when the temperature controller is not able to limit heat supplied by the device. Each heating channel is fitted with a standalone monitoring system that shuts down the device in the event of a malfunction. The protection operates at approximately 65°C	Yellow flashing Status Indicator Light illuminates. All heating is switched off.	Contact RI Service or distributor.

SECTION 7- CARE AND MAINTENANCE

Cleaning

RI Witness Embryology Heated Plate and Tube Reader Antenna may be cleaned with a soft cloth and mild detergent. The device may be lifted and returned to its original location. Do not disconnect the cables attached to the device.

If the Tube Reader Antenna is removed for cleaning be mindful to allow the contact surfaces on both the Heated Plate and the Tube Reader Antenna to fully dry before reattaching to ensure cleaning products are not trapped in the interface.


Do not use solvents for cleaning.


Do not disconnect readers.


Do not change the position of readers.

SECTION 8 - REPAIRS AND RETURNS

Reuse Statement

Assuming RI Witness is regularly maintained and routinely serviced, it should perform as required for a minimum of 7 years continual use, after which time we recommend you consider its replacement. Should you notice impaired performance and/or any issues where safety is compromised, or have any other concerns during the use of RI Witness, seek the advice of RI or their authorised representative promptly.

RI Repairs System

In the event that you have a problem with a RI instrument, please follow the procedure below to ensure prompt attention.

1. Read the 'Troubleshooting' section.
2. If you require any further help contact your distributor or RI directly. RI will try to resolve the problem as quickly as possible.

Product Disposal (European Union)

If the product is no longer serviceable it must be sent back to RI to be destroyed in an environmentally safe way. Do not dispose of RI Witness products with 'normal' waste.

RI Returns System

1. Contact RI to obtain a Returned Materials Authorisation (RMA) number.
   Note: Goods will not bereplaced or refunded without prior agreement and clearly stating the RMA number.
2. Pack the item carefully in its original packaging. RI will not accept responsibility for damage due to incorrect packaging. Replacement items or additional repairs will be invoiced.
3. Clearly label the package with the RMA number, mark the package "Urgent - Returned Items For Repair", and ship to the address on the next page. Goods should be insured for their full value during shipping.

Contact Details

Research Instruments Ltd, Bickland Industrial Park,
Falmouth, Cornwall, TR11 4TA, UK
Tel: +44 (0) 1326 372 753 Fax: +44 (0) 1326 378 783
E-mail: service@research-instruments.com
Website: www.research-instruments.com

Obligation to Inform

In compliance with the European Medical Device Directive 93/42/EEC as amended, it is your duty to inform RI if you believe this device has, or may have, caused or contributed to the death of a patient or user or to a serious deterioration in their state of health.

Feedback

Thank you for purchasing a RI product. To help RI develop the best tools for ART, we rely on customer feedback. If you have any suggestions for how we can improve our products or the information we provide with them, please send them to feedback@research-instruments.com. Your feedback will help us develop the product and supporting materials to meet your future needs.

Thank you.