




User Manual



Embryology Heated Plate

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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 assisted reproduction (AR) cycle.



Contraindications:

This device is not intended to be exposed to known sources of electromagnetic interference (EMI) with medical devices such as diathermy, CT, MRI, RFID (except other RI Witness RFID components) and electromagnetic security systems, eg metal detectors and electronic article surveillance systems.

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 WorkArea Software Manual
6-7-122UM	RI Witness Manager 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 has RFID reader capability. If it is the intention that it be employed in a clinical lab, we recommend its use alongside other medical devices and that the performance of these medical devices be monitored for potential effects of EMI disturbances, and reported when appropriate.

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.



WARNING Refer to Guidance and Manufacturer's Declaration Tables in this section of the User Manual for guidance on the environment suitable for this device.



WARNING The temperature of the plate should not be more than 1.5°C from the displayed temperature at any time. A temperature of more than 1.5°C will cause the temperature inside the dish to change more rapidly and samples are at risk of overheating. In this instance samples should be removed from the plate immediately.

We recommend the plate temperature be monitored periodically using a calibrated thermocouple thermometer.



WARNING Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.



WARNING There are no replaceable parts supplied with this device. Should any parts need to be replaced, contact RI or your distributor.













WARNING Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.



WARNING Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Embryology Heated Plate, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Safety/Information Symbols

Symbol	Meaning
	Do not dispose of product with normal waste.
	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.
	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.
	The five digit number is a unique identifier assigned to the product.
	Caution: US Federal law restricts this device for sale to or on the order of a licensed healthcare practitioner.
	Indicates the reference number.



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 proximity of metal objects or electrical equipment



Do not place metal objects near reader.



Do not place electrical equipment near reader.

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.

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 Commission (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. 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.
RF emissions CISPR 11	Class B	
Harmonic emissions EN 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions EN 61000-3-3	Complies	



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.”

Guidance and Manufacturer’s Declaration — Electromagnetic Immunity

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IMMUNITY Test	IEC 60601 Test level	Compliance level	Electromagnetic 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	30A/M	30A/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	Electromagnetic environment - guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p>	<p>3 Vrms</p> <p>3 V/m</p>	<p>Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Embryology Heated Plate, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.</p>



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.

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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

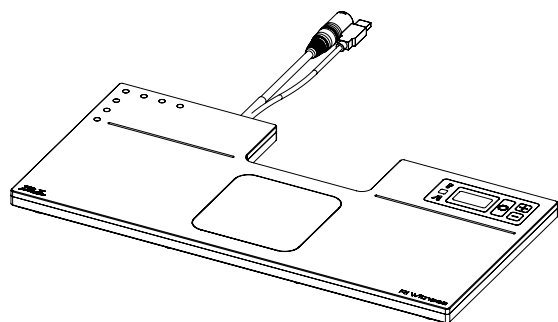


Figure 4-1 Sit on Top Heated Reader

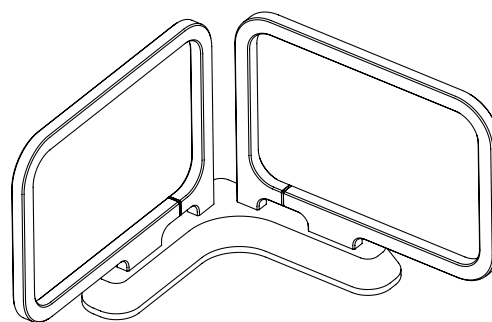


Figure 4-2 Tube Reader Accessory

RI Witness Embryology Heated Plate Specification Table

Part	Description
Temperature Sensor	5 x PT1000 (1 per Channel)
Temperature Control	<p>Electrical heating is controlled by a built-in 5-channel PWM temperature controller:</p> <ul style="list-style-type: none"> Channel 1-4: Work surface surrounding the ITO glass window is divided into quarters Channel 5: ITO glass window <p>Temperature controller accuracy: better than $\pm 0.2^{\circ}\text{C}$ when calibrated against a known reference.</p> <p>Displayed resolution: 0.1°C</p> <p>Setpoint temperature range: $30\text{-}45^{\circ}\text{C}$</p>
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	<p>Input: 85-264VAC (100-240VAC Nominal), 47-63Hz, <3A , Class I</p> <p>Output: 48VDC, Max 4.6A (220W)</p>
Operating Conditions	<p>Temperature: 15°C (59°F) to 40°C (104°F). Ambient temperature must be $> 5^{\circ}\text{C}$ below setpoint.</p> <p>Humidity: 15% to 85% RH (Non Condensing)</p>
RFID Specification	<p>Frequency: 13.56Mhz</p> <p>Power: 1W</p>
Dimensions	<p>Width: 460mm</p> <p>Depth: 220mm</p> <p>6-70-807 Thickness: 20mm</p> <p>6-70-807-A/-B Thickness: 34mm</p>
Mass	<p>6-70-807: 3.0kg (plus Power Supply 1.0kg)</p> <p>6-70-807-A/-B: 5.0kg (plus Power Supply 1.0kg)</p>

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.

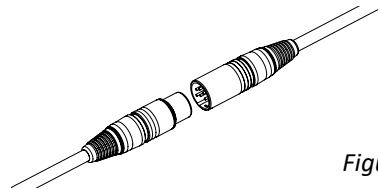


Figure 5-1 Power Supply In-Line Connector

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.



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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 WorkArea 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 WorkArea software.

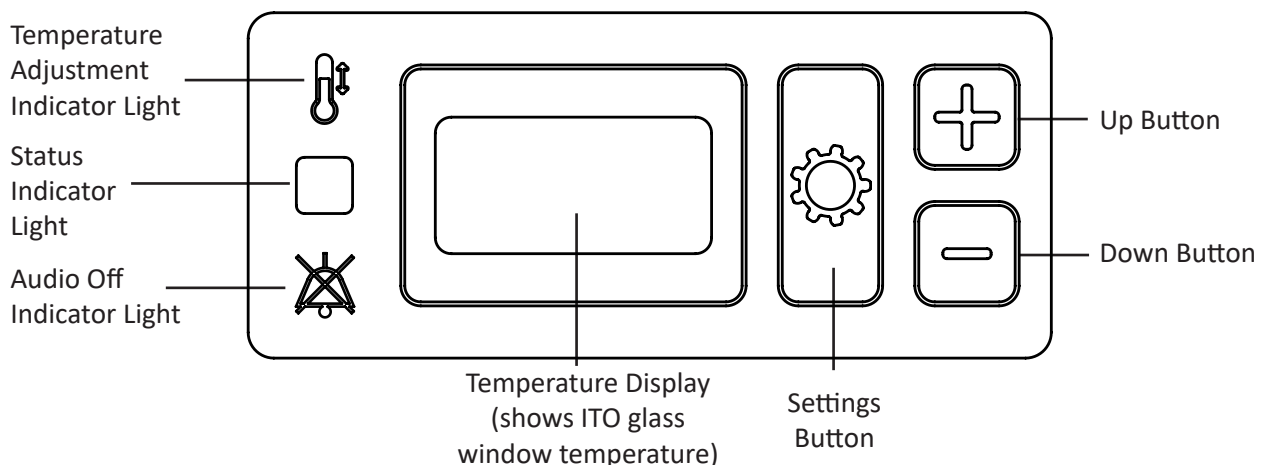


Figure 5-2 User Interface

Operator Position

The operator should be positioned in such a place to easily access the User Interface, work surface of the device and the connected touch screen (if used with the RI Witness WorkArea software).

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.

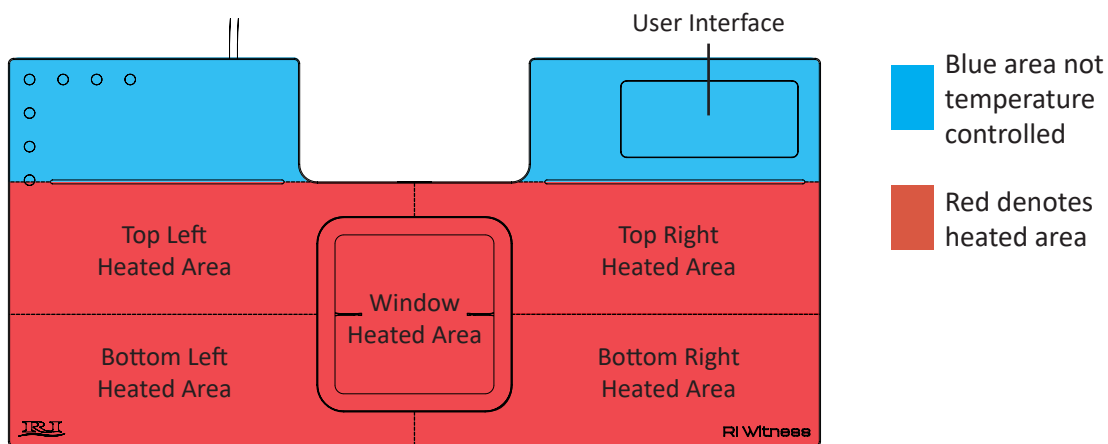




Figure 5-3 Embryology Heated Plate Heated Areas

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Ambient temperature must be $>5^{\circ}\text{C}$ from the set point for the temperature control to work effectively
- 

Place only plastic or glass ware on the window heated area.

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.

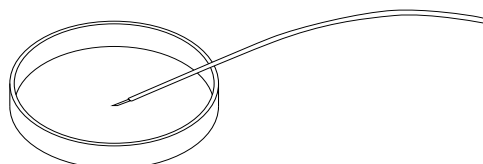


Figure 5-4 Thermometer Probe Positioned in a Petri Dish







Changing the Temperature Setpoint Using the Device

The maximum setpoint temperature allowed for this device is 45°C.



WARNING: In the event of sensor failure the plate may become hot (up to 65°C).

The temperature setpoint is applied to all heating channels and is set using the following procedure, or from within the RI Witness WorkArea 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 Temperature 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 Temperature 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 15 seconds and the device will return to normal operation (the Temperature Adjustment Indicator light will go out).

Changing the Temperature Setpoint Using a PC and RI Witness WorkArea 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: Using the built-in user interface on the Embryology Heated Plate, it is only possible to calibrate the temperature of the ITO glass window. To perform a full calibration of all 5 heated areas, this must be done from within the RI Witness WorkArea 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:

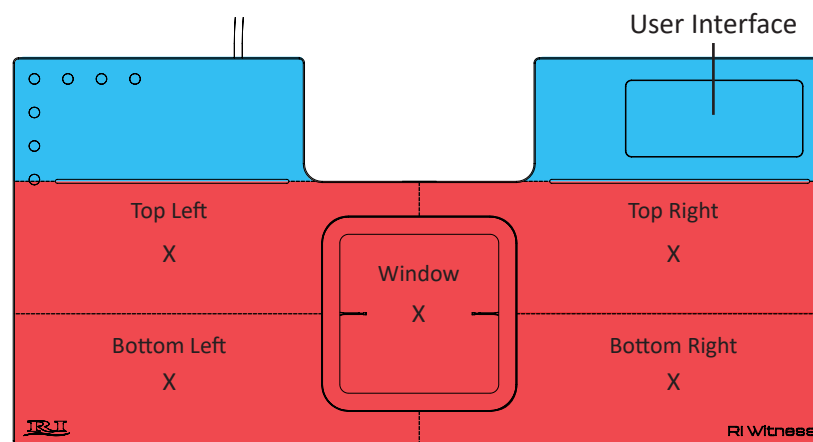









Figure 5-5 Recommended Thermocouple Positions for Temperature Calibration

ITO Glass Window Calibration Using Built-In User Interface

During calibration using the built-in user interface close the RI Witness WorkArea 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 Temperature Adjustment Indicator light  will flash. The Temperature Display will now flash between the current temperature (which may be a changing value) and the letters **CAL**.
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 Temperature 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 15 seconds and the device will return to normal operation. The Temperature Adjustment Indicator light will go out and the Temperature Display will stop flashing.

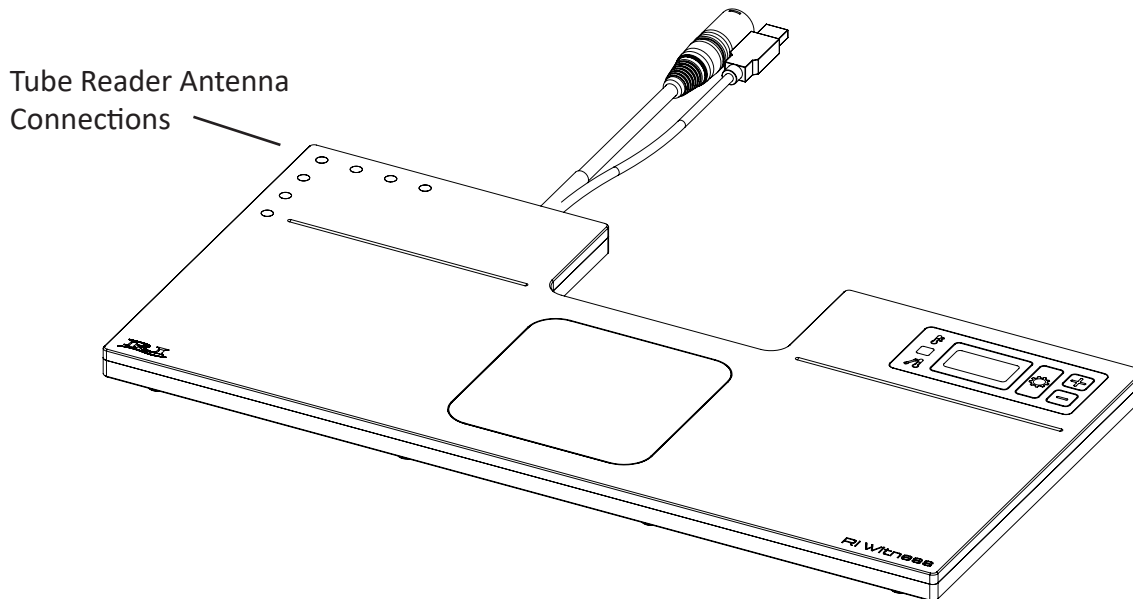
Full 5-channel Calibration Using PC and RI Witness WorkArea Software

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

1. Open the RI Witness WorkArea 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 automatically 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 WorkArea software with the thermometer reading.
5. A difference within $\pm 0.2^{\circ}\text{C}$ 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 to match the temperature displayed by the thermometer.
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.



5

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.

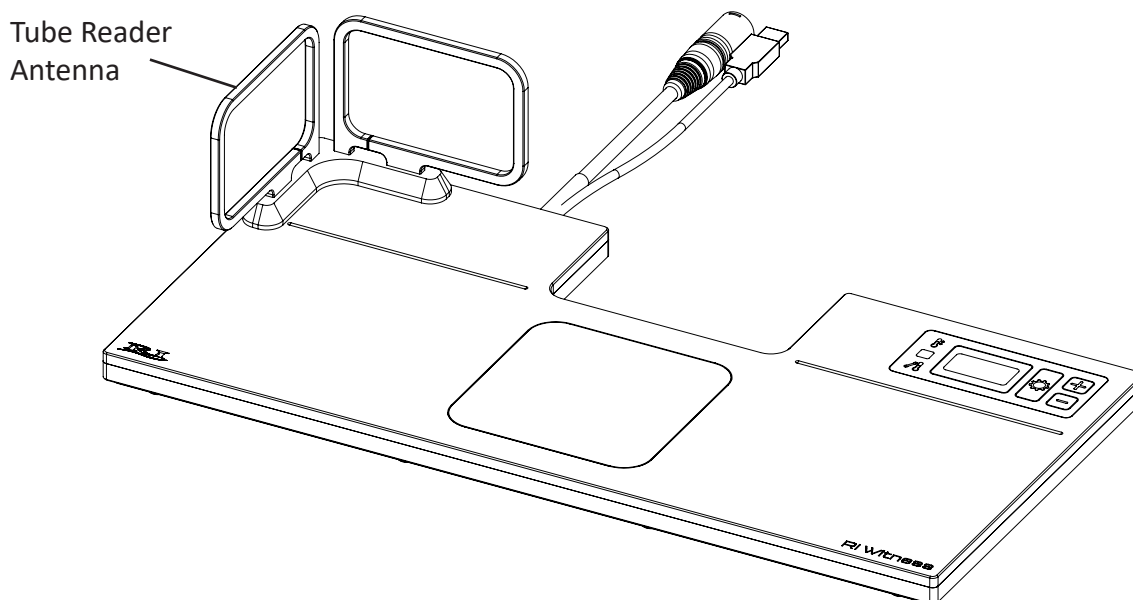


Figure 5-7 Tube Reader Correctly Mounted on the Embryology Heated Plate

SECTION 6 - TROUBLESHOOTING





RFID SYSTEM

Problem	Possible Cause	Solution
Tags Not Reading	Metal near reader	Remove any metallic objects from the area, check if the tags come back into Work Area
	Loose or no connection	Check security of USB and power cable connections. Verify that the light on the power supply is illuminated
	RF noise or interference	Other electrical devices in the lab can cause RF noise/interference. If a portable electronic device has been brought close to the device, remove it and check if the tags come back into the Work Area
	Broken tag	Check whether the tag is readable by a different RI Witness device. If it is not, discard that tag
	Antenna tuning problem	Navigate to the Work Area Settings screen, then click Connected Devices , then Embryology Reader , then RFID Tuning , check that all 5 channels (or 3 if you do not have the tube reader accessory connected) have green ticks next to them. If any have a yellow warning triangle next to them, contact an RI service representative

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Temperature Control: 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
 Off	Please wait Initial power up/setpoint/mode/calibration changed. The light will be off until temperature of all heating systems has stabilised.
 Green (constantly on)	Ready for use Temperature of all heating systems has stabilised.
 Yellow (constantly on)	Low Priority Alarm Built-in user interface and RI Witness WorkArea software will show current window temperature. Press the + button to cycle through the Alarm Condition Codes. Refer to tables on the following pages for details of each code. If the alarm sounds, finish the current procedure and 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 + button to cycle through the Alarm Condition Codes. Refer to the tables on the following pages for details of each code. If the alarm sounds, finish the current procedure and investigate the cause of the alarm.

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

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. Alarm Condition Codes are only displayed whilst the alarm is active and are cleared when the alarm is no longer active.

Audible Alarms


Audible alarms are sounded to indicate Low and Medium Priority Alarms, as described above. When in alarm condition it is possible to turn the Audio Off by pressing the down **—** button. The Audio Off Indicator Light  will illuminate for the duration of the alarm condition. The Audio will return if another alarm is activated or if the **—** button is pressed again.

Press the Up **+** button whilst alarms are active to cycle through the error codes. See pages 19 to 22 for full list of Alarm Condition Codes.

When multiple alarms are active, the audio for the highest priority alarm will be sounded. The alarm volume is not adjustable. Audible range for alarm system is as follows.

Priority	Range	Average
Medium Priority	44.4 - 55.5dB	53dB
Low Priority	41.5 - 55.5dB	51.5dB

Alarm System Testing

In order to test functionality of the alarm system hold down the  button for 3 seconds when there are no active alarms. This will trigger a medium priority alarm signal, (3 audible pulses and 3 yellow flashes of the status indicator light). This check should be performed at regular intervals to reduce the chance of missing an alarm due to failed loudspeaker or status indicator light.

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 $\pm 2.5^{\circ}\text{C}$ 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				
E06	ITO Window Sensor Failure	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 any of the ITO Window sensors fail the temperature display will show --.-°C	Possible sensor, cable or controller fault. May also be caused when the device is in over temperature condition. Restart the device by removing the mains power, then reconnect. Contact your distributor or RI Service if fault persists.
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.	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 $\pm 1^{\circ}\text{C}$	Medium	Heating channel has deviated by more than 1°C from the setpoint temperature. Alarm enabled 10 minutes after the temperature reaches $\pm 2.5^{\circ}\text{C}$ 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 $\pm 1^{\circ}\text{C}$				
E18	Bottom Left Heating Channel Temperature outside $\pm 1^{\circ}\text{C}$				
E19	Top Right Heating Channel Temperature outside $\pm 1^{\circ}\text{C}$				
E20	Top Left Heating Channel Temperature outside $\pm 1^{\circ}\text{C}$				

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Alarm Code	Fault Condition	Priority	Fault Description	Alarm Actions	Solution
E21	ITO Window Heating Channel Temperature outside $\pm 2.5^{\circ}\text{C}$	Medium	Heating channel has deviated by more than 2.5°C from the setpoint temperature. Alarm enabled once it has reached $\pm 2.5^{\circ}\text{C}$ from the setpoint temperature and is more than 1 minute after power on.	The temperature controller continues to operate to bring back within the allowable limits.	<p>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.</p> <p>May also be caused when the device is in over temperature condition.</p> <p>Restart the device by removing the mains power, then reconnect.</p> <p>Contact your distributor or RI Service if fault persists.</p>
E22	Bottom Right Heating Channel Temperature outside $\pm 2.5^{\circ}\text{C}$				
E23	Bottom Left Heating Channel Temperature outside $\pm 2.5^{\circ}\text{C}$				
E24	Top Right Heating Channel Temperature outside $\pm 2.5^{\circ}\text{C}$				
E25	Top Left Heating Channel Temperature outside $\pm 2.5^{\circ}\text{C}$				

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Alarm Code	Fault Condition	Priority	Fault Description	Alarm Actions	Solution
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				
E31	Memory Fault	Low	Memory/controller fault. System failed to read or write data correctly. If it happens during run time the system will carry on with current data. If it happens during start up the system will load the default values and needs reconfiguration of setpoint calibration.	System continues to operate until power is removed. When power is returned the system will operate with the default calibration and setpoint values.	Set the setpoint temperature then re-calibrate. If the problem persists then there may be a fault with the controller. If the problem is resolved then the memory may have been corrupted during saving of values, eg if the device loses power whilst saving values.

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. 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.

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 this device with 'normal' waste.

RI Returns System

1. Contact RI to obtain a Returned Materials Authorisation (RMA) number.
Note: Goods will not be replaced 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.

