

RI Witness™

Embryology Heated Plate User Manual

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R_X Only

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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 are being used. 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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Patents

Please go to this web page to see the patents that protect this product:

www.csipatents.com

Section 2

Introduction

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SECTION 2 - INTRODUCTION

Intended Use

To maintain the temperature of human reproductive samples such as oocytes and embryos through an assisted reproduction cycle.

Contraindications

The RI Witness Embryology Heated Plate 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, e.g. 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 in the country where the device is sold.

Intended Patient Population

For those who require assisted reproductive treatments to improve their chances of a healthy pregnancy and outcome.

Medical Condition

The medical condition is infertility and genetic disease.

Clinical Benefit

The clinical benefit of using this medical device during ART procedures is to improve the patient's chances of a viable pregnancy and long-term health of the offspring.

Intended Environment of Use

For use in a controlled clinical environment where Assisted Reproductive Techniques (ART) are used.

Intended User

Trained clinical professional working in Assisted Reproductive Techniques (ART) with locally relevant qualifications.

Obligation to Inform

Any serious incident is one that may have occurred in relation to this device should be reported to CooperSurgical via phone number +1 203-601-5200 Ext 3100 or by email at ProductSurveillance@coopersurgical.com and to the local Health Authority in your country. A serious incident may have caused or contributed to a death, a delay in a procedure which resulted in death or serious injury, or a malfunction that could have caused an adverse event.

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

6-70-121UM RI Witness WorkArea Software Manual

6-70-122UM RI Witness Manager Software Manual

Compatibility

RI Witness Embryology Heated Plate 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 CooperSurgical technician or other CooperSurgical authorised personnel. Incorrect installation could result in overall poor performance.

Section 3

Safety Warnings

SECTION 3 - SAFETY WARNINGS

Warnings



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 RI Witness Embryology Heated Plate, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Cautions



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



CAUTION: 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.



CAUTION: 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.

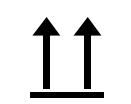
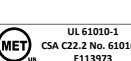
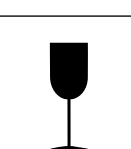
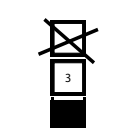
Section 3

Safety Warnings

Glossary of Safety/Information Symbols

Source: ISO 15223-1
ISO 60601-1

Symbol	Meaning
	In accordance with Annex II of the European Medical Device Directive 93/42/EEC, as amended by Directive 2007/47/EC
	In accordance with Radio Equipment Directive (RED) 2014/53/EU
	Caution: US Federal law restricts this device for sale to or on the order of a licensed healthcare practitioner
	Authorized representative in the European Community
	Consult instructions for use
	Consult instructions for use
	WARNING: Indicates a potentially hazardous situation which, if not avoided, could result in serious injury or death
	CAUTION: Indicates a potentially hazardous situation which, if not avoided, could result in a minor or moderate injury
	Manufacturer
	Date of manufacture
	Catalogue or Part number
	This product complies with FCC rules and regulations contained in US FDA 47 CFR

	Serial number
	Batch code
	Unique Device Identifier
	Medical Device
	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure
	Do not dispose of product with normal waste. Disposal of according to EU WEEE Directive
	Direct current (DC)
	Protect from sources of radiation and strong magnetic fields
	This way up
	This electrical product is independently certified by MET to meet USA and Canadian safety standards
	Fragile, handle with care
	Stacking limited to 3 units
	Keep dry

Section 3

Safety Warnings

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

Startup / Shutdown Procedure

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

“Section 5 - RI Witness Basic Operation” on page 14 describes the recommended startup and shutdown procedure for the RI Witness Embryology Heated Plate.



CAUTION: Do not place metal objects near reader.



CAUTION: Do not place electrical equipment near reader.

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 1	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	
Harmonic emissions EN 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions EN 61000-3-3	Complies	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.

Section 3

Safety Warnings

USA Only

Compliance with the emissions requirements of CISPR 32 Class B requires the following warning: "This is a class B 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

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
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	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.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 6 GHz	3 V/m	

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 double-checking and provides the 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 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 RI Witness Embryology Heated Plate (and associated Tube Reader accessory) in both its flush-fitted and sit-on-top configurations.

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

RI Witness Embryology Heated Plate

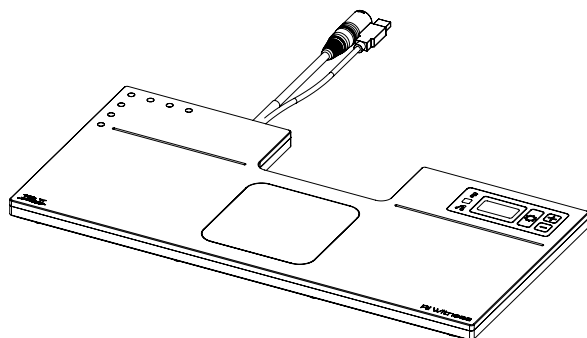


Figure 4-1 Sit on Top Heated Reader

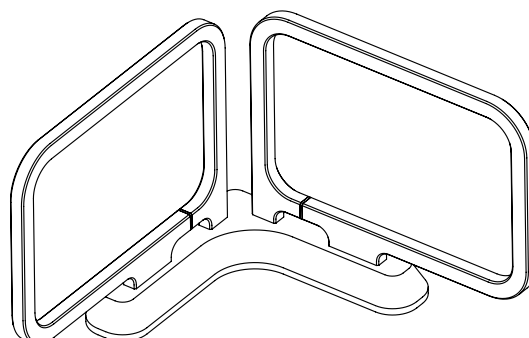


Figure 4-2 Tube Reader Accessory

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 $\pm 0.2^{\circ}\text{C}$ when calibrated against a known reference Displayed resolution: 0.1°C Setpoint temperature range: $30\text{--}45^{\circ}\text{C}$
Displays	3 x 7-segment LED display shows the temperature reading from the ITO glass window temperature sensor
Connectivity	USB plug type A For connection to tablet or PC approved to IEC 60950-1 or IEC 62368
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 $> 5^{\circ}\text{C}$ below setpoint Humidity: 15% to 85% RH (Non Condensing) Pressure Range: 70kPa to 108kPa
Transport/Storage Conditions	Temperature: -40°C (-40°F) to 60°C (140°F) Humidity: 5% to 95% RH (Non condensing) Minimum Pressure: 70kPa
RFID Specification	Frequency: 13.56Mhz Power: 1W
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

Basic Operation

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.

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 “Temperature Control: Alarms and System Status” on page 24 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.

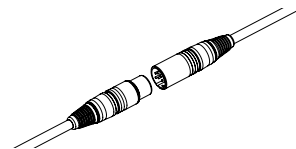


Figure 5-1 Power Supply In-Line Connector

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 RI Witness 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 RI Witness 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.

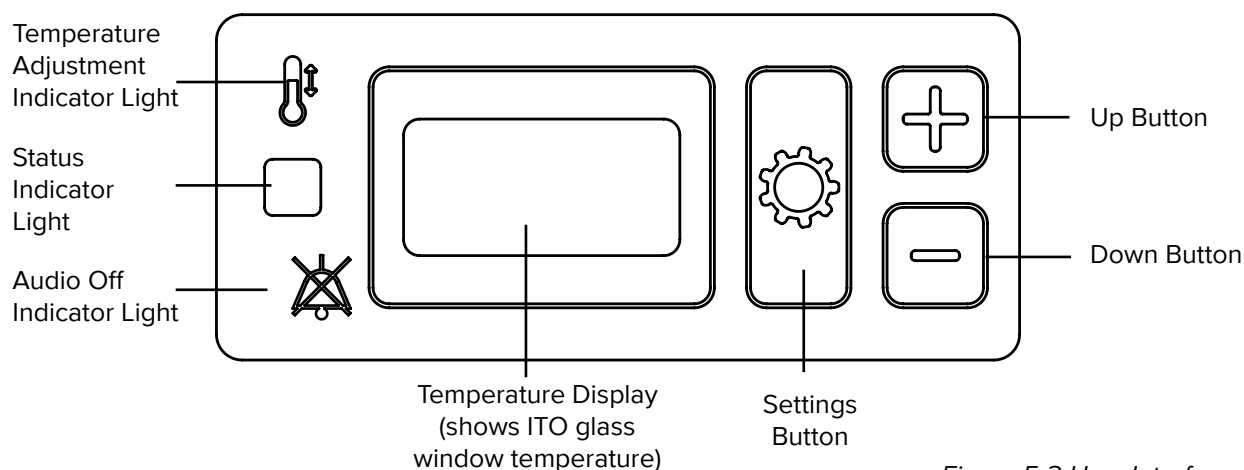


Figure 5-2 User Interface

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.

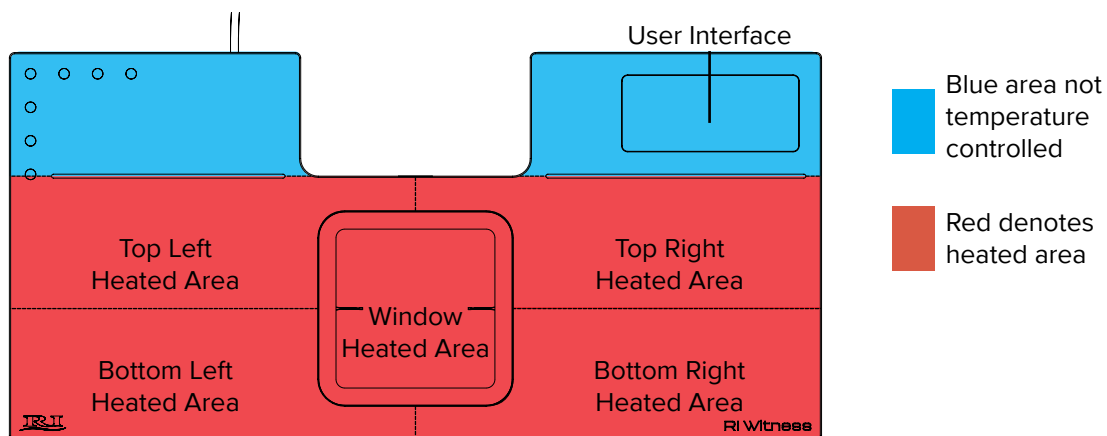


Figure 5-3 RI Witness Embryology Heated Plate heated areas



CAUTION: Ambient temperature must be $>5^{\circ}\text{C}$ from the setpoint for the temperature control to work effectively.



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

Section 5

Basic Operation

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.

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.

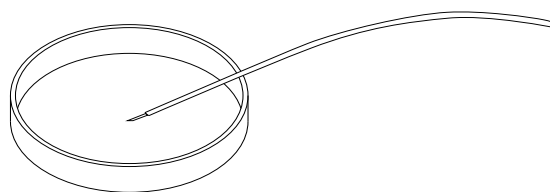


Figure 5-4 Thermometer Probe Positioned in a Petri Dish

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 RI Witness Embryology Heated Plate, it is only possible to calibrate the temperature of the ITO glass window. A full calibration of all 5 heated areas can only 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:

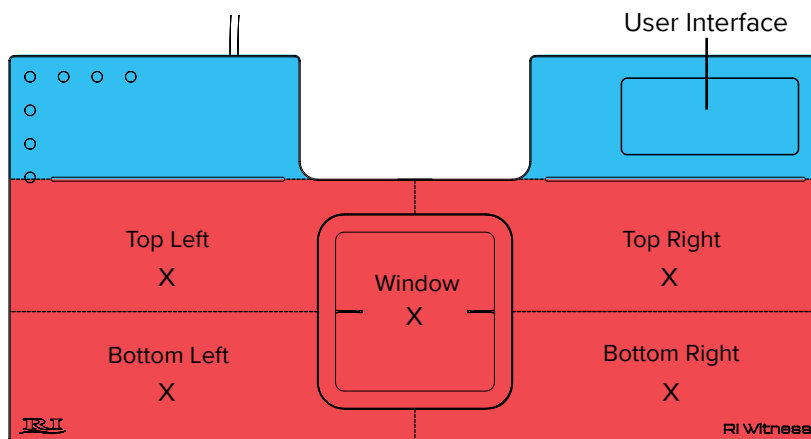


Figure 5-5 Recommended Thermocouple positions for temperature calibration

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 **CTL**.
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 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.

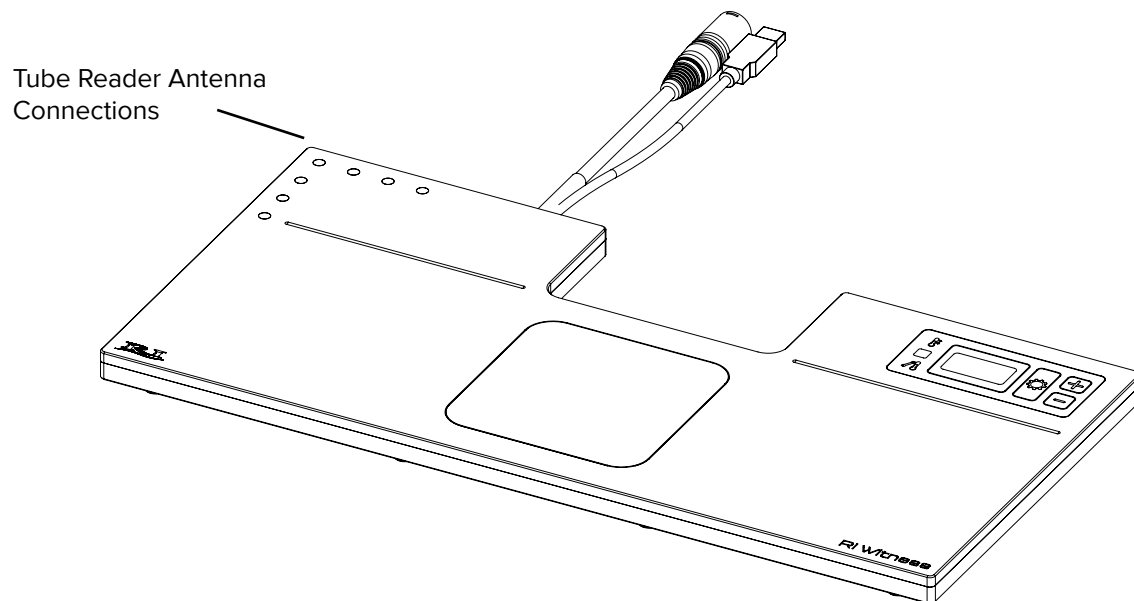
7. Open the RI Witness WorkArea software and navigate to the WorkArea Status window.
8. Click on the yellow triangle or the **(i)** icon then click **WorkArea Settings**, then **Connected Devices**, then **Temperature Controller**, then **Check Calibration**. The screen will now show the current temperature and calibration offsets of the five different heated areas.
Note: RF will be switched off automatically when on the Temperature Control screen.
9. Each heated area is independent so the order of calibration is not important. Place the thermocouple probe in one of the positions shown above.
10. Allow the reading to stabilise, then compare the temperature shown in the WorkArea software with the thermometer reading.
11. 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.

12. Repeat this process for all 5 heated areas.
13. 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 RI Witness 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 RI Witness Embryology Heated Plate. The correct mounting orientation position is shown below in Figure 5-7.



Refer to “Cleaning” on page 30 for cleaning precautions relating to the Tube Reader Antenna.

Figure 5-6 Tube Reader connections on the RI Witness Embryology Heated Plate

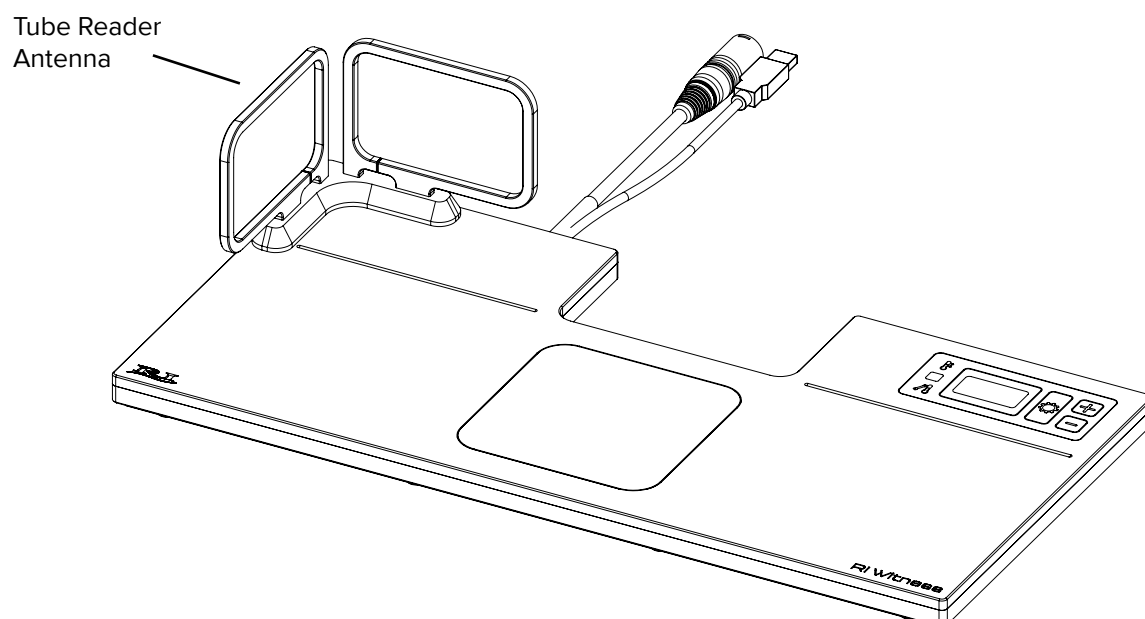


Figure 5-7 Tube Reader correctly mounted on the RI Witness Embryology Heated Plate

Section 6

RFID Tags

SECTION 6 - RI WITNESS RFID TAGS

RI Witness RFID Tags - Instructions for Use

Tagging Plasticware

Before use in the work area, all plasticware must be RFID tagged and labelled with patient identity and all patient ID cards (embedded RFID tag) must hold a patient identity.

Rectangular, Circular, Time-Lapse, Square and Slim Tags are available.

Dishes and Pots

RFID Tags must be positioned on a flat, horizontal surface of dishes and pots. The best place is usually the base of the dish or pot.

The Slim Tag, positioned on the front tab, is recommended for square dishes. The Square Tag, positioned diagonally, is recommended for a four well dish. The adhesive side of the tag must be in full contact with the container. Tags must not be bent around the edge of the container or fixed to the side as this may cause inability to read the tag or may cause the tag to detach from the container.

Tubes

The Rectangular Tag is recommended for tubes. Position the long edge of the tag along the length of the tube and hold in place using tape or a patient identity label. Position tags near the top of tubes to ensure they are not obscured by thermal blocks or tube warmers.

Handling RFID Tags

When removing tags, bend the backing strip away from the tag, rather than the tag away from the backing strip. This will reduce the risk of damaging tags.

Start peeling the backing strip away at the “peel from here” point shown in the diagram, to achieve a peel line as shown.

When sticking the tag to the dish, bring the tag into contact with the dish at one point. Then use your finger or thumb to work the tag onto the dish with a circular movement, moving away from the initial contact point so as to avoid any kinks in the tag as it sticks to the dish.

Additional identification

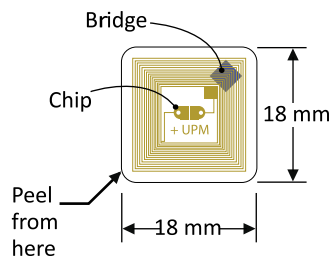
In addition to having an RFID Tag all plasticware must have a second means of identification, such as a printed RI Patient Identity Label (6-70-110/50 or 6-70-111/50). In the unlikely event of RFID tag failure, the sample must be moved to a new dish with a new RFID tag and identification label. Perform an “Admin Assign” on the new tag to bring the dish into the system (see RI Witness Work Area 6-70-121UM).

Storing Tags and Tagged Labware

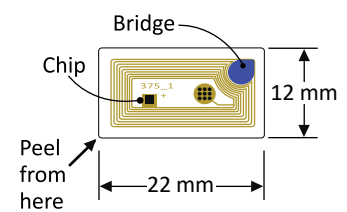
Unused tags and unused tagged plasticware should not be stored on or near a surface (safety cabinet or workbench) where an RI Witness reader is located.

Do not store tags near magnetic or radiation sources like MRI devices, Gamma ray equipment or X-ray rooms. Exposure to these may render labels and patient ID cards unusable.

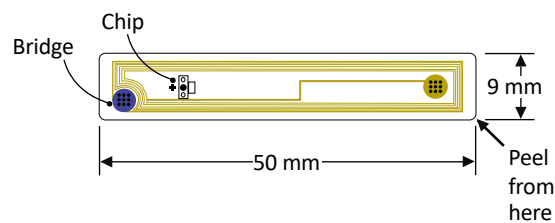
Square Tag



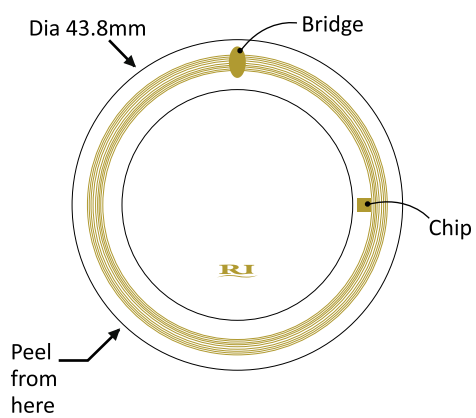
Time-Lapse Tag



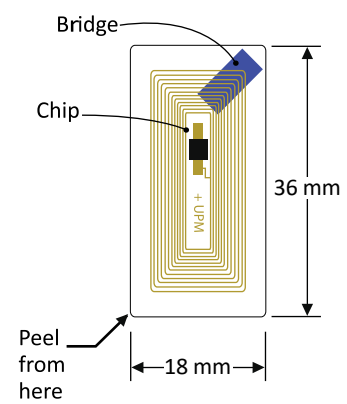
Slim Tag



Circular Tag

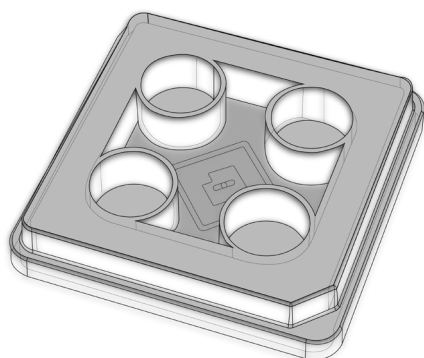
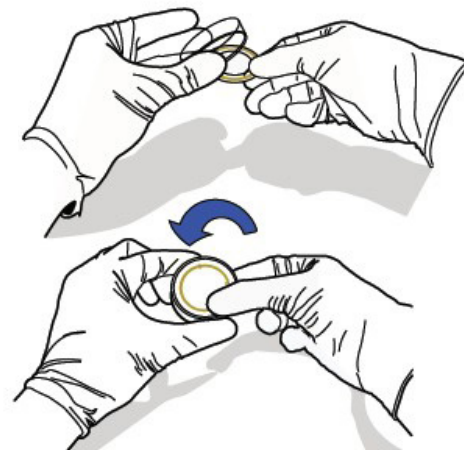
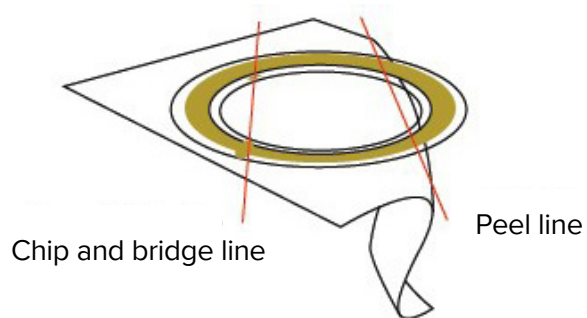


Rectangular Tag

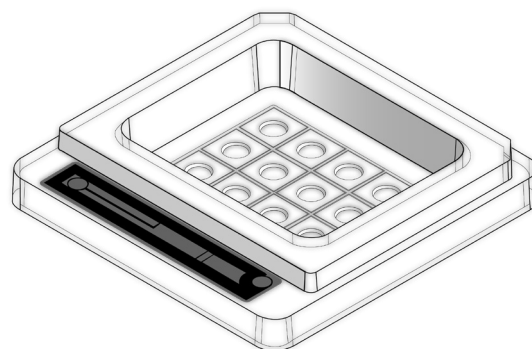


Section 6

RFID Tags



4-well dish with Square Tag
positioned on base



Square dish with Slim Tag
positioned on front tab



Round dish with Circular Tag
positioned on base



Test Tube with Rectangular Tag
positioned on side



Rectangular dish with Time-Lapse
tag positioned on base

SECTION 7 - 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 reappear 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

Section 7

Troubleshooting

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.

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 22 to 26 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				

Section 7

Troubleshooting

Alarm Code	Fault Condition	Priority	Fault Description	Alarm Actions	Solution
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 temperature is too high. 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				
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				

Alarm Code	Fault Condition	Priority	Fault Description	Alarm Actions	Solution
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 the temperature 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 $\pm 1^{\circ}\text{C}$				

Section 7

Troubleshooting

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 the temperature 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. May also be caused when the device temperature is too high. Restart the device by removing the mains power, then reconnect. Contact your distributor or RI Service if fault persists.
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 $\pm 2.5^{\circ}\text{C}$				

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 RI Service.
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 recalibration and setpoint adjustment.	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 8

Care & Maintenance

SECTION 8 - CARE AND MAINTENANCE

Cleaning

RI Witness Embryology Heated Plate and Tube Reader Antenna may be cleaned with a soft cloth and mild detergent solution. 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.



CAUTION: Do not use solvents for cleaning.



CAUTION: Do not disconnect readers.

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.

Storage

Where possible, if the heated plate is not to be used, place it in its original packaging, which can be stacked 3 high.

If original packaging is not available, store on a flat worksurface in its correct orientation.

DO NOT STACK if the product is stored outside of its original packaging.

Disposal of electrical and electronic equipment

CooperSurgical have taken the necessary steps to comply with the EC directive 2012/19/EU on waste electrical and electronic equipment (WEEE).



Environmental implications: WEEE contains materials that are potentially hazardous to the environment and to human health. Therefore, when this instrument has reached its end of life it must be collected and recycled separately from other waste according to national requirements. Please contact a local CooperSurgical distributor for instructions. Do not dispose of with 'normal' waste.

SECTION 9 - WARRANTY INFORMATION AND LIMITS ON LIABILITY

CooperSurgical warrants that this item will be free from defects in materials and workmanship for one year from the date of installation. If CooperSurgical determines that the product fails to conform to that warranty during the one-year period, CooperSurgical will repair or replace the product, at CooperSurgical's discretion, free of charge.

To return the product to CooperSurgical, a customer must comply with CooperSurgical's Returned Goods Policy described in this manual and the warranty requires the customer to return the product to CooperSurgical in accordance with the CooperSurgical Returns Instruction. CooperSurgical will return products (that it repaired or replaced under warranty) to the same customer who returned those products, at CooperSurgical's expense F.O.B. the customer's facility. Under all other circumstances, CooperSurgical will return products to the same customer who returned those products at the customer's expense.

CooperSurgical's warranties do not cover damage caused by misuse, improper care, improper use of chemicals or cleaning methods, loss, theft, use of non-authorized parts, servicing by non-authorized personnel or negligent or intentional conduct on the part of the owner or user of the product, nor do they cover normal wear and tear or general maintenance. Any modifications or changes to a product will void that product's warranty. CooperSurgical's warranties do not apply to any single- or limited-use, disposable or consumable components or items.

CooperSurgical is not responsible for, and the owner and operator of the product shall defend, indemnify and hold harmless CooperSurgical from and against, all claims, damages, and other losses resulting from the improper servicing, maintenance, repair, use or operation of the product or the owner or operator's negligence or willful misconduct, and use of inadequate packing and packaging when returning product for repair.

The above warranties are in lieu of, and CooperSurgical hereby disclaims, all other warranties, express or implied, written or oral, with respect to CooperSurgical products, including the warranties of merchantability and fitness for a particular purpose. No terms, conditions, understandings or agreements that purport to modify the above warranties or that make any additional warranties for any CooperSurgical product shall have any legal effect unless made in writing and signed by an authorized CooperSurgical corporate officer.

CooperSurgical shall not under any circumstances be liable for lost profits, damages from loss of use or lost data, or indirect, special, incidental or consequential damages under its warranties or otherwise for any claim related to CooperSurgical products, even if CooperSurgical has been advised, knew or should have known of the possibility of such damages. CooperSurgical's liability with respect to a product covered by a warranty or otherwise shall be limited in all circumstances to the purchase price of that product.

Section 10

Returning Products for Repair

SECTION 10 - RETURNING PRODUCT FOR REPAIR

Returned Goods Policy

Please refer to the 'Troubleshooting' section in this manual before returning product. If you continue to have a problem with your device, please follow these instructions:

Returned Goods Policy

Goods will be accepted for return for the following reasons:

- If shipment was made without the customer's authorization or order
- If incorrect items were shipped
- If defective items were shipped
- If defective goods are covered by the standard warranty

To return product, please contact Customer Service for a Returned Merchandise Authorization (RMA) number. Items will not be accepted without an RMA number. Please have the following information:

- Reason you wish to return the goods
- Quantity, description, part number, serial number of the goods
- Date of receipt of order
- Customer's purchase order and the CooperSurgical or Origio invoice number

All used products must be cleaned and sterilized prior to shipment. A signed decontamination declaration may be required.

All products should be carefully and adequately packed, preferably in original packaging. Replacement items or additional repairs will be invoiced.

All packaging should be clearly labeled with the RMA number and statement "Urgent – Returned Items for Repair". If authorisation to return a product is granted you will be provided with a return address label.

Shipments must be sent prepaid by the customer and insured for their full value during shipping. Freight collect shipments will not be accepted, and goods will be returned to the sender.

If the customer intends to return equipment ordered in error, the following restocking charges and terms will apply:

- 25 percent within 60 days from date of shipment
- Goods must be returned unused, in the original carton, and in marketable condition
- Refurbishing and replacement charges will be added to the restocking charges for damaged or missing items
- No return after 60 days
- No refund on sterile, single-use disposable products

Transport

To transport the RI Witness Embryology Heated Plate,

Follow the shutdown procedure (see page 14)

1. Disconnect the power and USB cables
2. Hold the RI Witness Embryology Heated Plate with both hands, tucking the cables under one hand so they do not drag on the floor.

Customer Service Contact details

Tel: +45 46 79 02 02

Fax: +45 46 79 03 02

E-mail: sales@coopersurgical.com

fertility.coopersurgical.com

Contact details for customers in the USA

Tel: 800-243-2974

Fax: 800-262-0105

fertility.coopersurgical.com

