a CooperSurgical Company

Installation and Service Manual

RI WITNESS™

Embryology Heated Plate

+44 (0) 1737 243869 | customerservice@origio.com | origio.com

Research Instruments Ltd, Bickland Industrial Park, Falmouth, Cornwall TR11 4TA, UK

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CE 0120

℞ only

CONTENTS

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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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.

CE 0120 Rx only

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

6-70-121UM RI Witness Software Manual

Compatibility

RI Witness is used in conjunction with the following:

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

This device 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.

All relevant sections of this manual should be read and understood fully before any use of RI Witness takes place. 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.

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 1.5ºC from the displayed temperature at any time. A temperature of more than 1.5ºC will cause the temperature inside the dish to change more rapidly and samples are at risk of over-heating. 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.
CE 0120	In accordance with Annex II of the European Medical Device Directive 93/42/EEC, as amended by Directive 2007/47/EC under the supervision of notified body No.0120, SGS, UK Ltd.
CE	In accordance with the European Directive for R&TTE, Directive 1999/5/EC.
	Indicates the medical device manufacturer.
	Indicates the date of manufacture.
	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Consult instructions for use.
SN	The five digit number is a unique identifier assigned to the product.
Rx Only	Caution: US Federal law restricts this device for sale to or on the order of a licensed healthcare practitioner.
REF	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

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.

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

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

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

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

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

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

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

Emissions test	Compliance	Electromagnetic environment guidance
RF emissions CISPR 11	Group 2	RI Witness must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	RI Witness is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions 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

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: *U*T 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 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable 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.

SECTION 4 - INSTALLATION

Installation Checklist

The following steps must be completed in this order before the system is used:

1. Examine all components for damage that may have occurred during transport, storage or use.
   i. Check for cracks in materials
   ii. Check for sharp edges
   iii. Check for damage to connectors
   iv. Check for worn or damaged cables
2. Install software and perform database set up. Refer to 6-70-121IT RI Witness IT Requirements.
3. Position the device in the desired location and adjust the movable aperture as shown below for flush fitted configurations.

i. Positioning of Sit On Top Embryology Heated Plate (6-70-807)

The sit on top Embryology Heated Plate is intended to fit around a stereo zoom microscope inside of your flow hood or on a workbench.

Initially place the heated plate so that the window is centred with the microscope optics. Adjust the position forwards and backwards if required, ie if the front of the device obstructs the air flow at the front of the cabinet then it can be moved back towards the microscope.

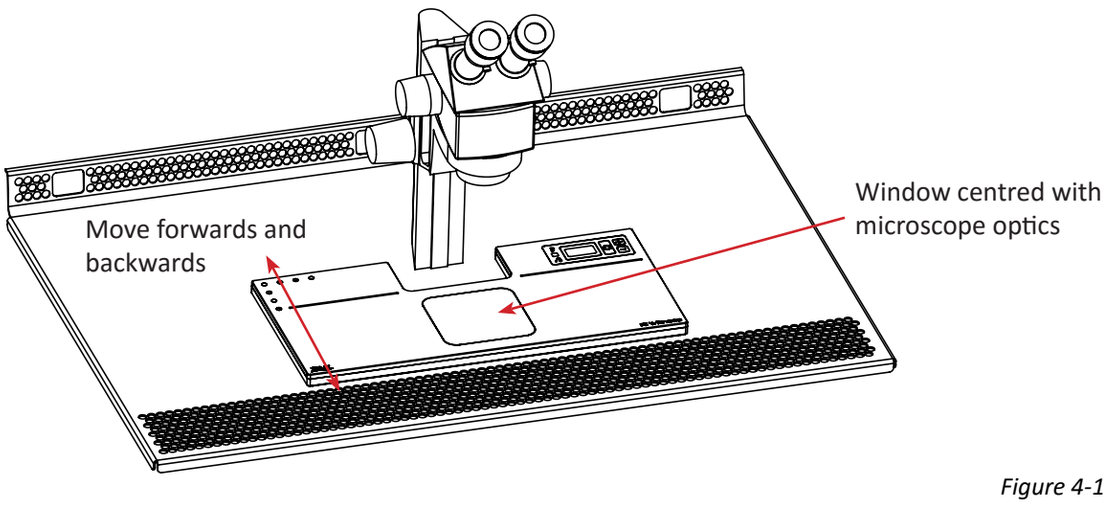

Figure 4-1

Legs are also available enabling the Embryology Heated Plate to be supported when placed on top of a stereo zoom microscope light base.

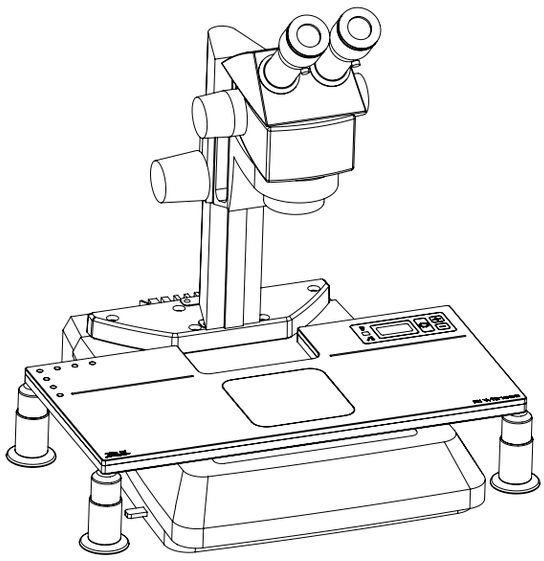

Figure 4-3

ii. Positioning of Flush Embryology Heated Plate (6-70-807-A/B)

The Flush Embryology Heated Plate should be mounted in a flow hood tray or other work surface prior to being installed. Mounting guidelines can be provided by RI upon request as each installation needs to be considered on an individual basis.

A movable aperture is provided on the underneath of the device which is intended to hide surfaces beneath the device from view. The movable aperture can be adjusted forwards and backward in order to centre it with the light source/microscope optics. Alternatively it can be removed completely if it is not required.

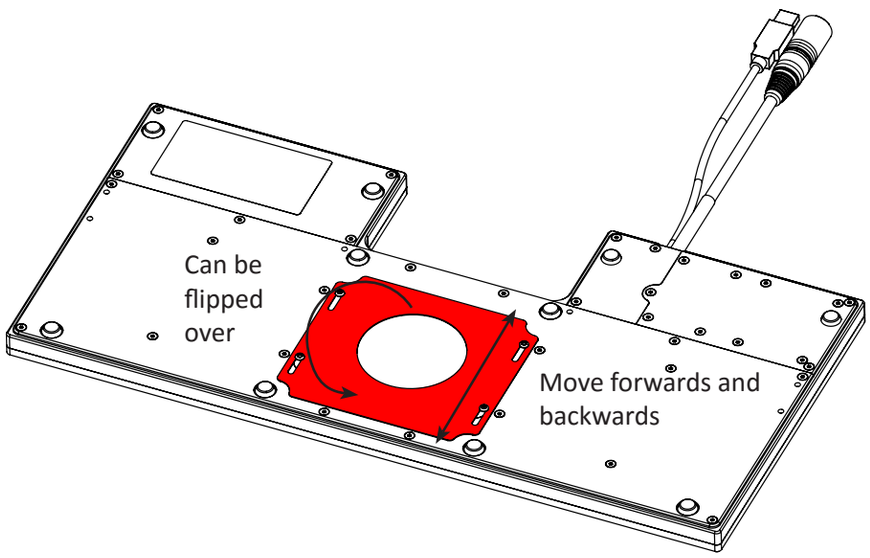

Figure 4-2

When installing a Flush Embryology Heated Plate the movable aperture will need to be adjusted in order that it is centred with the microscope optics. Refer to Sit On Top section for details of movable aperture adjustment.

To slide the movable aperture loosen the 4 screws, slide the aperture into the desired position then re-tighten the screws. Note that to move the aperture into position in front and behind the centre line of the window, it is necessary to turn the movable aperture over. The 4 screws will need to be removed in order to do this. See “Figure 4-2” on page 10.

4. Connect the Power connections as described in the ‘Start up procedure’ section in 6-70-807UM RI Witness Embrology Heated Plate User Manual.
5. Connect the USB A plug, that protrudes from the rear left corner of the Embryology Heated Plate, into an available USB socket on the PC or Tablet. Verify the connection to the software as described in ‘Connecting to the Software’ section in 6-70-807UM RI Witness Embrology Heated Plate User Manual.
6. Go into the RFID Tuning Screen and check that all connected antennas have a green tick next to them.
7. Perform temperature calibration of all five heating channels as described in the ‘Temperature Calibration’ section in 6-70-807UM RI Witness Embrology Heated Plate User Manual.

SECTION 5 – SERVICE CHECKS AND PROCEDURES

The following service activities should be performed to service an RI Witness work area.

Component and Connections Damage Checklists

1. Check data and power connections for security and damage.
2. Check cable layout.
3. Check for damage to all components.
4. Check that the power supply is positioned in a suitable location, ie where it cannot fall or get damaged.

Cleanliness

1. Where fitted, check that Tube Reader connections are clean and free from corrosion. Clean if required (Refer to 'Care and Maintenance' section in 6-70-807UM RI Witness Embryology Heated Plate User Manual).
2. Check cleanliness of both windows' internal and external surfaces.

   If required the lower glass can be removed from the underside of the Embryology Heated Plate for cleaning purposes (see below). When cleaning the internal surfaces of the glass use an optical cleaning wipe, or lint-free cloth moistened with isopropyl alcohol. It may be necessary to polish the glass afterwards with a dry lint-free cloth to remove smears. Take care not to touch the two temperature sensors attached to the surface of the glass.
3. To remove the lower window, first remove (4 screws) the movable aperture (if fitted) from the heated plate. Take a note of the position before removing.

   Remove one of the window clamp strips (2 screws) and loosen the others, then lift the glass. Adhere a small piece of sticky tape to lift the glass if required.

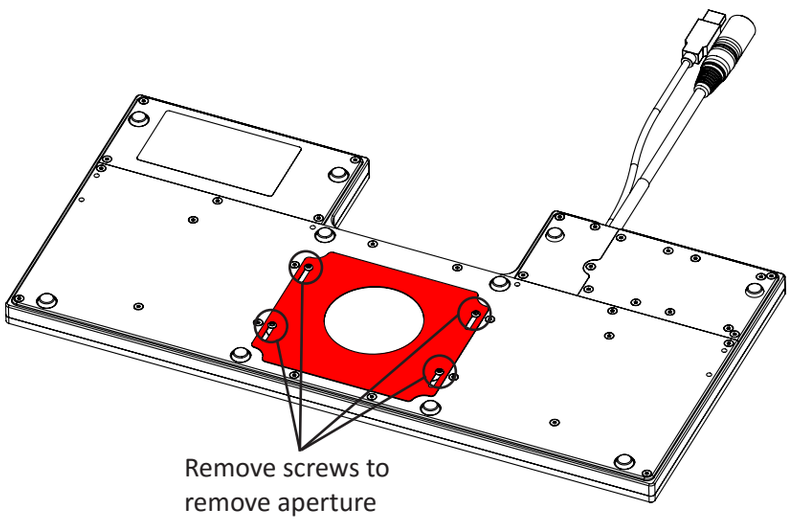

Figure 5-1

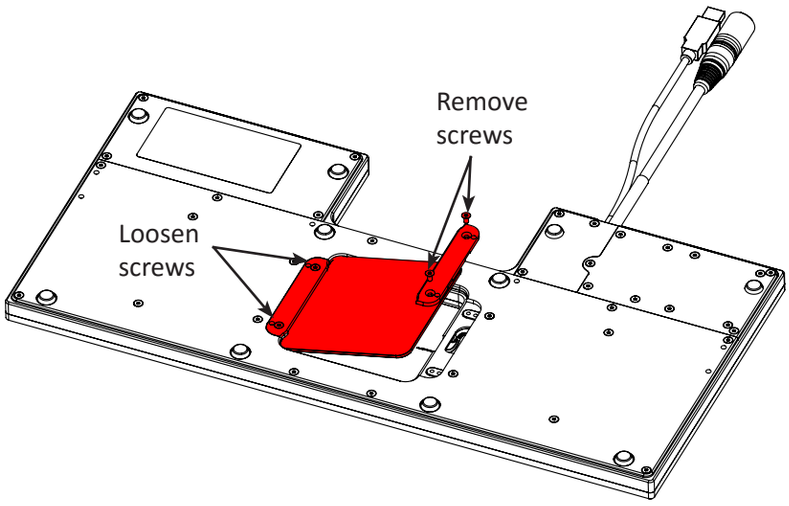

Figure 5-2

Temperature Calibration Checklist

Verify that the temperature indicated by built in user interface and software matches a reading taken by thermometer for all five heating channels. Refer to the 'Temperature Calibration' section of section in 6-70-807UM RI Witness Embrology Heated Plate User Manual.

SECTION 6 - 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 in the RI Witness Embryology Heated Plate User Manual (6-70-807UM).
2. If you require any further help contact your distributor or RI directly. RI will try to resolve the problem as quickly as possible.

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.

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.

Contact Details

ORIGIO a/s, Knardrupvej 2, 2760 Måløv, Denmark
Tel: +44 (0) 1737 243869
E-mail: customerservice@origio.com
Website: www.origio.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.