# RI Witness™

## Sperm Preparation Reader

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# CONTENTS

# SECTION 1 - PREFACE



Thank you for choosing RI Witness.

This manual provides all the necessary information to use RI Witness Sperm Preparation Reader 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 section for more information.

If you are unsure of any of the information contained in this manual then you 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

A hard copy of this user manual is available on request.

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.

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Bickland Industrial Park,
Falmouth, Cornwall TR11 4TA, UK

# SECTION 2 - INTRODUCTION TO RI WITNESS

## Indication for Use for RI Witness System

To identify and track human samples, using RFID technology, through the assisted reproduction (AR) cycle, including cryopreservation.



## Contraindication:

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, 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 within the country the device is intended to be sold into.*

## Applicable Part Numbers

| Part Number | Description |
|---|---|
| 6-70-854 | RI Witness Sperm Preparation Reader |

## Related Documents

6-70-121UM RI Witness WorkArea Software Manual

6-70-122UM RI Witness Manager Software Manual

## Compatibility

RI Witness is used in conjunction with the following:

- Essential medical devices, e.g. dishes and tubes, maybe AR or non-AR specific.
- Non-essential medical devices, e.g. safety cabinets, incubators, micromanipulators, lasers.
- Non medical devices (general laboratory equipment), e.g. 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 Sperm Preparation Reader 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 Sperm Preparation Reader, 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** 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 Sperm Preparation Reader, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

## Glossary of Safety/Information Symbols

*Source: ISO 15223-1*
*BS EN 60601-1*

| Symbol | Meaning | Symbol | Meaning |
|---|---|---|---|
| CE | In accordance with Radio Equipment Directive (RED) 2014/53/EU | SN | Serial number |
|  | 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. |  | Do not dispose of product with normal waste. Disposal of according to EU WEEE Directive |
| MET c us UL 61010-1 CSA C22.2 No. 61010-1 E113973 | This electrical product is independently certified by MET to meet USA and Canadian safety standards. |  | Direct current (DC) |
| FC | This product complies with FCC rules and regulations contained in US FDA 47 CFR. |  | This way up |
| coopersurgical.com  | Consult instructions for use - coopersurgical.com<br>Hard copies available on request |  | Stacking limited to 3 units |
|  | Manufacturer |  | Keep dry |
|  | Date of manufacture | | |
| REF | Catalogue or Part number | | |

## Safety and Reliability

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

## 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 the proximity of metal objects or electrical equipment that were not present during installation.

For cleaning, the reader may be lifted and returned to the same position. See “Cleaning” on page 8 for more details.

Do not place metal objects near reader.

Do not place electrical equipment near reader.

**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 (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 contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada’s licence-exempt RSS(s). 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.

# SECTION 4 - PRODUCT OVERVIEW

## Sperm Preparation Reader

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

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



RFID 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 holding 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 refers only to the Sperm Preparation Reader.

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

## Sperm Preparation Reader Specification Table

| Part | Description |
|---|---|
| RFID Reader | Frequency: 13.56 MHz<br>Power Output: 1W<br>No. of Antennas: 3<br>Read Range: Anywhere within the footprint of the product |
| Power Supply | Input: 100-240VAC, 50-60Hz, <3A , Class I, 0.8-0.4A<br>Output: 12VDC 2.5A Max (30W) |
| USB | USB 2.0 Socket Type Mini B<br>For connection to tablet or PC approved to IEC 60950-1 or IEC 62368 |
| Material(s) | Corian (Curved Baseplate),<br>Powder Coated Stainless Steel (Side Antennas)<br>ABS (Lower Cover)<br>Aluminium (Rear and lower covers) |
| Operating Conditions | Temperature: 10˚C (50˚F) to 42˚C (108˚F)<br>Humidity: 15% to 85% RH (Non condensing)<br>Pressure: Pressure Range: 70kPa. to 108kPa. |
| Storage/Transport Conditions | Temperature: -40˚C (40˚F) to 60˚C (140˚F)<br>Humidity: 15% to 85% RH (Non - condensing)<br>Pressure: Pressure Range: 70kPa. to 108kPa. |
| Dimensions | Width: 276 mm<br>Length: 234 mm<br>Height: 148.5 mm |
| Mass | 2.9kg + Power supply 0.3kg |

# SECTION 5 - RI WITNESS BASIC OPERATION

## Electrical Connections

1. In order to secure the USB and power cable into the device there are two silicone tubes provided that need to be placed around each cable before the cables are clamped in position.
2. Remove the thumb screw from the cable clamp at the rear of the device.
3. Plug both cables into their connectors with the cables running vertically down.
4. Refit the cable clamp and thumb screw such that the silicone tube is clamped in the slots in the cable clamp.

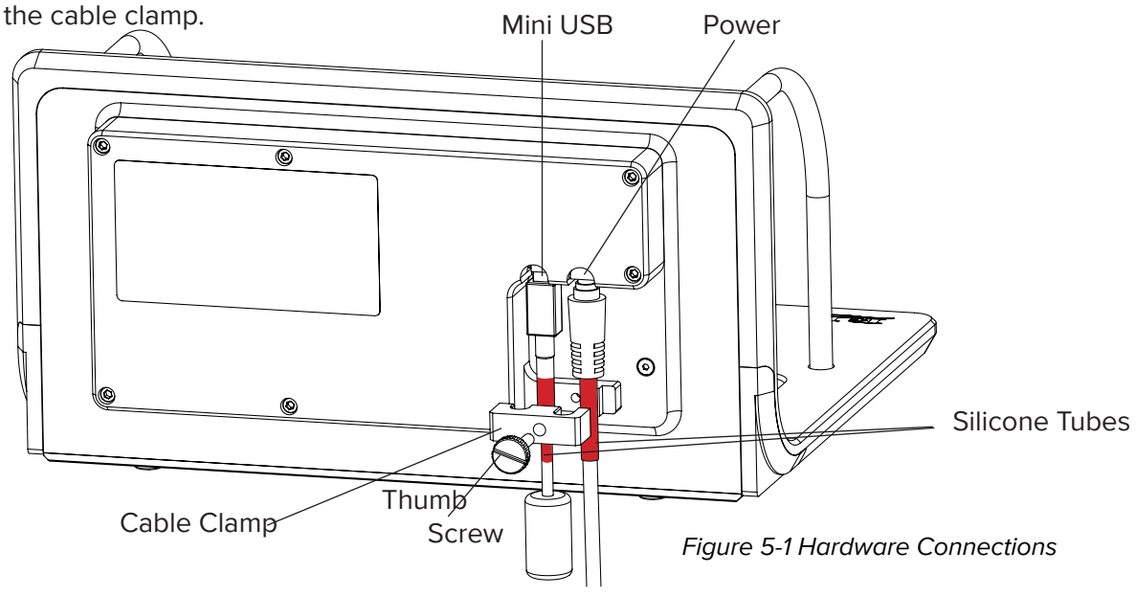


*Figure 5-1 Hardware Connections*

## Connection to the Software

Plug the device into the tablet or PC (or powered USB hub) using the USB cable provided with the device. Once the Windows operating system has recognised the device, open the RI Witness WorkArea software.

To verify that the RI Witness WorkArea software can communicate successfully, navigate to the WorkArea Status window, by clicking the yellow triangle or pressing the ⓘ icon. This will bring up the WorkArea Status window in which the Sperm Preparation Reader should be listed in the Connected Devices section with a green tick next to it.

For more detailed set-up information, refer to the RI Witness Software Manual (6-70-121UM).

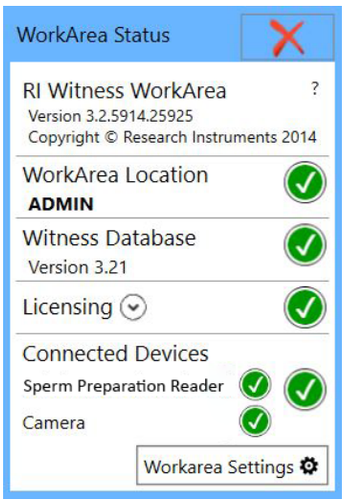


*Figure 5-2 WorkArea Status*

## Operation

The Sperm Preparation Reader detects tagged containers that are brought into the work area. When a sample is to be transferred between containers, bring both containers into the work area. The Sperm Preparation Reader will detect the tags and the RI Witness system will record the step.

## Cleaning

The Sperm Preparation Reader may be cleaned with a soft cloth and mild detergent. The device may be lifted and returned to its original location. Do not disconnect the cables attached to the device.

# 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 reappear in the 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 in 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 **Sperm Prep Reader**, then **RFID Tuning**, check that all 3 channels have green ticks next to them. If any have a yellow warning triangle next to them, contact an RI service representative |

# SECTION 7 - WARRANTY INFORMATION AND LIMITS ON LIABILITY

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

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

RI'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. RI's warranties do not apply to any single- or limited-use, disposable or consumable components or items.

RI is not responsible for, and the owner and operator of the product shall defend, indemnify and hold harmless RI 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 RI hereby disclaims, all other warranties, express or implied, written or oral, with respect to RI 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 RI product shall have any legal effect unless made in writing and signed by an authorized RI corporate officer.

RI 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 RI products, even if RI has been advised, knew or should have known of the possibility of such damages. RI'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 8 - RETURNING PRODUCT TO RI FOR REPAIR

Please refer to the 'Troubleshooting' section in this manual before returning product to RI. 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, you must 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".

**Return Address:**
**Research Instruments Ltd,**
**Bickland Industrial Park,**
**Falmouth, Cornwall, TR11 4TA, UK**

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 sender.

If 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

## Customer Service Contact details

Tel: +45 46 79 02 02

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E-mail: sales@coopersurgical.com

fertility.coopersurgical.com

## US only customers contact details

Tel: 800-243-2974

Fax: 800-262-0105

fertility.coopersurgical.com

## Serious Incident Event

Any serious incident that has occurred in relation to this device should be reported to customer service.

Please provide customer service with full details of the incident including any applicable serial numbers. In some instances, it may be necessary to return the device to the manufacturer to assist in their investigation of the incident.



## Feedback

Thank you for purchasing a CooperSurgical RI product. To help us 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 sales@coopersurgical.com. Your feedback will help us develop the product and supporting materials to meet your future needs.

Thank you