RI Witness™

Admin & Card Reader
User Manual
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SECTION 1 - PREFACE

Thank you for choosing RI Witness.

This manual provides all the necessary information to use RI Witness Admin & Card 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 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

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

Contraindications
This device is not intended to be exposed to known sources of electromagnetic Interference (EMI) with medical devices such as diathermy, and electromagnetic security systems, 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

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>6-70-808</td>
<td>RI Witness Admin &amp; Card Reader</td>
</tr>
</tbody>
</table>

Optional Part Numbers

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>6-70-811</td>
<td>RI Witness Admin &amp; Card Reader Wall Mount Kit</td>
</tr>
<tr>
<td>6-70-812</td>
<td>RI Witness Admin &amp; Card Reader Stand</td>
</tr>
</tbody>
</table>
Related Documents

6-70-121UM   RI Witness 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 Admin & Card Reader plate should be carried out by an 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 Admin & Card Reader, or substitute any component. Doing so may result in damage to samples. This voids the warranty and/or service contract.

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

Note: This equipment has been tested and found to complies 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.
# Safety/Information Symbols

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

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="CooperSurgical.com" alt="CE" /></td>
<td>In accordance with Radio Equipment Directive (RED) 2014/53/EU</td>
</tr>
</tbody>
</table>
| ![i](CooperSurgical.com) | Consult instructions for use - coopersurgical.com  
Hard copies available on request. |
| ![Consult instructions for use.](CooperSurgical.com) | Consult instructions for use. |
| ![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 device itself.](CooperSurgical.com) | 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 device itself. |
| ![Manufacturer.](CooperSurgical.com) | Manufacturer. |
| ![Date of manufacture.](CooperSurgical.com) | Date of manufacture. |
| ![Catalogue or Part number.](CooperSurgical.com) | Catalogue or Part number. |
| ![Serial number.](CooperSurgical.com) | Serial number. |
| ![Unique Device Identifier.](CooperSurgical.com) | Unique Device Identifier. |
| ![Indicates instruction for disposal of goods.](CooperSurgical.com) | Indicates instruction for disposal of goods. |
| ![Direct current (DC).](CooperSurgical.com) | Direct current (DC). |
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.

For cleaning, the reader may be lifted and returned to the same position. See “Cleaning” on page 13 for more details.

- Do not place metal objects near reader.
- Do not place electrical equipment near reader.
SECTION 4 - PRODUCT OVERVIEW

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

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

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

As samples are processed as part of an AR cycle, RFID readers (both heated and non-heated) read the tags on the container and their identity and status is confirmed on-screen. If containers 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 Admin & Card Reader.

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

The Admin & Card reader is a multifunctional device that can be used to identify RFID tags contained in patient cards or affixed to sperm tubes, sperm pots or even patient files. It can be used on a desk in the reception or office, or in the theatre mounted on a wall. A card slot is provided to securely hold a patient card. All other tags can be read by placing them against the surface of the device.

Figure 4-1 Admin & Card Reader
# Admin & Card Reader Specification Table

<table>
<thead>
<tr>
<th><strong>RFID Reader</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency</td>
<td>13.56 MHz</td>
</tr>
<tr>
<td>Power Output</td>
<td>0.5 W</td>
</tr>
<tr>
<td>Read Range</td>
<td>&gt;3cm</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Power Supply</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Input</td>
<td>5VDC Max 0.5A</td>
</tr>
<tr>
<td>Output</td>
<td>2.5W Max</td>
</tr>
<tr>
<td>USB</td>
<td>USB 2.0 Socket Type B</td>
</tr>
</tbody>
</table>
| Material(s)      | Corian (Housing)  
|                  | ABS (Lower cover) |
| Operating Temperature | Temperature: -25°C (-13°F) to 60°C (140°F)  
|                  | Humidity: 5% to 95% RH (Non Condensing) |
| Dimensions       | 160x100x18 mm |
| Mass             | 0.4 kg |
SECTION 5 - RI WITNESS BASIC OPERATION

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 (click the yellow triangle or press the (i) icon). This will bring up the WorkArea Status window in which the Admin & Card 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).

Card Reader Function

The device can be mounted in the theatre on the wall or on the side of a flow hood. In this orientation the patient ID card is intended to be inserted into the slot and kept there for the duration of the procedure. Instructions and all necessary hardware for mounting the device on the wall are included in the wall mount kit.

Figure 5-1 Card Reader Function
Admin Reader Function

The device can also be used in the Reception or Manager’s office. The large flat surface allows plenty of room to place patient ID cards and various other tag types against the surface of the device.

![Figure 5-2 Admin Reader Function](image)

IUI Function

The optional stand allows the user to insert a patient ID card into the card slot whilst simultaneously reading a sperm tube during an IUI procedure. Instructions and all necessary hardware for mounting the card onto the stand are included with the stand.

![Figure 5-3 IUI Function](image)
# SECTION 6 - TROUBLESHOOTING

<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible Cause</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tags Reading Intermittently or Only in Certain Areas</td>
<td>Loose connection</td>
<td>Check the USB cable is fully inserted at both the PC and device socket. Replace cable if necessary to ensure it is not the cable itself at fault.</td>
</tr>
<tr>
<td></td>
<td>RF Noise/interference</td>
<td>Many devices, especially large metallic surfaces can cause RF Noise, interference or affect the tuning of the antenna. Move the reader away from metallic surfaces if possible. Contact an RI service representative.</td>
</tr>
<tr>
<td></td>
<td>PCB faulty</td>
<td>Contact an RI Service representative</td>
</tr>
<tr>
<td>Tags Not Reading</td>
<td>Broken tag</td>
<td>Check the tag on another device</td>
</tr>
<tr>
<td></td>
<td>Tag not encrypted</td>
<td>Navigate to the WorkArea Settings screen, then click Connected Devices, then Admin &amp; Card Reader, then click the down arrow next to Tags. Non encrypted tags are shown as Not Valid.</td>
</tr>
<tr>
<td></td>
<td>RF noise</td>
<td>Many devices, especially large metallic surfaces can cause RF Noise, interference or affect the tuning of the antenna. Move the reader away from metallic surfaces if possible. Contact an RI service representative.</td>
</tr>
<tr>
<td></td>
<td>Loose connection</td>
<td>Check the USB cable is fully inserted at both the PC and device socket. Replace cable if necessary to ensure it is not the cable itself at fault.</td>
</tr>
<tr>
<td></td>
<td>WorkArea configuration</td>
<td>Ensure that the device is correctly being identified by the PC, Admin &amp; Card Reader should be displayed in the connected device display.</td>
</tr>
<tr>
<td></td>
<td>PCB faulty</td>
<td>Contact an RI Service representative.</td>
</tr>
</tbody>
</table>
SECTION 7- CARE AND MAINTENANCE

Cleaning

The reader may be cleaned with a soft cloth and mild detergent. Ensure that no liquid is spilled down the card slot, permanent damage can be caused.

- Do not use solvents for cleaning.
- Do not disconnect readers.
SECTION 8- 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 9- RETURNING PRODUCT TO RI FOR REPAIR

Please refer to the ‘Troubleshooting’ section in this manual before returning product to RI. If problems continue with the 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 for returning 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 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

Customer Service Contact details:
Tel: +45 46 79 02 02
Fax: +45 46 79 03 02
E-mail: customerservice@origio.com
coopersurgical.com

Contact details for customers in the USA:
Tel: 800-243-2974
Fax: 800-262-0105
coopersurgical.com
Section 9
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.

Product Disposal (European Union)

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

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 customerservice@origio.com. Your feedback will help us develop the product and supporting materials to meet your future needs.

Thank you