a CooperSurgical Company

RI WITNESS™

Admin & Card Reader User Manual

RESEARCH INSTRUMENTS LTD
Bickland Industrial Park, Falmouth, Cornwall TR11 4TA, UK
t: +44 (0) 1326 372 753 | f: +44 (0) 1326 378 783 | e: sales@research-instruments.com
www.research-instruments.com

Document 6-70-808UM, Issue 2,DRF: 3646, 28 July 2016

CONTENTS

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.

The use of ™ in this manual indicates a trademark of Research Instruments Ltd. Any other brand names, referred to in this manual, are trademarks of their respective owners.

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.

CE

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

Part Number	Description
6-70-808	RI Witness Admin & Card Reader

Optional Part Numbers

Part Number	Description
6-70-811	RI Witness Admin & Card Reader Wall Mount Kit
6-70-812	RI Witness Admin & Card Reader Stand

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 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

Symbol	Meaning
	Indicates instruction for disposal of goods.
CE	In accordance with the European Directive for R&TTE Directive 99-5-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 device itself.
	Consult instructions for use.
SN	The five digit number is a unique identifier assigned to the product.
REF	Indicates the RI 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.

For cleaning, the reader may be lifted and returned to the same position. See “Cleaning” on page 12 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.

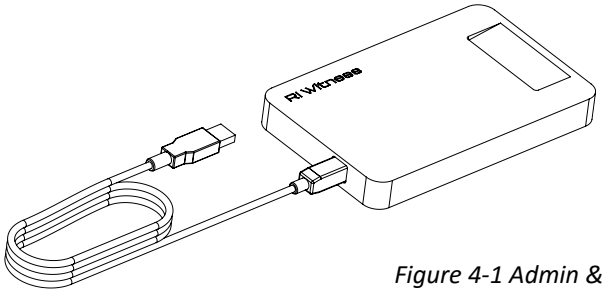

Figure 4-1 Admin & Card Reader

Admin & Card Reader Specification Table

RFID Reader	
Frequency	13.56 MHz
Power Output	0.5 W
Read Range	>3cm
Power Supply	
Input	5VDC Max 0.5A
Output	2.5W Max
USB	USB 2.0 Socket Type B
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.

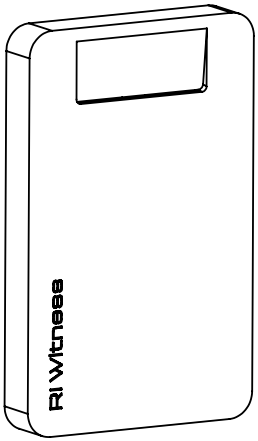

Figure 5-1 Card Reader Function

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.

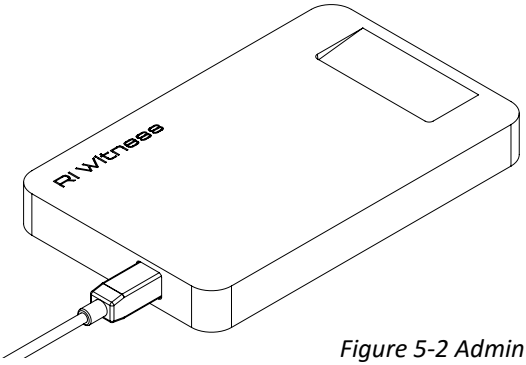

Figure 5-2 Admin Reader Function

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.

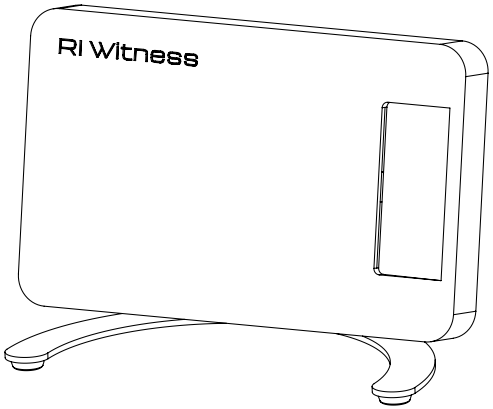

Figure 5-3 IUI Function

SECTION 6 - TROUBLESHOOTING

Problem	Possible Cause	Solution
Tags Reading Intermittently or Only in Certain Areas	Loose connection	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.
	RF Noise/ interference	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.
	PCB faulty	Contact an RI Service representative
Tags Not Reading	Broken tag	Check the tag on another device
	Tag not encrypted	Navigate to the WorkArea Settings screen, then click Connected Devices, then Admin & Card Reader, then click the down arrow next to Tags. Non encrypted tags are shown as Not Valid.
	RF noise	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.
	Loose connection	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.
	WorkArea configuration	Ensure that the device is correctly being identified by the PC, Admin & Card Reader should be displayed in the connected device display.
	PCB faulty	Contact an RI Service representative.

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 - 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 an RI instrument, please follow the procedure below.

1. Read the 'Troubleshooting' section.
2. If you require any further help contact your distributor or RI directly. RI will try to resolve the problem as quickly as possible.

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 RI Witness products with 'normal' waste.

Contact Details

Research Instruments Ltd, Bickland Industrial Park, Falmouth, Cornwall, TR11 4TA, UK
Tel: +44 (0) 1326 372 753 Fax: +44 (0) 1326 378 783
E-mail: service@research-instruments.com
Website: www.research-instruments.com

Feedback

Thank you for purchasing an RI product. To help RI develop the best tools for ART, we rely on customer feedback. If you have any suggestions for how we can improve our products or the information we provide with them, please send to feedback@research-instruments.com. Your comments will help us develop the product and supporting materials to meet future needs.

Thank you.