RI Witness™

Sperm Preparation 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 the CooperSurgial, Inc RI Witness Sperm Preparation Reader. All sections of this manual 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 Purpose section for more information.

If the operator is unsure of any of the information contained in this manual then they should contact CooperSurgical, Inc (CSI) or an appointed representative before attempting to use this equipment.

In no event does CSI assume the liability for any technical or editorial errors of commission, or omission; nor is CSI 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. CSI is constantly updating its products, and therefore, reserves the right to introduce changes in design, equipment and technical features at any time. 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 CooperSurgical, Inc. Any other brand names, referred to in this manual, are trademarks of their respective owners.

Patents - please go to this web page to see the patents that protect this product: www.csipatents.com

EC REP

CooperSurgical Distribution B.V.
Celsiusweg 35, 5928 PR Venlo,
The Netherlands

SECTION 2 - INTRODUCTION TO RI WITNESS SPERM PREPARATION READER

Intended Purpose

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 intended purpose is 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, may be 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 CooperSurgical technician or other CSI authorised personnel. Incorrect installation could result in overall poor performance.

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: 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 CSI 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 Sperm Preparation Reader, 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 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.

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.

Safety/Information Symbols

Source: ISO 15223-1, ISO 60601-1

Symbol	Meaning	Symbol	Meaning
	In accordance with Radio Equipment Directive (RED) 2014/53/EU		Radio Equipment Regulations 2017 (2017 No. 1206)
	Consult instructions for use		Catalogue or Part number
	Authorized representative in the European Community/ European Union		This product complies with FCC rules and regulations contained in US FDA 47 CFR
	Serial number		Unique Device Identifier
	Manufacturer		Date of manufacture
	**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
	Do not dispose of product with normal waste. Dispose of in accordance with the EU WEEE Directive Do not dispose of product with normal waste		Direct Current
	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure. *For RFID Tags only		Protect from sources of radiation and strong magnetic fields

Section 3
Safety Warnings

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 Fragile, handle with care		Stacking limited to 3 units
	This way up		Keep dry
	Fragile, handle with care		

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 9 for more details.

CAUTION: Do not place metal objects near reader.

CAUTION: 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

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.

Guidance and Manufacturer’s Declaration (Radio Equipment Standards - Canada)

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.

Conseils et déclaration du fabricant (Normes applicables au matériel radio - Canada)

L’émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d’Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L’exploitation est autorisée aux deux conditions suivantes :

1. L’appareil ne doit pas produire de brouillage;
2. L’appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d’en compromettre le fonctionnement.

SECTION 4 - PRODUCT OVERVIEW

RI Witness 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 RI Witness Sperm Preparation Reader.

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

RI Witness Sperm Preparation Reader Specification Table

Part	**Description**
RFID Reader	Frequency: 13.56MHz Power output: 1W No. of antennas: 3 Read range: anywhere within the footprint of the product
Power Supply	Input: 100-240VAC, 50-60Hz, <3A , Class I, 1.0-0.5A Output: 12VDC 3.4A Max (40W) Device consumption: 0.4A 4.8W Max
USB	USB 2.0 Socket Type Mini B For connection to tablet or PC approved to IEC 60950-1 or IEC 62368
Material(s)	Corian (curved base) Powder coated stainless steel (side antennas) Aluminium (rear and lower cover)
Dimensions	Width: 276mm Length: 234mm Height: 148.5mm
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.

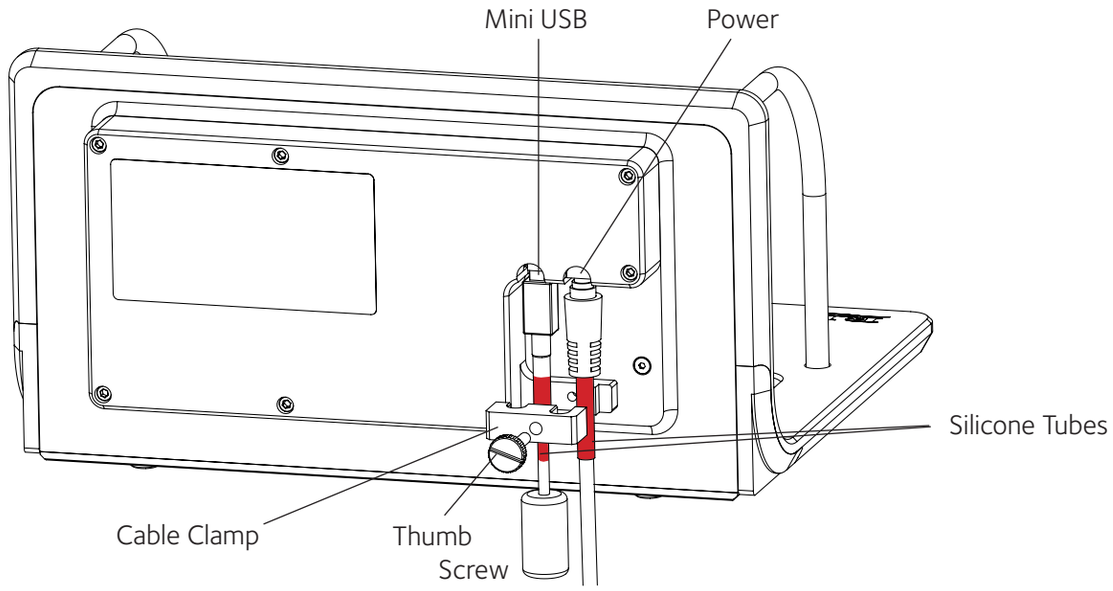


Figure 5-1 Hardware Connections

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 RI Witness 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).

Operation

The RI Witness 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 RI Witness Sperm Preparation Reader will detect the tags and the RI Witness system will record the step

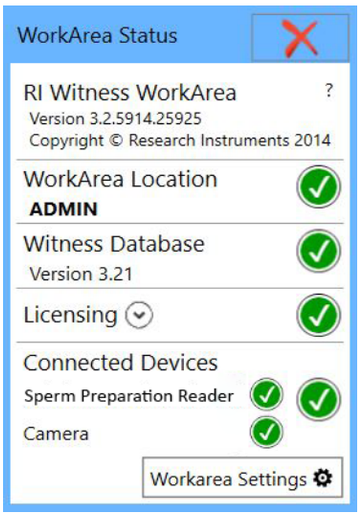


Figure 5-2 WorkArea Status

Cleaning

The RI Witness Sperm Preparation Reader may be cleaned with a soft cloth and mild detergent solution. Ensure that no liquid is spilled down the back of the device. The device may be lifted and returned to its original location. Do not disconnect the cables attached to the device.

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 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

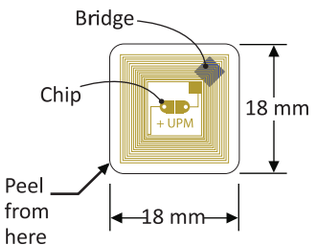
In addition to having an RFID Tag all plasticware must have a second means of identification, such as a printed RI Patient Identity Label (6-70-110/50 or 6-70-111/50). In the unlikely event of RFID tag failure, the sample must be moved to a new dish with a new RFID tag and identification label. Perform 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

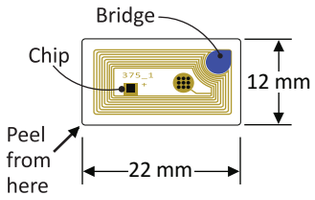
Unused tags and unused tagged plasticware should not be stored on or near a surface (safety cabinet or workbench) where an RI Witness reader is located.

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.

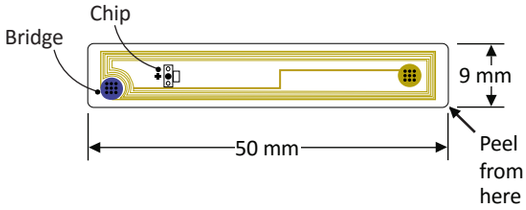
Square Tag



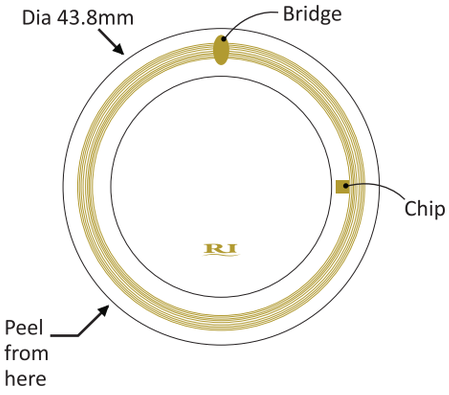
Time-Lapse Tag



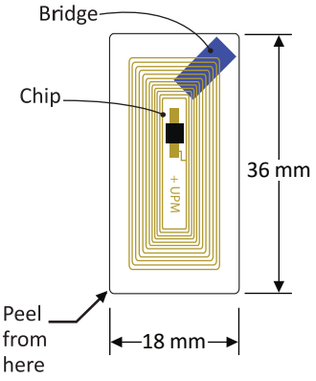
Slim Tag

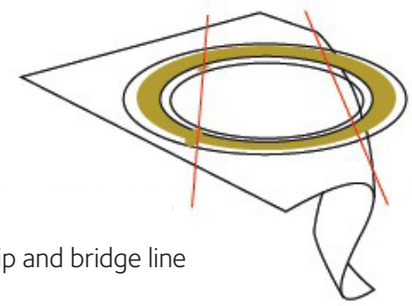


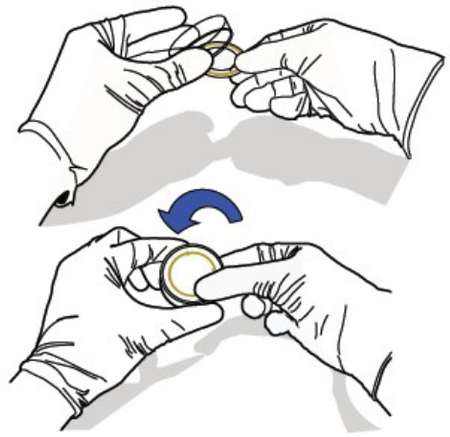
Circular Tag

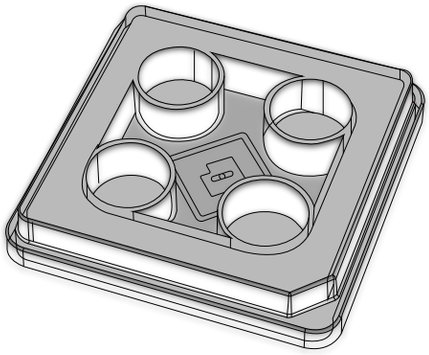


Rectangular Tag

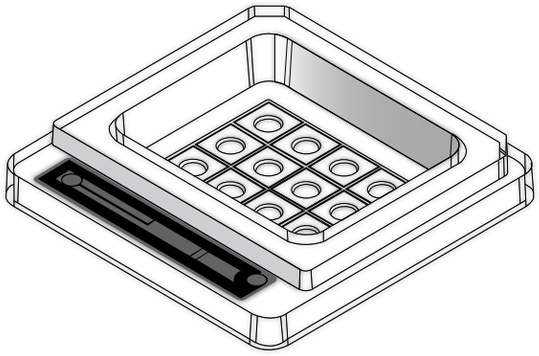








4-well dish with Square Tag positioned on base



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 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 CSI service representative

SECTION 8 - WARRANTY INFORMATION AND LIMITS ON LIABILITY

CooperSurgical Inc, 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 9 - RETURNING PRODUCT FOR REPAIR

Please refer to the 'Troubleshooting' section in this manual before returning product. If the problem continues with the device, please follow the instructions below.

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 CSI 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".

Shipment 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

Fax: +45 46 79 03 02

E-mail: sales@coopersurgical.com

coopersurgical.com

Contact details for customers in the USA

Tel: 800-243-2974

Fax: 800-262-0105

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.

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 CooperSurgical or their authorised representative promptly.