# User Manual

## RI Witness™

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## SECTION 1 - PREFACE

Thank you for choosing RI Witness™.

The RI Witness™ family of products is made up of RI Witness™, Data Capture, Traceability, Imaging and Cryo.

This manual provides all necessary information to use RI Witness™. 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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**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.**

# SECTION 2 - INTRODUCTION TO RI WITNESS™

## Intended Use

For RI Witness™ heated work areas only.

To identify and track human samples through the assisted reproduction (AR) cycle and where required, to maintain sample temperature.

**Contraindications:** There are no contraindications associated with the use of this device.



## Medical Device Component

CE 0120

The heated plate (and temperature control) components of this system are classified as a class II medical device in accordance with Article 9, Annex IX, rule 9 of the Directives 93/42/EEC & 2007/47/ EC, ie it 'administers or exchanges energy' to or from the human body. In respect of the RI Witness™ system, energy is emitted in the form of heat, to or from the AR sample. There is no direct patient contact.

*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 |
|---|---|
| 6-70-801 | Sit on Top Heated Work Area Assembly |
| 6-70-801/C | Sit on Top Heated Work Area Assembly with Card Reader |
| 6-70-801/T | Sit on Top Heated Work Area Assembly with Test Tube Reader |
| 6-70-801/TC | Sit on Top Heated Work Area Assembly with Card and Test Tube Reader |
| 6-70-802 | Flush Fitted Heated Work Area 1 Channel Assembly |
| 6-70-802/C | Flush Fitted Heated Work Area 1 Channel Assembly with Card Reader |
| 6-70-802/T | Flush Fitted Heated Work Area 1 Channel Assembly with Test Tube Reader |
| 6-70-802/TC | Flush Fitted Heated Work Area 1 Channel Assembly with Card and Test Tube Reader |
| 6-70-803 | Slim Heated Work Area Assembly |
| 6-70-803/C | Slim Heated Work Area Assembly with Card Reader |
| 6-70-803/T | Slim Heated Work Area Assembly with Test Tube Reader |
| 6-70-803/TC | Slim Heated Work Area Assembly with Card and Test Tube Reader |
| 6-70-804 | Flush Fitted Heated Work Area 2 Channel Assembly |
| 6-70-804/C | Flush Fitted Heated Work Area 2 Channel Assembly with Card Reader |
| 6-70-804/T | Flush Fitted Heated Work Area 2 Channel Assembly with Test Tube Reader |
| 6-70-804/TC | Flush Fitted Heated Work Area 2 Channel Assembly with Card and Test Tube Reader |

| Part Number | Description |
|---|---|
| 6-70-805 | ITO Reader |
| 6-70-805/C | ITO Reader with Card Reader |
| 6-70-805/T | ITO Reader with Test Tube Reader |
| 6-70-805/TC | ITO Reader with Card Reader and Test Tube Reader |
| 6-70-806 | Sit on Top Heated Work Area 2 Channel Assembly |
| 6-70-806/C | Sit on Top Heated Work Area 2 Channel Assembly with Card Reader |
| 6-70-806/T | Sit on Top Heated Work Area 2 Channel Assembly with Test Tube Reader |
| 6-70-806/TC | Sit on Top Heated Work Area 2 Channel Assembly with Card and Test Tube Reader |
| 6-70-852 | Sperm Preparation Work Area Assembly |
| 6-70-852/C | Sperm Preparation Work Area Assembly with Card Reader |
| 6-70-853 | Unheated Work Area Assembly |
| 6-70-853/C | Unheated Work Area Assembly with Card Reader |
| 6-70-853/T | Unheated Work Area Assembly with Test Tube Reader |
| 6-70-853/TC | Unheated Work Area Assembly with Card and Test Tube Reader |

## Compatibility

RI Witness™ is used in conjunction with the following:

- Essential medical devices - dishes and tubes, maybe AR or not-AR specific.
- Non essential medical devices - safety cabinets, incubators, micromanipulators, lasers.
- Non medical devices (general laboratory equipment), eg work benches, microscopes, PCs.

## Installation

Installations of RI Witness™ 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™, 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.

## 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 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 his 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<br>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<br>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<br>IEC 61000-3-2 | Not applicable | |
| Voltage fluctuations/<br>flicker emissions<br>IEC 61000-3-3 | Not applicable | |

## Guidance and Manufacturer's Declaration — Electromagnetic Immunity

| IMMUNITY Test | IEC 60601 Test level | Compliance level | Electro magnetic environment - guidance |
|---|---|---|---|
| Electrostatic discharge (ESD)<br>IEC 61000-4-2 | ± 6 kV contact<br>± 8 kV air | ± 6 kV contact<br>± 8 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<br>IEC 61000-4-4 | ± 2 kV for power supply lines<br>± 1 kV for input/output lines | ± 2 kV for power supply lines<br>± 1 kV for input/ output Lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge<br>IEC 61000-4-5 | ± 1 kV line(s) to line(s)<br>± 2 kV line(s) to earth | ± 1 kV differential Mode<br>± 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<br>IEC 61000-4-11 | <5 % UT<br>(>95 % dip in UT ) for 0.5 cycle<br>40 % UT<br>(60 % dip in UT) for 5 cycles<br>70 % UT<br>(30 % dip in UT) for 25 cycles<br><5 % UT<br>(>95 % dip in UT)<br>for 5s | <5 % UT<br>(>95 % dip in UT) for 0.5 cycle<br>40 % UT<br>(60 % dip in UT) for 5 cycles<br>70 % UT<br>(30 % dip in UT) for 25 cycles<br><5 % UT<br>(>95 % dip in UT)<br>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<br>(50/60 Hz)<br>magnetic field<br>IEC 61000-4-8 | 3A/m | 3A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |

**Note:** *UT* 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 | Electro magnetic environment - guidance |
|---|---|---|---|
| Conducted RF IEC 61000-4-6<br><br>Radiated RF IEC 61000-4-3 | 3 Vrms<br>150 kHz to 80 MHz<br>3 V/m<br>80 MHz to 2.5 GHz | 3 Vrms<br><br>3 V/m | Portable and mobile RF communications equipment should be used no closer to any part of RI Witness™, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>Recommended separation distance<br>$d = [3.5/V_1] \sqrt{p}$<br>$d = [3.5/V_1] \sqrt{p}$ *80MHz to 800MHz*<br>$d = [3.5/V_1 \sqrt{p}$ *800MHz to 2.5GHz*<br>where *p* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:  |

**Note 1:** At 80 MHz and 800 MHz, the higher frequency range applies.

**Note 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

**Note 3:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which RI Witness™ is used exceeds the applicable RF compliance level above, RI Witness™ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating RI Witness™.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V] V/m.

## Safety/Information Symbols

| Symbol | Meaning |
|---|---|
|  | Indicates instruction for disposal of goods. |
| 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 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. |
|  | Follow instructions for use. |
| SN | The first four digits are a unique identifier assigned to the product and the last 2 digits signify the year of manufacture, eg 5001/13 (this denotes a unique serial number of 5001 and a year of manufacture of 2013). |
| Rx Only | Caution: US Federal law restricts this device for sale to or on the order of a licensed healthcare practitioner. |

## 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 on the control unit display if the currently selected temperature cannot be maintained.

A touch screen warning triangle will also be shown if temperature control has been disabled using the Turn Off button.

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.

## Mains Power Supply

Products from RI require a stable and noise free power supply ( 100V - 240V ). The supply must provide an earth connection.

The RI Witness™ control unit for heated readers contains a mains power supply.

**Do not remove the cover from any RI Witness™ product.**



## RFID Reader Environment

An RI Witness™ system uses readers to monitor a work area. Readers detect RFID tagged containers that are placed in the work area.

Each reader is individually tuned to its environment and must not be repositioned after installation. The performance of RFID tag detection may be compromised by repositioning readers and by the proximity of metal objects or electrical equipment that were not present during installation.

For cleaning, readers may be lifted and returned to the same position. See “Cleaning” on page 100 for more cleaning details.

**Do not move readers.**
**Do not place metal objects near readers.**
**Do not place electrical equipment near readers.**
**Do not disconnect readers.**
**Do follow the startup/shutdown procedures.**

## Startup / Shutdown Procedure

RI Witness™ hardware may be damaged by incorrect startup and shutdown procedures.

“Section 5 - RI Witness™ Basic operation” describes the recommended startup and shutdown procedure for the RI Witness™ work area.

# SECTION 4 - PRODUCT OVERVIEW

Welcome to the User Manual for the Research Instruments (RI) RI Witness™ System.

RI Witness™, Data Capture, Traceability, Imaging and Cryo are members of the RI Witness™ family of products. RI Witness™ products share a common database usually referred to as the “Witness” database.

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 containing samples of incompatible origin come into contact at any stage of this process, the system activates an alarm and prompts the clinician to respond.

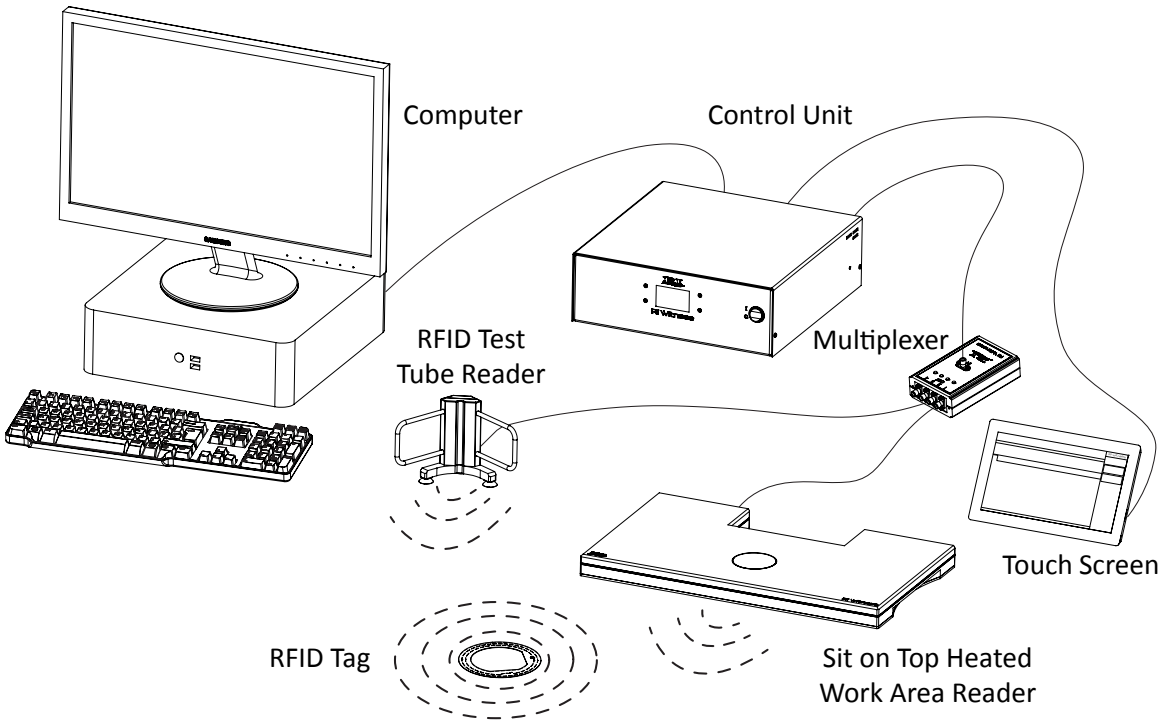


*Figure 4-1 RFID tag communicating with various antennas*

An antenna is incorporated into a work area reader. A control unit feeds an RF signal to the antenna. An RFID tag is passive until energised by the signal from the antenna. The energised tag then transmits an identification code back to the same antenna. See Figure 4-1.

An AR procedure is conducted within the monitored work area. The procedure is defined by a sequence of Witness Points which are presented on the touchscreen.

## Data Capture

Hand written notes are often taken whilst performing laboratory procedures. For example embryo scores and sperm volumes might be written down on a data sheet and later manually transcribed into a clinic fertility database.

The features of Data Capture allow data sheets to be designed in RI Witness™ Manager and data entry to be performed in the laboratory using the work area touch screen. See Figure 4-2.

Data entry may also be performed in RI Witness™ Manager.


*Figure 4-2*
*Lower: Data entry using a RI Witness™ WorkArea touchscreen*
*Upper: Data sheet design using RI Witness™ Manager*

## Imaging

With the Imaging feature, you are able to capture images and videos from every microscope in the laboratory, at every stage of the patient cycle, in real time. All the latest information on a cycle can be accessed immediately from any networked PC. Images can also be sent to the embryo room to show the patient prior to embryo transfer.

The Imaging feature is compatible with RI Integra™ and Saturn™ lasers.


*Figure 4-3 Example of patient view shown in embryo room*

## Traceability

Traceability is a software product that links patient treatment cycles with the batches of materials that are in use.

A barcode reader may be used to scan batches as they are delivered or made ready for use.

The links between treatment cycles and material batches may be explored to generate various reports, for example a report showing all patients that have been exposed to a particular material batch.

## Cryo

The Cryo feature extends the RI Witness™ security system, allowing patient samples to be tracked as they enter and leave cryo storage, creating a complete record of the patient cycle.

A barcode reader is placed at the work area and used to scan a sample in or out of the cryo storage.

## RI Witness™ Work Area


*Figure 4-4 An RI Witness™ work area*
*RFID tagged items are displayed on a touchscreen running RI Witness™ WorkArea software.*

A typical RI Witness™ work area includes a PC, touchscreen, one or more tag readers and an RF control unit. The work area PC runs RI Witness™ WorkArea software to present an operator interface on the touch screen. See Figure 4-4.

The data presented on the touchscreen is generated from the shared Witness database, all work area events are logged to the shared Witness database.

## RI Witness™ Manager for Traceability, Data Capture and Imaging

RI Witness™ Manager runs on any Windows PC and provides Witness, Data Capture, Cryo, Traceability and Imaging functionality.

The “patients” RI Witness™ Manager page is used by all operators, the “materials” RI Witness™ Manager page is unique to Traceability operators and the “witness points” page is unique to Witness operators. See Figure 4-5.

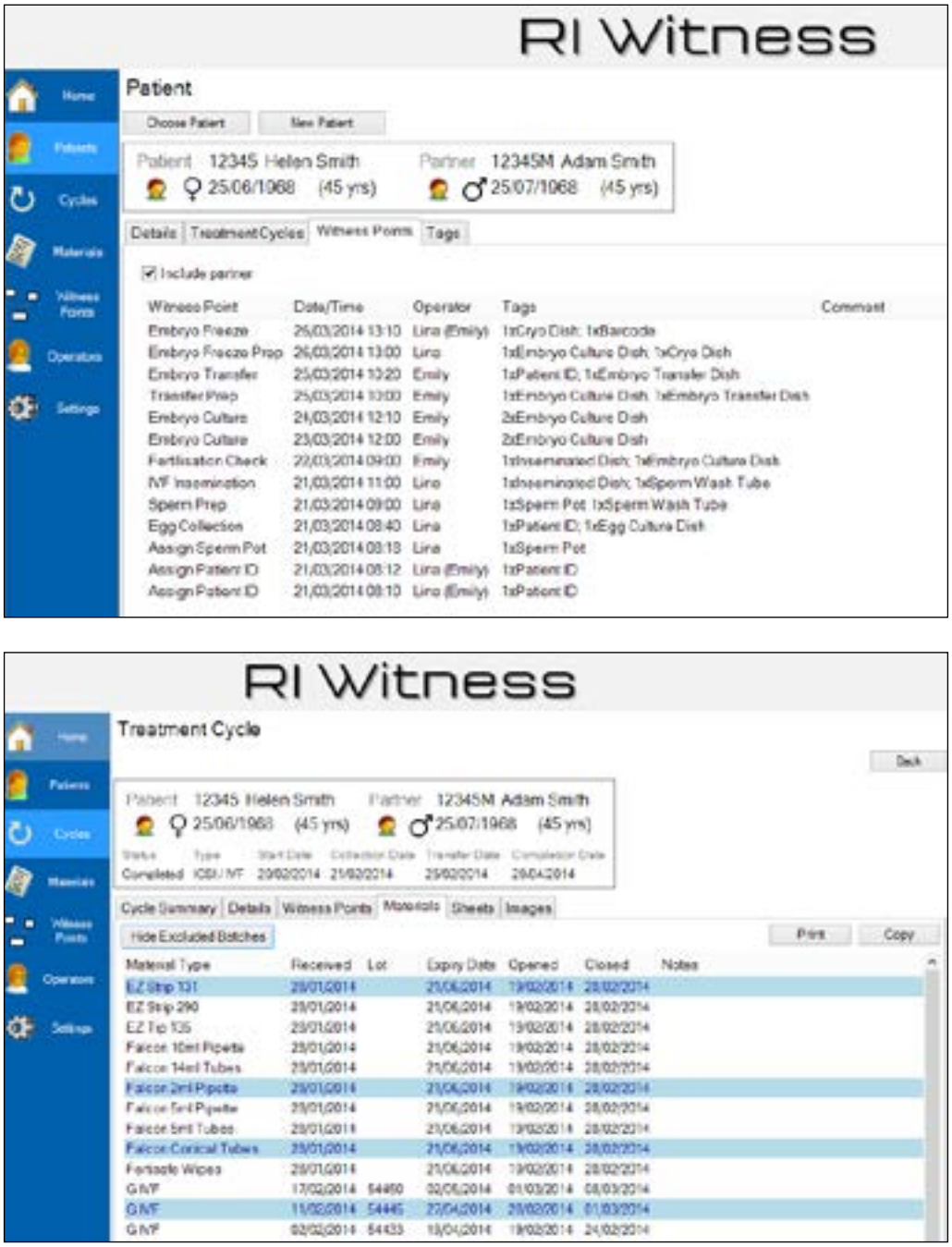


*Figure 4-5 RI Witness™ Manager is used by RI Witness™, Data Capture, Traceability, Imaging and Cryo*

## The Shared RI Witness™ Database

An example RI Witness™ installation is shown in Figure 4-6. Four work areas with RI Witness™ WorkArea software, two RI Witness™ Manager PCs and an admin reader PC share a common RI Witness™ database. Traceability, RI Witness™ and Data Capture management functions may be performed at each RI Witness™ Manager PC.

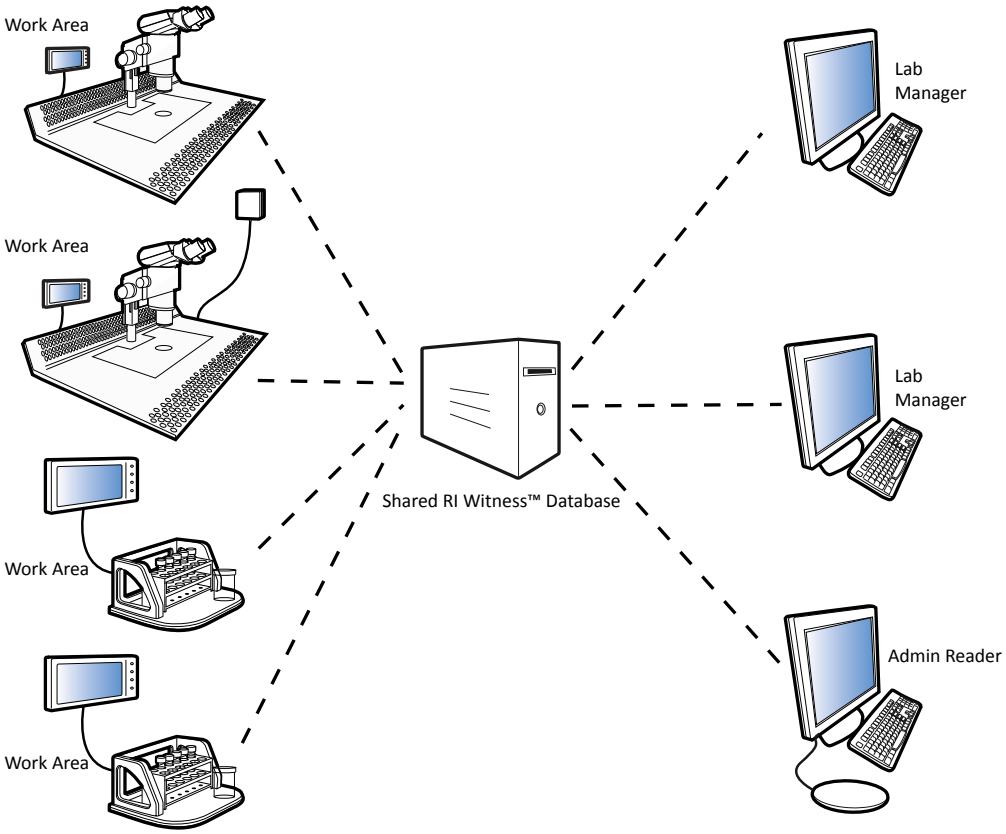


*Figure 4-6 The RI Witness™ database is shared by All RI Witness™ WorkArea and RI Witness™ Manager PCs*

## RFID Overview

Radio-frequency identification (RFID) is the technology used by RI Witness™ to identify tagged plasticware.

A control unit feeds an RF signal to a matched antenna. An RFID tag is passive until energised by the signal from the antenna. The energised tag then transmits an identification code back to the same antenna. See Figure 4-1.

An RFID system works on the principle of inductive coupling, which requires that the antenna be tuned to match the frequency in use and optimised for the physical environment. Specific cable lengths must be used for all RF connections.

Each RI Witness™ work area requires a computer, a control unit and at least one antenna. Multiple antenna work areas require a multiplexer to switch the RF signal between antennas.

Antennas are built into RI Witness™ Readers.

# Hardware Overview

## Work Area Reader Types

Readers detect RFID (Radio Frequency Identification) tags using tuned antennas. The test tube reader (2 axis) and the sperm preparation reader (3 axis) use one tuned antenna for each axis. All other readers use a single tuned antenna.

A flush fitting variant of the heated reader is available, this is integrated into the surface of the safety cabinet for ease of use. Legs can be fitted to allow further integration with other light bases.



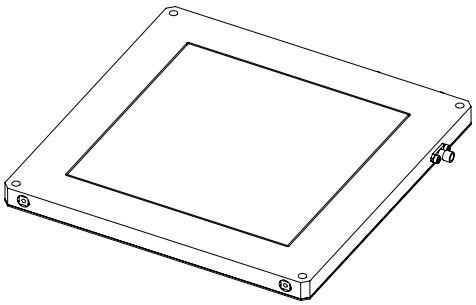

*Figure 4-7 ITO reader*

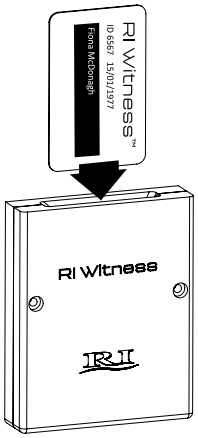


*Figure 4-8 Card reader*

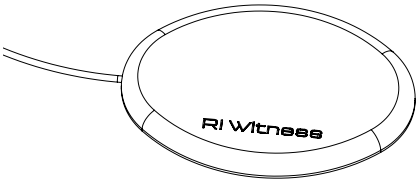


*Figure 4-9 Admin reader*

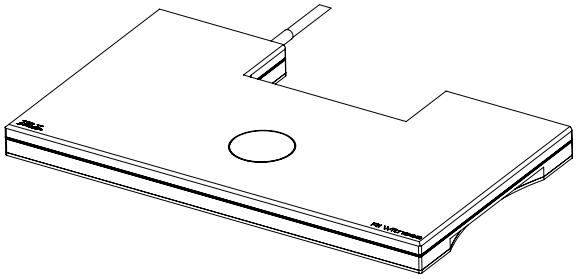

*Figure 4-10 Sit on top heated reader*

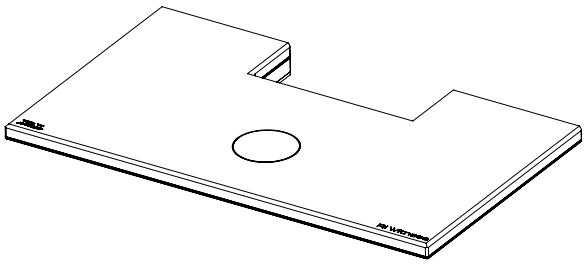

*Figure 4-11 Sit on top unheated reader*

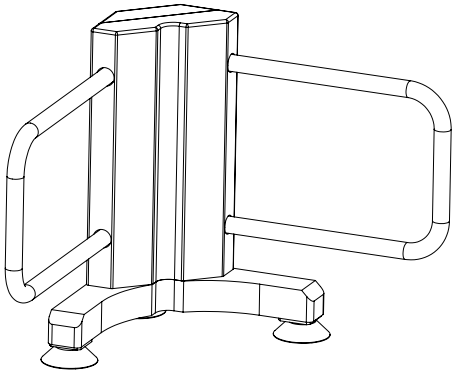

*Figure 4-12 RFID Test tube reader*

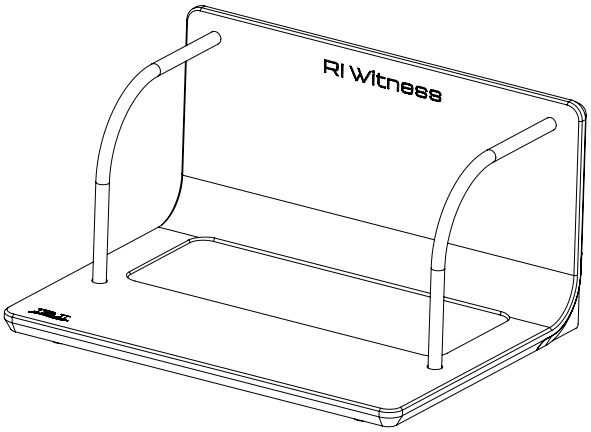


*Figure 4-13 Sperm preparation reader*

## Multiplexer

A multiplexer distributes RF power to multiple antennas. A multiplexer can feed up to four antennas.

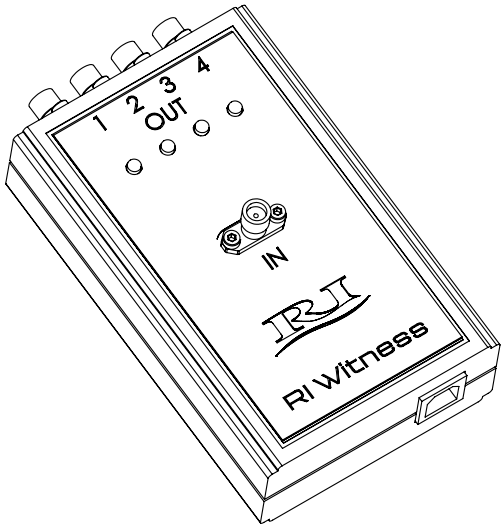


*Figure 4-14 An RI multiplexer*

## Control Units

Control units provide the RF power for readers. They may be used for heated or non-heated work areas depending on the procedures conducted there.

## Unheated Control Unit

The unheated control unit may be used with a multiplexer to drive up to four antennas.

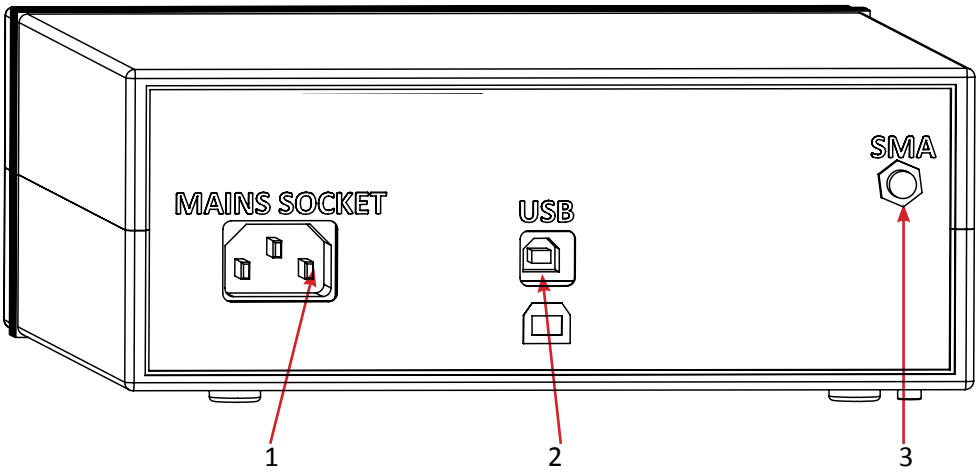


*Figure 4-15 Back panel of unheated control unit*

**Connections:**

1. Mains socket
2. USB to PC
3. RF Coaxial OUT to multiplexer or heated reader

## Heated Control Unit

The heated control unit contains a temperature controller and may be used with a multiplexer to drive up to four antennas.

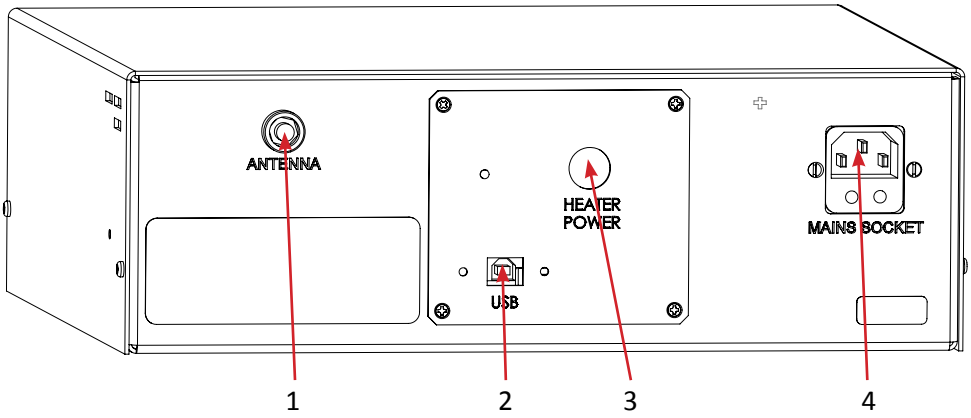


*Figure 4-16 Back panel of heated control unit*

**Connections:**

1. RF Coaxial OUT to multiplexer or heated reader
2. USB to PC
3. Heater cable to reader
4. Mains socket

## Auto Tuning Readers

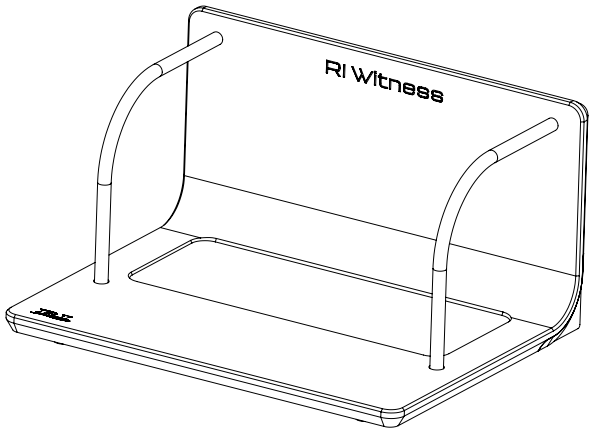


*Figure 4-17 Sperm preparation reader*

**Connections:**

1. Place the reader in the desired area
2. Remove the cable clamp
3. Connect the power supply
4. Connect the Mini-USB connector
5. Replace the retaining bracket and tighten screw
6. Connect the USB-A connector to the PC, Tablet or USB

Connections are made up of a USB A-B cable and a power supply. The power supply is a 12V power supply and is external to the device. The USB is a standard USB 2.0 cable. These are located on the rear of the device and held in place by a retaining bracket and screw.

## RF Calibration

Calibration of the RI Witness™ Sperm Prep Reader is made a lot simpler by having an automatic tuning system. The procedure for this is as follows.

1. Open RI Witness™ WorkArea. Make sure the RFID reader and Multiplexer are detected.


*Figure 4-18*

2. Click the **Change Settings** button on the bottom right of this window.
3. From this you will see the Workarea Settings window. Click on the RFID Reading tab to bring up the RFID Configuration Window.

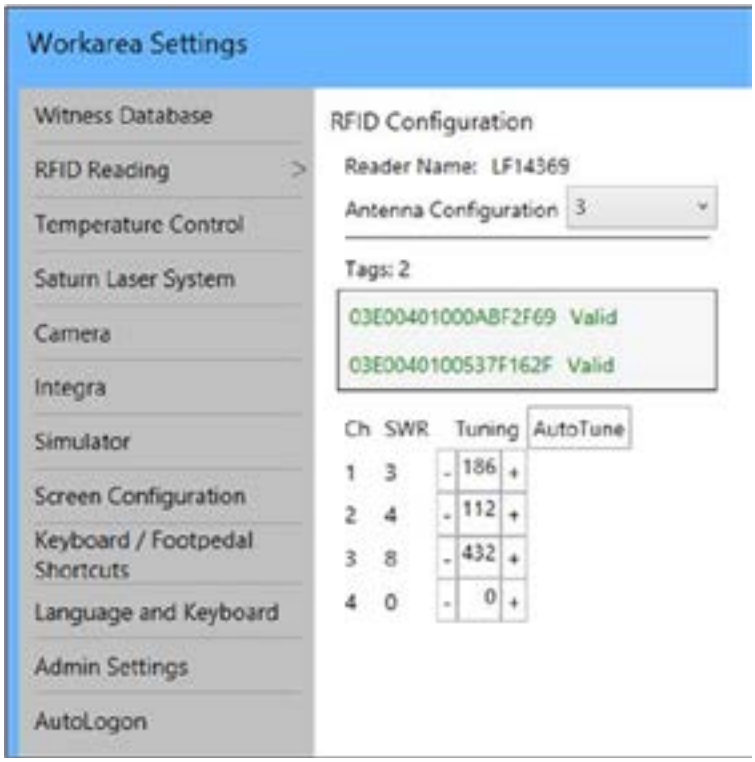


*Figure 4-19*

4. For the Sperm Prep, set the Antenna Configuration to 3. The next thing to do is to click on **Autotune**. This will tune the antennas for the area they are situated in. Every time the device is moved this will need to be done. This will take a few moments but when done the SWR for each channel should show a value of 1-50. If there are any RI tags in the work area, then they will be displayed in the grey box. You are now ready to use the RI Witness™ Sperm Prep Reader.

## RI Witness™ Work Area Specification Table

| Part | Description |
|---|---|
| Heating Systems* | Heated metal and glass. |
| Temperature Sensor* | Digital 14-bit SHT-15 or Analogue PT1000. |
| Displays* | LCD Display. Accurate to 1 decimal place. |
| Connectivity | USB Type B socket for connection to PC. Connected PC to be compliant with IEC 60950-1. |
| Supply Voltage | 100-240VAC, 50-60Hz, Max. 2.6A, Class I. |
| Operating Temperature* | Temperature: 10°C (50°F) to 42°C (107.6°F).<br>Humidity: 15% to 85% RH (Non Condensing). |
| Heater Channels* | 2 Channel 1 22VDC at 6A Max. Channel 2 22VDC at 1A max. |
| RFID | 50Ω Load at 13.56Mhz 1.4W Max. I-4 Antennas. |

*For heated work areas only

# SECTION 5 - RI WITNESS™ BASIC OPERATION

## Introduction

RI Witness™ uses one or more readers to monitor RFID tagged containers in a work area.

The work area interface is presented on a touch screen. See Figure 5-1. The operator touches screen buttons to log in and select Witness Points.



*Figure 5-1 The RI Witness™ WorkArea interface is presented on a touch screen*

# RI Witness™ RFID tags

## Tagging Plasticware

Before use in the work area, all plasticware must be RFID tagged and labelled with patient identity.

Rectangular, circular and square tags are available. See Figure 5-2. The sample identity may be assigned to the RFID tag once the tagged plasticware is placed in a RI Witness™ work area.

## Dishes and Pots

RFID tags must be positioned on the base of dishes and pots. The square tag, positioned diagonally, is recommended for a four well dish.

**Do not pre assign. Identity should be assigned as samples are transferred into the plasticware.**

**If tagging plasticware in advance of procedures, it is recommended that you test the tag on a reader prior to transferring patient sample.**

## 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.

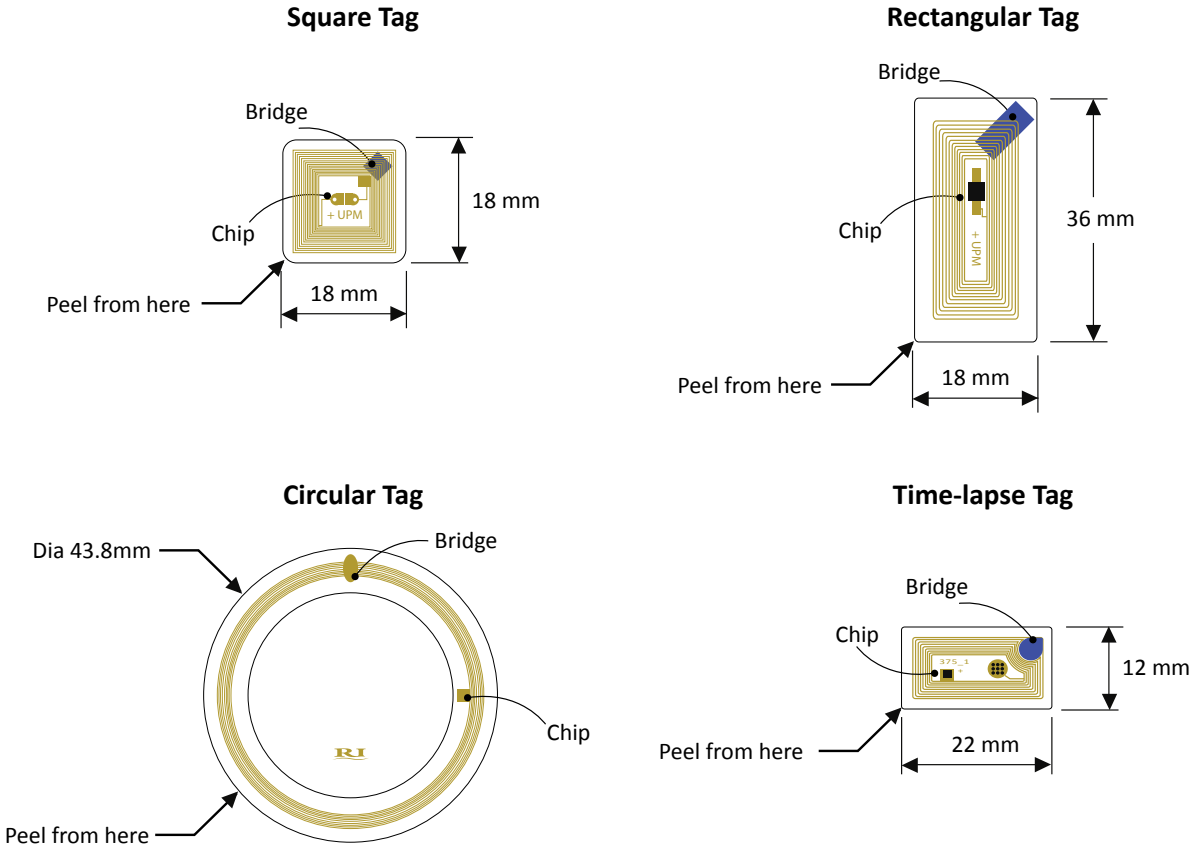


*Figure 5-2 RI Witness™ tags*

## 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.

1. Start peeling the backing strip away at the “peel from here” point shown in Figure 5-3 to achieve a peel line as shown.

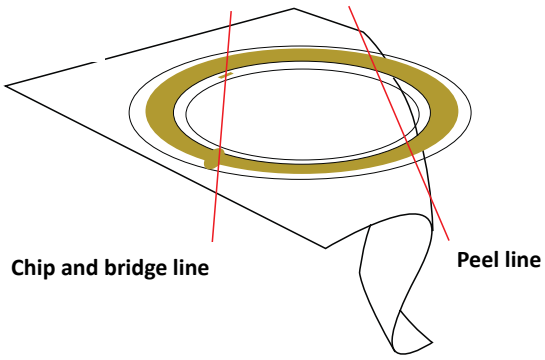


*Figure 5-3*

2. 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. See Figure 5-4.

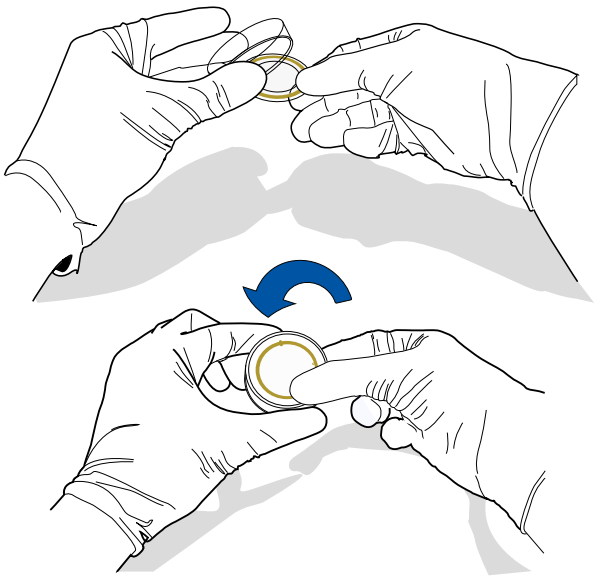

*Figure 5-4*

## 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 a RI Witness™ reader is located.

## How to Switch On

RI suggests that you keep the RI Witness™ computers and work areas switched on. This means that the heating and monitoring is constant.

If you have switched off a heated RI Witness™ work area, please allow 45 minutes for the work area to return to the required temperature. Please check there is power at the wall socket, the PC and touch screen (or tablet) and control tower.

You may want to check the work area heating and touch screen calibration for accuracy before commencing work. See “Section 12 - Temperature Calibration” on page 97.

## System Information

The system information panel will show:

1. Version numbers for software and firmware
2. Work area location
3. Database version
4. Licensing status including Imaging dongle
5. RFID reader status and multiplexer
6. Temperature control status
7. Saturn™ Laser System status, serial number, firmware details
8. Camera status
9. Integra™ status


*Figure 5-5*

## To Open the System Information

1. Press the **Information** icon in the work area or click the **Settings** icon from the Imaging screen.
2. The System Information window shows the current state of the RI Witness™ system.
3. Indicates there is no problem.
4. Indicates a problem needs resolving.
5. In system Information, clicking on the closed **Padlock** at the bottom of the page will unlock all the existing configuration settings and also reveal the following settings that are hidden when the System Information is locked:
   - Keyboard / foot pedal controls
   - Auto logon
   - Language
   - Screen configuration



The System Information is locked by default and clicking on the **Padlock** again will re-lock the settings.

## How to Shut Down a Work Area

Do not switch off any RI hardware whilst the WorkArea software is running. To log out, select the user name, and then select **Quit** in the user name window. The system will then shut down. See Figure 5-8.

## Logging In

It is important to ensure that all RI Witness™ hardware is switched on before the work area software is activated.

The RI Witness™ software may be activated automatically when the computer is started. If not, double click the **RI Witness™ WorkArea** desktop icon.

*Figure 5-6 RI Witness™ WorkArea icon*

To log in either touch **Login,** then your username or scan your operator ID tag and enter the appropriate 4 digit PIN if requested.

**Note:** Operators can change the PIN assigned by the administrator and may assign an ID tag. See Figure 5-9.

## Auto Logon

After unlocking the system information, screen navigate to the auto logon section. There you can set up the username and password (of the machine) for RI Witness™ to auto logon the PC.

1. Click **System Information.**
2. Unlock settings.
3. Click **AutoLogon.**
4. Click **Yes** to the user **Account Control** message.
5. Enter the details required (contact IT department if unsure).
6. Click **Save to Registry.**
7. Tick **AutoLogon.**
8. Click the close window cross.

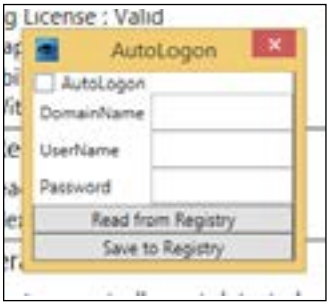


*Figure 5-7 AutoLogon*

On installation of the application the application shortcut is placed in the start-up. This causes the work area to automatically start with windows.


*Figure 5-8 Logging into RI Witness™*


*Figure 5-9 RI Witness™ WorkArea logon and PIN entry windows*

## Logging Out

Log out of the work area when you have finished your procedures by pressing your **Username** in the top right corner, then the **Red Cross** . An automatic logout may be programmed after a period of inactivity. This is set using the RI Witness™ Manager Settings page.

## The WorkArea Interface

The WorkArea interface screen is divided into 7 regions. See Figure 5-10 .

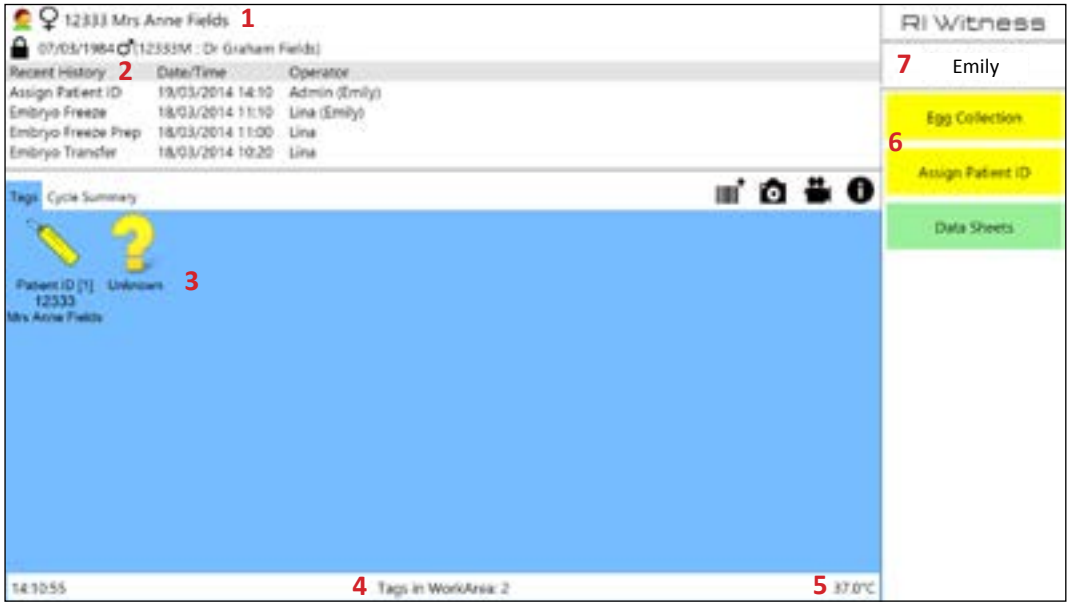


*Figure 5-10 The WorkArea interface*

1. **Current patient**
   This region shows the current patient name, date of birth and ID. When tags from both partners are present the name shown will be the female patient. The partner's name will appear in brackets.
2. **Recent history**
   The recent history region presents the four most recent actions that have been recorded against the current patient, eg witness points (action/protocol step), operator mismatches, etc. A timestamp and operator name are also shown.
3. **Work area**
   The work area region displays an icon for each RFID tag detected by the work area. As tags progress through the witness points of a procedure they are assigned and reassigned appropriately. A question mark icon will be shown for any tags that have yet to be assigned an identity by the RI Witness™ system.
4. **Status**
   The status region summarises the work area contents. It is recommended that the number of tags displayed in the status area is visually confirmed at each stage of a procedure to verify that each tag has been detected.

**Monitor the number of tags in the work area.**

5. **Temperature**
   For heated systems this region displays the temperature of the work area. Click the temperature readout to show a **Temperature Control** window from where the temperature may be set.

6. **Witness Points**
   The witness points region displays options available for the next step as specified by the lab defined protocol. The top one is the preceding action and the current contents of the work area determine what next steps are possible. An administrator will also see an **Admin Assign** option to assign or reassign dishes outside of the prescribed protocol.

7. **Current operator**
   The current operator region shows who is logged on. A suffix (Admin) is added for operators who belong to the administrator group. All witness points performed will be attributed to the operator who is logged in at that time.

## Performing A Procedure in RI Witness™

Bring the dish or tube you wish to work on into the work area. If the tag has been identified by RI Witness™ the patient and the history will be shown on the screen. The options for the next actions will be shown in yellow on the witness point region.

In the example shown below a “Sperm Wash Tube” and an “Egg Culture Dish” have been placed into the work area and RI Witness™ has determined that the only appropriate procedure is represented by the **IVF Insemination** witness point. See Figure 5-11.




*Figure 5-11 The IVF insemination witness point is the only match for the contents of this work area*

## Beginning a New Cycle in RI Witness™

The first step in the RI Witness™ procedure is when the identity card for the patient is assigned. This is the most important step in the protocol as if the identity of the patient is correctly assigned at this point, the security of the cycle is assured.

## Starting a New Procedure

1. To start a new procedure, log in then place one or more unassigned, tagged items into the work area (usually a patient ID card, egg collection dish or sperm pot). A yellow question mark will show that the tag has been detected and is unassigned. See Figure 5-12. Press the icon.
2. In the **All Patients** tab type the patient name or ID number to locate the correct patient in the database. See Figure 5-13.
3. Alternatively, the **Daily Lists** tab shows all Egg Collections and Embryo Transfers scheduled for the day. Click the patient cycle for either Egg Collection or Embryo Transfer, this will display the chosen patients details in the work area.
4. Choose which action you intend to register/perform and then click the **Confirm** icon again.
5. If a double check by another person has been set at this point, a 2nd Witness window will appear. This requires a colleague to verify the action by inputting their name and PIN. See “Double Witness Points” on page 30.




*Figure 5-12 Unassigned tag has been detected*

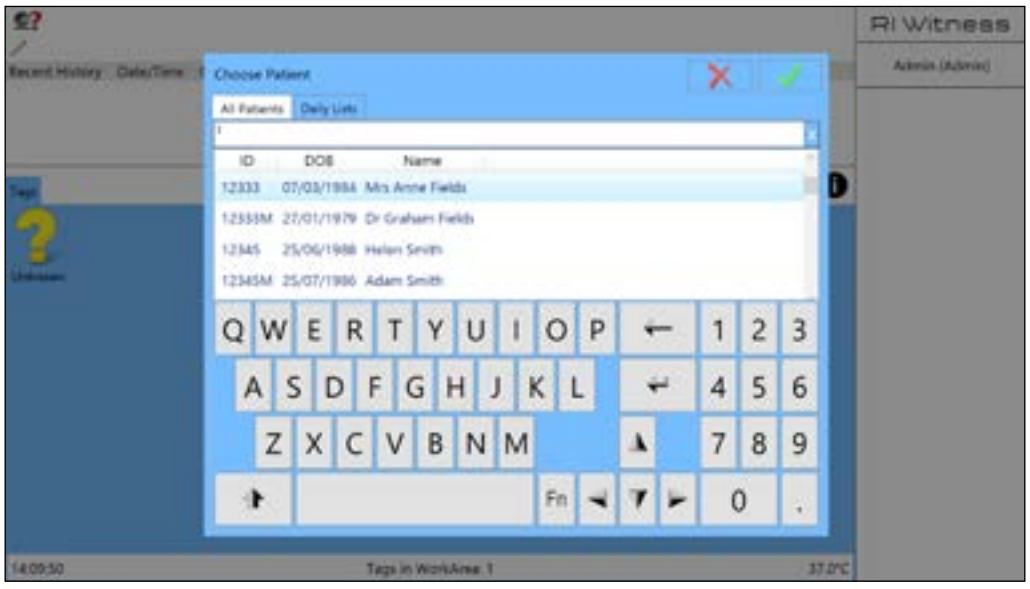


*Figure 5-13 Choose Patient/All Patients window to assign ID*

## Witness Point Confirmation

At every step in the procedure, a witness point (action) must be registered in the system. Therefore when an action is performed, select the relevant witness point and confirm by checking the details in the confirmation window and clicking the **Confirm** icon ✅ .

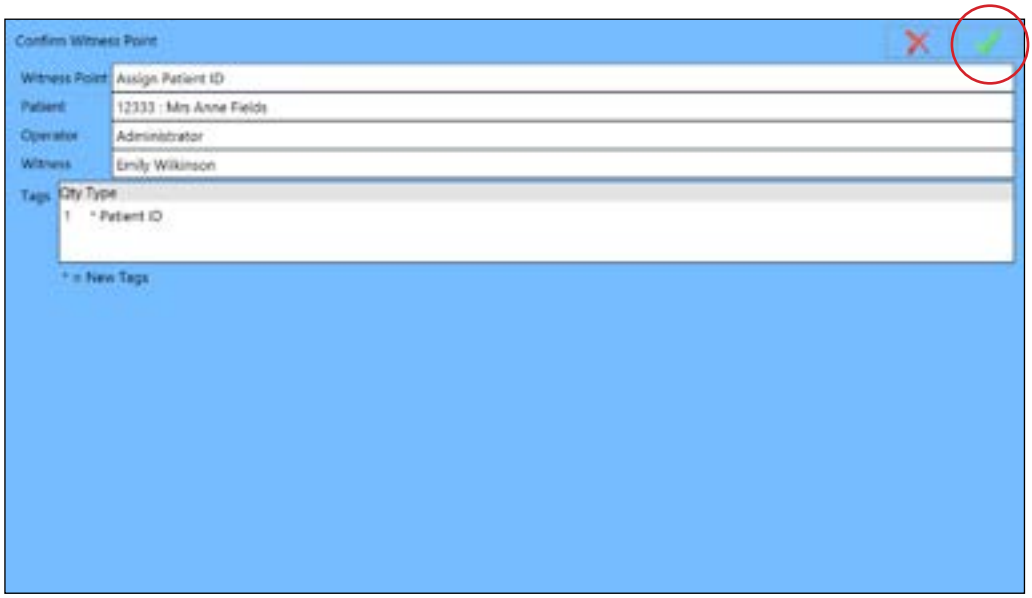


*Figure 5-14 Confirming a witness point*

## Double Witness Points

Critical points, as defined by the administrator, must be witnessed by a second operator. The second witness must enter their PIN. See Figure 5-15.


*Figure 5-15 A double witness point*

## Question Witness Points

Question Witness Points, as defined by the administrator, require a response from the operator. Examples of text and numeric questions are shown in Figure 5-16 and Figure 5-17.

The Witness Point question and the operator response is displayed during the final witness point confirmation window. The question and response also form part of the history logged for this event.

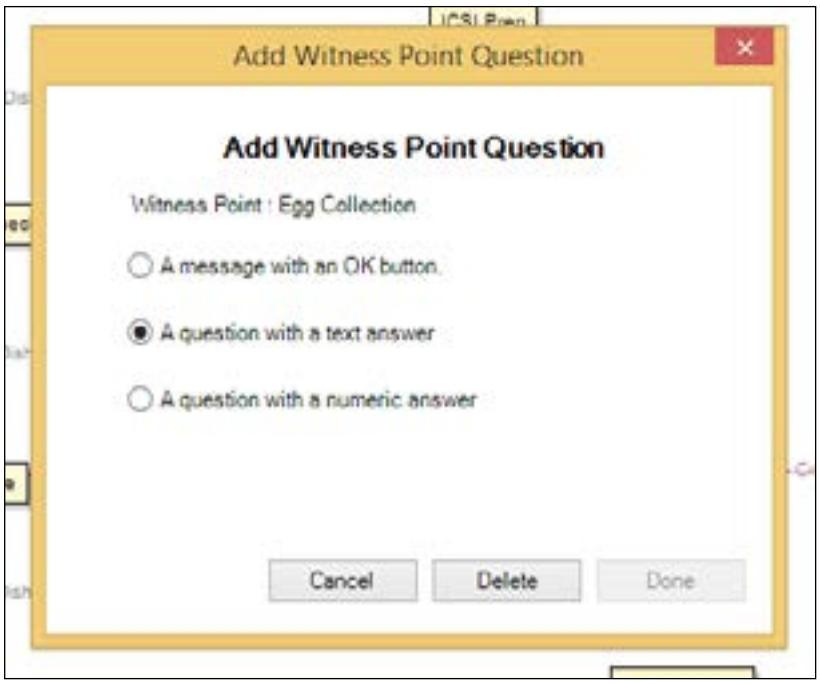


*Figure 5-16 Add witness point question*

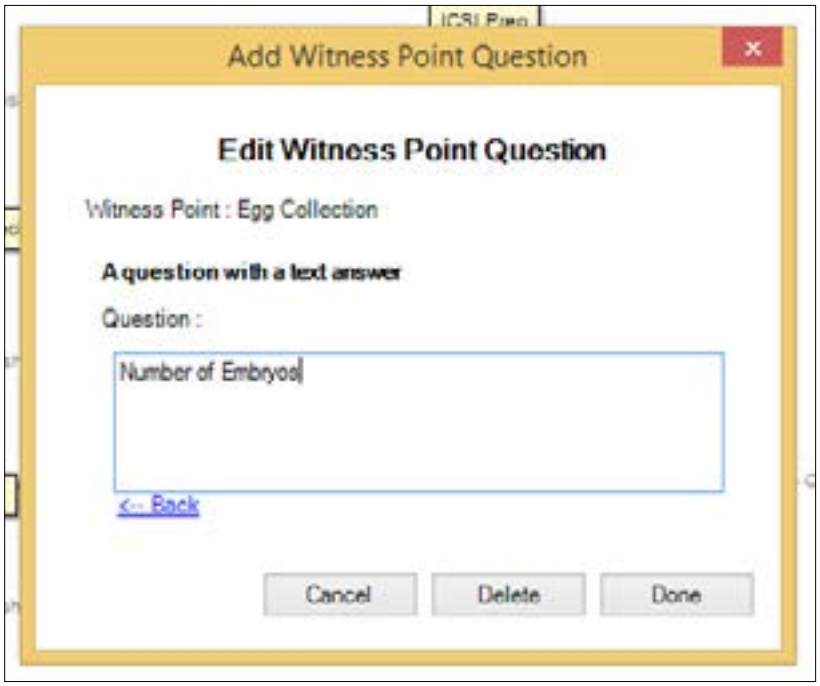


*Figure 5-17 Edit witness point question*

## Record Witness Points

Gather all the (tagged) plasticware that are required to perform a procedure and place them in the work area.

A window representing the work area will display all the tags and show the identity of any tags already “known” to the system.

An active patient is selected either manually or automatically; manually by clicking on the **Patient Details** section of the work area and choosing a patient from the list, or by the system automatically selecting the patient identified by the tags in the work area:

- If there is one patient in the work area then this is the current patient.
- If there are 2 patients in the work area who are male/female partners then the female patient is the current patient.
- If there are 2 or more patients after a donation where the patients are donor / recipient(s) then the donor is the current patient.

A list of possible witness points is shown, determined by the selected patient and visible tags. Choose the appropriate witness point.

If the witness point is a tagged donation type, then the recipient will need to be chosen from a list at this point.

If the witness point requires further information entered by the operator, then this will be asked for.

If the witness point requires a 2nd witness, then another operator will now need to choose their name and enter their PIN.

A confirmation window summarises all the details relating to the witness point that will be recorded. If all the details are correct, then selecting the tick will record the witness point.

If any new tags are added to the work area during the processing of a witness point (or admin assign) then the witness point will be cancelled. Also, if during the processing of a witness point one of the tags in the work area drops out of range of the reader(s), then the witness point can be completed and the tag(s) will be reassigned successfully.

## Unassigned Tags

The tags on unused plasticware are unassigned and are shown as a question mark icon in the work area display. See Figure 5-18. When selecting a witness point unassigned tags are automatically assigned to the patient currently displayed on the screen. They will be identified as the sample tag defined by the witness point.

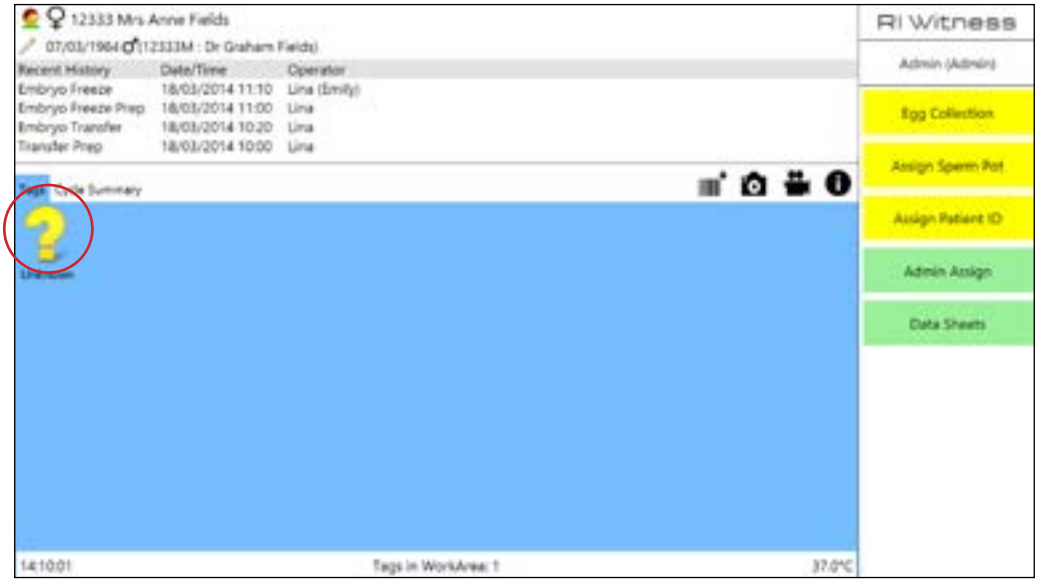


*Figure 5-18 The question mark icon represents an unassigned tag*

## Unassigned Tag Removal

A **STOP** warning is displayed when an unassigned tag is removed from the work area. See Figure 5-19. This message informs the operator that an unassigned tag entered and exited the work area without being registered in the current procedure. If that is correct select **Close** and continue. If not, replace the sample/labware in the work area and perform a witness point.


*Figure 5-19 Unassigned tag removal*



## Tag Mismatch

The RI Witness™ system will only allow one patient (with donor) or a couple's samples to be placed in a work area at any time. If an unlinked sample is placed in the work area, a continuous alarm will sound and a mismatch window will appear immediately. The **STOP** message is displayed.


*Figure 5-20 Tag mismatch*

1. Remove the samples in order to stop the alarm and select **Close** to close the window.
2. A mismatch reason window is displayed. The operator must enter an explanation for the mismatch before work can continue. The explanation will appear in both patients' cycle histories and will be visible in the RI Witness™ Manager software.

**Note**: If the mismatch occurred while no operator was logged in, an explanation for the mismatch is associated with the operator explaining but not the mismatch itself.

## Record Location of Tags

At each work area, a location name can be set through the System Information window that uniquely identifies that work area. In RI Witness™ Manager a list of all the configured locations can be viewed.

When a tag is placed into a work area, the location will be stored with the tag details; then when the tags associated with a patient are displayed, their last known location will also be displayed. See Figure 5-21.

The name of each work area can be configured initially by any user. An administrator can modify any location name. A list of locations can be seen in RI Witness™ Manager from where they can be disabled and enabled. Disabling a location will cause the related work area's name to be reset to Unknown so it can then be renamed by a user. Any disabled location can be re-enabled. This will set its name back to the previous value.

To name a work area:

1. When the work area is started initially you will be required to give the work area location a name. Any user can initially set the name of a work area. A red cross icon will appear as well as the **System Information** icon as a warning triangle.
2. Click the **Warning Triangle** to open system information.
3. Unlock the settings.
4. Click **WorkArea Location**.
5. Enter a location description/name.
6. Click the **Confirm** Icon  .

When a witness point is completed, the location at which it took place will be recorded.

**Note:** PCs connected to the RI database must have unique computer names, if connected to a domain this will be set, otherwise please check.

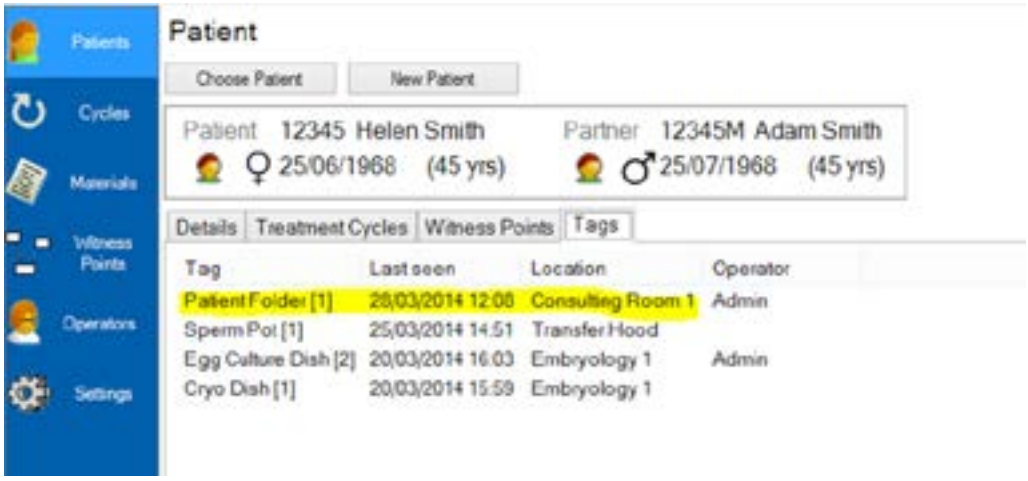


*Figure 5-21 Tags tab*

## Training Mode

For training and testing, any RI Witness™ work area may be set to Training Mode.

1. Log in as an admin operator.
2. Open **System Information**.
3. Select **Screen Configuration / Training Mode**.
4. Then tick the **Training Mode** box.

In Training Mode, the normal work area screen is replaced with an orange background. See Figure 5-22.

On logging out of Training Mode, the training work area events will automatically be deleted.

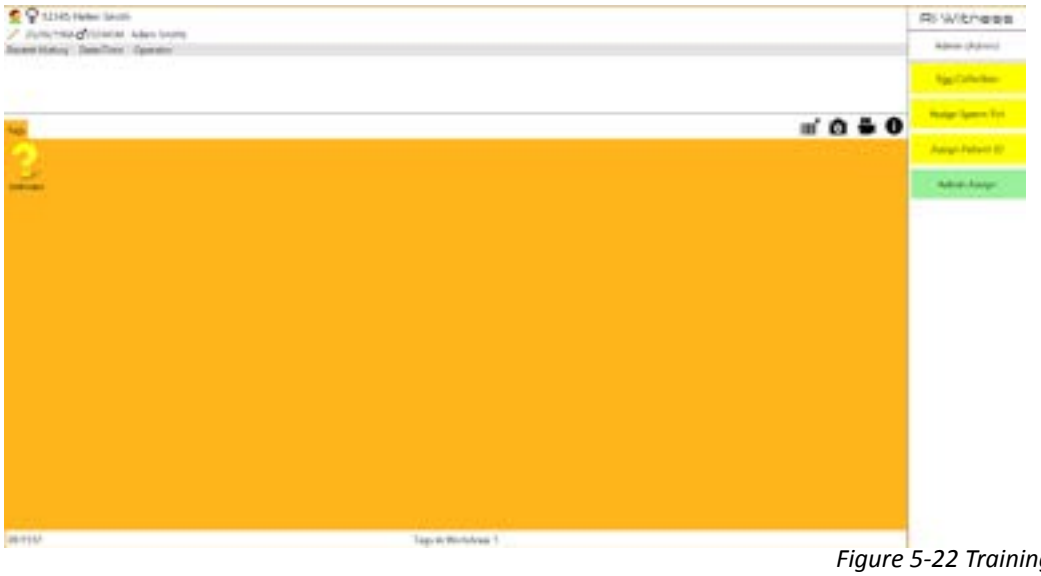

*Figure 5-22 Training mode*

## Clear Demo Tables (legacy work areas for pre software version 2.3 only)

Training work area events are stored in a demonstration database which may be cleared using RI Witness™ Manager. An admin operator may click **Clear Demo Tables** on the **General Settings** page of RI Witness™ Manager. Figure 5-23.

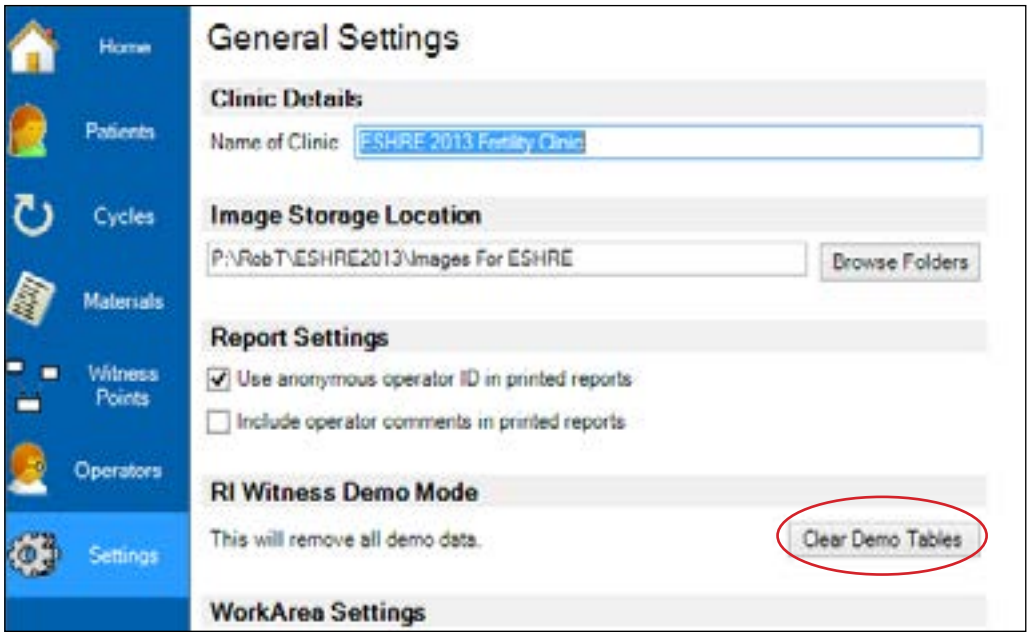


*Figure 5-23 The RI Witness™ Manager general settings page*

## Admin Assign

Designated operators may use the **Admin Assign** button, see Figure 5-24, to assign any tag type (sperm pot, inseminated dish, sperm wash tube, etc) to an unassigned tag at any point.

**Note**: Admin Assign should only be used under exceptional circumstances and by trained personnel only.

**Note:** With Admin Assign you can also change the type of dish already assigned to a patient.

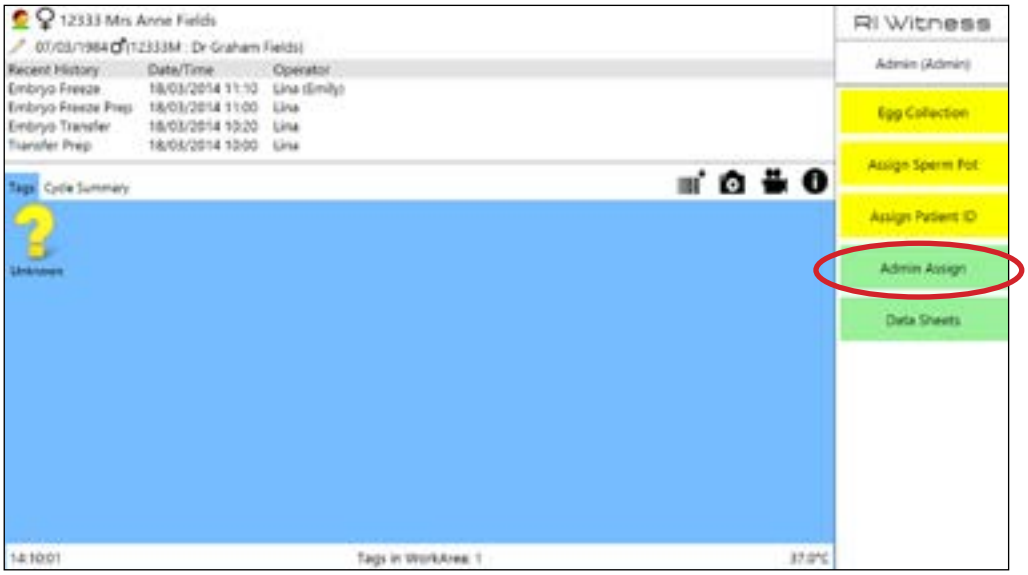


*Figure 5-24 Admin assign*

## Discards

When a single tag is placed in the work area the **Discard** button is enabled, see Figure 5-25. Pressing it will display a confirmation screen with a green tick and red cross. The **red cross** will cancel the discard and close the confirmation window, whilst the green tick will mark the tag as discarded - changing how it is displayed in the work area and preventing any witness points taking place whilst it is in the work area.

There is also the option from within RI Witness™ Manager to enable Discards to require a Witness. Once enabled, a witness will be prompted to log in on the screen following the operator selecting the **Discard** button, after a successful login the confirmation window will be displayed as usual.


*Figure 5-25 Discard*

*Figure 5-26 Confirm discard*


*Figure 5-27 Discard in the work area*



## Cycle Summary

The cycle summary is displayed in the work area at all times; it is a datasheet that has been selected to be shown from the RI Witness™ Manager. If a patient is not selected, or there is no cycle summary for a selected patient, the cycle summary display will say **"<No Details Available>"**. If the selected patient contains a cycle summary sheet, this sheet will be displayed in the **Cycle Summary** area.

## Daily Lists

On the patient select window, you can select the daily list which showing list of patients for today. The date is displayed in the top left of the window. To choose another date and view its related procedures, click on the left and right arrows at the top of the window. (The left arrow moves the date back one day and the right arrow advances the date by one day). To select a patient, click on the patient ID number.

## Windowed Work Area

For admin stations with admin readers, the WorkArea application can be windowed to allow easy access to the tag reading functionality.

1. Open the RI Witness™ WorkArea application.
2. Click **System Information.**
3. Unlock the settings.
4. Click **Screen Configuration** / **Training mode**.
5. Tick **Windowed WorkArea**.
6. Click **Save** and **Quit**.
7. If you have multiple screens set up, the work area will now revert to one single work area screen.

## Language and Keyboard Layout

After unlocking the system information screen, navigate to the Language and Keyboard settings. From there the language on-screen and keyboard style can be changed using a drop-down menu. If the selected item in either drop down menu is changed, then clicking the **red cross** will save these changes and modify the language and keyboard.

1. Click **System Information.**
2. Unlock the settings.
3. Select your required language from the drop down list.

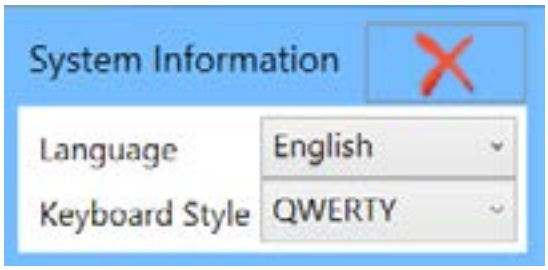


*Figure 5-28 Language selection*

4. Select your required keyboard style from the dropdown list.
5. Click the **red cross**  to save and close the window.

The language used can also be changed from RI Witness™ Manager

1. Click **Settings**
2. Choose your required language from the drop down list in the Language section

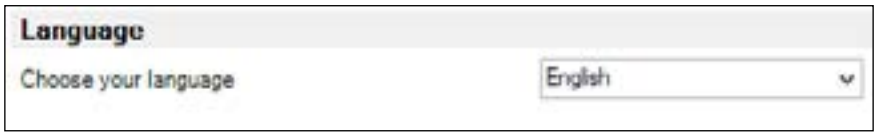


*Figure 5-29 RI Witness™ Manager Language Setting*

## Foot Pedal Control

In the work area the System Information Panel contains a **Keyboard / Foot Pedal Shortcuts** button which launches the **Keyboard Shortcut Configuration** dialog.

Within the keyboard shortcut configuration dialog, each available command is listed followed by an input box and clear button (with a cross).

To assign a keyboard shortcut to a command, click in the corresponding text / input box and then hold down the keys you want to assign to this command. The input box will change from “Please Enter Shortcut Key” to a list of the currently held down keyboard keys separated by +s. Once the keyboard keys are released those keys are saved to the input box.

Pressing the **Clear** button will remove the keyboard shortcut for that command.

In order to save these changes you must press the **Save and Quit** button at the bottom of the dialog.

In the work area, once the shortcuts are set up, simply press the shortcut keys to activate the command.

List of commands:

- Fire / Enter Laser Mode.
  - Enters laser control mode.
  - If already in laser control mode this command fires the laser.
- Preset Laser Down.
- Preset Laser Up.
- Start / Stop Recording.
- Take Picture.
- Zoom In / Zoom Out.
  - Zooms out fully if already zoomed in.
  - If zoomed out zooms into pre-set zoom value at centre.
- Zoom In.
  - Zooms into centre one step.
- Zoom Out.
  - Zooms out from centre one step.
- Freeze Frame.



**Please Note:** Shortcut keys should be limited to the function keys to avoid conflicts with typing or barcodes.

## To Rename the Work Area

1. Log in as an Admin user.
2. Click **System Information.**
3. Click **WorkArea Location.**

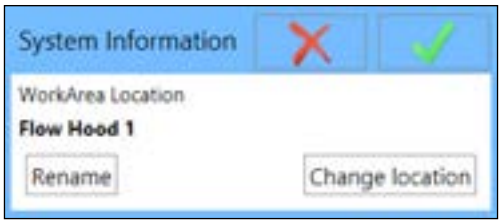


*Figure 5-30*

4. Type the name of the work area using the on screen keyboard.
5. Click the **Confirm** Icon.

*Figure 5-31*

## To Change the Location of a Work Area

1. Log in as an Admin user.
2. Click **System Information**.
3. Click **WorkArea Location**.
4. Click **Change Location.**
5. Choose the location required from the list or click **Create New Location** to set another location name.
6. Click the **Confirm** Icon to accept the change.

## To View Work Area Locations or Disable a Work Area

1. Open RI Witness™ Manager.
2. Click **Settings**.
3. Click **WorkArea Locations**, you will now see all named work area locations.
4. Highlight the work area and click **Disable**.
5. Disabled accounts can be viewed by ticking **Show Disabled Accounts.**


*Figure 5-32*

## Alarm if Tags Left in Work Area

To help avoid mismatches being recorded – “Card Left in Reader”.

1. Open RI Witness™ manager.
2. Click **Settings**.
3. Click **General Settings**.
4. Under work area settings tick **Warn on logout if tags left in WorkArea.**

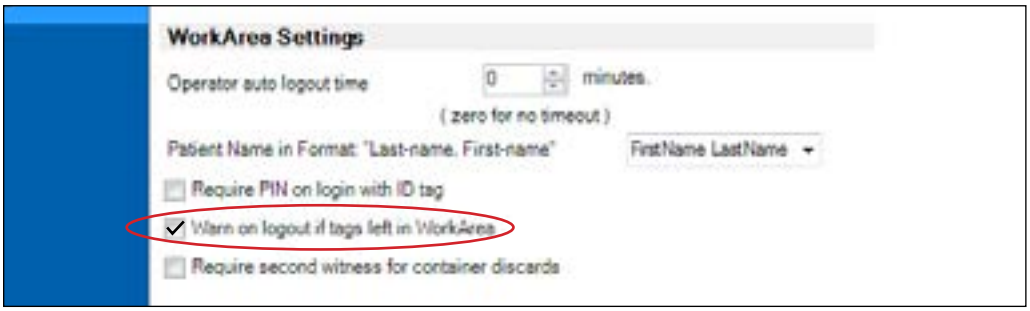


*Figure 5-33*


RI Witness
Please choose your user name
Admin
Emily
Lina
RobW
Trystan
STOP
Tag(s) left in WorkArea?
Close
Quit

*Figure 5-34*

# SECTION 6 - RI WITNESS™ MANAGER

RI Witness™ Manager can be used on PCs or tablets outside of the RI Witness™ work areas, predominately for administration purposes.

## Logging In

1. Double click the **RI Witness™ Manager** desktop icon.
2. Choose your assigned operator name from the list.
3. Enter your 4 digit PIN.
4. Click **Login**

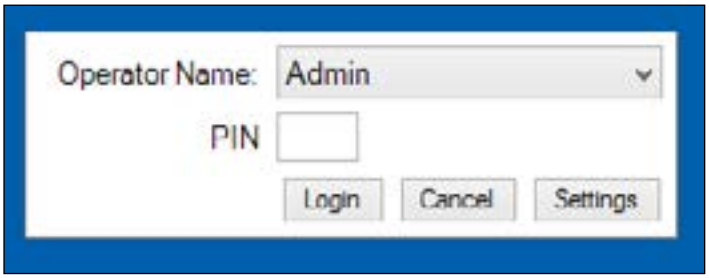


*Figure 6-1 Logging in*

## License Management

RI Witness™, Traceability, Data Capture, Cryo and Imaging must be licensed.

Licensing information is stored in the shared RI Witness™ database.

**On first use of RI Witness™ Manager a license warning window will be shown.**

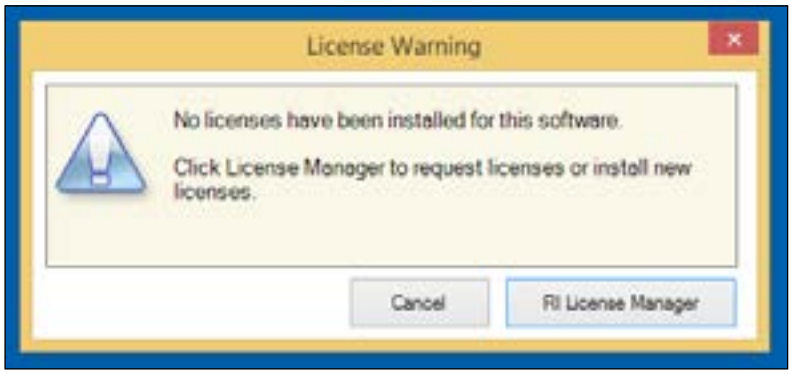


*Figure 6-2 License warning*

On each subsequent use of RI Witness™ Manager, a license check is made and a similar license warning window will inform the operator if any licenses are close to expiration.

At any time, the RI License Manager may also be invoked as a separate application by clicking **Settings** and then RI License Manager.

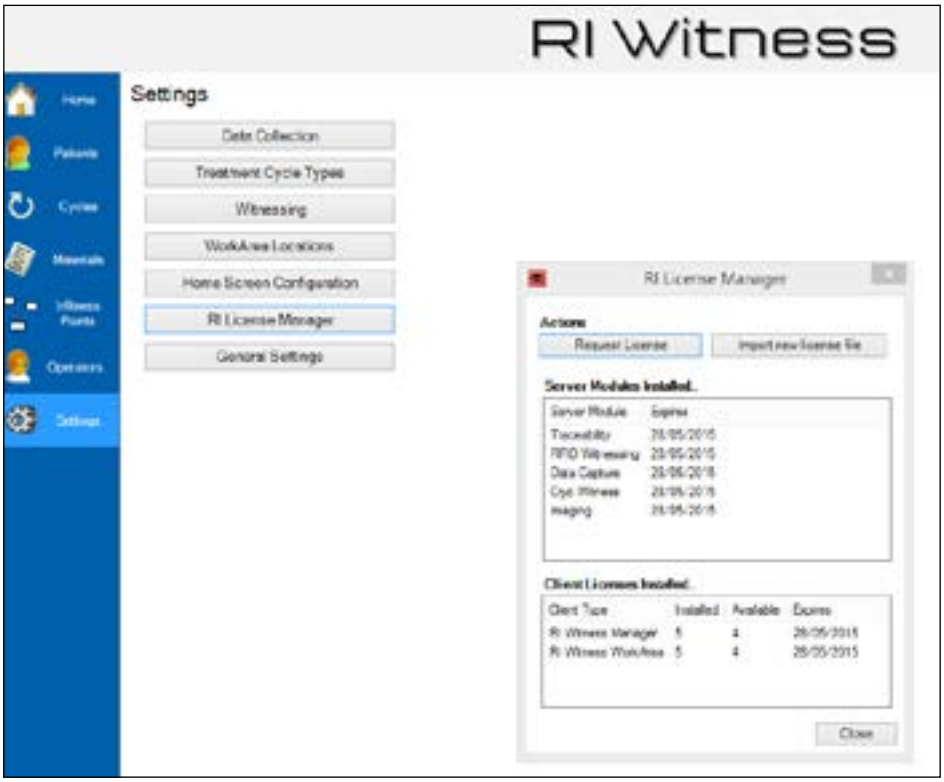


*Figure 6-3 RI License Manager*



## License Request Form

If your license is close to expiration, you can quickly renew your license.

1. Click **License Manager** in the RI Witness™ Manager license warning window. A license request form will open. See Figure 6-4.
2. Complete the details on the form.
3. If you have a Registration Code issued by RI, enter it at the bottom of the form.
4. Click **Send Request** after completing all the fields.
5. If internet access is available, a response will be returned by the RI Licensing Server. See Figure 6-5.


*Figure 6-4 The license request form*

6. If internet access is not available, please follow the displayed instructions to save a license request file. The file should then be emailed to RI at activate@research-instruments.com.
7. Once RI has received your request, a License Data file will be emailed by return.

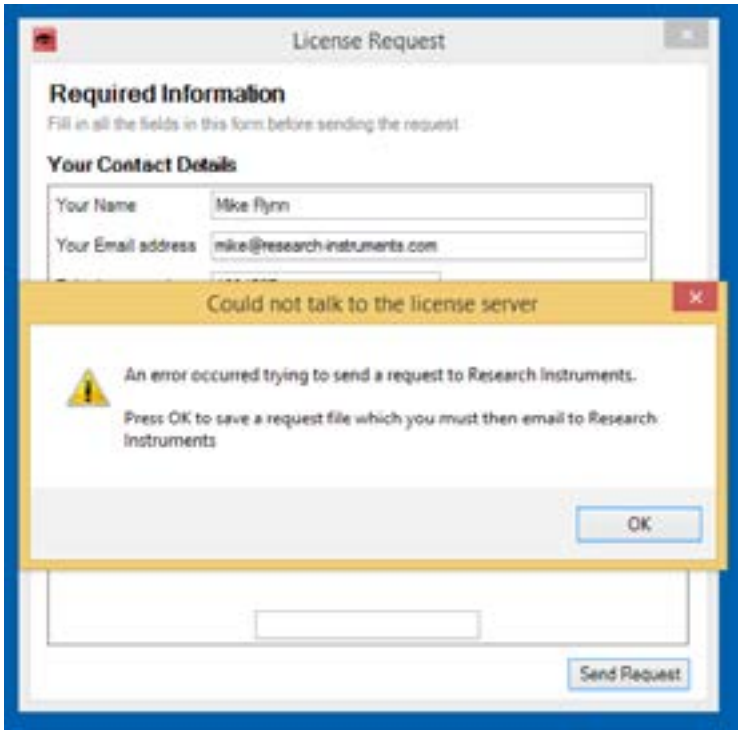


*Figure 6-5 A response from the RI license server*

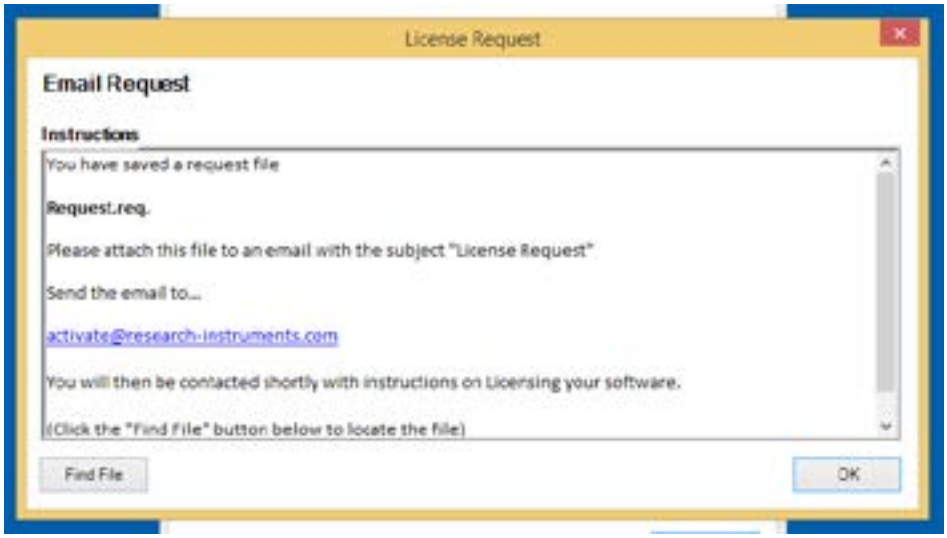


*Figure 6-6 The license request email*

8. The License Data file should be made available to the RI Witness™ Manager PC where licensing is performed.
9. Each time RI Witness™ Manager is opened following license request, License Manager window will be displayed. See Figure 6-7.
10. On receipt of the License Data file, click **Import New License File** in the license manager dialogue box. Browse to the emailed license data file and select. The License Manager will now be updated with the new license details.


*Figure 6-7 The License Manager window*



## Database Management

RI Witness™ Manager must connect to the shared RI Witness™ database.

1. At RI Witness™ Manager login, a database connections window will be shown if a connection cannot be made. See Figure 6-8.

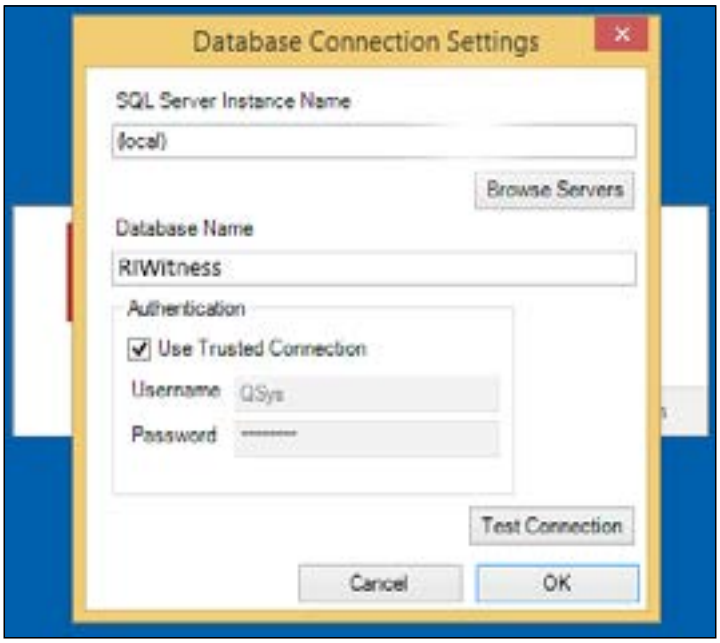


*Figure 6-8 The RI Witness™ database connection is unavailable*

2. Click the **Database Settings** page button to show the database connection settings window and enter the appropriate server name, database name and authentication details. See Figure 6-9.

See the IT Requirements Manual for more details on database management.

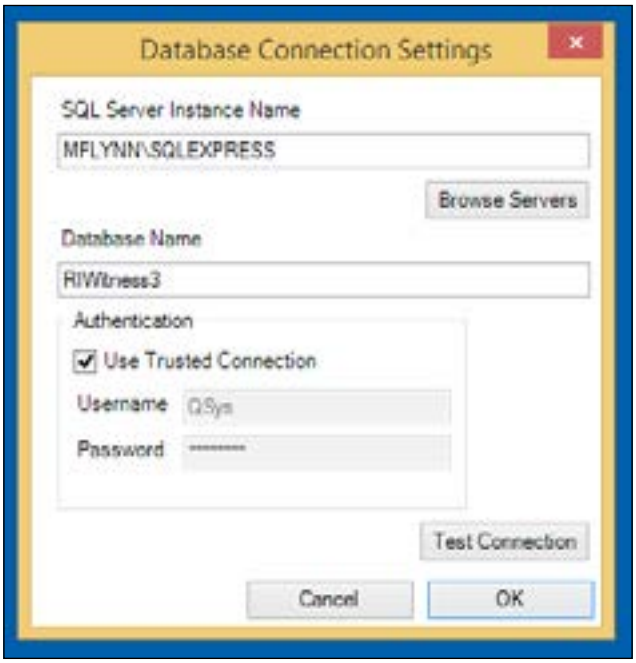


*Figure 6-9 Database connection settings*

## Initial Screen - Main Menu Buttons

After login, an initial screen shows a number of main menu buttons. The main menu buttons presented will depend on operator group membership (administrator, normal) and the mixture of installed products (RI Witness™, Traceability, Data Capture, Imaging and Cryo).

## Home

When first logging into RI Witness™ Manager the Cycles Overview Board is displayed. Clicking the **Home** button on the left hand toolbar will return the user to the Home screen. The **Refresh** button on the Home screen causes the display to refresh by re-querying the database to find the active treatment cycles.

1. To see the cycle details of a patient, double click on the row with the patient's details. A **Treatment Cycle** page will open.

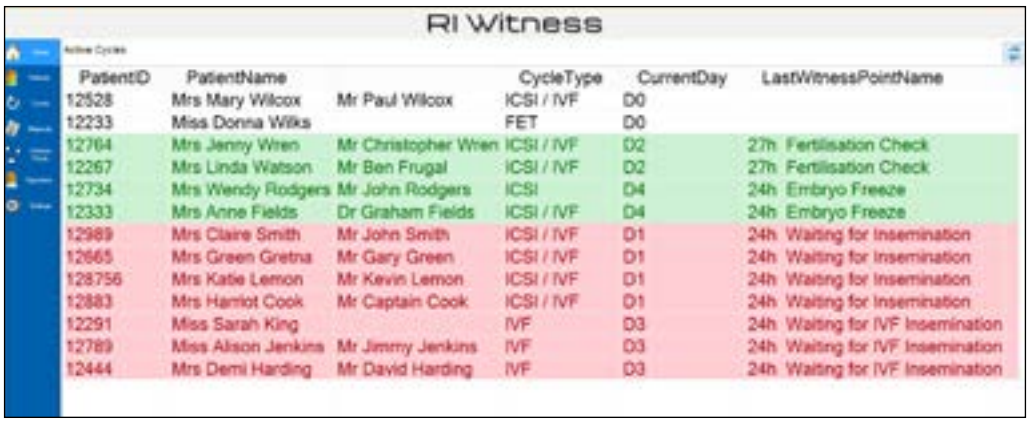


*Figure 6-10 Home screen*

## How to Configure the Home Screen

Each day of a cycle or an event can be given a different colour code to aid easy and quick identification of the cycle status. This can also assist the ordering of procedures.

To configure the colour coding within the Home screen, follow the steps below. Exact spellings of Cycle Types and Events used in the Witness Point Diagram must be used.

1. Click **Settings.**
2. Click **Home Screen Configuration.**
3. Firstly you will need to set up “States”. These can be days or events and are colour coded.
   **Tip:** You could simply do Day 1,2,3,4,5 to start with.
4. Click **+** within the States field.
5. Type the name of the State, eg Embryo Freeze, Day 0, Day 1, etc.
6. On clicking the background or foreground (Text Colour) box, a colour picker will appear. Select the desired colours.
7. Press **Save.**
8. Next add a cycle type. Click the **+** button within the Cycle types field. A Cycle Type box will appear. Type in the cycle type carefully, ensuring there are no spelling mistakes. The cycle type will need to match what you have already set within the Treatment Cycle Types fields within the database (See “Cycle Types” on page 70.) An example of a cycle type could be IVF, ICSI / IVF, FET, ICSI, etc.




*Figure 6-11 Home screen*

9. Click **Save**.
10. Select the **Cycle Type** drop down arrow you would like to colour code.
11. Click **Add Day** or **Add Event.**
12. Assign a day number, ie 3 for Day 3.
13. Within the Message field, type the Day description, ie Day 3.
14. In the State drop down field, chose one of the States that has been set up.
15. **Save.**
16. Repeat for each Cycle Type.

## Patients

Click the **Patients** button to show the **Choose Patient** window if no patient has been selected or to view details of a selected patient.

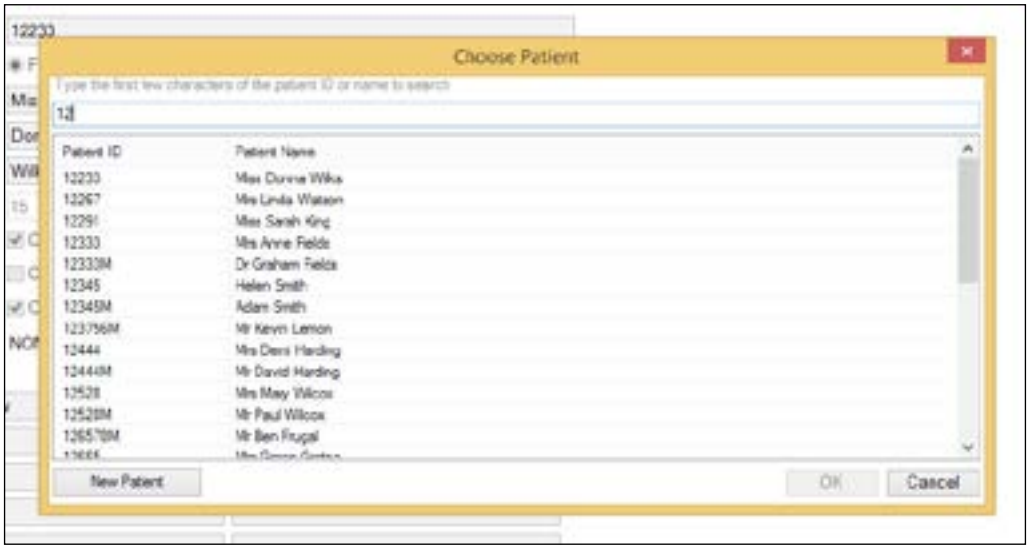


*Figure 6-12 Choose patient screen*

1. Type the first few characters of a name or patient ID to browse a selection of matching patients.
2. Highlight the required patient and click **OK** or double click the required patient to view their details.
3. Treatment cycles, witness points and tags for the selected patient can also be viewed by selecting the tabs in this screen.
4. Clinics with Cryo enabled, can print barcodes for the selected patient by clicking **Barcode Printing**. Barcodes printed from here will be recognised by the RI Witness™ system as belonging to the selected patient.
5. Click **Label Printing** to create adhesive sheets with the selected patient details. These can be attached to plasticware for this patient's samples. For further details regarding label printing see "Printing Patient Labels" on page 54.

## Entering New Patient Details into RI Witness™ Manager

1. Click the **Patients** button to show the **Choose Patient** window.
2. Click on **New Patient** button.
3. Enter details into appropriate fields – all fields which have been edited are highlighted in pink.
4. Save all changes.

**Note:** From the Patients page there is also an option to add or choose a new patient.

**Note:** A patient cannot be assigned to a partner until the partner has also been entered into the RI Witness™ Manager software separately – See "Assigning Partners" on page 50.

**Note:** Label sheets and barcodes can be printed from this page.


*Figure 6-13 New patient details*



## Editing Existing Patient Details

Open Patient details as outlined above.

1. Click the **Edit** button  to change to the editable window.
2. Click the **Save** button to save changes.

## Looking Up Patient Histories

1. From the Patients page, select the **Treatment Cycles** tab to view all previous cycles undertaken for a patient or couple.
2. Select the **Witness Points** tab to view all witness points registered in an open cycle.
3. Select the **Tags** tab to see all locations that tags assigned to the patient have been seen by RI Witness™.

Refer to Frequently Asked Questions if necessary.


*Figure 6-14 Looking up patient histories*

## Assigning Donor Status

In the Patient details window select relevant donor options.

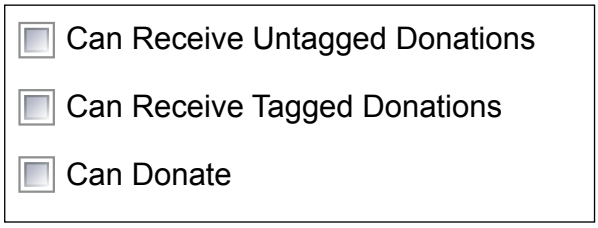


*Figure 6-15 Assign Donor Status*

The availability of the donate checkboxes will depend on the gender of the patient, ie only female patients can receive donations.

## Assigning Partners

1. Create a new patient entry, or choose existing patient, leaving the partner field blank.
2. Create a new patient for partner.
3. To link the 2 patients, select the **Choose Partner** button to show the Choose Patient window.
4. Locate partner by typing the first few characters of a name or patient ID in the search window to browse a selection of matching patients.
5. Click on the patient name and then confirm selection by clicking **OK**. See Figure 6-16.

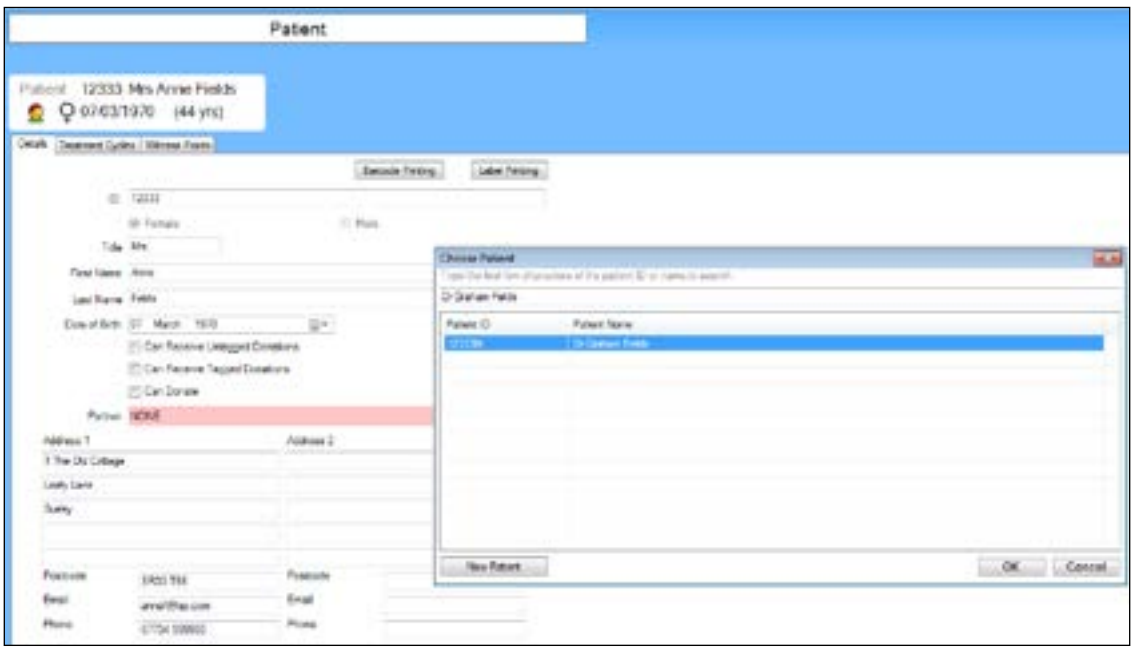


*Figure 6-16 Assign Partners*

## Cycle Types

A cycle relates to a specific course of treatment (IVF, ICSI, IUI, etc).

Only “administrator” operators may create cycle types.

1. Click the **Settings** main menu button and then click **Cycle Types** to view all treatment cycle types. See Figure 6-17.
2. Click **New** to add each cycle type.
3. Use a right click to **Rename** a cycle type.

Traceability operators may specify the range of materials that are used in a cycle type. Data Capture operators may specify the data sheets that are used in a cycle type.

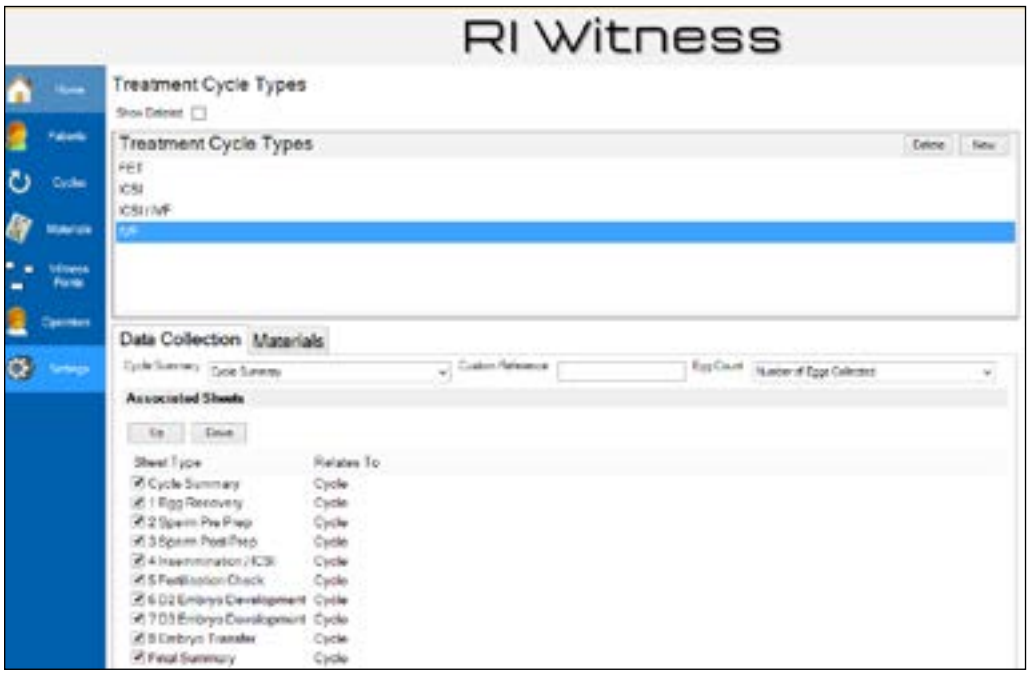


*Figure 6-17 The Treatment Cycle Types Window*

## Starting a New Cycle

1. Click the **Patients** main menu button and select a patient by entering a name or patient ID.
2. Click the **Treatment Cycle Type** tab to show the list of treatment cycles for this patient. For a new patient this list will be empty.
3. On the **Treatment Cycle Types** tab of the patient screen click **Add New Cycle** to create a new cycle. The new cycle is shown with a status of “In Progress” and a cycle type of “Unknown”. See Figure 6-18.
4. Traceability operators may click the **Materials** tab to view a list of material batches related to this cycle.
5. All operators may click the **Witness Points** tab to view a list of witness points performed during this cycle.

## Assign a Cycle Type

Select a cycle type from the pulldown list.

## Collection and Transfer Dates

If Egg Collection / Embryo Transfer dates are entered on the **Details** tab of a treatment cycle then these events will be available from the work area **Show Daily Lists** touch button.

See “Performing A Procedure in RI Witness™” on page 28 for more details of patient selection using **Daily Lists**.

## Cycle Status

A newly created cycle will be assigned the status “In Progress”. When the patient treatment has been completed click **End Cycle** to change the status to “Completed”.

## Revert Status

An administrator operator may click the **Revert Status** button of a “Completed” cycle to return the status to “In Progress”.


*Figure 6-18 Starting a new cycle.*

1. Click **Add New Cycle** from the Patients window.
2. Select a Cycle Type from the pulldown on the **Treatment Cycle** window.

## RI Patient Identity Labels

Laser printable adhesive patient identity labels are available from RI.

The sheet provides a range of label sizes with a selection of normal and reverse printing. See Figure 6-19.


*Figure 6-19 RI laser printable label sheet.*

Reverse printed labels are viewable through the base of containers.

Label categories such as “Petri Dish” and “Test Tube” are for guidance only. Please select a label appropriate to your plasticware.

“Test tube” labels may be used to hold a rectangular RFID tag in position along the length of a tube.

The reverse printed “4 well dish” label and the square RFID tag are the recommended choice for a 4 well dish. See Figure 6-20.

RI Labels are an optional component of RI Witness™.

*Figure 6-20 Positioning of patient identity labels*

## Printing Patient Labels

1. From the patient details window click **Label Printing** See Figure 6-21.
2. Load a blank label sheet into a laser printer. For repeatability of alignment use a manual feed path and take care when placing each sheet.
3. Set all “Sheet Alignment” values to zero and click **Print Labels**.
4. Check the printed sheet. Measure the offsets required to correctly position the printed details within a label boundary. Pay particular attention to vertical positioning within the smallest label. See Figure 6-22.

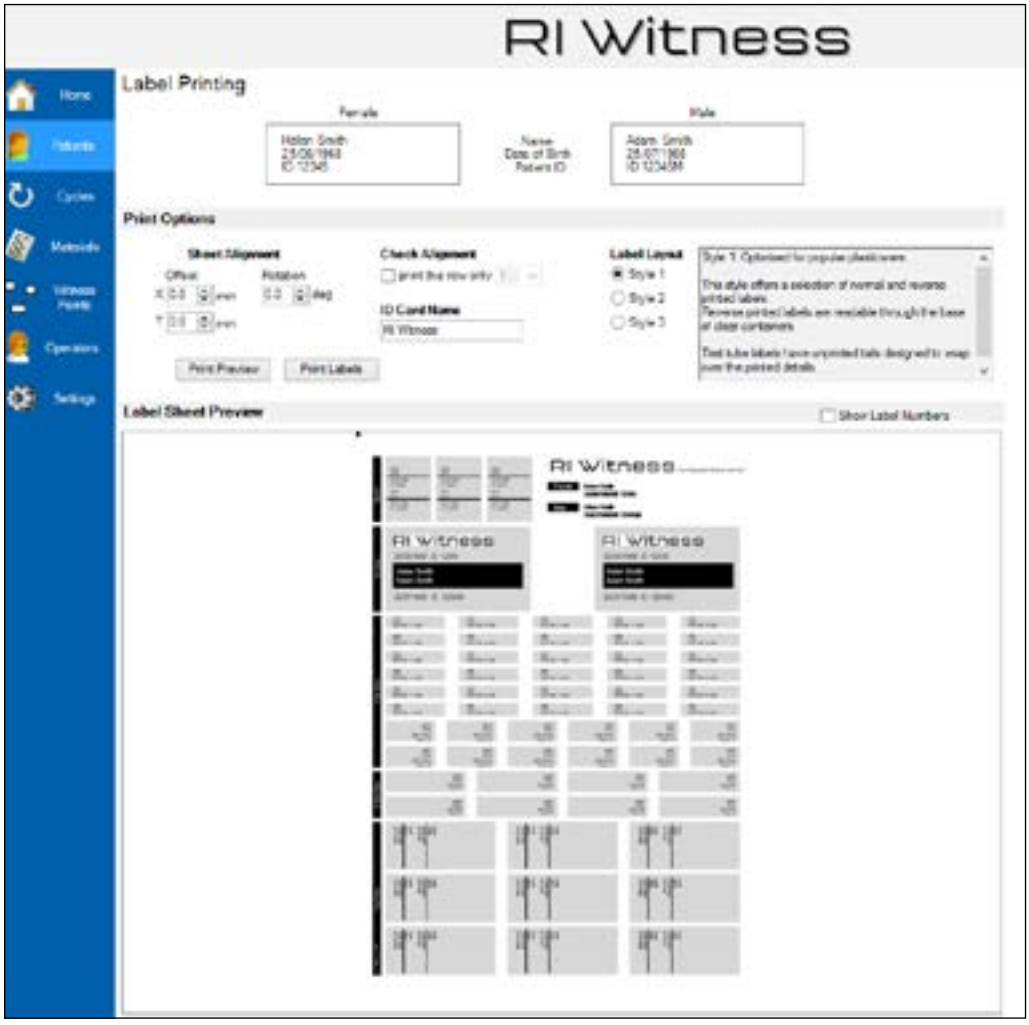


*Figure 6-21 The label printing manager*

The example shown in Figure 6-22 shows details of an alignment correction within the boundary of the smallest label.

5. The first print shows incorrect alignment.
6. Vertical alignment is corrected by a negative Y offset.
7. Horizontal alignment is corrected by a positive X offset.

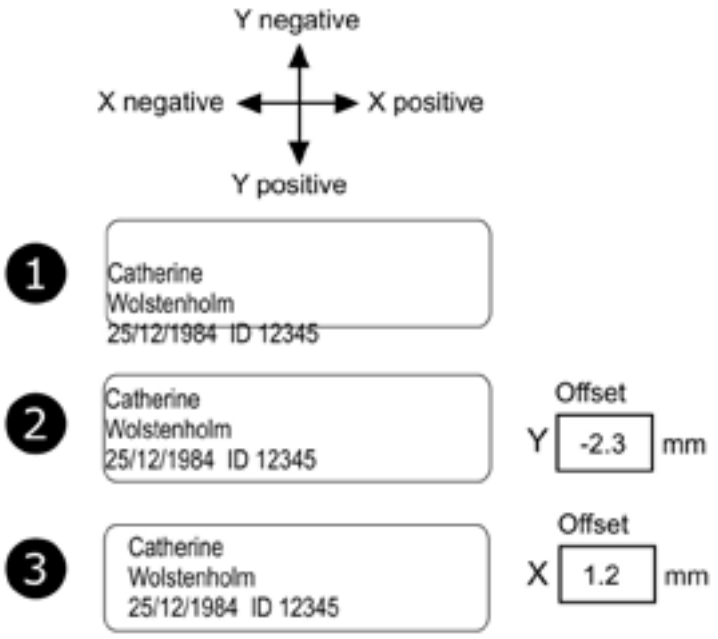


*Figure 6-22 Label text alignment*

## 6 Label Styles

Use the Label Layout buttons to select an appropriate style.

Style 1 is optimised for popular plasticware, Style 2 maximises the use of available space and Style 3 is a mixture of Styles 1 and 2.

**Note:** A rotation alignment correction is rarely required.

**Note:** Check **Print this row only** and select a row number to print a single row of the smallest labels only. This may be useful if reusing a sheet during the alignment process.

## Operator Management

Click **Operators** to display a list of all enabled operators. See Figure 6-23.

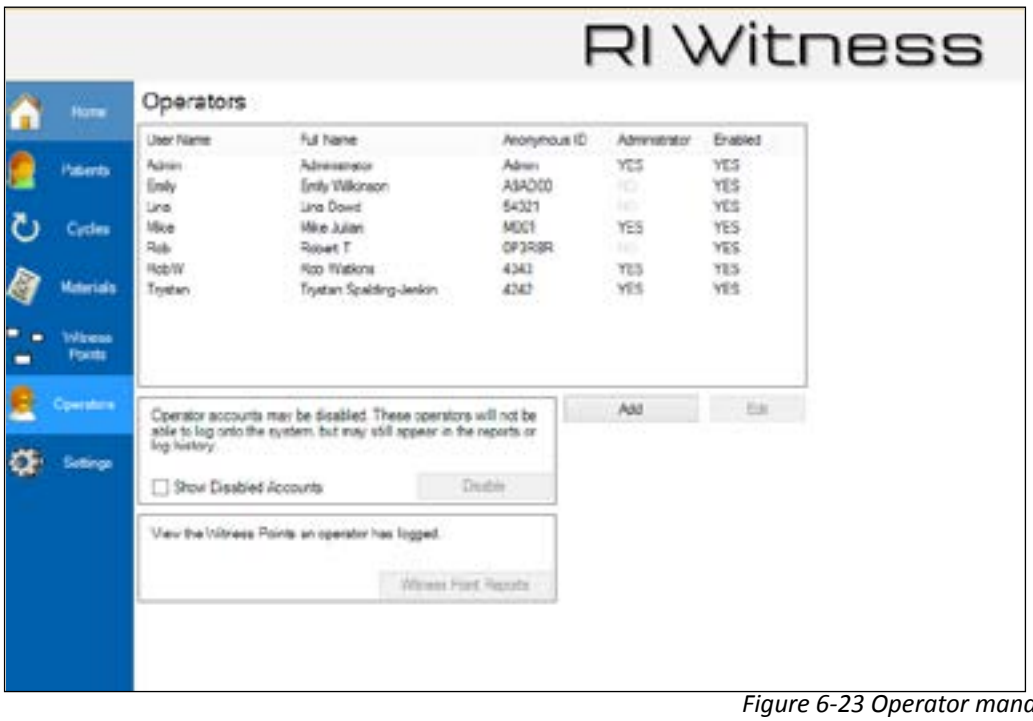


*Figure 6-23 Operator management*

## Operator Details

1. Click **Add** to specify details for a new operator. See Figure 6-24.
2. Select an operator and click **Edit** to change operator details.

An operator must have a Username, Full Name and Anonymous ID. The Anonymous ID is used for printed reports.

## Group Membership

Group membership is specified as “normal” or “administrator”.

Some RI Witness™ features are only available to an “administrator” operator. Administrator only features include the use of admin assign and making changes to the witness point diagram.


*Figure 6-24 Operator Details*

## Enabled Operators

Only enabled operators may log in. Click **Disable** to remove an operator from the enabled list. Check “Show Disabled Accounts” to view all operators.

## Operator PIN

The operator PIN must be a sequence of 4 numbers.

## Clinic Details

Click the **Settings** main menu button then click **General Settings** to specify the Name of Clinic that will appear in all printed reports. SeeFigure 6-25.

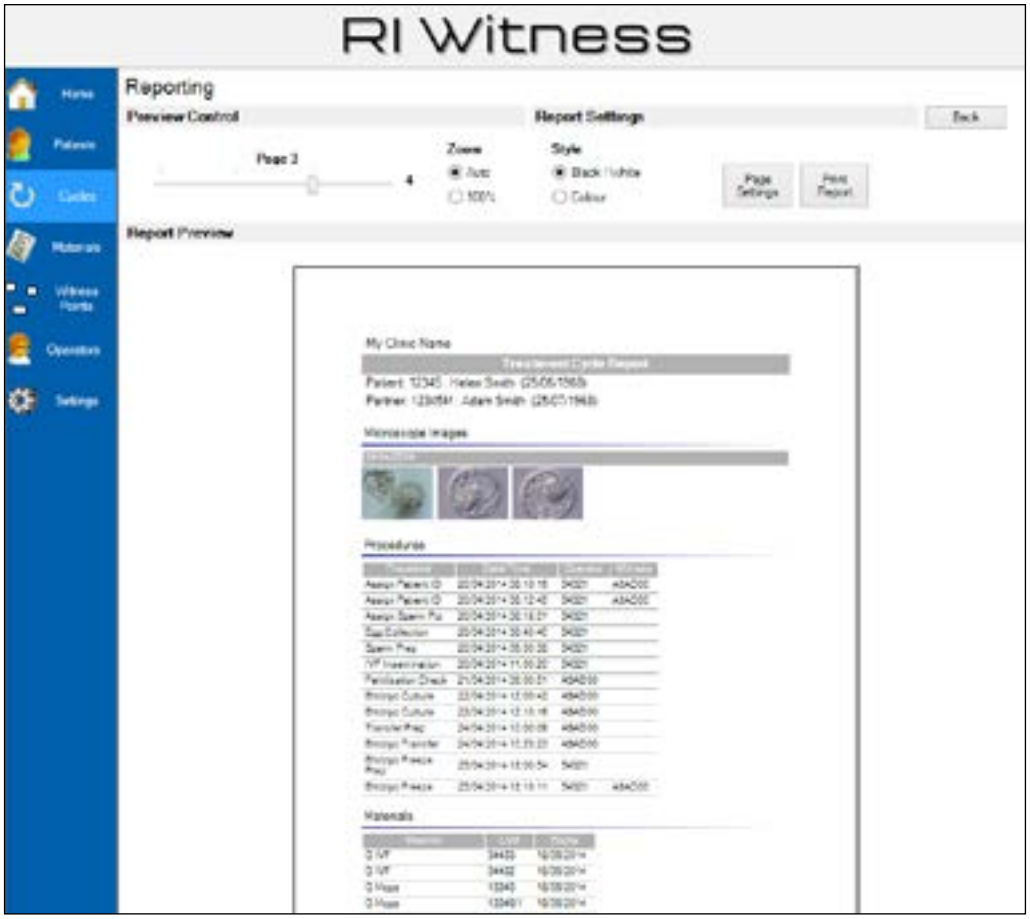


*Figure 6-25 The heading of a printed report will show "My Clinic Name" as specified by "Name of Clinic" on the general settings page.*



## Mismatch Comments In RI Witness™ Manager

Users can add extra comments to further explain any mismatches in the history

1. Open RI Witness™ Manager.
2. Click the **Cycles** button.
3. From **Treatment Cycles** double click the cycle required to view. This can be seen by clicking patients also.
4. Click the **Witness Points** tab.
5. Double click the **Mismatch** witness point.
6. Click the **Edit** icon.
7. Enter additional comments.
8. Click **Done.**

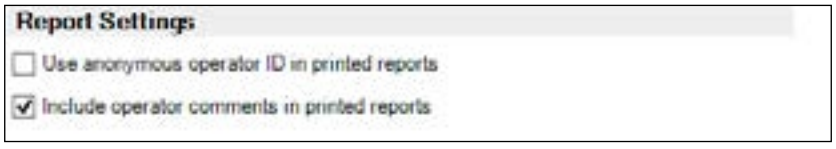


*Figure 6-26 Report settings*

## The Witness Point Diagram

The witness points that are presented to all work area operators are defined in RI Witness™ Manager by a witness point diagram.

To view the witness point diagram click the **Settings** main menu button and then click **Witnessing**. See Figure 6-27 and Figure 6-28.


*Figure 6-27 The settings screen*
*Click "Witnessing" to view the witness point diagram*

To add a new witness point, click **New Witness Point** and then click anywhere in the diagram. Enter a name for the witness point, eg "IVF Insemination"

Use the Witness Point Info panel to specify the attributes of a witness point. Witness point attributes, eg reassign an "egg culture dish" tag to become an "inseminated dish" tag, are described below.

Tag names such as "inseminated dish" must be defined before they may be referenced by a witness point. See "Tag Types" on page 63.

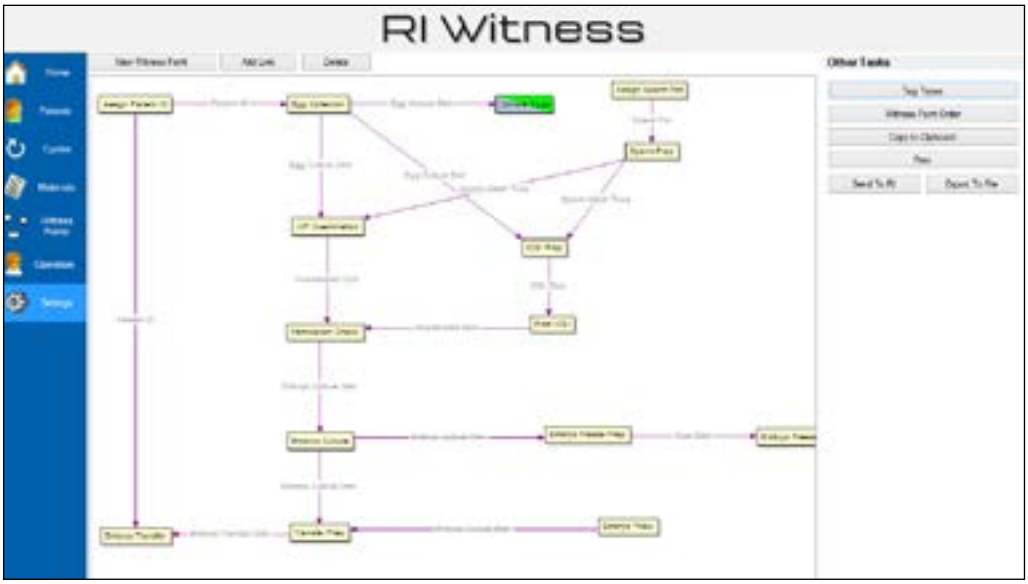


*Figure 6-28 The witness point diagram.*

## Links

The links (arrows) between witness point boxes represent tags (dishes, test tubes, etc) that are the required inputs and produced outputs of the procedure defined by that witness point.

To create a link, click **Add Link** and then drag between two witness points.

## Reassigned Tags

A witness point may represent the reassignment (transformation) of one tag type into another, eg an "Egg Culture Dish" becomes an "Inseminated Dish" as the sperm is introduced.

A reassignment is illustrated in Figure 6-29 where the **Reassign this dish** checkbox is checked to specify that the selected tag type "Egg Culture Dish" will be reassigned as an "Inseminated Dish" when this witness point is exercised by the work area operator.

## Unassigned Tags

Witness points may require that unassigned (empty, unused) tags be introduced into the work area.

**Note:** The "IVF Insemination" Witness Point does not require an unassigned tag as the "Unassigned tags will be assigned to:" pulldown in Figure 6-29 shows "none".

Where a witness point requires the introduction of an unassigned tag, use the "Unassigned tags will be assigned to:" pulldown to select the target tag type.

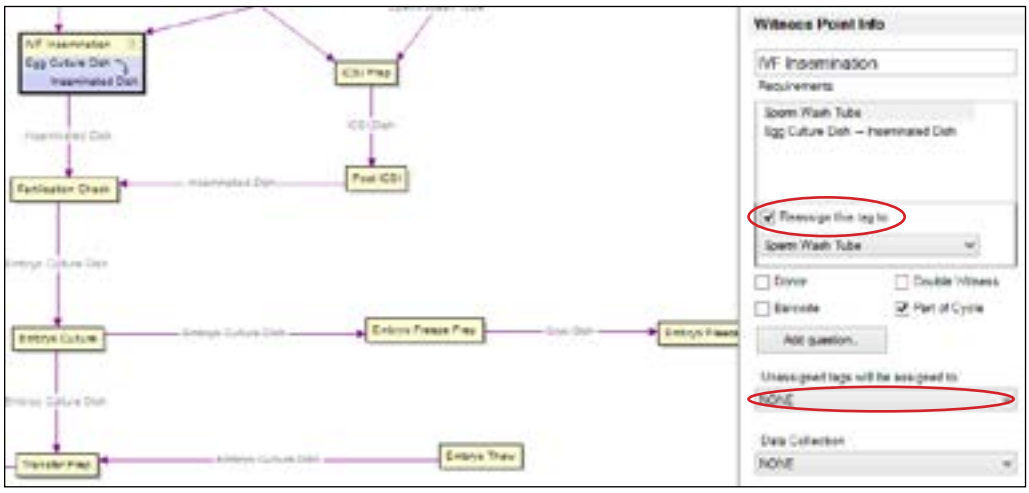


*Figure 6-29 Detailed information for the "IVF Insemination" witness point*

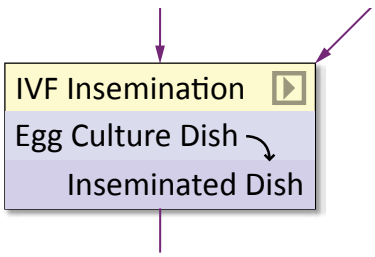


*Figure 6-30 A reassigned tag is represented by a curved line between the two tag names*

An unassigned tag is represented by a straight line between a question mark and the target tag name. A witness point may specify both a reassignment and the use of an unassigned tag.

## Witness Point Inputs

Incoming links to a witness point specify the tags that must be present before the procedure represented by the witness point can be performed. If an unassigned tag is specified then that container must also be present before the procedure can be performed.

## Multiple Sources of the Same Tag Type

A witness point with multiple input links of the same tag type eg “dish X”, represents an OR operation, ie the required container may be sourced from the procedure represented by witness point A OR B.

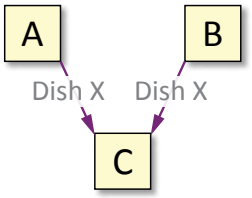


*Figure 6-31 Dish X must be available to witness point C*
*Witness point A OR B may be the source*

## Multiple Tag Types

A witness point with multiple input links of differing tag types represents an AND operation, ie this tag type AND that tag type are required to perform the procedure represented by this witness point. See Figure 6-32.

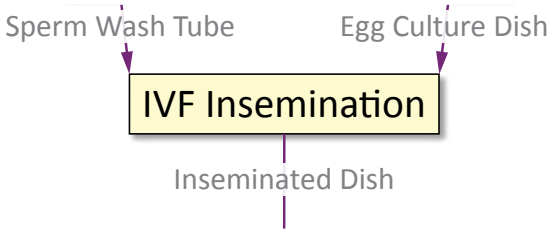


*Figure 6-32 The “IVF Insemination” witness point represents a procedure that requires a “Sperm Wash Tube” AND a “Egg Culture Dish”*

## Entry Witness Points

Entry (initial, starting) witness points have no incoming links. An entry witness point will always require an unassigned tag which will become assigned on completion. See Figure 6-33.

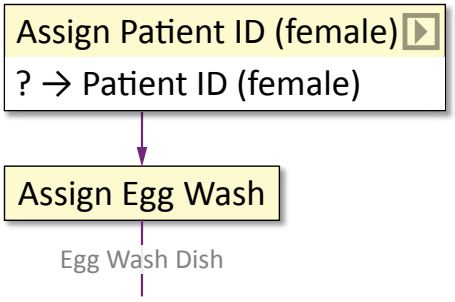


*Figure 6-33 “Assign Patient ID (female)” is an entry witness point as it has no input links*
*An unassigned tag (here an unassigned ID card ) is required*

## Double Witness Points

Checking the **Double Witness** box, see Figure 6-29, changes the completion sequence for a witness point. A second operator must log in to approve the procedure. Entry witness points are generally double witness points.

## Donor Witness Points

A mismatch alarm will be generated if tags assigned to patients who are not specified as partners are introduced to the work area.

The exception to this rule is provided by donor witness points. Checking the **Donor** box will create a donor witness point which is given a diagonal colouring. See Figure 6-34.

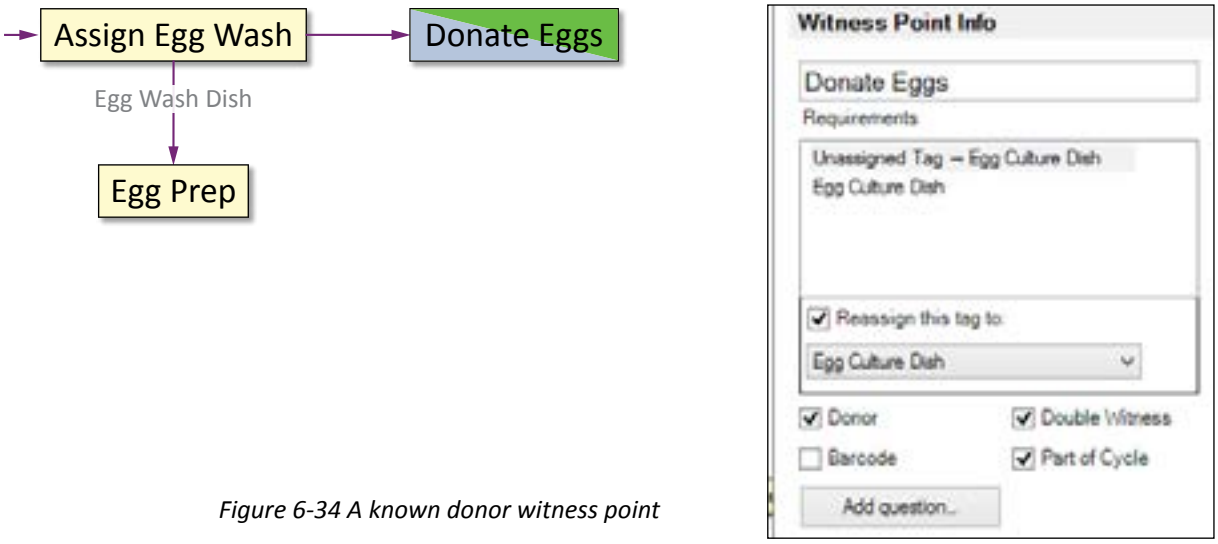


*Figure 6-34 A known donor witness point*

## Tagged Donations

An incoming link to a donor witness point specifies a tagged donation and covers procedures such as egg/embryo donation/sharing as well as surrogacy.

When the witness point is selected the operator chooses the donation recipient. The recipient identity is assigned to the tag containing the donated material. The work area now contains tags with a mixture of donor and recipient identities. This does not trigger a mismatch because the tags have the donor witness point in common.

Tagged Donations require that the donor and recipient be specified as such via the **Can Donate** and **Can Receive Tagged Donation** check boxes available in the patient details. See Figure 6-35.

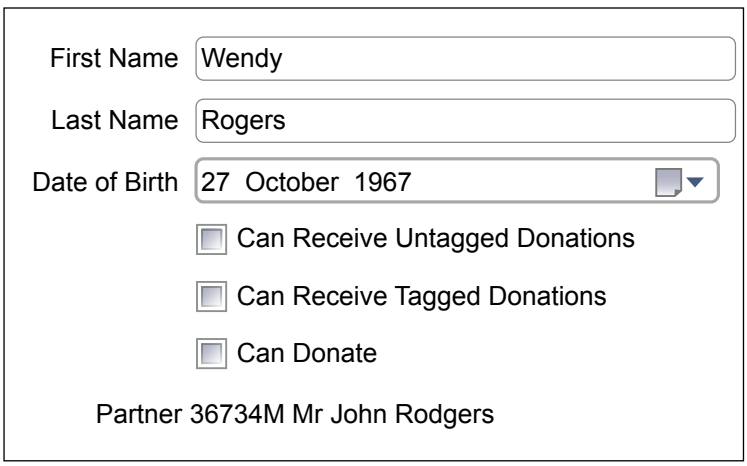


*Figure 6-35*

The **Can Donate** checkbox specifies the ability to make a tagged donation.

The **Can Receive Tagged Donations** checkbox must be checked for the recipient.

The donor witness point ensures that donated tagged material is only available to patients that have the **Can Receive Tagged Donations** box checked in their patient details.

## Untagged Donations

Sperm donations are usually untagged.

An donor point will be an entry witness point for a female recipient of donated sperm. The donated sperm will be transferred to an unassigned tag that is then assigned to the female recipient when the donor witness point is selected.

The donor witness point ensures that untagged sperm is only available to patients that have the **Can Receive Untagged Donations** box checked in their patient details.

## Witness Point Questions

A question may be presented to a work area operator. The question and response will be recorded in the history log.

To set a question for the selected witness point:

1. Click the **Add Question** button.
2. Choose a question type and enter the question text. See Figure 6-36.
3. The diagram will show an **Exclamation** ! appended to the witness point name if a question has been added.
4. Click the **Exclamation** ! to edit the question details.



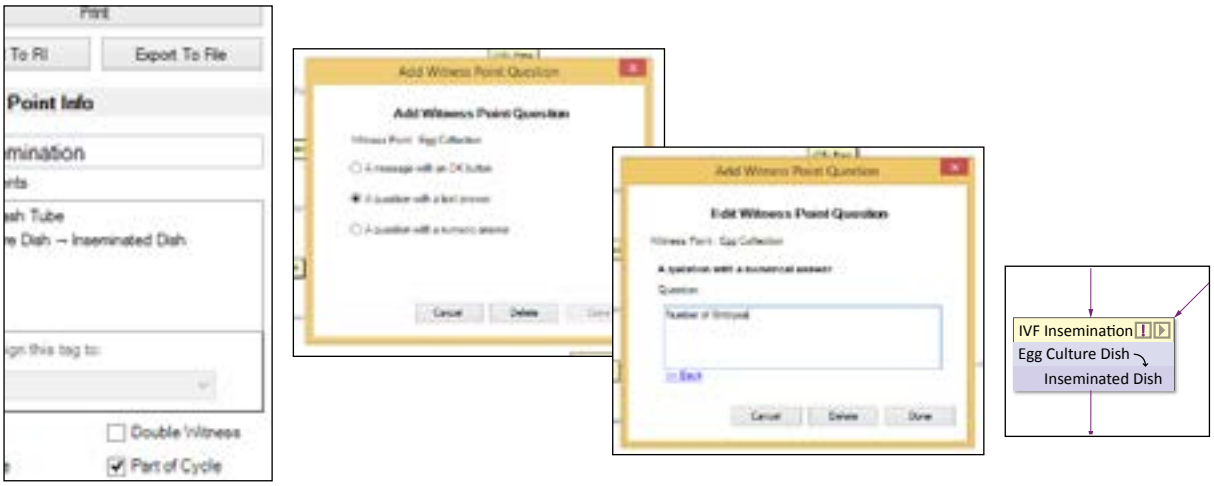


*Figure 6-36 Adding a witness point question that requires a numerical answer*
*Note the exclamation after the witness point name*

## Tag Types

Click **Tag Types** to specify the name and icon for each RFID tagged item used in the witness point diagram. See Figure 6-37


*Figure 6-37 Tag types*

6

## Witness Point Order

From the witness point diagram page click **Witness Point Order** to specify the order in which points will be displayed to the work area operator. Click **Up** or **Down** to change the order. See Figure 6-38.


*Figure 6-38 Setting the witness point order.*

## The Witness Point Log

Work area events, eg witness point selection and tag mismatches, are logged in the shared database. The witness point log may be explored in detail or viewed as a summary. A printed report may be generated from any view of the witness point log.

Click the **Witness Points** main menu button then click **Statistics** or **Explore** to view the witness point log. See Figure 6-39.


*Figure 6-39 The witness points screen*
*Click statistics or explore to view the witness point log*

## Witness Point Log Statistics

The statistics view summarises the witness point log by presenting significant totals, eg “Tags used” , “Patients seen”, etc. The view may be filtered by date. See Figure 6-41.


*Figure 6-41 Statistics from the witness point log*

## Explore the Witness Point Log

The Witness Point Explorer shows events from the witness point log.

The view may be filtered by date, operator, patient and tag type. Shortcut links are provided for common filters, eg “Monday”, “Admin assigns this week”. See Figure 6-40.


*Figure 6-40 Exploring the witness point log*

# SECTION 7 - CRYO WITNESSING

## An Introduction to Cryo Witnessing

Many embryology labs wish to extend witnessing and reporting to include samples stored in cryo storage. The Cryo feature is a barcode labelling solution for cryo straws.

Clinics have the option of scanning barcodes that they have already been assigned to samples, and RI barcodes that have been printed from RI Witness™ Manager and are assigned to a particular patient.

If a clinic only wishes to be able to scan a barcode printed from the RI Witness™ Manager application

1. Open **RI Witness™ Manager**.
2. Click **Settings.**
3. Click **General settings.**
4. Tick the checkbox under the Barcode section **Only use RI Barcodes**.

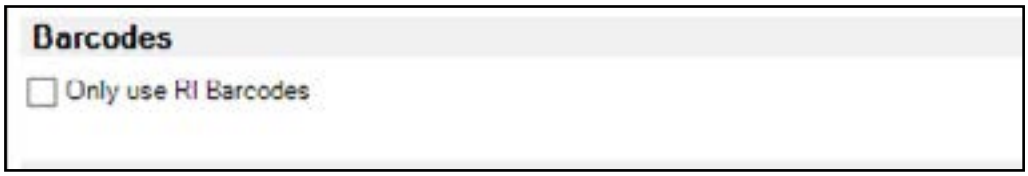


*Figure 7-1 Only use RI barcodes*



## Printing Barcodes

1. Open **RI Witness™ Manager.**
2. From the patient details window click **Barcode Printing**. See Figure 7-2.


*Figure 7-2 RI Witness™ Manager*


*Figure 7-3 Barcode printing window*

3. To print barcodes make sure that a correct label printer is plugged into the computer with the correct label stock loaded into it.
4. Select
   - The required number of barcodes
   - The starting number
   - The freeze date of the barcodes.
5. A preview of the barcodes that will be printed is shown in the **Label Preview**. The last number on the second line is the sample number for this patient. This can be edited allowing reprinting of a particular barcode, for example if the initial printing was misaligned.
6. Click **Print Labels**.
7. If you are using small style labels you may need to print a blank row to gain access to the printed labels. To print a blank row of labels, click **Print Blank Row**.
8. To check the printed labels, measure the Y Offset between the top of the barcode and the top of the next label and set the print head position on the printer to this value.


*Figure 7-4 Aligning the label print stock*
1. *The first print shows incorrect alignment.*
2. *Alignment is corrected by setting the printhead Y position*

## Scanning Barcodes

In the work area a patient can be chosen by scanning in a sample barcode that has previously been assigned to this patient.

When completing a witness point that includes a barcoding step, the barcode, either a brand new barcode or a barcode previously assigned to the current patient, must be scanned prior to the Witness Point Confirmation screen. See Figure 7-5.

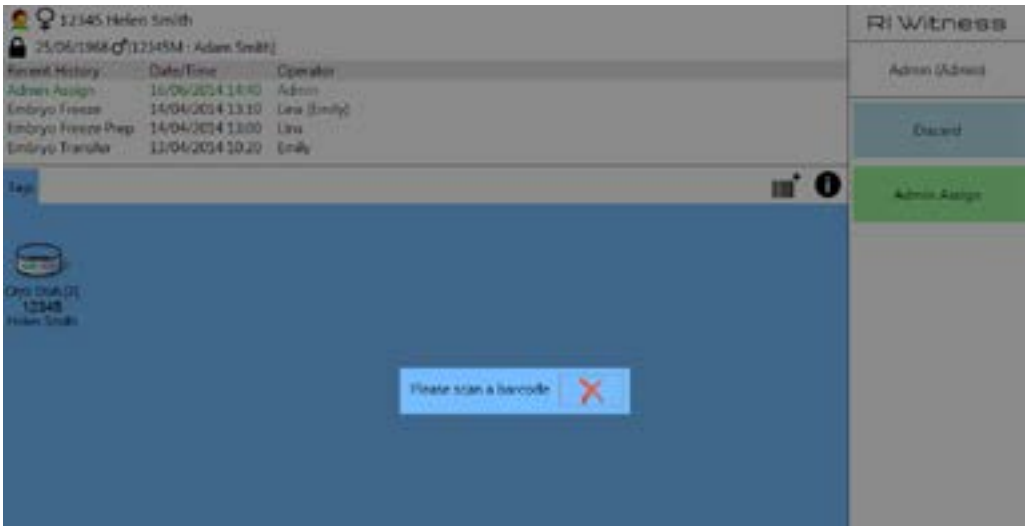


*Figure 7-5 Scanning a barcode*



If the barcode has not been seen by the system before it will be assigned to the patient after the witness point is confirmed.

If the barcode has already been scanned and assigned to a different patient, the mismatch alarm is activated and the differing patient is shown on the mismatch screen. Clicking on the small **Red cross** next to the displayed mismatched patient will allow the mismatch screen to be closed and a reason attached. See Figure 7-6.


*Figure 7-6 Barcode mismatch*

# SECTION 8 - RI WITNESS™ MANAGER FOR TRACEABILITY

## Managing Materials

Material types, eg dishes, pipettes and media must be defined for use within Traceability. A barcode reader may be used to identify batch lot numbers, expiry dates, etc or these details may be entered manually. Batches are opened or closed to reflect their availability within the lab.

Click the **Materials** main menu button to view the materials related features of Traceability. See Figure 8-1.


*Figure 8-1 Materials management*

## Material Types

Material types must be configured before the details of a delivered batch may be recorded.

1. Click the **Materials** main menu button.
2. Then click **Actions** to view a list of all material types.
3. Use **Add New Type** and **Add New Group** to specify the top level of your materials hierarchy. See Figure 8-2.
4. Right click a group and select **Add Group** to extend the hierarchy.
5. Right click a group and select **Add Type** to add a new material type to that group. See Figure 8-3.

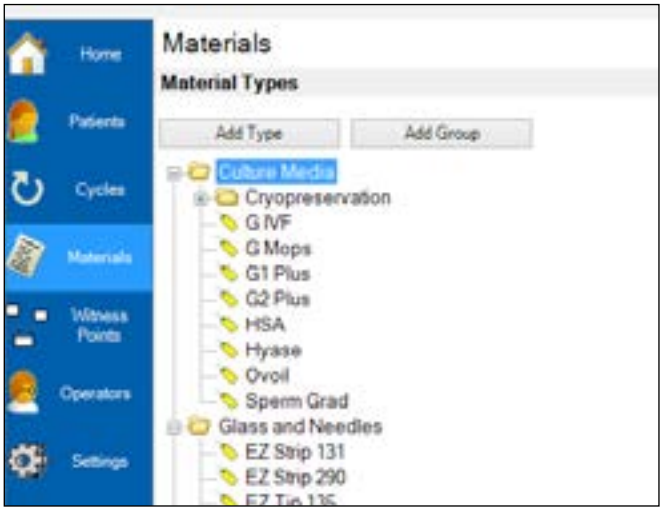


*Figure 8-2 Viewing all material types*

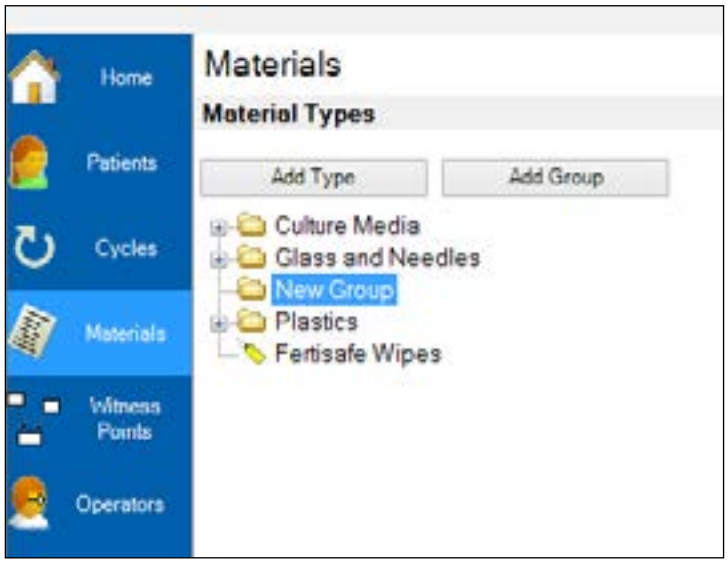


*Figure 8-3 Right click to add a sub group*

## Material Type Details

Double click a material type, or right click and select **View Material Type** to view the material type details. See Figure 8-4.

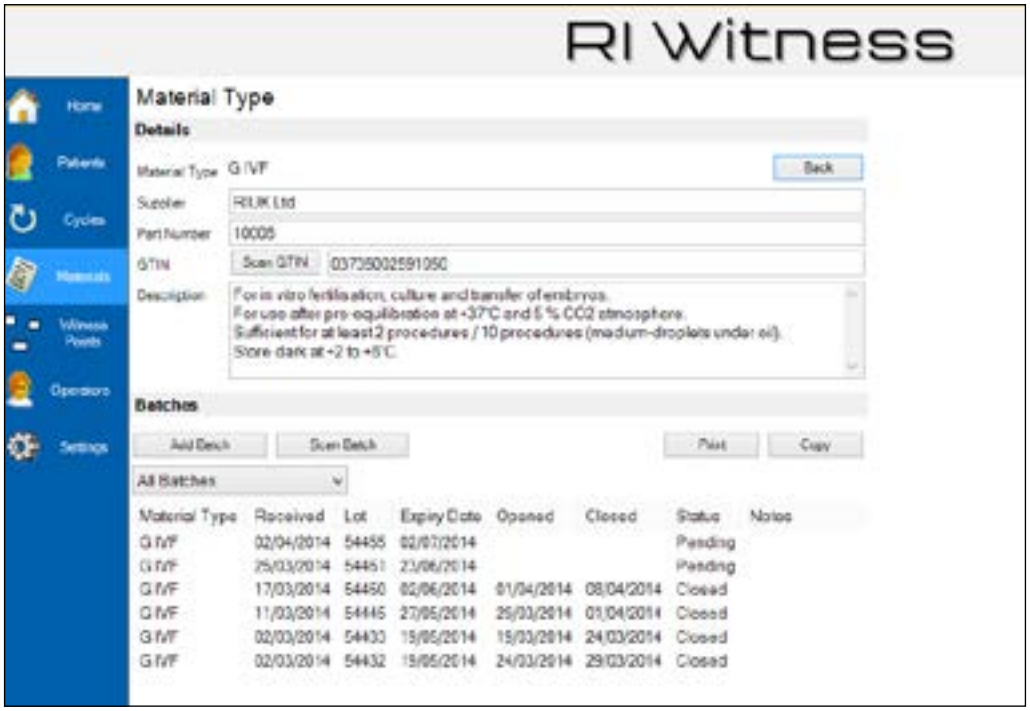


*Figure 8-4 Material type details*

Some materials are marked with a GS1 barcode. A GS1 barcode may contain various combinations of expiry date, lot number and a unique product identifier known as a GTIN. Here we are only interested in a product identifier.

1. If you have a barcode, click **Scan GTIN** and scan the barcode.
2. Manually enter a unique product part number if no GTIN is available.

## Notes on GS1 Barcodes

GS1 is a global barcode standard that may contain a Unique Product Identifier (GTIN ) and may also contain lot number and expiry date information. Some products have a barcode that does not adhere to the GS1 standard. Some GS1 barcodes do not contain all the information highlighted above, eg a box of bottles may have a barcode that contains GTIN, lot and expiry information but an individual bottle barcode may only have Lot and Expiry information but no GTIN.

Traceability can interpret GS1 barcodes.

A Traceability button must be clicked to interpret a GS1 barcode, eg click **Scan It** or **Scan Batch** or **Scan GTIN**.

## Cycle Types

Treatment cycle types must be configured and linked with material types.

1. Click **Settings**.
2. Then **Treatment Cycle Types**.
3. Then the **Materials** tab to view the materials linked to a cycle type.
4. Tick the materials within the list that are to be associated with the treatment cycle type.
5. Press **Save**.

As previously described in “Section 6 - RI Witness™ Manager” only administrator operators may create cycle types. Traceability admin operators may additionally configure the range of materials that are used when performing a treatment cycle type.

A newly created cycle type will not be associated with any materials. Use the materials check boxes to specify the range of materials that will be used for the selected cycle type. See Figure 8-5.

## Creating a New Batch

A new batch of a GTIN barcoded material may be scanned directly into Traceability.

1. Click the **Materials** main menu button and then click the **Scan It** button.
2. You will be prompted to use the barcode scanner to read the barcode. Scan the barcode.
3. As the materials type is already logged in the system, it will recognise the GTIN barcode and add the necessary details of that batch of materials to the system, eg lot, expiry date, etc within the Batch Details page.

Materials that are not GTIN barcoded are selected by navigating to the appropriate “material type details” screen.

1. Click the **Materials** main menu button then click **Actions** to show a list of all materials.
2. Double click the material that is being processed to show the Batch Details page for that material. See Figure 8-7.
3. A list of existing batches of this material is shown. Click **Add New Batch** to open the batch details window for a newly created batch and fill in the batch details. See Figure 8-6.
4. Click **Scan Batch** to create a new batch if a GS1 barcode is available.

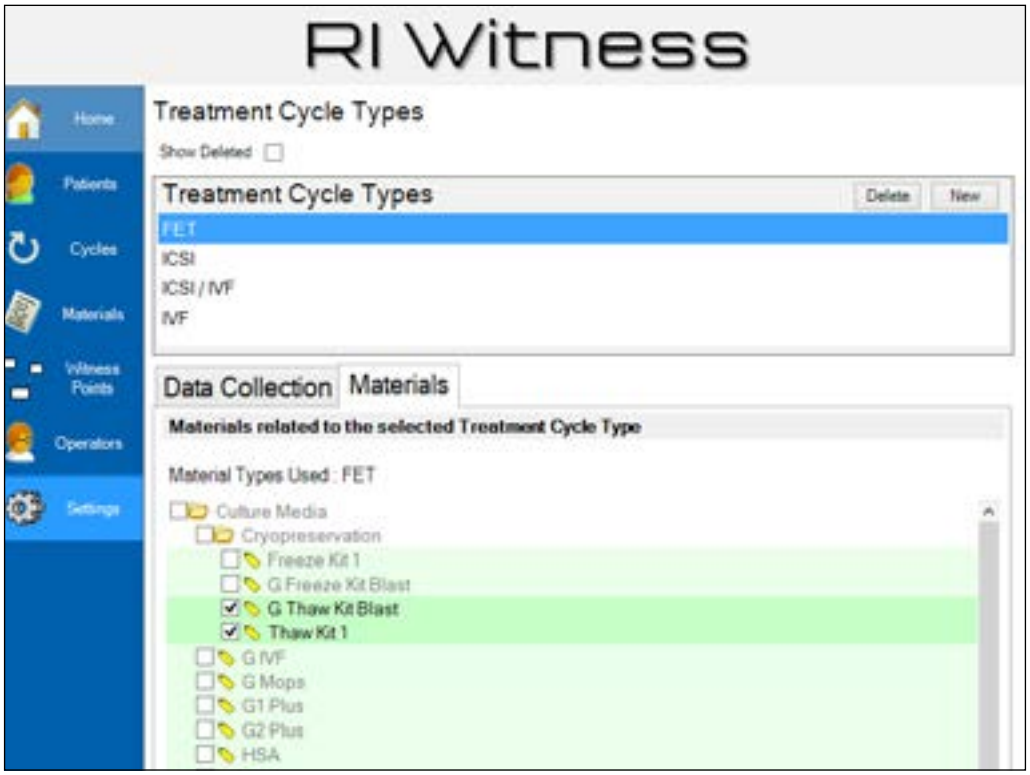


*Figure 8-5 Material type details checkboxes specify the range of materials associated with each cycle type*

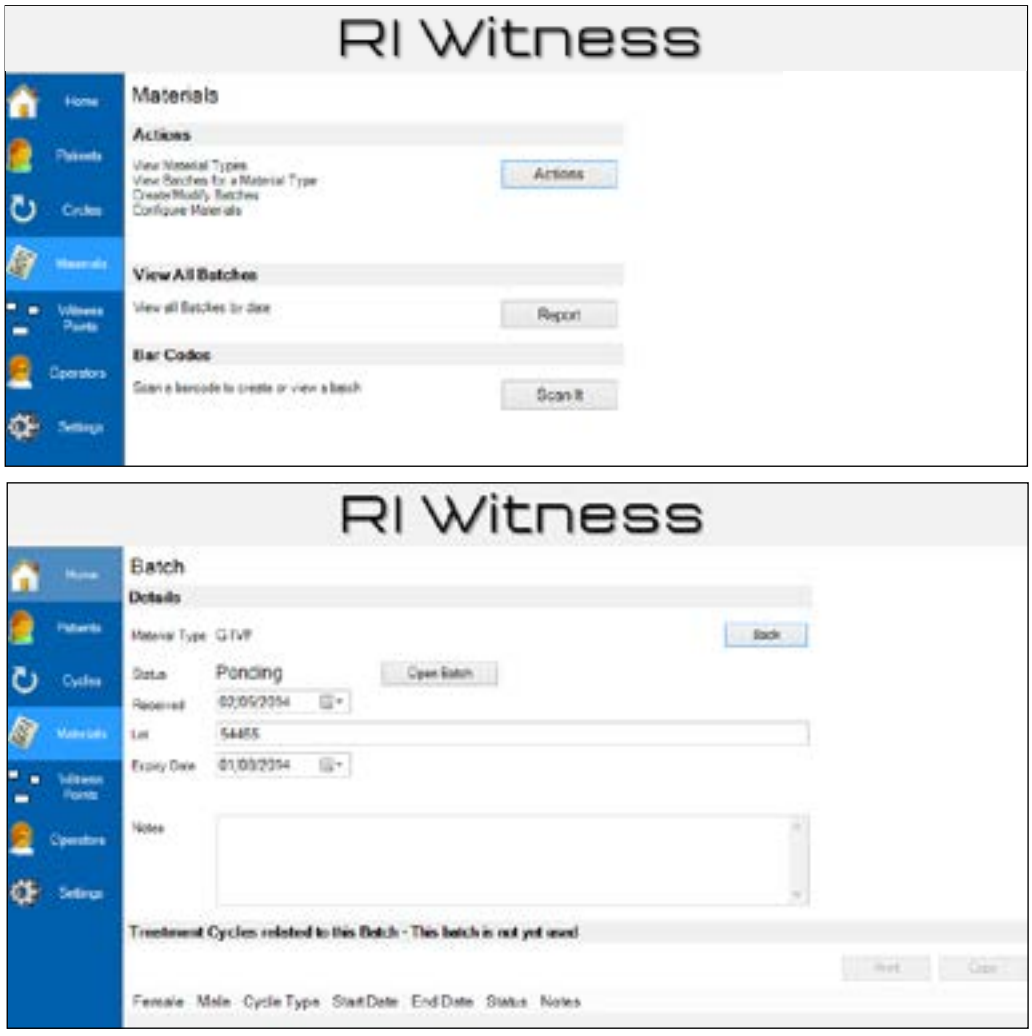


*Figure 8-6 Creating a new batch by scanning a barcode*

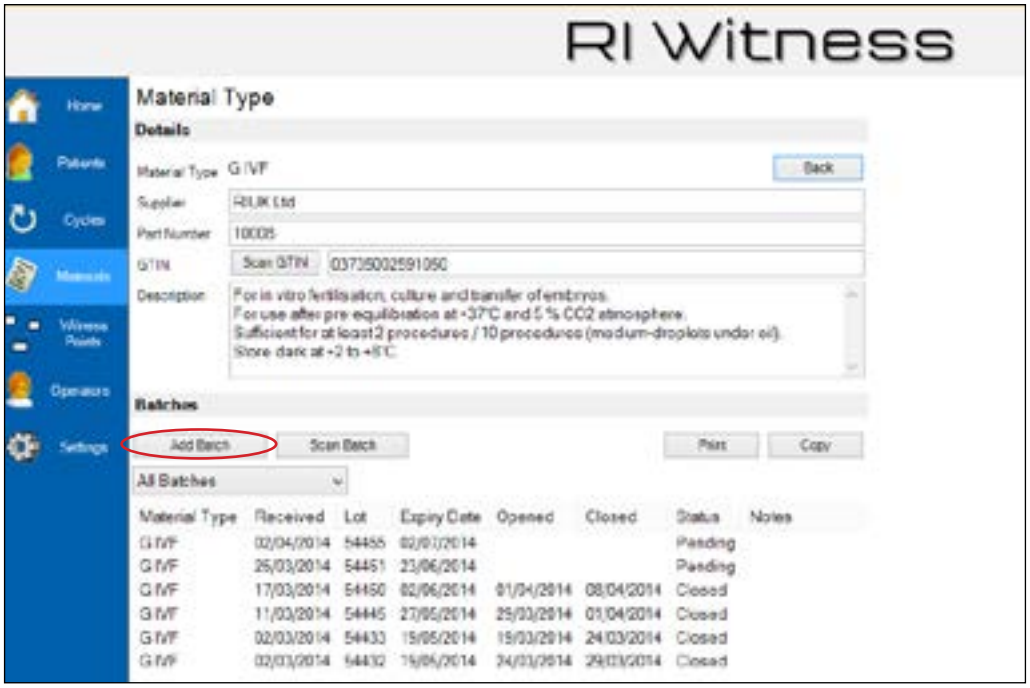


*Figure 8-7 Listing all batches of a specific material type*
*Click "Add Batch" to manually create a batch*

## Deleting a Batch

Normal batch operations are status changes, eg

- **Pending**: The batch of materials will shortly be opened and used
- **Open:** The batch of materials has been opened and is in use within the lab
- **Closed:** The batch of materials has been closed, has all been used up, has expired, can no longer be used.

Batches are not routinely deleted.

**Admin Operators Only**

If a batch is created in error then an admin operator may delete it.

1. Click the **Materials** main menu button.
2. Click **Actions**.
3. Double click the material type to be deleted.
4. The list of batches will be shown. Right click the appropriate batch and select **Delete**.

## Batch Status

A newly created batch will be assigned a status of "Pending". Click **Open Batch** when the batch is made available for use. The details displayed for an open batch will include all patient treatment cycles that are in progress. See Figure 8-8.

When a batch is no longer in use, click **Close Batch** to change the batch status from "Open" to "Closed".

**Admin Operators Only**

If a batch is opened in error, click the **Revert Status** button to return the batch status to "Pending".

If a batch is closed in error, click the **Revert Status** button to return the batch status to "Open".

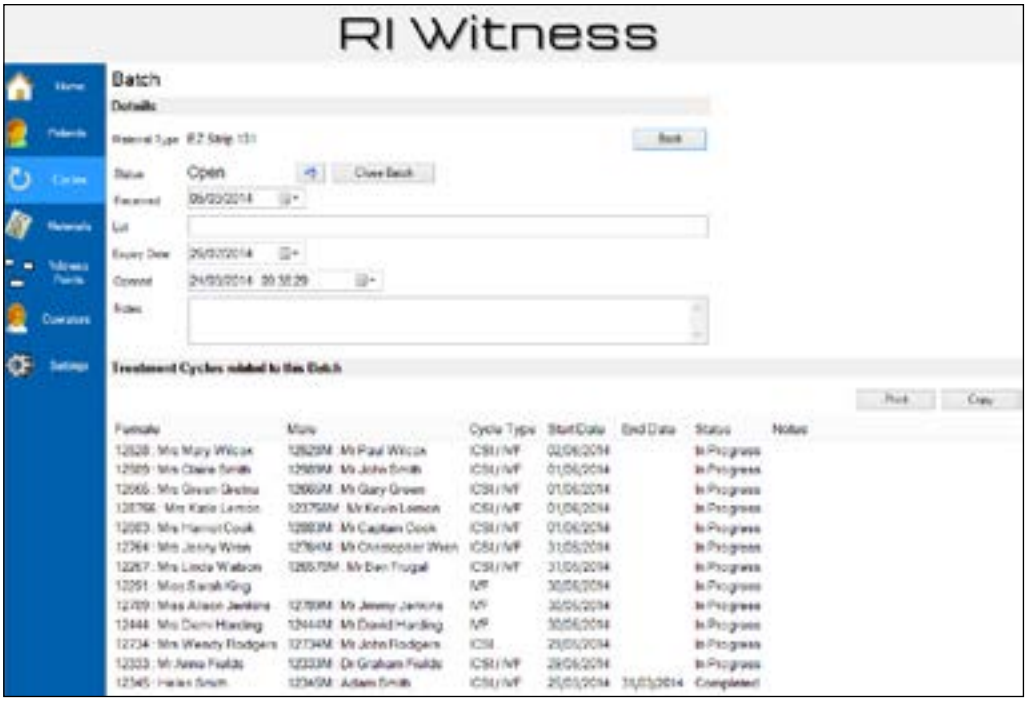


*Figure 8-8 Patient treatment cycles related to a batch of materials*

## Expired Batches

When batches are created an expiry date is recorded. If any currently “Open” or “Pending” batches are expired or within 7 days of expiry then an expiry **Report** button will be available on the main Materials screen. See Figure 8-9.

Double click an expired batch to show the batch details screen from which the batch may be closed. Now remove the batch from use.

The expiry period can be set to your required time period, ie extended to 10 days or shortened to 5 days.

1. Click **Settings** in the main menu.
2. Click **General Settings**.
3. Within the Materials section amend the batch expiry warning field.

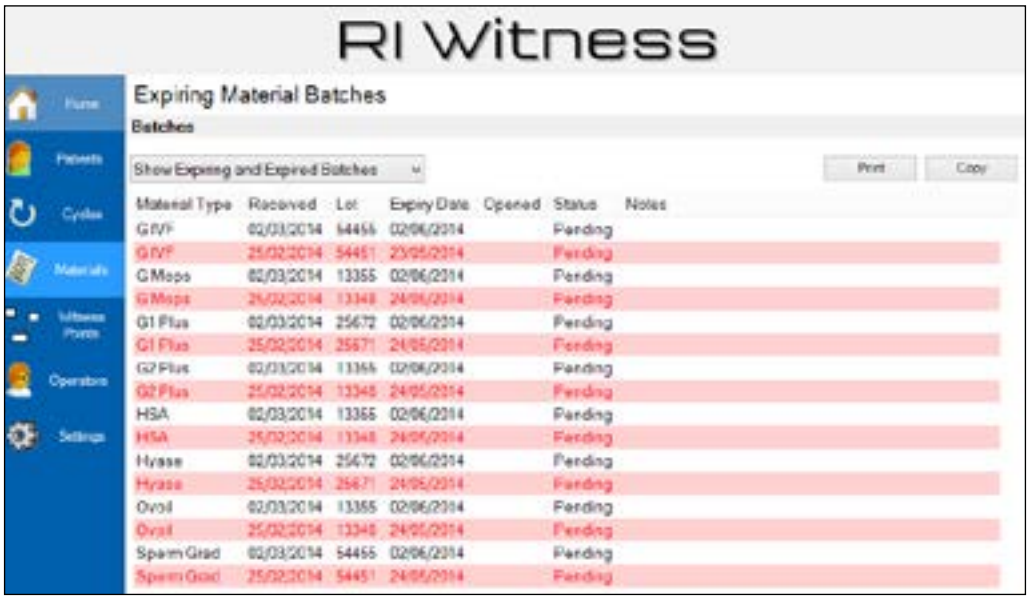


*Figure 8-9 Expired and expiring batches*

## View All Batches

From the main Materials screen click **Report** to view all batches. A filtered list of all batches is shown, expired batches are highlighted in red. This list may be filtered by date and by batch status. See Figure 8-10.

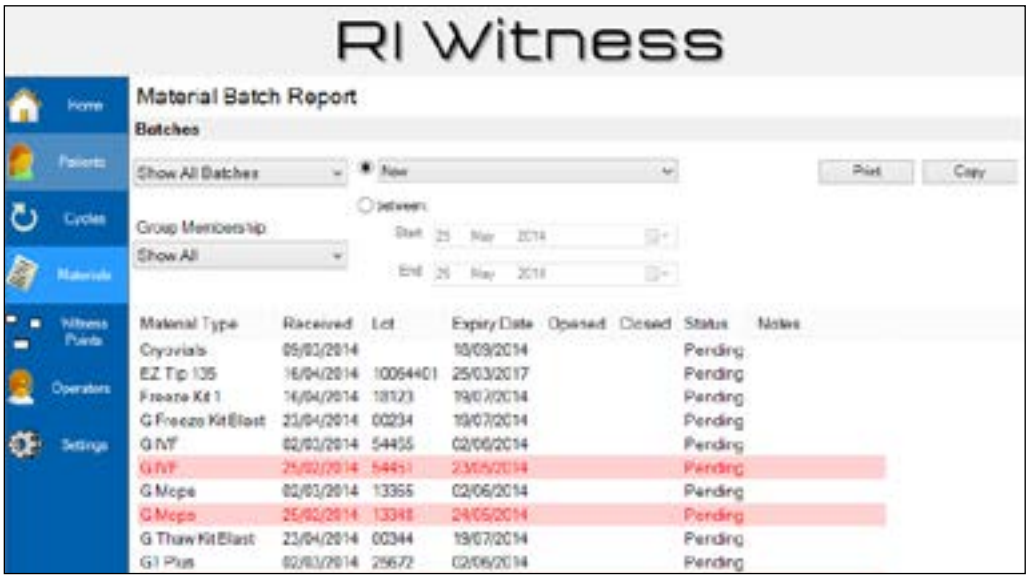


*Figure 8-10 A filtered view of all batches*

## Patients - Managing Treatment Cycles

See “Section 5 - RI Witness™ Basic operation” for details of creating and managing a treatment cycle.

When viewing the details of a treatment cycle Traceability operators may click the Materials tab to show material batches related to this cycle. See Figure 8-11.

## Excluding and Including Batches for a Cycle

Batches can be excluded from cycles by right clicking on the batch and choosing **Exclude Batch** on the context menu.

Excluded batches can be viewed or hidden by clicking the **Hide Excluded Batches** button above the batches list. Excluded batches will be highlighted blue.

An excluded batch can be included again by right clicking on an excluded batch and from the context menu left clicking **Include Excluded Batches**. The batch will now be visible in the list of batches for the cycle.


*Figure 8-11 Material batches related to this cycle*

# SECTION 9 - DATA CAPTURE

## An Introduction to Data Capture for Data Collection

Hand written notes are often taken whilst performing laboratory procedures. For example embryo scores and sperm volumes might be written down on a data sheet and later manually transcribed into a clinic fertility database.

The features of Data Capture described in this chapter allow data sheets to be designed in RI Witness™ Manager and data entry to be performed in the laboratory using the work area touch screen. Data entry may also be performed in RI Witness™ Manager.

## Collected Data Setup

1. Click **Settings.**
2. Then click **Data Collection** to enter the setup screen for data collection. Sheet design is performed using this screen.

The Collected Data Setup screen, Figure 9-1, is divided into 4 regions. Note that region 4 shows the properties of an entry selected from regions 1,2 or 3.

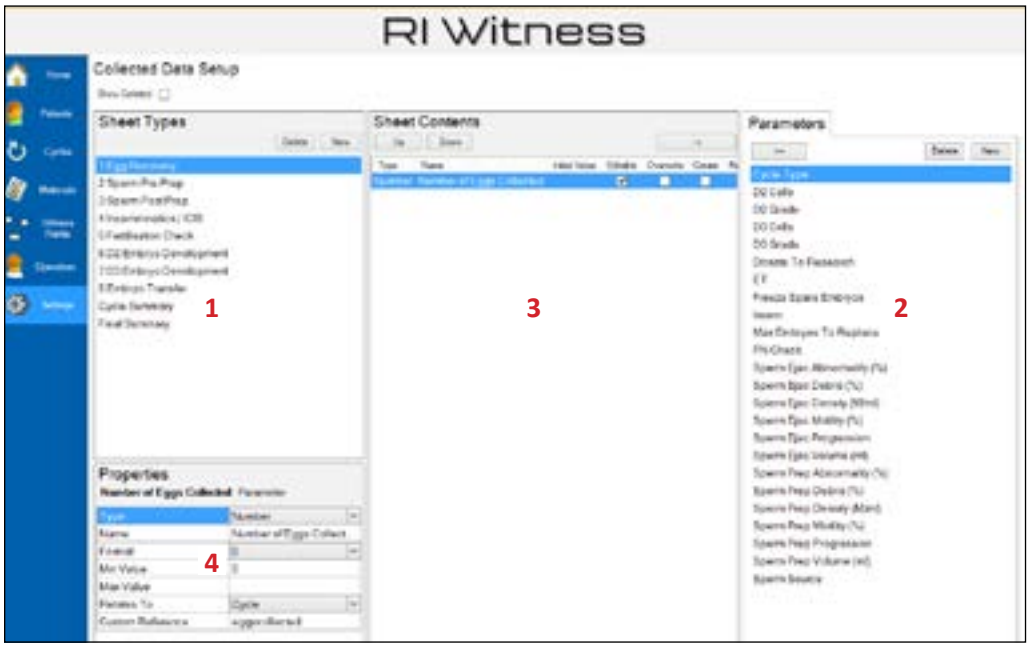


*Figure 9-1 Collected data setup*

1. **Sheet Types**
   Region 1 shows a list of all the sheet types that have been created. Click **New** to add a new sheet, set the name of the new sheet using the properties in region 4.
2. **Parameters**
   Parameters are fields that may be placed on a data sheet. For example, a parameter named “Sperm Volume” that required a numerical value might be added to an “Andrology” data sheet.

   Region 2 lists the parameters that have been created and may be added to the contents of a sheet.

   Click the **Add** button to add a parameter to a sheet contents. The parameter will move from region 2 to region 3.

3. **Sheet Contents**
   Region 3 shows the content layout of the selected sheet type. The contents of a sheet are parameters that have been added to the sheet from region 2. To change the layout order, highlight the parameter by clicking it. Then use the **Up** and **Down** buttons to position it in the order required.

   Once a parameter has been added to a sheet contents, additional attributes may be set. For example, an default value can be set or a parameter can be marked as required so that an operator must provide a value.

   See “Parameter Attributes” on page 87 for more details.

4. **Properties**
   The properties shown in region 4 reflect the most recently selected entry from regions 1, 2 or 3. See Figure 9-2.

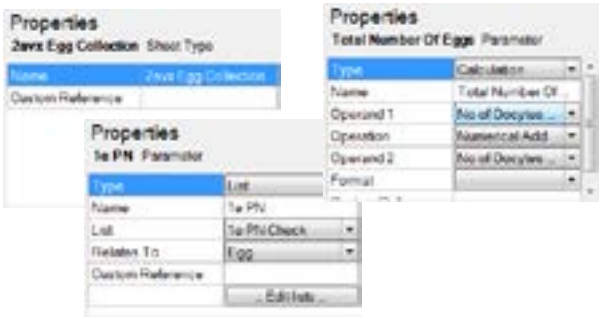


*Figure 9-2 Examples of parameter properties and sheet properties shown in region 4*

## Parameter Configuration

The contents of a sheet are called parameters.

1. Click **New** in the parameters region (2) to create a new parameter. The properties region(4) will show details of the newly created parameter. See Figure 9-3.
2. Enter a name for the new parameter, eg “Sperm Volume”.
3. The first action to perform on a newly created parameter will be to select a parameter type from the Properties Type drop down menu. Parameter properties depend on the selected parameter type. For example the text type has properties min and max length whereas a calculation has two operands and an operation.

Figure 9-3 shows the properties of each parameter type. Figure 9-4 shows the Parameter Type drop down menu.

## Numerical Parameters

The properties of a numerical parameter include a minimum value, a maximum value and an output format. The format specifies the number of decimal places to be used when displaying numbers.

Format **None** means that the value entered by an operator will not be formatted. Figure 9-5 shows the Format pull down.

## Text Parameters

The properties of a text parameter include a minimum length and a maximum length. Leave these properties blank if length restrictions are not required when the operator enters a value for this parameter.

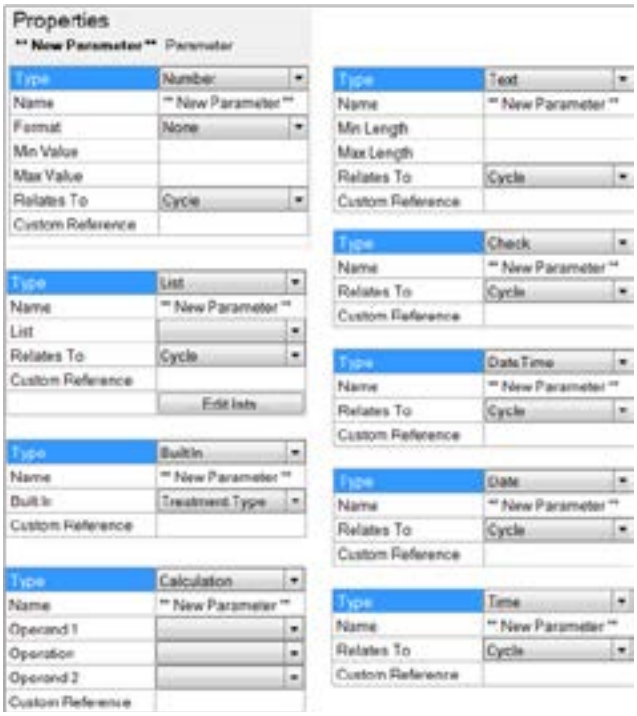


*Figure 9-3 Parameter properties depend on the selected parameter type*
*Select from: Number, Text, Check, List, Date, Time, Date Time, Built In and Calculation*

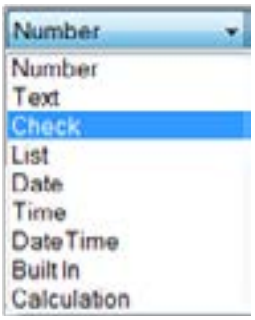


*Figure 9-4 Selecting a parameter type*

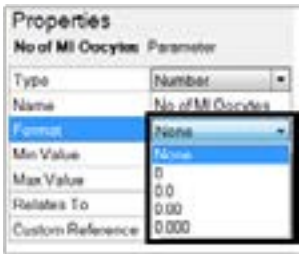


*Figure 9-5 Selecting a numerical format*


*Figure 9-6 The properties of a list parameter*

## List Parameters

List parameters allow the operator to choose a value from a pre-defined list. The properties of a list parameter are shown in Figure 9-6.

Click the **Edit Lists** button to show the Manage Lists window. The example shown in Figure 9-7 highlights the "Polar Body Position" list that contains the 3 values **"PB6"**, **"PB12"** and **"No Injection"**. The "Polar Body Position" list is assigned to the "**Inj**" list parameter. See Figure 9-6.

## Check Parameters

Check parameters take Yes/No values.

Sheets presented by RI Witness™ Manager will show checkboxes. A work area touch screen will offer a selection of **Yes** or **No**.

## Date, Time and Date Time Parameters

Date and time values are viewed and edited using RI Witness™ Manager. An operator may type a value, eg 12:30 or 14/08/2010 15:35. A date picker window is also available. Figure 9-8.

## Calculation Parameters

Calculations perform an operation on two operands, eg add two numbers or join two pieces of text. The operands of a calculation may be parameters of any type including calculation types. A example calculation is shown in Figure 9-9.

## Built In Parameters

Built in parameters will display values derived from the associated treatment cycle, eg the egg collection date. Figure 9-10 shows the available built in values.

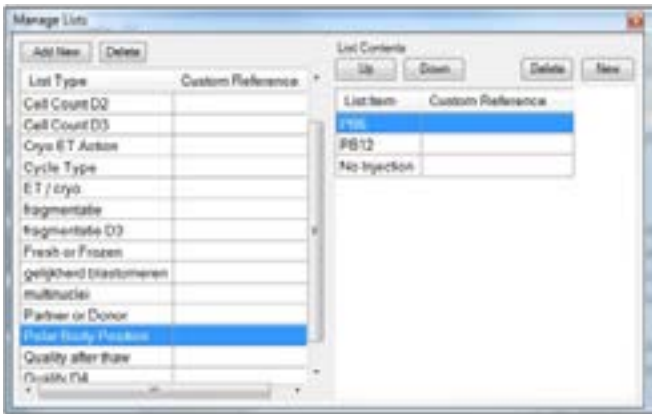


*Figure 9-7 The manage lists window*


*Figure 9-8 Setting a date time value*

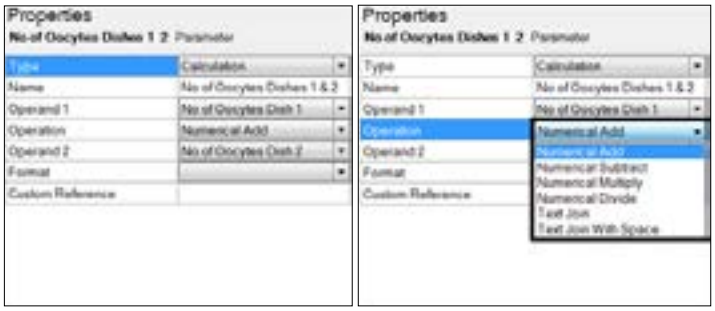


*Figure 9-9 Adding two numbers using a calculation parameter*

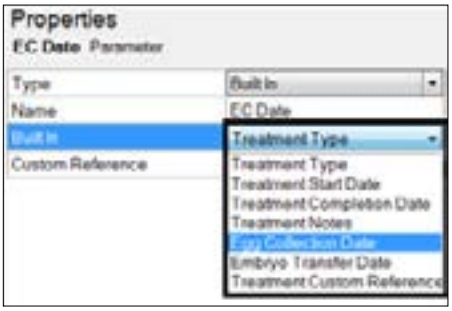


*Figure 9-10 Selecting a built in value*

## Sheet Contents

Click the parameters **Add** button to move parameters to a sheet contents (region 3). In the example shown in Figure 9-11, four list parameters have been added to the contents of the **Embryo Development** sheet.

Figure 9-12 shows another example of sheet contents where two list parameter and four number parameters form the contents of the Sperm Pre Prep sheet.


*Figure 9-11 Adding parameters to the Embryo Development sheet*


*Figure 9-12 Adding parameters to the Sperm Pre Prep sheet*



## Shared Between Sheets

A parameter may be part of the contents of many sheets. The same parameter may be editable on sheet A and sheet B and but not editable on sheet C. A parameter that appears on many sheets has a single shared value. In the above example a value change on sheet A would automatically appear changed on sheets B and C.

The contents of a summary sheet might take parameters from many other sheets. See “Cycle Summary Sheets” on page 86 for more details. See “Parameter Attributes” on page 87 for more details of the editable/ non editable parameter attribute.

## Treatment Cycle Sheets

Treatment cycle types, eg IVF, ICSI or IUI, will have different data collection requirements. For example, a sheet designed for IUI would not be used during an ICSI treatment.

1. Click **Settings** then **Treatment Cycle Types** to associate sheet types with a treatment cycle type.
2. The Data Collection tab lists all available sheets. Check the boxes of those that are associated with the selected cycle type. See Figure 9-13.
3. Click **Save**.

When a list of sheets is presented to an operator, they will be ordered as specified here. Use the **Up** and **Down** buttons to change that order.

## Viewing and Editing Sheets

During a treatment cycle an operator may view and edit the values on a sheet. Each treatment cycle will start with blank copies of the sheet types that have been associated with the treatment type being performed.


*Figure 9-13 Use the checkboxes to associate sheets with the selected treatment cycle type*

## Editing Sheets at the Work Area Touch Screen

Sheets may be viewed and edited on a laboratory work area touch screen.

If sheets have been associated with the treatment cycle type being performed, then a **Data Sheet** button will be shown on the touch screen. See Figure 9-14.

Touch the **Data Sheet** button to see a list of available sheets. Touch a **Sheet Name** button to view or edit the sheet values. See Figure 9-15 and Figure 9-16.

Use the touch screen **Up** and **Down** arrow buttons to highlight the sheet value to be edited. Notice that the type of the value required is indicated to the left of the value entry box, eg 123 for numerical input, ABC for text input and indicating use of the arrow keys for list and Yes/No input.

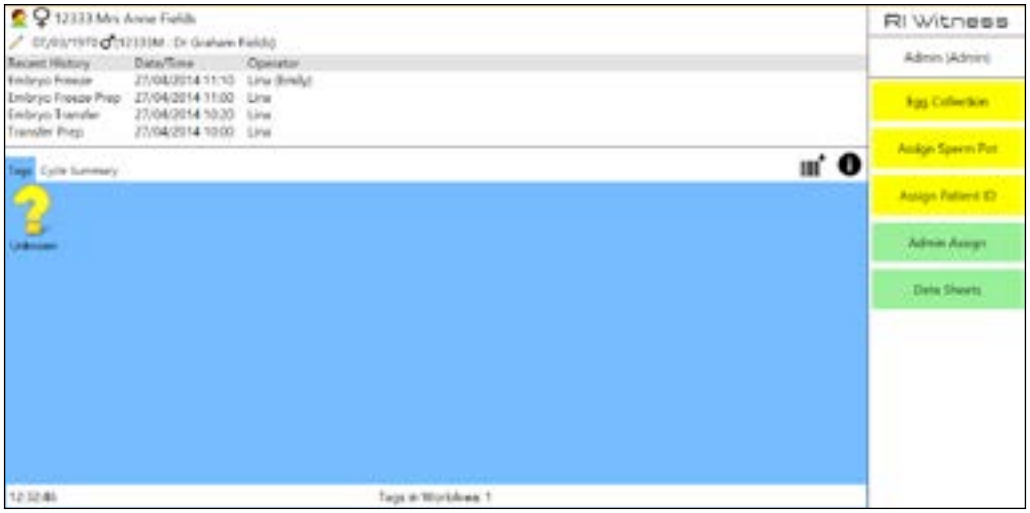


*Figure 9-14 Touch the "Data Sheets" button to view or edit all sheets associated with this treatment*

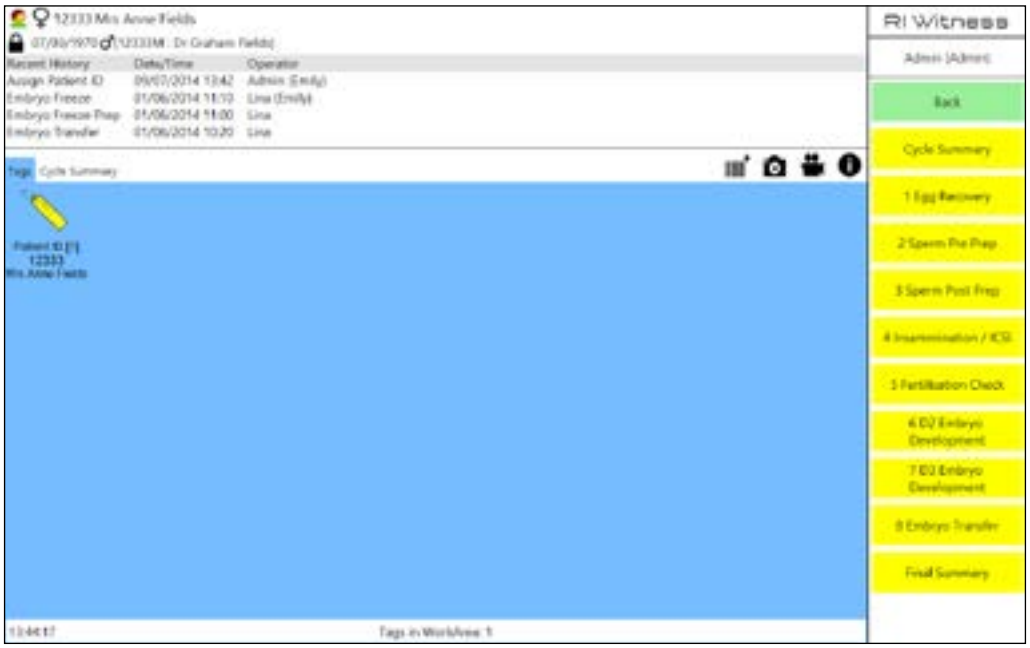


*Figure 9-15 Touch buttons for each available sheet are shown in the work area*

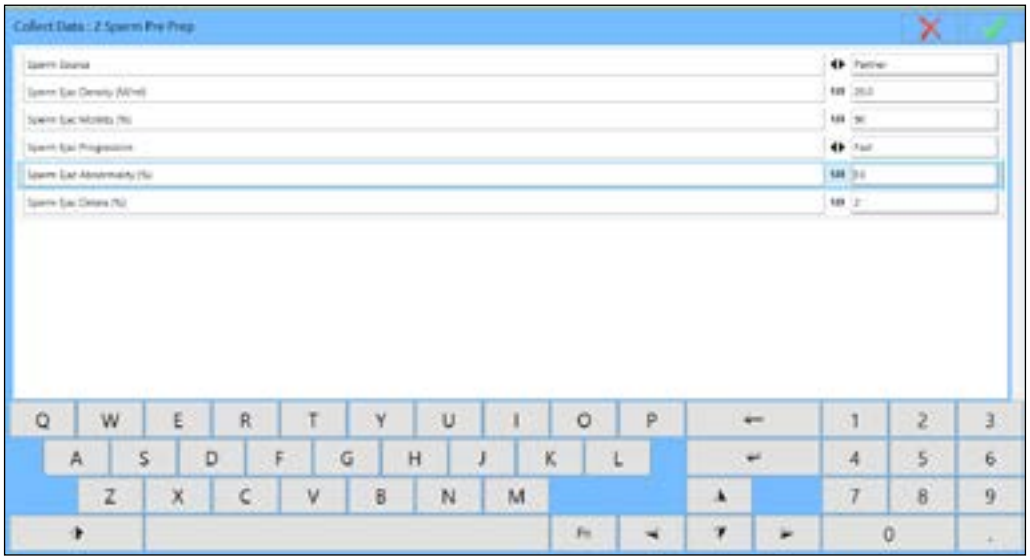

*Figure 9-16 Use the touch keyboard to edit sheet values*

## Viewing and Editing Sheets with RI Witness™ Manager

Data values will most likely be entered at the work area touch screen but sheets may also be viewed and edited using RI Witness™ Manager.

1. Select a patient.
2. Click the **Treatment Cycles** tab and then double click a cycle to show the Treatment Cycle screen.
3. Click the **Sheets** tab to view or edit any sheet associated with this treatment shown in Figure 9-17.

## Egg Parameters

The properties of a parameter include a **Relates To** setting that defaults to Cycle, ie a treatment cycle does not have multiple values for this parameter. See Figure 9-18.

However many parameter values will relate to an individual egg. Change the **Relates To** setting from “Cycle” to “Egg” for such parameters. Egg related parameters are displayed to the operator as a table containing one row for each egg. See Figure 9-19 and Figure 9-20.

On the work area touch screen, touch a row of the egg table to edit the values for that egg. See Figure 9-21. **Note:** The circular arrow buttons at the top of the screen may be used to select another egg without returning to the table view.


*Figure 9-17 Editing sheet values with RI Witness™ Manager*

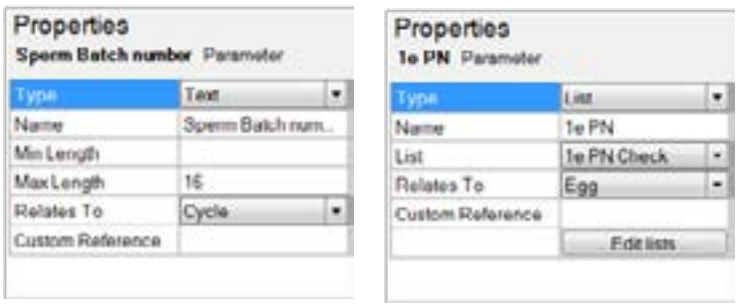


*Figure 9-18 The relates to setting defaults to cycle*


*Figure 9-19 A RI Witness™ Manager view showing a table of egg related parameters.*

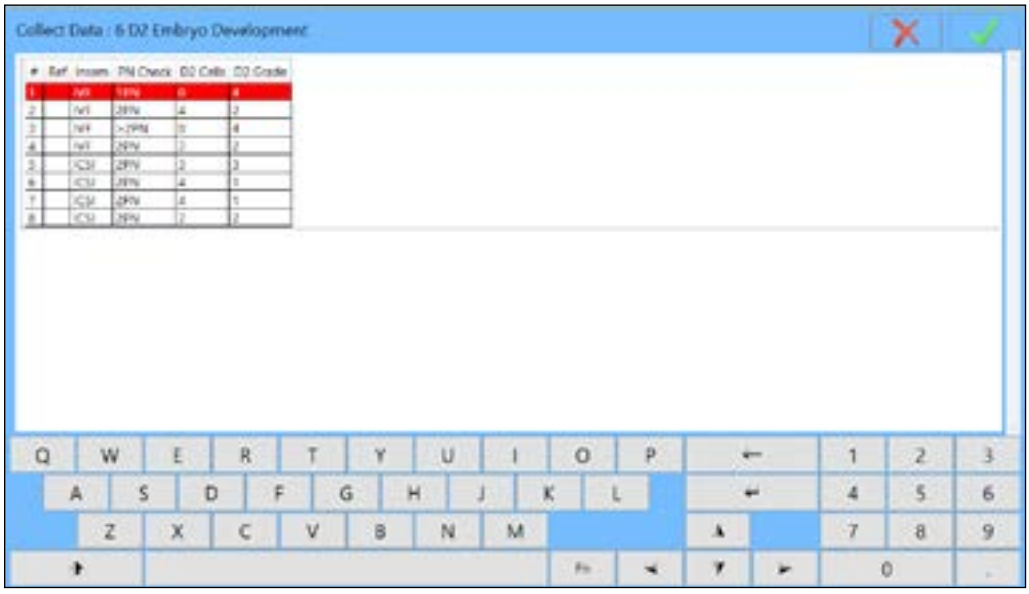


*Figure 9-20 A RI Witness™ work area touch screen view showing a table of egg related parameters*

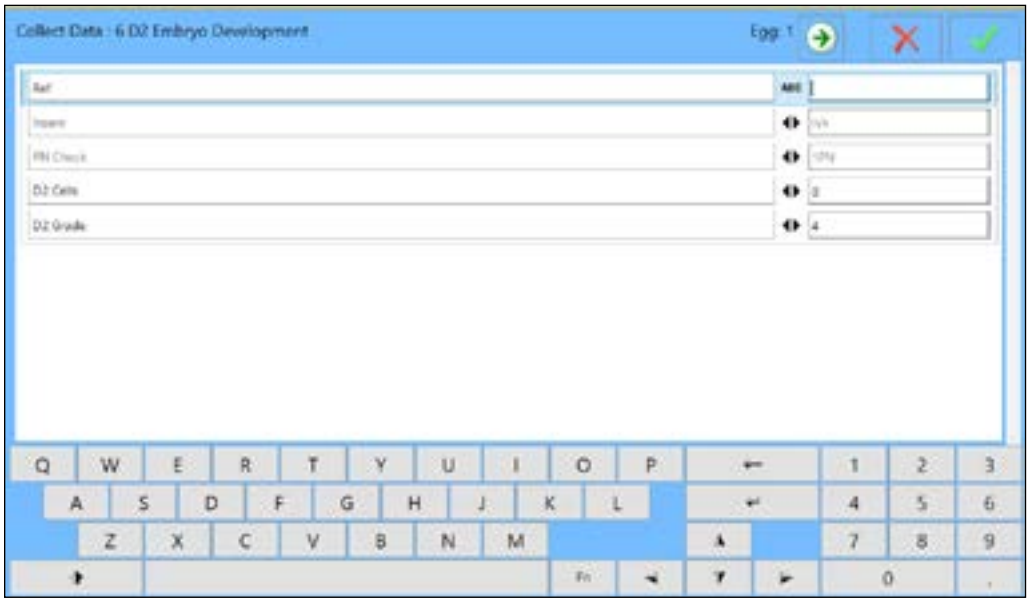


*Figure 9-21 Entering values for egg number 1 at the work area touch screen*

## The Number of Eggs

1. Click **Settings**.
2. Then **Treatment Cycle Types** to view a list of treatment types.

The Data Collection tab is used to associate sheet types with a treatment type as described earlier in this chapter. The Data Collection tab also offers an Egg Count Parameter setting. The drop down menu for the Egg Count Parameter is a list of all parameters. Select one parameter that will contain a numerical value. The selected parameter will control the number of rows in any table of egg related parameters.

## Egg Count Parameter

The parameter selected to represent the egg count can be any parameter with a numerical value that relates to a cycle. In Figure 9-22 the parameter called “Total Number of Eggs” has been selected from a list of all parameters.

As an example, “Total Number of Eggs” might be a calculation parameter whose operands are other parameters. See Figure 9-22.


*Figure 9-22 The number of eggs involved in a treatment is set using the egg count parameter*

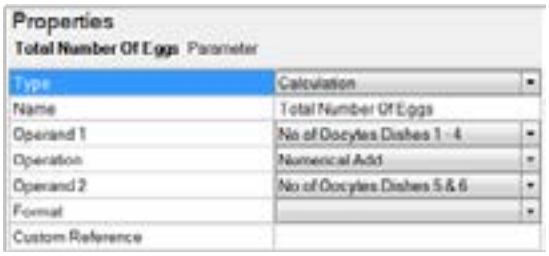


*Figure 9-23 This calculation parameter has been selected as the egg count parameter in the example shown in Figure 9-22*

## Egg Count Conflict

Changes to the value of the parameter set as the **Egg Count Parameter** will change the number of rows in any table of egg related parameters.

If the number of eggs is increased, then the number of rows in all egg tables will automatically increase. If the number of eggs is decreased, then the number of rows in all egg tables will not automatically decrease. A decrease in the number of eggs will be indicated in RI Witness™ Manager as an **Egg / Embryo Count Conflict**. See Figure 9-24.

A conflict resolution window is shown when the **Egg/Embryo Count Conflict** button is clicked. See Figure 9-25. The conflict resolution window allows the operator to manually select the egg records that will be deleted to achieve the required decrease in egg count. The conflict will be resolved when the number of egg records equals the value indicated by the Egg Count Parameter.

If it is decided that a decrease must be "undone", then click the **Cancel** button to exit the conflict resolution window and increase the value of the Egg Count Parameter to match the number of egg records.


*Figure 9-24 The Egg/Embryo Count Conflict button is shown if the value of the parameter selected as the egg count parameter is decreased*

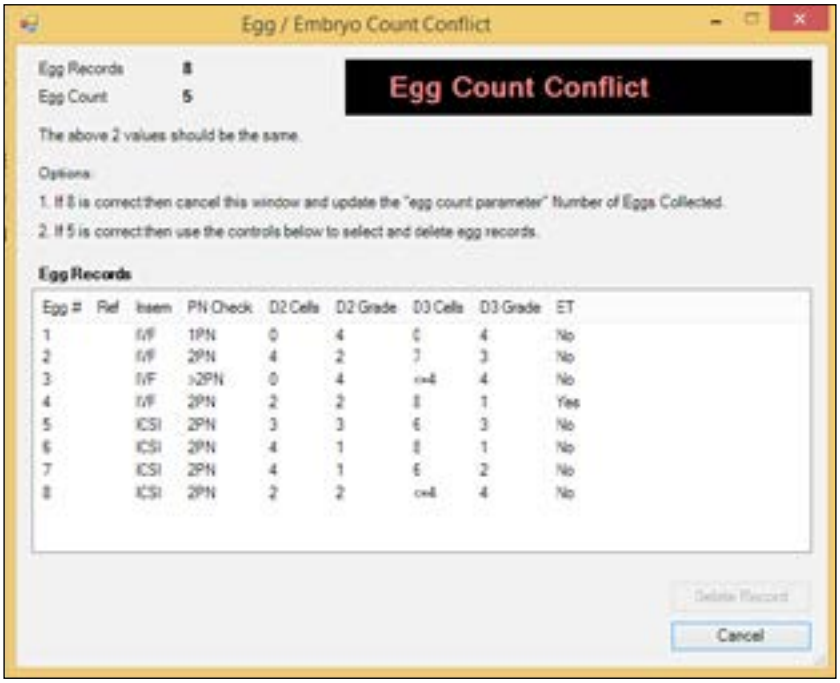


*Figure 9-25 The Egg/Embryo Count Conflict window*

## Sheets and Witness Points

The work area touch screen **Data Sheets** button offers access to all the data sheets that have been associated with a treatment type.

A more selective approach to data collection is possible by linking a sheet type to a witness point. See Figure 9-26.

When a touch screen **Witness Point** button is touched, the linked sheet will be automatically presented so that the operator may enter data related to the procedure being performed. See Figure 9-27.

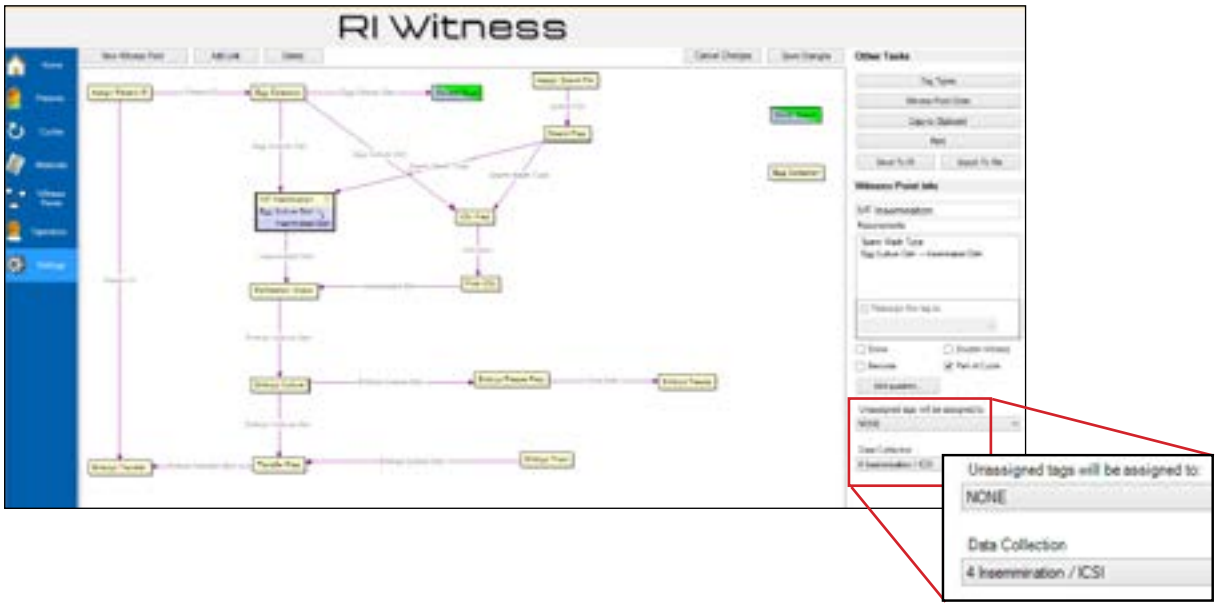


*Figure 9-26 The selected witness point "IVF Insemination" is linked to the data collection sheet " 4 Insemination/ICSI", see above at bottom right*

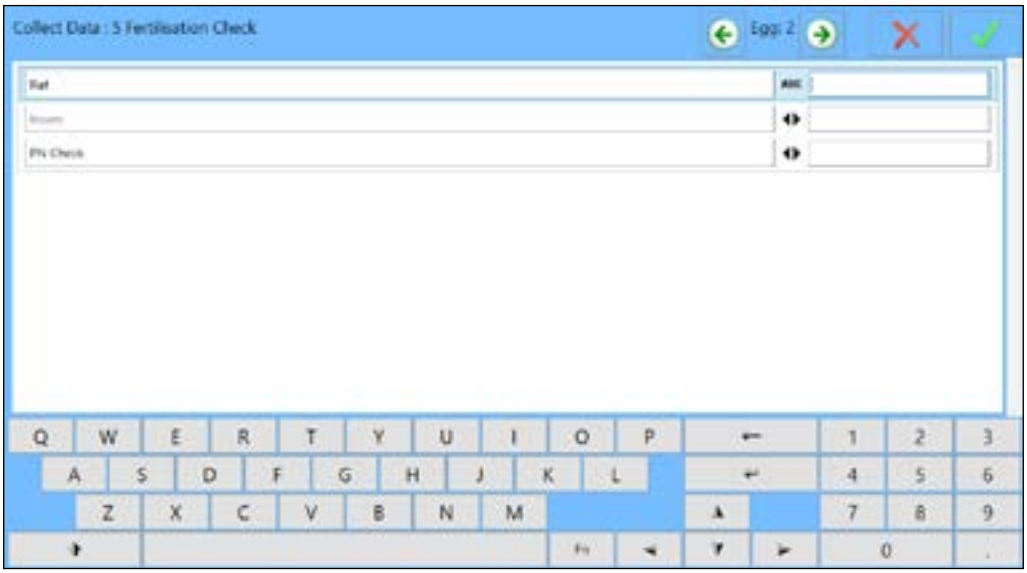


*Figure 9-27 A witness point will trigger the presentation of a linked data collection sheet*

## Cycle Summary Sheets

Any sheet type may be selected as the cycle summary sheet.

1. Click **Settings** in the main menu bar.
2. Then click **Treatment Cycle Types**.
3. Use the **Cycle Summary** drop down menu to select the sheet type that will become the summary sheet for this treatment type. See Figure 9-28.

A typical summary sheet would show parameter values from many other sheets. See “Shared Between Sheets” on page 79 for more details.

Quick access to a read only view of the cycle summary sheet is visible in the work area via the touch screen **Cycle Summary** Button. See Figure 9-29.


*Figure 9-28 Select one sheet to become the cycle summary sheet*

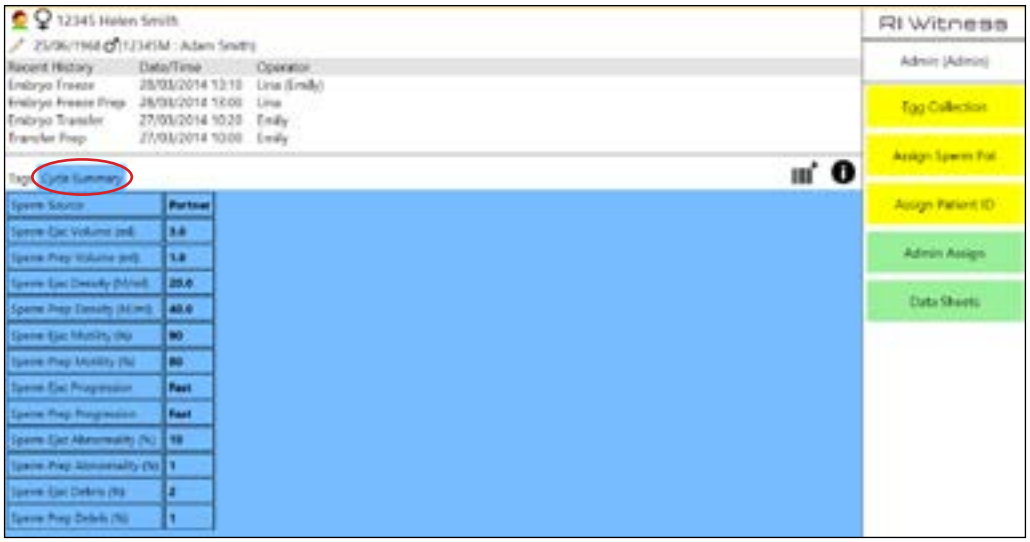


*Figure 9-29 Touch the cycle summary button to see the cycle summary sheet Touch again to return to the original display*

## Parameter Attributes

Parameters that have been added to a sheet contents may be given sheet specific attributes. Click **Settings** then **Data Collection**. See Figure 9-30.

## Initial Value

Click in the **Initial Value** column and enter a value.

Initial values are linked with the **Overwrite** and **Create** checkboxes.

An initial value setting will be ignored unless a combination of **Overwrite** and or **Create** is also checked. See Figure 9-31.

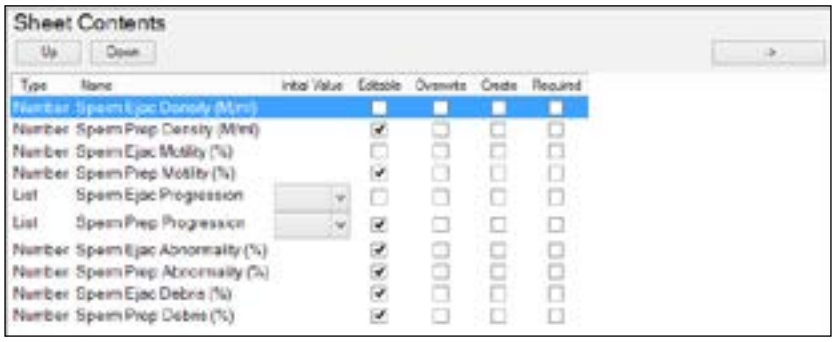


*Figure 9-30 Setting parameter attributes.*
*Initial Value, Editable, Overwrite, Create and Required*

## Editable

The value of editable parameters may be changed. If this checkbox is not checked then the parameter will be shown “greyed out” and may not be changed on this sheet.

## Required

An operator must enter a value for a required parameter. The sheet cannot be saved until a value is entered. Required parameters are highlighted with an asterisk on the work area touch screen and in red when viewed in RI Witness™ Manager.

| Create | Overwrite | Editable | Required | **Description**<br>What does this combination mean ? |
|---|---|---|---|---|
| | | | | The value may not be edited |
| | | | ● | n/a |
| | | ● | | Editing allowed but may be left blank. |
| | | ● | ● | A value must be entered but it may not be left blank. |
| | ● | | | If a value already exists it will be overwritten with the initial value. The user cannot change the value. |
| | ● | | ● | n/a |
| | ● | ● | | If a value already exists it will be overwritten with the initial value. The user may change the value. |
| | ● | ● | ● | If a value already exists it will be overwritten with the initial value. The user may change the value but it may not be left blank |
| ● | | | | If no value exists then show the initial value.<br>The user may not change this value. |
| ● | | | ● | n/a |
| ● | | ● | | If no value exists then show the initial value.<br>The user may change this value. |
| ● | | ● | ● | If no value exists then show the initial value.<br>The user may change this value but it may not be left blank. |
| ● | ● | | | The initial value **will** be shown, overwriting any existing value.<br>The user may not change this value. |
| ● | ● | | ● | n/a |
| ● | ● | ● | | The initial value **will** be shown, overwriting any existing value.<br>The user may change this value. |
| ● | ● | ● | ● | The initial value **will** be shown, overwriting any existing value.<br>The user may change this value but it may not be left blank. |

*Figure 9-31 Combining parameter attributes*

# SECTION 10 - IMAGING

## How to View Live Images

A camera will need to be connected to the PC running RI Witness™ and the drivers installed correctly to view live images within RI Witness™. The Imaging security dongle must also be fitted to a USB port and a valid Imaging license issued.

RI Witness™ software will automatically recognise both analogue and compatible digital camera devices connected to the PC. If there is only one camera device detected, it will show the live image for that device. If multiple camera devices are connected, it will use the camera that was last selected from the video source drop down box.

If there are multiple cameras attached to the PC, the device you want the live image to be viewed from may be selected.

To do this, select the Camera from the dropdown list on the **Settings** panel.

## Multiple Screen Configuration

Multiple Imaging screens can be configured for use with Imaging.

1. Open **System Information.**
2. Unlock settings.
3. Touch **Screen Configuration / Training Mode**.

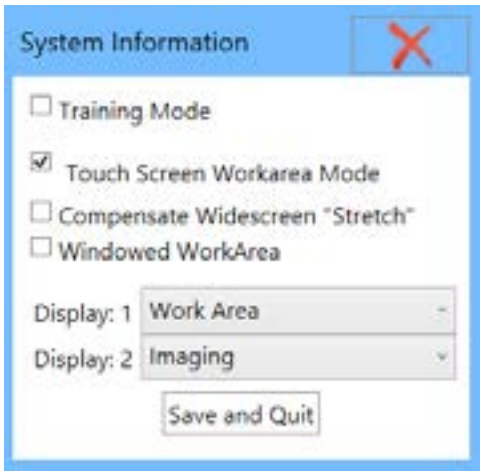


*Figure 10-1 Combining parameter attributes*

4. Set your desired configuration

   If the work area is windowed, then multiple displays will not be shown. Windowed work area is recommended for Admin PCs with readers connected. To enable simply tick the **Windowed WorkArea** box.

5. The current operator and patient will be displayed on the secondary Imaging screen.


*Figure 10-2 Imaging screen showing operator and patient*

Both operators and patients may be changed by clicking the appropriate area on the Imaging screen.

Images are captured for the patient's cycle currently active in the work area. Images captured for the active cycle will be displayed in the RI Witness™ Manager sorted by date and time.

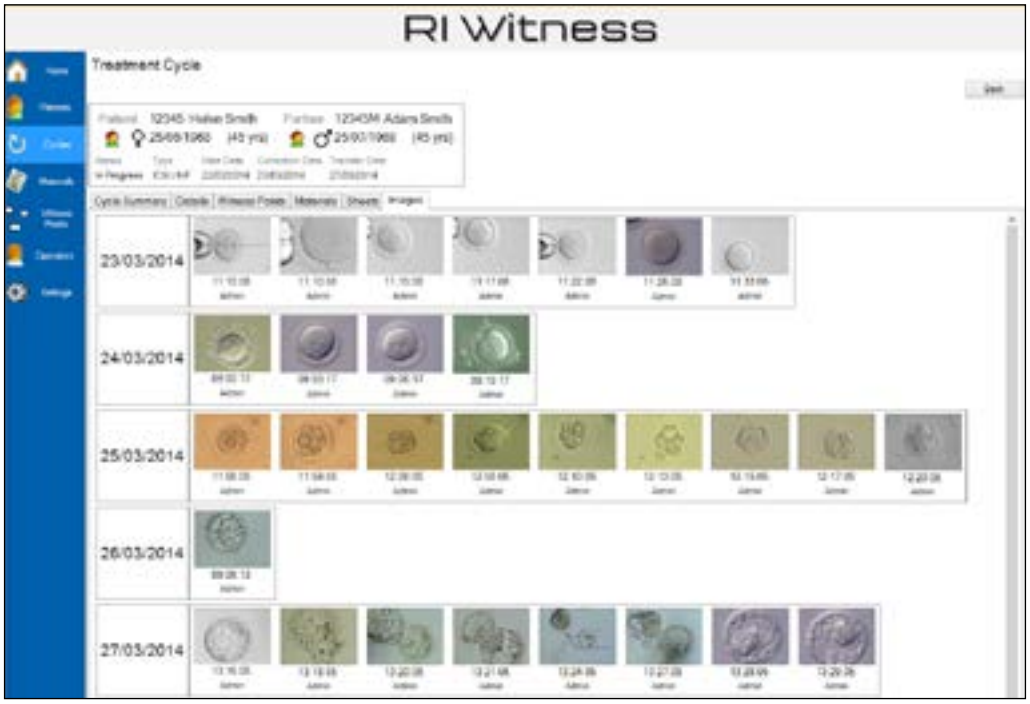


*Figure 10-3 Images captured shown in the RI Witness™ Manager screen*

Ensure that there is a location set to store captured images. This is set in RI Witness™ Manager.

1. Click **Settings** in the Main Menu tool bar.
2. Click **General Settings**.
3. Set the desired file path within the Image Storage Location field.

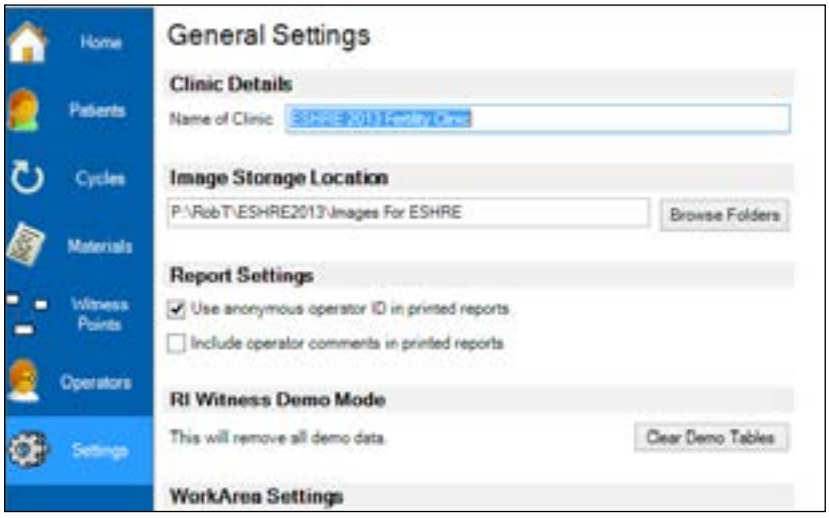


*Figure 10-4 Image storage location*

## How to Take a Picture

This is available on both the work area screen and secondary Imaging screen.

1. Log in using your operator name and PIN.
2. Ensure there is a patient with an active / open cycle in the work area.
3. Press the **Camera** icon .

## How to Record Video

This is available on both the work area screen and secondary Imaging screen.

1. Login using your operator name and PIN.
2. Ensure there is a patient with an active / open cycle in the work area.
3. Click the **Film** icon .
4. Each video recording can last for a maximum of one hour. This eliminates the problem of accidentally leaving the software recording and possibly rendering the computer unusable.
5. When freeze frame is set as keyboard shortcut, the live image recording can be paused. A second press of the shortcut key will restart the live image recording.
6. Press or click **Pause** to stop recording.

## How to Zoom & Pan the Image

Available on the Imaging screen

There are three ways to zoom into an area on the screen.

1. Place the mouse at a point on the screen. Click and hold the right mouse button, then release. This will zoom to the preset zoom level into the spot where the mouse is placed. To zoom out, click and hold the right mouse button.
2. Place the mouse at a point on the screen and use the scroll wheel on the mouse (if available). This will give the user control over how much digital zoom is given.
3. Using the tool bar at the bottom of the screen, click the **+** icon to zoom in incrementally. To zoom out by the same amount, click on the **-** icon on the tool bar. The magnifying glass icon will zoom in and out by the preset zoom.

Whilst using digital zoom, a thumbnail image of the screen will appear in the top left of the screen. At the top of this panel is the amount of magnification you are using. When zoomed out fully, this panel will not appear on the screen.

Zooming in and zooming out can also be achieved using the foot pedal.

## How to Perform Measurements

Available on the Imaging screen



1. Click **Measure** icon on the tool bar.
2. Click on the screen to select a start point for the measurement.
3. Click on the screen a second time to select an end point for the measurement.

The ends of the line can be dragged to change the measurement.

Lines can be removed by clicking the cross in the context window.

During laser operation, lines are shown but cannot be dragged/created and no measurements will be displayed.

Lines and measurements are shown on an image when images are taken in Line Mode.

## How to Select Cameras

Available on both the work area screen and secondary Imaging screen.

1. Open **System Information.**
2. Unlock settings.
3. Press 

4. Click on the **drop down box** to allow the selection of cameras. Clicking on the required camera in the list will change the live image to that of the selected camera.

## Camera Flipping

Available on both the work area screen and secondary Imaging screen.

1. Open **System Information.**
2. Unlock settings.
3. Press 

4. Tick **Flip Video Horizontal** (for camera devices that support these options).
5. Tick **Flip Video Vertical** (for camera devices that support these options).

## How to Set the Preset Zoom

Available on the Imaging screen.

1. Click the **Image Settings** icon  from the Imaging screen.
2. Drag the Preset Zoom slider to the required zoom.

## How to Configure the Foot Pedal/Keyboard

Available on both the work area screen and secondary Imaging screen.

1. Open **System Information.**
2. Unlock settings.
3. Press 

4. Click the corresponding edit button to assign a shortcut.
5. Hold down the key or press the foot pedal to assign.
6. Click or press the **green tick**  to save the shortcut.

Once the shortcuts are set up, press the shortcut keys or the corresponding foot pedal to activate the command.

## How to Select Objectives

Available on the Imaging screen.

1. Click the **Magnification** 

on the tool bar.
2. Click the required objective magnification.

## How to Add Objectives

Available on the Imaging screen.

1. Click on the tool bar.
2. Click the **Objective Calibration** button.
3. Click **New Objective.** The magnification will be the same as the current magnification.
4. Click the required objective to edit objective magnification and fine adjustment values.

## How to Remove Objectives

Available on the Imaging screen.

1. Click on the tool bar.
2. Click the **Objective Calibration** button.
3. Click **X** next to an objective.

## How to Check Objective Calibration

Available on the Imaging screen

1. Click on the tool bar.
2. Click the **Objective Calibration** button to open the Objective Calibration panel.
3. Place an object of known dimensions (a stage micrometer is supplied with each system for this purpose) in the field of view.
4. Ensure that the objective selected in Imaging matches that being used on the microscope.
5. The stage micrometer supplied measures 100µm between the longer lines. For best accuracy, position each end point of the line at exactly the same relative position on the scale, for example at the right hand edge of each vertical line.
6. Drag the rulers to the point where the stage micrometer is going to be measured from and use the fine adjustment up and down until the ruler scale matches the stage micrometer.

## Patient Display

1. To configure a screen as a patient display simply select the **Patient Display Configuration** for the desired screen. The screen will display the RI logo until the display is turned on.

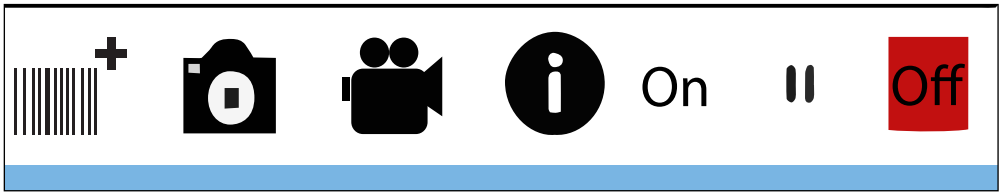


*Figure 10-5*

2. To turn the patient display on/off so that it shows the video from the camera, click the **On** or **Off** button either on the work area or on the patient display panel on the Imaging display. The Imaging display shows a preview of what the patient display will show. See Figure 10-5.
3. To take a snapshot of the video to use on the patient display, press the **Pause** button on the work area or patient display panel.
4. To re-enable live streaming of the video, press **Play**.


*Figure 10-6 Information shown on patient display*

**Note:** When a current patient is activated via the work area, the patient name and ID will appear on the Patient Display. It will only be visible if the patient display is turned on. See Figure 10-6.

5. Closing the main window will also close the patient display.

## Use of Saturn™ Laser Systems with RI Witness™

RI Witness™ can be run alongside and in conjunction with Saturn™ Laser Systems. Please refer to the Saturn™ Laser System user manual for full instructions.

## How to Access Saturn Laser System Information from a Work Area

To access settings and information from the work area

1. Open **System Information.**
2. Unlock settings.
3. Detailed information about the Saturn™ Laser System will be displayed.
4. Press **Setting** icon ⚙ to enable Biopsy or Multi-Pulse Modes.

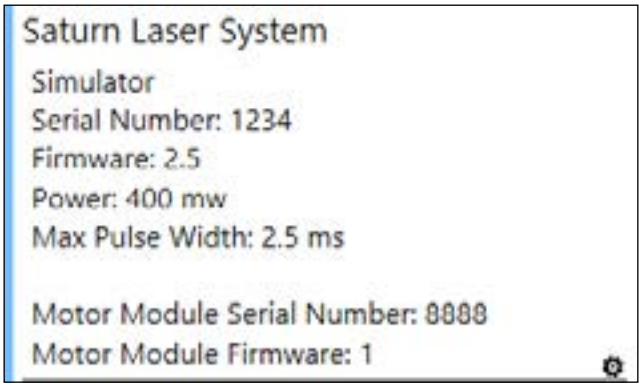


*Figure 10-7 Saturn™ Laser System information*

## SECTION 11 - TROUBLE SHOOTING

| Problem | Possible Cause | Solution |
|---|---|---|
| Tags Reading Intermittently or Only in Certain Areas | RF noise | Many devices in the lab can cause RF noise. Contact RI or a RI representative. |
| | Antenna not tuned | Metal objects may change antenna tuning. Position the antenna where it will be used. If the antenna that is not tuned is an auto tuning antenna follow the instructions shown in “RF Calibration” on page 19, otherwise contact RI or a RI representative to retune the antenna. |
| | Antenna not tuned | Metal objects may change antenna tuning. Position the antenna where it will be used. If the antenna that is not tuned is an auto tuning antenna follow the instructions shown in “RF Calibration” on page 19, otherwise contact RI or a RI representative to retune the antenna. |
| | Loose connection | Check for any cables unplugged or not tightened fully. |
| | Control unit / antenna / multiplexer faulty | Contact RI or a RI representative. |
| Tags Not Reading | Broken tag | Check the tag on a different antenna. |
| | Tag not encrypted | Use the **System Information**. Non encrypted tags are shown in red. |
| | RF noise | Many devices in the lab can cause RF noise. Contact RI or a RI representative. |
| | WorkArea configuration | Use the **System Information** to check that the number of antennas matches the number in the work area. Also check that the temperature controller is specified correctly. |
| | Antenna not tuned | Metal objects may change antenna tuning. Position the antenna where it will be used. If the antenna that is not tuned is an auto tuning antenna follow the instructions shown in “RF Calibration” on page 19, otherwise contact RI or a RI representative to retune the antenna. |
| | Loose connection | Check for any cables unplugged or not tightened fully. Contact RI or a RI representative. |
| | Control unit / antenna / multiplexer faulty | Contact RI or a RI representative. |

| Problem | Possible Cause | Solution |
|---|---|---|
| Multiplexer / Control Unit / Temp Controller Missing | RI Witness™ WorkArea configuration | Use the **System Information** to check that the number of antennas matches the number in the work area. Also check that the temperature controller is specified correctly. |
| | Loose connection | Check for any cables unplugged or not tightened fully. |
| | Control unit / antenna / multiplexer faulty | Contact RI or a RI representative |
| Database Missing | RI Witness™ WorkArea configuration | Use the **System Information** to check that database connection is specified correctly. Contact your IT department for assitstance. |
| | Loose connection | Check for any unplugged or loose network cables. Replace with a known good cable. |

# SECTION 12 - TEMPERATURE CALIBRATION

## Temperature Profile

Before checking the temperature profile, it is important to establish if the reader is a one or two channel reader. This can be done by turning off the control box and restarting. At the beginning of the start-up procedure the control box screen will show a tick or a cross next to the channel number (see heated control box display warnings). If the reader is a single channel it will display a tick next to channel one and a cross next to channel two, while a 2 channel will display a tick next to both.

The temperature gradient over the heated plate should not exceed 1.5°C. In a single channel reader the temperature difference between the centre of the glass window and the highest temperature measured away from the window should not exceed 3.0°C. For a dual channel reader the temperature difference between the centre of the glass window and the highest temperature measured away from the window should not exceed 1.5°C.

## Temperature Profile Checklist

1. Follow this guide to position small amounts of thermal paste at each point to be measured.

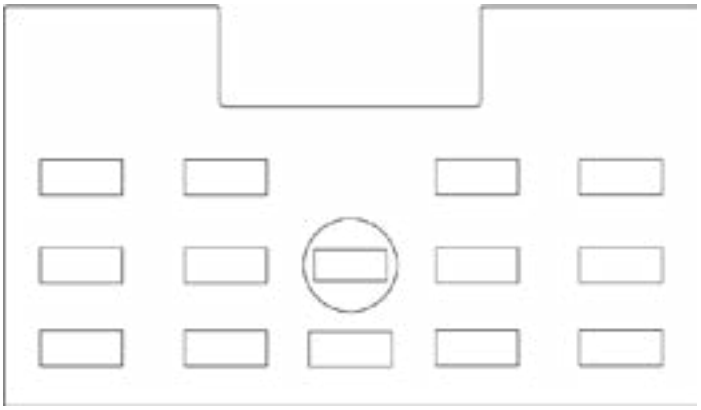

*Figure 12-1 Temperature profile template*

2. Complete the form 'RI Witness™ Heated Antenna Service Record' for each heated reader. The latest forms are available by contacting RI.
3. Use a thermometer probe secured with masking tape to measure the temperature at each of the 14 points. Allow 3-5 minutes for the probe reading to stabilise at each measurement point.

## Temperature Calibration



The objective of temperature calibration is to ensure that the temperature indicated by the RI Witness™ software is within 0.2°C of the temperature measured on a heated reader surface.

Ensure that the work area setup is as it will be used, eg microscope light on, fan on, etc.

We recommend using a thermometer calibrated at 37°C fitted with a small thermocouple probe, such as the RI IVF Thermometer.

## Temperature Calibration Service

1. Switch the control unit **ON**.
2. Make sure the control unit RF power is switched off to avoid interference with a thermometer reading.
3. Place a small amount of thermal compound 5cm to the right of the reader window. Position a thermometer probe in the compound and secure the probe with masking tape.
4. Wait until the thermometer temperature stabilises. This can take up to 45 minutes.
5. Compare the temperature shown in the work area software with the thermometer reading. A difference within +/-0.2°C is acceptable.
6. If the readings are outside the above requirement then click **temperature** to open the temperature offset settings and make adjustments. Increase the offset to increase the displayed reading, decrease the offset to decrease it.
7. Allow a small delay for the offset change to register.

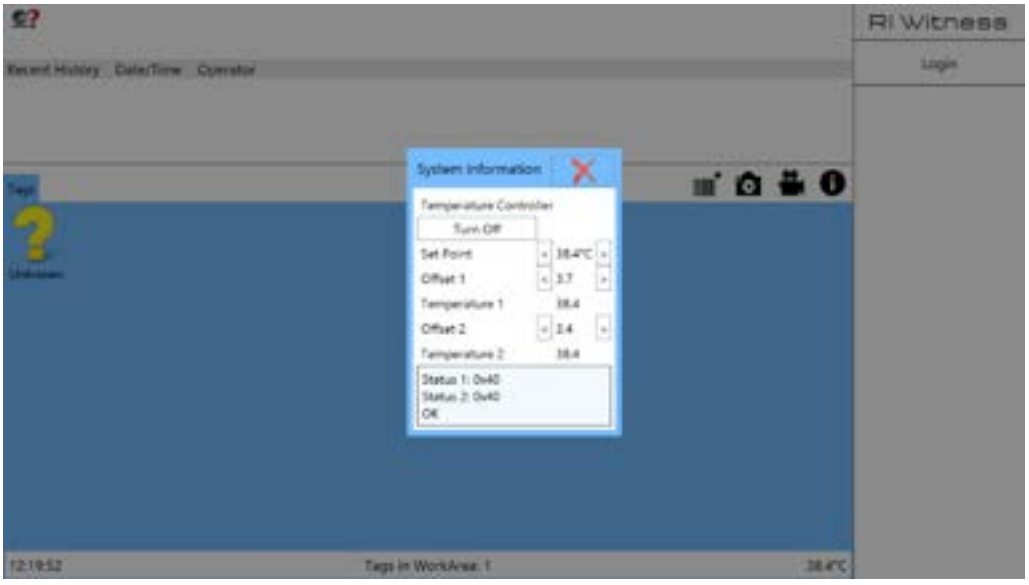


*Figure 12-2*

## Touch Screen Calibration Checklist

The touch screen cursor should accurately track the position of an operator finger. If accuracy problems are experienced then use a mouse to activate the calibration utility and perform the following checklist.

1. Double click the **touchkit** desktop icon, then click **4 Points Calibration** on the **Tools** tab.
2. The touch screen shows a blinking **X** in the lower left corner. Touch and hold the blinking **X** until it stops blinking and moves to the next corner position. Repeat the touch and hold for each corner of the screen. On completion a “calibration finished” message is displayed.
3. Touch the screen in a few random locations. Repeat the calibration if the cursor is not correctly positioned.

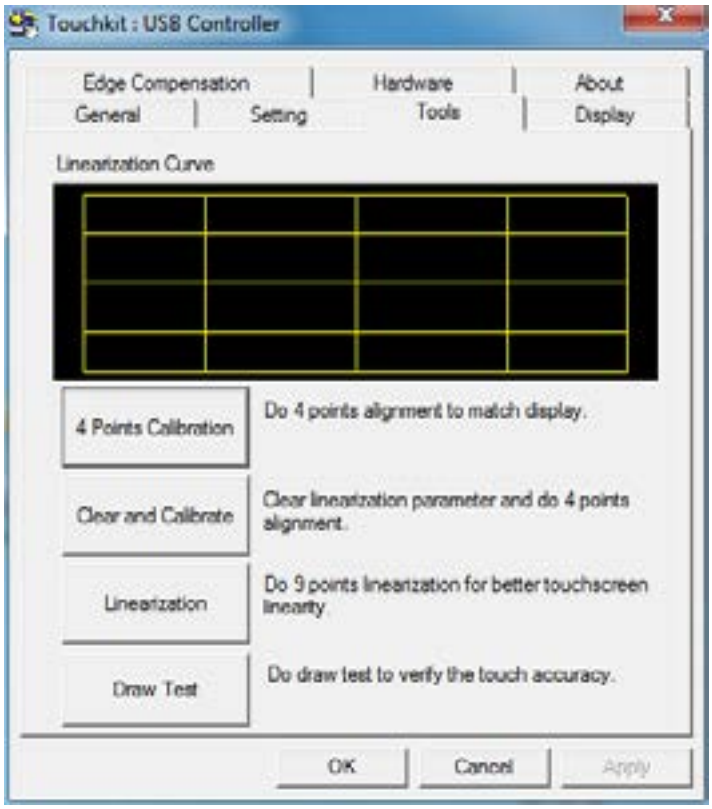


*Figure 12-3 Touchkit : USB controller screen shot*

# SECTION 13- CARE AND MAINTENANCE

## Cleaning

RI Witness™ readers may be cleaned with a soft cloth and mild detergent. A reader may be lifted and returned to its original location. Do not disconnect the cables attached to any reader.

Do not use solvents for cleaning.

Do not disconnect readers.

Do not change the position of readers.

# SECTION 14 - 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.
2. If you require any further help contact your distributor or RI directly. RI will try to resolve the problem as quickly as possible.

## 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.

## 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.

## 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

## 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.

## Feedback

Thank you for purchasing a 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 them to feedback@research-instruments.com. Your feedback will help us develop the product and supporting materials to meet your future needs.

Thank you.