User Manual

RI WITNESS™

Manager Software
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SECTION 1 - PREFACE

Thank you for choosing RI Witness.

This manual provides all necessary information to use the RI Witness Manager Software and should be read in conjunction with any manuals provided with other RI Witness hardware or software components that you are using. The system should be operated by trained personnel only. All sections of this manual should be read and understood fully before any operation of the system.

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. This manual belongs with the RI Witness system and should be passed on with the system if relocated to another clinic.

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SECTION 2 - INTRODUCTION TO RI WITNESS

RI Witness offers a number of features that will help you save time, allow for increased capture of cycle information and speed up the auditing process.

Indication for Use for RI Witness System

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

Related Documents

6-70-121UM  RI Witness WorkArea Software User Manual
6-70-121IT   RI Witness IT Requirements
6-70-807UM   RI Witness Embryology Heated Plate User Manual
6-70-808UM   RI Witness Sperm Preparation Reader User Manual

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 2-1.

Data entry may also be performed in RI Witness Manager.

Figure 2-1
Lower: Data Entry Using an RI Witness WorkArea Touchscreen
Upper: Data Sheet Design Using RI Witness Manager
Imaging

The Imaging feature enables you to capture images and videos from every microscope equipped with a camera, 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 transfer room to show the patient prior to embryo transfer.

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

![Figure 2-2 Example of Patient View Shown in the Embryo Transfer Room](image)

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 security level of the RI Witness system, by 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

A typical RI Witness work area includes a PC, touchscreen and one or more tag readers. The work area PC runs RI Witness WorkArea software to present an operator interface on the touchscreen. See Figure 2-3.

The data presented on the touchscreen is generated from the shared RI Witness database. All work area events are logged in the shared RI Witness database.
RI Witness Manager

RI Witness Manager runs on any Windows PC and provides RI Witness, Data Capture, Cryo, Traceability and Imaging functionality. See Figure 2-4.

![RI Witness Manager Screenshot]

**Figure 2-4 RI Witness Manager is Used by RI Witness, Data Capture, Traceability, Imaging and Cryo**

**Note:** The pages available after logging in depends on the permission level of the operator account.
SECTION 3 - RI WITNESS MANAGER INITIAL STEPS

RI Witness Manager can be used on PCs or tablets outside of the RI Witness work areas, predominantly 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.

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.

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 opened by clicking Settings and then RI License Manager. See Figure 3-3.
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 3-4.
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.

Figure 3-3 RI License Manager

Figure 3-4 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. See Figures 3-5 and 3-6.

7. Once RI has received your request, a License Data file will be emailed to the registered email address.

8. The License Data file should be made available to the RI Witness Manager PC where licensing is performed.

9. On receipt of the License Data file, click Import New License File in the License Manager dialogue box. See Figure 3-7. Browse to the emailed license data file and select it. The License Manager will now be updated with the new license details.
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 3-8.

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 3-9.

See the IT Requirements Manual (6-70-121IT) for more details on database management.
Figure 3-9  Database Connection Settings
SECTION 4 - AMENDING THE WITNESS POINT DIAGRAM

The Witness Point Diagram

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

To view the witness point diagram click the Settings main menu button and then click Witnessing. See Figure 4-1 and Figure 4-2.

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 is shown in Figure 4-3.

Tag names such as “Inseminated Dish” must be defined before they may be referenced by a witness point. See “Tag Types” on page 21.
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 4-3 where the “Reassign this tag to:” 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 unassigned (empty, unused) tags to 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 4-33 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.

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. See Figure 4-5.

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 4-6.

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 4-7.

Double Witness Points
Checking the Double Witness box, see Figure 4-33, 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 4-8.

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 checkboxes available in the patient details. See Figure 4-9.
Untagged Donations

Sperm donations are usually untagged.

A 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.
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 4-10 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 4-11.

![Figure 4-11 Tag Types](image)

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 4-12.

![Figure 4-12 Setting the Witness Point Order](image)

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, Explore or Analytics to view the witness point log. See Figure 4-13.
Section 4
Amending the Witness Point Diagram

Witness Point Log Statistics
The statistics view summarises the witness point log by presenting significant totals, e.g. “Tags used”, “Patients seen”, etc. The view may be filtered by date. See Figure 4-14.

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, e.g. “Monday”, “Admin assigns this week”. See Figure 4-15.
SECTION 5 - RI WITNESS MANAGER BASIC OPERATION

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, Staff, etc) and the mixture of installed products (RI Witness, Traceability, Data Capture, Imaging and Cryo).

Home

When first logging into RI Witness Manager, the Home screen is displayed. See Figure 5-1. 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.

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

<table>
<thead>
<tr>
<th>Patient ID</th>
<th>Patient Name</th>
<th>Cycle Type</th>
<th>Collection Date</th>
<th>Current Day</th>
<th>Last Witness Point</th>
</tr>
</thead>
<tbody>
<tr>
<td>12233</td>
<td>Mrs Donna Wills</td>
<td>IET</td>
<td>15/08/2016</td>
<td>D0</td>
<td></td>
</tr>
<tr>
<td>12528</td>
<td>Mrs Mary Wilcox</td>
<td>ICSI / IVF</td>
<td>16/08/2016</td>
<td>D0</td>
<td></td>
</tr>
<tr>
<td>12889</td>
<td>Mrs Claire Smith</td>
<td>ICSI</td>
<td>15/08/2016</td>
<td>D1</td>
<td>Post ICSI</td>
</tr>
<tr>
<td>12565</td>
<td>Ms Green Granta</td>
<td>ICSI / IVF</td>
<td>13/08/2016</td>
<td>D1</td>
<td>Post ICSI</td>
</tr>
<tr>
<td>128756</td>
<td>Miss Katie Lemon</td>
<td>ICSI / IVF</td>
<td>15/08/2016</td>
<td>D1</td>
<td>Post ICSI</td>
</tr>
<tr>
<td>128781</td>
<td>Mrs Harriet Cook</td>
<td>ICSI / IVF</td>
<td>15/08/2016</td>
<td>D1</td>
<td>Post ICSI</td>
</tr>
<tr>
<td>12784</td>
<td>Ms Jimmy Wilson</td>
<td>ICSI</td>
<td>14/08/2016</td>
<td>D2</td>
<td>Fertilisation Check</td>
</tr>
<tr>
<td>12897</td>
<td>Mrs Linda Watson</td>
<td>ICSI / IVF</td>
<td>14/08/2016</td>
<td>D2</td>
<td>Fertilisation Check</td>
</tr>
<tr>
<td>12789</td>
<td>Miss Alice Jenkins</td>
<td>ICSI / IVF</td>
<td>13/08/2016</td>
<td>D3</td>
<td>Embryo Culture</td>
</tr>
<tr>
<td>12191</td>
<td>Miss Sarah King</td>
<td>IVF</td>
<td>11/08/2016</td>
<td>D3</td>
<td>Embryo Culture</td>
</tr>
<tr>
<td>12444</td>
<td>Ms Deni Harding</td>
<td>IVF</td>
<td>13/08/2016</td>
<td>D3</td>
<td>Embryo Culture</td>
</tr>
</tbody>
</table>

For details on how to configure the colour scheme used on the Home screen, see Section 12.

Choosing a Patient

Click the Patients button to show the Choose Patient window if no patient has been selected, or to view details of the selected patient. See Figure 5-2.

Figure 5-1 Home Screen

Figure 5-2 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 on 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. See Section 9.
5. Click Label Printing to create adhesive sheets for 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 36.

**Entering New Patient Details into RI Witness Manager**

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

![Figure 5-3 New Patient Details](image)

**Editing Existing Patient Details**

Open Patient details as outlined above.
1. Click the Edit button to change to the editable window.
2. Edit the patient’s details as needed.
3. 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. This will include any mismatches that may have occurred.
3. Select the Tags tab to see the last location that tags assigned to the patient have been seen by RI Witness.

Mismatch Comments

Users can add extra comments to further explain any mismatches in the Patient Histories.

1. Open RI Witness Manager.
2. Click the Cycles button.
3. From Treatment Cycles double click the cycle required to view. This can also be seen by clicking Patients, opening the Treatment Cycles tab then double clicking the required cycle.
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.

To show these additional comments on printed reports, enable the ‘Include additional comments in printed reports’ setting from the General Settings page. See Figure 5-5.

Note: Extra comments can also be added to explain any Admin Assigns.
Assigning Donor Status

In the Patient details window select the relevant donor options.

- Can Receive Untagged Donations
- Can Receive Tagged Donations
- Can Donate

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

Assigning Partners

For a patient who has no partner assigned, one can be assigned that already exists in the RI Witness system or a new partner record can be created.

To create a new partner record:
1. Click new partner.
2. Enter the required information in the fields.
3. Click save.

To choose an existing patient as partner:
1. Click Existing Partner.
2. Choose the sex to search from the drop down list.
3. Type the ID number or name in the text field.
4. Highlight the patient to be chosen.
5. Click OK.
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 5-9.
2. Click New to add each cycle type.
3. Right click to Rename a cycle type.

The range of materials and data sheets related to each cycle type are specified on the Materials and Data Collection tabs.
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 Cycles tab to show the list of treatment cycles for this patient. For a new patient this list will be empty.
3. 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 5-10.

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

Assign a Cycle Type
Select a cycle type from the pull down list.

Setting Collection and Transfer Dates
If Egg Collection/Embryo Transfer dates are entered on the Details tab of a treatment cycle then this cycle will be available from the work area Daily Lists screen.

See “Section 5 - Witnessing in RI Witness WorkArea” in the RI Witness WorkArea Software Manual (6-70-121UM) for more details of patient selection using Daily Lists.
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.

![WorkArea Locations Screen](image)

**Figure 5-11 RI Witness Manager WorkArea Locations Screen**

Alarm if Tags Left in Work Area

To help avoid mismatches being recorded an alarm can be raised if tags are left in the work area when the operator logs out, eg when an ID card is left in the reader.

1. Open RI Witness Manager.
2. Click Settings.
3. Click General Settings.
4. Under WorkArea Settings tick Warn on logout if tags left in WorkArea.

![General Settings](image)

**Figure 5-12 General Settings**
SECTION 6 - RI WITNESS OPERATORS

Operator Management

Click Operators to display a list of all enabled operators. See Figure 6-1.

Figure 6-1 Operator Management

Operator Details

1. Click Add to specify details for a new operator. See Figure 6-12.
2. Select an operator and click Edit to change operator details.

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

Figure 6-2 Operator Details
Group Membership

Some RI Witness features are only available to a specific operator group. Clicking the help button for the Group Membership will open a table showing operator types and access level to the RI Witness system.

<table>
<thead>
<tr>
<th>Operator types</th>
<th>RI Witness Manager</th>
<th>RI Witness WorkArea</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administrator</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Senior Staff</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Staff</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Traceability</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Read Only</td>
<td>✗</td>
<td>✔️</td>
</tr>
</tbody>
</table>

= Read and Write  
= Read Only

Figure 6-3 Group Membership Help Screen

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 four 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. See Figure 6-4.
SECTION 7 - REPORTING AND ANALYTICS

Reporting

Using the RI Witness manager application, many reports can be viewed, printed or copied for pasting into applications that allow for advanced data manipulation.

- **Cycles Report** - can show a list of active cycles between two dates or over a specified period of time. Select using the Cycles button.

- **Operator Report** - can show the witness points carried out by an operator between two dates or over a specified period of time. Select using the Operators button.

- **RI Witness Statistics** - can show specific statistics related to the number of witness points, tags and cycles that have been seen by the system during a specific period or between two dates.

- **Materials Reports** - can show a variety of data linked to the use of consumables during cycle periods. These reports are based on the state of batches and type of consumable used during a specified period.

- **Patient Reports** - Selecting a specific patient allows reports to be generated that show data about the treatment cycles and witness points the patient has undergone. The witness point report can also include data for the partner if the patient has one.

Treatment Cycle Report

To create a printable report that summarizes all of the gathered information for a cycle.

1. Select a cycle, either from the Patients page and the Treatment Cycles tab or from the Cycles page.
2. Click the Treatment Cycle Report button at the top of the page. See Figure 7-1.

3. The Treatment Cycle Report page will open that showing a preview of the report to be printed. See Figure 7-2.
4. Use the Report Settings to control which sections are included in the report. See Figure 7-3.

5. Click Print Report.
Analytics

All procedures monitored by RI Witness are automatically timed and the duration is recorded along with the location at which the procedure was performed and the staff member who carried it out. RI Witness Manager provides analytical tools that can be used to analyse this timing and location data.

1. Click Witness Points.
2. Click Analytics.
3. The default view shows three visual representations of the data.

The view can be changed to display a variety of data by using the drop down menus above the graphs.

![Figure 7-4 Default Analytics Screen](image)

![Figure 7-5 Analytics Options](image)

![Figure 7-6 Analytics Screen Showing Filtered Data](image)
SECTION 8 - PATIENT LABELS

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 options. See Figure 8-1

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 8-2.

RI Labels are an optional component of RI Witness.
Printing Patient Labels

1. From the patient details window click Label Printing to open the Label Printing Screen. See Figure 8-3.
2. Load a blank label sheet into a laser printer. For repeatability of alignment use a manual feed tray 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 8-4.

The example shown in Figure 8-4 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.

Sheet Types
There are two types of label sheet available for use with RI Witness, their part numbers are 6-70-110 and 6-70-113, and they offer a different selection of label types. Use the Sheet Type buttons to select the correct sheet type in Witness Manager to match the type of label sheet to be printed.

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 re-using a sheet during the alignment process.
SECTION 9 - 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 to scan barcodes that they have already attached to samples, or use RI barcodes that have been printed from RI Witness Manager that are assigned to a particular patient.

If a clinic only wishes to scan barcodes 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.

Printing Barcodes

1. Open RI Witness Manager.
2. From the patient details window click Barcode Printing. See Figure 9-2.
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. See Figure 9-4.

---

**Figure 9-3 Barcode Printing Screen**

**Figure 9-4 Aligning the Label Print Stock**

1. The First Print Shows Incorrect alignment.
2. Alignment is Corrected by Setting the Printhead Y Position

Printhead position Y +7.2 mm
SECTION 10 - 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 10-1.

![Figure 10-1 Materials Management](image)

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. 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 10-2.
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 10-3.

![Figure 10-2 Viewing all Material Types](image)
Material Type Details

Double click a material type, or right click and select View Material Type to view the material type details. See Figure 10-4.

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 Number and Expiry information but no GTIN.

Traceability can interpret GS1 barcodes.

A Traceability button must be clicked before a GS1 barcode can be scanned, eg click Scan It, Scan Batch or Scan GTIN.

**Cycle Types**

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

1. Click Settings.
2. Click Treatment Cycle Types.
3. Click 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 Operators” on page 30 only administrator operators may create cycle types.

A newly created cycle type will not be associated with any materials. Use the materials checkboxes to specify the range of materials that will be used for the selected cycle type. See Figure 10-5.

![Figure 10-5 Material Type Details Checkboxes Specify the Range of Materials associated with Each Cycle Type](image_url)
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. See Figure 10-6.
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 Number, 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 Material Type page. See Figure 10-7.
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 details. See Figure 10-8.
4. Click Scan Batch to create a new batch if a GS1 barcode is available.

Figure 10-6 Creating a New Batch By Scanning a Barcode

Figure 10-7 Listing all Batches of a Specific Material Type
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RI Witness Manager for Traceability
Research Instruments Ltd

Figure 10-8 Filling in the New Batch Details

Deleting a Batch

Normal batch operations are status changes, for example:

- **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 of the batch 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 10-9.

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 10-9 Patient Treatment Cycles Related to a Batch of Materials

Figure 10-10 Expired and Expiring Batches

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 10-10.

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, eg extended to ten days or shortened to five days.

1. Click Settings.
2. Click General Settings.
3. Within the Materials section amend the batch expiry warning field.
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 and type. See Figure 10-11.

![Figure 10-11 A Filtered View of all Batches](image)

Excluding and Including Batches for a Cycle

See “Section 5 - RI Witness Manager Basic Operation” on page 23 for details of creating and managing a treatment cycle.

When viewing the details of a treatment cycle, click the Materials tab to show material batches related to this cycle. See Figure 10-12.

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 choosing Include batch on the context menu. The batch will now be visible in the list of batches for the cycle.

![Figure 10-12 Material Batches Related to this Cycle](image)
SECTION 11 - 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. Click Data Collection to enter the setup screen for data collection. Sheet design is performed using this screen.

The Collected Data Setup screen, Figure 11-1, is divided into four regions. Note that region 4 shows the properties of an entry selected from regions 1, 2 or 3.

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 requires 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’s contents. The parameter will move from region 2 to region 3.
3. **Sheet Contents**
   Region 3 shows the content layout of the selected sheet. 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 and then use the Up and Down buttons to position it in the order required.

   Once a parameter has been added to a sheet’s contents, additional attributes may be set. For example, a 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 59.

4. **Properties**
   The properties shown in region 4 reflect the most recently selected entry from regions 1, 2 or 3. See Figure 11-2.

![Figure 11-2 Examples of Parameter Properties and Sheet Properties Shown in Region 4](image)

**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 11-3.
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 11-3 shows the properties of each parameter type. Figure 11-4 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 11-5 shows the Format drop down menu.

**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.
Section 11

Data Capture

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 11-6.

Click the Edit Lists button to show the Manage Lists window. The example shown in Figure 11-7 highlights the “Polar Body Position” list that contains the three values “PB6”, “PB12” and “No Injection”. The “Polar Body Position” list is assigned to the “Inj” list parameter. Figure 11-6.

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 can only be 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 11-8.
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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. An example calculation is shown in Figure 11-9.

Built In Parameters
Built in parameters will display values derived from the associated treatment cycle, eg the egg collection date. Figure 11-10 shows the available built in values.

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

Figure 11-12 shows another example of sheet contents where two list parameters and four number parameters form the contents of the Sperm Pre Prep sheet.
A parameter may be part of the contents of many sheets. The same parameter may be editable on sheet A and sheet B but not editable on sheet C. A parameter that appears on many sheets has a single shared value. For 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 58 for more details. See “Parameter Attributes” on page 59 for more details of the editable/non editable parameter attribute.
Section 11

Data Capture

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 11-13.
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 11-13 Use the Checkboxes to Associate Sheets with the Selected Treatment Cycle Type](image)

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 11-14.

Press the Data Sheet button to see a list of available sheets. See Figure 11-15. Press one of the buttons to view or edit the sheet values. See Figure 11-16.

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.
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Figure 11-14 Touch the “Data Sheets” Button to View or Edit All Sheets Associated with this Treatment

Figure 11-15 Touch Buttons for Each Available Sheet are Shown in the Work Area

Figure 11-16 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 11-17.

![Figure 11-17 Editing Sheet Values with RI Witness Manager](image)

Egg Parameters

The properties of a parameter include a Relates To setting that defaults to Cycle, i.e., a treatment cycle does not have multiple values for this parameter. See Figure 11-18.

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 11-19 and Figure 11-20.

On the work area touch screen, touch a row of the egg table to edit the values for that egg. See Figure 11-21. **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 11-18 The Relates to Setting](image)
Section 11

Data Capture

Figure 11-19 An RI Witness Manager View Showing a Table of Egg Related Parameters

Figure 11-20 An RI Witness Work Area Touch Screen View Showing a Table of Egg Related Parameters

Figure 11-21 Entering Values for Egg Number 1 at the Work Area Touch Screen
Section 11
Data Capture

The Number of Eggs

1. Click Settings.
2. Click 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 11-22 the parameter called “Number of Eggs Collected” has been selected from a list of all parameters.

As an example, “Number of Eggs Collected” might be a calculation parameter whose operands are other parameters. See Figure 11-223.

![Figure 11-22 The Number of Eggs Involved in a Treatment is Set Using the Egg Count Parameter](image)

![Figure 11-23 This Calculation Parameter Has Been Selected as the Egg Count Parameter in the Example Shown in Figure 11-22](image)

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 11-24.
A conflict resolution window is shown when the Egg/Embryo Count Conflict button is clicked. See Figure 11-25. 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 11-24 The Egg/Embryo Count Conflict Button is Shown If the Value of the Parameter Selected as the Egg Count Parameter is Decreased

Figure 11-25 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 11-26.

When a Witness Point is recorded, the linked sheet will be automatically presented so that the operator may enter data related to the procedure being performed. See Figure 11-27.

Cycle Summary Sheets

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

1. Click Settings in the main menu bar.
2. 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 11-28.
A typical summary sheet would show parameter values from many other sheets. See “Shared Between Sheets” on page 51 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 11-29.

Parameter Attributes

Parameters that have been added to a sheet’s contents may be given sheet specific attributes. See Figure 11-30.

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 11-31.
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Figure 11-30 Setting Parameter Attributes
Initial Value, Editable, Overwrite, Create and Required

Editable

The value of editable parameters may be changed. If this checkbox is not fixed then the parameter will be “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.

<table>
<thead>
<tr>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>What does this combination mean?</td>
</tr>
<tr>
<td>The value may not be edited</td>
</tr>
<tr>
<td>n/a</td>
</tr>
<tr>
<td>Editing allowed but may be left blank.</td>
</tr>
<tr>
<td>A value must be entered but it may not be left blank.</td>
</tr>
<tr>
<td>If a value already exists it will be overwritten with the initial value. The user cannot change the value.</td>
</tr>
<tr>
<td>n/a</td>
</tr>
<tr>
<td>If a value already exists it will be overwritten with the initial value. The user may change the value.</td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td>If no value exists then show the initial value. The user may not change this value.</td>
</tr>
<tr>
<td>n/a</td>
</tr>
<tr>
<td>If no value exists then show the initial value. The user may change this value.</td>
</tr>
<tr>
<td>If no value exists then show the initial value. The user may change this value but it may not be left blank.</td>
</tr>
<tr>
<td>The initial value will be shown, overwriting any existing value. The user may not change this value.</td>
</tr>
<tr>
<td>n/a</td>
</tr>
<tr>
<td>The initial value will be shown, overwriting any existing value. The user may change this value.</td>
</tr>
<tr>
<td>The initial value will be shown, overwriting any existing value. The user may change this value but it may not be left blank.</td>
</tr>
</tbody>
</table>

Figure 11-31 Combining Parameter Attributes
SECTION 12 - HOW TO CONFIGURE THE HOME SCREEN

The Home Screen shows the currently active treatment cycles, giving an overview of what is happening in the lab.

The Cycle Type and Collection Date are set in the Treatment Cycle details section. The Collection Date on this screen determines what is day 0 for this cycle.

To appear on the Home Screen, a cycle must have a Collection Date and Cycle Type set and be between Day -3 and 7.

The Home Screen can be configured to colour each cycle according to its current progress. The example below shows step by step how to set up the Home Screen using a traffic light-style colour scheme.

For simplicity, a configuration for just the IVF Cycle Type will be created. The patients’ details will appear in red when no action has been taken that day, yellow when something further needs doing, and green when all actions have been completed that day.

1. Click Settings.
2. Click Home Screen Configuration.
3. Click inside the Initial Colour box and set the background to white. Press Save.

   Please note, it doesn’t have to be white, none of the colours suggested in this example are compulsory.

4. Under States, click the + button to add a new state. Write “Action” in the textbox then choose a red background colour.

   Figure 12-1 Home Screen Configuration

   Figure 12-2 Adding a State
5. Click the + button to add another state. Write “Further Action” in the textbox then choose an amber background colour.

6. Click the + button again to add the final state. Write “Complete” in the textbox then choose a green background colour. Press Save.

7. Under Cycle Types, click the arrow in the IVF box then click Add Day.

8. In the Day box select 0, in the Message box write “Egg collection” and from the drop down menu under State choose “Action”. Press Save.

Events are added to Days to define which Witness points should happen that day for the selected Cycle Type. Events determine the colour to which the cycle will change after the associated Witness Point takes place. A Message can also be added to an Event, This will appear in the last Witness Point column, and can act as a prompt for the next action to take place.

9. Click Add Event. In the Day box select from the name drop down menu choose “Egg Collection”. In Message write “Waiting for IVF Insemination”, then choose the state “Further action”. Press Save.

The Name of the Event is the name of the Witness Point.
Section 12

How to Configure the Home Screen

10. Add another Event, also for Day 0, but this time in Name select “IVF Insemination” from the drop down menu. In Message write “Insemination done” and select the state Complete. Press Save.

![Figure 12-5 Home Screen Configuration](image)

11. Add Day - this will be Day 1. Write in Message “Fert check/media change needed” and select the State “Action”. Press Save.

12. Add Event, Day 1. In the Name field select “Fertilisation check”. In Message write “Fert check/media change done” and in the State field choose “Complete”. Press Save.


Return to the Home screen, it should now show all active cycles highlighted in appropriate colours.

![Figure 12-6 Home Screen](image)
SECTION 13 - CONTACT DETAILS AND FEEDBACK

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

Thank you.