



# RI Witness™

## Security and ART Management System

ORIGIO • SAGE • Humagen • TPC • K-Systems • **RI** • Wallace • LifeGlobal • CooperGenomics

**CooperSurgical**  
Fertility and Genomic Solutions

# Market leading technology for IVF

## RI Witness has more clinical installations than any other electronic witnessing system (EWS) for IVF<sup>1</sup>

As market leader in electronic witnessing for IVF clinics, we have established an in-depth understanding of our customers' needs and a comprehensive portfolio of solutions. Our experienced local representatives support RI Witness customers all over the world so we are always on hand to offer advice and support.

1. Based on information publically available at time of print

## Pioneers in laboratory security and IVF data management

In 2004, double checking of all critical steps in the IVF cycle became mandatory for clinics in the UK. In collaboration with embryologists, engineers and designers at RI, it was soon identified that technology could improve double witnessing. Three years later RI Witness was launched.



\* The name, date of birth and patient id is fictitious and does not represent an actual patient.  
For references please see page 14

# RI Witness for peace of mind

Since 2007, RI Witness has been helping to prevent potential errors and managing activity in IVF laboratories all over the world. Using RI Witness means that laboratory staff members, fertility clinics and IVF patients enjoy extra peace of mind as well as additional benefits in efficiency and potential cost savings.

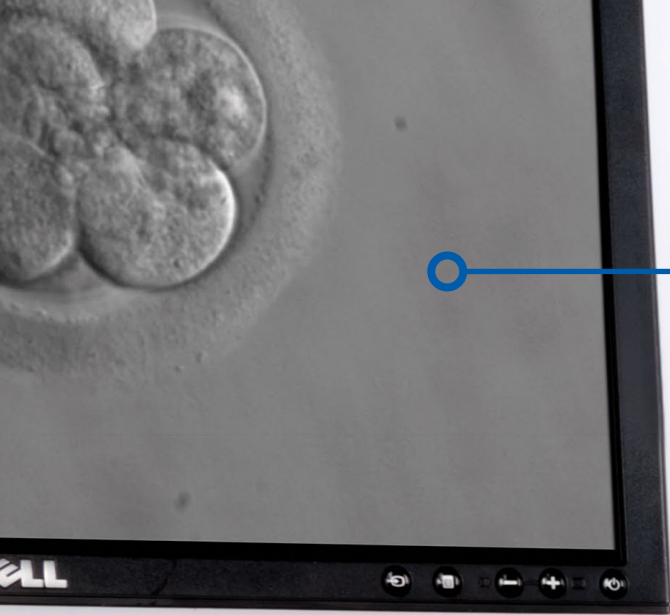
For larger clinics and clinic groups, RI Witness technology can be used as a versatile quality control tool to oversee a large team, high volumes of work, data collection and auditing<sup>1</sup>. Equally, smaller clinics can use it to help establish accountability and reduce liability; for the first time clinics have the ability to document what happens in a patient cycle, even if an embryologist is working alone.

RI Witness works as a constant safeguard to help minimize stress and interruptions, protecting and managing every aspect of daily workloads.



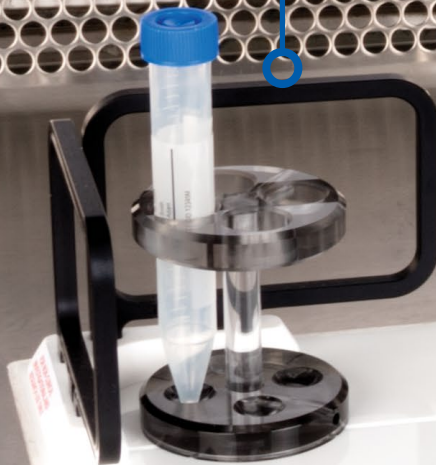
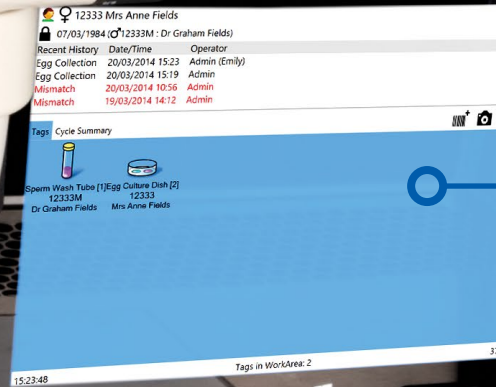
**“Since I started using RI Witness in my laboratory the embryologists sleep better and so do the patients.”**

Jean-Claude Jacquet, Medical Biologist in Reproduction,  
Oriade PMA Grenoble, Rhône Alpes, France



Imaging screen

RFID tube reader



# What is RI Witness?

RI Witness uses Radio Frequency Identification (RFID) to detect and monitor all activity in the IVF laboratory. The system helps mitigate the risk of human error every time samples are moved from one dish or tube to another, and safeguards every step of the IVF cycle.

Throughout the lab, RI Witness readers are situated wherever work is undertaken, critically where samples are handled. Embryology heated or unheated plates with in-built RFID readers can be integrated into a worktop. They are active all day, every day, so a check cannot be overlooked.

An RI Witness work area has a tablet computer connected to the server, integrated with a clinic's patient database\*. Thanks to self-adhesive RFID tags attached to all the laboratory plasticware, it is possible to ensure protocols are followed and only compatible samples are worked on at any one time.

The system is automatic, so it does not require additional steps by embryologists to identify samples, which are necessary with human double witnessing or barcode witnessing systems.

By automatically tracking, monitoring and recording across all your work areas, RI Witness frees up time, energy and expertise. This secured process provides everyone with total confidence<sup>2</sup>.

\* Subject to compatibility, some programming may be required



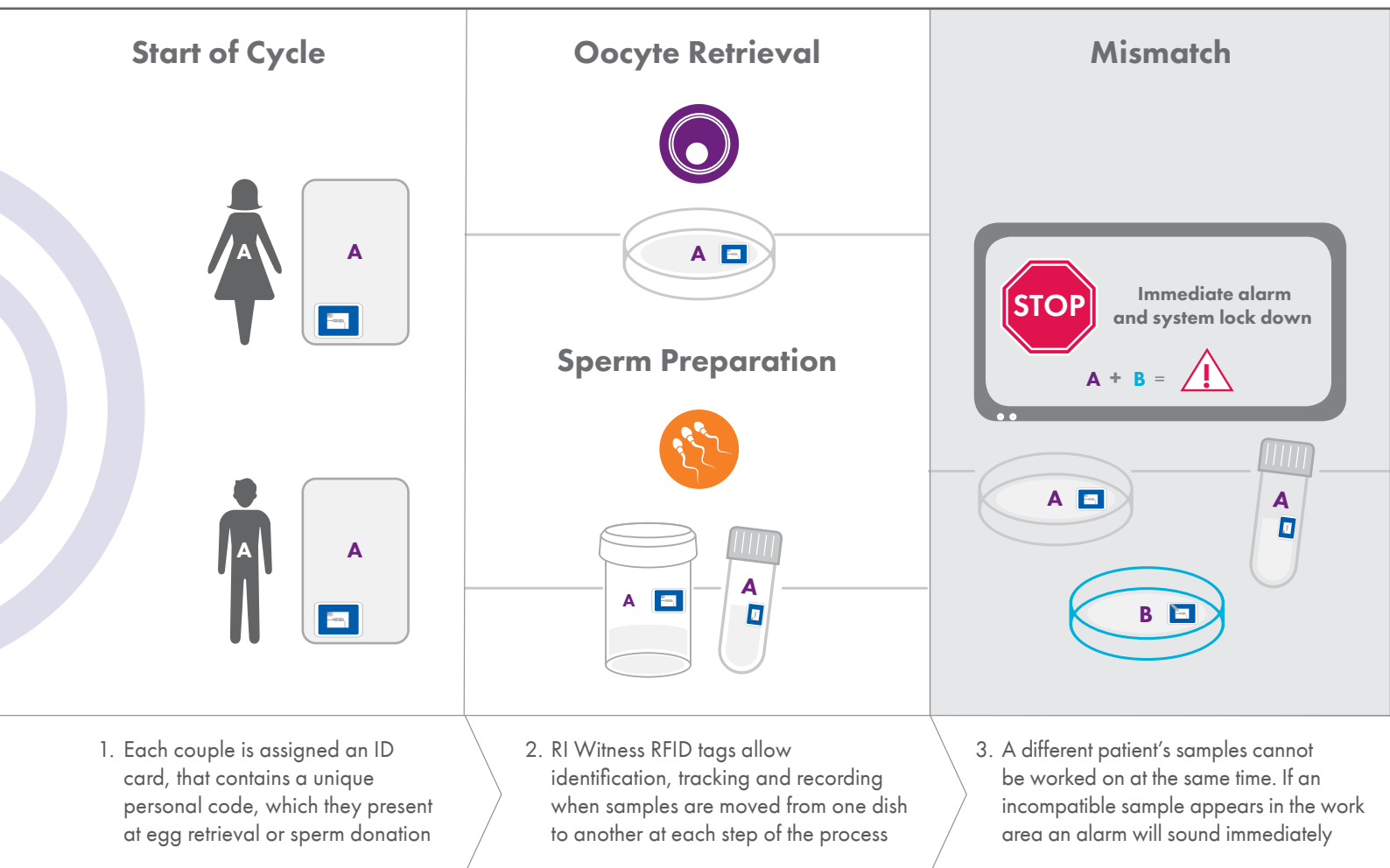
**Tablet computer running RI Witness work area software**

**Embryology heated plate with in-built RFID reader**

**Self-adhesive RFID tag on Petri dish**



# How does it work?



## Why do I need RI Witness?

### What if you had a mix-up?

Many embryologists tell us this concerns them, and from time to time, the media reports an error which has wide-reaching effects; not only on the family but also the embryologists, the lab and the wider community's perception of IVF practices.

Primarily, RI Witness was designed to mitigate this risk. Through constant monitoring it reduces the chance of human error associated with repetitive tasks and misperception<sup>1,3</sup>.

Compared to other witnessing protocols it involves less disruption and accelerates the speed of witnessing which can reduce the time

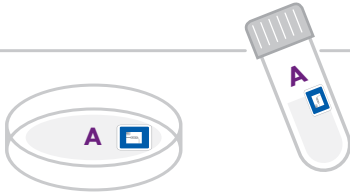
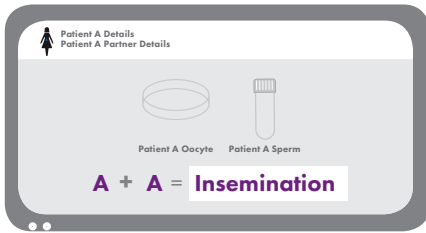
an embryo is out of the incubator<sup>3</sup>.

In response to ongoing customer feedback, RI Witness has been developed to include many time-saving features to make laboratory work easier.

RI Witness does the work of many people, potentially freeing up staff members to carry out more procedures, increasing overall laboratory efficiency. It can also be used as a quality management tool, ensuring consistent adoption of laboratory protocols, monitoring staff performance and simplifying audits.

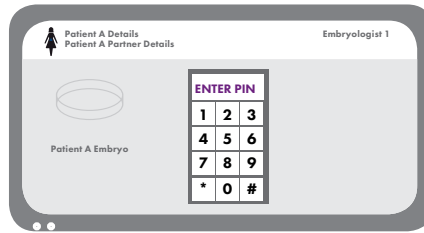
Using RI Witness, provides your clinic with a competitive advantage while offering a secure, patient-oriented service.

## Insemination



4. RI Witness validates the identity of the samples and allows operators to proceed to the next step, such as insemination

## Embryo Culture

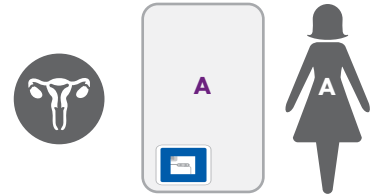


5. The location of the embryo, activity and operator's ID is logged – whenever it is brought into a work area

## Biopsy



## Transfer



## Cryopreservation



6. Whether the embryo will be biopsied, transferred, or cryopreserved, RI Witness will continue to secure and monitor its progress



**“RI Witness has improved efficiency by streamlining our working practice - laboratory procedures are performed at the optimum time with a real-time witness. The ease of operation is great and the system has proved to be a versatile audit tool.”**

Sophie Jewitt, Senior Clinical Embryologist  
Gateshead Fertility Unit, England

# RFID versus Barcodes

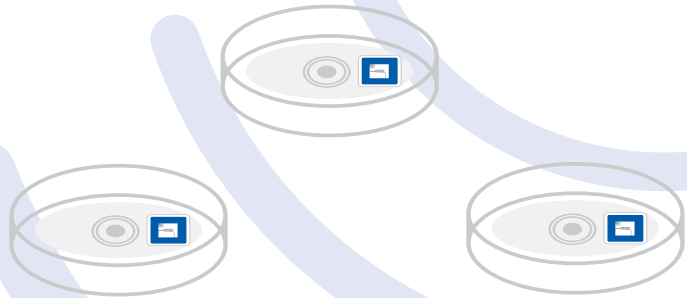


RI Witness uses RFID technology instead of barcodes to constantly safeguard the IVF process, from start to finish. Only RI Witness can monitor every procedure with no workflow interruptions.

## Multiple Dishes

### RFID

RI Witness reads all dishes simultaneously and automatically allows the operator to work uninterrupted.



## Recording Activities

### RFID

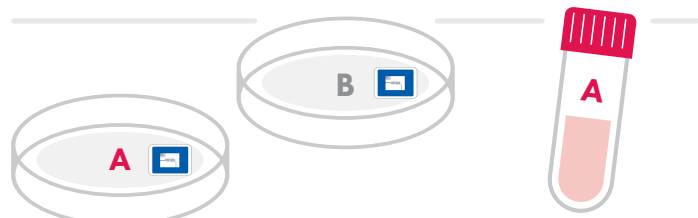
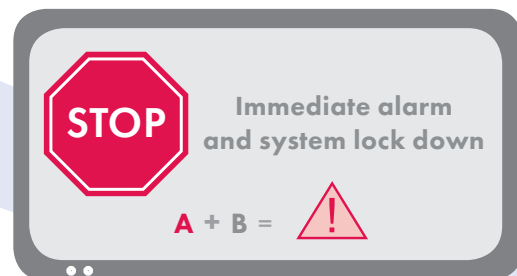
RI Witness monitors the work area under the microscope constantly. Giving 24/7 protection, a check cannot be unintentionally overlooked.



## Mismatches

### RFID

RI Witness will alert the operator immediately, before samples are manipulated, if incompatible samples are in the same work area. This allows corrective action to be taken while the security of the sample is intact.

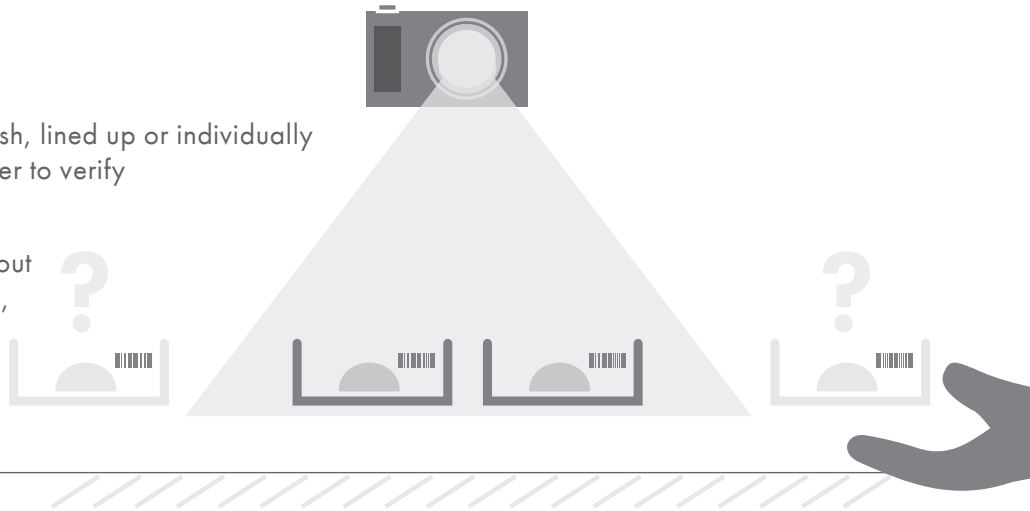




## Barcodes

Barcodes need to read each dish, lined up or individually in the line of sight for the scanner to verify that they are compatible.

Samples will need to be taken out of the work area to be checked, which can be disruptive.



## Barcodes



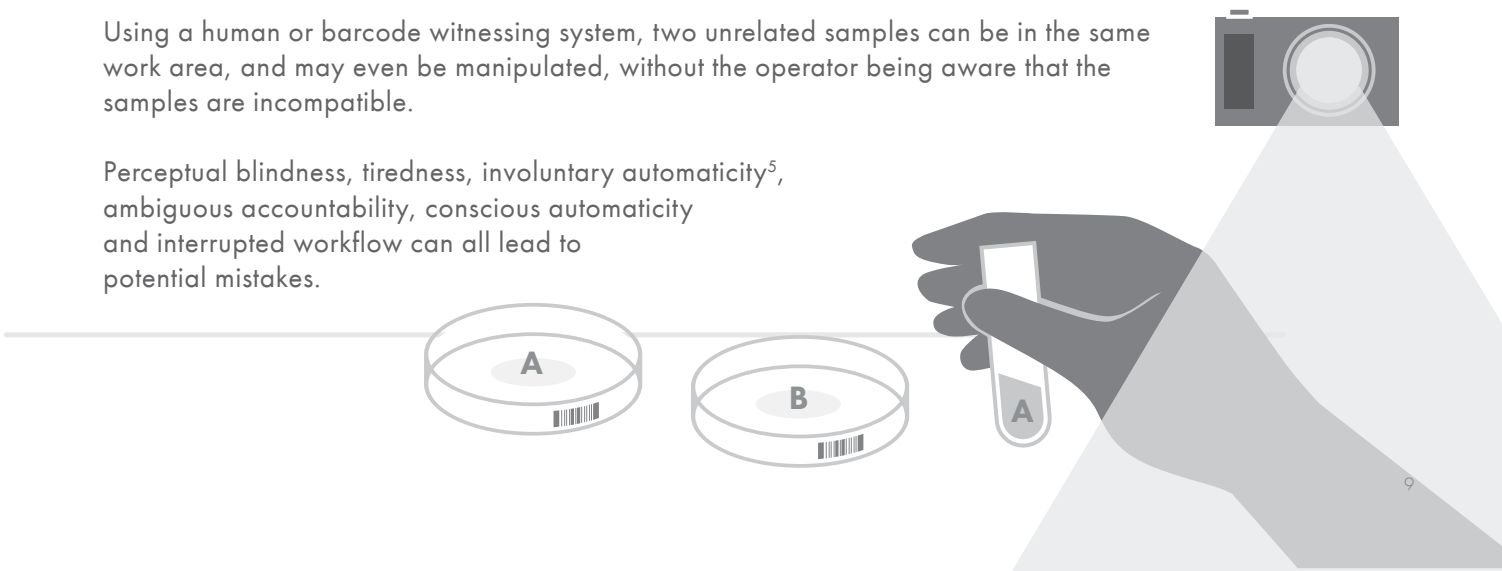
Barcode security relies on the operator remembering to do checks. In fact, a procedure can be performed without the activity being logged in the system, no alert or action will be instigated. The IVF cycle's security could be compromised.



## Barcodes

Using a human or barcode witnessing system, two unrelated samples can be in the same work area, and may even be manipulated, without the operator being aware that the samples are incompatible.

Perceptual blindness, tiredness, involuntary automaticity<sup>5</sup>, ambiguous accountability, conscious automaticity and interrupted workflow can all lead to potential mistakes.



# Safety of RFID and RI Witness

We understand it is imperative lab conditions are optimized for ART procedures. There is no room for compromise. That is why we use technology that does not harm embryos or humans.

## Tested

We asked an independent test center, the University of Liège, Belgium, to conduct a comprehensive experiment to prove our theories about the safe use of RFID with gametes and embryos.

For the test they:

- Increased the output power of the reader by 10 times
- Increased the time that the embryos were in the radio frequency field by 70 times that would normally be expected in an IVF cycle
- In the experiment total exposure was 700 times what would be expected in an IVF lab

Results:

- Normal development to mouse blastocyst compared to the control group
- Normal live birth rate (LBR) compared to the control group
- Normal fertility in the female pups with normal 2nd generation LBR

## RFID

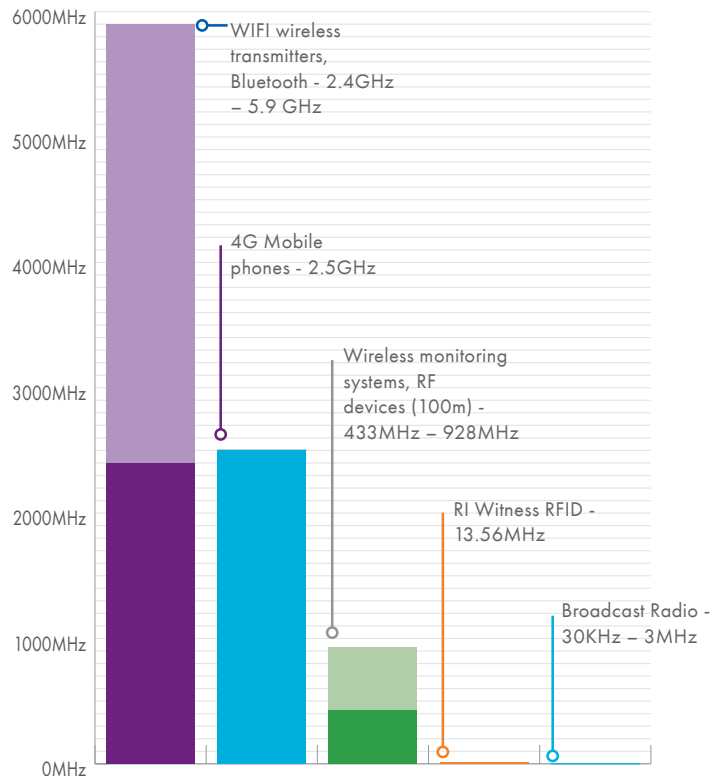
Every day, we are surrounded by radio frequency (RF) emissions from modern technology. The potential effects radio frequencies have on cells and tissues depend on the frequency and power density to which they are exposed.

The facts:

- RI Witness RFID tags do not emit or receive radio waves when they are not on a reader or in the incubator
- The tags are passive, with no internal energy source, so they are only activated when placed in a 1-5cm range of an RI Witness reader
- Embryos and gametes are only exposed to the radio frequency fields for short time periods



Andrology reader



RI Witness Radio frequency compared with other standard RF devices in the laboratory

## Statistical evidence

A four-year statistical analysis in one clinic looked at more than 10,000 live births, before and after the introduction of RI Witness. The analysis showed no changes to results in both live births and malformations over the two periods<sup>7</sup>.

## Certificated

Our embryology heated plates are CE marked as medical devices (GB98/13044) and FDA cleared. They offer highly stable heating across the reader.

Our tags and labels are batch tested to MEA >80% survival to blastocyst stage<sup>6</sup>.



Admin and card reader

# A proven and validated system

Thanks to widespread clinical use of our EWS for over 10 years, multiple posters and papers have been published that cover and discuss questions often raised about RI Witness.

## The real risk of human error

**What is the actual risk of mismatches, for labs relying on human double witnessing, without an electronic system to ensure the cycle is secure?**

Using RI Witness, several laboratories analyzed data from witnessed steps to establish a “true rate of human error”. The studies found their mismatch rate was up to 0.11%<sup>1</sup> of witnessed actions. A true mismatch involves mistaking an identity check, other errors, such as administration errors, were discounted.

This is the first time true error rates have been studied in an IVF laboratory<sup>1</sup>.

## Efficiency in the lab

**How can RI Witness make my lab more efficient?**

Human double witnessing means a colleague must double check the identity of patient samples at critical points. This has been mandatory in the UK since 2004.

Since then, extensive comparisons have been undertaken to compare human, barcode and the RI Witness RFID systems. The evidence concluded that RI Witness was faster, more efficient, and ensured samples were out of the incubator for less time overall<sup>4</sup> when compared to human double witnessing.



RI Witness

**“RI Witness’s electronic verification reinforces adherence to Standard Operating Procedures and validation of chain of custody for all samples in the IVF process. It provides peace of mind for the practice and the patient.”**

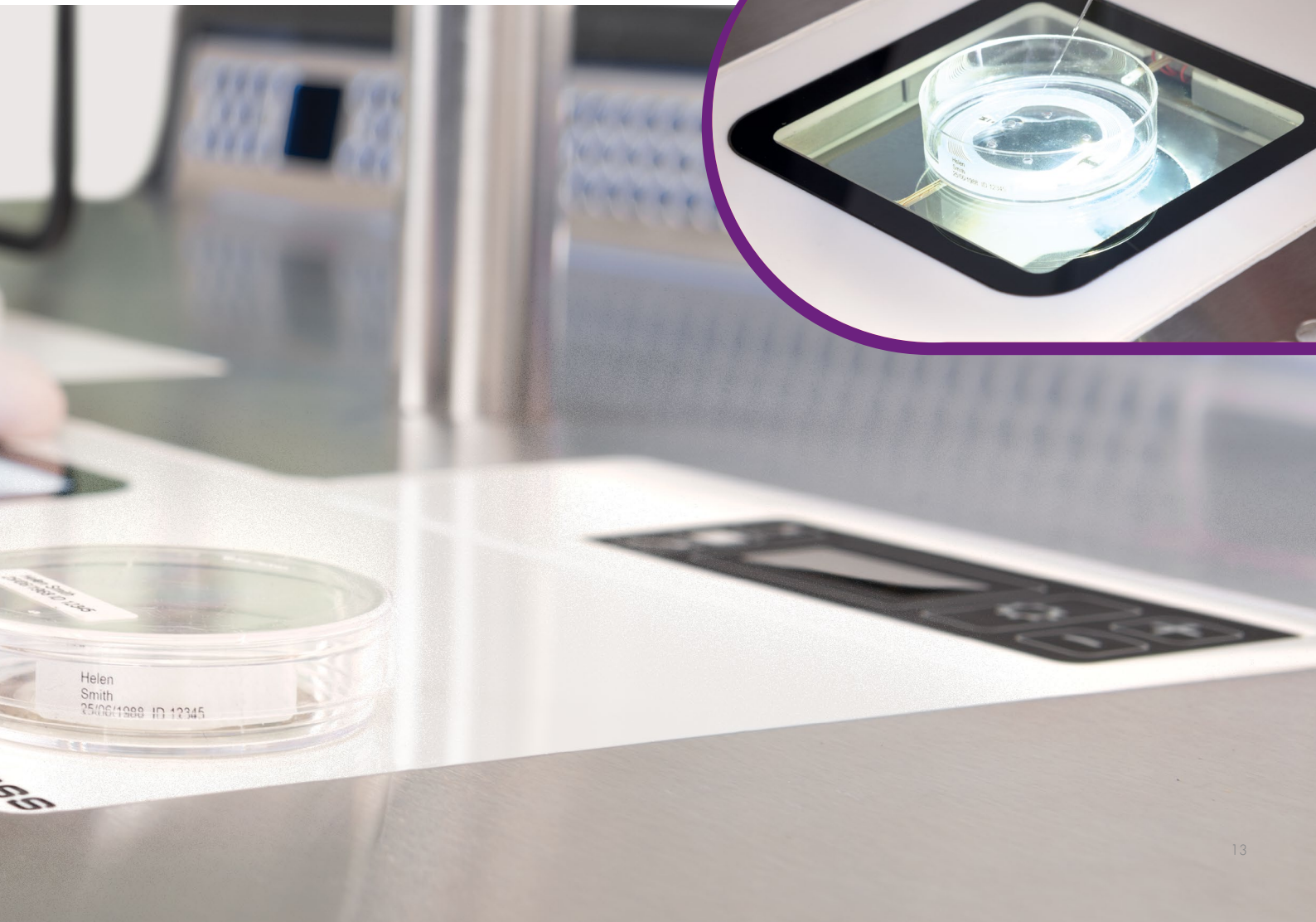
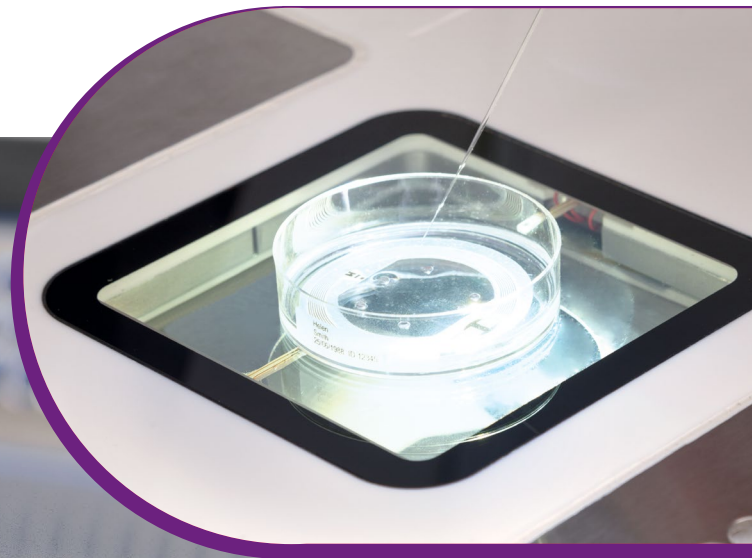
Jim Kontio, Lab Coordinator and Senior Embryologist,  
Southern Illinois University School of Medicine

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**“Numerous patients have informed us that they feel better knowing that this safeguard, RI Witness, is in place”**

Laboratory Director, Overlake Reproductive Health, USA

**The embryology reader includes heating across the plate and glass**



# Staff and patient considerations

Assessing how the implementation of an EWS might affect your patients and embryologists is very important. Evidence shows they feel the benefits of using the system in a short space of time.

## Patient reassurance

**How might my patients feel about the use of an electronic witnessing system?**

One study found that patients and embryology teams felt reassured when using RI Witness, and that it could be used as a trusted strategy to decrease patient stress concerning mismatches; 97.1% of patients confirmed they were more reassured if an EWS was used in their clinic<sup>8</sup>.

## Key staff concerns

**Will the installation of an EWS be disruptive?**

The installation of RI Witness and the staff training required takes less than a week to complete, under normal circumstances. A testing and validation phase of one month follows, after installation. A study conducted in an Italian clinic found system users were 96% satisfied with its performance immediately after validation<sup>3</sup>.





**“The integration of RI Witness into our daily routine was fast and simple and allowed for an improvement in system usage after a short period of time”**

Dr Roberta Maggiulli,  
Biologist Laboratory Coordinator,  
Clinica Genera, Italy

## References

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1. Thornhill A, Orriols Brunetti X, Bird S, (2013). Measuring human error in the IVF laboratory using an electronic witnessing system. 17th World Congress on Controversies in Obstetrics, Gynaecology and Infertility, Lisbon.
2. Townsend N, Ah-Moye M, Bunyan K, Engley S, Evans D, Glover L, McClure A, Ogutu D, Richardson L, (2016). Can electronic witnessing with RFID tags safeguard patients and mitigate risk in an IVF laboratory?
3. Sanges F, Maggiulli R, Albricci L, Romano S, Scarica C, Schimberni M, Giallonardo A, Vatraino G, Ubaldi F, Rienzi L, (2013). Implementing an electronic witnessing system into a busy IVF clinic- one clinic's experience.
4. Patel B, Schnauffer K, Gregoire R, Kingsland C R, Troup S, (2011). An investigation into the efficiency of RFID electronic witnessing compared to manual witnessing.
5. Department of Health (2004). *Independent review of the circumstances surrounding four adverse events that occurred in the Reproductive Medicine Units at The Leeds Teaching Hospitals NHS Trust.* [online] London. Available at: [http://www.who.int/patientsafety/information\\_centre/reports/Independent\\_review\\_Leeds.pdf](http://www.who.int/patientsafety/information_centre/reports/Independent_review_Leeds.pdf) [Accessed 12 May 2017].
6. Research Instruments Ltd. (2005). Test Report on Mouse testing of RFID Tagging System "IVF Witness". Certificate of Analysis (Ectors, FJ, August 2005, GIGA Université de Liège, Belgium) Certificate of Calibration (Wragge-Morley, B. ETC, UK, May 2005) Certificate of Analysis (Pearce, J, May 2007, Embryotech, Wilmington USA)
7. Obradors, A. (2016). *How can we mitigate the risk of error in the IVF Lab?*
8. Forte, M., Faustini, F., Maggiulli, R., Scarica, C., Romano, S., Ottolini, C., Farcomeni, A., Palagiano, A., Capalbo, A., Ubaldi, F. and Rienzi, L. (2016). Electronic witness system in IVF - patients perspective. *Journal of Assisted Reproduction and Genetics*, 33(9), pp. 1215-1222.





## Bespoke protocol management

As part of the installation, a bespoke flow chart (Witness Point Diagram) is created with the assistance of a CooperSurgical installation specialist.

It is designed by you and works in line with your existing Standard Operating Procedures (SOPs). Each critical step carried out by every operator, wherever they are in the laboratory, is logged in a manner compatible with your working practices. The Witness Point Diagram is then tested step by step.

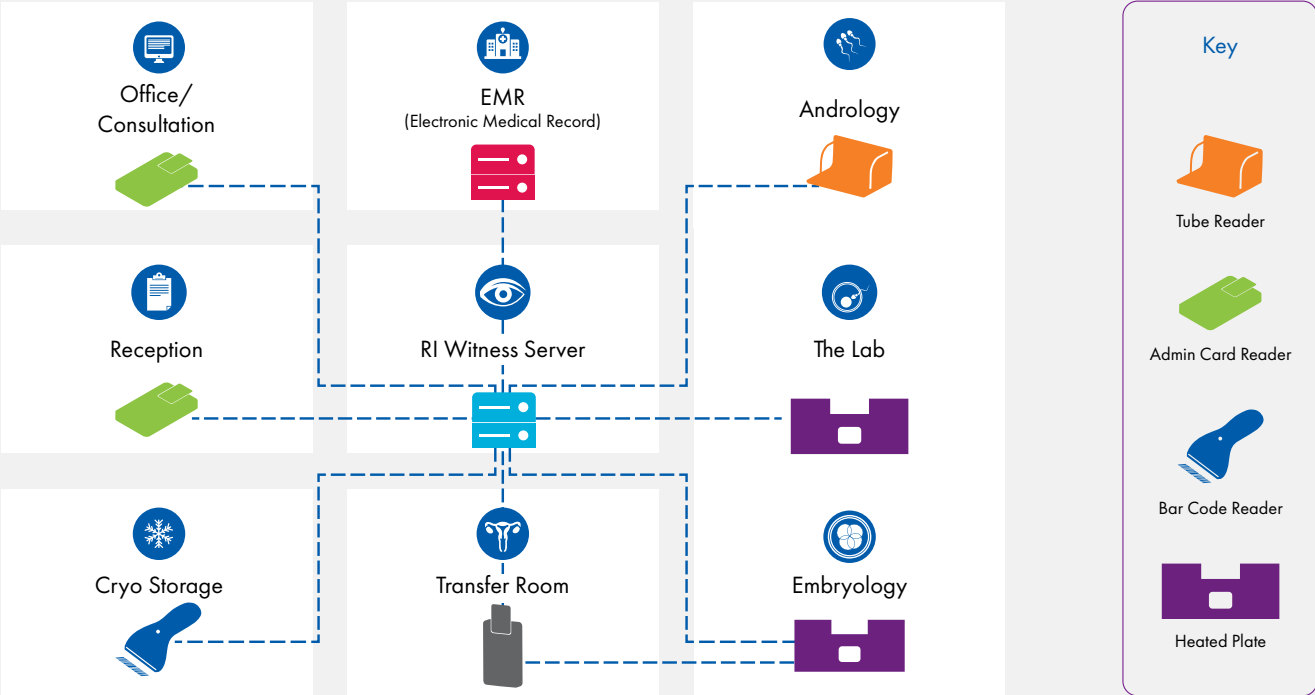
The easy-to-use software interface allows you to amend the diagram as your SOPs and needs evolve. You are in control, so there are no delays such as waiting for outside assistance.



# Whole lab integration

Every process in every part of the lab is automatically detected, logged and protected

Before installation, together we create a plan that outlines your exact requirements including the mapping out of locations for readers and server connections.



## Integration

We can fit embryology heated plates into all workstations from major suppliers; flush fitted integration is possible with K-Systems and ORIGIO cabinets. Work areas can be connected through Wi-Fi or LAN cables to a central server which means everything works together and data updates in real time.

Our software works with leading patient management databases. We also work closely with clinics and their database administrators on an individual basis to ensure smooth integration with RI Witness.

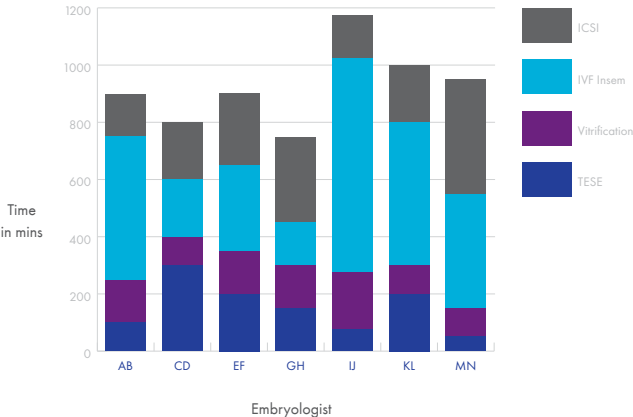


# Additional functionality

## Use RI Witness to its full potential\*

On top of the security advantages with RI Witness, the bespoke infrastructure can also be used to improve other aspects of your laboratory's daily work load.

\*Some of these features require additional purchases



## Workflow management tool

You can look at the activity being done in the lab, how long it takes, where it takes place and who performed it. This information may indicate that staff training is needed, that there are bottle necks in the process or that equipment requires upgrading or replacing. All of this data allows you to make informed decisions about laboratory work improvements.

Procedure data can be explored in detail or summarized into pie or bar charts.

## Cryopreservation tracking

Patient samples can be tracked as they enter and leave cryo storage. The RI Witness RFID system converts data to cryo-suitable barcode identification labels. Durable, laboratory-proven Brady labels are used to identify the vials or vitrification straws. On thawing/warming, the barcode information is linked automatically with the embryo thaw dish.

## Paperless data capture

You can enter data directly into patient records using small touch screen displays or a keyboard and mouse interface installed at your work areas. By inputting directly, transcription errors are minimized and multiple data handling is avoided. Data can be accessed and analyzed immediately.



## Daily overview board

Using a Cycles Overview Display you can view active cycles in the lab. For each cycle the last procedure and current status for the day is shown, for example, in progress, finished or not started. This information is displayed on a big screen fixed to the lab wall and can be accessed from any networked PC. The entire team gains an overview of the lab's daily activities and how the day's work is progressing.

RI Witness						
Active Cycles	PatientID	PatientName	Mr Paul Wilcox	CycleType	CurrentDay	LastWitnessPointName
	12528	Mrs Mary Wilcox		ICSI / IVF	D0	
	12233	Miss Donna Wilks		FET	D0	
	12764	Mrs Jenny Wren	Mr Christopher Wren	ICSI / IVF	D2	27h Fertilisation Check
	12267	Mrs Linda Watson	Mr Ben Frugal	ICSI / IVF	D2	27h Fertilisation Check
	12734	Mrs Wendy Rodgers	Mr John Rodgers	ICSI	D4	24h Embryo Freeze
	12333	Mrs Anne Fields	Dr Graham Fields	ICSI / IVF	D4	24h Embryo Freeze
	12989	Mrs Claire Smith	Mr John Smith	ICSI / IVF	D1	24h Waiting for Insemination
	12665	Mrs Green Gretna	Mr Gary Green	ICSI / IVF	D1	24h Waiting for Insemination
	128756	Mrs Katie Lemon	Mr Kevin Lemon	ICSI / IVF	D1	24h Waiting for Insemination
	12883	Mrs Harriot Cook	Mr Captain Cook	ICSI / IVF	D1	24h Waiting for Insemination
	12291	Miss Sarah King		IVF	D3	24h Waiting for IVF Insemination
	12789	Miss Alison Jenkins	Mr Jimmy Jenkins	IVF	D3	24h Waiting for IVF Insemination
	12444	Mrs Demi Harding	Mr David Harding	IVF	D3	24h Waiting for IVF Insemination



## Imaging function

Capture images and videos from every microscope in the laboratory, at any stage of the patient cycle. Information and images for each patient's cycle can be saved in the patient's file and accessed immediately from any networked PC.

## Patient display screen

Show the patient their embryo pre-transfer while checking it against their patient ID card in the transfer room. This enables the patient to be directly involved.

## Materials traceability

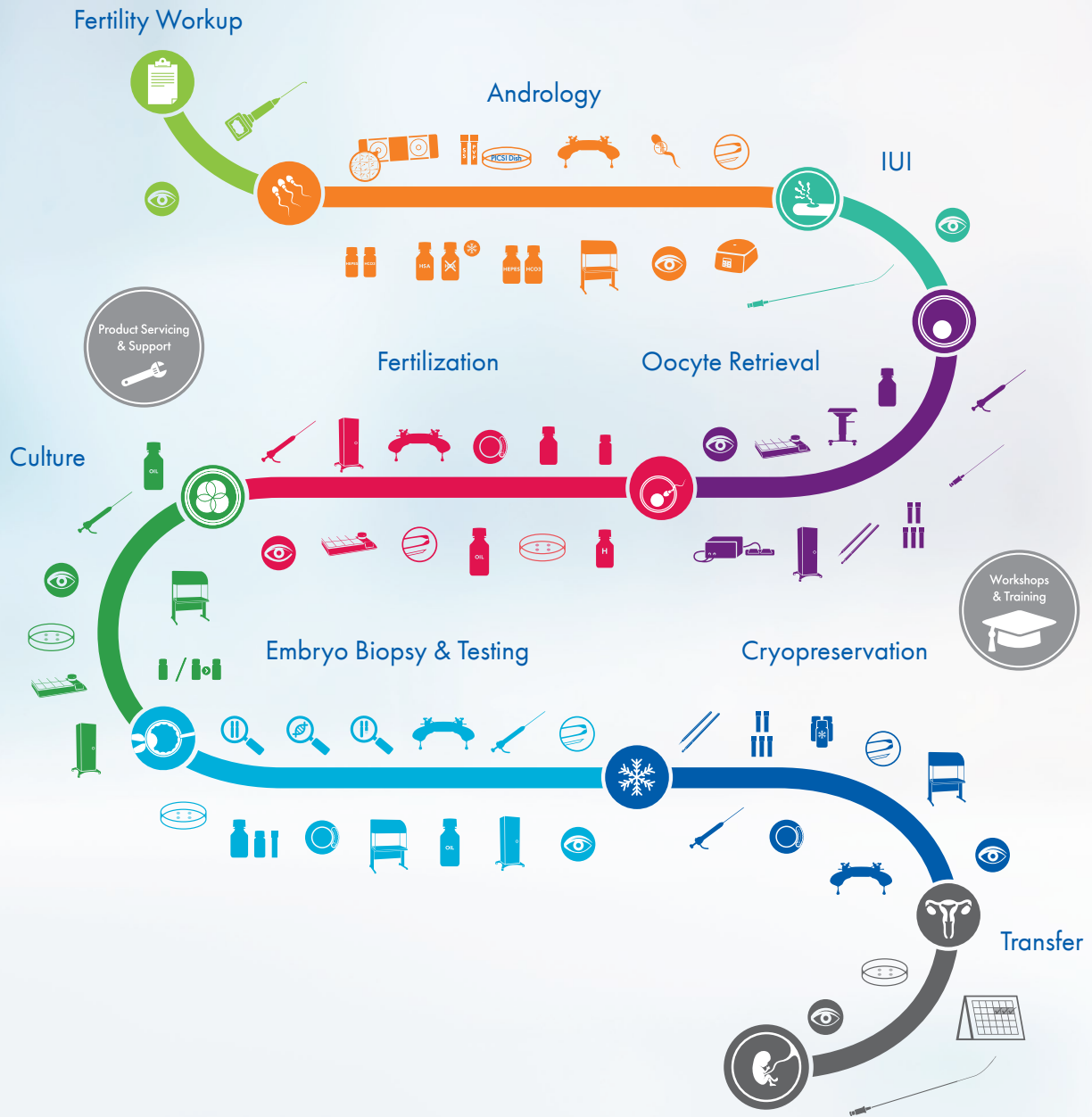
You can record which products are used for each cycle type. Records can be sorted and filtered in various ways to cross-reference patient cycles and material batches. It allows you to keep a full record of consumables used in the laboratory, which is often a requirement of regulatory authorities.





# RI Witness

for every step of the ART cycle



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Availability of a device for clinical use is dependent on its regulatory approval status within the country in which it is intended to be sold.