RI WITNESS™ART MANAGEMENT SYSTEM

Confidence, Efficiency and Trust



Pioneers in electronic witnessing

The RI Witness[™] system has more clinical installations than any other assisted reproductive technology (ART) electronic witnessing system (EWS).



Electronic witnessing is now an established, proven methodology and is increasingly becoming a global gold standard for mismatch avoidance.¹

Our commitment to innovation is as strong today as it was in 2007 when the RI Witness system was first launched. Working in close partnership with clinics around the world, we have continued to develop and improve the system, focusing on the universal need to improve security, efficiency and transparency.

Today, RI Witness is an established and trusted ART electronic witnessing system. With installations across six continents, it continues to be the most popular electronic witnessing system. Not only does it greatly increase the chance of mismatch detection,¹ it also brings added confidence. By automatically registering and logging each sample brought into the work area, there is no need for embryologists to take additional action.

Having RI Witness in your clinic can build on the trust your patients have in you. It helps you and your team have confidence that your processes are as secure and efficient as possible.



A true e-witnessing system, rather than an e-logging system

Thanks to automatic detection, procedural electronic witnessing steps are less likely to be circumvented by the operator.²



1. Sterckx, J. et al. (2023). Electronic witnessing in the medically assisted reproduction laboratory: insights and considerations after 10 years of use. Human Reproduction, 38(8), pp.1529-1537

2. Rienzi, L. et al. (2015) Failure mode and effects analysis of witnessing protocols for ensuring traceability during IVF. Reproductive Biomedicine 2015 Oct;31(4):516-22.

- 3. De los Santos, M. J., & Ruiz, A. (2013). Protocols for tracking and witnessing samples and patients in assisted reproductive technology. Fertility and Sterility. 2013 Dec;100(6):1499-502. https://doi.org/10.1016/j.fertnstert.2013.09.029
- 4. Witness Case Study: Nurture Fertility Report Increased Productivity Following the Introduction of RI Witness™ (2020). Available at coopersurgical.com.
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Benefits of radio frequency identification (RFID) technology

Why choose RFID?

The RI Witness system provides automatic and immediate detection and monitoring of samples within the work area without requiring human interaction to check a sample's identity.

Simply put, RFID technology enables seamless, continual monitoring with no interruptions. Crucially, it is a proactive system. Double witnessing, reactive systems and handheld devices, on the other hand, all require your embryologists to remember to stop and perform a check. If a single error occurs, the whole process is compromised as the chain of custody is broken.

Proactive, continual monitoring will detect instances where two unrelated samples are brought into the work area at the same time. Prevention against mismatch is significantly increased.²





- 2) RFID readers are situated wherever samples are handled or ID checks are performed
- 3) Each RI Witness work area has a networked tablet or PC
- To ensure best practice is adhered to:
- The RFID tags are read automatically at each station
- A digital record of each tag's location is created, showing the stage in the overall process, the timings, and which staff member handled it

1) Self-adhesive RFID tags are attached to all laboratory plasticware

• Visual and auditory alarms indicate when a potential mismatch has occurred so it may be promptly corrected

What the RI Witness[™] system is designed to do

Helps to mitigate against risk^{1,2}

- Reduces potential risk and helps prevent misidentification before procedures are performed²
- Uses continual automatic witnessing within RI Witness work areas to lock patient identity to every gamete, embryo, biopsy and cryo sample for continuous monitoring and complete chain of custody within the lab
- Accelerates ID witnessing through the patient cycle³
- Stays active all day, every day: no sample movement within the work areas goes unchecked
- Improves security management throughout the sample's journey including the biopsy procedure⁴

GREATER EFFICIENCIES

Electronic witnessing gives time back to the embryology team³



Supports efficiency improvements

REDUCES COSTLY ERRORS

to very high (≈100%) at all

stages of IVF⁵

Increases the chances of error detection from high ($\approx 70\%$)

- Can reduce handling time by approximately 50% compared to human double witnessing³
- Potentially reduces each embryo's time outside the incubator by decreasing the time spent waiting for a manual witness^{3,6}
- Can increase productivity, reduce staff stress and improve resource reallocation to meet upscaling targets^{3,7}
- Helps, supports and guides staff through their clinic's standard operating procedures (SOPs), and accelerates staff training⁸

Offers reassurance and confidence

- · Can reduce patient concerns relating to identification errors to benefit patient's well-being, especially during periods when mismatches are reported in the media⁹
- Increases likelihood of patients choosing a clinic using the system, according to staff¹⁰

PATIENT PREFERENCE



≈79% of patients reported high or extremely high satisfaction levels

towards the IVF clinic using this electronic witnessing system⁹

	A	Assists lab
	• Pr	ovides a sir
Optimize lab	• All	ows compa ultiple labs
management with customizable reports	• Ide	entifies tea
on selected metrics	• He	lps to stan ultiple labs

Reduces data inputting and administration

- Supports audit activity and changes to documentation
- Records and organizes consumables, cross-referencing patient cycles and material batches for traceability
- Saves time with paperless data capture via a tablet touch screen¹¹
- Minimizes transcription errors by connecting to your patient database and enabling direct data input

Keeps everyone informed

- Helps support and guide the lab team through workflow pathways, helping ensure SOPs are followed
- Displays easily accessible data in the lab, showing every cycle's progress at a glance
- Enhances efficiency with uninterrupted workflow³
- Provides customizable reports on selected lab metrics to ensure access to meaningful data insights

Continuously evolves to meet your changing need

 Continues to evolve and offer new functionality. Since its launch in 2007, RI Witness has continued to develop and offer new functionality and features in line with the changing needs of IVF clinics, patient profiles, cycle types, regulatory and lab practice requirements.

https://doi.org/10.1016/j.fertnstert.2022.12.038

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- 7. Witness Case Study: Nurture Fertility Report Increased Productivity Following the Introduction of RI WitnessTM (2020). Available at coopersurgical.com.
- 8. CooperSurgical (2022) How the RI Witness IQTM solution can help improve standards and clinical outflow across a clinic group. https://fertility.coopersurgical.com/ fertility-care/how-the-ri-witness-iq-solution-can-help-improve-standards-and-clinical-outflow-across-a-clinic-group/
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- 2024, Lison Portugal.

b optimization

single dashboard view of lab activity for authorized users nparison of lab efficiencies and performance data from

- team training requirements⁷
- standardize your procedures across workstations or

• Highlights workflow bottlenecks to help increase efficiency







1. Applebaum, J. et al. (2023) Malpractice litigation surrounding in vitro fertilization in the United States: a legal literature review Fertil 2013 Apr;119(4):572-580

2. Sterckx, J. et al. (2023). Electronic witnessing in the medically assisted reproduction laboratory: insights and considerations after 10 years of use. Human Reproduction,

11. Thomson, A. (2024). How can digitisation help solve the biggest challenges facing embryologists today: Time, Staffing levels, Burnout [Powerpoint presentation]. Alpha,

What RI Witness[™] means to my clinic

Clinic Management

My staff can focus on their clinical work with total confidence – and as my clinic grows, so does my safeguarding system. RI Witness has proven to provide timesaving advantages and answers to address patients' concerns in a way that attracts interest in my clinic and helps differentiate it from others.

"If we can save time on processes we can reduce our costs and help more patients."

"I want staff and patients to have complete faith in our processes."

"I'm always considering ways my clinic can stand out to attract more patients."



Embryologist

Thanks to RI Witness, we have a permanent digital record of 'who' did 'what' and 'when' and 'where' each procedure was performed. Moreover, with a camera installed, we can even film procedures to record 'how' they were performed. We work with fewer interruptions as manual double witnessing steps are considerably reduced. Screens, updated in real time, display the lab activity which we can refer to at any time.

" I'd like to work with fewer interruptions."

"An overview of the status of my tasks and the cycles scheduled that day, visible from my workstation, gives me more control of my work."

Laboratory Management

A bespoke workflow chart was created for my clinic that I can easily update as our SOPs evolve. Analytics allow me to see where and how my lab could run more efficiently. Audits are made easier thanks to versatile reporting tools. Staff training and practice consistency have become easier too, and staff morale has increased following RI Witness use.

"I want to create a lab where my staff are focused on working, not checking."

" I'm interested in ways to work smarter and increase our cycle volumes."



"I'd like to know more about my IVF cycle. It'd be great to be involved and able to see the journey."

> "It's important for me to know our eggs and embryos are in safe hands; knowing they're tracked is reassuring."



Patient

I can reassure my patients throughout their time with us through accessible literature, up-to-date technology and a record of their cycle including images and videos captured from every microscope used. Additionally, prior to transfer, I show them their embryo, linked to their patient ID, demonstrating how seriously we take their security.

A solution to the challenges faced by ART clinics

Constantly communicating with your patient management system, RI Witness, either visibly or invisibly, will have an impact at every level.

The cost of manual witnessing

RI Witness makes sound commercial sense. In the context of ART, the time spent by one embryologist leaving their task to complete the witnessing requirement for another cycle is a loss. RI Witness gives back much of that time cost by removing this manual witnessing step.^{1,2}

Thanks to implementing RI Witness, Nurture Fertility managed to simplify their workflow,² relieving staff from supporting colleagues on numerous witnessing steps on a daily basis.

This has resulted in an increased efficiency, taking the clinic from 165 - 191 cycles per full-time employee, within two years of implementing RI Witness.²



Active Audits

In many countries, it is a regulatory requirement to track and document the consumables (including batch number) used throughout every single ART cycle. This is a requirement which clinics are able to handle efficiently using the Traceability functionality in RI Witness.



Clinic productivity increased from 165 - 191 cycles per full-time employee, within two years of implementing RI Witness.²

The Anatolia clinic in Ankara, Turkey, documents the usage of 40 different types of consumables, linking them to every cycle by simply scanning consumable batches at receipt, when opened and when closed. This helps to free up hours of manpower on a monthly basis, to avoid transcription errors and support the clinic in preparation for and during the audit process.

Checks and measures. costs and benefits

On the other side of the balance sheet, according to a recent survey, results showed that having RI Witness in your lab may help you attract more patients and expert staff. Experienced staff were more likely to be attracted to clinics that continually invested in technology, while potential patients were aware of the possibility of a mismatch are increasingly reassured when they see your clinic is safeguarded by RI Witness.³ As well as an informative leaflet you can give to potential patients, we can also provide promotional materials you can customize to make your clinic stand out.

Mitigate errors

Since introducing RI Witness in 2011, IVF Brussels has benefitted from a vast amount of data captured on lab performance.

Its review of the 109,655 cycles undertaken during a 10-year period showed a critical event rate of 0.017% per witness point, 0.129% per cycle. In total, 144 potential critical mismatches were identified and prevented from taking place thanks to RI Witness.⁴



Stress reduction in these stressful times

Depression and anxiety disorders cost the global economy US\$1 trillion each year in lost productivity. Reducing work-related risk factors is the WHO's key recommendation for protecting your staff's mental well-being.⁵ Because they do not have to remember to stop and check for mismatches, RI Witness reduces your staff's worries about making mistakes.⁶ Genera Clinic, Rome, reported "a reduction of staff workload and distractions, thus increasing operator satisfaction."7

Peace of mind for your staff benefits them, your lab's efficiency and your bottom line.



- 1. Patel, B. et al. (2013). An investigation into the efficiency of RFID electronic witnessing compared to manual witnessing. The Hewitt Centre of Reproductive Medicine.
- 2. Witness Case Study: Nurture Fertility Report Increased Productivity Following the Introduction of RI Witness™ (2020). Available at coopersurgical.com. 3. Lynch, C. et al. (2022). Impact of the use of RI Witness Electronic Witnessing System on the IVF Laboratory Staff and Patient Experience. Reproductive
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- 5. World Health Organization (2022). Mental health at work. World Health Organization. Available at: https://www.who.int/news-room/fact-sheets/detail/ mental-health-at-work.
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Laboratory staff user satisfaction after the installation of RI Witness⁷

Analyze your workflow

RI Witness goes beyond electronic witnessing. It's about optimizing your practices.



Dynamic lab management

Make informed decisions about best practice using our analytics data.

By identifying where bottlenecks occur, you can determine staff training requirements, any equipment needs or laboratory reconfiguration and upgrades. You can use the reporting features to drill down into detail or stand back for a broader overview of your lab. For multi-site clinics, or clinics with multiple laboratories, having this information helps you standardize your protocols, and supports continual professional training as your clinic expands. Once your core Witness Point Diagram is established, our straightforward user interface makes it easy to keep it aligned with your lab SOP updates.

Remove administrative redundancy

Stay on top of your regulatory requirements by simplifying audits.

Real-time patient cycle data is entered directly into patient records using touch screens installed at every workstation. Record which products are used during each cycle type for easy organization of your consumables batch data. Records can then be sorted, filtered, and cross-referenced with patient IDs.

Keep everyone informed

View your team's progress at a glance.

The RI Witness Cycle Overview Display in the laboratory shows your team's progress at a glance – with each cycle's current status and the last procedure undertaken updated in real time. The screen helps your embryologists to control and prioritize their own workflow. When everyone is literally on the same (screen) page, your team will stay on track.

Configure to match your existing Standard Operating Procedures (SOPs)

Mirroring your existing SOPs, the Witness Point Diagram (WPD), created by your clinic's laboratory management and our installation specialist, provides you with a comprehensive workflow overview. Each critical step carried out during every type of patient cycle is identified and captured in the WPD. Once tested and in place, the WPD allows the RI Witness system to automatically record real-time 'who', 'what', 'where', 'when' and 'how long' data across all laboratory activity.

The WPD is flexible and future-proof as you will be trained to amend and evolve your protocols going forward. Different types of cycles can be accommodated.



Implementation and support

The logistics and practicalities of implementing a new system of any kind can be extremely daunting for a busy IVF clinic. However, our team of service engineers and product specialists will do everything possible to ensure a smooth transition.

They will work with you to communicate with clinic database providers to facilitate integration of data, if feasible.

Our installation team will support and guide the Senior Embryologists during the configuration of the workflow ensuring it is precisely how you want it. RI Witness requires very little change in daily tasks, which means that most normal users will see little difference in how they work. However, the team will ensure all users understand the principles of the system and are trained to use it confidently.

RI Witness IQ[™] Solution

You can't manage what you don't measure

Most clinics have defined SOPs. They provide guidelines for certain process steps (and intervals between those steps), setting out a specific time frame within which they should be carried out. However, clinics often lack the time to monitor how accurately SOPs are followed. They may also lack the right tools to compare the performance of both lab staff and equipment.

The RI Witness IQ[™] solution provides lab managers with unique access to data and insights, enabling them to compare performance against defined clinic KPIs. While the RI Witness[™] system is primarily designed to protect clinics from mismatches, RI Witness IQ is used to analyze how well the lab is adhering to clinic SOPs. It can help managers identify differences in performance, between staff members and work areas.

Improving fact-based lab management

RI Witness IQ allows you to compare any two witness points or process steps. This means you can track not only average performance month by month, but also outlier events where SOPs may not have been followed.

These insights help identify potential training needs and, in some cases, they create an opportunity to discuss if SOPs need to be adjusted.



Monitor one or two labs - or multiple settings

Performance data is pushed from the clinic's RI Witness server to a cloud-based server hosting the RI Witness IQ data. Each lab determines who gets access to monitor the data from their lab – access which is protected by two-factor authentication.

This means clinic performance can be monitored from anywhere at any point in time. With data updated every minute, data comparisons can be made on a daily, weekly, or monthly basis – or any other interval deemed relevant by the user.

For groups of clinics, remote access is of particular interest. Users can monitor and compare the performance of multiple labs in one overview or report, showcasing differences in performance across the group. This data could help lab managers understand differences in outcome.

Reports automatically received in your mailbox

Different members of staff may focus on different aspects of lab management and monitor different KPIs.

With the RI Witness IQ solution, each user can create their personal dashboard, highlighting data that is of particular interest. For example, a user could:



Determine whether changing the supplier of needles has reduced the time

Check that the defined minimum time between sperm prep and IUI

The RI Witness IQ Solution lets you take the next step beyond witnessing. Intelligent data collection and analysis offer the insight clinics need for

How PGT cycles are managed with the RI Witness[™] system

Every year, more than three million IVF cycles are carried out globally.¹ A growing percentage now include preimplantation genetic testing (PGT). It's an emerging trend that presents exciting opportunities for patient care but may also add to the laboratory's responsibilities.

PGT-A Testing can provide information that might:





Reduce the likelihood of experiencing a miscarriage^{4,5}

Help increase chances for live birth following IVF treatment⁶



It is imperative that lab witnessing protocols are updated to accommodate the addition of embryo biopsy and sample tubing.

Often, two or more embryos from the same patient's IVF cycle are sent for genetic testing and the results are reported back to the IVF clinic. This step can pose an additional risk of an error, as the labeling of the biopsy samples may suffer from transcription errors. This could potentially lead to the transfer of an unintended embryo.

In the worst-case scenario, despite using genetic testing to avoid it, an incorrect embryo⁷ carrying a hereditary disease could be transferred to the patient.

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- 2. Buldo-Licciardi, J. et al. (2023) Utilization of standardized preimplantation genetic testing for aneuploidy (PGT-A) via artificial intelligence (AI) technology is correlated with improving pregnancy outcomes. J Assist Reprod Genet. 2023 Feb;40(2):289-299. doi: 10.1007/s10815-022-02695-7. Epub 2023 Jan 7. PMID: 36609941; PMCID: PMC9935782.
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The correct embryo for the right patient

With the RI Witness system, based on the tracking of each embryo from the point of fertilization, the identity of each unique embryo is labeled onto the cryo-carrier at the point of vitrification. When biopsying an embryo for PGT, a similar, unique identity for the biopsy sample is created – and a link between the two identities is established.

Biopsy samples for PGT are associated with their cryopreserved embryo throughout. The RI Witness system labels and tracks samples prior to testing for PGT. Once the results are analyzed, RI Witness records which individual embryos have been approved for transfer (or ongoing storage) by the clinician.

At the Reproductive Partners Medical Group (RPMG) in Redondo Beach, CA, USA, 800 cycles per year are supervised by RI Witness. For the 80% of the cycles that include PGT a unique link between embryo and biopsy ID is created. Once test results are received from the genetics lab, based on the unique biopsy ID, RPMG can identify the embryos corresponding to each test result, and mark the embryos as 'approved' or 'not approved' for transfer.

consequences for patients and staff.



What is Embryo & Biopsy Tracking?



Understanding individual embryo tracking

The RI Witness system allows clinics to register the number of oocytes retrieved with each patient cycle. Following insemination, the system allows the laboratory team to assign a unique identity to each embryo and track them into individual wells or droplets within a dish.

This system provides clinics with a comprehensive log of the location and pathway report of each embryo involved in an IVF cycle. The log documents the number and identities of the oocytes or embryos per dish, and timestamps each occasion when the individual samples are moved from one dish to another.

Customizable to support any dish or droplet configuration

Large touchscreen tablets offer users a clear view of individual dishes and droplet configuration, giving a high level of control over every process step.

The RI Witness system comes preloaded with a list of common dishes and dish configurations. In addition, clinics can build their own bespoke dish configuration, supporting any size and shape of dish and any unique ID.

Users digitally record which embryos are located in which unique well or droplet, eliminating the need for manual annotations.

Safely moving embryos between dishes

When embryos are moved from one dish to the next, the RI Witness reader detects the additional dish(es) being introduced in the work area. This prompts the user to register the embryos being moved – making users responsible for recording and updating the status and location of all embryos.

By electronically tagging every step, the system enables users to maintain a real-time status of all samples and embryos at any point in the cycle.



Track each embryo and associated biopsy dish maintaining a link between embryo and biopsy

The RI Witness[™] system in the laboratory

How RI Witness helps safeguard your clinic and your patients

Every workstation where a patient or sample will be treated is installed with an RI Witness reader. Radio frequency ID (RFID) tags are fixed to all plasticware involved in the patient cycle. As they are used, these tags are registered with each couple's unique code to identify their gametes, embryos and samples throughout the cycle. Whenever plasticware is brought onto a workstation, the tags are automatically read, identified and logged. If two incompatible codes are present on a workstation, the system immediately sounds an alert. The embryologist can only continue once a match and an action are confirmed. Personalized ID cards or fingerprint readers also capture the patient interactions at entry and exit points.



Constantly communicating with your patient management system, RI Witness, either visibly or invisibly, will have an impact at every level. Developed in response to industry voices, there are many features to choose from so you can select as many or as few as you require, leaving the option to expand at a later date. Each installation is tailored to your laboratory, and our experienced, specialist team will manage the implementation of RI Witness from start to finish.

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RI Witness is a companion to every lab activity; this safeguard works everywhere the staff work, identifying and tracking individual gametes, embryos and biopsies



Andrology A read

A reader detects every sample cup or tube

TRAIN WITH COOPERSURGICAL® AND OPTIMIZE YOUR PERFORMANCE, LEARN NEW SKILLS AND NETWORK WITH INTERNATIONAL PEERS

We invite customers and partners to learn new techniques and share best practices in our fully equipped laboratories.

We provide evidence-based training by skilled, experienced embryologists which includes demonstrations and hands-on training in a comprehensive range of ART techniques and procedures.



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