Genea BIOMEDX

Gidget

STREAMLINE CRITICAL STEPS OF YOUR IVF PROCESS

Gidget®: A comprehensive witnessing and ART workflow management system designed to aid quality control and improve lab efficiencies

Gidget

THE IDENTIFICATION OF PATIENTS AND TRACEABILITY OF THEIR REPRODUCTIVE CELLS ARE CRUCIAL IN ART.[1-3]

Despite manual double witnessing, embryologists are exposed to human errors during the manipulation of IVF samples.[1-2,4]

In addition, the increasing complexity of the ART laboratory impacts the number of processes to be witnessed and the time spent in manual witnessing.[1,5]

Gidget® **can facilitate the identification and traceability of IVF samples,** in accordance with EU directives and best-practice scientific guidelines[3,6-7] for electronic witnessing.

INTRODUCING Gidget®

A MODULAR, EASY-TO-USE SOLUTION FOR EVERY LAB

Gidget® is an electronic witnessing and workflow management system within the ART lab and clinic environment, enabling high workflow visibility, process and consumable traceability and streamlined reporting.[1,8]

Increased confidence for the lab: reduced distraction and stress[4,8-10]

Risk mitigation and traceability: mismatches and procedure deviations[8]

Increased* efficiency of operations and time-savings[5,8-10]

Supports **reliable services for patients**[11]

Designed to adapt to a **lab's existing infrastructure and ART procedures**[8]

Tracking of consumables used within specific cycles[8]

1. De los Santos, MJ. et al. "Protocols for tracking and witnessing samples and patients in assisted reproductive technology." Fertility and sterility 100.6 (2013): 1499-1502. 2. Adams, S. et al. "IVF Witnessing and electronic systems Final Report." IVF Risk Assessment Report (2006): 1-18. 3. HFEA Code of Practice 8th Edition, 2010, Revised July 2016. 4. Toft, B. et al 'Involuntary automaticity: a work system induced risk to safe health care'. Health Services Management Research 18 (2005): 211-216. 5. Alikani, M. et al. "Comprehensive evaluation of contemporary assisted reproduction technology laboratory operations to determine staffing levels that promote patient safety and quality care." Fertility and sterility 102.5 (2014): 1350-1356. 6. De los Santos MJ, et al. "Revised guidelines for good practice in IVF laboratories (2015)." Human Reproduction 31.4 (2016): 685-686. 7. European Commission directives 2004/23/EC; 2006/86/EC. 8. QFRM883 Gidget® User Manual. 9. Thornhill, AR et al. "Reducing human error in IVF with electronic witnessing. " Fertility & Sterility (2011):96 (3) S179. 10. Rienzi, L. et al. "Failure mode and effects analysis of witnessing protocols for ensuring traceability during IVF." Reproductive biomedicine online 31.4 (2015): 516-522. 11. Forte, M. et al. "Electronic witness system in IVF—patients perspective." Journal of Assisted Reproduction and Genetics (2016): 1-8. * Compared to manual methods

DESIGNED TO ADAPT TO YOUR LAB'S EXISTING INFRASTRUCTURE AND ART PROCEDURES

The **low complexity** of Gidget® enables easy and fast integration into the lab. Gidget® communicates via Wi-Fi* and **no modification to the lab furnishing** is needed.[1] In addition, its **modular approach** enables integration of new functionalities with minimal disruption for the lab.

The **Active Patients screen** is the main Gidget® WebApp interface, providing a summary of all patients that currently have an active cycle along with information on their cycle status.[1]

Gidget® can be **customised to suit individual laboratory needs.**[1]
The **Gidget® WebApp** is the **proprietary web-based software** package for creating, managing and witnessing patient samples and workflow processes in an embryology laboratory.

The **Gidget® Handheld Scanner** is a barcode reader integrated with an Apple iPod Touch® running the dedicated Gidget® application.

Patient names are fictitious. Any resemblance to real patients is purely coincidental.
* Internet connectivity and QBOX IVF are required to enable connectivity to compatible EMR systems.
Screens not included, for illustrative purposes only. The number of Gidget® handheld scanners is scalable according to lab needs.

SUPPORTING VISIBILITY OF YOUR WORKFLOW THROUGHOUT THE DAY

Busy days are streamlined with ease with smart information in real time. The **Gidget® Dashboard** automatically updates via Wi-Fi as procedures progress.

With a **user-friendly interface** and easy-to-read symbols with **colour coding,** Gidget® enables high visibility of daily activity until Day 7, positively impacting workflow management and lab efficiencies.[1]

The **cycle information and detailed procedure status by patient** can be conveniently accessed through both handheld and WebApp.

Using a wireless network connection, the hand-held devices communicate with a **centralised computer system (CCS).**[1] All transactions are recorded to a database.

1. QFRM883 Gidget® User Manual

ELECTRONIC WITNESSING

Gidget® aids the identification and tracking of patient samples during ART procedures, substantially reducing the risk of biological sample mismatch errors by confirming barcode matching.[1]

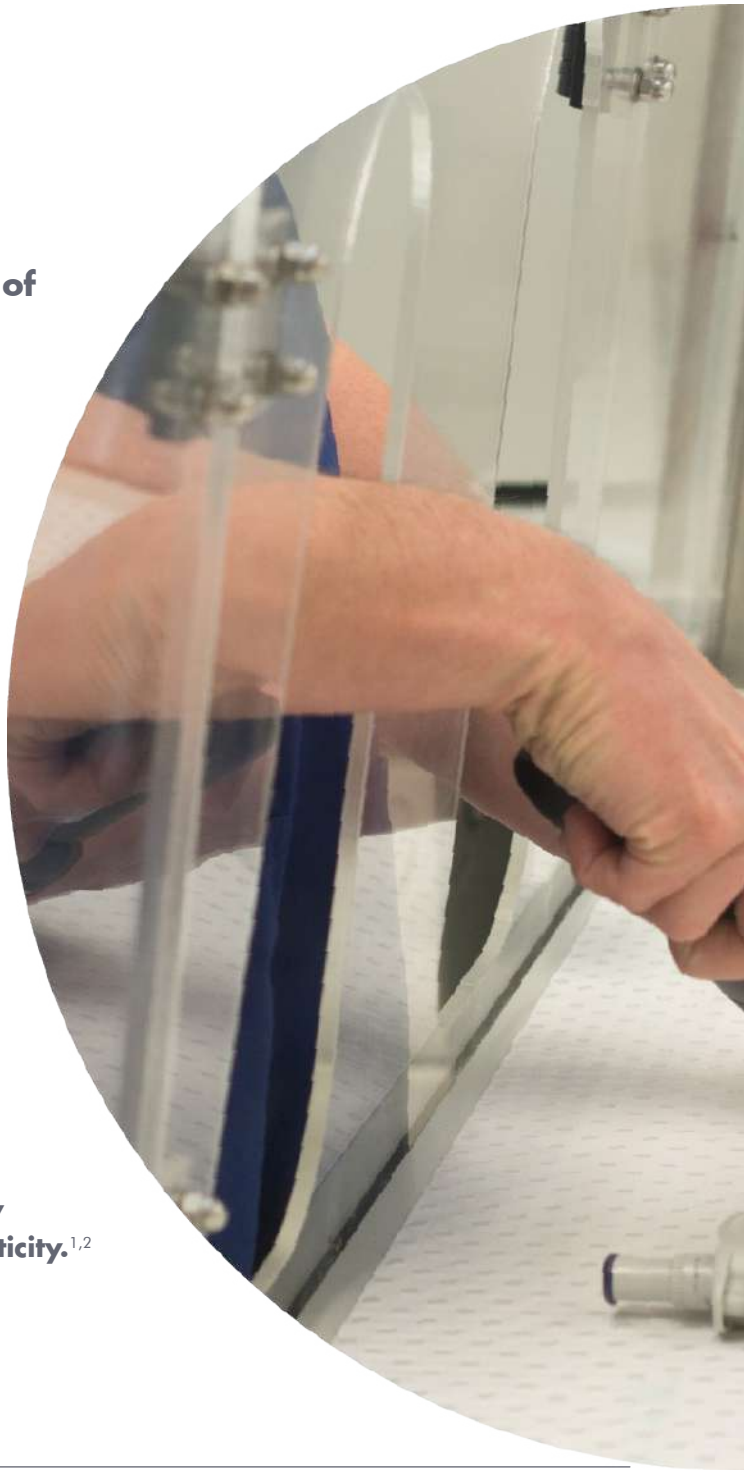
REDUCED POTENTIAL FOR HUMAN ERROR

Unique barcoded patient labels are identified, matched and **tracked throughout the entire lab lifecycle.[1]**

- ✓ **Two levels of critical mismatch error.[1]**
- ✓ **Noticeable audio cues** further support error recognition by the handheld user.[1]
- ✓ **Samples can be identified and recorded down to embryo- and gamete -level,** enabling full traceability for FET cycles.[1]

MINIMISE WITNESSING INTERRUPTIONS

Gidget® can facilitate focused and undisturbed gamete/embryo handling by **reducing the need to call for a second person to confirm a manual witness, thereby minimising risk for errors** in lab processes **and automaticity.[1,2]**



CONFIGURABLE AND EASY TO USE

- QR code enables **multi-directional scanning.**
- Compatibility with the **two main printer brands* in the market.**[3]
- **Configurable label templates** that fit the most commonly used consumables in ART practice.[3]
- **Compliance with the SEC** (Single European Code) labelling requirements for transport of IVF samples between clinics.[1]
- **Different patient roles** are used to designate the distinct function of a patient within a cycle; Gidget® allows to assign label types to patient roles **for improved** traceability.**[1]

DESIGNED WITH EMBRYO SAFETY IN MIND

Gidget® barcode reader uses image-based scanner technology **causing no significant effect on embryo development,** as important safety considerations of laser power, wavelength and pulse are met.[4-7] The 650 nm, visible laser diode **can be turned off** if aiming-scanning assistance is not required.

1. QFRM883 Gidget® User Manual 2. Toft, B. et al. "Involuntary automaticity: a work system induced risk to safe health care". Health Services Management Research 18(2005): 211-216. 3. QRTM212 Gidget® Consumables. 4. QRTF173 Electronic Witnessing in a Clinical Setting. 5. Ebner, T. et al. "Possible applications of a non-contact 1.48 um wavelength diode in assisted reproduction technologies". Human Reproduction Update, 11.4 (2005): 425-35. 6. QRTM134 Gidget® Laser Safety. 7. Bedient, C. et al. "Laser Pulse Application in IVF". INTECH Open Access Publisher (2011). * Compatible printers Zebra GX430t and Brady BBP12 and labels are not included (Zebra GX430t and Brady BBP12) ** Compared to former versions of Gidget®

ELECTRONIC WITNESSING

Two levels of critical mismatch errors are highlighted across devices as soon as they happen and require supervisor approval to proceed, further aiding quality control.[1]

PATIENT MISMATCH ERROR

When patient labels not belonging to the current cycle are scanned during the same Witness Session, **a critical Error Alert**[1] **will be triggered in Gidget®.**

SAMPLE MISMATCH ERROR

The sample-level labels are used to identify specific embryos and/or gametes from the same patient during freezing procedures to **enable a correct matching of intended embryos or gametes in subsequent FET cycles*.**

A sample mismatch occurs when a sample-level label is scanned but it is not specifically linked to a new active cycle.[1]

1. QFRM883 Gidget® User Manual
* Please see note in back cover
Illustrative example. Patient names are fictitious. Any resemblance to real patients is purely coincidental.

VISUALISING AND RESOLVING CRITICAL ERROR ALARMS

In the Gidget® Dashboard and the Active Patient List, the relevant Patient Card will be highlighted red and will appear at the top of the list, enabling to track any issues at a glance.[1]

A **mismatch error** will temporarily **log the user out** of the handheld and lock the patient within the system.

The error **must be resolved by a supervisor or administrator** before further Gidget® processes can continue.

Both the PATIENT and the SAMPLE mismatch errors are **logged and recorded in the Witness report.**

WORKFLOW MANAGEMENT

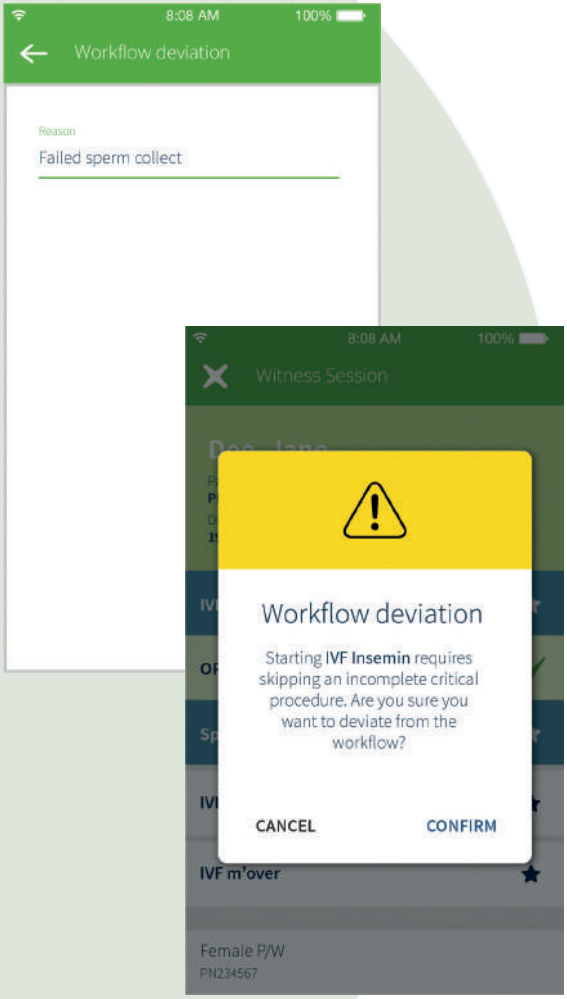
In addition to electronic witnessing, Gidget® incorporates process scheduling tools to help manage task workflow and improve traceability in the laboratory.[1]

The **list of active patients is related to cycle days** to allow visibility of patient progress.[1]

Workflow rules can be tailored to each lab[1] helping to prevent the omission of key tasks in the witnessing process and supporting quality control.

- ✓ **Labels marked as critical must be scanned** for a procedure to be logged as complete in a given cycle day.[1]
- ✓ **Procedures can also be marked as critical**[1] to aid workflow and change management.
- ✓ **Procedures can be linked**[1] if they may be scanned simultaneously e.g. Andrology/OPU.

1. QFRM883 Gidget® User Manual
(Illustrative examples. Patient names are fictitious. Any resemblance to real patients is purely coincidental.)



RISK MINIMISATION AND CHANGE CONTROL FOR INCREASED RELIABILITY

The **order of procedures within a day can be enforced.**[1]

Workflow deviations, including skipping an incomplete procedure, starting a skipped procedure, starting a completed procedure, or starting an added procedure, **require a confirmation via a pop-up window.**[1]

The **critical procedure designation** is intended to further aid change control management. **Skipped critical procedures not only trigger a deviation warning, but also require user justification** text input for deviation response.[1]

Deviation of procedures is **conveniently performed through the hand-held scanner.**

All deviations to lab process are recorded in the Gidget® cycle history audit report.[1]

CONSUMABLE TRACKING

TRACEABILITY IN THE ART LAB BEYOND WITNESSED PROCESSES

FACILITATING INVENTORY MANAGEMENT
Gidget® allows you to register, activate and deactivate a consumable lot, and includes a consumable expiry warning*.[1]

KEEPING TRACK OF CONSUMABLES USED IN EACH CYCLE
Additionally, Gidget® enables **active consumable lots to be conveniently linked to one or more patient cycles.**[1]

* Expiry warning 9 days prior to expiration as well as a further warning when expired

TRACEABILITY & REPORTING

Gidget® PROVIDES EXPORTABLE USER TRACEABILITY LOGS AND STREAMLINED REPORTS WHICH COULD BE USED FOR AUDITS, INSPECTION AND ACCREDITATION*

- Reports contain a full record of activities completed with the scanner by each user, ensuring **transparency and traceability**[1] of the processes.
- Each **user has a unique barcode log in**[1] to the handheld scanning system**.
- **Reports can be viewed, exported or printed.**

Three types of reports:[1]

1. **Witness report includes** relevant information associated with each witness session (incl. warnings, mismatches and error resolutions).
2. **Cycle history report records procedure deviations** and procedure history by patient-day.
3. **Consumable report displays all patients associated with a particular consumable.**

1. QFRM883 Gidget® User Manual
* Subject to applicable local rules and procedures. Check with your local authorities/notified bodies for confirmation.
** Recommended by Best Practice Guidelines ESHRE and HFEA

HOW Gidget WORKS

Upon installation, Gidget® will be configured according to your clinic processes. Laboratory supervisors and administrators define workflow rules. Consumable types and lots are defined in the new consumable tracking environment.

1

PATIENT SET UP

Enter incoming patient data* and **define cycle details.** Print labels.

2

Administrator

SCAN UNIQUE USER ID

And verify entering the 4 digit pin.

3

START SCANNING PATIENT LABELS

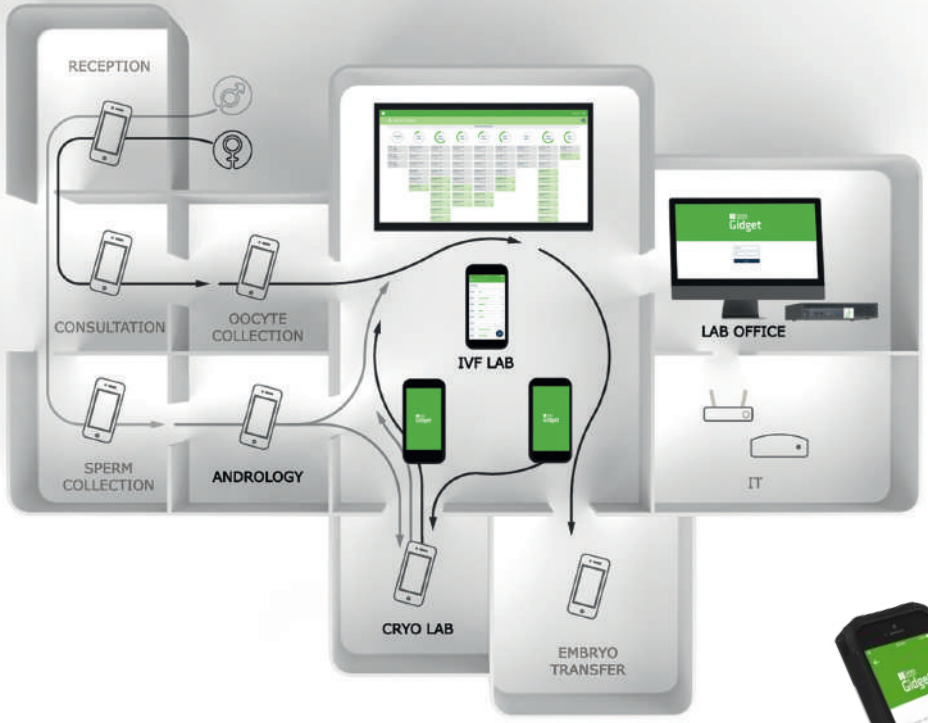
Gidget® will recognise the patient and display a list of procedures for that label; **The next logical procedure is highlighted blue.** Any **consumable used during sample processing can be recorded** and linked to patient cycle.

4

AS PROCEDURES PROGRESS

Gidget® will confirm the match of patient details and/or flag any deviation or mis-match, on the screen and with **noticeable audio cues** during scanning to support recognition.

Source: QFRM883 Gidget® User Manual
* QBOX IVF is required to enable connectivity of Gidget® with compatible EMR systems.



5

BENEFIT FROM HIGH VISIBILITY

of patient activities at all times.

6

ADD NEW TASK TO CYCLE

If not planned upfront, Gidget® provides the **flexibility to add a procedure after the cycle starts from the WebApp. Confirm the new procedure in the handheld** and continue scanning normally.

7

COMPLETE CYCLE

When all the relevant witness sessions for a patient cycle have been completed, the cycle must be logged as complete.

8

VIEW AND/OR PRINT REPORTS

Reports contain a full record of activities completed with the scanner: **witnessing sessions, cycle history and consumables linked to patient cycles.**

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For healthcare professionals only. Please refer to the instructions for use.

For further information, please contact your Service Representative or visit:

www.geneabiomedx.com

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