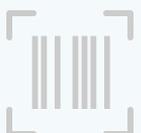


Genea BIOMEDX Gidget

User Manual



PART NO. AND REV ON THIS SURFACE REFER NOTE 23 & 24



PART NO. AND REV ON THIS SURFACE REFER NOTE 23 & 24

GENERAL INFORMATION

Copyright

This user manual and all contents contained herein are subject to copyright. All rights reserved. No part of this user manual may be reproduced, copied, translated or transmitted in any form or by any means without the prior written approval of Genea Biomedx.

iPod®, iPod® touch, App Store® and iPhone® are registered trademarks of Apple Inc®.

DISCLAIMER OF LIABILITY FOR THIRD PARTY MATERIALS, PRODUCTS AND SERVICES

Installation and use of GIDGET may involve underlying third party materials, products or services including, but not limited to, printers, labels, handheld base and Internet access. GENE AND ITS DISTRIBUTORS DISCLAIM ANY AND ALL LIABILITY, INCLUDING ANY EXPRESS OR IMPLIED WARRANTIES, WHETHER ORAL OR WRITTEN, FOR SUCH THIRD PARTY MATERIALS, PRODUCTS OR SERVICES. CUSTOMER ACKNOWLEDGES THAT NO REPRESENTATION HAS BEEN MADE BY GENE OR ITS DISTRIBUTORS AS TO THE FITNESS OF THE THIRD PARTY MATERIALS, PRODUCTS OR SERVICES FOR THE CUSTOMER'S INTENDED PURPOSE.

Technical Support

Genea Biomedx Pty Ltd

Level 2, 321 Kent Street

Sydney, New South Wales, 2000, Australia

Email: info@geneabiomedx.com

Web: www.geneabiomedx.com

TABLE OF CONTENTS

1. ABOUT GIDGET	1
1.1. Overview.....	1
1.2. Intended Use.....	1
1.3. Features.....	2
1.4. Included Items.....	3
1.5. Recommended Items.....	3
1.6. Symbols Used in Gidget.....	4
2. BASIC SETTINGS	6
2.1. Settings.....	6
2.2. Adding a User.....	7
2.3. Editing a User.....	8
2.4. Reactivating a User.....	8
2.5. Deactivating a User.....	8
2.6. Selecting a Printer.....	8
2.7. Printing a User ID.....	9
2.8. Licenses.....	9
3. LAB PROCESS	11
3.1. The Label Library.....	11
3.1.1. Formatting Labels.....	11
3.1.2. Editing Label Formats.....	12
3.1.3. Adding Labels.....	13
3.2. Procedures.....	13
3.2.1. Adding a Procedure.....	14
3.2.2. Adding Labels to a Procedure.....	14
3.3. Cycle Types.....	15
3.3.1. Adding Procedures and Labels to a Cycle.....	16
4. CONSUMABLE TRACKING	17
4.1. Consumable Types (WebApp).....	17
4.1.1. Adding a Consumable Type.....	17
4.1.2. Deleting a Consumable Type.....	18
4.1.3. Editing a Consumable Type.....	18
4.2. Consumable Lots.....	19
4.2.1. Adding a Consumable Lot (WebApp).....	19

4.2.2. Adding A Consumable Lot (Handheld)	19
4.3. Activating a Consumable Lot (WebApp)	19
4.3.1. Activating a consumable lot (Handheld)	19
4.3.2. Closing a Consumable Lot (WebApp only)	20
4.3.3. Editing a Consumable Lot (WebApp)	20
4.3.4. Editing a Consumable lot (Handheld)	21
4.3.5. Linking a consumable to a Patient Cycle dish. (Handheld only)	21
5. BASIC OPERATION: WEBAPP	22
5.1. Logging In	22
5.2. Active Patients Screen	22
5.3. Patient Cycle Information Preparation	24
5.3.1. Linking Patients in a Cycle	24
5.3.2. Linking samples to a Cycle	24
5.3.3. Creating Concurrent Patient Cycles	25
5.3.4. Cycle Details	26
5.4. Printing Labels for a Prepared Cycle	26
5.5. Completing Cycles	27
5.6. The Patient List Screen	28
5.6.1. Editing or Reviewing Patient Cycle Information	28
5.6.2. Sample Transport using Single European Code (SEC) settings	29
5.7. Cancelling Cycles	30
5.8. My User Settings	30
5.9. Reporting	30
5.9.1. Viewing or Exporting a Report	31
6. BASIC SCANNER OPERATION	33
6.1. About	33
6.1.1. Storage	33
6.1.2. Cleaning & Maintenance	33
6.2. Logging in	34
6.3. Witness Sessions	34
6.3.1. Performing a Witness Session	34
6.3.2. Witnessing 'Sample-level' labels	35
6.3.3. Manually Witnessing Labels	35
6.4. Reviewing Patient Information	36
6.4.1. Reviewing Lab Progress Information	36

6.4.2. Reviewing Individual Patient Information.....	36
6.4.3. Handheld audio.....	37
6.5. Manual Control of Cycle Day Status.....	39
6.6. Cycle Completion.....	39
7. ERROR ALERTS	40
7.1. Patient Mismatch Error.....	40
7.2. Sample Mismatch Error.....	40
7.3. Remaining Licenses Warning.....	41
8. GLOSSARY	42
9. TECHNICAL SPECIFICATIONS & MAINTENANCE	45
APPENDIX	46
10. PREREQUISITES & RESPONSIBILITIES	46
10.1. Prerequisites.....	46
10.2. Customer Responsibilities.....	47
11. PRE-INSTALLATION	48
11.1. Overview.....	48
11.2. Supported Label Printers & Consumables.....	48
11.2.1. Creating an Apple ID.....	48
11.3. Zebra GX430t with Ethernet Connection Setup.....	49
11.4. Brady BBP12 with Ethernet Connection Setup.....	51
12. POST-INSTALLATION	52
12.1. Overview.....	52
12.2. Recommended Post-Installation Task.....	52
12.3. Customer Logins.....	52
12.4. Backup & Disaster Recovery.....	52
12.4.1. Backup & Restore FAQ.....	53
12.4.2. Setting the Backup Location.....	54
12.4.3. Setting the Backup Time & Frequency.....	55
12.4.4. Performing a Manual Backup.....	55
12.4.5. Performing a Restore.....	56
12.4.6. Adding, Changing or Removing Label Printers.....	56
12.4.7. Adding Additional Handheld Scanners.....	56
12.4.8. Importing a Genea Supplied Lab Process (Optional).....	57
12.5. Handheld Scanners: Checking WebApp Version.....	58
12.6. Retrieving System Log files.....	58

12.7. Removing all Patient Data.....	58
13. INDEX.....	59
14. NOTES.....	61

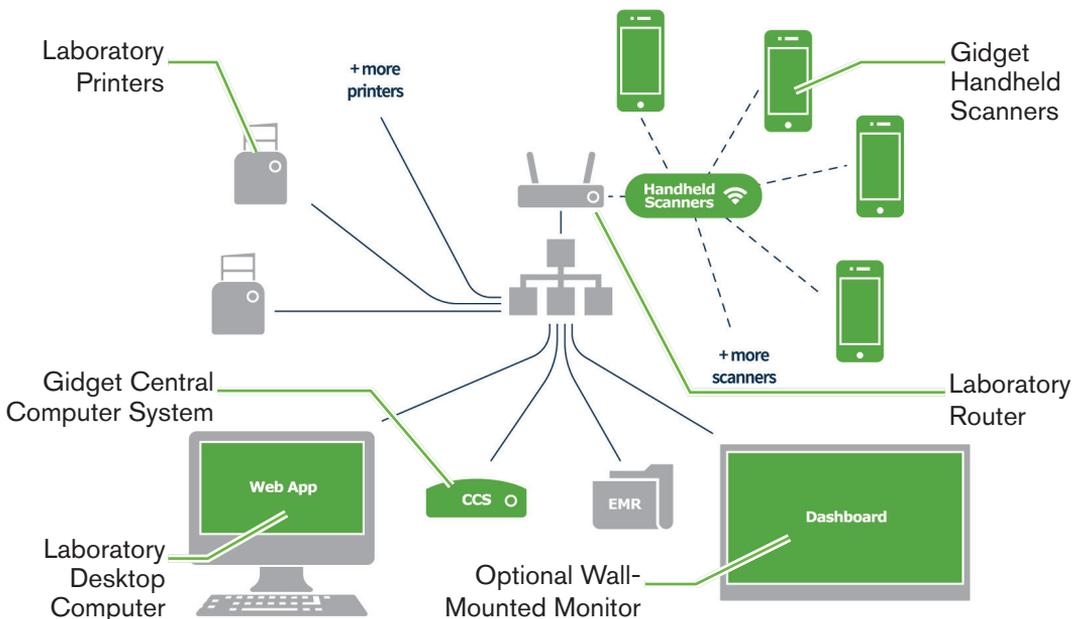
1. ABOUT GIDGET

1.1. Overview

Gidget is an electronic system for identification of patient samples and the management of workflow sequence for ART procedures within the laboratory and clinic environment. Gidget can be operated by a single user to identify and match patient samples throughout the laboratory workflow. The system utilises a unique patient barcode that is printed onto labels and attached to the containers and paperwork associated with that patient.

The Gidget system consists of Gidget Handheld Scanners and a Gidget Central Computer System. The scanner reads the barcodes and the software confirms the match of patient details. Using a wireless network connection, all transactions are recorded to a database within the Central Computer System that keeps track of all users and all labels scanned into the system, as well as any errors or warnings. Reports can be viewed, exported or printed. Information from the Gidget system is displayed via the Gidget WebApp.

The Gidget Witnessing System



1.2. Intended Use

Gidget is intended for use as an electronic system for identification of patient samples and the management of workflow sequence for ART procedures in IVF clinics and laboratory environments. Gidget is intended to support users during Witnessing sessions and is not intended to replace or alter the requirement for users to read and confirm labels.

1.3. Features

The Gidget system provides a number of features to support the scientists in the laboratory.

Workflow Visibility:

Workflow progress is organised by Cycle Days and is displayed on any suitable desktop computer as well as on the Gidget Handheld Scanner. Gidget also allows for monitoring on an optional wall-mounted monitor for even greater workflow visibility.

Workflow Tracking:

Laboratory supervisors and administrators define workflow practices, including number and type of containers that must be scanned in each Cycle and in which Cycle Day they must be scanned.

Error Alerts:

Any errors or warnings are highlighted and logged as soon as they occur.

Electronic Witnessing:

Labels are scanned to identify patient samples and perform Witnessing functions. Samples can be identified down to embryo and gamete level.

Labeling:

Unique barcoded patient labels are generated and assigned to specific days within the patient's Cycle before any Procedures are performed. During Procedures, these labels are scanned whenever Witnessing is required.

Traceability and Reporting:

Gidget allows for viewing and exporting of Reports. Reports contain a full record of activities completed with the scanner, including all errors, warnings and incomplete sessions.

Consumables Tracking

Any consumable used as part of the sample processing can be recorded, linked to Patient Cycles and reported upon to assist laboratory management.

1.4. Included Items

The following items are supplied with Gidget:

- Gidget Scanner Pack. **[REF]** GIDG-SCAN-01, **[REF]** GIDG-SCAN-03
 - 1 x Gidget Handheld Scanner
 - 1 x Charging Dock
- Gidget Central Computer System. **[REF]** GIDG-CCS-01, **[REF]** GIDG-SCAN-04
 - 1 x CCS with Gidget Software
 - 1 x Power Supply
- 1 x Gidget User Manual

If required, additional Gidget Handheld Scanners and chargers are available. Contact your authorised local representative for further information. **[REF]** GIDG-SCAN-01.

NOTE: Scanner & Central Computer system order codes may vary slightly depending on your region.

1.5. Recommended Items

- Plastic cards with lanyards for printed User ID labels
- Wall-mounted flat screen monitor (requires either a PC-on-a-stick or a laptop/PC to be connected to the wall-mounted monitor)
- Google Chrome web browser

1.6. Symbols Used in Gidget

Icon	Description	Icon	Description
	Active Patient		Manual Witness
	Add		Manually Witnessed Label
	Reporting		Drop-down Menu
	Back		Multi-Part Label
	Cancel or clear		Next
	Cancel Witness Session		Patient List
	Confirm		Prepare Patient Cycle
	Cycle		Print Settings
	Date		License Purchase Request
	Delete		Save
	Edit		Thaw
	Export		Thaw Cycle
	History		Unlocked Patient
	Lab Process		Witness Session
	Critical Error		Critical

	Warning		Previous Cycle Exists
	Default Printer		Linked Procedure
	Reorder Procedure		Unlink Procedure
	Complete Day		Resume Day
	Complete Cycle		Next
	Current Procedure		Workflow Deviation
	Cancel Cycle		Complete Cycle
	Active Consumable Lot		Closed Consumable Lot

2. BASIC SETTINGS

Your authorised local service technician will install Gidget and work closely with you to configure the system to your individual laboratory's requirements.

Once installed and configured only users authorised as supervisors or administrators can access Gidget settings and management screens.

2.1. Settings

The Settings screen allows for the basic configuration of the Gidget WebApp.

To access Settings: select Settings from the drop-down menu located on the top right of the screen. The Settings screen is displayed.

To save changes: click  to save any changes. **NOTE:** the save icon will only appear if any changes are made on the Settings screen.

The following options can be made from the Settings screen:

Language:

The initial Gidget release is only available in English, including special characters and diacritic marks (additional languages may be available in future software updates).

Automatic Logout After:

This allows laboratory supervisors or administrators to set a specified time of inactivity before a user is automatically logged out (in five-minute intervals up to a maximum of sixty minutes).

Account Number:

The account number is supplied during installation and setup.

Site Name:

The site name is a user defined site description that will appear on Reports to identify individual laboratories or clinics. **NOTE:** Clinic names should not be longer than 20 characters.

Remaining License Warning at:

This allows laboratory supervisors or administrators to set the warning threshold for the remaining cycles available in a License.

License Requisition E-mail:

This allows laboratory supervisors or administrators to specify the address to which license purchase requests are sent.

Country Identifier:

This allows laboratory supervisors or administrators to specify a 2 character identifier that will appear as part of the Single European Code (SEC).

TE Code:

This allows laboratory supervisors or administrators to specify a 6 character TE Code that will appear as part of the Single European Code (SEC).

Label Variable 1:

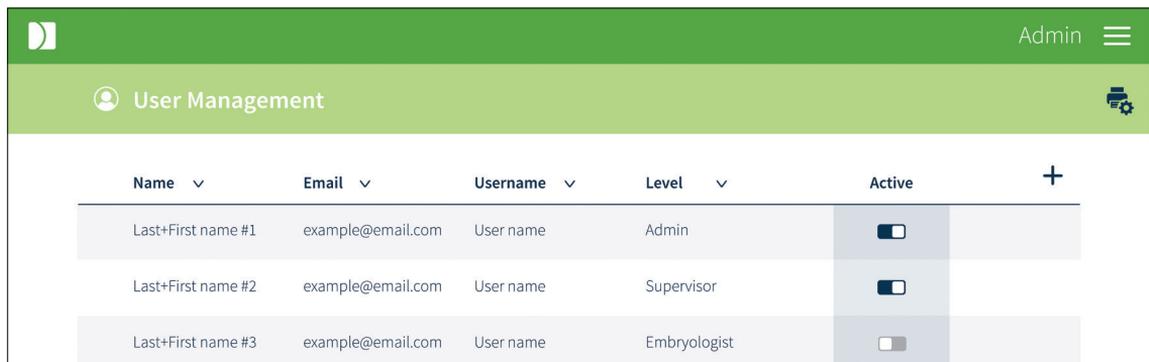
This allows laboratory supervisors or administrators to specify whether Variable 1 on the SEC label will appear as a Last Name, Patient # or remain blank. (NOTE: The default for the SEC label variable is <blank>).

2.2. Adding a User

Only supervisors or administrators can add individual users to Gidget. During this process, users are assigned a User Name, PIN and User ID that enables them to log on and use the Gidget WebApp and Scanner.

To add a user:

1. Click User Management from the drop-down menu located on the top right of the screen. The User Management screen is displayed.
2. Click **+** located on the top right of the screen. The User Settings screen is displayed.
3. Add the new user's name.
4. Add email address (optional).
5. Select User Level (Admin, Supervisor or Embryologist) from the Level drop-down menu.
6. Add desired User Name.
7. Add the user's desired four digit numerical PIN.
8. Confirm the PIN.
9. Click  to save any changes and add the user or  to cancel.
10. Repeat the above steps to add any additional users.



Name	Email	Username	Level	Active	
Last+First name #1	example@email.com	User name	Admin	<input checked="" type="checkbox"/>	
Last+First name #2	example@email.com	User name	Supervisor	<input checked="" type="checkbox"/>	
Last+First name #3	example@email.com	User name	Embryologist	<input type="checkbox"/>	

NOTE:

- A fourth user role, Dashboard, is included with the Gidget WebApp. Logging

in using Dashboard will display a non-interactive version of the Active Patients screen that can be used on a laboratory based wall-mounted monitor to maximise workflow visibility. This user will not log out after 24 hours. Contact your authorised service representative for further information on using this feature.

- Mandatory fields are marked with an asterisk.

2.3. Editing a User

To edit user information:

1. Click User Management from the drop-down menu located on the top right of the screen. The User Management screen is displayed.
2. Roll the cursor over the desired user row and click  when it appears. The User Settings screen is displayed.
3. Edit information as required.
4. Click  to save any changes or  to cancel.

2.4. Reactivating a User

If a user is locked out of Gidget their status will need to be reactivated, (for example, if they have entered their PIN incorrectly three times).

To reactivate a user:

1. Click User Management from the drop-down menu located on the top right of the screen. The User Management screen is displayed.
2. Locate the desired user.
3. Click the toggle in the Active column next to the appropriate user to  (Active).

2.5. Deactivating a User

1. Click User Management from the drop-down menu located on the top right of the screen. The User Management screen is displayed.
2. Locate the desired user.
3. Click the toggle in the Active column next to the appropriate user to  (Inactive).

2.6. Selecting a Printer

To select a printer:

1. Click User Management from the drop-down menu located on the top right of the screen. The User Management screen is displayed.
2. Click  located on the top right of the screen. The User Label Print Settings screen is displayed.
3. Select the desired printer from the Printer drop-down menu.
4. Click  to save any changes or  to cancel.

2.7. Printing a User ID

Each user must have a User ID to log in to the Gidget Handheld Scanner. It is recommended that this User ID is printed on to a label and then affixed to a plastic card or lanyard that users can carry with them in the laboratory.

NOTE: Ensure that an appropriate printer and printer stock are installed and/or available prior to printing.

To print a User ID label:

1. Click User Management from the drop-down menu located on the top right of the screen. The User Management screen is displayed.
2. Roll the cursor over the desired user row.
3. Click  when it appears to the right of the user row.
4. A popup window will appear confirming printing and the label will print.

2.8. Licenses

Gidget Licenses are required for every Cycle used on the Gidget system and are available for purchase in lots of 50, 100, 500 and 1000 cycles. A License Key is supplied with each License.

Gidget License 50 Cycles:  GIDG-LIC-50.

Gidget License 100 Cycles:  GIDG-LIC-100.

Gidget License 500 Cycles:  GIDG-LIC-500.

Gidget License 1000 Cycles:  GIDG-LIC-1000.

To add a License:

NOTE: A License Key is required to add a new License.

1. Click Licenses from the drop-down menu located on the top right of the screen. The Licenses screen is displayed.
2. Click  located on the top right of the screen. The Enter Purchased License screen is displayed.
3. Enter the supplied License Key.
4. Click  to save any changes or  to cancel.

The License will now appear in the License History window and the number of cycles remaining on the License will be displayed next to Cycles Remaining.

To request a new License:

1. Click Licenses from the drop-down menu located on the top right of the screen. The Licenses screen is displayed.
2. Click  located on the top right of the screen. A popup email window addressed

to your License Provider is displayed.

3. Add the License **REF** code for the required number of Cycles (See Licenses above).
4. Click send.

NOTE: The License requisition email address can be changed from the Settings drop-down menu (see [“2.1. Settings”](#) on page 6).

3. LAB PROCESS

Gidget can be customised to suit individual laboratory processes while keeping track of processes where Witnessing is required.

To access the Lab Process screen: click Lab Process from the drop-down menu located on the top right of the screen. The Lab Process screen is displayed.

NOTE: The three Lab Process steps shown on the Lab Process screen (1 Label Library, 2 Procedures, and 3 Cycle Types) must be performed in sequence and are grayed out until the prior steps have been completed.

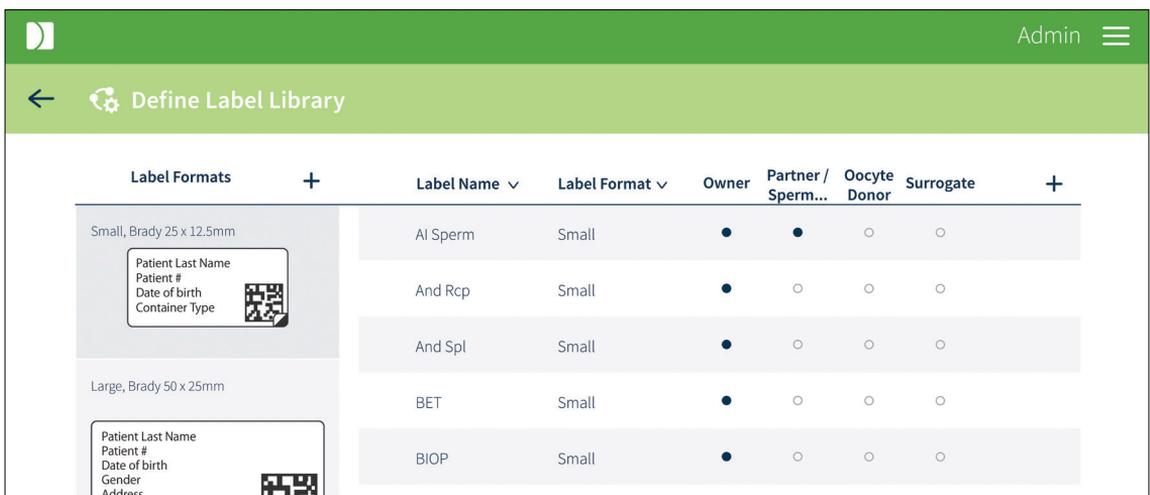
3.1. The Label Library

The Label Library is used to create and format labels for the containers and paperwork/files required for the electronic Witnessing of patient samples.

3.1.1. Formatting Labels

To format labels:

1. Click Lab Process from the drop-down menu located on the top right of the screen. The Lab Process screen is displayed.
2. Click 1 Label Library from the Lab Process screen. The Define Label Library screen is displayed.
3. Click **+** located at the top of the Label Formats column. The Define Label Format screen is displayed.
4. Create a descriptive name for the format (for example, small, medium or large).
5. Select the appropriate label stock from the Stock drop-down menu.
6. Select the desired printer from the Printer drop-down menu.
7. Specify the variables for every label that will use this label format in the laboratory.
8. Click  to save any changes or  to cancel.



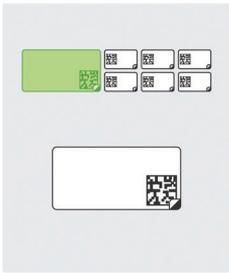
Label Formats	Label Name	Label Format	Owner	Partner / Sperm...	Oocyte Donor	Surrogate
Small, Brady 25 x 12.5mm Patient Last Name Patient # Date of birth Container Type	AI Sperm	Small	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
	And Rcp	Small	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	And Spl	Small	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Large, Brady 50 x 25mm Patient Last Name Patient # Date of birth Gender Address	BET	Small	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	BIOP	Small	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Once the label format is saved, the new label will appear under the Label Formats column on the Define Label Library screen.

NOTE:

- The available variables displayed will depend on the stock selected.
- It is recommended that one of the variables be called Container Type to make it easier to pair a printed label with the correct container type.
- A test print can be printed by clicking  from the top right of the Define Label Format screen.
- A printer does not have to be connected to create label formats.
- Only Wrap-around and Gavi 7-set labels can be designated as 'sample-level' as applied to embryos, gametes and biopsy tubes. Gavi 7-set small, (ie 'pod') labels are 'sample-level' but the large (ie, 'cassette') label behaves as patient cycle.

Example



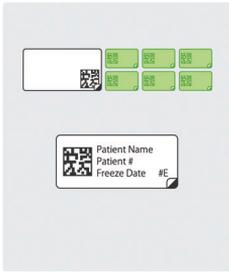
Variable 1

Variable 2

Variable 3

Variable 4

Example



Variable 1

Variable 2

Variable 3

Variable 4

3.1.2. Editing Label Formats

To edit label formats:

1. Click Lab Process from the drop-down menu located on the top right of the screen. The Lab Process screen is displayed.
2. Click 1 Label Library from the Lab Process screen. The Define Label Library screen is displayed.
3. Click the desired label from the Label Formats column. The Define Label Format screen for that label will be displayed.
4. Edit as desired.
5. Click  to save any changes or  to cancel.

3.1.3. Adding Labels

To add labels:

1. Click Lab Process from the drop-down menu located on the top right of the screen. The Lab Process screen is displayed.
2. Click 1 Label Library from the Lab Process screen. The Define Label Library screen is displayed.
3. Click  located on the top right of the screen. The Define Label screen is displayed.
4. Create a name for the container to which the label will be associated. This is used to populate the Container Type variable in the label format (for example, OPU).
5. Select the desired format from the Format drop-down menu (**NOTE:** ensure that the label size is appropriate for the desired container).
6. Check the Multi-Part Label checkbox if required (see below for further information).
7. Select the desired Patient Role Applicability (**NOTE:** at least one of these roles must be selected. See below for further information).
8. Repeat the above steps to add additional labels as required.
9. Click  to save any changes or  to cancel.

NOTE:

- The Multi-Part Label checkbox is used for containers that require two parts (for example, a lid and container). If the Multi-Part Label is checked, both labels will require consecutive scanning during a Witnessing Session. Once a label is saved as a Multi-Part Label, the checkbox cannot be changed.
- All labels **MUST** be linked to at least one Patient Role Applicability role when a new label is added.
- Patient Role Applicability ensures that the correct patient information is printed on the label. It also ensures that the correct number of labels is printed for the Patient Roles in the Cycle. For example, labels relating only to sperm samples would normally only apply to the Partner/Sperm Donor role. However, a Patient File label would also normally be required for every Patient Role in the Cycle.
- Labels cannot have the same name.
- Label barcodes cannot be used for tracking and identification on other Gidget systems, for example, for transferring a patient sample from one laboratory to another.
- Once a label has been added to the Label Library and printed it can only be edited, it cannot be deleted.

3.2. Procedures

A Procedure is the name given to each technique performed in the laboratory and would generally occur together in the timeframe of a Witnessing Session, such as an OPU or insemination. One or more labels are grouped together to make a Procedure and they are used to ensure that the correct labels are printed for the relevant Patient.

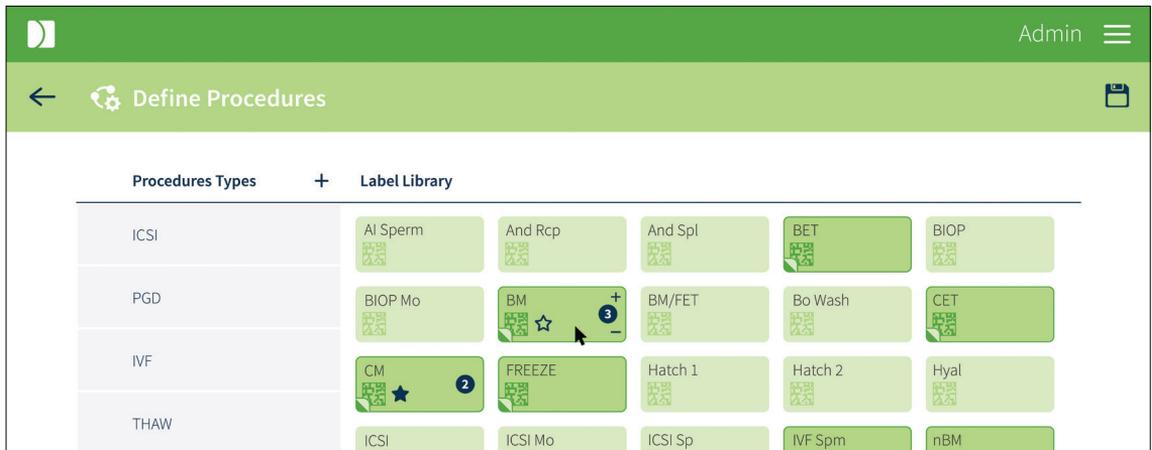
Procedures:

Procedures should contain labels that are appropriate for specific tasks performed in the laboratory (for example OPU or Insem).

3.2.1. Adding a Procedure

To add a Procedure:

1. Click Lab Process from the drop-down menu located on the top right of the screen. The Lab Process screen is displayed.
2. Click 2 Procedures from the Lab Process screen. The Define Procedures screen is displayed.



3. Click + located at the top of the Procedure Types column. The Define Procedure screen is displayed.
4. Create a descriptive name for the Procedure (it is recommended that the name relates to the type of Procedure you are creating, for example IVF or ICSI. **NOTE:** names are limited to 11 characters).
5. If required, select a previously created Procedure from the Copy From drop-down menu. This copies an existing Procedure that can then be assigned (for example, thaw 1 or thaw 2).
6. Click  to save any changes or ← to cancel.

3.2.2. Adding Labels to a Procedure

To add labels to a Procedure:

1. Click Lab Process from the drop-down menu located on the top right of the screen. The Lab Process screen is displayed.
2. Click 2 Procedures from the Lab Process screen. The Define Procedures screen is displayed.
3. Click the desired Procedure from the Procedure Types column.
4. Click the desired labels from the Label Library that are to be included in the

Procedure print group.

5. Click  to save any changes or  to cancel.

NOTE:

- To select the number of labels printed by default for a procedure, select the **+** or **-** at the right of the label icon. The number can be set to zero to avoid printing multiple copies of this label if it appears multiple times in the same or different procedures in a cycle. Eg, Geri dish label.
- To mark a label as critical for the selected Procedure, rollover the desired label and select . Critical labels are indicated by .
- **Critical Labels** are utilised within a Procedure to trigger Procedure completion in a given Cycle Day. During laboratory processes, once all critical labels for a Cycle Day have been scanned, the relevant Patient Card on the Active Patients screen will be displayed as complete (green with a tick). This allows full visibility of patient progress throughout the day. If a Procedure does not contain any critical labels then that Procedure will be marked as complete upon completion of any Witness Session by tapping  on the Handheld Scanner.

3.3. Cycle Types

Cycles:

When preparing Cycle information for a patient you will need to specify the appropriate Cycle that is to be undertaken (for example Thaw or IVF). The options you will have are defined by the Cycle Types that you create and should contain the Procedures that are common for that Cycle Type. Any labels that are not contained within a Procedure (such as a patient paperwork label) can also be assigned to a Cycle Type.

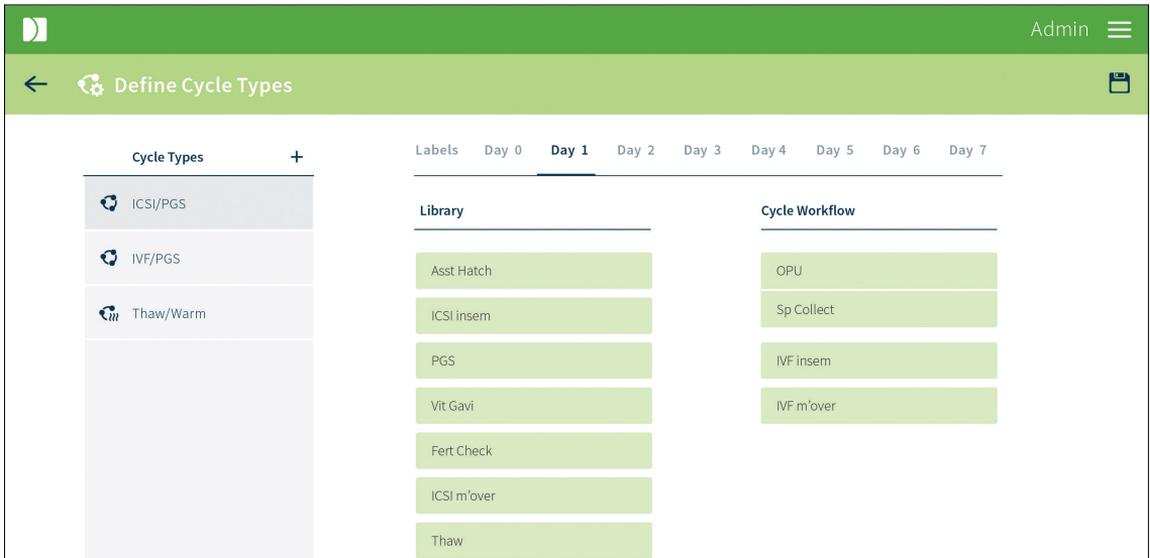
NOTE: When preparing Cycle information for a patient you have the option of including additional Procedure label sets outside those defined in the Cycle Type. The options you will have are defined by the Procedures created in Lab Process.

To add a Cycle Type:

1. Click Lab Process from the drop-down menu located on the top right of the screen. The Lab Process screen is displayed.
2. Click 3 Cycle Types from the Lab Process screen. The Define Cycle Types screen is displayed.
3. Click **+** located at the top of the Cycle Types column. The Define Cycle Type screen is displayed.
4. Create a descriptive name for the Cycle Type (it is recommended that the name relates to the type of Cycle Type you are creating, for example IVF or Thaw).
5. Check the **Involves Thaw Process** checkbox if the Cycle starts with the thawing of an embryo. Checking this box allows you to specify the correct thaw day when preparing Cycle information for a patient.
6. If required, select a previously created Cycle Type from the Copy From drop-down

menu. This copies an existing Cycle Type that can then be assigned to the new Cycle Type.

- Click  to save any changes or  to cancel.



NOTE:

- Once a Cycle Type has been added it can only be edited, it cannot be deleted.
- Once a Cycle Type is saved, the **'Involves Thaw Process'** checkbox cannot be changed.

3.3.1. Adding Procedures and Labels to a Cycle

To add Procedures to a Cycle:

- Click Lab Process from the drop-down menu located on the top right of the screen. The Lab Process screen is displayed.
- Click 3 Cycle Types from the Lab Process screen. The Define Cycle Types screen is displayed.
- Click the desired Cycle from the Cycle Types column.
- Select the desired day from the tabs.
- Click and hold to drag the desired Procedures from the Library into the Cycle Workflow column to include.
- Click  to save any changes or  to cancel.
- Repeat this process for each Day of the Cycle

To add Labels to a Cycle:

- To mark a label as critical for every Witness Session select the Labels tab. Rollover the desired label and select . Critical labels are indicated by .

NOTE:

- To link Procedures, drag and drop a Procedure onto another Procedure. The  icon will appear on hover. To unlink, hover over the centre line of the two linked Procedures and select . Linked Procedures can be scanned at the same times by different handhelds without triggering a deviation, (eg, OPU and sperm prep procedures).
- To add a Procedure between existing Procedures, drag a Procedure from the Library and hover over the desired position in the Cycle list. The  icon will appear to indicate where the Procedure will be positioned when dropped.
- A Cycle selected as **'Involves Thaw Process'** cannot have procedures set on any day prior to the Thaw Day
- To reorder Procedures, drag the Procedures from the Cycle Workflow into the desired order. A  will appear to indicate where the Procedures will be placed.
- Any label that has not been selected in any Procedure will be available in the Labels tab for selection as an *'every witness session'* label (eg, Paperwork labels).
- When an *'every witness session'* label is marked as critical, it will not appear in the list of critical labels for that procedure on the handheld.
- The star icon  is used to mark labels or Procedures as critical.
- **Critical Procedures** are used to trigger a deviation response from the user when they are skipped. When a Procedure other than the next expected Procedure in the Cycle Day is selected, a warning will appear to indicate the user is skipping a Procedure. If that Procedure is critical, a deviation response will be required to continue the Witness Session and must be typed into the Handheld Scanner. If the skipped Procedure is not marked as critical, the warning will still appear but there is no deviation response required by the user. In both instances the event is recorded in the Cycle History report.

4. CONSUMABLE TRACKING

Gidget can be customised to suit individual laboratory processes while keeping track of required consumables.

To access the Consumable Tracking screen: click Consumable Tracking from the drop-down menu located on the top right of the screen. The Consumable Tracking screen is displayed.

NOTE: Consumable expiry dates entered into Gidget should be used as a guide only and should not be used to determine product expiry. Please refer directly to the expiry dates provided by the product manufacturers on the product or product packaging.

4.1. Consumable Types (WebApp)

4.1.1. Adding a Consumable Type

To add a Consumable Type:

1. Click Consumable Tracking from the drop-down menu located on the top right of the screen. The Consumable Tracking screen is displayed.

2. Click  located at the top next to the Manufacturer column. The Define Consumable Type screen is displayed.
3. Create a descriptive name for the Consumable Type (it is recommended that the name relates to the type of Consumable Type you are creating, for example Fertilisation Medium).
4. Select either Media, Plasticware or Ancillary from the Category drop-down menu.
5. Enter in the Manufacturer name.
6. Enter in the Catalog Number.
7. Click  to save any changes or  to cancel.

NOTE: Catalog # is not mandatory

4.1.2. Deleting a Consumable Type

To delete a Consumable Type:

1. Click Consumable Tracking from the drop-down menu located on the top right of the screen. The Consumable Tracking screen is displayed.
2. Locate the desired Consumable Type.
3. Roll the cursor over the desired Consumable Type and click  when it appears.
4. The Consumable Tracking screen is displayed and the Consumable Type is no longer available.

NOTE: Only Consumable Types which do not have an associated Lot # can be deleted.

4.1.3. Editing a Consumable Type

To edit a Consumable Type:

1. Click Consumable Tracking from the drop-down menu located on the top right of the screen. The Consumable Tracking screen is displayed.
2. Locate the desired Consumable Type.
3. Roll the cursor over the desired Consumable Type and click  when it appears. The Define Consumable Type screen is displayed.
4. Edit as desired.
5. Click  to save any changes or  to cancel.



Name	Category	Manufacturer	Lot #	Expires	Status	Active/Close
 Fert Media	Media	Genea Biomedx	 3456	2018-11-15	Active	2018-11-19
Geri Dish	Plasticware	Genea Biomedx	988655	2018-12-07	Active	2018-11-08
 Oocyte retrieval buffer	Media	Genea Biomedx	654345	2021-01-07	In Storage	
			8755	2018-11-14	Closed	2018-11-19

NOTE: Only Consumable Types which do not have an associated Lot # can be edited.

4.2. Consumable Lots

4.2.1. Adding a Consumable Lot (WebApp)

To add a Consumable Lot:

1. Click Consumable Tracking from the drop-down menu located on the top right of the screen. The Consumable Tracking screen is displayed.
2. Click on the desired Consumable Type from the Consumable Type column on the left. (**NOTE:** Any existing Active or Closed Lots are shown in the Consumable Lot column on the right).
3. Click  located at the top next to the Active/Close column. The Define Consumable Lot screen is displayed.
4. Create a descriptive name for the Consumable Lot. (**NOTE:** The Consumable name cannot be changed once saved).
5. Enter in the Consumable Lot Number.
6. Select the Consumable Expiry date.
7. Click  to save any changes or  to cancel.

4.2.2. Adding A Consumable Lot (Handheld)

To add a consumable lot;

1. Login to handheld. Select Track consumables from the left hand menu.
2. Scan the barcode from the consumable to be added
3. Complete information for Lot# Consumable Type, Expiry Date and Status

4.3. Activating a Consumable Lot (WebApp)

To activate a Consumable Lot:

1. Click Consumable Tracking from the drop-down menu located on the top right of the screen. The Consumable Tracking screen is displayed.
2. Click on the desired Consumable Type from the Consumable Type column on the left.
3. Roll the cursor over the desired Consumable Lot and click  when it appears.
4. Click Okay to activate the Consumable Lot or Cancel to cancel any changes. (**NOTE:** The date will appear in the Active/Close column when the Consumable Lot is activated).

4.3.1. Activating a consumable lot (Handheld)

To activate a consumable lot:

1. Login to the handheld. Select Track consumables from the left-hand menu

2. Scan the consumable barcode.
3. Select the lot to activate.
4. Drag the slider to activate the lot and press the tick to complete



4.3.2. Closing a Consumable Lot (WebApp only)

To close a Consumable Lot:

1. Click Consumable Tracking from the drop-down menu located on the top right of the screen. The Consumable Tracking screen is displayed.
2. Click on the desired Consumable Type from the Consumable Type column on the left.
3. Roll the cursor over the desired Consumable Lot and click  when it appears.
4. Click Okay to close the Consumable Lot or Cancel to cancel any changes. (NOTE: The date will appear in the Active/Close column when the Consumable Lot is closed).

NOTE: Once closed, lots cannot be re-opened.

4.3.3. Editing a Consumable Lot (WebApp)

To edit a Consumable Lot:

1. Click Consumable Tracking from the drop-down menu located on the top right of the screen. The Consumable Tracking screen is displayed.
2. Click on the desired Consumable Type from the Consumable Type column on the left.
3. Roll the cursor over the desired Consumable Lot and click  when it appears. The Define Consumable Lot screen is displayed.
4. Edit as desired.
5. Click  to save any changes or  to cancel.

4.3.4. Editing a Consumable lot (Handheld)

To edit a consumable Lot:

1. Login to the handheld. Select Track Consumable from the left-hand menu:
2. Scan the consumable to edit
3. Select the consumable in the list
4. Make changes as required and press the Tick to complete

4.3.5. Linking a consumable to a Patient Cycle dish. (Handheld only)

Consumables can be directly linked by scanning to dishes from one or more patient cycles. To link a consumable to a patient cycle;

1. Login to the handheld. Select Track Consumables from the left-hand menu.
2. Scan the consumable to link.
3. Select the lot to link (activate if required).
4. Scan a label from the patient cycle to link. (**NOTE:** Multiple patient labels can be scanned if many patient dishes are being prepared at once).

NOTE: Linking consumables directly to patient dishes can be used when multiple lots of a consumable are open on the same day.

NOTE:

- A  symbol will be displayed when a Consumable Lot has expired.
- A  symbol will be displayed when a Consumable Lot is due to expire in 9 days or less.
- Only consumable lots which are not currently active can be edited.

5. BASIC OPERATION: WebApp

To access the Gidget WebApp:

1. Open the Google Chrome browser (Version 51 or later).
2. Type the IP address of the CCS into the browser's address bar and press enter (**NOTE:** the IP address is specified by the Lab manager or IT administrator in the pre-installation checklist).
3. The login page will be displayed.

5.1. Logging In

To log in: enter your User Name and PIN on the Gidget Login screen. The Active Patients screen is displayed.

NOTE:

- A User Name and PIN are required to log in to the WebApp.
- If the PIN is entered incorrectly three times the user will be locked out of Gidget. If this occurs, see your laboratory supervisor or administrator. (see [“2.4. Reactivating a User”](#) on page 8)

5.2. Active Patients Screen

The Active Patients screen is the main Gidget screen, providing a summary of all Owners/Patients that currently have an active Cycle along with information on their Cycle status.

The screenshot shows the 'Active Patients' screen with the following elements:

- 1:** Header area with 'Active Patients' and '52 Licenses Remaining'.
- 2:** Progress indicator for 'Day 2 of 6' (highlighted in red).
- 3:** Progress indicator for 'Day 2 of 6' (highlighted in red).
- 4:** Progress indicator for 'Day 7 of 3'.
- 5:** Table header 'Lastname, First'.
- 6:** Table header 'Lastname, First'.
- 7:** Table header 'Lastname, First'.

Incoming	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
1	2 of 3	2 of 4	2 of 6	1 of 3	2 of 6	4 of 5	1 of 3	
Lastname, First 123456789 WF, 12345678900-1								
Lastname, First 123456789 WF, 12345678900-1								
Lastname, First 123456789 WF, 12345678900-1								
Lastname, First 123456789 WF, 12345678900-1								
Lastname, First 123456789 WF, 12345678900-1								

① The Genea Logo

Clicking the Genea logo from any screen will return you directly to the Active Patients screen.

② Incoming

The Incoming column contains all patients that are scheduled to start Day 0 on the current working day and their appointment times. For an incoming patient, Day 0 will commence when their first Witness Session is completed. Their card will then move from the incoming column to the Day 0 column.

③ Critical Error

Critical errors are highlighted in red on both the Patient Card and the corresponding Progress Status Indicator. Critical errors must be resolved by a laboratory supervisor or administrator before any further Gidget processes can continue.

④ Progress Status Indicators

These indicators show how many cycles require additional Cycle Day tasks for the current working day.

⑤ Gray Patient Cards

A Gray Patient Card indicates that not all critical labels have been scanned for that patient's Cycle Day. The Active Patients screen provides an easy way to check that all necessary tasks have been completed for the current Cycle Day. At the end of the working day, all cards displayed should be green if all critical labels have been scanned. At 00:00 (midnight), Patient Cards automatically move to the next Cycle Day and will appear gray. Any cycles without Procedures planned for that Cycle Day will appear as completed (green with a tick).

⑥ Mismatch

▪ Patient Mismatch Error

A Patient Mismatch Error is a Critical Error that occurs if unlinked patient labels are scanned during the same Witness Session. The relevant Patient Card will be highlighted red and appear at the top of the list. The error must be resolved by a laboratory supervisor or administrator before further Gidget processes can continue.

▪ Sample Mismatch Error

A Sample Mismatch Error is a Critical Error that occurs when a label from a previous cycle is scanned and the label has not been linked to the active cycle. The relevant Patient Card will be highlighted red and will appear at the top of the list. The error must be resolved by a laboratory supervisor or administrator before further Gidget processes can continue.

⑦ Green Patient Cards

A green Patient Card indicates that all required tasks have been completed for that patient's Cycle Day.

NOTE: The Cycles Remaining Top Bar shows the remaining Cycles left in the current

License. When Patient Cycle information is saved, the number of Cycles remaining in your current License is reduced by one (1.0) or a half (0.5) depending on the value of the Cycle. If a Cycle is cancelled without Witnessing a session, the number of Cycles is refunded by one (1.0) or a half (0.5) depending on the value of the Cycle. This can be viewed on the Active Patients and Licenses screens.

5.3. Patient Cycle Information Preparation

Before commencing the clinical processes for a Patient Cycle you need to enter information about the Cycle. During this Cycle preparation you will be required to specify Patient Roles for the Cycle as well as specify any additional patients to be linked to the Cycle and their respective roles (for example, Partner, Sperm Donor, Oocyte Donor and Surrogate). You will also specify what Cycle and Procedures will be required to ensure that you print the correct labels.

NOTE:

- Patients are only linked for the duration of the Cycle.
- It is possible to select only a single role for donors without an allocated recipient.

5.3.1. Linking Patients in a Cycle

To link patients:

1. Click Active Patients from the drop-down menu located on the top right of the screen. The Active Patients screen is displayed.
2. Click the  located on the top right of the screen. Step 1 on the Prepare Cycle Information screen is displayed.
3. Enter the patient's name or patient number in the desired role search box and then select the desired patient from the autocomplete search field. The patient's details will be displayed. If the patient name or number does not appear in the autocomplete search box, click on Create New Patient and add patient details as required.
4. Review patient details to ensure they are correct.
5. Enter the name or patient number of the patient(s) to be linked to the Cycle Owner in the desired Patient Role field (Partner/Sperm Donor, Oocyte Donor, Surrogate).
6. Enter the name or patient number for any remaining linked Patient Roles.
7. Click  located on the top right of the screen. Step 2 on the Prepare Cycle Information screen is displayed.

NOTE: When Create New Patient is selected, the user can specify an Anonymous Donor provided there is an underlying patient entered into that role. The Anonymous Donor checkbox is not available for the Surrogate role.

5.3.2. Linking samples to a Cycle

Samples such as previously stored embryos or gametes can be linked to a cycle to enable them to be witnessed as part of that new cycle, eg for Thaw cycles.

To Link a sample:

1. In Prepare Cycle, Step 1, navigate to cycle linking table below patient information

5.3.4. Cycle Details

1. Enter the desired Cycle Number. (**NOTE:** The Cycle Number suffix will be pre-filled for any concurrent cycles that are created. This input field can be edited until first label scan).
2. Specify Cycle Type from the drop-down menu (**NOTE:** If the selected Cycle Type begins with a thaw process then an additional field will appear allowing the Thaw Day to be specified. If no Cycle Types are listed see your laboratory supervisor or administrator).
3. Specify Laboratory Start Date (year-month-day). **NOTE:** this refers to the date that the processes start **within the laboratory**.
4. Tap the Tab for each day to check the scheduled procedures for that Cycle. If an additional procedure is required for a particular day, select  to add it and select it from the dropdown menu. (**NOTE:** Added Procedures will be Critical by default and can be deleted up until the scan of the first label).
5. Specify the Procedure time (time displayed in 24-hour time). (**NOTE:** this field will not appear if the selected Cycle Type involves a thaw process).
6. Click  located on the top right of the screen. A Summary screen is displayed.
7. Ensure that all information is correct.
8. Click  to save any changes or  to return to any of the previous steps.
9. Click  to Print labels for the current Patient Cycle.

Once any changes have been saved, the Owner and all linked patients will be displayed on the Active Patients screen with their Stage displayed as Scheduled. On the date the patient's Cycle will begin, their Stage will be displayed as Incoming.

NOTE: Once the patient Cycle Information is saved, the quantity of Licenses is reduced by one (1.0) or a half (0.5) depending on the value of the Cycle. If a Cycle is cancelled without Witnessing a session, the quantity of Licenses is refunded by one (1.0) or a half (0.5) depending on the value of the Cycle (see Cancelling a Cycle).

5.4. Printing Labels for a Prepared Cycle

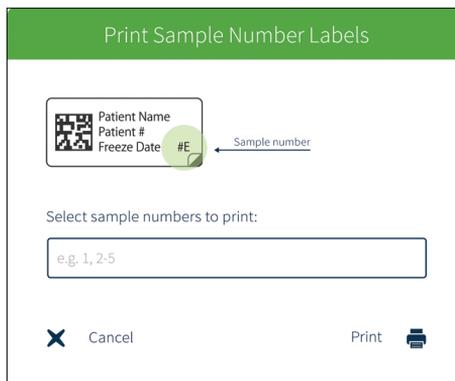
To print labels:

1. Click Patient List from the drop-down menu located on the top right of the screen. The Patient List screen is displayed.
2. Rollover the desired patient name and click  when it appears. The Print Labels screen is displayed showing all the labels that are associated with the specified Cycle, grouped in Procedures and by day.
3. Select whether to print all or one type of label stock using the drop-down menu.
4. Select the desired printer/s to print from using the drop-down menus.
5. Click on the desired labels to highlight and select, or check Select All. (**NOTE:** To select the required number of each label (for multiple labels), rollover the desired label and use  and  to select the desired number. The number will only appear on the label if it is greater than one. A label is still associated with the Procedure

when the number of labels to print is set to 0).

- Click  located on the top right of the screen.

NOTE: If any 'sample-level' labels are being printed, a Dialog box will appear requesting the user to select the item number of the labels. For example, if labels for embryos 1, 2, 3, 4, 9 & 12 are being printed the user would type 1-4, 9, 12. The maximum sample number is 99.



- Affix the labels to the appropriate containers and paperwork/files.

NOTE:

- Container labels appearing across multiple Procedures (for example, Geri dish) will have multiple copies by default. Deselect copies in Lab Process/Procedures as required. Criticality designation will remain on labels selected as zero copies.
- Wrap-around will print with a 1D barcode and are unique across all Gidget databases.
- The  icon indicates a default printer.

5.5. Completing Cycles

When all the relevant Witness Sessions for a Patient Cycle have been completed the Cycle must be logged as complete.

To log a Patient Cycle as complete:

- Click on the desired Patient Card from the Active Patients screen. The Review Patient screen is displayed showing the details for the selected patient.
- Tab through to review the Patient Details, Cycle Details, Linked Cycles and Linked Patients and ensure that all relevant Witness Sessions have been completed for the patient's Cycle.
- Click  located on the top right of the screen to log the Cycle as complete.
- Click Okay to confirm or Cancel to cancel any changes (**NOTE:** once the Cycle has been logged as complete it cannot be undone).

Once a Patient Cycle has been logged as complete that Cycle will no longer appear on the Active Patients screen and all patients linked to that Cycle will be unlinked. On the Patient

List screen their Stage will be displayed as None.

5.6. The Patient List Screen

To access the Patient List screen: Click Patient List from the drop-down menu located on the top right of the screen. The Patient List screen is displayed.

Licenses Remaining: shows the remaining licenses left. When Patient Cycle information is saved, the number of licenses remaining is reduced by one (1.0) or a half (0.5) depending on the value of the Cycle. If a Cycle is cancelled without Witnessing a session, the number of licenses is increased by one (1.0) or a half (0.5) depending on the value of the Cycle. This can be viewed on the Active Patients and Licenses screens.

Stage: indicates the Cycle status for each patient (**NOTE:** this applies to all linked patients in a Cycle).

- **None:** indicates that the patient has no prepared Cycle Information or Active Cycle and is not linked to any other patients.
- **Scheduled:** indicates that the patient has Cycle Information prepared and a Scheduled start date for the commencement of their laboratory processes.
- **Incoming:** indicates that the patient's laboratory processes are scheduled to start on the current workday.
- **Day 0-7:** shows the current Cycle Day for all Active Patients.

NOTE: A search filter is available to quickly find patients by first or last name or by patient number.

5.6.1. Editing or Reviewing Patient Cycle Information

CAUTION: Labels will require reprinting if patient details are changed, and may require reprinting if a Procedure is added to a Cycle. Ensure that labels affected by changes for an active cycle that have already been printed are replaced with newly printed labels once changes have been made.

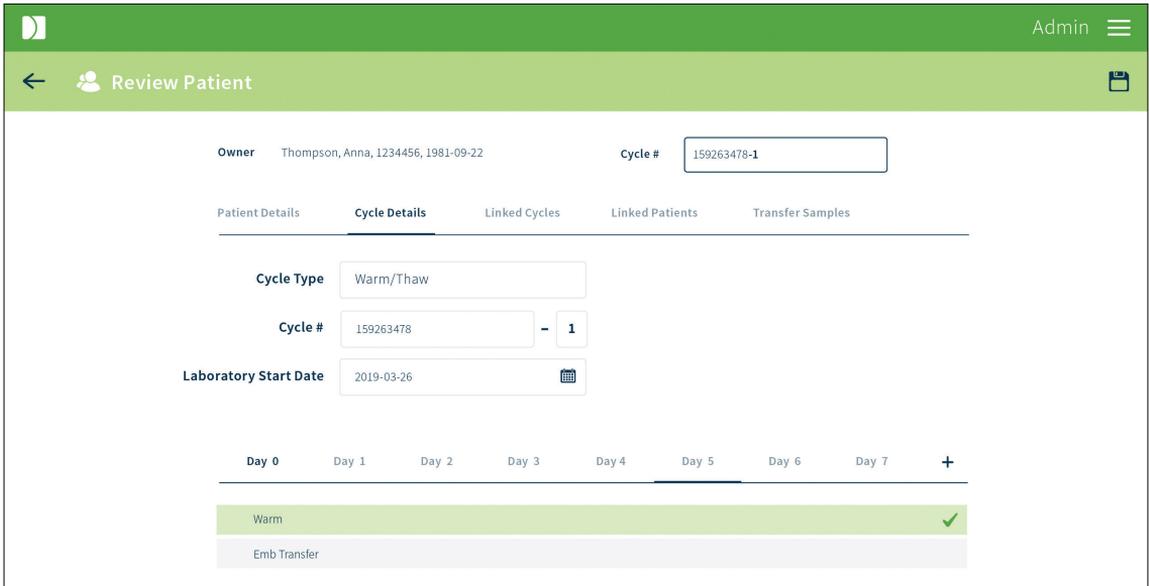
NOTE:

- Cycle Information can only be edited if the Patient Cycle is not active.
- If a Patient Cycle is already active, additional Procedures can be added or deleted.
- If any further information requires updating for an Active Cycle the Cycle will need to be canceled.
- Patient information for Active Cycles can also be reviewed directly from the Active Patients screen by clicking on the relevant Patient Card. Additional samples (eg, embryos or gametes) can also be linked to an active cycle

To edit or review Cycle information:

1. Click Patient List from the drop-down menu located on the top right of the screen. The Patient List screen is displayed.
2. Rollover the desired patient name to highlight and click  when it appears. The Review Patient screen is displayed.

3. Update information as required.
4. Click  to save any changes or  to cancel.



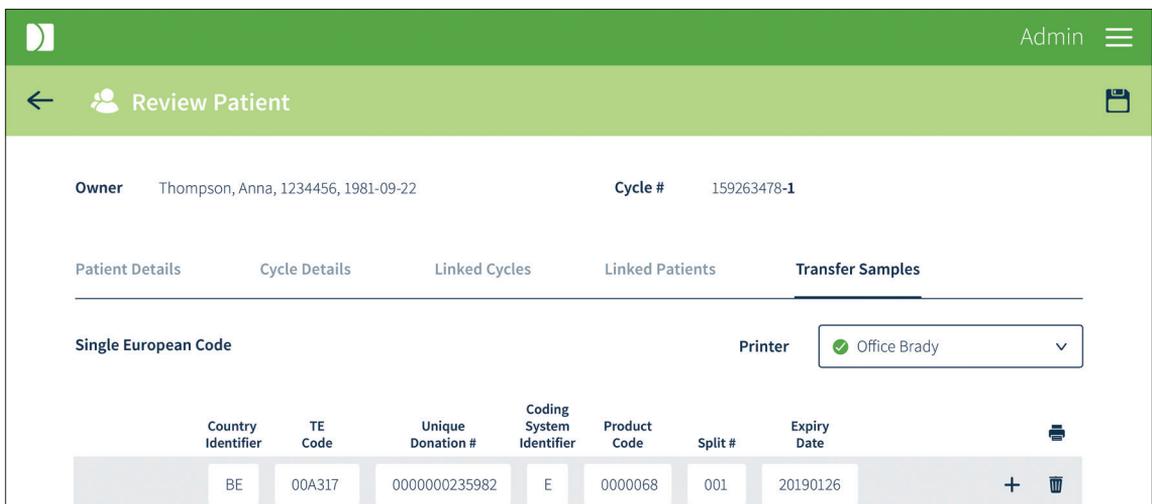
The screenshot shows the 'Review Patient' interface. At the top, there is a navigation bar with a back arrow, a user icon, and the text 'Review Patient'. Below this, the 'Owner' is listed as 'Thompson, Anna, 1234456, 1981-09-22' and the 'Cycle #' is '159263478-1'. A tabbed interface is visible with 'Cycle Details' selected. Under 'Cycle Details', there are input fields for 'Cycle Type' (set to 'Warm/Thaw'), 'Cycle #' (set to '159263478 - 1'), and 'Laboratory Start Date' (set to '2019-03-26'). Below these fields is a timeline from 'Day 0' to 'Day 7'. Under 'Day 0', there are two options: 'Warm' (highlighted in green with a checkmark) and 'Emb Transfer'.

NOTE: Type a patient name or patient ID number in the search box at the top of Patient List screen to quickly find the relevant patient.

5.6.2. Sample Transport using Single European Code (SEC) settings

Gidget enables the printing of labels that comply with the SEC labelling requirements. To print SEC labels;

1. Click Patient List from the drop-down menu located on the top right of the screen. The patient list is displayed.
2. Locate the desired patient and click  to enter Review Patient



The screenshot shows the 'Review Patient' interface with the 'Transfer Samples' tab selected. The 'Owner' and 'Cycle #' information is the same as in the previous screenshot. Below the tabs, there is a 'Single European Code' section and a 'Printer' dropdown menu set to 'Office Brady'. At the bottom, there is a table with the following data:

Country Identifier	TE Code	Unique Donation #	Coding System Identifier	Product Code	Split #	Expiry Date	
BE	00A317	0000000235982	E	0000068	001	20190126	  

3. Select the Transport Samples tab. (**NOTE:** If this tab is not present go to Settings

and complete fields under Single European Code).

4. Complete print fields according to SEC requirements
5. Select Printer from the dropdown list and click (print icon) to print.

NOTE:

- Labels will always print in duplicate for device and transport paperwork.
- SEC labels are only printed on Wrap-around label format.

5.7. Cancelling Cycles

If required, any prepared Cycle that is not already active can be cancelled.

To cancel a Cycle:

1. Click Patient List from the drop-down menu located on the top right of the screen. The Patient List screen is displayed.
2. Locate the desired patient.
3. Roll the cursor over the desired patient and click  when it appears. The Review Patient screen is displayed.
4. Click  located on the top right of the screen to cancel the Cycle.
5. Click okay to confirm or cancel to cancel any changes.

NOTE:

- Active Cycles cannot be cancelled. They must be set to complete to remove them from the Active Patients screen.
- Any labels that have been printed for a canceled Cycle must be discarded.
- Any saved cycle cancelled prior to start will still 'consume' the cycle number. However, that cycle number can be re-used with a different Cycle suffix.

5.8. My User Settings

Individual users are able to update or edit their Name, PIN and email address.

To edit My User Settings:

1. Click My User Settings from the drop-down menu located on the top right of the screen. The My User Settings screen is displayed.
2. Edit the desired information.
3. Click  to save any changes or  to cancel.

5.9. Reporting

Reporting allows for the export of Reports. Reports contain a full record of activities completed with the Gidget Handheld Scanner, including all errors, warnings and incomplete sessions.

5.9.1. Viewing or Exporting a Report

To export a Report:

1. Click Reporting from the drop-down menu located on the top right of the screen. The Reporting screen is displayed.
2. Select either Witness Session, Cycle History or Consumable from the Report Type drop-down menu.

The screenshot shows the 'Reporting' interface. At the top, there's a green navigation bar with 'Admin' and a menu icon. Below it, a light green bar contains a checkmark icon and the word 'Reporting', along with a search icon. The main area is titled 'Reporting' and is divided into two sections: 'Report type' and 'Filters'. Under 'Report type', there's a dropdown menu currently showing 'Cycle history', with 'Witness session' and 'Consumable' as other options. The 'Filters' section contains several input fields: 'Patient' (set to 'All'), 'Start Date' (2019-01-17), 'End Date' (2019-03-26), and 'Anonymous' (set to 'Hide anonymous patients'). There is also a checkbox labeled 'Only show workflow deviations' which is currently unchecked.

3. If desired, specify filters for the Report:
 - Select the desired Start Date and End Date range (the maximum selectable range is three months and the system will default to a three-month period prior to the current date. Create multiple reports for longer time periods)
 - Enter the desired patient's name or number in the Patient box
 - Select the desired User name from the User name drop-down menu
 - Select the desired Anonymous state from the Anonymous drop-down menu

NOTE: The primary patient information is always shown in the report. The other patients can be anonymised based on: 1. *Show anonymous patients:* The underlying patient is shown in all relevant fields of the report. 2. *Hide Anonymous patients:* Anonymous patients' names will be masked using the Cycle Owner name however the patient number of the Anonymous patient will be retained. 3. *Hide non-primary patients:* Non-primary patients will be masked by the name of the primary patient (Owner and Single role donors) displaying only the patient number. This feature can be used to mask patients who have not been anonymised during cycle preparation but where the lab later requires anonymisation in the report.

 - Select desired filters from the Filter checkboxes
4. Click  located on the top right of the screen. The Search Results screen is displayed

NOTE:

- In a Witness Session Report each line on the search results page represents one Witness Session. Clicking on any line will display the individual scans for that Witness Session.
 - In a Cycle History Report each line represents an event (for example, skipped, added or missed Procedures).
5. Click  located on the top right of the screen to export the Report or  to return to the Reporting screen. (**NOTE:** Witness Session and Cycle History Reports are exported as a PDF. Consumable Reports can be exported as a CSV or PDF. To export a Consumable Report as a CSV or PDF select the desired file type from the menu that is displayed when the export button is clicked).

Reports automatically saved to the location specified on your laboratory web browser. If required, consult your browser user guide or see your laboratory supervisor or administrator.

6. BASIC SCANNER OPERATION

6.1. About

The Gidget Handheld Scanner consists of either: an Apple iPod touch® and a Linea Pro 5® scanning cradle, or, an Apple iPhone SE® and a Linea Pro 7® scanning cradle.

The scanner is used to scan labels during Cycle Day Witness Sessions.

NOTE:

- The scanner will automatically log you out after 120 seconds of inactivity and you will be required to log back in.
- Once a Witness Session has been started the scanner will log you out after 60 seconds of inactivity.
- It is recommended that the iPod or iPhone's Auto-Lock feature is disabled (go to Settings > Display & Brightness > Auto-Lock, and select Never).



6.1.1. Storage

Ensure that the scanner is always stored in the supplied Gidget Charging Docks.

Ensure that you have the correct charging dock for your scanner model. The Linea Pro 5 or Linea Pro 7 scanner charging docks are not cross compatible.

Contact your authorised local representative for further information.

6.1.2. Cleaning & Maintenance

Care should be taken to avoid touching or scratching the scanner window as this may impair the scanner's performance. If required, the scanner window may be cleaned using a lens tissue or cloth and a lens cleaner.

For disinfection of the screen and scanner, a 70% solution of Isopropyl Alcohol may be applied by moistening a non-abrasive tissue or cloth and carefully wiping the affected areas. Care should be taken to use a damp cloth only and not wet the screen with droplets.

For additional cleaning and maintenance information please refer to the relevant manufacturer's documentation provided during installation of the Gidget system.

Charge status is indicated by the charge bar in the top right of the iPod screen. Charge status is indicated by the charge bar in the top right of the iPod or iPhone screen. A charged Handheld unit will ordinarily last 10 hours with normal laboratory usage. Please follow the manufacturers instructions for battery maintenance information.

NOTE: Use of products containing Volatile Organic Compounds (VOCs) should be used in compliance with the laboratories standard operating procedures.

6.2. Logging in

To log in to the Gidget Handheld Scanner you will require your User ID or User Name, and PIN.

To log in:

1. Remove the scanner from the charging dock.
2. Press the iPod/iPhone SE home button to power up the Scanner. Avoid using the scanner Power Button as this may affect communication to the Gidget CCS.
3. Slide or Swipe to Unlock. The iPod/iPhone home screen is displayed.
4. Tap . The Login screen is displayed.
5. Scan your User ID barcode or enter your User Name and tap Go.
6. Enter your PIN.

You are now logged in and the scanner's Active Patients screen is displayed.

NOTE: If this is the first login to the device, a service engineer will be required to enter a configuration key and IP address.

6.3. Witness Sessions

A Witness Session is used in situations that would ordinarily require a second person to double witness a task. A Witness Session is performed by scanning all the labels associated with that task. Gidget will actively check any workflow rules that your laboratory has assigned and verify that all labels scanned match the patient or linked patients within a Cycle.

6.3.1. Performing a Witness Session

NOTE:

- During a Witness Session, the scanner will automatically log you out after 60 seconds of inactivity.
- It is highly recommended that the Witness Session is performed prior to beginning any tasks.
- Prepare and collect all relevant materials required to complete the relevant Cycle tasks, such as containers and patient files.
- Ensure that all the labels are affixed to all the relevant containers and files that are to be witnessed.

- If you are unable to scan a label barcode, the label can be manually witnessed (see Manually Witnessing Labels below).
- When scanning clear labels through media, avoid placing droplets directly above the barcode as this may impede scanning.
- Clear labels will scan correctly from both directions.
- There is no limit to the number of times you can perform a Witness Session.

To perform a Witness Session:

1. Scan any of the patient label barcodes. The Witness Session is initiated and a list of Procedures containing that label are displayed with the next logical Procedure highlighted blue. The patient details will be displayed along with the information relating to the label barcode that was scanned (for example, container type or file). If there is only one procedure to perform that day, it will be automatically selected.
2. Continue scanning all labels associated with the Witnessing Session.
3. When all labels have been scanned, Tap  to log the Witness Session. The Active Patients screen is displayed.

NOTE:

- A Witness Session can be started by scanning a Patient label from the Active Patients screen, Witness Session screen, and the Patient History screen.
- 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.
- A workflow deviation that skips an incomplete critical Procedure requires confirmation and a text response by the user providing a reason for the deviation.

6.3.2. Witnessing 'Sample-level' labels

NOTE: Sample-level labels (Wrap-around labels and Gavi 7-set labels) are witnessed the same way as patient cycle-level labels. These labels will not trigger a sample-level mismatch unless specifically linked to a cycle, such as during a FET. Witness scans performed on different sample level labels during biopsy procedures (eg, post-biopsy dish and tissue transfer tube for the wrong embryo) will be recorded on the handheld and in the Witness Report but will not trigger a mis-match.

Sample-number (ie, Embryo number) for Sample-level labels is recorded on the handheld at time of scanning and also in the Witness Report.

6.3.3. Manually Witnessing Labels

If for any reason a barcode label cannot be scanned during a Witness Session, a Manual Witness can be performed of that label to ensure that it is logged as part of the Witness Session.

NOTE:

- A second person (witness) with a User ID is required to perform a Manual Witness.

- To perform a Manual Witness, a Witness Session must have already begun.
- During a Manual Witness, the scanner will automatically log you out after 120 seconds of inactivity.

To perform a Manual Witness:

1. Tap . The Manual Witness screen is displayed.
2. Enter the Patient ID for the label you are manually Witnessing.
3. Specify the Container Type in the drop-down menu. (**NOTE:** If a Procedure containing a Wrap-around or Gavi 7-set label is selected, then a sample number is required.)
4. Have the witness verify that the information entered on the screen matches the label.
5. The witness must scan or enter his or her User ID.
6. Scan second user ID following selection of container type. Do not select "Scan User ID" field'

The label will be logged as part of the Witness Session and will appear on the Witness Session screen as having been manually witnessed. The User ID of the second witness will also be recorded

6.4. Reviewing Patient Information

6.4.1. Reviewing Lab Progress Information

To review lab progress information:

1. Select the desired Cycle Day from the Active Patients screen. The Cycle Day screen is displayed showing all the patients currently on that day of the Cycle and their status.
2. Tap any of the patient entries to display information relating to that patient, including Day Progress for Procedures relevant to that day and the Witness Sessions for that patient ordered by Procedure.
3. Tap  to return to the Cycle Day screen.

6.4.2. Reviewing Individual Patient Information

To review patient information:

1. Tap Patient History from the drop-down menu located on the top left of the Active Patients screen. The Patient History screen is displayed.
2. Scan any patient label barcode. The Patient information is displayed showing information relating to that patient, including Day Progress for Procedures relevant to that day and the Witness Sessions for that patient ordered by Procedure.

6.4.3. Handheld audio

Gidget provides audio cues during scanning to minimise the need to view the handheld screen

-  High beep
-  High-low beep
-  Low beep
-  Short high beep
-  No sound



High-low beep indicates to the user that there is an action required on the touchscreen. Usually this relates to selecting the next procedure



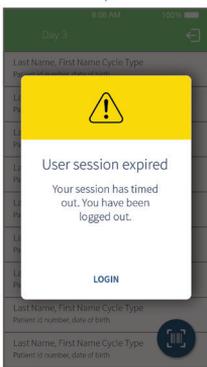
High beep indicates normal witnessing behaviour.



Tap confirm

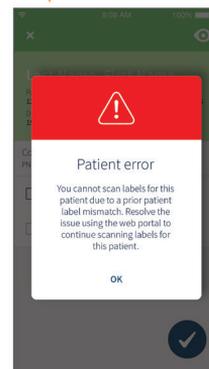
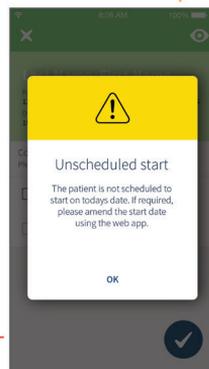


Timing out of a witness session sounds a **short high beep**.



Warning

Error

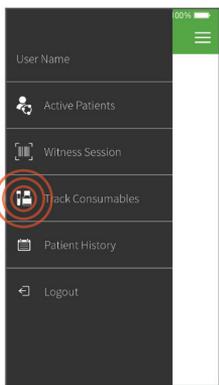


Ignoring a **high-low beep** and continuing to scan will trigger a **low error beep**. this will continue to sound until the message on the touchscreen has been attended to.
NOTE: Audio for errors such as patient mis-match are the same as warnings.

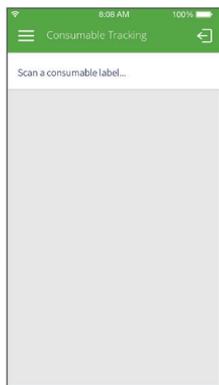
Consumable tracking audio cues



Tap Menu

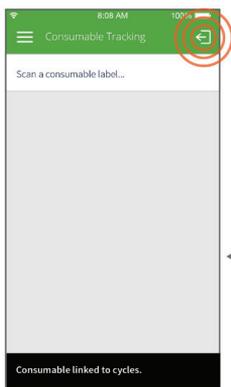


Tap Track Consumables



Scan a consumable label

Audio cues for Consumables Tracking are similar to witnessing whereby double high-low beeps indicates to the user that there is an action required on the touchscreen



Logout



Complete information and tap confirm



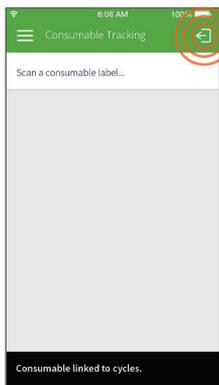
Tap + to add a consumable lot



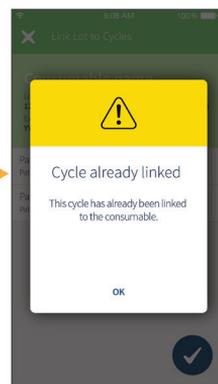
User scans one or more valid patient labels to link to consumable lot



Tap confirm



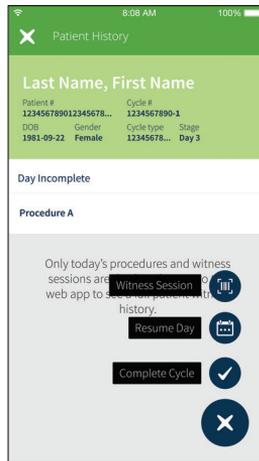
Logout



Warning

6.5. Manual Control of Cycle Day Status

Gidget tracks all scanned labels and automatically updates patient status based on user assigned workflow rules.



NOTE:

- Workflow rules determine what tasks require Witnessing for each Cycle Day to be logged as complete. Once these tasks have been witnessed Gidget automatically logs the Cycle Day as complete with no further input required from the user. However, Gidget also allows full manual control of the Cycle Day Status if required.
- Cycle Day status changes can be undone if required.

To manually change Cycle Day status:

- Tap Patient History from the drop-down menu located on the top left of the Active Patients screen. The Patient History screen is displayed.
- Scan any patient label barcode. Patient information is displayed showing information relating to that patient, including the Witness Sessions for that patient ordered by Procedure.
- Tap  located on the bottom right of the screen and select either  (Complete Day) or  (Resume Day).

6.6. Cycle Completion

CAUTION: Once a Cycle has been logged as complete it cannot be undone.

To complete a Patient Cycle on the scanner:

- Tap Patient History from the drop-down menu located on the top left of the Active Patients screen. The Patient History screen is displayed.
- Scan any patient label barcode. Patient information is displayed showing information relating to that patient, including the Witness Sessions for that patient ordered by Procedure.
- Tap  located on the bottom right of the screen and select .

7. ERROR ALERTS

7.1. Patient Mismatch Error

A Patient Mismatch Error will occur if unlinked patient labels are scanned during the same Witness Session. A patient mis-match will also occur between labels of the same patient printed from two different cycles. Care should be taken when performing concurrent active cycles from the same patient where the same container types are in use at the same time.

On the Active Patients screen, on both the scanner and WebApp, the relevant Patient Card will be highlighted red and appear at the top of the list. The error must be resolved before any further Witness Sessions can be performed for that patient.

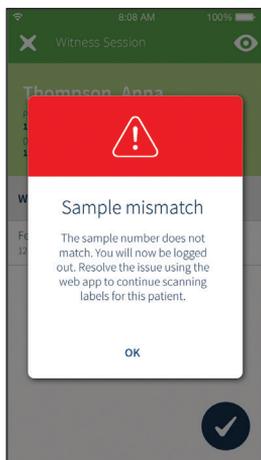
NOTE: Only a laboratory administrator or supervisor can resolve a Patient Mismatch Error. If this error occurs see your laboratory supervisor or administrator.

To resolve a Patient Mismatch Error:

1. Click on the affected red Patient Card. The Review Patient screen is displayed.
2. In the text box enter details relating to the circumstances of the error (**NOTE:** this explanation will be logged and visible in the Reports).
3. Click  to allow further Witness Sessions for that patient.

7.2. Sample Mismatch Error

Sample Mismatch Error occurs when a label from a previous cycle is scanned and the label has not been linked to the active cycle. On the Active Patients screen, on both the scanner and WebApp, the relevant Patient Card will be highlighted red and appear at the top of the list. The error must be resolved before any further Witness Sessions can be performed for that patient. A list of valid linked samples that can be scanned can be viewed via the Gidget WebApp in the Linked Cycles tab of the Review Patient section.



NOTE: Only a laboratory administrator or supervisor can resolve a Sample Mismatch Error. If this error occurs see your laboratory supervisor or administrator.

To resolve a Sample Mismatch Error:

1. Click on the affected red Patient Card. The Review Patient screen is displayed.
2. In the text box enter details relating to the circumstances of the error (NOTE: this explanation will be logged and visible in Reports).
3. Click  to allow further Witness Sessions for that patient.

7.3. Remaining Licenses Warning

A Remaining Licenses Warning occurs when a user specified minimum number of Licenses remaining is reached. A popup window will prompt the user to purchase a new License. If this warning occurs, alert your laboratory supervisor or manager.

Licenses Remaining shows the remaining Licenses left. When Patient Cycle information is saved, the number of Licenses currently remaining is reduced by one (1.0) or a half (0.5) depending on the value of the Cycle. If you cancel a Cycle, the number of Licenses is refunded by one (1.0) or a half (0.5) depending on the value of the Cycle. This can be viewed on the Active Patients and Licenses screens.

8. GLOSSARY

Active Cycle:

Refers to any Patient Cycle that is currently undergoing laboratory processes – taken from the first completed Witness Session through to the Cycle being logged as complete. Cycle Days are tracked from Day 0 to Day 7.

Active Patients screen:

The Active Patients screen provides a summary of all patients that currently have an active Cycle in progress, organised by Cycle Days. The screen also shows patients who are scheduled to start their laboratory processes on the current working day.

Concurrent Cycles:

Concurrent cycles are two or more cycles that are active or scheduled at the same time for a single patient in any role.

Critical Labels:

Critical Labels are utilised within a Procedure to trigger Procedure completion in a given Cycle Day. During laboratory processes, once all critical labels for a Cycle Day have been scanned, the relevant Patient Card on the Active Patients screen will be displayed as complete (green with a tick). This allows full visibility of patient progress throughout the day. If the Procedure does not contain any critical labels then the Procedure will be marked as complete upon completion of the Witness Session by tapping  on the Handheld Scanner.

Critical Procedures:

Critical Procedures are used to trigger a deviation response from the user when they are skipped. When a Procedure other than the next expected Procedure in the Cycle Day is selected, a warning will appear to indicate the user is skipping a Procedure. If that Procedure is critical, a deviation response will be required to continue the Witness Session and must be typed into the Handheld Scanner. If the skipped Procedure is not marked as critical, the warning will still appear but there is no deviation response required by the user. In both instances the event is recorded in the Cycle History report.

Cycle:

The Cycle refers to the specific time during which a patient process begins (either with an oocyte pick up or the thaw of an embryo) and ends (either when the embryo is transferred to a patient or when an embryo is frozen).

Cycle Type:

Cycle Types are used to identify the Procedures and labels required for standard Cycle Types.

Cycle suffix:

Cycle suffix is a single character field which appears after Cycle number and is separated by a hyphen in the Gidget laboratory cycle. It is used to distinguish concurrent cycles for the same patient from each where the same Cycle number is used. Where the Cycle number is communicated to external databases such as EMRs, only the base Cycle number is transmitted. Cycle suffix can be set to any alpha-numeric character prior to the start of the cycle.

Gidget WebApp:

The Gidget WebApp is a proprietary web-based software package that is used for creating, managing and Witnessing patient samples and workflow processes in an embryology laboratory.

Incoming:

A patient is designated as Incoming if their laboratory process is scheduled to start Day 0 of the current workday.

Lab Process:

This refers to a software function that allows you to configure Gidget to match your individual labs processes and workflow.

Label Formats:

Label Formats are templates with customisable content that can be assigned to one or more labels.

Label Library:

The Label Library is a complete set of container and paperwork labels that require Witnessing for ALL Cycles and Procedures performed in the embryology laboratory.

Labels:

Labels are the self-adhesive tags that contain user or patient information with a data-matrix barcode that can be scanned and tracked throughout the laboratory process.

License:

Gidget Licenses are required for every Cycle used on the Gidget system and are available for purchase in lots of 50, 100 and 1000 cycles. A License Key is supplied with each License.

Linked Patients:

Linked Patients are additional patients that a user links to the Owner during a Cycle. Patients remain linked until the Cycle is set to complete or is cancelled.

Multi-Part Label:

This refers to labels that will be used for containers that have two parts (for example, a lid and container). Multi-Part Labels require both labels to be scanned consecutively during a Witness Session.

Oocyte Donor:

This Patient Role is used if an Oocyte Donor is associated with the Cycle.

Owner:

The Owner is the designated primary Patient Role in the Cycle. The Owner is usually the mother or, where Cycles involve a Surrogate, the recipient of the baby after birth.

Partner/Sperm Donor:

This is a Patient Role that must be specified in a Cycle for either the Partner or the Sperm Donor.

Patient Card

The Patient Card is displayed on the Active Patients screen and provides a summary of

information relating to patients with an Active Cycle. A gray Patient Card indicates that not all critical labels have been scanned for that patient's Cycle Day. A green Patient Card indicates that all specified tasks have been completed for that patient's Cycle Day. A red Patient Card indicates that a critical error has occurred that must be resolved.

Patient Mismatch Error:

A Patient Mismatch Error is a critical alert that occurs if two unlinked patient labels are scanned within the same Witness Session.

Patient Role Applicability:

Patient Role Applicability is used to assign label types to Patient Roles to ensure that the correct patient information is printed on the label. It also ensures that the correct number of labels are printed for the number of Patient Roles in the Cycle.

Patient Role:

This is used to designate the distinct function of a patient within a Cycle, for example Owner, Partner/Sperm Donor, Oocyte Donor or Surrogate.

Primary Patient:

A Primary patient is the term used to collectively describe both the Owner and Donor in a single Role Cycle.

Procedure:

Procedures are tasks that will be performed as part of a standard Cycle, for example, TESE.

Procedure Type:

These are collections of labels that are required for containers and paperwork during a Procedure.

Report:

Reports contain a full record of activities completed with the Gidget Handheld Scanner, including all Witness Sessions, errors, warnings and incomplete sessions. The Witness Session and Cycle History Reports can be exported as PDF. The Consumable Report can be exported as either a PDF or CSV document.

Scheduled:

Refers to all patients that have Cycle information prepared and are Scheduled to start Day 0 on a day other than the current workday.

Stock:

Stock refers to the paper, brand, type and dimensions of labels used by a printer.

Surrogate:

This Patient Role is used if the birth mother is different to the Owner.

User ID:

The User ID is a unique User Name or barcoded label that allows a user to log in to the Gidget system.

Witness Session:

A Witness Session replaces any situation where you would normally require a second person to double witness a task. A Witness Session is performed by scanning the labels associated with that task. In doing this Gidget will verify that all labels scanned match the patient or Linked Patients within a Cycle.

Workflow Rules:

Refer to user specified critical labels that must be scanned for that patient's Procedures, and subsequently their Cycle Day, to be logged as complete. Once all critical labels have been scanned for a patient's Cycle Day the relevant Patient Card will be displayed on the Active Patients screen as complete (displayed with a tick and highlighted in green).

Workflow:

Workflow relates to the ordered steps required in the laboratory for embryo development during a patient Cycle.

9. TECHNICAL SPECIFICATIONS & MAINTENANCE

For technical specifications, EMC compliance and/or other issues related to the use, maintenance and storage of the hardware components supplied with Gidget, please refer to the relevant component's user documentation provided during the installation of the Gidget system.

For basic cleaning and maintenance of the Gidget components, please refer to the relevant manufacturer's documentation provided during installation of the Gidget system.

APPENDIX

10. PREREQUISITES & RESPONSIBILITIES

10.1. Prerequisites

The following list provides an overview of the main prerequisites for using a Gidget system.

NOTE: These items are not included with Gidget and must be provided by the customer.

For the full list of requirements, equipment, tasks, and responsibilities, please refer to the Customer Pre-Installation Form in the Gidget Service Manual (QFRM898). This form is available upon request from your authorised Genea service technician.

Title	Criticality	Details
Network with both WiFi and Ethernet Access	Required	<p>Although it is anticipated that most customers will incorporate Gidget onto their existing laboratory networks, customers may also choose to set up a standalone network exclusively for Gidget (for example, via a basic router with WiFi functionality).</p> <p>Minimum Requirements:</p> <ul style="list-style-type: none"> ▪ WiFi access in all areas where Gidget is to be used to allow connection of Gidget wireless Handheld Scanners. ▪ There must be a sufficient number of Ethernet ports to allow the Gidget CCS to connect to label printers. ▪ Must allow communications traffic between Gidget CCS and the other devices (such as Handheld Scanners, printers and storage devices). <p>Recommended Network Functionality:</p> <ul style="list-style-type: none"> ▪ DHCP enabled. (Reason: simplicity of connecting devices, including Gidget Handheld Scanners and label printers). ▪ Internet connection (Reason: for time synchronisation and easier connection of new Gidget Handheld Scanners).
Label Printers	Required	<p>Type: Zebra GX430t or Brady BBP12 with Ethernet connectivity.</p> <p>Quantity required: One for each label size and type that will be used for printing.</p> <p>NOTE: Having only one printer with multiple label sizes/types is not advisable as embryologists would be required to keep swapping the different labels in and out of the printer.</p>
Label Printer Consumables	Required	<p>Items: Labels, Transfer Ribbon, Rollers.</p> <p>NOTE: Currently, the choice of labels and other printer consumables is restricted to a specific set of options (see “11.2. Supported Label Printers & Consumables” on page <?>).</p>
Wall-mounted Monitor	Recommended	<p>Minimum display resolution of 1080p with WiFi and ability to connect via kiosk mode. To log in to a Chrome browser, the customer will also require either a PC-on-a-stick or a laptop/PC to be connected to the wall-mounted monitor.</p>

Electronic Storage Device for Backups	Required	For disaster recovery purposes. Supported Storage Types: <ul style="list-style-type: none"> ▪ USB External Drive. ▪ Networked Drive. Estimated Space Required: Up to 140MB per backup. Recommended Space: Up to 1 GB to allow for default quantity of seven backups .
Computer Peripherals for the Gidget CCS	Required	<ul style="list-style-type: none"> ▪ USB keyboard. ▪ USB mouse. ▪ Monitor with HDMI cable. ▪ Ethernet cables.
Computers with Chrome Browser Installed (Version 51 or later)	Required	Gidget users need to access the Gidget WebApp user interface from a computer connected to the same network as Gidget. Computer Requirements: <ul style="list-style-type: none"> ▪ Must be connected to the Gidget network. ▪ Must have the Chrome web browser installed.
Apple ID	Required	When Gidget Handheld Scanners are first installed they must briefly connect to the Apple App Store via the internet. This requires each customer site to have its own Apple ID (see “11.2.1. Creating an Apple ID” on page <?>).
Wifi Network with Internet	Required Only During Installation	When Gidget Handheld Scanners are first installed they must briefly connect to the Apple App Store via the internet. NOTE: This does not need to be on the laboratory network. The scanners are only briefly connected to the network, activated, and then disconnected.

10.2. Customer Responsibilities

The customer is responsible for all aspects of the following (including purchase, setup, operation, maintenance and security):

- Setup and maintenance of the network that the Gidget system operates on.
- Setup and maintenance of the label printers, including installation and replacement of consumables.
- Setup and maintenance of the electronic storage device and all backups.

For detailed pre-installation instructions: see “11. Pre-Installation” on page 48.

For detailed post-installation instructions: see “12. Post-Installation” on page 52.

11. PRE-INSTALLATION

11.1. Overview

To prepare for installation customers must complete the Customer Pre-Installation Form contained in the Gidget Service Manual (QFRM898).

The Customer Pre-Installation Form is available on request and will be sent to authorised Genea customers by the service technician as a normal part of the pre-installation process. The form contains the actions and information required for a successful installation, including the purchase and setup of all prerequisite equipment.

Installation of the Gidget system should only be performed by an authorised service technician. **NOTE:** The technician will request a completed copy of the Customer Pre-Installation Form before the agreed day of installation.

The rest of this section provides an overview, and some additional guidance, to help customers complete the Customer Pre-Installation Form.

11.2. Supported Label Printers & Consumables

**CAUTION:**

Consumables for use with Gidget must be selected **ONLY** from the approved lists, including consumable sizes and the specific manufacturer/supplier. The list of approved consumables will be expanded in line with feedback from users. No other solutions will be supported.

As every manufacturer uses slight variations in stock and format, **DO NOT** use any unauthorised consumables as they are highly likely to result in label printing errors (for example, variations in the space between labels on the rolls may cause the printed information to drift off the labels).

NOTE: For the latest information related to supported consumables please refer to: QRTM212 Gidget Consumables.

11.2.1. Creating an Apple ID

When Gidget Handheld Scanners are first installed they must briefly be connected to the Apple App Store via the internet. This requires each customer site to have its own Apple ID. At the time of writing, Apple IDs can be created free of charge at appleid.apple.com

NOTE:

- The Apple ID must be created before the installation day.
- A single Apple ID may be used for up to ten Gidget Handhelds concurrently.
- An Apple ID is an account set up with the company Apple.
- A customer representative must be available on installation day to input the Apple ID username and password for each Handheld Scanner.

11.3. Zebra GX430t with Ethernet Connection Setup

This section provides guidance for setting up the Zebra GX430t with Ethernet Connection ready for Gidget Installation.

NOTE:

- These instructions are intended as a guide only and DO NOT replace the printer manufacturer's documentation.
- By default, the Zebra GX430t printer will print test labels that are not visible due to insufficient darkness level settings. Following the steps below will ensure that the labels print correctly.
- In some of the steps below you will be instructed to press and hold the printer feed button until the green status light flashes a specific number of times. Holding down the printer's feed button will make the light cycle through a series of 'flash groups', first flashing once, then twice, then three times, and so on. For example, if you are instructed to press and hold the feed button until it flashes rapidly five times, you continue to hold the button down until it has reached the five 'flash group' before releasing it.
- Some steps require you to be ready to press a button within a short time frame. Read through all the instructions before commencing.

Recommended printer setup steps:

1. Follow the manufacturer's instructions to install the printer labels.
2. Follow the manufacturer's instructions to install the printer ribbon.
3. Switch the printer on and wait for the indicator light to turn green (fixed or flashing).
4. Briefly press the feed button once. The printer will feed a number of blank labels.

NOTE: Confirm that the indicator light is fixed green (not flashing) before proceeding. If it is still flashing, try pressing the feed button briefly once. If the light continues to flash there may be a problem with the way the consumables are installed (consult the manufacturer's documentation).

To adjust the printer darkness settings:

5. Press and hold the feed button until it flashes rapidly six times and then release. This will cause the printer to start printing successive labels with increasing darkness. **NOTE:** The first printed labels will appear blank (see below).



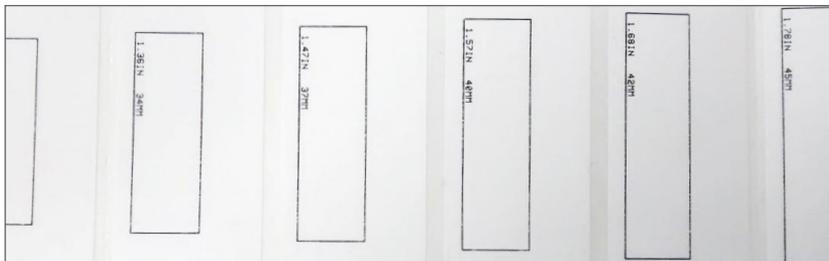
6. Be ready. When the printer reaches a darkness setting of 25, briefly press the feed

button once to select the setting.

NOTE: Printing certain finer characters, such as Asian or Arabic script, may require a darker setting to obtain the desired legibility.

To adjust the printer width settings:

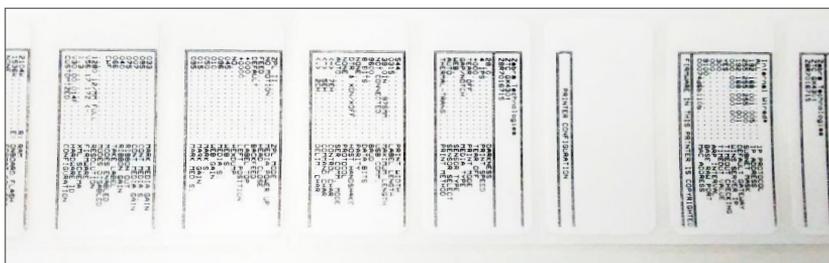
7. Press and hold the feed button until it flashes rapidly five times, then release. This will cause the printer to start printing labels of increasing width (see below).



8. Be ready. When the printer reaches a width almost at the edges of your label width, briefly press the feed button once to select the width setting. **NOTE:** It is not necessary to get the exact setting in this step as the aim is to get the width approximately correct to enable a test label to be printed.

To print a test label and locate the printer's current IP address:

9. Connect the printer to a DHCP-enabled network using an Ethernet cable.
10. Wait ten seconds to allow the printer to obtain an IP address from the network. **NOTE:** The printer will not give any sign of success or failure so continue with the steps after ten seconds.
11. Press and hold the feed button until it flashes once, then release. This will print a test label.
12. Confirm that the appearance of the printed label is similar to the image below.



13. Locate the printer's current IP address on the printed test label.

To set the printer to a static IP address:

14. Connect a computer to the same network as the printer.
15. Open a web browser.

16. Type the printer's current IP address (located on the printed test label) into the browser's address bar and press enter. The Zebra Printer Management web page should be displayed.
17. Select **Print Server Settings** from the web page.
18. Select **Print Server**. If prompted for a password, the default is:
 - Username: admin
 - Password: 1234
19. Select **TCP/IP Configuration**.
20. Make changes as required, including:
 - IP Address: <Type the Static IP address you want to assign>
 - IP Protocol: Permanent
 - Subnet Mask: <As per your network>
 - Default Gateway: <As per your network>
21. Select **Submit Changes** and follow all prompts to reset the printer.

To confirm that the Printer is now located at the desired static IP address:

22. Connect a computer to the same network as the printer.
23. Open a web browser
24. Type the printer's static IP address into the browser's address bar and press enter.
25. Confirm that the Zebra Printer Management web page is shown.

11.4. Brady BBP12 with Ethernet Connection Setup

For printer setup instructions download the *Brady_BBP12_Printer_Setup.pdf* document from the manufacturer's support page: www.qualityserviceandsupport.com/brady/article/7498

12. POST-INSTALLATION

12.1. Overview

This section outlines the tasks, including ensuring that Disaster Recovery (backups) are in place, that customers must perform following installation to ensure that Gidget will continue to operate correctly.

12.2. Recommended Post-Installation Task

#	Description	As per
1	Perform manual backup of the Gidget.	"12.4.4. Performing a Manual Backup" on page <?>.
2	Confirm automatic backups of Gidget are working.	"12.4.3. Setting the Backup Time & Frequency" on page <?>.
3	Ensure that Gidget's automated backup files are being backed up in the clinic's backup systems.	Customer's own IT procedures.

12.3. Customer Logins

The following logins will be available to the customer:

System Level	Username	Default Password	Intended Usage
Gidget CCS Windows	Admin	GldG3T4dm1n!	Customer IT administrator. For all Gidget post-installation tasks performed at a Windows level, including making backups, restores and adding printers.
Gidget CCS Windows	Dashboard	D4shbo4rd!	To allow the Gidget WebApp to be displayed.
Gidget WebApp	Refer to Install Documentation	Refer to Install Documentation	Customer administrator. For Gidget post-installation tasks performed in the Gidget WebApp, including adding new users and assigning Admin privileges.

12.4. Backup & Disaster Recovery

	<p>CAUTION:</p> <p>Restoring from a backup may result in loss of work. Any work (for example, Witnessing, new cycles or report history) or changes that were performed in the Gidget WebApp after the backup was created will be lost. Also, any labels from cycles or procedures that were created after the backup was made will not be recognised by the Gidget system.</p>
---	---

For disaster recovery purposes the Gidget CCS makes daily backups of the Gidget WebApp database to a user-specified location. Each backup consists of a single file with a .7z extension (for example, gidget-2016-11-10.bak.7z).

The backup and restore of the Gidget WebApp database are performed by running scripts on the Gidget CCS. Restoring from an earlier backup will replace the existing Gidget database with the backup database, including:

- Lab Processes
 - label library
 - Procedures and Cycle Types
 - workflow rules
- Patient and Cycle Information
 - all active and historical patients/cycles
 - Witnessing history and report logs
- Users
 - permissions
 - IDs and logins
- General Settings

12.4.1. Backup & Restore FAQ

1. Q: How much storage space will the backup files require?
A: The database size increases with the number of cycles performed so the storage space required will depend on how much, and for how long, the Gidget system has been used. As a starting point, it is estimated that Gidget's backup file may grow by 100-200MB per year. By default Gidget will make a backup each day and allow up to seven backup files to remain in the specified location (older files will be deleted). This means allowing between 0.7GB and 1.4GB per year of Gidget Operation. **NOTE:** These are estimates only and it is customer IT administrator's responsibility to monitor and provide for required backup.
2. Q: Are the backups incremental?
A: No, each backup is a complete backup of the entire database.
3. Q: I can't open the .7z file, because Gidget is asking for a password. What's the password?
A: Passwords are not required, and not provided for the Gidget backup (.bak.7z) files. You will be able to perform restore without this password.
4. Q: What is not included in the Gidget backup?
A: Certain data is not included in the backup and restore files. **NOTE:** This data does not require customer backup and is included only for your information. Data that is not backed up includes:
 - Gidget system log files – these are located at C:\GidgetData\Logs
 - The Gidget application – these are located at C:\Installs
 - The automated backup schedule settings – this is accessed via the Windows Task Manager
 - Gidget Handheld App versions.

12.4.2. Setting the Backup Location

NOTE: The backup location is set to a customer-nominated location during installation. Instructions are provided here to allow the customer to change this location.

To set a backup location:

1. Log in to Windows on the Gidget CCS using an account with Admin privileges.
2. Locate the file **C:\Management-Scripts\config.json** using Windows Explorer.
3. Open **config.json** using a text file editor (such as Notepad).
4. Edit the entry for **“backupPath”** to contain the full path to the folder location where you want the Gidget backups to be stored. **You must ensure that:**
 - a. Any paths to a networked location (such as a mapped network drive) are entered as a full UNC path, NOT using a mapped drive letter.
 - b. Any backslash characters in the path have an extra backslash character inserted adjacent to them.
 - c. If the backup location requires login credentials (such as network location), these are provided.

Example of Desired Backup Location	How it should look in config.json
Network drive not requiring login credentials: \\geneaserver001\GidgetBackups	“backupPath”: “\\geneaserver001\GidgetBackups”, “backupUser”: “”, “backupPwd”: “”, “numberOfBackupsToKeep” : 7
USB drive plugged directly into Gidget CCS: D:\Gidget_baks	“backupPath”: “D:\Gidget_baks”, “backupUser”: “”, “backupPwd”: “”, “numberOfBackupsToKeep” : 7
Network drive requiring login credentials: \\clinicXYZserver002\GidgetArchive Example User Login: clinicXYZadmin Example Password: admin1234	“backupPath”: “\\clinicXYZserver002\GidgetArchive”, “backupUser”: “clinicXYZadmin”, “backupPwd”: “admin1234”, “numberOfBackupsToKeep” : 7

12.4.3. Setting the Backup Time & Frequency

NOTE: By default, Gidget creates a backup every day at 3:00 am local time. This is done via the Task Scheduler in Windows on the Gidget CCS, which runs a task called Gidget DB Backup. This task runs the same backup script used to create a manual backup.

To set the backup time and frequency:

1. Log in to Windows on the Gidget CCS using an account with Admin privileges.
2. Open the **Task Scheduler** app in Windows (type **Task Scheduler** into the Windows search bar).
3. Locate the **Gidget DB Backup** task in the Active Tasks pane.
4. Double-click the task. You can then edit the Triggers of this task via Properties. If you are unsure how to do this, please refer to Windows Server 2012 documentation.
5. Confirm that Gidget is successfully making these backups by checking that a backup file (for example, gidget-2016-11-18.bak.7z) is created at the specified backup location with the expected timestamp(s).

12.4.4. Performing a Manual Backup

NOTE:

- The following section describes how to immediately make a backup of the Gidget system data to the location specified in the config.json file.
- If more than one backup is made on the same day only the latest backup is kept (the later backup will overwrite the previous backup).

To perform a manual backup:

1. Log in to Windows on the Gidget CCS using an account with Admin privileges.
2. Open **Windows Powershell ISE** as an administrator, as follows:
 - a. Type **Powershell** into the Windows search bar.
 - b. Locate the icon named **Windows Powershell ISE** in the search results.
 - c. Right-click and select **Run as administrator**.
3. Navigate to the directory **C:\Management-Scripts\Backups** (You need to be familiar with command line commands. If you are unsure, refer to Windows Powershell documentation).
4. Enter the command:
.\db_backups.ps1
5. Confirm that the script completes with a message indicating success.
6. Confirm that a backup file was created with the current day's date by navigating to the folder where the backup should have been made (as specified in the config.json file). You can do this via Windows Explorer (it does not have to be via PowerShell).

12.4.5. Performing a Restore



CAUTION:

- The Gidget system should not be accessed while the restore operation is taking place. If Gidget is being used during a restore the users will be logged off, however, the restore should still complete successfully.
- Restoring from a backup may result in loss of work. Any work (for example, Witnessing, new cycles or audit history) or changes that were performed in the Gidget WebApp after the backup was created will be lost. Also, any labels from cycles or procedures that were created after the backup was made will not be recognised by the Gidget System.

To perform a restore:

1. Ensure the backup file is located in the directory being pointed to within the config.json file (see “12.4.2. Setting the Backup Location” on page 54).
2. Open a **Powershell** window as an administrator (type **Powershell** into the Windows search bar, then right-click the **Windows Powershell** icon and then select **Run as administrator**).
3. In the **Powershell** window, navigate to the **C:\Management-Scripts\Backups** directory (You need to be familiar with command line commands. If you are unsure, refer to the Windows Powershell documentation).
4. Enter the following command:
.\db_restore.ps1 <Backup filename>
 where <Backup filename> is the name of the archive to restore to.

Example:

If you want to restore the archive 'gidget-2016-11-10.bak.7z', then type in the command:
.\db_restore.ps1 gidget-2016-11-10.bak.7z

5. Answer yes to all prompts.
6. Confirm that the script has completed and returned to the windows **PowerShell** prompt, with no error messages.
7. Confirm that the restore has succeeded by logging in to the Gidget WebApp.

12.4.6. Adding, Changing or Removing Label Printers

Contact your authorised Genea Service Representative.

12.4.7. Adding Additional Handheld Scanners

Contact your authorised Genea Service Representative.

12.4.8. Importing a Genea Supplied Lab Process (Optional)



CAUTION:

- The Gidget system should not be accessed while the lab process import operation is taking place. If Gidget is being used during a lab process import, the users will be logged off, however, the import should still complete successfully.
- A new lab process can only be imported into a brand new Gidget system that has never had patients or cycles. If any data exists, the import will fail, and the lab process will not be updated.
- Importing a lab process will replace any existing lab process configuration, including labels, procedures and cycle types

To import a Genea supplied lab process:

1. Ensure the lab process file as supplied by your authorised Genea Service Representative is located in the directory that is accessible from the Gidget CSS. Take note of the full path to this file.
2. Open a Powershell window as an administrator (type Powershell into the Windows search bar, then right-click the Windows Powershell icon and then select Run as administrator).
3. In the Powershell window, navigate to the C:\Management-Scripts\Backups\ directory (You need to be familiar with command line commands. If you are unsure, refer to the Windows Powershell documentation).
4. Enter the following command: `.\labconfig_import.ps1 <Lab process filename>` where `< Lab process filename >` is the full path and name of the lab process to import.

Example:

If you want to import the lab process file named 'gidget-labconfig-2016-11-10.bak.7z' on a USB External Drive available at D:\Gidget_labprocess, then type in the command:

```
.\labconfig_import.ps1 D:\Gidget_labprocess\gidget-labconfig-2016-11-10.bak.7z
```

5. Answer yes to all prompts.
6. Confirm that the script has completed and returned to the windows PowerShell prompt, with no error messages.
7. Confirm that the import has succeeded by logging in to the Gidget WebApp and checking the expected labels, procedures and cycle types exist in the Lab Settings area.

12.5. Handheld Scanners: Checking WebApp Version

To check the Gidget WebApp version on the Handheld Scanner:

1. Press the home button on a Gidget Handheld Scanner. The OS Desktop should be displayed.
2. Tap **Settings > General > Storage & iCloud Usage > Manage Storage**. The storage screen should be displayed.
3. Locate Gidget from the list and select. An information screen should be displayed.
4. Locate the Gidget App version listed.

12.6. Retrieving System Log files

NOTE: Log files may be useful in the event of a system malfunction. While it is not expected that customer IT will be required to interpret and debug the log files, they may be asked by an authorised Genea service representative to retrieve and send the log files.

To retrieve system log files:

1. Log in to Windows on the Gidget CCS using an account with Admin privileges.
2. Locate the log files at the following directory:
C:\GidgetData\Logs

12.7. Removing all Patient Data



CAUTION:

The Gidget CCS contains confidential patient data. The handling of such data, and the systems that contain them, is governed by laws in most regions.

Contact your authorised Genea service representative.

13. INDEX

A

Active Patients Screen, 22

Apple ID,
creating, 48

B

Backup, 52

backup location, 54
FAQ, 53
manual backup, 55
restore, 56
setting time and frequency, 55

C

Consumables, 17

activating consumable lot, 19
adding a consumable lot, 19
adding consumable type, 17
closing consumable lot, 20
deleting consumable type, 18
editing a consumable lot, 20

Customer Tasks,

recommended tasks, 50

Cycle Day Status (Scanner),

manual control, 39

Cycle Types, 15

adding cycle types, 15
adding labels to, 16

D

Disaster Recovery. See Backup

E

Embryo Level Identification,

resolving a sample mismatch, 41
sample mismatch error, 40
witnessing sample level labels, 35

Errors,

patient mismatch, 40

remaining cycles warning, 41

G

Gidget,

basic operation, 22
basic settings, 6
intended use, 1
overview, 1

H

Handheld Scanners. See Scanner

I

IP Address,

printer, locating, 50
static, 50

L

Labels,

adding to a procedure, 14
adding to label library, 11
critical label, 15
editing formats, 11
formatting, 11
Single European Code (SEC) 29

Licenses,

adding new licenses, 9
requesting new, 9

Linking Patients, 24

Linking Samples, 24

Log Files,

retrieving files, 58

Logging In,

login names, 49
scanner, 34
WebApp, 22

P

Patient Cycles, 24

- cancelling, 30
- completing cycles, 27
- cycle completion, 39
- linking patients, 24
- printing labels for, 26

Patient Information,

- reviewing, 36

Patient List Screen, 28**Performing 34****Pre-Installation, 48****Presale Information,**

- customer responsibilities, 46, 47
- prerequisites, 46

Printer,

- adding, 56
- Brady BBP12 setup, 51
- changing, 56
- darkness settings, 49
- removing, 56
- selecting a printer, 8
- supported printers, 48
- width settings, 50
- Zebra GX430t setup, 49
 - darkness setting, 48
 - label width setting, 50

Procedures, 13

- adding labels to, 14
- adding procedures, 13
- critical procedures, 17

R**Reports, 30**

- exporting reports, 31
- viewing reports, 31

Restore,

- from backup, 56

S**Scanner,**

- adding scanners, 56
- audio, 37

- basic operation, 33
- checking WebApp version, 58
- logging in, 34

Symbols, 4**U****User,**

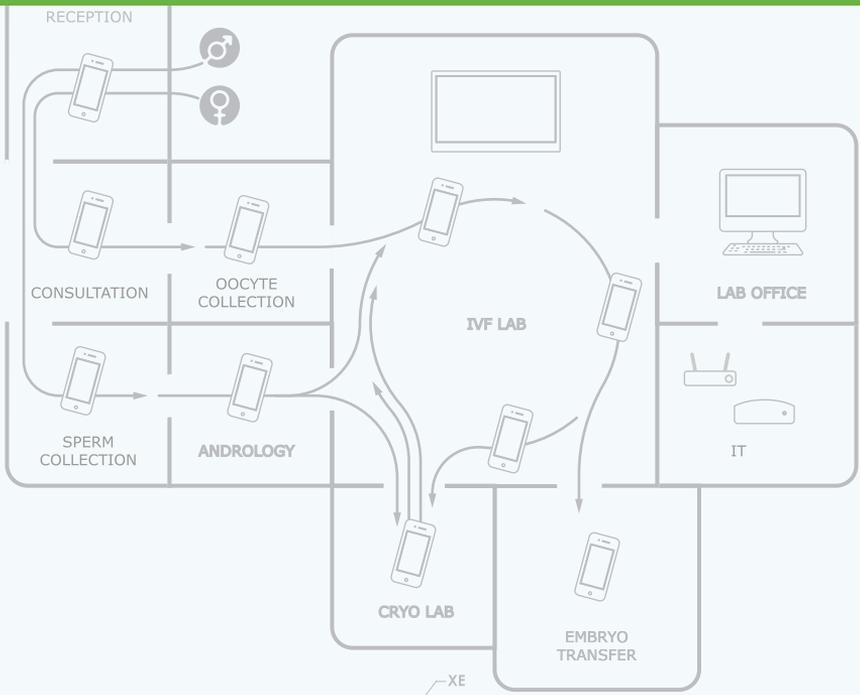
- adding, 7
- editing information, 8
- my user settings, 30
- printing user id, 9
- reactivating, 8

W**Witness Sessions, 34**

- manual witness session, 35
- performing witness sessions, 34
- 'sample level' witnessing, 35

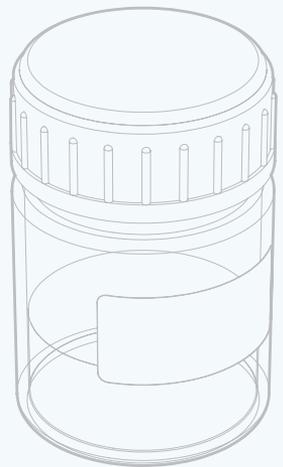
Workflow Rules,

- creating rules, 16



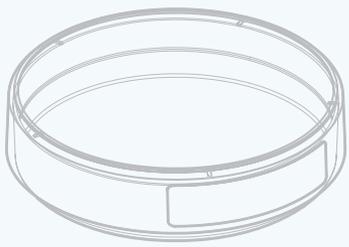
Incoming
3

Day 0
5 of 6



LastName, FirstName
123456789012345
OPU

XE



Cycle Types	Labels	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	
<ul style="list-style-type: none"> ICSI PGD IVF THAW Group 5 TESE 	<p>Library</p> <ul style="list-style-type: none"> fert chk hatch icsi inseml icsi m'over ivi sp prep ivf m'over pgs transfer vitrify 									
						<p>Cycle</p> <ul style="list-style-type: none"> opu ivf sp prep ★ ivf inseml ivf to icsi hyal icsi sperm prep 				