

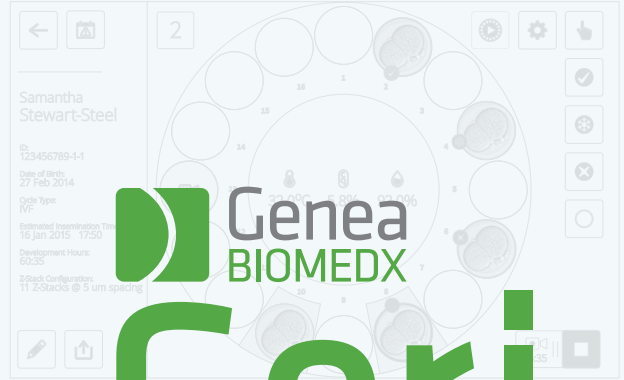


# Geri Connect

User Manual



# Geri Assess



Incubator 3			
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1	2	3	4
55:41	60:35	62:44	44:23

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Federal Law (USA) restricts this device to sale by or on the order of a licensed physician or other healthcare practitioner.

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## INTRODUCTION

It is the owner's responsibility to ensure that all users of Geri and Geri Connect & Geri Assess have read and understood QFRM869 Geri User Manual before operating the instrument. This user manual and QFRM869 Geri User Manual are for readers who are familiar with clinical and laboratory techniques, instruments and personal safety procedures and equipment. Before operating Geri, please ensure that you have the proper clinical and laboratory training.

## Warnings & Cautions






The following warnings and cautions appear in the user manual. It is the owner's responsibility to ensure that all users of Geri and Geri Connect & Geri Assess have read and understood these warnings and cautions before operating the instrument.

	<p><b>WARNING:</b></p> <p>It is the owner's responsibility to ensure that all users of Geri and Geri Connect &amp; Geri Assess:</p> <ul style="list-style-type: none"> <li>▪ are trained in all laboratory safety procedures, including the handling of hazardous materials</li> <li>▪ have read and understood the instructions and warnings contained in this user manual</li> <li>▪ have received adequate training in the correct operation of the instrument.</li> </ul>
	<p><b>WARNING:</b></p> <p>Geri Connect &amp; Geri Assess is not a substitute for a remote alarm system. The Geri Instrument includes an audible alarm and a remote alarm that serve as primary alarm notifications. The notifications on the Geri Connect &amp; Geri Assess are for user convenience only. Please refer to QFRM869 Geri User Manual for more information.</p>
	<p><b>WARNING:</b></p> <p>During the synchronization process, available playback of video on Geri Connect may not include up to the last five images taken on Geri instrument.</p>
	<p><b>WARNING:</b></p> <ul style="list-style-type: none"> <li>▪ It is recommended that patient details and embryo fates be updated on Geri Connect &amp; Geri Assess. If patient details and/or embryo fates are updated on the Geri instrument, the user should wait until the changes are visible on Geri Connect &amp; Geri Assess before making any further changes to the relevant patient on other Geri instruments or Geri Connect &amp; Geri Assess. If changes are made simultaneously on both products (Geri instruments or Geri Connect &amp; Geri Assess), only the latest changes will be saved and other changes will not be recorded.</li> <li>▪ If the Geri instrument is disconnected from Geri Connect &amp; Geri Assess, perform all session and patient editing on the Geri instrument. When the Geri instrument is reconnected to Geri Connect &amp; Geri Assess, all changes made on the Geri instrument will be synchronized with Geri Connect &amp; Geri Assess.</li> </ul>

	<p><b>WARNING:</b></p> <ul style="list-style-type: none"><li>▪ Changes to the Score Configuration will automatically apply to all sessions available in Geri Connect &amp; Geri Assess.</li></ul>
	<p><b>WARNING:</b></p> <ul style="list-style-type: none"><li>▪ Automated Annotations will not be correct and accurate in all instances and as such, the Geri Connect &amp; Geri Assess software is not intended to replace clinical practices for review and assessment of embryos. Users are responsible for manually reviewing embryo developmental events they consider critical.</li></ul>

## Definition of Symbols

The following symbols are used on the Geri Connect & Geri Assess:

Symbol	Title	*ISO 15223-1 Reference #
	Date of Manufacture	5.1.3
	Caution	5.4.4
	Serial Number	5.1.7
	Reference	5.1.6
	Caution, Consult the User Manual	5.4.3
<b>RxOnly</b>	Federal Law (USA) restricts this device to sale by or on the order of a licensed physician or other healthcare practitioner	

\* ISO 15223-1 Medical Devices: symbols to be used with medical device labels, labeling and information.



This option is not available in the US market.

# SAFETY INSTRUCTIONS

**WARNING:**

It is the owner's responsibility to ensure that all users of Geri and Geri Connect & Geri Assess:

- are trained in all laboratory safety procedures, including the handling of hazardous materials
- have read and understood the instructions and warnings contained in this user manual and QFRM869 Geri User Manual
- have received adequate training in the correct operation of the instrument and server.

## Installation

The installation of Geri Connect & Geri Assess must be performed only by an authorized service technician.

The following software is required:

- Google Chrome (version 50 or later)
- A compatible operating system:
  - Microsoft Windows (version 7 or later)
  - OS X (version 10.9 or later)

**NOTE:** The software is optimized to operate with a screen resolution of 1920 x 1080 and 100% zoom.

**NOTE:** Newer versions of Chrome browser are released regularly, and the user may decide to update the browser to the latest version. It is not expected that changes in the newer versions will impact the viewing of the user interface.

# 1. ABOUT GERI CONNECT & GERI ASSESS

## 1.1. Indications for Use/Intended Use

The Geri Embryo Incubator is intended to provide an environment with controlled temperature and mixed gas (CO<sub>2</sub> and other gases) for the development of embryos. The Geri Embryo Incubator has an integrated camera and optics for imaging and viewing embryos during incubation, for a maximum time of 120 hours.

Geri Connect and Geri Assess are optional software accessories for the Geri Embryo Incubator. Geri Connect is intended for access and review of time-lapse data generated by the Geri Embryo Incubator on a local area network. Geri Assess is intended for viewing and recording embryo development events from images captured using the Geri Embryo Incubator. Geri Assess includes a user annotation function for capturing information on embryo development parameters and a user-defined modeling function that allows the user to combine annotated information on embryo development parameters to aid in embryo selection. Geri Connect and Geri Assess do not control any hardware components in the Geri Embryo Incubator. Geri Connect and Geri Assess are combined in the same software package and must be used together.

The Geri Dish is intended to be used for preparation, storage and imaging of human embryos. The Geri Dish is intended to be used only with the Geri Embryo Incubator.

## 1.2. The Key Features of Geri Connect & Geri Assess

Geri Connect & Geri Assess connects one or more Geri incubators through a LAN. The Geri Connect & Geri Assess software enables multiple users to access and review patient/embryo data, using a Chrome browser on their PC workstations.

Key functionality in Geri Connect & Geri Assess 2.0:

- Multiple embryo assessment tools available, including automated annotations
- Enhanced video playback using best focal plane, embryo-cropped images
- Ability to utilize multiple custom scoring algorithms\*
- Connect one or more Geri instruments to a LAN for one centralized database of patient information
- Two levels of user management with Administrator (unrestricted access) and Lab Staff (restricted access)
- Data Synchronized between Geri Connect & Geri Assess and Geri incubators:
  - patient information
  - time-lapse sessions
  - embryo fate decisions
- Ability to export data

**NOTE:** Geri Connect & Geri Assess is a web-based application. Minimize the number of applications open on the PC workstation to optimize performance of Geri Connect & Geri Assess.

\*Custom scoring algorithms must be uploaded to Geri Connect & Geri Assess by an authorized service technician.

## 1.3. Embryo Assessment Tools

### 1.3.1. Geri Assess 1.0 – Manual Annotations

Geri Assess 1.0 is the user-defined annotation and scoring system used to assess/grade embryos.

Key functionality in Geri Assess 1.0:

- A user-defined scoring system
- Display only relevant events and observations during embryo development divided into six Development Chapters
- Key Events: each of the six Development Chapters holds at least one key embryo development event
- Custom Events/Observations: administrators can adjust existing event/observation names and scores, as well as create new customized events/observations to reflect the lab's specific and individual protocols
- Scores are displayed on both the patient review page and patient summary page
- Free text field for comments and lab specific embryo grading
- Keyboard shortcuts that control all playback functionality

### 1.3.2. Geri Assess 2.0 – Automated Annotation Tool

Geri Assess 2.0 is a premium embryo assessment tool that automatically annotates and scores embryo development events. Licenses for this feature are sold separately.

Key functionality in Geri Assess 2.0:

- Using the best focal plane, embryo-cropped video, automatically detects key embryo events and place annotations on the timeline bar
- Ability for the user to utilize multiple custom scoring algorithms\* that display an overall embryo score based on developmental timings.

\*Custom scoring algorithms must be uploaded to Geri Connect & Geri Assess by an authorized service technician.

See "3.4.4. List Of Events & Observations" on page 31 for a full description of embryo events and observations



#### **WARNING:**

- Automated Annotations will not be correct & accurate in all instances and as such, they are not intended to replace clinical practices for review and assessment of embryos. Users are responsible for manually reviewing embryo developmental events they consider critical.

## 2. ABOUT GERI CONNECT & GERI ASSESS

### 2.1. Logging in to Geri Connect & Geri Assess

Your administrator or authorized service technician will provide you with the HTTP address, username and password required to access Geri Connect & Geri Assess.

Access to Google Chrome (version 50 or later) is also required. Type the HTTP address provided into a new Chrome window. It is recommended to close all other applications and just have the Google Chrome window running Geri Connect & Geri Assess open.

**To log in to Geri Connect & Geri Assess:** Enter a username and password on the Login page. The Patient List tabs are displayed.

#### NOTE:

- If the username and password combination entered is not correct the following notification will be displayed:
  - **Username and password don't match. Try again.**
- If the user makes five unsuccessful attempts to log in, the user's account will be locked for one minute and the following notification will be displayed:
  - **Too many invalid login attempts. Account has been locked.**
- Locked accounts are automatically unlocked after one minute. If the user attempts to log in while their account is locked, the one minute period will restart and the following notification will be displayed:
  - **Account is locked. Try another account.**
- All Geri Connect & Geri Assess screens have **Inactivity Timeouts**. If there is no interaction with Geri Connect & Geri Assess for over five minutes (such as moving the mouse or pressing a key), an automatic logout will occur. The user will be automatically redirected to the Login page and the following notification will be displayed:
  - **Your session has timed out due to inactivity. Please log in again to resume.**

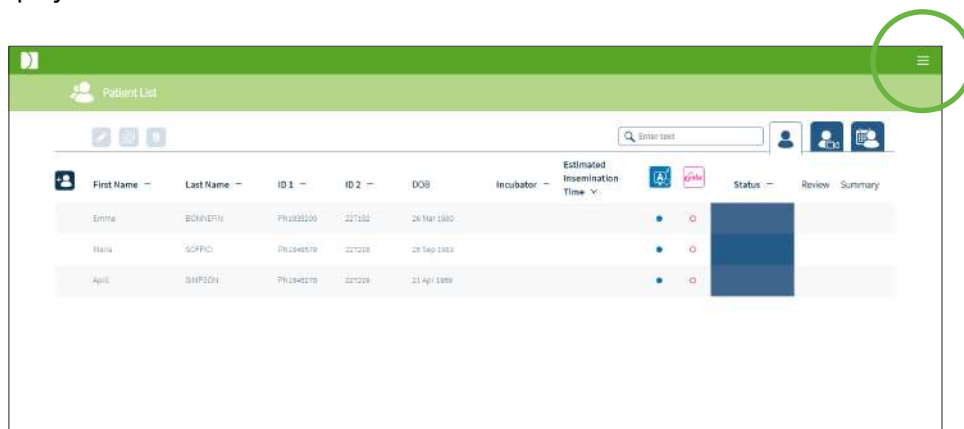
**NOTE:** Use F11 to enter or exit full screen mode. It is recommended that full screen mode be used. The software is optimized to operate with a screen resolution of 1920 x 1080 and 100% zoom.

### 2.2. Logging out of Geri Connect & Geri Assess

**To log out of Geri Connect & Geri Assess:** Select Logout from the User Menu, the drop-down menu located on the top right of the page.

## 2.3. Basic Navigation of Geri Connect & Geri Assess

Once a user has successfully logged in to Geri Connect & Geri Assess, the Patient List Tabs are displayed.



Clicking on the User Menu, located on the top right of the page (highlighted in green above) displays the following menu options, depending on the level of administration.

Menu Option	Admin Menu	User Menu
Patient List	Yes	Yes
Your User Settings	Yes	Yes
Geri Status Hub	Yes	Yes
User Management	Yes	No
Score Configuration	Yes	No
PDF Templates	Yes	No
Settings	Yes	No
Licenses	Yes	No
Information	Yes	Yes
Logout	Yes	Yes

Geri Connect & Geri Assess has two levels of access: Administrator (unrestricted access) and Lab Staff (restricted access).

Administrators have unrestricted access and are able to:

- create/edit users and assign permissions (See “4.1. Administrator User Management” on page 35)
- view, create and edit Geri Assess Events/Observations (See “4.2. Score Configuration in Geri Assess 1.0” on page 37)
- approve Geri instrument connections with Geri Connect & Geri Assess (See “4.1.5. Connecting Geri Incubators to Geri Connect & Geri Assess” on page 36)
- view, create and edit PDF patient report templates. (See “4.3. PDF Templates” on



page 41)






Lab Staff (restricted access) do not have these capabilities. Both Lab Staff and Administrators are able to:

- log in/log out of Geri Connect & Geri Assess (See “2.1. Logging in to Geri Connect & Geri Assess” on page 3 and “2.2. Logging out of Geri Connect & Geri Assess” on page 3)
- change their password (See “2.4. Your User Settings” on page 6)
- create/edit patients (See “3.1. Patient List Tabs” on page 12)
- review and tag embryos (See “3.2. Patient Review Page” on page 18)
- view a summary of all embryos from the one patient and sort results (See “3.3. Patient Summary Page” on page 24)
- annotate embryos (See “3.4. Annotating Embryos Using Geri Assess” on page 25)
- view the instruments that are connected to Geri Connect & Geri Assess and warnings/alarms and environmental data (See “2.5. Geri Status Hub” on page 6)
- view the remaining space on the Geri Connect & Geri Assess Server (“2.6. Information Page” on page 10)

All Events and Observation annotations recorded through Geri Assess are marked together with the user name of the person logged in to the system.

## Icons

The following icons are displayed throughout Geri Connect & Geri Assess:


Icon	Description
	Save: Click to save your changes.
	Back: Click to return to the previous menu.
	Edit: Click to edit patient details.
	Home: Click to return to the Patient List Tabs, located on the top left-hand side corner.
	User Menu: Button to open the User Menu, located next to the Username in the top right-hand corner.

The rest of the icons seen in Geri Connect & Geri Assess are specific for the pages and will be described in the relevant sections.

## 2.4. Your User Settings

All users can access and edit their account details, including password and email address.

**To access the Your User Settings Page:**

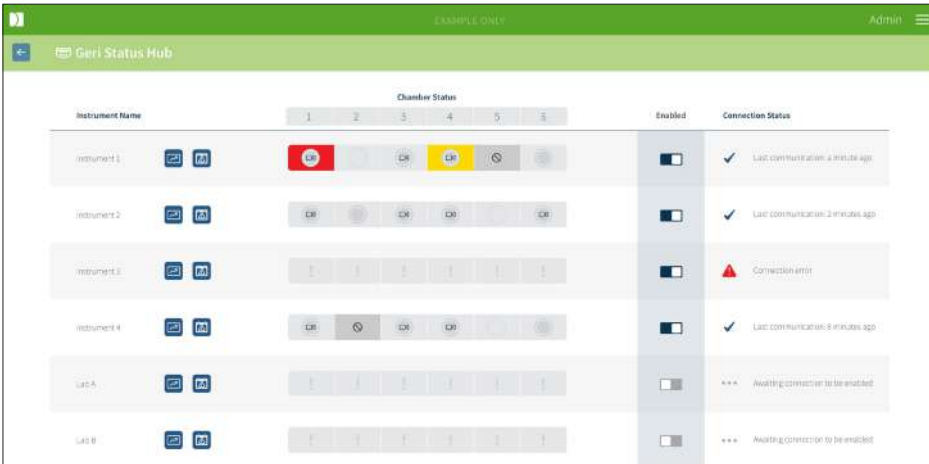
1. Select Your User Settings from the User Menu located on the top right of any page in Geri Connect & Geri Assess.
2. Edit account details as required (name, email address, password).  
**NOTE:** the Password must contain more than four characters and is case sensitive.
3. Click the Save icon  to save changes.

## 2.5. Geri Status Hub

Geri instruments connect with Geri Connect & Geri Assess through an Ethernet cable. Contact your authorized service technician to connect your Geri instruments with Geri Connect & Geri Assess.

All Geri Connect & Geri Assess users have access to the Geri Status Hub, however, only Administrators are able to set up new Geri instruments and enable them to communicate with Geri Connect (See “4.1.5. Connecting Geri Incubators to Geri Connect & Geri Assess” on page 36).

Geri Status Hub presents real-time Geri instrument connection status, in addition to real-time and historical alarms, warnings and environmental data (temperature, CO<sub>2</sub> and relative humidity values) of individual Geri instrument chambers.












The screenshot shows the Geri Status Hub interface. At the top, there is a header with 'Geri Status Hub' and 'Admin' on the right. Below the header is a table with columns for 'Instrument Name', 'Chamber Status' (with sub-columns 1-6), 'Enabled', and 'Connection Status'. The table contains six rows of instrument data.

Instrument Name	Chamber Status						Enabled	Connection Status
	1	2	3	4	5	6		
Instrument 1	CR	CR	CR	CR	CR	CR	<input checked="" type="checkbox"/>	✓ Last communication: 2 minutes ago
Instrument 2	CR	CR	CR	CR	CR	CR	<input checked="" type="checkbox"/>	✓ Last communication: 2 minutes ago
Instrument 3							<input checked="" type="checkbox"/>	⚠ Connection error
Instrument 4	CR	CR	CR	CR	CR	CR	<input checked="" type="checkbox"/>	✓ Last communication: 6 minutes ago
Lab A							<input type="checkbox"/>	*** Awaiting connection to be enabled
Lab B							<input type="checkbox"/>	*** Awaiting connection to be enabled


**To access the Geri Status Hub Page:** Select Geri Status Hub from the User Menu located on the top right of any page in Geri Connect & Geri Assess. The Geri Status Hub Page is displayed showing the incubator name, chamber status and connection status.

The following icons are displayed in the Geri Status Hub:

Icon	Name	Description	More Information
	Environmental Data	Button to view environmental data of connected Geri instruments.	Section 2.5.1
	Alarms and Warnings	Button to view alarms and warnings of connected Geri instruments.	Section 2.5.2
	Export	Button to export selected Geri instrument environmental data and/or alarms and warnings.	Sections 2.5.1 and 2.5.2
	Free Chamber	The chamber is currently active and not allocated to a patient.	Section 2.5.3
	Allocated Chamber	The chamber is currently allocated to a specific patient, but time-lapsing has not yet started.	Section 2.5.3
	Time-Lapsing Chamber	The chamber is currently allocated to a specific patient and time-lapse recording is in progress.	Section 2.5.3
	Inactive Chamber	The chamber is currently inactive and cannot be used for patient allocation or time-lapse recording.	Section 2.5.3
	Yellow Warning	The chamber has a warning.	Section 2.5.2
	Red Alarm	The chamber has an alarm.	Section 2.5.2

### 2.5.1. Instrument Status

From the Geri Status Hub, the instruments connected to Geri Connect & Geri Assess can be viewed, as well as the environmental data and any alarms and warnings. Environmental data, alarms and warnings can be exported as a CSV file download in the Chrome browser.


**To view temperature, CO<sub>2</sub> and humidity readings:** Click the Environmental Data icon  located next to the desired instrument. The Environmental Data Page is displayed showing the latest readings of temperature, CO<sub>2</sub> and humidity for seven days, by default.



**To select a different time period:** Click on **1 Day**, **7 Days** or **30 Days** located at the top left of the chart. The charts will display the environmental data for the selected time period.

**To select a different chamber:** Click on the desired Chamber Status icon located above the chart. The chart showing environmental data for the selected chamber will be displayed.

**NOTE:** Chamber one is selected by default.

**To export environmental data:** Click the Export icon  to export the data from the desired instrument or chamber. The data is exported as a CSV file.

**NOTE:** The exported file only contains the last 6 weeks of data.


**To return to the Geri Status Hub Page:** Click on the Back icon .

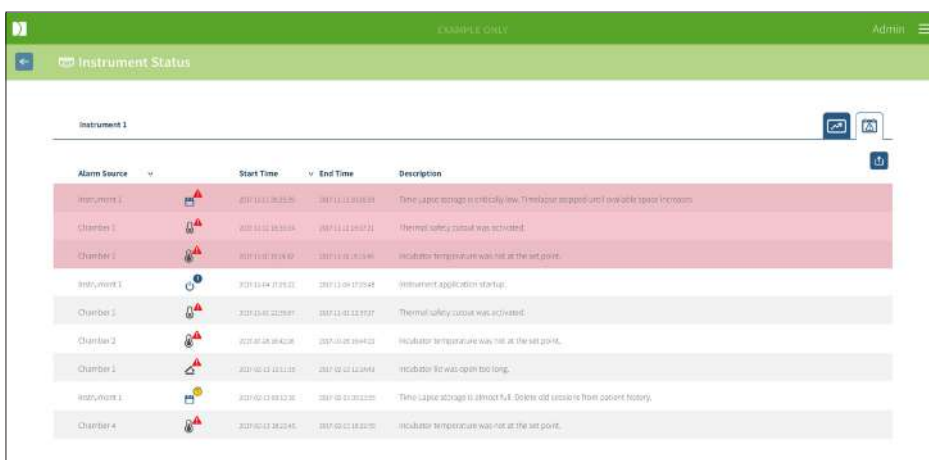
## 2.5.2. Alarms & Warnings



### WARNING:



Geri Connect & Geri Assess is not a substitute for a remote alarm system. The Geri Instrument includes an audible alarm and a remote alarm that serve as primary alarm notifications. The notifications on the Geri Connect & Geri Assess are for user convenience only. Please refer to QFRM869 Geri User Manual for more information.

**To view alarms and warnings:** Click the Alarms and Warnings icon  located next to the desired instrument. The Alarms and Warnings Page is displayed showing the latest alarms and warnings, as well as historical alarms and warnings.




Alarm Source	Start Time	End Time	Description
Instrument 1	2017-11-11 08:23:20	2017-11-11 08:23:20	There is poor storage in critically low. Threshold triggered and available space increases
Chamber 1	2017-11-11 08:23:04	2017-11-11 08:23:21	Thermal safety control was activated
Chamber 2	2017-11-11 08:23:07	2017-11-11 08:23:08	Incubator temperature was not at the set point
Instrument 1	2017-11-04 17:29:01	2017-11-04 17:29:04	Reimbursement application starting
Chamber 1	2017-11-02 22:29:07	2017-11-02 22:29:27	Thermal safety control was activated
Chamber 2	2017-11-01 08:42:08	2017-11-01 08:42:02	Incubator temperature was not at the set point
Chamber 1	2017-10-12 11:11:10	2017-10-12 11:29:43	Incubator lid was open too long
Instrument 1	2017-09-13 09:22:28	2017-09-13 09:22:28	There is poor storage in almost full. Delete old records from current history
Chamber 4	2017-09-12 18:22:45	2017-09-12 18:22:50	Incubator temperature was not at the set point

Alarms and warnings are displayed as a table showing the Alarm Source, Alarm Type, Start Time, End Time and Description.

- Ongoing alarms are highlighted in red with an alarm icon  and always appear at the top of the chart. Ongoing alarms do not show an End Time.
- Ongoing warnings are highlighted in yellow with a warning icon , always appear after ongoing alarms. Ongoing warnings also do not show an End Time.
- The Alarm Source column displays the chamber number for alarms and warnings related to a specific chamber, or the Geri instrument name for alarms and warnings on a Geri instrument level.

For detailed information about Alarms and Warnings see “8. Alarms & Warnings” in QFRM869 Geri User Manual.

### To export alarms and warnings:

1. Click the Export icon  to export data from the desired instrument or chamber. The data is exported as a CSV file.

### NOTE:







- The exported file only contains the last 6 weeks of data.

- Any alarms triggered and corrected within 5 minutes are not exported. These alarms are displayed in the Geri Status Hub.

**To return to the Geri Status Hub page:** Click on the Back icon .

### 2.5.3. Chamber Status

The Geri Status Hub displays the latest available status of the Geri instrument chambers. Each chamber is represented by one of the following states:

Icon	Name	Description
	Free Chamber	The chamber is currently active and not allocated to a patient.
	Allocated Chamber	The chamber is currently allocated to a specific patient, but time-lapse recording has not yet started.
	Time-Lapsing Chamber	The chamber is currently allocated to a specific patient and time-lapse recording of the embryo is in progress.
	Inactive Chamber	The chamber is currently inactive and cannot be used for patient allocation or time-lapse recording.
	Yellow Warning	The chamber has a warning (See “8. Alarms & Warnings” in QFRM869 Geri User Manual).
	Red Alarm	The chamber has an alarm (See “8. Alarms & Warnings” in QFRM869 Geri User Manual).

### 2.5.4. Connection Status

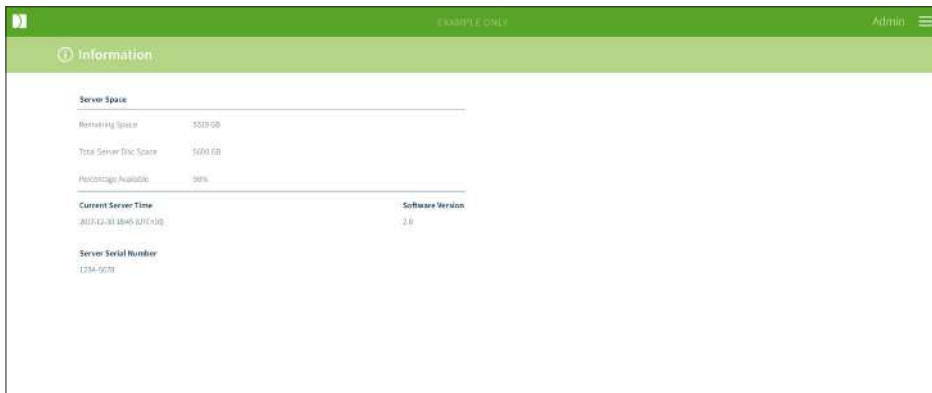
The connection status is located on the right-hand column of the Geri Status Hub and displays the time since the last communication between the Geri instrument and Geri Connect & Geri Assess. The time since last communication is refreshed whenever the Geri instrument attempts to synchronize with Geri Connect (even if no new data is available). If there is no communication between the Geri instrument and Geri Connect & Geri Assess for over 60 minutes, a warning symbol is displayed to indicate a communication error.

## 2.6. Information Page

All patient images and videos are stored on the Geri Connect & Geri Assess server. As the volume of data stored is high, it is important to monitor the available storage space on Geri Connect & Geri Assess. The Information Page displays Geri Connect & Geri Assess disk space data as three parameters:

- Remaining Space
- Total Server Disk Space
- Percentage Available

The Information Page also displays the current Geri Connect & Geri Assess server time and software version. Date and time values displayed across Geri Connect & Geri Assess pages will always be calculated according to the Geri Connect & Geri Assess server time.



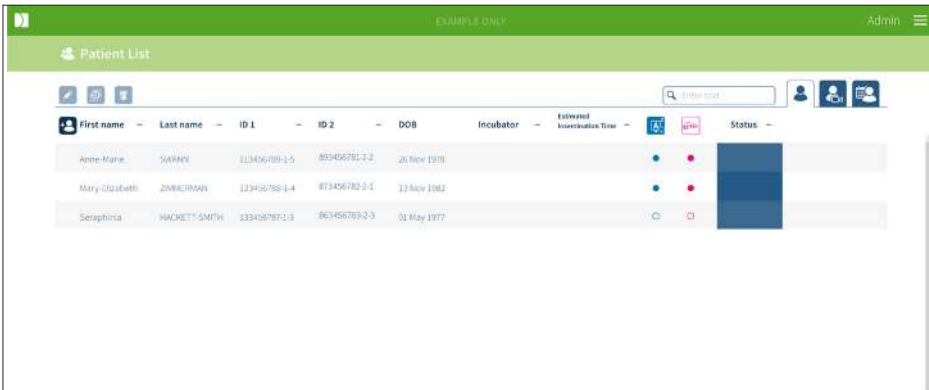
**To access the Information Page:** Select Information from the User Menu located at the top right of any page in Geri Connect & Geri Assess.

**NOTE:** A 'low disk' warning will appear when the server 'disk free' space falls below 720GB. At 20GB remaining disk space, the data synchronization with Geri(s) will pause. Steps should be taken to always ensure sufficient space is available on the server. (See section "5.5.1. Monitoring Available Storage Space" on page 54).

## 3. USING GERI CONNECT & GERI ASSESS





### 3.1. Patient List Tabs

Once logged into Geri Connect & Geri Assess, the Patient List Tabs are the default first page. From the Patient List Tabs, one can navigate to the User Menu, or start adding new patients, or viewing existing or historical patients.



Icon	Name	Description	More Information
	Added and unallocated patients	Tab to go to added and unallocated patient list.	Section 3.1.1
	Allocated and recording patients	Tab to go to list of patients that are allocated to a chamber and recording images.	Section 3.1.2
	Historical and data (image) reduction patients	Tab to go to list of historical patients stored on the Geri Connect & Geri Assess server.	Section 3.1.3
	New patient	Icon to add a new patient to the unallocated patients list	Section 3.1.4
	Edit patient details	Icon to edit patient details.	Section 3.1.5
	Data image reduction	After selecting an historical patient, icon used to reduce the video size.	Section 3.1.3
	Delete patient	After selecting a patient, this icon will delete all patient details and videos.	Section 3.1.3
	Geri Assess 2.0	Column indicating Geri Assess 2.0 enabled patients.	Section 3.1.6




Icon	Name	Description	More Information
	Patient Review Page	Quick link to display a highlighted patient's Patient Review Page	Section 3.2
	Patient Summary Page	Quick link to display a highlighted patient's Patient Summary Page.	Section 3.3
	Number of displayed items	Enables the selection of the number of patients displayed on a single page	
	Page numbers and navigation	Enables navigation between next and previous pages.	

The Patient List can be sorted by clicking on any of the following column headings:




- First Name
- Last Name
- Patient IDs (ID 1 & ID 2)
- Incubator Name
- Estimated Insemination Time
- Patient Status.

The Patient List can also be filtered using the search box located to the left of the Added and Unallocated Patients List Tab. By default, the Patient List Tabs are sorted by estimated insemination time, when first viewed. Where the list of patients extends over one page, page numbers are shown in the lower left corner and can be selected to navigate directly to that page. The number of patient displayed may also be modified in the lower right corner.

### 3.1.1. Unallocated Patients

The first tab  displays a list of Added and Unallocated Patients. The patients listed in this tab are indicated by no icon in the Status column, as shown above.

### 3.1.2. Allocated and Recording Patients

The second tab  displays a list of the Allocated and Recording Patients. The patients listed in this tab that are allocated, but not recording are indicated by a white dot  in the Status column. Those patients that are recording are indicated by a white camera  in the Status column.

First name	Last name	ID 1	ID 2	DOB	Incubator	Estimated Implantation Time	Status	Review	Summary
Sora	SUNGERLARO	133456788-1-3	833456785-2-1	25 Feb 1983	Inc 2 - 2	24 Nov 2017 11:25			
Jennifer	CHANG	833456787-1-6	843456784-2-2	13 Nov 1980	Inc 2 - 4	13 Nov 2017 14:35			
Abigail	SMITH	173456786-1-4	853456783-3-3	01 May 1977	Inc 2 - 3	11 Nov 2017 13:20			
Amanda	GARDNER	863456785-1-7	863456782-2-4	21 Apr 1982	Inc 2 - 5	07 Oct 2017 14:15			
Madeline	WINSLOW	133456784-3-9	873456781-0-5	06 Mar 1979	Inc 1 - 1	02 Oct 2017 00:10			

### To view currently recording images of a patient:

1. From the Allocated and Recording Patients Tab, locate the desired patient name.
2. Click on the Patient Review Page icon located to the right of the patient name. The Patient Review Page of the selected patient will be displayed.

### To view a summary of the embryos for a currently recording patient:

1. From the Allocated and Recording Patients Tab, locate the desired patient name.
2. Click on the Patient Summary Page icon located to the right of the patient name. The Patient Summary Page of the selected patient will be displayed.

### 3.1.3. Historical Patients

The third tab displays a list of the Historical Patients, which are patients that have finished recording and are saved on the Geri Connect & Geri Assess server. The patients listed in this tab are indicated by a white calendar in the Status column.

First name	Last name	ID 1	ID 2	DOB	Incubator	Estimated Implantation Time	Status	Review	Summary
Samantha	STEWARTSTEELE	132286789-1-7	823456713-2-3	26 Nov 1978	Inc 2 - 3	28 Nov 2017 11:15			
Caroline	COWAN	80456789-1-6	823456713-2-4	13 Nov 1982	Inc 2 - 4	15 Nov 2017 12:45			
Mylien	SHERWILL	19876788-1-5	823456714-2-5	01 May 1977	Inc 2 - 3	12 Nov 2017 13:35			
Rachel	PHILLIPS	14526786-1-4	823456715-2-6	21 Apr 1982	Inc 2 - 2	25 Oct 2017 20:35			
Alexa	ELLIOTT	17856789-1-8	823456716-2-7	08 Mar 1979	Inc 1 - 1	21 Oct 2017 09:30			





### To view previously recorded images of a patient:

1. From the Historical Patients Tab, locate the desired patient name.
2. Click on the Patient Review Page icon located to the right of the patient name. The Patient Review Page of the selected patient will be displayed.

### To view a summary of the embryos for an historical patient:


1. From the Historical Patients tab, locate the desired patient name.
2. Click on the Patient Summary Page icon located to the right of the patient name. The Patient Summary Page of the selected patient will be displayed.

**To perform data (image) reduction of a patient:**

1. From the Historical Patients tab, click to highlight the name of the desired patient.
2. Click on the Data Image Reduction icon  located between the edit and delete icons.
3. A pop-up window appears confirming deletion of the non-default playback videos. NOTE: This action cannot be undone.
4. Click on the Continue icon  to confirm image reduction.
5. A pop-up window will appear confirming successful image reduction. Click on the Continue icon  to return to the Historical Patient Tab.
6. Once the patient data is data image reduced, the Data Image Reduction icon  will appear in the Status column.

**NOTE:** data (image) reduction will delete all the focal planes, except the best focal plane, embryo-cropped z-plane.

**To delete a patient:**

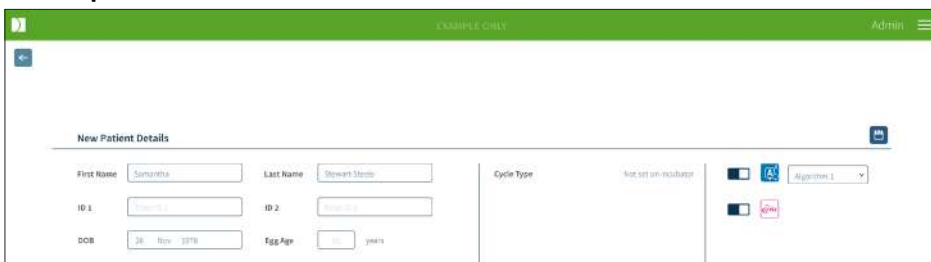
1. From any of the Patient List Tabs, click to highlight the name of the desired patient.
2. Click on the Delete icon .
3. A pop-up window appears confirming deletion of all videos from the selected session. NOTE: This action cannot be undone.
4. Click on the Delete Session icon to confirm session deletion.
5. A pop-up window will appear confirming successful deletion. Click on the Continue icon to return to the Historical Patient Tab.

**To export multiple historical patients:**

1. Ensure that you are logged in to Geri Connect & Geri Assess.
2. In the address field of the Chrome Browser, type: `http://{Server IP address of Geri Connect & Geri Assess or Domain}/candle/export_csv`
3. After pressing the Enter key, the download file will be generated.
4. A pop-up window will confirm the successful download of the CSV file, which can be opened in Excel.



**3.1.4. Adding a New Patient**

New patients are added from the Unallocated Patient List Tab, the first tab in the Patient List Tabs.

**To add a new patient:**


The screenshot shows the 'New Patient Details' form. The form is titled 'New Patient Details' and has a 'Save' button in the top right corner. The form contains the following fields and values:

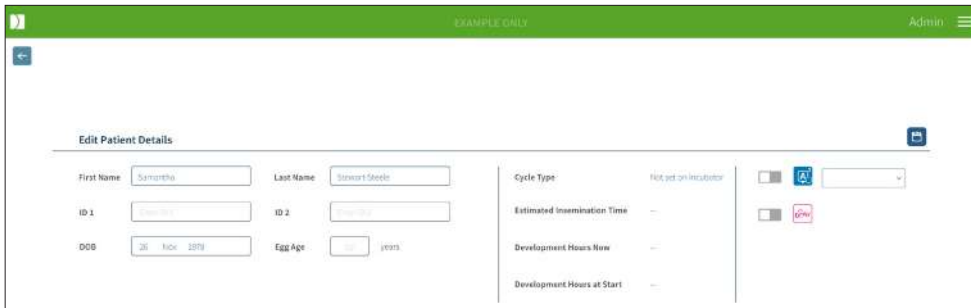
- First Name: Samantha
- Last Name: Steward Stone
- ID 1: [Empty]
- ID 2: [Empty]
- DOB: 28 Nov 1978
- Egg Age: 30 years
- Cycle Type: Not set on incubator
- Algorithm: 1

1. Click on the New Patient icon . The New Patient Details Page is displayed.
2. Using the computer keyboard, type in the new patient name, patient IDs and date of birth (DOB).
3. Click the Save icon  to add the new patient details.



**NOTE:** Cycle Type selection is performed on the Geri instrument once the Geri Dish is placed in the allocated chamber.

### 3.1.5. Editing Patient Details

Patient details can be edited from any of the Patient List Tabs.



**To edit patient details:**



1. Click on the desired patient name.
2. Click the Edit icon . The Edit Patient Details Page is displayed.
3. Using the computer keyboard, edit the patient details as required.
4. Click the Save icon  to update and save the patient details.

### 3.1.6. Adding a Geri Assess 2.0 Enabled Patient

Geri Assess 2.0 enabled patients are added from the Edit Patient Details Page.



**To add a Geri Assess 2.0 enabled patient:**

1. Click on the patient name to be edited.
2. Click on the Edit icon . The Edit Patient Details page is displayed.
3. Ensure that the switch located next to the Geri Assess 2.0 icon  is in the on

position .

4. Click the Save icon  to update and save the patient details.

**NOTE:** prior to starting recording, a Geri Assess 2.0 Enabled Patient can be disabled by moving the switch located next to the Geri Assess 2.0 icon to the off position. Click the Save icon to update and save the patient details.

### 3.1.7. Allocating a Patient to a Chamber

A patient can only be allocated to an empty chamber on a Geri instrument that is connected to the Geri Connect & Geri Assess server. Please see “7.4.6. Allocating a Patient to a Chamber” in QFRM869 Geri User Manual.

### 3.1.8. Synchronization Status



**WARNING:**

During the synchronization process, available playback of video on Geri Connect & Geri Assess may not include up to the last five images taken on Geri instrument.

Synchronization is a process of synchronizing the available patient data on a Geri instrument to Geri Connect & Geri Assess. Once the connection is enabled by an Administrator, the Geri instrument will start sending patient data to Geri Connect & Geri Assess. Due to the high volume of images and videos associated with each patient, the initial Synchronization process may take some time. The Synchronization Status field displays the percentage of data that was transferred from the Geri instrument to Geri Connect & Geri Assess for each patient. Synchronized patients will display a Synchronization Status of (or close to) 100%.

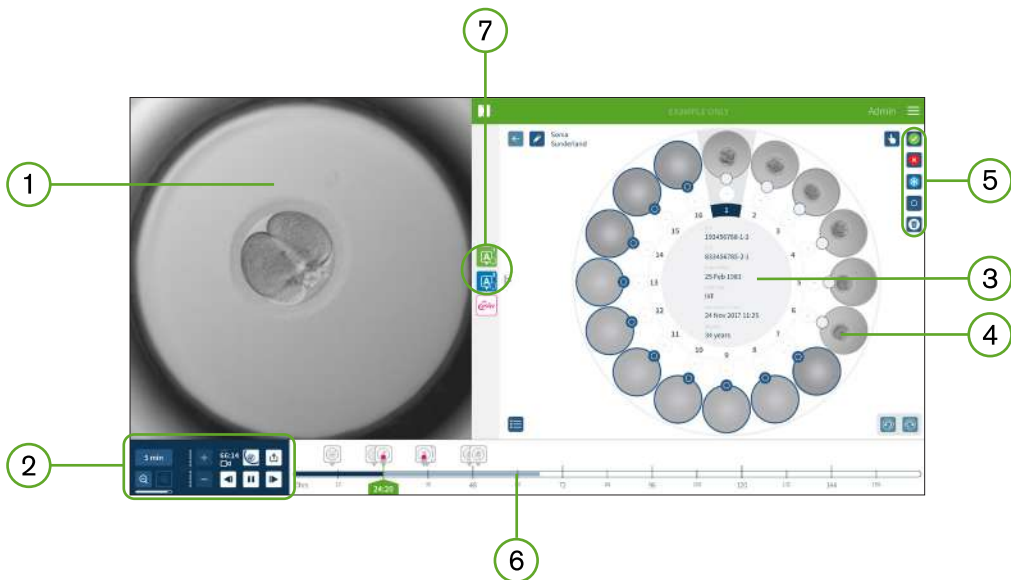
Geri Connect & Geri Assess Synchronization times are stated in the following table:

Video Playback on Geri Connect & Geri Assess	Up to 35 minutes behind real-time
Geri Instrument Alarm Status & History	Up to two minutes behind real-time
Patient Details Synchronization	Up to five minutes behind real-time
Embryo Fate Synchronization	Up to two minutes behind real-time
Geri Instrument Environmental Monitoring Data	Up to six minutes behind real-time


## 3.2. Patient Review Page

Patient embryos are reviewed, tagged and annotated\* from the Patient Review Page. It is similar to the Geri instrument user interface and features similar functionality.

\*Annotating embryos is explained in further detail in “3.4. Annotating Embryos Using Geri Assess” on page 25.


















- ① Display of the selected embryo
- ② Video playback controls
- ③ The Geri Dish with patient details
- ④ Embryos in the micro-wells
- ⑤ Embryo tagging icons
- ⑥ Timeline Bar shown in hours with any annotations detected by the automated annotation software module
- ⑦ The Geri Assess 1.0 and Geri Assess 2.0 Tabs

**NOTE:** The image that is displayed by default is the embryo-cropped, best focal plane image. To view a full view of the micro-well and move through the z-stacks, click on the Full View  icon.


### 3.2.1. Playback Controls

The following icons are displayed for the Playback Controls of the Patient Review Page:

Icon	Action	Keyboard Shortcut
	Playback Speed: the speed of playback can be adjusted to display an image taken every 5, 10 or 30 minute. Click the button to change the speed.	1, 2, 3
	Zoom In and Zoom Out: click to zoom in or out of the image. The bar below these icons represents the zoom range and its current position within that range.	
	Z-stack (focal plane): click <b>+</b> or <b>-</b> to move up or down between the focal planes. <b>NOTE:</b> This feature is turned off when the embryo crop button is active.	W – up S – down
	Hours: recording – the total time of recording up to this point.	
	Embryo Crop: detects the central focal plane of the embryo.	
	Full View: entire view of micro-well – can use the z-stack option.	
	Export Data: to export an image, video, patient report or CSV file containing the annotation data.	
	During Playback: 40 frames forward	D
	During Pause: 1 frame forward	D
	During Playback: 40 frames backward	A
	During Pause: 1 frame backward	A
	Play	Space Bar
	Pause	Space Bar
	View the previous micro-well.*	Q
	View the next micro-well.*	E

\*These two controls are found on the right-hand side of the Patient Review Page under the Geri Dish and when clicked will take you to the exact time of the previously selected embryo.

The embryo can also be moved around the field of view by clicking and dragging it with the mouse.

	<p><b>WARNING:</b></p> <ul style="list-style-type: none"> <li>▪ It is recommended that patient details and embryo fates be updated from Geri Connect &amp; Geri Assess. Where update of patient details or embryo fates is performed on the Geri instrument, the user should wait until the changes are visible on Geri Connect &amp; Geri Assess before making any further changes to the relevant patient on other Geri instruments or Geri Connect &amp; Geri Assess. When changes are made simultaneously on different instruments (Geri instruments or Geri Connect &amp; Geri Assess) only the latest change will be saved and other changes will not be recorded.</li> <li>▪ Should Geri be disconnected from Geri Connect &amp; Geri Assess, perform all session and patient editing on the Geri instrument. When Geri is reconnected to Geri Connect &amp; Geri Assess, all changes made on the Geri instrument will be synchronized with Geri Connect &amp; Geri Assess.</li> </ul>
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### 3.2.2. Video Playback Watermark Information

When viewing the videos of the embryos in the micro-well, a number of warnings regarding the videos may be displayed.

During video playback the following warnings may appear:

**No Video Available:** The video has not yet been captured, for example, images have not been taken, server synchronization delay, or data image reduced patient.

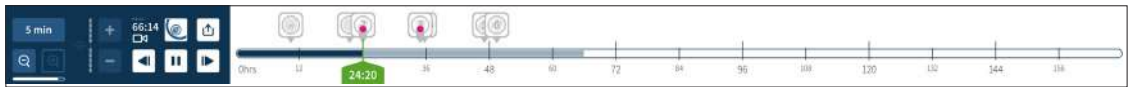
**Loading...:** The video file is loading. This may occur when switching between z-stacks or micro-wells.

**Empty well:** The micro-well has been tagged as empty. Videos have been captured although the micro-well preview and playback have been disabled. Remove the empty well tag to remove these restrictions.

**No stream selected:** Occurs when no well is selected in the Patient Review Page. Click on another micro-well to clear this error.



## 3.2.3. Timeline Bar



The Timeline Bar displays the timeline during embryo development and is displayed in hours.

Color on the timeline bar indicates the following:

- **Light Blue:** Time-lapse playback has been recorded but not yet reviewed.
- **Dark Blue:** Time-lapse playback has been viewed.
- **Blank:** No video prior to starting time-lapse, after it had finished, or because it is in the future and therefore not yet captured.
- **Green Position Indicator:** the position on the timeline of the current displayed image. The number displayed represents the time since insemination in hours and minutes.




**NOTE:** To update an existing event annotation, move the green slider to the position of the annotation, right click on the green slider to display a list of existing annotations and select the event as required. The position will now update on the timeline bar.



## 3.2.4. Tagging Embryos

All embryos tagged in Geri Connect & Geri Assess are synchronized with the Geri instrument. Likewise, all embryos tagged on the Geri instrument are synchronized to Geri Connect & Geri Assess.

Icon	Description
	Multi-Select: Click this icon to highlight multiple micro-wells.
	Cryopreservation Tag: Click this icon to tag an embryo for cryopreservation.
	Discard Tag: Click this icon to tag an embryo for discard.


	Transfer Tag: Click this icon to tag an embryo for transfer.
	Empty Micro-Well Tag: Click this icon to tag an empty micro-well. Images from these micro-wells will not be exported to Geri Connect & Geri Assess and cannot be played back on the timeline.
	Delete Tag: Click this icon to remove a tag placed against an embryo.

### 3.2.5. Exporting Data

The following data can be exported from the Patient Review Page in Geri Connect & Geri Assess:

- **Image:** a static image of the embryo in the micro-well that is displayed on the page.
- **Video:** an MP4 file and current focal plane of the embryo in the micro-well that is displayed on the page. **NOTE:** the MP4 file is compatible with QuickTime® or VLC Media Player, but not Windows Media Player.
- **PDF:** a Patient Report in a PDF format. This report lists patient and clinic information and contains static images of the first image taken of all the embryos, as well as an image from each embryo every 24 hours during embryo development.
- **CSV:** a CSV file containing key data points for each embryo, including patient information and annotation data of Events and Observations from Geri Assess 1.0 and Geri Assess 2.0 (if enabled). The score column displays the Geri Assess 1.0 score for each event.

**To export data:**

1. In the Patient Review Page, click on the desired embryo to be exported.
2. Click on the Export icon  and select the desired output.





3. A Report Well Selection dialog box will appear. Select the wells to export to the PDF report.
4. The \*.png and video files will download to the Chrome Downloads folder. The patient reports as PDF files and CSV files will generate and then download to the Chrome Downloads folder. A pop-up window will inform the user that the export was successful and ask to confirm to continue.

### 3.3. Patient Summary Page

The Patient Summary Page displays a summary of all embryos in the micro-wells of the Geri dish and all the event and observation annotations.



- ① The patient details are displayed at the top of the page. This information can be edited by clicking on the Edit icon .
- ② The embryos contained in the Geri Dish are shown down the left side of the page with a Timeline Bar for each embryo.
- ③ A score (if applicable), Geri Assess 1.0 and Geri Assess 2.0 columns are shown on the right.
- ④ The hours are indicated at the bottom of the page.
- ⑤ The embryo tag selected in the Patient Review Page is shown here and to view the embryo in the Patient Review Page, click on the image of the desired embryo.
- ⑥ The Score, Geri Assess 1.0 and Geri Assess 2.0 columns can be used to sort the embryos in the Patient Summary Page by clicking on the appropriate column icon.
- ⑦ Any comments entered on the Patient Review Page can be seen by clicking on the Comments icon .

#### 3.3.1. Timeline Bar

The Timeline Bar in the Patient Summary Page again displays the timeline during embryo development and is displayed in hours. However, this Timeline Bar relates to where the latest annotation is placed.

The Timeline Bar will be dark blue to the point of the latest annotation, after that time point, the Timeline Bar will be light blue. If no annotations are placed, the Timeline Bar will be light blue as shown in Micro-Well 2 above.

Preliminary Geri Assess annotations will be shown in gray on the Timeline Bar. Once those annotations have been reviewed and finalized the annotations will change to dark blue.


### 3.4. Annotating Embryos Using Geri Assess



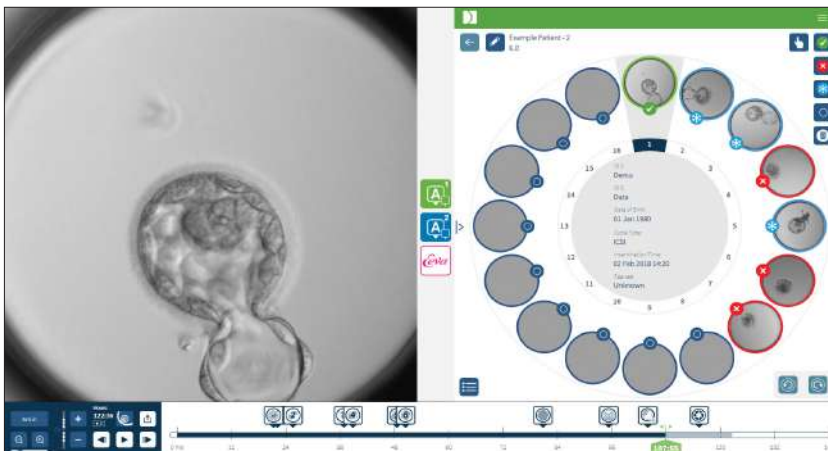
#### WARNING:

- Automated Annotations will not be correct and accurate in all instances and as such, the Geri Connect & Geri Assess software is not intended to replace clinical practices for review and assessment of embryos. Users are responsible for manually reviewing embryo developmental events they consider critical.

Embryos can be annotated manually or automatically, by assigning Events and/or Observations. Events are defined as milestones in the development on an embryo. Events can be key, representing a major milestone in embryo development, for example, PN appearance, 4-cell. Observations are defined as abnormalities that can affect the quality of an embryo, such as fragmentation and reverse cleavage.

**NOTE:** The image that is displayed by default is the full view of the micro-well, allowing adjustment through the z-stacks. To view the embryo-cropped, best focal plane image, click on the Embryo Crop  icon.

All playback controls and features of the Timeline Bar are described in sections “3.2.1. Playback Controls” on page 18 and “3.2.3. Timeline Bar” on page 21.




#### 3.4.1. Accessing Geri Assess




#### WARNING:

- Automated Annotations will not be correct and accurate in all instances and as such, the Geri Connect & Geri Assess software is not intended to replace clinical practices for review and assessment of embryos. Users are responsible for manually reviewing embryo developmental events they consider critical.

Geri Assess can be accessed from the middle panel on the Patient Review Page.

**To access Geri Assess 1.0:** Click the Geri Assess 1.0 icon  located in the middle panel of the Patient Review Page.

The Geri Assess 1.0 Tab is shown with the first Development Chapter shown as default (see image below)

**To access Geri Assess 2.0 (for Geri Assess 2.0 enabled patients):** If Geri Assess 2.0 is enabled, click the Geri Assess 2.0 icon  located in the middle panel of the Patient Review Page.

The Geri Assess 2.0 Tab is shown, with a list of key Events and Observations shown as default (see image below).


If Geri Assess 2.0 is not enabled, the Geri Assess 2.0 tab is not accessible. A red Not Available icon will appear when hovering over the tab.

Geri Assess 1.0



Geri Assess 2.0



**To close the Geri Assess Tabs:** Click on the Close icon  located in the center of the page, to close the annotation tabs.

### 3.4.2. Geri Assess 1.0 – Manually Annotating Events & Observations

**To display the six Development Chapters:** In the Patient Review Page, click on the Geri Assess 1.0 Tab.

Each Development Chapter can be accessed and expanded by clicking on the Development Chapter heading - the heading will be highlighted in blue. The next Development Chapter can be displayed by pressing the TAB key on the keyboard and the previous Development Chapter can be displayed by pressing Shift-TAB.

The playback functions (green position indicator, icons and/or keyboard shortcut keys) can be used to review embryo development images. See “3.2.1. Playback Controls” on page 18 and “3.2.3. Timeline Bar” on page 21 for further information.

### To manually annotate an Event or Observation:

When an Event or Observation is observed by a user during image playback, it is annotated by manually clicking on the Event/Observation listed on the Geri Assess 1.0 Tab.

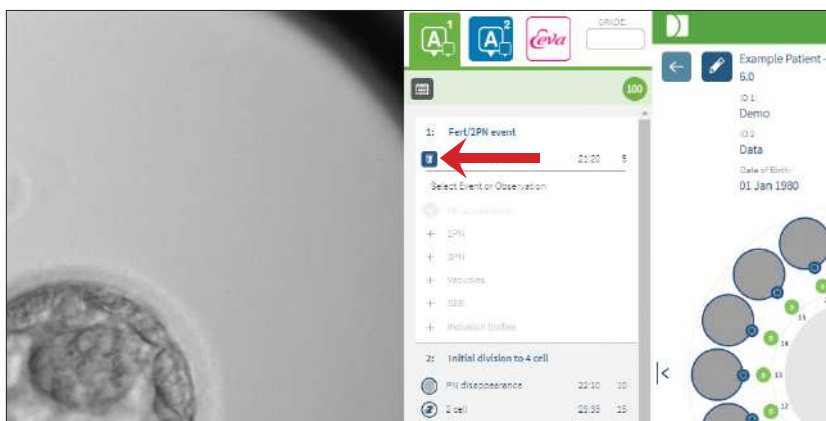
An embryo development Event only occurs once, as a result, Events can only be annotated once. Annotations can be placed in any Development Chapter, regardless of the other chapters.


After a Key Event has been annotated, a filled blue icon will appear on the Timeline Bar at the time-point the annotation was made. Hovering over the icon displays the Event name and Event time-point. Non-key events if annotated will also appear as a filled blue icon on the Timeline Bar. New events that are added in the Score Configuration page are displayed as a placeholder with a blue dot.

There may be multiple instances of Observations during a single Development Chapter. As a result, Observations may be annotated multiple times within the same Development Chapter. Observations if annotated will appear as downward facing arrows on the Timeline Bar.

### To delete an Event or Observation in Geri Assess 1.0:

1. On the Geri Assess 1.0 Tab, click the desired Event or Observation line, ensuring that the Event is not in the gray highlighted area.



2. Click on the Discard icon  that appears to the left of the selected Event or Observation, as indicated by the red arrow. The time stamp for the selected Event or Observation will be removed, as will the icon on the Timeline Bar.


**To move the playback video to an Event or Observation:** Click the desired Event or Observation in the Geri Assess 1.0 Tab, or the icon in the Timeline Bar.

The video will move to the selected time-point.

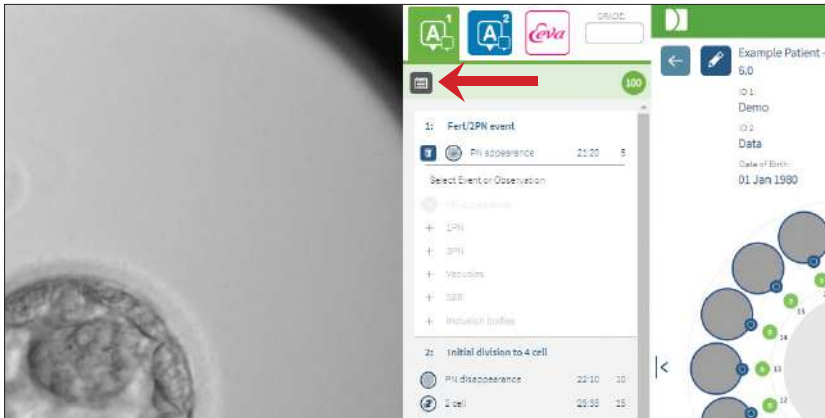
**To make comments about an embryo in Geri Assess 1.0:** Type free text into the Comments

box underneath the Events and Observations.

Comments can also be viewed by clicking on the Comments box in the Patient Summary Page.

**To view assessment history:** Click on the Assessment History icon  from the Geri Assess 1.0 Tab, as indicated by the red arrow in the image below.

A log of the Events and Observations annotated with Geri Assess 1.0 will be displayed in a pop-up window. It will include the annotation details, user name and time and date of the user making the annotation.



### 3.4.3. Geri Assess 2.0 – Automatically Annotating Events & Observations



#### **WARNING:**

- Automated Annotations will not be correct and accurate in all instances and as such, the Geri Connect & Geri Assess software is not intended to replace clinical practices for review and assessment of embryos. Users are responsible for manually reviewing embryo developmental events they consider critical.

Geri Assess 2.0 is the automated scoring system/software to annotate embryos, using the best focal plane, embryo-cropped video. When enabled, it will automatically populate the Geri Assess 2.0 tab and Timeline Bar with Key Events and Observations that the automated annotations algorithm is able to successfully detect.

If the patient is Geri Assess 2.0 enabled, Geri Assess 2.0 will review the time-lapse images as recording progresses, starting after the first 24 hours of recording have passed, annotating certain developmental events and observations automatically. The annotated events are pronucleus/ pronuclei appearance, pronucleus/ pronuclei disappearance, divisions to 2-, 3-, 4-, 5- and 6-cell stages, transitions to morula, early blastocyst, expanded and hatching blastocyst stages. The observations are reverse cleavage and failed cytokinesis back to 2-cell stage and embryo fragmentation. These events/observations will be initially shown as gray event markers on the Timeline Bar and as annotated times in the Geri Assess 2.0 tab. At the end of recording, Geri Assess 2.0 will finalize the annotations and change the event




markers on the Timeline Bar from gray to blue.

If a custom scoring algorithm has also been selected, the algorithm that has been used is shown in the Geri Assess 2.0 gray header tab, just under the tabs, as indicated by the arrow in the following screen-shot.



For the automated annotations, each embryo development Event must fall between a specific range to be included in the annotations. This is to exclude any annotations that are biologically impossible for the given event. These ranges have been determined by literature review (Balaban, B. *et al.* (2011) "Istanbul consensus workshop on embryo assessment: proceedings of an expert meeting." *Reproductive BioMedicine Online* **22(6)**: 632-646 and Ciray, H.N. *et al.* (2014) "Proposed guidelines on the nomenclature and annotation of dynamic human embryo monitoring by a time-lapse user group." *Human Reproduction* **29(12)**: 2650-2660.).

If embryo development falls within the specified range, annotation icons are presented on the Timeline Bar and the time will be noted on the Geri Assess 2.0 Tab. The same information will also be presented on the Patient Summary Page.


If embryo development falls outside the specified range, a yellow triangle  is marked in the Geri Assess 2.0 Tab and the time stamp shown in red. No annotations will be presented on the Timeline Bar in this case.

Geri Assess 2.0 can also detect **fragmentation**, which will be presented as a blue bar above the Timeline Bar and noted as a percentage range in the Geri Assess 2.0 Tab.

**NOTE:** Automated Annotations will not be correct and accurate in all instances and as such, they are not intended to replace clinical practices for review and assessment of embryos. Users are responsible for manually reviewing embryo developmental events they consider critical.

If an automated annotation is viewed by an embryologist and deemed as incorrect, it can be modified. The modification is performed in the Geri Assess 1.0 Tab and then noted as modified in the Geri Assess 2.0 Tab.

**To modify an automated annotation:**

1. Click on the Geri Assess 1.0 Tab.
2. Select the Event or Observation line that you want to modify, ensuring that it is not in the gray highlighted area.
3. Click on the Discard icon  that appears to the left of the selected Event or Observation. The Event or Observation will be deleted from the Timeline Bar and the Geri Assess 1.0 Tab.
4. Review the playback video for the embryo of interest, find the time that the Event or Observation occurred.
5. In the Geri Assess 1.0 Tab, click on the desired Event or Observation to add it to the Timeline Bar.

**NOTE:** In the Geri Assess 2.0 Tab, the Event or Observation will be shown as modified, with a time stamp. If the modified annotation needs to be modified again, or reverted back to the original automated annotation, click on the reverse icon beside the modified annotation in the Geri Assess 2.0 Tab.

**NOTE:** if the modified annotation had a yellow triangle, the yellow triangle will remain to indicate that the automated annotation has fallen outside the specified range.

**To move the playback video to an Event or Observation:** Click on the Event or Observation listing in the Geri Assess 2.0 tab, or the icon in the Timeline Bar.

The video will move to the selected time-point.

**NOTE:** If embryos from a patient do not develop as expected, it is best to review and assess the developmental events of the embryos.

**NOTE:** Automated Annotations will not be correct and accurate in all instances and as such, they are not intended to replace clinical practices for review and assessment of embryos. Users are responsible for manually reviewing embryo developmental events they consider critical.

### 3.4.4. List Of Events & Observations

The following is a list of the Development Chapters, **Key Events**, other **Events** and **Observations** in Geri Assess. The Key Events, Reverse Cleavage and Fragmentation will be automatically annotated if Geri Assess 2.0 is enabled.

1. Fert/2PN Event
  - **PN Appearance**
  - Vacuoles
  - 1PN
  - Smooth Endoplasmic Reticulum (SER)
  - No halo formation
  - 3PN
  - Inclusion bodies
2. Initial Division to 4 Cell
  - **PN disappearance**
  - **2 cell**
  - **3 cell**
  - **4 cell**
  - Vacuoles
  - Fragmentation up to 10%
  - Fragmentation 11-25%
  - Fragmentation >25%
  - Multi-nucleation
  - Direct Cleavage
  - Uneven Blastomere Size
  - Irregular Division
  - **Reverse Cleavage (back to 2-cell)**
3. Up to 8 Cell
  - **5 cell**
  - **6 cell**
  - 7 cell
  - 8 cell
  - Vacuoles
  - Fragmentation up to 10%
  - Fragmentation 11-25%
  - Fragmentation >25%
  - Multi-nucleation
  - Uneven Blastomere Size
  - Irregular Division
  - Reverse Cleavage
  - >8 Cell no compaction
4. Up to Morula
  - Compaction
  - **Morula**
  - Vacuoles
  - Fragmentation up to 10%
  - Fragmentation 11-25%
  - Fragmentation >25%
  - Multi-nucleation
  - Reverse Development
  - >8 Cell no compaction
5. To Expanded Blastocyst
  - **Cavitation/Early Blast**
  - Full Blastocyst
  - **Expanded Blastocyst**
  - Blastocyst Collapse
  - No Inner Cell Mass
  - Fragmented/vacuole Inner Cell Mass
  - Fragmented/vacuole Trophectoderm
  - Incomplete compaction of ICM
  - Low Trophectoderm Number
  - Double Inner Cell Mass
6. To Fully Hatched Blastocyst
  - **Hatching Blastocyst**
  - Half Hatched Blastocyst
  - Fully Hatched Blastocyst
  - Blastocyst Collapse
  - Fragmented/vacuole Inner Cell Mass
  - Fragmented/vacuole Trophectoderm
  - No Inner Cell Mass
  - Low Trophectoderm Number
  - Double Inner Cell Mass
  - Incomplete compaction of ICM

## 3.5. Custom Scoring Algorithms

Custom Scoring Algorithms enable the user to define how Geri Connect & Geri Assess scores embryos based on timings of the annotations. The algorithm will be defined in a text file of comma separated values.

Custom Scoring algorithms are installed by an authorized service technician.

### 3.5.1. Terminology

- **Algorithm:** A set of instructions.
- **Models File:** File defining criteria for embryo grading using annotations.
- **Rule:** A condition defining how to evaluate a given event.
- **Clause:** A line in the Models File, a set of 3 rules assigned to a given Model.
- **Model:** A set of Clauses which have an associated grade.
- **Annotation:** Observations or events, either identified by Geri Assess 2.0 automatically or manually added by a user.

### 3.5.2. Creating Models File

1. The first line is the fields:

Model\_name,Grade,Start1,End1,Condition1,Minimum1,Maximum1,Start2,End2,Condition2,Minimum2,Maximum2,Start3,End3,Condition3,Minimum3,Maximum3

2. Each line (Clause) after this follows the template in the top line, separated by commas.
  - a. **Model\_name:** The name to assign to the model. All rules with the same Model\_name will be grouped together.
  - b. **Grade:** The score added to the embryo if the rule matches.
  - c. **Rules:** Each Clause has 3 rules. For the Grade to be applied, all 3 rules must match.
    - i. **Start:** The annotation name to start the rule (for example – 3 cell)
    - ii. **End:** The annotation name to end the rule
    - iii. **Condition:** Specify Between or Not between
    - iv. **Minimum:** Minimum time between the annotations in seconds
    - v. **Maximum:** Maximum time between the annotations in seconds

#### NOTE:

- There is a special annotation Start which indicates the insemination time. If the Start and End fields of a rule are both set to Start then the rule will be ignored. You can use this to provide less than 3 rules in a Clause.
- You can find a sample Models File in Section 4.5.3.
- All fields in the actual Models File must be separated by commas.

3.5.3. Sample Models File

**NOTE:** This is a sample reference for building a models file based on embryologist knowledge. **DO NOT** load this template onto a live system.

Model name	Grade	Start1	End1	Condition1	Minimum1	Maximum1	Start2	End2	Condition2	Minimum2	Maximum2	Start3	End3	Condition3	Minimum3	Maximum3
Model1	100	Start	C	Between	1900	2100	B	C	Between	900	1100	Start	E	Between	3900	4100
Model1	88	Start	C	Between	1900	2100	B	C	Between	900	1100	Start	E	Not between	3900	4100
Model1	75	Start	C	Between	1900	2100	B	C	Not between	900	1100	Start	E	Between	3900	4100
Model1	63	Start	C	Between	1900	2100	B	C	Not between	900	1100	Start	E	Not between	3900	4100
Model1	50	Start	C	Not between	1900	2100	B	C	Between	900	1100	Start	E	Between	3900	4100
Model1	38	Start	C	Not between	1900	2100	B	C	Between	900	1100	Start	E	Not between	3900	4100
Model1	25	Start	C	Not between	1900	2100	B	C	Not between	900	1100	Start	E	Between	3900	4100
Model1	13	Start	C	Not between	1900	2100	B	C	Not between	900	1100	Start	E	Not between	3900	4100
Model2	100	B	E	Between	2900	3100	C	E	Between	1900	2100	Start	Start	Between	0	0
Model2	75	B	E	Between	2900	3100	C	E	Not between	1900	2100	Start	Start	Between	0	0
Model2	50	B	E	Not between	2900	3100	C	E	Between	1900	2100	Start	Start	Between	0	0
Model2	25	B	E	Not between	2900	3100	C	E	Not between	1900	2100	Start	Start	Between	0	0
Model3	100	Start	C	Between	1800	1900	B	C	Between	900	950	Start	E	Between	3900	4100
Model3	88	Start	C	Between	1800	1900	B	C	Between	900	950	Start	E	Not between	3900	4100
Model3	75	Start	C	Between	1800	1900	B	C	Not between	900	950	Start	E	Between	3900	4100
Model3	63	Start	C	Between	1800	1900	B	C	Not between	900	950	Start	E	Not between	3900	4100
Model3	50	Start	C	Not between	1800	1900	B	C	Between	900	950	Start	E	Between	3900	4100
Model3	38	Start	C	Not between	1800	1900	B	C	Between	900	950	Start	E	Not between	3900	4100
Model3	25	Start	C	Not between	1800	1900	B	C	Not between	900	950	Start	E	Between	3900	4100
Model3	13	Start	C	Not between	1800	1900	B	C	Not between	900	950	Start	E	Not between	3900	4100

### 3.5.4. Uploading a New Custom Scoring Algorithm



Custom scoring algorithms are installed by an authorized service technician. Contact your authorized service technician for more information.

### 3.5.5. Updating a Custom Scoring Algorithm

When more than one custom scoring algorithm is to be used in Geri Connect & Geri Assess, all the models files in the system must be represented in the one file to be uploaded and replaced by an authorized service technician.

### 3.5.6. Applying a Custom Scoring Algorithm

**To access and apply a custom scoring algorithm:**

1. On the Edit Patient Details Page, ensure that the switch located next to the Geri Assess 2.0 icon  is in the on position . (see “3.1.6. Adding a Geri Assess 2.0 Enabled Patient” on page 16)
2. Select the desired custom scoring algorithm from the drop-down menu located to the right of the Geri Assess 2.0 switch. An average option is also available, which combines the custom scoring algorithms to provide an average score. The selected algorithm will be applied to the selected patient and a pop-up window will confirm that a new algorithm has been selected.
3. Click OK to return to the Patient Review Page.

**NOTE:** If a custom scoring algorithm is changed, the new custom scoring algorithm can be applied retrospectively on historical patients that are Geri Assess 2.0 enabled. If patients are deleted, the new algorithm will not be applied.

## 4. ADMINISTRATOR TASKS

### 4.1. Administrator User Management



Administrators have unrestricted access in Geri Connect & Geri Assess.

**NOTE:** The number of users with Administrator access should be restricted to maintain quality control and security in a standardized system.

#### 4.1.1. Adding a New User



**NOTE:** Only Admin users have access to the functionality in this section.

**To add a new user:**

1. Select User Management from the User Menu located on the top right of any page in Geri Connect & Geri Assess. The User Management Page is displayed.
2. Click the Add New User icon . The New User Details Page is displayed.
3. Enter the new user's name, email, username and password, as required.  
**NOTE:** the password must contain more than four characters.
4. Click the Save icon  to save any changes.




#### 4.1.2. Managing an Existing User

**To edit and manage existing users:**


1. Select User Management from the User Menu located on the top right of any page in Geri Connect & Geri Assess. The User Management Page is displayed.
2. Click to highlight the name of the desired user.
3. Click the Edit icon . The Edit User Details Page is displayed.
4. Edit the name, email or password as required.  
**NOTE:** The Username cannot be edited.
5. Click the Save icon  to save any changes.

#### 4.1.3. Disabling and Re-enabling an Existing User


**To disable an existing user:**

1. Select User Management from the User Menu located on the top right of any page in Geri Connect & Geri Assess. The User Management Page is displayed.
2. Click to highlight the name of the desired user.
3. Click the Active switch from active  to inactive .  
**NOTE:** User details are never deleted or removed, as all annotations are recorded together with the user details.
4. Click the Save icon  to save any changes.


**To re-enable an existing user:**

1. Select User Management from the User Menu located on the top right of any page in Geri Connect & Geri Assess. The User Management page is displayed
2. Click to highlight the name of the user to re-enable.
3. Click the Active switch from inactive  to active .
4. Click the Save icon  to save any changes

**4.1.4. Assigning and Disabling an Administrator****To assign administrator capabilities to a user:**

1. Select User Management from the User Menu located on the top right of any page in Geri Connect & Geri Assess. The User Management Page is displayed.
2. Click to highlight the name of the desired user.
3. Click the Admin switch from inactive  to active .
4. Click the Save icon  to save any changes.

**To disable administrator capabilities of a user:**

1. Select User Management from the User Menu located on the top right of any page in Geri Connect & Geri Assess. The User Management Page is displayed.
2. Click to highlight the name of the desired user.
3. Click the Admin switch from active  to inactive .
4. Click the Save icon  to save any changes.

**NOTE:** Users with administration privileges cannot disable their own user accounts or remove their own administration privileges (this must be performed by another user with Administrator privileges). This ensures that at least one Administrator will be defined in Geri Connect & Geri Assess at all times.

**4.1.5. Connecting Geri Incubators to Geri Connect & Geri Assess**

After installation by an authorized service technician, the instrument name is displayed as New Incubator. All chambers are displayed as inactive and the Connection Status is displayed as "...Awaiting connection by admin user."

**NOTE:** To change the instrument name, please refer to "4.8. Incubator Information (Including Instrument Name)" on page 26 in QFRM869 Geri User Manual.

**To enable connection of the Geri Incubator:**

1. Select Geri Status Hub from the User Menu list on the top right of any page in Geri Connect & Geri Assess. The Geri Status Hub Page is displayed.
2. In the Enabled column, change the Enabled switch to the On position .

Geri Connect & Geri Assess will start to communicate with the Geri incubator and synchronize data.

**NOTE:** After synchronization, the data presented in the Geri instrument row on the Geri Status Hub will change to reflect the latest available instrument status.



## 4.2. Score Configuration in Geri Assess 1.0

Geri Assess 1.0 is a subjective, user-defined scoring system based on manual annotation of Events and Observations of embryo development during playback of time-lapse videos. Based on scores assigned to each Event and Observation, the system produces a score that ranks the patient's embryos. This score is the sum of the maximum event score, plus the accumulated total of all defined observations (observations include reverse cleavage in chapter 2).

Thus the score for Geri Assess 1.0 = maximum of the Events + Sum of the Observations.

Geri Assess 1.0 software by default has all Event and Observation score weightings set to zero ("0"). Only administrators are able to adjust the score weightings for each Event and Observation to reflect the lab's specific and individual protocols. Any changes made to the score weightings are reflected across all current and historical patients, including any annotations that have already completed. Users will see changed scores of embryos already annotated as a result of adjusting the score weightings.

- **Events** are milestones in the development of an embryo. Each Event should have a positive score. Each Event score is an absolute accrued total of all Events up to that development point. For example: if an early stage development point (e.g. 2PN) Event score is set at 20, then a subsequent later stage development (e.g. 4-cell) Event score is set at 25. In this example, the scoring system will only take into account the latest development Event (e.g. 4-cell) and its score of 25. The scoring system does not add the two positive scores together.
- **Key Events** are Events that represent major milestones in the embryo development. These are represented on the Timeline Bar with their own representative icon. Key Events cannot be disabled on the Score Configuration Page and also represent those annotations that are automatically annotated in Geri Assess 2.0.

Reverse Cleavage to 2-cell is an automated annotation that is recognized by Geri Assess 2.0 and therefore has an icon which cannot be disabled and it can only be placed on the timeline once. However, it is considered a negative observation, thus it will have a negative score and contribute to the Sum of the observations.

- **Observations** are notable abnormalities known to affect the quality of an embryo (and the likelihood of a viable pregnancy). Each Observation will have a positive or negative score, based on the lab's specific and individual protocols. Multiple annotations of the same Observation (e.g. fragmentation) can be made in a Development Chapter and the scores are aggregated. For example: if an Observation has a score of -5 and the Observation was annotated twice, then the scoring system will take into account a score of -10 to offset the positive Event scores.
- **Development Chapters** represent different stages of an embryo's development. Geri Assess lists six Development Chapters (and only the relevant Events and Observations based on the embryo's development to date are shown while annotating in Geri Assess). The scores of the same Observation can be different in different Development Chapters. Administrators can edit the Development Chapter names on the Score Configuration page according to the lab's specific and individual protocols.

### 4.2.1. Managing the Score Configuration Page

**To access the Score Configuration Page:** Select Score Configuration from the User Menu on the top right of any page in Geri Connect & Geri Assess. The Score Configuration Page is displayed.

**To show Events and Observations of a specific Development Chapter:** Click on the down arrow located at the right end of each Development Chapter row to expand the Development Chapter.




A list of all the Events and Observations within the Development Chapter are displayed.

**To hide Events and Observations of a specific Development Chapter:** Click on the up arrow located at the right end of each Development Chapter row to hide the Development Chapter.

Or



Click on the down arrow located at the right end of another Development Chapter row to hide the previous one and expand the selected one.

#### To edit a Development Chapter name:


1. Click on the down arrow located at the right end of the desired Development Chapter row to expand the Development Chapter.
2. Click on the Development Chapter name to display the Edit icon .
3. Click the Edit icon  located to the right of the Development Chapter name, the Edit icon will change to a white background. Edit the Development Chapter name as required.
4. Click the Save icon  to save any changes. A pop-up window will ask to confirm the changes, as it could alter the final scores of existing results. Another pop-up window will confirm that the change was successful. Click continue to return to the Score Configuration Page.

**NOTE:** an Edit icon  will appear in the Development Chapter heading until all changes are saved.


#### To edit the name and score of an Event and/or Observation:

1. Click to select the desired Event/Observation row.
2. Click the Edit icon  located to the left of the Event/Observation name, the Edit icon will change to a white background.
3. Enter the new name and score using the keyboard (or arrow icons for adjusting the score).
4. Click the Save icon  to save any changes. A pop-up window will ask to confirm the changes, as it could alter the final scores of existing results. Another pop-up window will confirm that the change was successful. Click continue to return to the Score Configuration Page.


**To disable an Event and/or Observation:**

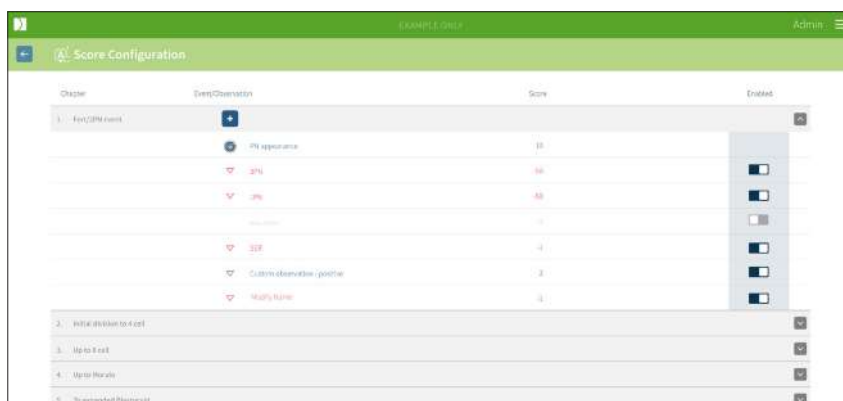
1. Locate the desired Event/Observation and click the Enabled switch from active  to inactive .
2. Click the Save icon  to save any changes. A pop-up window will ask to confirm the changes, as it could alter the final scores of existing results. Another pop-up window will confirm that the change was successful. Click continue to return to the Score Configuration Page.


**To enable a disabled Event and/or Observation:**

1. Locate the desired Event/Observation and click the Enabled switch from inactive  to active .
2. Click the Save icon  to save any changes. A pop-up window will ask to confirm the changes, as it could alter the final scores of existing results. Another pop-up window will confirm that the change was successful. Click continue to return to the Score Configuration Page.

**To create a new Event and/or Observation:**

1. Click on the down arrow located at the right end of the desired Development Chapter row to expand the Development Chapter.
2. Click on the Add icon  located to the right of the Development Chapter name.
3. Select the entry type (Event or Observation) from the pop-up menu.



4. Enter the name and score into the relevant fields, if required.
5. Click the Save icon  to save any changes. A pop-up window will ask to confirm the changes, as it could alter the final scores of existing results. Another pop-up window will confirm that the change was successful. Click continue to return to the Score Configuration Page.

**NOTE:** newly created Events and/or Observations will appear at the end of the Development Chapter's Events/Observations list.

## To discard any changes made to Development Chapters, Events and Observations:

1. Click on the Discard icon .
2. Follow the instructions in the pop-up window to discard or cancel.

**NOTE:** Events and observations cannot be deleted from the Score Configuration Page, they can only be disabled.



### **WARNING:**

Changes to the Score Configuration will automatically apply to all sessions available in Geri Connect & Geri Assess.

### 4.3. PDF Templates

Only Administrators are able to view the PDF templates and image files through the PDF Templates Page. PDF templates hold the Patient Report template file and image files.

Patient Report templates have three elements that can be customized for each clinic:

- Clinic name
- Clinic address
- Clinic logo
- In addition, headers within the report can be renamed to facilitate language or regional changes required by the clinic

**To access the PDF Templates Page:** Select PDF Templates from the User Menu located at the top right of any page in Geri Connect & Geri Assess.

The PDF Templates Page will be displayed.



**NOTE:** Service technicians can include lab specific information in the Patient Report, including clinic name, address and logo.

**To download an existing PDF template:** Select the template from the list on the left and click on the download icon .

The download file process will start in the Chrome browser.

**To customize a template with clinic-specific elements:**



1. Download the Patient Report.html PDF template file (see above).
2. Use a text editor (such as Notepad) to open the downloaded Patient Report.html file.
3. Search for geri.png in the file and replace it with the exact filename of the clinic's logo image.
4. Search for class="detailsTable" so that the following details can be updated:
  - a. Change the "detailsData" value of "Clinic Name" from "Genea" to the clinic's name.


- b. Change the “detailsData” value of “Clinic Address” from “Level 2, 321 Kent St. Sydney NSW 2000” to the clinic’s address.

```


883 <body>
884   <div class="header">
885     <div class="headerHolePunch">
886       <span>&nbsp;</span>
887     </div>
888     <table class="headerTable">
889       <tbody>
890         <tr>
891           <th class="regular">IVF CLINIC <span>NAME</span></th>
892           <th class="headerRight">
893             <p>321 Kent St, Sydney NSW 2000</p>
894             <p>01234 567890</p>
895             <p>IVFclinic@domain.com</p>
896           </th>
897           <th></th>
898         </tr>
899       </tbody>
900     </table>
901   </div>

```

5. Save the modified PDF template with a new file name (in HTML format). The file name will be used to identify the PDF template in Export Menu on the Patient Review Page. For example, if the template is named “patient.html”, the PDF template option in the Export Menu will be named “patient”.
6. Click on the Upload Template icon  and select the newly created PDF template file from the file dialog box to upload the newly created template file into Geri Connect & Geri Assess.
7. Click the Continue icon  when the file has successfully uploaded. **To add a new PDF template:** Click the Add a New PDF Template icon  and upload a new HTML template file. Once the new file is uploaded, it will appear in the PDF templates list.

**To add a new image file:** Click the Add a New Image File icon  and upload a new image file from disk. Once the new file is uploaded, it will appear in the image files list.

**To delete an existing PDF template or image file:**

1. Select the template/image file from the relevant list.
2. Click the Discard icon  and follow the delete confirmation dialog instructions.

**NOTE:** Once deleted, the template or image file will no longer appear in the list.

For further information on PDF template editing refer to QRTM126 Geri Connect PDF Report Template Customisation.

## 4.4. Geri Connect & Geri Assess Settings Tabs

### 4.4.1. Account Settings

To access the Account Settings page:

1. Select Settings from the User Menu located on the top right of any page in Geri Connect & Geri Assess. The External Services Tab is displayed by default.
2. Click on the Account Settings Tab to display information about licenses for Geri Assess 2.0.

**NOTE:** For more information regarding licenses, see “4.5. Licensing for Geri Assess 2.0 and Custom Scoring Algorithms” on page 44.

### 4.4.2. System Settings

To access the System Settings Tab:

1. Select Settings from the User Menu located on the top right of any page in Geri Connect & Geri Assess. The External Services Tab is displayed by default.
2. Click on the System Settings Tab to select a different language. English is shown as default.
3. Click on the drop-down menu to select:
  - a. English
  - b. Chinese
  - c. Japanese
4. Once the language has been changed, the user interface will retain the newly selected language until changed.

**NOTE:** Once the user interface language is changed, the change is immediately applied for all users

### 4.4.3. External Services

The External Services tab shows connection status of external services such as Geri Assess 2.0 and Qbox. This tab is where the specific service is enabled and an IP address assigned.

**To access the External Services Tab:** Select Settings from the User Menu located on the top right of any page in Geri Connect & Geri Assess. The External Services Tab is displayed by default.



## 4.5. Licensing for Geri Assess 2.0 and Custom Scoring Algorithms

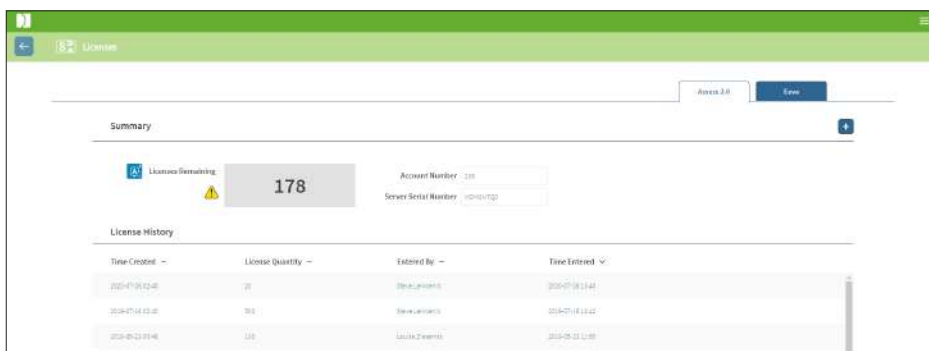
Every installation of Geri Connect & Geri Assess will include the base functionality of Geri Assess 1.0 which enables the user to manually annotate embryo development and using the Score Configuration Page, assign a user-defined score to the developing embryos. (See “3.4.2. Geri Assess 1.0 – Manually Annotating Events & Observations” on page 26 and “4.2. Score Configuration in Geri Assess 1.0” on page 37).

Users will also have the option of purchasing licenses for Premium content, which is activated and consumed on a pay-per-cycle basis. The Premium package functionality will be visible, but disabled, when not in use. This package includes Geri Assess 2.0, as well as custom user-defined scoring algorithms. (See “3.4.3. Geri Assess 2.0 – Automatically Annotating Events & Observations” on page 28 and “3.5. Custom Scoring Algorithms” on page 32).

**NOTE:** Only administrators can make changes to the licensing in Geri Connect & Geri Assess.


### To access the Licenses Page:

1. Select Licenses from the User Menu located on the top right of any page in Geri Connect & Geri Assess.
2. The Licenses Page is displayed and provides information about the number of licenses remaining, the account number and serial number of the Geri Connect & Geri Assess server, as well as the license history.




### 4.5.1. Adding New Geri Assess 2.0 Licenses

#### To add new licenses:

1. Select Licenses from the User Menu located on the top right of any page in Geri Connect & Geri Assess. The Licenses Page is displayed.
2. Select the Assess 2.0 tab.
3. Click the Add icon  located in the top right corner of the page. A pop-up window is displayed.
4. Paste the 295 digit license key into the pop-up window from the email that was sent.  
**NOTE:** ensure that the license key is for the same account number and server serial number that is displayed.




- Click the Save icon  to add the licenses to the Geri Connect & Geri Assess server. A pop-up window is displayed to confirm that the licenses were added. The number of licenses remaining and license history will reflect the newly added licenses.

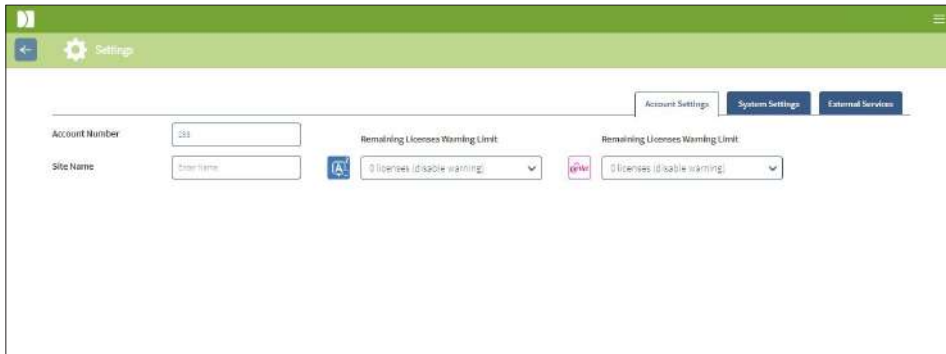
#### 4.5.2. Setting a Remaining License Warning Limit

To ensure that licenses are always available, a Remaining License Warning Limit can be set in the Account Settings.

##### To set a Remaining License Warning Limit:

**NOTE:** only Admin users have access to this functionality.

- Select Settings from the User Menu on the top right of any page in Geri Connect & Geri Assess. The Settings Page is displayed and defaults to the External Services Tab.
- Click on the Account Settings Tab.
- Select an appropriate limit from the Remaining License Warning Limit drop-down menu.
- Once the number of licenses remaining reaches the set limit, a yellow warning  is displayed in the Licenses Page and a yellow banner is displayed at the top of the Patient List Tabs.



The screenshot displays the 'Settings' page with the 'Account Settings' tab active. It includes input fields for 'Account Number' (value: 33) and 'Site Name' (value: Star Home). Below these are two dropdown menus for 'Remaining Licenses Warning Limit', one for 'A' and one for 'Geri', both currently set to '0 licenses (disable warning)'.

## 5. LAB IT INSTRUCTIONS

**NOTE:** These instructions are only applicable to Lab IT department personnel.

This section specifies Geri Connect & Geri Assess installation and maintenance procedures to be performed by the Lab IT department personnel. The specified procedures are affected by each lab's private and custom IT requirements. As a result, following the specified procedures is in the responsibility of the Lab IT department.

### 5.1. Technical overview

This section will provide an overview of Geri Connect & Geri Assess technical components and infrastructure. The hardware and software versions described in this section are default Geri Connect & Geri Assess components. Any deviation from the specified default versions should be approved by Genea Biomedx and recorded in Geri Connect maintenance logs.

#### 5.1.1. Hardware

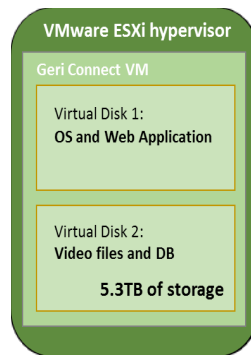
The default Geri Connect & Geri Assess server hardware platform is based on "Dell PowerEdge T440 server". The server comprises the following main components:

- **CPU:** Intel Xeon 3106 (Minimum 1.7 GHz)
- **RAM:** 32GB RDIMM
- **RAID:** RAID 10
- **Network Controller:** 2 x 1 GB Ethernet NICs
- **Remote Monitoring:** A dedicated port for iDRAC (integrated Dell Remote Access Controller) with iDRAC version 9
- **Virtualisation:** VMware ESXi 6.7 (required to run Geri Connect virtual machine)  
Geri Connect

Full server specification is available upon request from Genea Biomedx.

### 5.1.2. Storage & Virtualization

The Geri Connect & Geri Assess virtual machine is configured to contain two virtual disks. The disks are reflected as two partitions within the virtual machine operating system. The Geri Connect & Geri Assess virtual machine is configured to use all available physical server memory and CPUs processing resources. No other virtual machines shall be deployed on the host server. Current default configuration of 5.3TB of storage allocated to video files and DB partition is estimated to provide four years of storage for three Geri incubators in full use, assuming 10 micro-wells (out of maximum 16 micro-wells) and 11 z-stacks, with sessions reduced to contain only the central z-stack video after three months. The following scheme presents Geri Connect & Geri Assess Virtualization layers:



### 5.1.3. Software

All Geri Connect & Geri Assess software components are deployed as a single image on a virtual machine running on VMware ESXi. The following section specifies the main Geri Connect & Geri Assess software components, supplied as part of the deployment image:

- **Operating System:** Linux Debian 'Jessie' 8.2
- **Database:** PostgreSQL Server 9.4
- **HTTP Server:** Nginx
- **Client application framework:** Web2Py

Access to the specified components and the Geri Connect & Geri Assess server file system is restricted to Genea Biomedx service engineers.

### 5.1.4. Network Layout

The Geri Connect & Geri Assess network layout comprises two segregated networks:

- **Geri Instruments Network:** This network provides connectivity between Geri instruments and Geri Connect & Geri Assess and is fully detached from the main lab network. The only devices allowed to use this network are Geri instruments and the Geri Connect & Geri Assess server. Genea Biomedx support engineer is allowed to connect a laptop to this network for Geri Connect & Geri Assess maintenance purposes. The Geri instruments network uses 10.100.22.x IP mask.

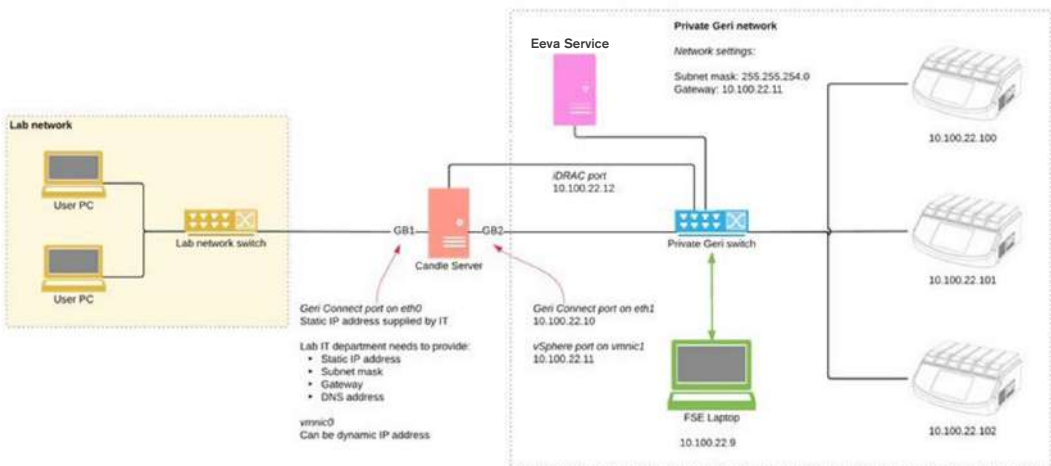
**NOTE:** Set-up of the Geri instruments network is under the responsibility of Lab IT department and is required to be completed before Geri Connect & Geri Assess installation.

- **Lab Network:** This network is used by Geri Connect & Geri Assess end users for everyday work (usually this will be the pre-existing lab network).

**NOTE:**

- For privacy and security reasons, the Geri Connect & Geri Assess server should be the only machine connected to both the Geri instruments network and the lab network.

The Geri Connect & Geri Assess network layout:



## 5.2. Geri Connect & Geri Assess Installation Prerequisites

The following section summarizes the steps to be performed by the Lab IT department personnel prior to Geri Connect & Geri Assess installation by the Genea Biomedx service engineer. All specified steps must be completed before the Genea Biomedx service engineer arrives on-site to perform the installation process. Any questions, delays or inconsistencies in the specified steps shall be communicated to Genea Biomedx as soon as they are identified. Any missing or incomplete steps may result in Geri Connect & Geri Assess installation delays or cancellation of Geri Connect & Geri Assess installation on the due date.

### 5.2.1. Prerequisite 1: Lab Network Set-Up for Geri Connect & Geri Assess

Prior to the Geri Connect & Geri Assess installation process, the Lab IT department personnel must provide Genea Biomedx service engineer with the lab network configuration and a static IP address for the Geri Connect & Geri Assess server. The following items should be provided by the Lab IT department:

- Static IP for Geri Connect & Geri Assess service
- Lab network subnet mask
- Lab network gateway
- DNS address for Geri Connect & Geri Assess service

### 5.2.2. Prerequisite 2: VMware vSphere License

By default, the VMware vSphere Virtualization platform deployed to host the Geri Connect & Geri Assess service is configured to use “60 days” evaluation license. The Lab IT department is required to provide the Genea Biomedx service engineer with a replacement for the evaluation license prior to the Geri Connect & Geri Assess installation. Failing to follow this requirement will result in the Geri Connect & Geri Assess service shutting down once the evaluation period expires.

- Obtain a valid VMware vSphere license key

In case the lab already deploys other VMware hosts, the Lab IT department may already have a license that could be used for the Geri Connect & Geri Assess server. If not, there are two relevant VMware vSphere license options:

- Free license

or

- Essentials license

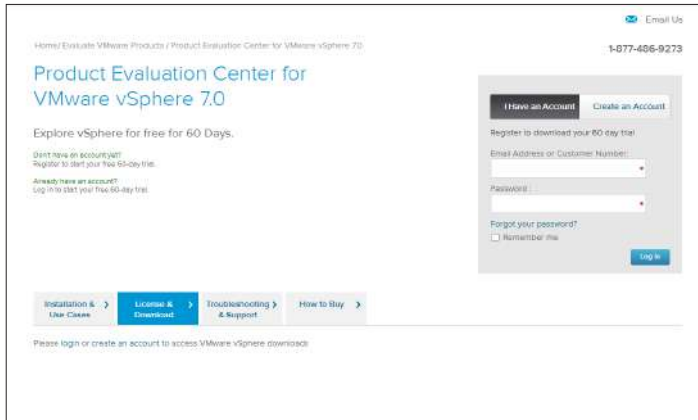
The main reason to purchase a commercial Essentials license is to enable the use of particular back-up tools, which may rely on features such as the Storage APIs.

The Free license is sufficient for everyday use of Geri Connect & Geri Assess.

**To obtain a Free license for VMware vSphere:**

1. Register an account at the VMWare website
  - <https://my.vmware.com/web/vmware/registration>
2. Visit <https://my.vmware.com/en/web/vmware/evalcenter?p=vsphere-eval> and click “Register”.

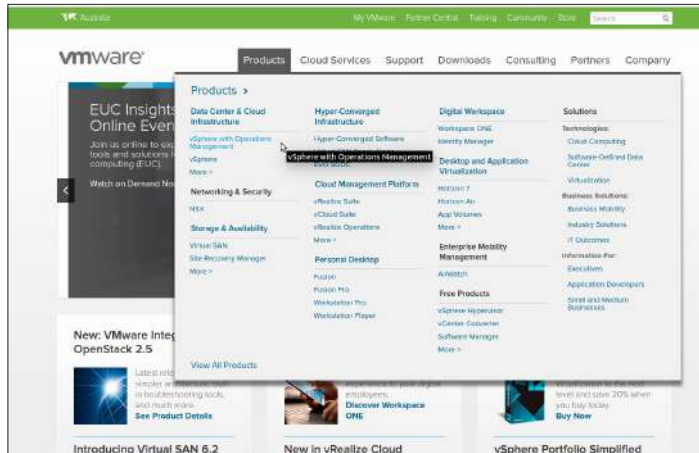
The license key will appear in a table under “License information” as seen in the figure below.



The Essentials license enables access to a wider range of VMware Virtualization management tools. For Geri Connect & Geri Assess, the main reason to purchase this license is to obtain access to back-up tools, which may rely on VMware features such as the Storage APIs.

## To obtain an Essentials license for VMware vSphere:

1. Register an account at the VMware website (<https://my.vmware.com/web/vmware/registration>).
2. Open the **Products** menu.
3. Open **Data Center & Cloud Infrastructure** submenu.
4. Click on **vSphere with Operations Management**.



5. Click on **Pricing**.
6. Scroll down to **VMware vSphere Essentials Kits** and click on **Buy Now** for VMware vSphere Essentials Kit.

## To update a licence key (required for ESXi 5.5 upgrades to ESXi 6.7):

1. Visit website (<https://kb.vmware.com/s/article/2006974>) and follow the instructions for the relevant license.

vmware Knowledge Base    Training    Community    Store    My VMware    Tips on searching for a KB

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## How to upgrade license keys in My VMware (2006974)

[Details](#)

This article provides information about license key version upgrades in My VMware

**Notes:**

- If you experience issues when upgrading license keys, see [Upgrading license keys in My VMware fails \(2020939\)](#)
- For more information on Licensing VMware Workstation, see [How to License VMware Workstation \(2014291\)](#)
- For information on an edition upgrade, see [Upgrading a license edition in My VMware \(2006986\)](#)

### 5.2.3. Prerequisite 3: Network Access to Internet Network Time Protocol (NTP) Servers

By default, the vSphere host and the Geri Connect & Geri Assess VM are configured to synchronize their times with public internet servers supplied by planetinnovation.pool.ntp.org. To support this, the Lab IT department must enable access to addresses at planetinnovation.pool.ntp.org and enable NTP traffic (UDP port 123) through the firewall. Geri devices are configured to receive time updates from the connected Geri Connect & Geri Assess VM. If not connected to a NTP server, Geri Connect & Geri Assess VM will synchronize its time with the vSphere host.

- Provide lab network gateway
- Firewall allows outbound UDP traffic on port “123”
- Firewall allows access to planetinnovation.pool.ntp.org addresses

The current version of Geri Connect & Geri Assess does not support time servers hosted on-site. Please contact Genea Biomedx if this is required.

**NOTE:** Please see “5.5.3. Manual Monitoring & Setting Geri Connect & Geri Assess Clock” on page 56 if connection to planetinnovation.pool.ntp.org public time servers can’t be established.



## 5.3. Optional Features & Customization

Default installation of the Geri Connect & Geri Assess is supplied with a predefined set of settings and licenses. Some of the default configuration items may not fit your lab network policies. The following section specifies customization options available for the Geri Connect & Geri Assess. All sections of this chapter are optional and should be evaluated against your specific lab needs.

### 5.3.1. Integrated Dell Remote Access Controller

Geri Connect & Geri Assess server installation includes Dell hardware management platform called “integrated Dell Remote Access Controller” (iDRAC). The iDRAC web interface provides an overview of the status of various Geri Connect server hardware components. The iDRAC service can also be configured to send alerts and notifications. Please see the Dell website for more information about iDRAC functionalities.

The Genea Biomedx service engineer can configure iDRAC to be accessible to the lab network at the Lab IT department request. Once iDRAC is configured, credentials to the user interface will be provided to the Lab IT department by the Genea Biomedx service engineer as part of the Server Configuration Record.

- Request iDRAC configuration from Genea Biomedx (optional)

### 5.3.2. HTTPS Certificate

Default installation of Geri Connect & Geri Assess is provided with a self-signed HTTPS certificate generated by Genea Biomedx. In case your lab security policy requires a certified HTTPS certificate, or in order to avoid presenting browser security warning to Geri Connect & Geri Assess users, the default self-signed HTTPS certificate should be replaced by the Genea Biomedx service engineer. If required, the certified HTTPS certificate and private key file should be provided to the Genea Biomedx service engineer prior to Geri Connect & Geri Assess installation.

The certificate should be in PEM format and in a separate file to the private key.

- Purchase/Generate certified HTTPS certificate (optional).
- Provide certified HTTPS certificate and private key file to the Genea Biomedx service engineer (optional).

A certified HTTPS certificate may be purchased from a recognized Certificate Authority by the Lab IT department.

Alternatively, the new certificate could be generated from the Lab IT department internal CA. If the lab CA is centrally managed and distributed to computers on your network (for example via Active Directory’s Group Policy Management), the Geri Connect & Geri Assess user browsers will recognize the certificate as trusted and will not present a security warning.

## 5.4. Geri Connect & Geri Assess Installation Day

- The Lab IT department should verify that all the mandatory requirements listed in “5.3. Optional Features & Customization” on page 53 are met and available to the Genea Biomedx service engineer.
- The Lab IT department should verify that all the relevant optional requirements listed in “5.3. Optional Features & Customization” on page 53 are met and available to the Genea Biomedx service engineer.
- A representative of the Lab IT department should be available to assist the Genea Biomedx service engineer during installation.
- A lab employee filling the role of a Geri Connect & Geri Assess Administrator must make the initial validation of the Geri Connect & Geri Assess installation, while the Genea Biomedx service engineer is on-site and confirm successful installation.
- The Server Configuration Record must be provided by the Genea Biomedx service engineer to the Lab IT department upon successful Geri Connect & Geri Assess installation.

## 5.5. Everyday Maintenance

Geri Connect & Geri Assess is a stable web service that requires minimal everyday maintenance effort. However, some maintenance tasks are still required to be performed by the Lab IT department to ensure stable and continuous service and prevent loss of data.

### 5.5.1. Monitoring Available Storage Space

A single Geri incubator, which has 6 chambers, can generate 1TB of data in 14 weeks. As a typical Geri Connect & Geri Assess server storage capacity is limited to 5.4TB, it is important to periodically monitor available Geri Connect & Geri Assess storage space. Geri Connect & Geri Assess server storage information is presented on the Geri Connect & Geri Assess Information Page. See “2.6. Information Page” on page 10 for further instructions.

The Lab IT department is responsible for periodic monitoring of available storage space. Once a defined minimal limit of available storage is reached, the Lab IT department should notify the lab clinical staff to delete non-central videos of historical patients from the Historical Patients Tab. See “3.1.3. Historical Patients” on page 14 for further instructions.

### 5.5.2. Backup, Restore & Disaster Recovery

The Lab IT department holds the responsibility to 1) back-up the system, 2) test the back-up procedure to ensure back-ups can be restored and 3) implement a disaster recovery plan.

The following data should be considered by the Lab IT department when building and executing back-up, restore and disaster recovery plans:

- Geri Connect back-up is performed on VM image level. Partial back-up and restore of data is not supported.
- Due to large data volumes, back-up and restore procedures could be time consuming.
- Geri Connect server uses a RAID 10 configuration for its hard disks, to protect against drive failure.

- The server runs on vSphere ESXi as its hypervisor. It is recommended to back up the Geri Connect & Geri Assess virtual machine via a vSphere compatible back-up tool. Please see “5.2.2. Prerequisite 2: VMware vSphere License” on page 49.
- Other recommended free back-up options are:
  - Veeam Backup Free - will only work with a commercially licensed (Essentials license) VMware vSphere and requires at least 1Gbit network link
  - HP Enterprise VM Explorer
  - The Geri Connect & Geri Assess server could also be added into any existing vSphere based back-up regime.  
Such tools enable the back-up to be completed while the server is running and interacting with end users and Geri instruments.
- Network monitoring and alerting of failures is highly recommended.
- For disaster recovery purposes, it is recommended that the back-up media will be taken offline and moved to an off-site location, to protect against data corruption and physical loss.

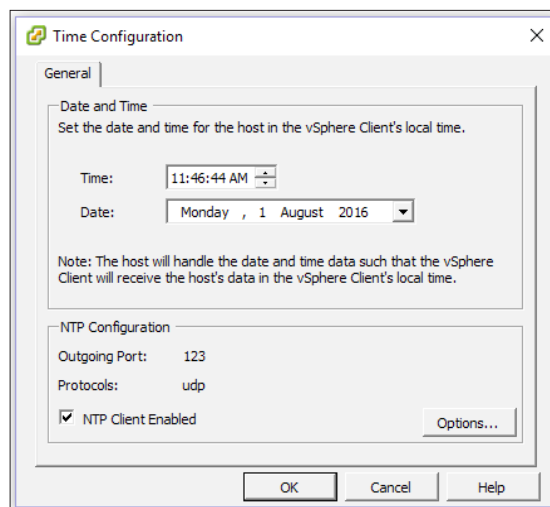
### 5.5.3. Manual Monitoring & Setting Geri Connect & Geri Assess Clock

If access to planetinnovation.pool.ntp.org public time servers can't be established, the Lab IT department must manually maintain correct time on the vSphere host. Due to expected clock drifts, it is recommended to manually monitor and correct the clock once a month.

If vSphere clock has more than a 5 min difference from real-time per month, it is advised to monitor and correct the clock more frequently.

Please follow the steps below, to manually set up the clock on the vSphere host:

1. Open vSphere Client and connect to the server, as user "admin" (see the Server Configuration Record provided by the Genea Biomedx service engineer for the password).
2. Click on the Configuration Tab.
3. Under "Software", select "Time Configuration"
4. Click "Properties..." at the far right.
5. In the Time Configuration dialog, set the time manually.



6. Click OK to save.
7. Reboot Geri Connect & Geri Assess VM.

## 6. NOTES

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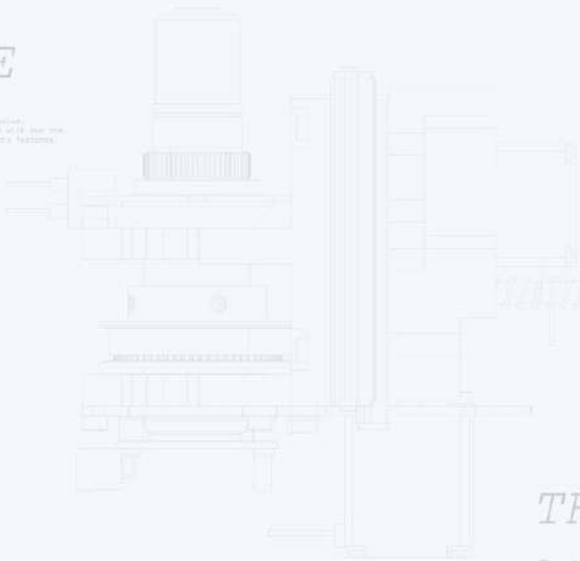
# MODULE

Efficient, thoughtful modular design is what makes Genea's ability to tailor your system to your needs.

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Temperature  
Carbon  
Humidity



## THE DISH

3xWASHING WELLS  
16xEMBRYOS PER DISH

Efficient, thoughtful modular design is what makes Genea's ability to tailor your system to your needs. Efficient, thoughtful modular design is what makes Genea's ability to tailor your system to your needs.

