



Amersham ImageQuant 800 GxP

User Manual

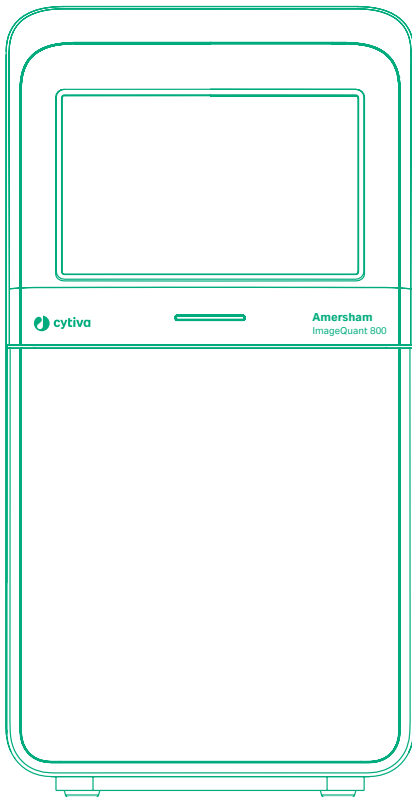


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1 Introduction

About this chapter

This chapter contains information about this manual and associated user documentation, important user information and intended use of the product.

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1.1 About this manual

About this manual

The Amersham™ ImageQuant™ 800 GxP *User Manual* provides information and instruction for use of the Amersham ImageQuant 800 GxP. Amersham ImageQuant 800 GxP is a Amersham ImageQuant 800 imaging system that has an Amersham ImageQuant 800 GxP License to activate the GxP features on the imaging system. The extension adds support for work in a GxP regulated environment.

Scope of this manual

The *User Manual* covers the specific features of the Amersham ImageQuant 800 GxP enabled by the activation of the Amersham ImageQuant 800 GxP License.

For general information about the imager, safety and regulatory features that are common to use in GxP and non-GxP contexts refer to [Additional documentation, on page 7](#).

The illustration below shows the Amersham ImageQuant 800 GxP system.



Software versions

The Amersham ImageQuant 800 GxP License is currently available for Amersham ImageQuant 800 Control Software 2.0 and later versions.

Typographical conventions

Software items are identified in the text by ***bold italic*** text.

Hardware items are identified in the text by **bold** text.

In electronic format, references in *italics* are clickable hyperlinks.

Notes and tips

Note: *A note is used to indicate information that is important for trouble-free and optimal use of the product.*

Tip: *A tip contains useful information that can improve or optimize your procedures.*

1.2 Important user information

Read this before operating the product



All users must read the entire *Operating Instructions* before installing, operating or maintaining the product.

Always keep the *Operating Instructions* at hand when operating the product.

Do not install, operate, or perform maintenance on the product in any other way than described in the user documentation. If you do, you may be exposed or expose others to hazards that can lead to personal injury and you may cause damage to the equipment.

Intended use of the product

The Amersham ImageQuant 800 GxP is intended for users who work in regulated environments.

The Amersham ImageQuant 800 GxP is intended for research and development use only and may not be used for diagnostic purposes in any clinical or *in vitro* procedures.

Disclaimer

Using the Amersham ImageQuant 800 GxP does not guarantee compliance with regulatory requirements. The user is responsible to validate their analysis and evaluation procedures and to maintain the required documentation.

Cytiva cannot be held responsible for failure to conform to validation requirements.

Prerequisites

In order to use the Amersham ImageQuant 800 GxP in accordance with the intended purpose the following prerequisites must be met:

- The system should be installed according to the instructions in the *Installation* chapter of the *Operating Instructions*.
- A system administrator must be assigned.
- You should have a general understanding of the use of a personal computer running Microsoft® Windows® in the version provided with your product.
- You should be acquainted with the use of general laboratory equipment and with handling of biological materials.
- You should be acquainted with the use of your Amersham ImageQuant 800 system that supports the Amersham ImageQuant 800 GxP License.

- You must follow applicable laws and restrictions for working in a regulated environment.

Additional documentation

This *User Manual* only describes the specific GxP-related features of the imaging system. General information, safety, and regulatory features that are common to use in GxP and non-GxP contexts are described in the additional documentation provided with the system.

- *Amersham ImageQuant 800 Operating Instructions (29372604)*
- *Amersham ImageQuant 800 User Manual (29383813)*

Privacy and security considerations of the use of Amersham ImageQuant 800 GxP are described in *Amersham ImageQuant 800 GxP Privacy and Security Manual (29656756)*.

Additional documentation can be downloaded at cytiva.com/IQ800.

1.3 Abbreviations and definitions

Abbreviations

Abbreviation	Meaning
GxP	Collective abbreviation for Good x Practice where x refers to a field or work environment, for example GLP (Good Laboratory Practice) or GMP (Good Manufacturing Practice).
FDA 21 CFR Part 11	US Food and Drug Administration Code of Federal Regulations, Title 21— <i>Food and Drugs</i> ; Chapter I— <i>Food and Drug Administration Department of Health and Human Services</i> ; Subchapter A— <i>General</i> ; Part 11— <i>Electronic Records; Electronic Signatures</i>
EU GMP Annex 11	EudraLex, <i>The Rules Governing Medicinal Products in the European Union</i> , Volume 4, <i>Good Manufacturing Practice, Medicinal Products for Human and Veterinary Use</i> , Annex 11: <i>Computerized Systems</i>
SOP	Standard Operating Procedure
VFS	Validation Support File

Definitions

Term	Definition
Closed system ¹	Environment in which system access is controlled by persons who are responsible for the content of electronic records that are on the system.
Electronic record ¹	Any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system.
Equipment qualification	Quality assurance of equipment.
Control Software	Software used to control the instrument (Amersham ImageQuant 800 Control Software 2.0 and later versions).
Analysis Software	Software used to evaluate images after acquisition (IQTL 8.2 and later versions).

¹ According to FDA 21 CFR Part 11.

2 Overview of the GxP environment

About this chapter

This chapter provides an overview of the GxP environment and functions, the scope of GxP, and how it is supported by Amersham ImageQuant 800 GxP.

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2.1 System description

Introduction

Amersham ImageQuant 800 is an imaging system for chemiluminescence, fluorescence and colorimetric imaging. Amersham ImageQuant 800 GxP is a Amersham ImageQuant 800 imaging system that has an Amersham ImageQuant 800 GxP License to activate the GxP features on the imaging system. These features are designed to help users comply with quality regulations requirement such as:

- integrity of electronic data
- access control of system users
- traceability of imaging operations in standard operating procedures (SOP)

Note: *Amersham ImageQuant CONNECT Software is not available when GxP features are activated.*

2.2 GxP regulations and scope

Introduction

Regulatory authorities require pharmaceutical development and manufacturing companies to use quality assured equipment and to follow detailed and carefully documented analytical and manufacturing procedures. The purpose of this control effort is to ensure consistent and reliable quality in pharmaceutical products that reach the market.

GxP regulations describe requirements for companies and laboratories, and include guidelines on how standard protocols can be used for safe electronic record keeping.

GxP regulations cover:

1. **Traceability:** the ability to reconstruct the development history of a drug or medical device.
2. **Accountability:** the ability to resolve who has contributed what to the development and when.
3. **Data Integrity:** the reliability of data generated by the system
 - Identifying data generated by the system
 - Defining data integrity requirements during the data lifecycle
 - Identifying risks and mitigation strategies

GxP Scope

Amersham ImageQuant 800 GxP software products can be used in a GxP regulated environment for creating and maintaining electronic records. This software includes functions that enable compliance with FDA 21 CFR Part 11 and EU GMP Annex 11. A list with the functions that support GxP for all requirements of the electronic record (FDA 21 CFR Part 11 Subpart B) can be found in [Chapter 5 Functions supporting GxP, on page 34](#).

The Amersham ImageQuant 800 GxP is intended to be used as a closed system.

The user is responsible to make sure that:

- Only relevant employees with controlled access are allowed to operate the system.
- The entire process and the Standard Operating Procedures are compliant.

Equipment qualification

The equipment qualification makes sure that analytical and manufacturing equipment performs reliably according to the specifications of the manufacturer. Cytiva offers IQ/OQ services to provide the necessary documentation for equipment qualification.

2 Overview of the GxP environment

2.2 GxP regulations and scope

Quality system

The Quality Management System of Cytiva is certified according to ISO 9001. ISO 9001 is an internationally accepted series of quality management standards. Certification requires rigorous auditing by an independent accredited agency, which examines the quality documentation system and confirms that the organization operates in accordance with stipulated principles and instructions. The current Certificate of Approval to the Quality Management System Standard ISO 9001 is available on request.

The Validation Support File

The Validation Support File (VSF) is a suite of documents to help the customer validate processes for working in a regulated environment. The VFS includes:

- a description of the imager
- a self-assessment checklist
- a description of the quality system of Cytiva
- an external assessment report

The VSF supports the user to introduce the imager in a SOP at the stage when the process needs validation by the user. The documentation shows how Amersham ImageQuant 800 GxP reduces the workload to make sure that the electronic records and signatures are used according to regulation requirements. To access VSF and subscribe to Change Control Notifications (CCN), register at cytiva.com/rsf.

2.3 Electronic records

Captured image files

Captured image files are the primary electronic record in Amersham ImageQuant 800 GxP and each image file contains all information relevant of the image capture. This includes:

- username
- date and time
- time zone
- capture settings
- version of the software and hardware

Image raw data in .tif format is used for analysis. The file tags containing information can be viewed in analysis software like IQTL.

2.4 Authorized access

Log in

Amersham ImageQuant 800 GxP makes sure that:

- Only authorized individuals use the system.
- Different user roles perform specific tasks on the system.

Amersham ImageQuant 800 GxP Control Software uses the Windows user login information to log into the software and allow use and control based on user role. An administrator (Admin in the Control Software) manages the user roles within the software.

User roles

The table below shows the user roles and rights supported by Amersham ImageQuant 800 GxP.

Tasks available on Amersham ImageQuant 800 GxP					
User role	Manage users	Create methods	Use methods	Capture image w/o method	Basic image editing
Admin	✓	X	X	✓	✓
Developer	X	✓	✓	✓	✓
User	X	X	✓	✓	X

Legend: ✓ = allowed ; X = not allowed

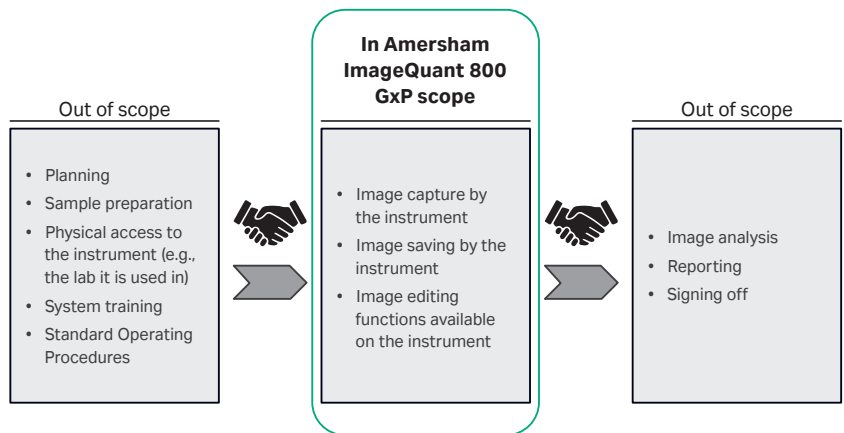
2.5 Workflow in regulated environment

GxP Workflow

Amersham ImageQuant 800 GxP Control Software enables the user to comply with GxP regulations for functions performed by the imager such as image capture and saving.

The process of planning an experiment and the steps leading to the imaging are out of scope for the Amersham ImageQuant 800 GxP Control Software. Similarly the analysis steps which are normally performed on a different software (such as IQTL) are also out of scope for the Amersham ImageQuant 800 GxP.

The image below summarizes the typical workflow with Amersham ImageQuant 800 GxP.



Traceability

Amersham ImageQuant 800 GxP includes reference inputs and image verification steps to secure and trace activities leading to imaging and post imaging.

- **Before Imaging:** It is recommended that the user gives the image that will be captured an ID (Image ID) prior to the start of the experiment at the sample preparation stage. This Image ID must be entered into the Amersham ImageQuant 800 GxP Control Software at the time of saving the captured image. This reference text is saved in the image file and is thus part of the electronic record. This ensures the experimental steps prior to imaging are connected to the image itself.
- **After Imaging:** Usually, image capture is followed by analysis in a software. We recommend using IQTL GxP Analysis Software. The images generated by the Amersham ImageQuant 800 GxP imager carry a special integrity tag that is read by IQTL GxP software. This step verifies that the original image has not been edited or tempered with between the capture and analysis step.

The embedded Image ID reference and integrity tag makes sure that the work from start to finish is traceable.

2.6 Archiving of electronic records

Introduction

Archiving is the process of moving files that are no longer actively used to a separate storage location for long-term retention. Archived files are important to the organization and may be needed for future reference or must be retained for regulatory compliance. Record management vary based on company and industry.

Recommendations

Cytiva recommends that archiving of electronic records such as image files and event logs are done based on individual company policy and after consultation with your relevant teams such as legal, compliance, IT, etc.

2.7 Log files

Types of log files

Amersham ImageQuant 800 GxP system generates and supports different types of log files.

Log type	Description	Examples of use
Event log	The event log provides a history of events, which can be used to check activities on the imager, for example capturing of images, making of methods, editing of images, and adding or deleting users.	Event logs can be used to verify images and imager history on a regular basis or by auditors during a formal audit.
Service log	A service log file is possible to create if needed. This file describes device characteristics, for example error codes or total on-time of LED lights. The purpose of this file is to allow for better servicing of the imager.	Service logs are for use by Cytiva to diagnose any issues/ problems when they arise.

3 Operation

About this chapter

This section contains information on how to use Amersham ImageQuant 800 GxP. For general information on how to switch on and to start the Amersham ImageQuant 800 GxP system via Amersham ImageQuant 800 GxP Control Software, refer to *Amersham ImageQuant 800 User Manual (29383813)*. For information on how to set up and install the system, see *Amersham ImageQuant 800 Operating Instructions (29372604)*.

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3.1 Getting Started

About this section

This section contains information on how to log in and begin using the Amersham ImageQuant 800 GxP.

Starting the system in the GxP environment

Start the Amersham ImageQuant 800 GxP as described in *Amersham ImageQuant 800 Operating Instructions (29372604)* and *Amersham ImageQuant 800 User Manual (29383813)*.

Note: *Amersham ImageQuant CONNECT Software can not be used with the GxP extension.*

Log in

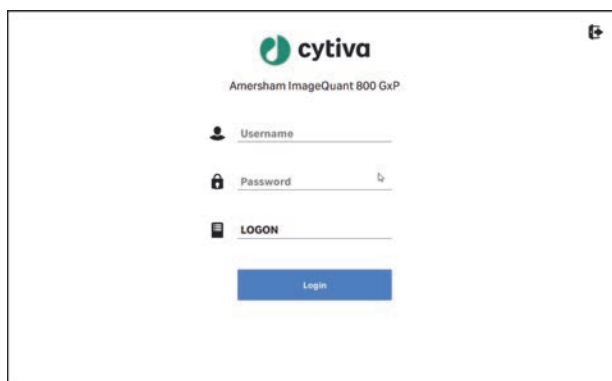
The login for the Amersham ImageQuant 800 GxP system is based on the Windows authentication system and therefore uses the same login credentials as Windows. When the GxP extension is installed, the Admin role must be assigned to a user. The Admin must then add other Windows usernames in the Control Software. See [User roles, on page 14](#) for more details on the Admin user role.

Note: *Some Windows user profiles display an e-mail or a name upon login. To find the login username go to **Your Info** in the Windows settings and check the login username. For example, if in **Your Info** panel the username is displayed as **LOGONI123456789**, use 123456789 as login username for the Control Software.*

Follow these steps to log in.

Step	Action
1	Check with the Control Software Admin that your Windows login credentials are added in the Control Software.
2	The system is switched on.
3	Log into Windows. <i>Result:</i> Desktop is displayed.
4	Wait for the Control Software to start automatically.

Step	Action
------	--------



Result:
The Login screen is displayed.

5 Log in with your Windows username and password.

6 Click **Login**.

The Landing screen opens.

3.2 Managing users

About this section

This section contains information on how to add and manage users in the Amersham ImageQuant 800 GxP Control Software.

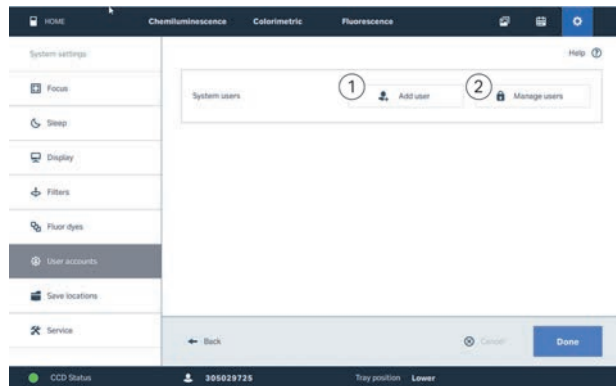
Note: Only users who have an existing Windows user account can be added as users to the Amersham ImageQuant 800 GxP Control Software.
Only Control Software Admin have access to add and manage users.

Add users

Follow the steps below to add an existing Windows user account to the Amersham ImageQuant 800 GxP Control Software.

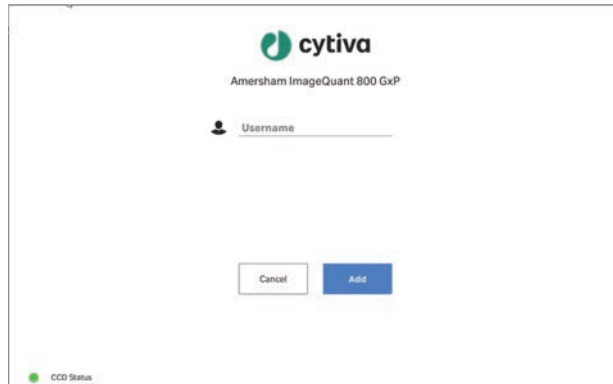
Step	Action
------	--------

- 1 Go to **Settings**.
- 2 Select **User accounts**.
- 3 Select **Add user** (1)



- 4 Insert the Windows login username of the user and click **Add**.

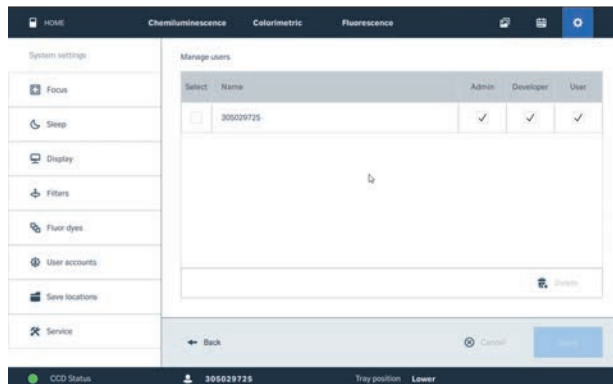
Step Action



5 Select **Manage Users** (2).

Result:

The list of the users appears as shown below.



6 Select the added user and select the user roles based on the job function or responsibility of the user. For new added accounts, User is selected as user role by default. For details on the available user roles, refer to [User roles, on page 14](#).

Change role of users

Follow the steps below to change the role of an existing user of the Amersham ImageQuant 800 GxP Control Software.

Step Action

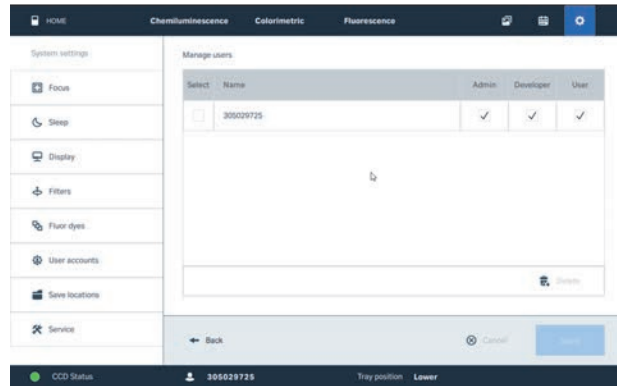
- 1 Go to **Settings**.
- 2 Select **User accounts**.

Step	Action
------	--------

3	Select Manage Users .
---	------------------------------

Result:

The list of the users appears as shown below.



4	Select the user and change the user roles based on the job function or responsibility of the user.
---	--

Deleting users

Follow the steps below to delete a user from the Amersham ImageQuant 800 GxP Control Software. This procedure will not delete the Windows user account.

Step	Action
------	--------

1	Go to Settings .
---	-------------------------

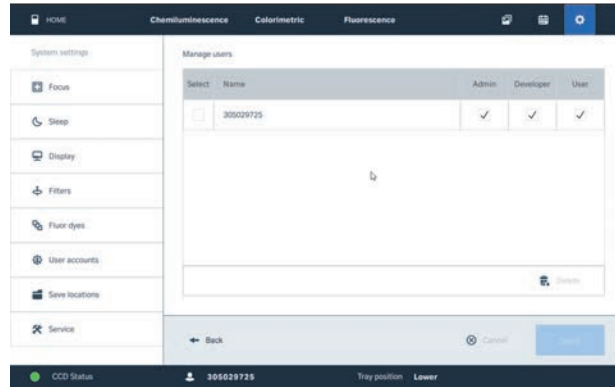
2	Select User accounts .
---	-------------------------------

3	Select Manage Users .
---	------------------------------

Step **Action**

Result:

The list of the users appears as shown below.



- 4 Select the user that needs to be deleted and select **Delete** in the bottom right corner.

Result:

The user is deleted from the Control Software.

3.3 Imaging

About this section

This section contains information on how to image samples and manage image files using Amersham ImageQuant 800 GxP.

Image file acquisition

For more information on how to operate the imager, refer to:

- *Amersham ImageQuant 800 Operating Instructions (29372604)*
- *Amersham ImageQuant 800 User Manual (29383813)*

Viewing image information

Image information can be used:

- to compare with the event log at time of audit.
- to identify when the image was taken to check something related to other steps in workflow.
- to see what imaging conditions (e.g., exposure time), username, date, time, etc. have been used at the image acquisition.

Follow the steps below to view the image information.

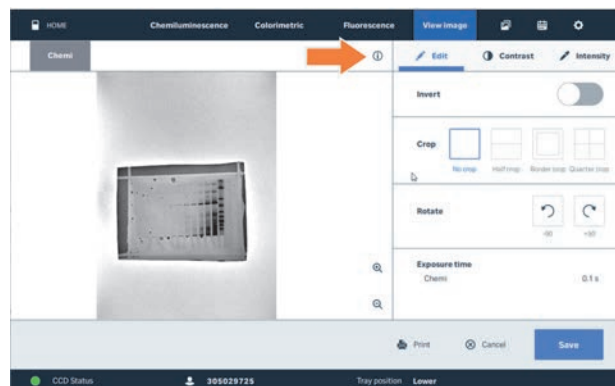
Step	Action
------	--------

1	Select an image from the library.
---	-----------------------------------

2	Click Open .
---	---------------------

Result:

The image is opened in the **View image** panel of the control software.



3	Click on the information icon (i) on the top right corner.
---	--

Step	Action
-------------	---------------

	<i>Result:</i> The image information is displayed.
--	---

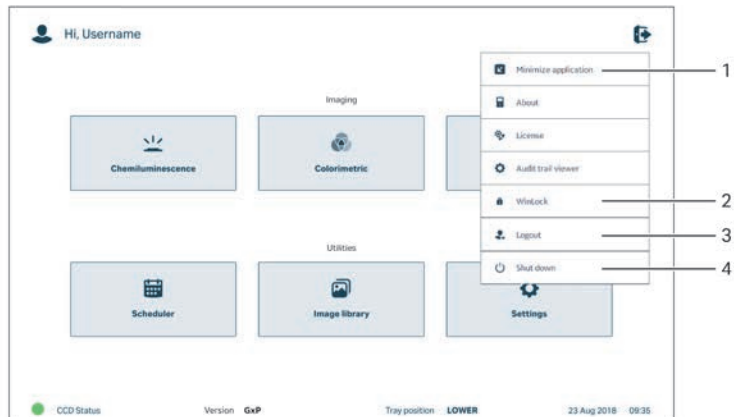
3.4 Terminating the session

About this section

This section describes how to suspend or terminate an imaging session, and shut down the system.

The Amersham ImageQuant 800 GxP exit menu

The following illustration describes the functions of the exit menu for Amersham ImageQuant 800 GxP.



Part	Function
1	Minimize application tab. Select to minimize the Control Software window and access Windows.
2	WinLock tab. Select to lock the system.
3	Logout tab. Select to logout from the Control Software and Windows.
4	Shut down tab. Select to shut down the system .

Access Windows while running the control software

Select **Minimize application** from the exit menu.

The control software runs in background while the user can access Windows.

Note: *This operation does not log off the user. Only one logged in Windows user at a time can run the Control Software.*

To return to the Control Software, click its icon on the task bar.

Lock the control software while imaging

Select **WinLock** from the exit menu.

This function can be used when imaging is ongoing but the user needs to step away. This feature ensures the Control Software is locked and other users are not able to log in. The imaging continues in the background uninterrupted.

Upon return, the user can log in and proceed to save the image. The Control Software can only be unlocked by the current user.

Logging out

Select **Log Out** from the exit menu.

This operation logs out the user from both the Control Software and Windows. It is recommended once imaging is completed by a user. Other users can then log in to use the instrument for another imaging session.

Shut down the system

Select **Shut down** from the exit menu to shut down the imager and log out from the Control Software.

If an external display is used, the PC will continue to run while if the touchscreen is used, also the control PC will shutdown.

This operation is recommended at the end of the workday.

3.5 Audit trail

About this section

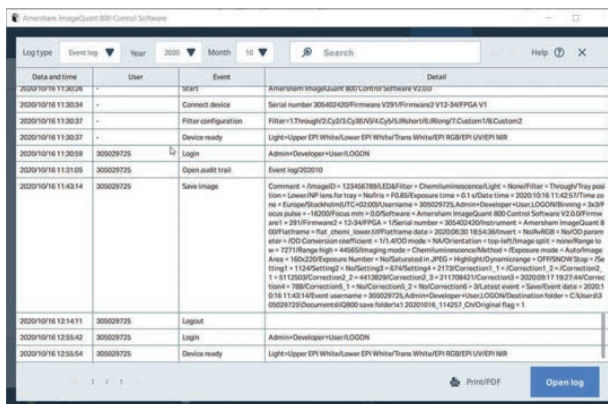
This section contains information on how to access and save the log files as audit trail with Amersham ImageQuant 800 GxP.

Viewing and printing the audit trail

Follow the steps below to view and print the audit trail.

Step Action

- 1 Select **Audit trail viewer** from the exit menu.



- 2 Select the log type among **Event log** or **Service log** from the **Log Type** drop down menu.
- 3 Select the year and month from the drop down menus.
- 4 Click **Open Log**.
Result:
The audit trail for the selected period opens up.
- 5 Click **Print/PDF** to print or save as PDF the audit trail.

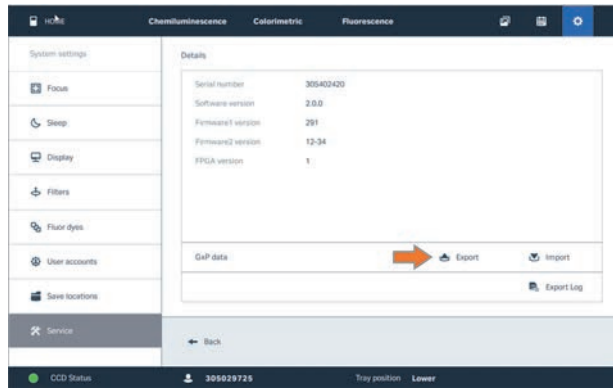
Export of the event log as backup

Follow the steps below to export a backup copy of the event log .

Step Action

- 1 Select **Service** from the System setting menu.
- 2 Click **Export** to save a back-up copy of the event log.

Step Action

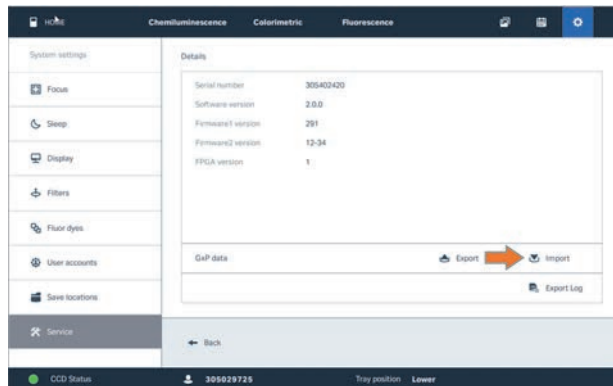


Import a backup copy of the event log

Follow the steps below to import a backup copy of the event log for example if a PC is changed or the system is upgraded..

Step Action

- 1 Select **Service** from the System setting menu.
- 2 Click **Import** to import a back-up copy of the event log.



Note:

*Importing an event log will replace the current event log.
Cytiva recommends to maintain backup copies of relevant files according to the user company policy.*

4 GxP recommendations

About this chapter

This chapter offers some practical guidelines for working in GxP environments, and considers some aspects that are not directly regulated through the functionality of the Amersham ImageQuant 800 GxP.

Operating system

While Amersham ImageQuant 800 GxP supports work in a regulated environment, it does not in itself provide security for experimental results and proprietary information. It is the responsibility of the user to make sure that the operating system settings provide a proper user management system and adequate security in accordance with site policies.

Details of security options and requirements may vary according to the site requirements and the operating system version, and are outside the scope of this User Manual. For further information, see *Amersham ImageQuant 800 GxP Privacy and Security Manual (29656756)*.

System clocks need to be correctly set on all computers, to ensure correct time-stamping of objects and coordination of procedure activation times. Time stamps are created as local time on the computer. The time zone is saved in the image properties, as part of the image file.

Locking the software

For maximum security, the control software can be locked when the screen is unattended, to restrict access to the activity queue and ongoing runs. Follow the instructions in [Lock the control software while imaging on page 29](#) to lock the control software while imaging.

Standard Operating Procedures (SOPs)

SOPs that specify in full detail how an analysis should be performed and documented are an essential feature of validated assays in a GxP environment. As a guiding principle, an SOP should give complete and unambiguous instructions for how a procedure should be performed from start to finish, in such a way that a user with a minimum of prior knowledge can perform the assay correctly.

Preparation of SOPs for validated assays is the responsibility of the customer. Some aspects that should be considered are listed below.

- Include detailed instructions concerning preparation of buffers, reagents and samples. Calibration requirements for measuring equipment (e.g., balances, pipettes, and pH meters) should be clearly stated and calibration procedures should be documented. Reagent specifications, including lot numbers where appropriate, should be documented.
- The SOP can also specify any archiving requirements.
- In order to make sure that Amersham ImageQuant 800 GxP is maintained correctly, procedures to be followed on completion of an imaging session should be included in the SOP.
- Regular cleaning and maintenance of the instrument is important for best performance, and should be specified in a separate SOP. In particular, cleaning of the sample trays is important to avoid contamination and poor results. More information is available in the *Amersham ImageQuant 800 Operating Instructions (29372604)*.

5 Functions supporting GxP

The functions of Amersham ImageQuant 800 GxP that support GxP requirements of the electronic record (FDA 21 CFR Part 11 Subpart B) are described in the table below.

FDA 21 CFR Part 11 Requirement	Support	Comments
11.10 (a) Validation of systems to ensure accuracy, reliability, consistent intended performance	Yes	<p>Amersham ImageQuant 800 GxP has been validated according to the ISO 9001 certified quality system of Cytiva.</p> <p>The Validation Support File (VSF) describes in detail how the Amersham ImageQuant 800 GxP is compliant and also includes a self-assessment checklist for the users. To access the VSF, register at cytiva.com/rsf.</p> <p>Amersham ImageQuant 800 GxP has been further assessed by an external third party. The assessment report can be found in the VSF.</p>
11.10 (a) and the ability to discern invalid or altered records	Yes	Any editing or tampering of files generated by the system are detected and a notification is given to the user.
11.10 (b) The ability to generate accurate and complete copies of records ...	Yes	The file system is based on Windows 10 operating system.
11.10 (c) Protection of records to enable their accurate and ready retrieval throughout the records retention period.	Yes	<p>The electronic records are standard .tif files which can be saved in standard file archives. The embedded checksum will ensure there is no editing of the files.</p> <p>The user is responsible for file backup systems and file storage.</p>
11.10 (d) Limiting system access to authorized individuals.	Yes	Amersham ImageQuant 800 GxP uses Active Domain Windows log in.
11.10 (e) Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Record changes shall not obscure previously recorded information.	Yes	The Audit trail event log record all relevant events. It is not possible to obscure previously recorded information.

FDA 21 CFR Part 11 Requirement	Support	Comments
11.10 (f) Use of operational system checks to enforce permitted sequencing of steps and events, as appropriate.	Yes	Operational checks are in place for creation of capture methods and prevents post-capture editing of images.
11.10 (g) Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand.	Yes	Control Software user identification with username and password is based on the Windows active domain. In addition the control PC uses the same Windows authentication system.
11.10 (h) Use of device (e.g., terminal) checks to determine, as appropriate, the validity of the source of data input or operational instruction	Yes	The control PC is directly connected to the imager via a USB cable and communicates with device specific protocols.
11.10 (i) Determination that persons who develop, maintain, or use electronic record/ electronic signature systems have the education, training, and experience to perform their assigned tasks.	N/A	<p>Cytiva development teams are trained and have necessary education and experience to develop products such as the Amersham ImageQuant 800 GxP. Cytiva also supports customers with training on how to use the imaging system.</p> <p>The user organization is responsible to make sure that new users are trained and follow the User Manual and the Operating Instructions.</p> <p>The user is responsible for the education and training of new users.</p>
11.10 (j) The establishment of, and adherence to, written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures, in order to deter record and signature falsification.	N/A	<p>The system captures user information in the audit log as well as in the image file (i.e., the electronic record).</p> <p>The user is responsible for written policies that hold individuals accountable and responsible for actions.</p>
<p>11.10 (k) Use of appropriate controls over systems documentation including:</p> <p>(1) Adequate controls over the distribution of, access to, and use of documentation for system operation and maintenance.</p> <p>(2) Revision and change control procedures to maintain an audit trail that documents time-sequenced development and modification of systems documentation.</p>	Yes	<p>All documents describing the operation and use of the imager are version controlled and accessible at cytiva.com. Additional validation support files are available upon request.</p> <p>Upon registration, change control notifications will be activated.</p>
11.30 Controls for open systems.	N/A	Amersham ImageQuant 800 GxP should be operated as a closed system.

5 Functions supporting GxP

FDA 21 CFR Part 11 Requirement	Support	Comments
<p>11.50 Signature manifestations.</p> <p>(a) Signed electronic records shall contain information associated with the signing that clearly indicates all of the following:</p> <p>(1) The printed name of the signer;</p> <p>(2) The date and time when the signature was executed; and</p> <p>(3) The meaning (such as review, approval, responsibility, or authorship) associated with the signature.</p>	N/A	<p>The username of the logged in user is saved and embedded in the .tif electronic record. There is no need for electronic signatures in Amersham ImageQuant 800 GxP.</p> <p>Electronic signatures are implemented in IQTL GxP analysis software where the images from Amersham ImageQuant 800 GxP are analyzed and reports are generated.</p>

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