

Aperio eSlide Manager

Administrator's Guide





Aperio eSlide Manager Administrator's Guide

This document applies to Aperio eSlide Manager Release 12.5 and later.

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Customer Resources

For the latest information on Leica Biosystems Aperio products and services, please visit www.LeicaBiosystems.com/Aperio.

Contact Information – Leica Biosystems Imaging, Inc.

Headquarters	Customer Support	General Information
1360 Park Center Drive Vista, CA 92081	Contact your local support representative with any query and service request. https://www.leicabiosystems.com/service-support/technical-support/	US/Canada Tel: +1 (866) 478-4111 (toll free) Direct International Tel: +1 (760) 539-1100 Email: ePathology@LeicaBiosystems.com

Worldwide: 23SPOKE, 23SPOKETOHUB; U.S. Only: 23ESM5Y01, 23SPOKE5Y01

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Notices

Revision History

Rev.	Issued	Sections Affected	Detail
A	January 2022	All	New manual for Aperio eSlide Manager 12.5. Based on existing Aperio eSlide Manager Administrator's Guide, MAN-0045, Revision P.

Cautions and Notes

- Specifications and Performance For information on the requirements for client workstations and monitors, and Aperio eSlide Manager performance characteristics, refer to the document Aperio eSlide Manager System Requirements.
- Installation Aperio eSlide Manager must be installed by a trained Leica Biosystems Technical Services representative.
- Accessories For information on using Aperio eSlide Manager with third-party accessories such as a Laboratory Information System (LIS) or image analysis algorithms not provided by Leica Biosystems, contact your Leica Biosystems Technical Services representative.
- Quality Control When viewing digital slides, the operator must confirm that the digital slide labels match the digital slide data for quality assurance.
- Maintenance To ensure optimal viewing of digital slides, periodic maintenance is required for the monitors connected to viewing stations. For information on monitor calibration, contact your Leica Biosystems Technical Services representative. For information on using a test image to verify monitor display, refer to the user guide for the Aperio Viewer being used.
- Cybersecurity Be aware that workstations are susceptible to malware, viruses, data corruption, and privacy breaches. Work with your IT administrators to protect workstations by following your institution's password and security policies. For Aperio recommendations on protecting your workstations and servers, see "Cybersecurity" on page 46.
- Training This manual is not a substitute for the detailed operator training provided by Leica Biosystems or for other advanced instruction. Leica Biosystems Technical Services should be contacted immediately for assistance in the event of any malfunction.



CAUTION: Use normal care in maintaining and using Aperio servers. Interrupting network connections or turning off servers while they are processing data (such as when they are analyzing digital slides or generating an audit report) can result in data loss.

Symbols

The following symbols appear in device labeling:



Manufacturer



Catalog number



Unique Device Identifier



The exclamation point within an equilateral triangle is intended to alert you to the presence of important operating and maintenance (servicing) instructions.

Customer Service Contacts

Please contact the office for your country for technical assistance.

Australia:

96 Ricketts Road Mount Waverly, VIC 3149 AUSTRALIA

Tel: 1800 625 286 (toll free)

Between 8:30 AM-5 PM, Monday-Friday, AEST Email: lbs-anz-service@leicabiosystems.com

Austria:

Leica Biosystems Nussloch GmbH Technical Assistance Center Heidelberger Strasse 17 Nussloch 69226 GERMANY

Tel: 0080052700527 (toll free) In-country Tel: +43 1 486 80 50 50 Email: support.at@leicabiosystems.com

België/Belgique:

Tel: 0080052700527 (toll free) In-country Tel: +32 2 790 98 50

Email: support.be@leicabiosystems.com

Canada:

Tel: +1 844 534 2262 (toll free)

Direct International Tel: +1 760 539 1150 Email: TechServices@leicabiosystems.com

China:

17F, SML Center No. 610 Xu Jia Hui Road, Huangpu District Shanghai, PRC PC:200025

CHINA

Tel: +86 4008208932 Fax: +86 21 6384 1389

Email: service.cn@leica-microsystems.com

Remote Care email: tac.cn@leica-microsystems.com

Danmark:

Tel: 0080052700527 (toll free) In-country Tel: +45 44 54 01 01

Email: support.dk@leicabiosystems.com

Deutschland:

Leica Biosystems Nussloch GmbH Technical Assistance Center Heidelberger Strasse 17 Nussloch 69226 GERMANY

Tel: 0080052700527 (toll free) In-country Tel: +49 6441 29 4555

Email: support.de@leicabiosystems.com

Eire:

Tel: 0080052700527 (toll free) In-country Tel: +44 1908 577 650 Email: support.ie@leicabiosystems.com

España:

Tel: 0080052700527 (toll free) In-country Tel: +34 902 119 094

Email: support.spain@leicabiosystems.com

France:

Tel: 0080052700527 (toll free) In-country Tel: +33 811 000 664 Email: support.fr@leicabiosystems.com

Italia:

Tel: 0080052700527 (toll free) In-country Tel: +39 0257 486 509 Email: support.italy@leicabiosystems.com

Japan:

1-29-9 Takadanobaba, Shinjuku-ku Tokyo 169-0075 JAPAN

Nederland:

Tel: 0080052700527 (toll free) In-country Tel: +31 70 413 21 00

Email: support.nl@leicabiosystems.com

New Zealand:

96 Ricketts Road Mount Waverly, VIC 3149 AUSTRALIA Tel: 0800 400 589 (toll free) Between 8:30 AM-5 PM, Monday-Friday, AEST Email: lbs-anz-service@leicabiosystems.com

Portugal:

Tel: 0080052700527 (toll free) In-country Tel: +35 1 21 388 9112 Email: support.pt@leicabiosystems.com

The Russian Federation.

BioLine LLC
Pinsky lane 3 letter A
Saint Petersburg 197101
THE RUSSIAN FEDERATION
Tel: 8-800-555-49-40 (toll free)
In-country Tel: +7 812 320 49 49
Email: main@bioline.ru

Sweden:

Tel: 0080052700527 (toll free) In-country Tel: +46 8 625 45 45 Email: support.se@leicabiosystems.com

Switzerland:

Tel: 0080052700527 (toll free) In-country Tel: +41 71 726 3434 Email: support.ch@leicabiosystems.com

United Kingdom:

Tel: 0080052700527 (toll free) In-country Tel: +44 1908 577 650 Email: support.uk@leicabiosystems.com

USA:

Tel: +1 844 534 2262 (toll free) Direct International Tel: +1 760 539 1150 Email: TechServices@leicabiosystems.com

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Aperio eSlide Manager Overview

This chapter introduces Aperio eSlide Manager.

Aperio eSlide Manager delivers an effective digital pathology information management system that treats high resolution digital slides—that can be viewed, managed, and analyzed—as an integrated element in pathology workflow. Aperio eSlide Manager displays information in context, with gross (macro) images, digital slide images, reports, case histories, and other associated documents and images cross-linked and concurrently viewable.

About This Guide

This guide is intended for Aperio eSlide Manager administrators who need to know how to set up and manage an Aperio eSlide Manager site. For general information on how to use Aperio eSlide Manager, refer to the *Aperio eSlide Manager User's Guide*.



Throughout this document, "eSlide" and "digital slide" in general mean the same thing; however, "eSlide" is used to discuss elements of the user interface, while "digital slide" is used in more generic contexts.

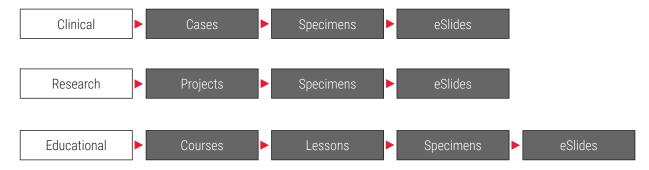
Aperio eSlide Manager Data Hierarchies

Three different types of Aperio eSlide Manager data hierarchies serve different types of users. (We discuss assigning a data hierarchy to a user role later in this guide.)

Aperio eSlide Manager organizes and displays data in a hierarchy that is tailored to the needs of three different types of users:

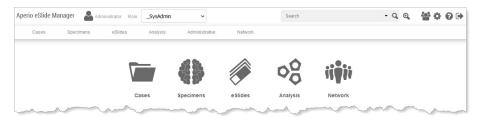
- Clinical Data is displayed and organized with cases at the top, followed by specimens and eSlides.
- **Research** Data is displayed and organized with projects at the top, followed by specimens and eSlides.
- **Educational** Data is displayed and organized with courses at the top followed by lessons, specimens, and eSlides.

(An additional data hierarchy is available for the optional Genie product—see the Genie User's Guide for details.)



Navigating Aperio eSlide Manager

When you log into Aperio eSlide Manager, you see the main Aperio eSlide Manager page:



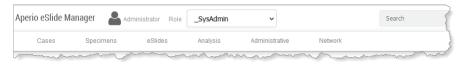
The exact appearance of this page depends on which data hierarchy the user role you logged in with uses and what optional modules are unlocked. For example, if your user role uses the Research data hierarchy instead of Clinical, the top-level data category is Projects instead of Cases.

The main features of this page include:

- **Data Icons** You use the data icons displayed on the Aperio eSlide Manager main page to access the information and images stored in Aperio eSlide Manager. For example, to see a list of digital slides click the eSlides icon.
- Menu Bar The commands on the menu bar help you use special Aperio eSlide Manager features and access Aperio eSlide Manager data in different ways. See the next section for information.
- **Logo** Click the Aperio eSlide Manager logo at the top of the page whenever you want to return to the main Aperio eSlide Manager page.
- ▶ Saved Searches The Search box at the top of every Aperio eSlide Manager page makes it quick and easy to search for any Aperio eSlide Manager data. For information on creating saved searches, see the *Aperio eSlide Manager User's Guide*.
- Open help for the page you are on.
- Log off the Aperio eSlide Manager site.

The Page Menu Bar

The Aperio eSlide Manager main page contains a menu bar that contains frequently used commands:



The first menus on the menu bar provide access to your data (in this case, Cases, Specimens, and eSlides). The specific data tables you see depend on which data hierarchy is assigned to your user role and which optional modules are unlocked. The remaining menus provide the following administrative functions:

- Analysis Register image analysis macros so that users can perform analyses on digital slides and check the image analysis queue.
- Administrative Perform basic administrative tasks. For example, define how data will be displayed on the Aperio
 eSlide Manager site, select password options, and so on.

Network – Aperio eSlide Manager Network provides a workflow-oriented approach to accessing the data maintained in Aperio eSlide Manager. For example, it provides histotechnicians the tools to assemble a case and assign it to a pathologist for review. Pathologists see a worklist of cases to review and may send a case back to the histotechnician for more work, review prior cases for the current patient, and send a case to another pathologist for review. For more on Network, refer to the Aperio eSlide Manager User's Guide.

You can also navigate by clicking on the Aperio eSlide Manager logo at the top of the page to return to the Aperio eSlide Manager main page.

Unique Device Identifier (UDI)

Regulatory bodies now require that devices and software contain a UDI (Unique Device Identifier) that uniquely identifies that product.

To see the UDI for Aperio eSlide Manager, go to the bottom of the Aperio eSlide Manager screen and click on the About eSlide Manager link:



For More Information

For information on accomplishing specific administrator tasks, see:

System Setup

Task	See
Changing the initial administrator password	"Step 1 – Log in and Change the Global Administrator Password" on page 16
Analyzing the needs of your users by determining what they do and what data they need to view/add/modify/ delete	"Step 2 – Analyze Users/Workflows" on page 17
Adding users	"Chapter 4: Adding Users" on page 27
Customizing data tables to change how Aperio eSlide Manager displays data, and defining clinical worklists	"Chapter 3: Editing Data Tables" on page 21
Creating the user roles for your site	"Chapter 5: Defining User Roles" on page 30
Setting up data groups	"Chapter 6: Creating Data Groups" on page 37

System Maintenance

Task	See
Creating system and data audit reports and enabling electronic signatures and reasons for change	"Chapter 10: System and Data Audits" on page 56
Changing page display options	"Chapter 11: System Settings Options" on page 64
Standardizing stain, body site, and comment entries	"Chapter 12: Managing Stains, Body Sites, and Comments Libraries" on page 70
Registering analysis macros	"Chapter 14: Adding Image Analysis Macros" on page 78
Options for scanning	"Chapter 2: Aperio eSlide Manager Initial Setup" on page 16
Configuring passwords for Aperio applications	"Aperio Application Password Protection" on page 54

User Maintenance

Task	See
Setting password options	"Chapter 9: Password and Login Options" on page 49
Changing login timeout	"Appendix A: Configuration Settings" on page 83
Unlocking user accounts	"Unlocking a User Account" on page 52
Setting clinical viewing mode for users	"Setting Clinical Viewing Mode" on page 29

Advanced

Task	See
Enabling SSL and secure certificates	"SSL and Certificates" on page 44
Setting up custom events	"Appendix D: Custom Event Handling" on page 92
Implementing cybersecurity protection	"Cybersecurity" on page 46
Entering a new Aperio eSlide Manager license	"Appendix E: License Administration" on page 93
Adding an RSS feed to the login page	"Adding an RSS Feed to the Login Page" on page 69

Aperio eSlide Manager Initial Setup

There are several steps you should take when you first start Aperio eSlide Manager to get it ready for your users. This chapter discusses these initial steps. We assume that Aperio eSlide Manager is already installed.

	Task
Step 1	Log in and Change the Global Administrator Password
Step 2	Analyze Users/Workflows
Step 3	Add Users
Step 4	Customize Aperio eSlide Manager Data Tables (Optional)
Step 5	Define User Roles
Step 6	Add Data Groups
Step 7	Customize Search

Step 1 - Log in and Change the Global Administrator Password

Open your Internet browser and in the address box type the URL of the Aperio eSlide Manager web site. You can get this address from the person who installed Aperio eSlide Manager on your organization's network.



The user password is case sensitive.

Log into Aperio eSlide Manager. If this is the first time anyone has logged onto the Aperio eSlide Manager site, obtain the default Aperio eSlide Manager user name and password from your Leica Biosystems Technical Services representative.

This is the user name and password used by the primary Aperio eSlide Manager administrator, known as the Aperio eSlide Manager global administrator.



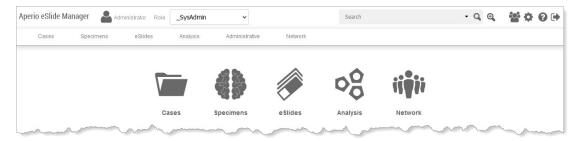
If an Aperio eSlide Manager administrator or user is logged on for a set period of time without any activity, the login session times out and the user is required to log in again. This timeout period is by default 30 minutes, but can be changed—See "Appendix A: Configuration Settings" on page 83.

Because you are logging in as the global Aperio eSlide Manager administrator, you are asked to choose a data hierarchy to log into. (Other Aperio eSlide Manager users will already have a data hierarchy assigned to the user role they log in with.) Click on the data hierarchy you want to use.



Now you see the main Aperio eSlide Manager page. The appearance of the page differs slightly depending on which data hierarchy you are using.

In the clinical data hierarchy, the Aperio eSlide Manager main page looks like this:



In the clinical data hierarchy, the data categories are Cases, Specimens, and eSlides—other data hierarchies have different categories. Additional icons may also appear depending on your site configuration.

Changing the Initial Global Administrator Password

To preserve the security of your Aperio eSlide Manager site, we recommend that you change the global administrator password to a new password unique to your installation.



See "Chapter 9: Password and Login Options" on page 49 for information on how to set password options for your Aperio eSlide Manager site. For example, you can require that passwords be a certain length or use special characters. If you are going to use these password options, keep them in mind when you select your administrator password.

To change the administrator password:

- From the Administrative menu on the top menu bar of the Aperio eSlide Manager page, select My Settings. The User Details page appears.
- 2. Type your new password into the **New Password** box and then repeat it in the **Retype New Password** box.
- Click Save.

(For information on other user options on this page, see the Aperio eSlide Manager User's Guide.)

Step 2 – Analyze Users/Workflows

Before you start setting up Aperio eSlide Manager, and well before you start adding users, it is important to stop and think about who the users of your Aperio eSlide Manager are and what they do.

Consider:

- Will your users want to use Aperio eSlide Manager in the clinical, research, or education data hierarchy?
- Will any of your users need a subset of the administrative privileges?
- Will any of your users need to log into the scanner Console to scan slides?
- Will any of your users need to analyze digital slides using image analysis?
- Will any of your users need to use optional modules like Genie, Reporting, or TMALab?
- Will you want some of your users to have access to certain data fields?

This allows you to separate your users into different types. Here are some sample user types:

- Lab Supervisor Works in the clinical data hierarchy and needs some administrative privileges to add or delete stains or body sites and set up slide-specific processing. This user will need to create algorithm macros as well as analyze digital slides.
- Pathologist Works in the clinical data hierarchy and needs access to cases, needs to run image analysis and generate reports, but will not need to change patient data.
- **Researcher** Works in the research data hierarchy and needs access to all projects, specimens, and digital slides, but will not scan slides or need administrative privileges.
- ▶ **Technician** Works in the clinical data hierarchy and needs to scan slides and enter patient data, but does not need to create algorithm macros.

By carefully considering each user type's workflow, you can determine what data each user type needs access to and what Aperio eSlide Manager actions that user needs to perform. In Step 4 you will create the user roles that fit your user types.

Will you want your users to use clinical viewing mode? (See "Setting Clinical Viewing Mode" on page 29 for information on this mode.)

Step 3 - Add Users

You will want to define users before defining data groups and user roles.

Additional options can also be set for each user, such as setting clinical viewing mode and LDAP user authentication.

For information on adding users and setting these options, see "Chapter 4: Adding Users" on page 27. Also, see "Chapter 9: Password and Login Options" on page 49 for information on choosing password options.

Step 4 - Customize Aperio eSlide Manager Data Tables (Optional)

The data that appears on the Aperio eSlide Manager pages can easily be customized by the Aperio eSlide Manager administrator. For example, you can rename column titles or add or remove data columns. This is done by editing the Aperio eSlide Manager data tables. Although this step is optional, if you are going to do it you will want to do it before you create user roles so that the data fields visible to users will already be set when you assign user role data permissions.

For information on customizing the data tables, see "Chapter 3: Editing Data Tables" on page 21. That chapter also contains information on setting up clinical worklists.

Step 5 - Define User Roles

User roles define what Aperio eSlide Manager actions a type of user can perform and what data that user type can see, modify, or delete.

You can now translate the user types you defined earlier into user roles.

The Administrative menu Role Management command allows you to create as many user roles as are necessary for your Aperio eSlide Manager location.

For details on creating user roles, see "Chapter 5: Defining User Roles" on page 30.

Note that you can fine-tune data access for users that use the same user role by using data groups to give specific users access to different data. See "Chapter 6: Creating Data Groups" on page 37. Define user roles after you add users, as you will want to assign users to the user roles as you create the user roles.

At this time you might also want to create user groups, which creates groups to which users with similar activities and permissions can belong. See "Chapter 7: Creating User Groups" on page 40 for information on user groups.

Step 6 - Add Data Groups

The Aperio eSlide Manager data hierarchy determines the main categories of data for your site (for example, cases/specimens/digital slides).

Another way Aperio eSlide Manager organizes data is by data groups. Data groups allow you to categorize data by who uses it. Later you will be able to set user permissions based on the data groups.

For example, if you have three pathologists who use Aperio eSlide Manager to organize their cases, you may want to set up a separate data group for each pathologist and assign user permissions so that each pathologist sees only his or her data. Or you can assign user permissions so that all pathologists see all pathologists' data, but can only modify/delete their own.

You should define data groups before you add users to Aperio eSlide Manager, as you will want to give your users access to specific data groups.



Data groups allow you to restrict user access to specific collections of data. Be careful when creating data groups and setting user permissions to make sure users have access to the data they need.

For information on adding data groups, see "Chapter 6: Creating Data Groups" on page 37.

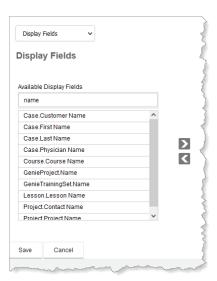
Step 7 – Customize Search

Aperio eSlide Manager Search is very comprehensive and so can return a great many results. You can structure the search for your Aperio eSlide Manager location to provide a user experience tailored for your organization.

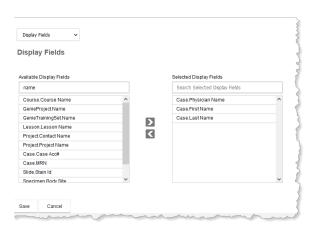
To customize the search:

- 1. Go to the Administrative menu and select Search Settings.
- 2. On the Search Fields page, click the drop-down list at the top of the page and select either Search Fields to define the data fields the users can search for or Display Fields to define the data fields that will be returned by the search. (Data table fields that are not set to visible status will not appear as choices in these lists. Also note that users who do not have full control or read-only access to these fields will not see them when performing a search.)

3. To filter the list of fields, type a few characters in the **Search Available** text box and only the fields containing those characters will be shown in the list. For example, by typing *name* in the search text box, only fields that contain those characters appear in the list:



4. To select a field to use, drag it from the left column to the right column or use the < and > buttons to move it. To remove a field, move it from the right to the left column in the same way.



3 Editing Data Tables

Data on Aperio eSlide Manager pages can be customized by changing column titles or adding your own columns.

For each category of data that appears on the main Aperio eSlide Manager page, a data table exists that defines what columns are displayed and the titles displayed for the columns. Data tables differ somewhat depending on the Aperio eSlide Manager data hierarchy you are logged in under. For example, the Aperio eSlide Manager research data hierarchy includes a Project data table, while the clinical data hierarchy includes a Case data table.

You can add your own columns with your own definitions of what data appears in those columns.

Before you begin, decide what fields will be used in each of the data tables to accommodate your workflow. For example, if a team of doctors needs access to a group of digital slides, you might want to add a column displaying the name of the lead researcher of the team. Or you might want to add a column for a diagnosis. It is very important that you think about how you want your data to be organized before you start adding data to Aperio eSlide Manager.

To see what data columns are already defined, open the data table as discussed below.



When changing data on an Aperio eSlide Manager page, remember to click **Save** to save your changes or click **Cancel** to exit the page without saving your changes.

Opening a Data Table

To open and edit a data table:

- 1. Go to the **Administrative** menu and select **Data Table Management**.
 - In Aperio eSlide Manager, all data tables for all data hierarchies are listed if you are the global administrator. Additional tables may be listed if your site has optional modules licensed.
- Click Edit next to the name of the data table you want to edit or click the name of the data table to open that data table.

Notes on Data Fields

- You cannot change the Column Name field, which is an internal identifier. But you can change the Display Name, which is the column title the user sees. See the next section for details on customizing a column title.
- The first data table field with the column name of Id is maintained by Aperio eSlide Manager and increments by one for every entry made. The Id numbers for projects, cases, specimens, and slides will most likely not be the same, as the number of slides is usually greater than the number of specimens, cases, or projects.
- The Data Type for specific data columns cannot be changed. The Data Type is used to validate user entries (for example, if Data Type = Date Time, then the user entry must be in the format of a date and/or time).

- Each data table contains an Events section at the bottom of the table—this is for creating custom events. See "Appendix D: Custom Event Handling" on page 92 for more information.
- The IncludeInReport and ReportDisplayOrder fields are used by the optional Aperio eSlide Manager Reporting module. For information, see the *Aperio eSlide Manager Reporting User's Guide*.

Customizing the Data Display

After opening a data table as discussed above, you will be able to:

- Re-order the columns of data that Aperio eSlide Manager displays into the order that makes sense for your installation.
- Make some columns visible and others invisible.
- Define a new column title.
- Add a custom column for additional data.
- Define a list of choices for your users to use when they enter data.

If you want to	Do this
Re-order columns	Edit the data table. For each data column, click the down-arrow in the Order column and select a number representing the order in which you want that data column to appear on the Aperio eSlide Manager page.
	For example, if you want the Accession Number to appear in the first column on the Specimen page, select 1 for that field.
Make columns visible or invisible	Edit the data table. For any data column, click the down-arrow in the Order column and select Not Visible if you don't want the column to appear on the Aperio eSlide Manager page.
	If you want to make a data column visible (that is, its order is currently set to Not Visible), select a number in the Order column representing the order in which you want it to appear on the Aperio eSlide Manager page.
Change the column title	Edit the data table. For any data column, type a new title in the Display Name field. This will appear as the new title of that column on the Aperio eSlide Manager page.
Select fields for access audits	The Access Audit column appears if you have the optional Compliance Module installed and licensed and you have selected Access Auditing Enabled on the System Settings page. Use the check boxes in this column to choose which fields you want to audit user access to. See "Chapter 10: System and Data Audits" on page 56 for more information on auditing.

Predefining Choices for a Field

For any data column, you can predefine a list of choices for the Aperio eSlide Manager user who will be filling in that field. For example, on the Specimen table, if procedures can be **Lumpectomy**, **Biopsy**, **Mastectomy**, or **None**, you can enter those choices in the Vocabulary field for the Procedure column. Separate each choice with a | symbol:



With the pre-defined choices above, when the user creates a new specimen and enters data in the Procedure field, a drop-down list appears giving the choices.

If you do not predefine choices, the user can enter anything he or she chooses as long as it is in a valid format for that field.

Adding User-Defined Columns



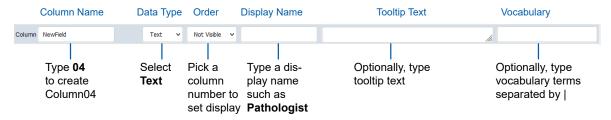
Note that future reporting or interface options may not recognize user-defined columns, so we recommend using the predefined columns with your appropriate display names whenever possible.

Almost every field in an Aperio eSlide Manager data table can be renamed by the administrator to tailor the appearance of the Aperio eSlide Manager page for the needs of your organization.

However, you can also add new columns.

At the bottom of each data table, a Column field allows you to create your own data column. The internal name of the field is prefixed by the word **Column**, followed by your own text (for example, **Column04**). You can select the type of data that can be entered in this field (Text, Memo, Number, Integer, or Date), and can also supply a display name and optionally a vocabulary list.

Suppose we want to add a data field for **Pathologist** on the Case data table.



After entering the data for the new column, click Save. It then appears in the appropriate list page.

Digital Slide Image Fields

A single digital slide can have multiple images associated with it. For the Slide data table only, an **Image Field** check box appears on the user-defined column line.



This check box allows you to specify whether the new data field applies just to a digital slide (check box not selected) or to all images associated with that digital slide (check box selected). If you select this check box, the new data field you defined will be available to edit for each image in the eSlides Image area of the appropriate detail page.

Configuring Non-Data Fields

The Data Tables pages include some non-data entry items as fields so you can make thumbnails invisible or change the column in which they appear on the page. On the TMA Spot Table page, you can make the Tasks links invisible or move them to another column.

Note that the Thumbnail Display Settings on the System Settings page do not override the data table settings; if thumbnails are made invisible on a data page, they will not appear even if enabled on the System Settings page. Likewise, if thumbnails are turned off for a user role, they will not appear for the user even if they are enabled on the System Settings page.

Because thumbnail images and TMA spot tasks are treated as data fields, you can change the way users use them by editing user role data table field permissions.

Defining Case Worklists

An important feature for maximizing user efficiency is the ability to define a case work list:

- 1. Edit the Case table. The Case Table page appears.
- In the Status Vocabulary box, type the different statuses you would like to apply to cases. (We suggest *Incomplete*, Pending, and Complete, but use the terms that are suitable for your operation.) Separate each vocabulary item with a | symbol.



Now **List Cases (Incomplete), List Cases (Pending)**, and so on appear in the Cases menu at the top of the Aperio eSlide Manager page (you might need to log out and then log back on to see the change).

And **Cases (Incomplete), Cases (Pending)**, and so on, now appear in the list of start pages on My Settings page. (See the *Aperio eSlide Manager User's Guide* for information on how each user can choose his or her own Aperio eSlide Manager starting page.)

Data Views

Aperio eSlide Manager provides an easy way to customize the user experience on Aperio eSlide Manager and Aperio eSlide Manager Network by using data views.

Case Worklist Data View

When a user goes to the case list page by using one of the case worklist commands, the fields displayed on the cases list page are limited to those fields useful in a clinical environment as defined by the Aperio eSlide Manager administrator.

For example, the case list page may contain patient information, but no information on data group or case sharing.

The Aperio eSlide Manager administrator defines the clinical worklist view:

- Select Data Table Management on the Administrative menu. At the bottom of the Data Tables page is a Data Views section.
- Click Case Worklist to edit that data view.

- 3. On the Case Worklist View page, you can view the fields that will be displayed for users using the case worklists. If you wish to make fields invisible, select **Not Visible** in the Order Column. To add additional fields to that view, click the + next to Case Worklist to expand the list of fields and select fields by changing Not Visible to a column number.
- 4. After clicking **Save**, any fields you set to Not Visible move to the bottom of the page. You can re-enable the fields by setting them to a position in the Order column and clicking **Save**.

Aperio eSlide Manager Network Data Views

Aperio eSlide Manager Network data views allow the administrator to select additional data fields to be displayed at the bottom of the Case Data tab in Aperio eSlide Manager Network. In most cases, these fields are read-only, but in some cases fields in the Case Assembly application may be modified by the user.

Each application has its own data view listed in the Data Views section of the Data Tables page.

To go to the Data Views list, go to the Administrative menu, and select Data Table Management.

At the bottom of the page, you see the Data Views section, which lists the Case Worklist data view followed by the Aperio eSlide Manager Network data views.

To edit an Aperio eSlide Manager Network data view, click the Edit link on the line for that data view.

By default, all fields for the data view are invisible so the first view of the Additional Information View page looks like this:



To see the available fields for this data view, click the + symbol next to Not Visible Fields.

After making one or more fields visible by selecting a column number, the Additional Information View page lists the visible fields and the additional fields appear on the bottom of the Case Data tab in the corresponding Aperio eSlide Manager Network case workflows.

Here are some tips on editing data views:

- To remove a field from the Additional Information area of the Case Data tab, edit the appropriate application data view and set the field to **Not Visible**.
- Aperio eSlide Manager Network data views do not support vocabulary lists.
- All Aperio eSlide Manager Network data view fields are read-only except for some fields used in the Case Assembly application, which can be modified by users.
- User-defined fields in the case table can be made visible in the case data views.
- Some fields are computed fields, which means they are created from multiple elements of data, such as PatientFullName. Computed fields are always read-only.

- Many of the fields listed on these data view pages should only be used by Leica Biosystems technicians.
- ▶ The fields we recommend for Aperio eSlide Manager Network users are:
 - CustomerId Converts to customer name.
 - MasterId System ID of initial case record.
 - PriorityId Converts to priority name.
 - **Description** Indicates the system-defined case state (read-only). We recommend changing the display name to *Case State*.

Custom Events

At the bottom of each data table page is an Events section in which you can define a custom event for that data table. See "Appendix D: Custom Event Handling" on page 92.

4

Adding Users

This chapter discusses how to add users to Aperio eSlide Manager.



When changing data on an Aperio eSlide Manager page, remember to click **Save** to save your changes or click **Cancel** to exit the page without saving your changes..

Adding a New User

- 1. Go to the **Administrative** menu and select **User Management** to open the Users page.
- 2. Click Add. The User Details page appears:



Tips on Using the User Details Page

If you want to	Do this
Select the user authentication method	If your organization uses an LDAP server to centralize user authentication and user information, and the Aperio eSlide Manager LDAP interface has been installed and configured, you can select LDAP from the Authentication Type drop-down list to tell Aperio eSlide Manager to use your LDAP server for these services. (For information on defining the connection between Aperio eSlide Manager and your LDAP server, see the <i>Configuring the Aperio LDAP Interface</i> document.) If you want Aperio eSlide Manager to handle user authentication and information, select Spectrum from the Authentication Type drop-down list.
Specify user details	If you use your LDAP server to authenticate a user to Aperio eSlide Manager, user information (such as phone number and email address) shown in Aperio eSlide Manager for that user is obtained from the LDAP server; therefore, those fields are disabled in Aperio eSlide Manager for that user. If Aperio eSlide Manager is handling authentication for this user, the user information is maintained in Aperio eSlide Manager and you can enter the Login, Full Name, Password and Retype Password in the User Details section of the page. Optionally add other information such as phone number and email address.
	Tips: • The Login is the user name the user enters to log into Aperio eSlide Manager (for example, "DSmith"). The login name must be at least 5 characters.
	• The Full Name is the name displayed on the Aperio eSlide Manager pages (for example, "Dr. David Thompson").
	The text you see next to the Password field (if any) depends on the system settings chosen by the administrator.
	Be sure your user knows that Aperio eSlide Manager passwords are case sensitive.
Make a user an administrator	If you want to give a user administrative privileges, assign him or her a user role that has the necessary administrator privileges enabled. See "Chapter 5: Defining User Roles" on page 30.
Delete users	On the Users list page, click Deactivate on the line of the user you want to delete (users that do not have a Deactivate link are system users and cannot be deleted).
Disable license warnings for a user	When you are reaching the limits of an Aperio eSlide Manager license (for example, approaching the maximum number of images allowed by the Aperio eSlide Manager license), an Aperio eSlide Manager user receives a warning message when or she logs into Aperio eSlide Manager. An administrator may disable license warnings for a specific user by editing the definition of that user and selecting the Disable license warnings check box.

Assigning User Roles, Data Groups, and User Groups

Once you have defined users, you can go to the Roles, Data Groups, and User Groups pages to assign the users to them. See:

- "Chapter 5: Defining User Roles" on page 30
- "Chapter 6: Creating Data Groups" on page 37
- Chapter 7: Creating User Groups" on page 40

Setting Clinical Viewing Mode

When a user has clinical viewing mode set, viewing a digital slide in Aperio ImageScope limits the tools shown and sets the Annotation window to summary view. This allows the user to focus on a clinical workflow without being distracted by other general-purpose tools.

Here are the ways that clinical viewing can be set:

- When creating a new user, the Aperio eSlide Manager administrator can select the default viewing mode for that user by selecting or clearing the Clinical Viewing Mode check box on the User Details page.
- Each user can override the default viewing mode by going to the **Administrative** menu, selecting **My Settings**, and then selecting or clearing the **Clinical Viewing Mode** check box.
- Within Aperio ImageScope, a user can enable or disable clinical viewing mode by going to the View menu and selecting View Clinical Toolbar or View Standard Toolbar. When in clinical viewing mode, the list of icons on the toolbar are limited to just those used in a clinical workflow. In addition, only the summary view of the Annotations window is available. (The summary view gives the user a way to quickly select tumor regions and analyze them using the appropriate algorithm for that tissue/stain combination in one easy step.)

For More Information

Please see "Chapter 9: Password and Login Options" on page 49 for information on the following Aperio eSlide Manager options:

- Changing the required password length or selecting whether special characters must be included in the password.
- Forcing a user to choose a new password.
- Seeing the status of a user's account.
- Setting a user's account to expire on a certain date and restoring it after that date.
- Locking a user's account after a specified number of invalid login attempts and unlocking it.
- Viewing a log of a user's login activities.

5

Defining User Roles

Aperio eSlide Manager user roles permit you to fine-tune an Aperio eSlide Manager user's access to specific data and Aperio eSlide Manager functions.



When changing data on an Aperio eSlide Manager page, remember to click **Save** to save your changes or click **Cancel** to exit the page without saving your changes.

A user role consists of a set of command and data permissions that define what a user can see, edit, delete, and do on Aperio eSlide Manager. User roles build on data groups, which provide access to a specific group of data, by creating a definition that builds a complete Aperio eSlide Manager environment tailored to a particular type of user.

The Aperio eSlide Manager administrator can define any set of user roles that suit his or her organization and workflow.



User role permissions work in conjunction with data group access permissions. If the data group access rights conflict with user roles permissions (for example, a user is given Full Control access to a data group, but the user's role prohibits viewing data in that data group), the most restrictive access permission prevails

Multiple User Roles

Each Aperio eSlide Manager user or administrator can be assigned multiple user roles. For example, when performing the duties of a pathologist (reviewing cases, annotating tumor regions, performing analyses, reviewing analysis results and scores, and generating reports), Dr. Edwards may log in with the Pathologist user role. When performing administrative duties, Dr. Edwards may log in with the ClinicalAdmin user role.

When a user has more than one user role assigned, after logging in the user is asked to choose which user role he or she wants to log in under:



System Roles

If a user role name begins with an underscore (for example, _SysAdmin), that is a system role that cannot be changed or deleted. If you want to use the permissions for such a role, but want to fine-tune them, you can create a new user role initialized with that system role and then change the permissions for the new role.

User Role Dependencies and Tips

We recommend you carefully consider user role definitions before creating them to make sure that all users have access to the data they need, but do not have access to data you want to keep confidential.

Be aware of the possible dependencies between user role permissions. For example:

- If a user can delete an Aperio eSlide Manager element (such as a case, project, course, lesson, and so on), you must also make sure they have permission to delete elements that belong to that case (such as a specimen, slide, or image).
- The user must have permission to perform all actions belonging to a particular product. For example, when using TMALab to segment a TMA slide using an existing block, the user must have permission to Segment Slide (under TMA Blocks), and must also be able to Add, Assign, and Export TMA Spots and TMA Cores.
- An Aperio eSlide Manager user who uses an Aperio scanner to scan slides must have a user role that permits logging into the scanner Console.
- Also, remember that you can use data group access to fine-tune the data access for members of the same user role by giving individual users access to different data groups. For example, if you want students to be able to draw annotations in Aperio ImageScope, but not save them to the digital slide, make their access to the data group that contains the slides Read Only.
- To analyze digital slides and to create and change algorithm macros, the user role you logged in with must have the following command permissions enabled:
 - Analysis Macros Add, Edit
 - Images Analyze
- Be sure you understand the effect of the user role settings. For example, the Operator Permissions Images settings "Import Annotations" and "Delete Annotations" do not refer to using annotations in Aperio ImageScope, but rather to the ability to import and delete annotations on digital slides in Aperio eSlide Manager (used when setting up validation studies).
- To make sure that users can use image annotations, ensure that the **Add, Edit, Assign, Export, Clone** permission is enabled for the appropriate user roles in the Command Permissions area of the Roles page. See "Assigning Command Permissions" on page 34.

Aperio eSlide Manager Global Administrator

Aperio eSlide Manager users can be given a set of administrator command and data permissions, so your site can have a hierarchy of Aperio eSlide Manager administrators. There is only a single, *global* administrator who has all the privileges and permissions that can be assigned to an administrator, while multiple Aperio eSlide Manager users can have a subset of the administrator rights.

The global administrator differs from other Aperio eSlide Manager administrators:

- The global administrator has the user name of administrator and is assigned the system user role of _SysAdmin.
- Other administrators may be assigned the user role of _SysAdmin, but are not considered global administrators.
- The global administrator can choose from any of the data hierarchies when logging in, while other administrators automatically log in with the data hierarchy assigned to their user role.

- The global administrator has the ability to see and edit all data tables regardless of what data hierarchy he or she logged in with, while other administrators can only see and edit the data tables for the data hierarchy they are logged in with.
- Only the global administrator can perform the initial Aperio eSlide Manager licensing functions of entering the System ID and entering the first license.

Permissions and Access Security

As a security measure, users cannot create and assign to themselves a role containing more permissions than the role they are logged in with. This results in a simple rule that you must keep in mind when creating and editing user roles:

You cannot create or modify user roles to have access to data and commands that the user role you are logged in with does not have access to.



These restrictions apply to Aperio eSlide Manager users whose user role allows them to create user roles. These restrictions do not apply to the Aperio eSlide Manager global administrator who by design has access to all user roles.

This affects all areas of creating and modifying user roles and users. Here are some examples of this principle in action:

- A user cannot initialize a new role with any role other than the one the user is currently logged in with.
- A user cannot modify permissions in any role so that they exceed the permissions granted to the role the user is logged in with. For example, if the user's logged in role has read-only access to a field, then the user can only give a user role read-only or no access to that field, not full control.
- A user cannot assign roles that are not assigned to the user's own account or that are assigned to the user's own account but belong to a data hierarchy other than the one the user is currently logged into.
- A user cannot edit existing data group permissions for a user if he does not have full control of that data group.

All users who create roles always have access to and can log in with the roles they create. To avoid the situation where these users see a large list of roles from which to choose when logging in, the **Hide** check box on the User Details page allows the administrators to choose which user roles such users see on login (by default this check box is selected to hide additional roles). See "Hiding User Roles on Login" below for details.

Hiding User Roles on Login

Any user whose role allows creating user roles has the option of whether or not to choose from all user roles he or she created when logging in. This is controlled by the **Hide** check box on the User Details page for that user:



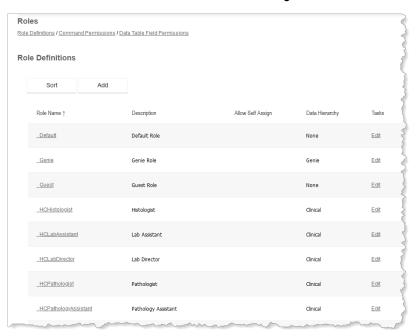
For situations in which you want to see specific user roles when you log in (for example, if you want to test a user role), clear the **Hide** check box for that role on your User Details page and you will be able to select that user role when you log in.

In some cases, the Hide check box will be automatically selected. In the example above, the LabAdmin role was initially assigned to user bedwards, which gave her the ability to create roles. She created the roles LabSupervisor and LabTech, which were automatically assigned to her. By default, the **Hide** check box is selected for those additional roles so she will not be able to choose them when logging in. At least one role must be unhidden.

Defining User Roles

To define user roles:

1. Go to the **Administrative** menu and select **Role Management**. You see the Roles page:



Click **Add** to add a new role. You see the Role Details page (see the illustration in the next section).

2. On the Role Details page, type a user role name (at least three characters and no spaces), a description for that user role and choose the data hierarchy that user role will see when logged in.

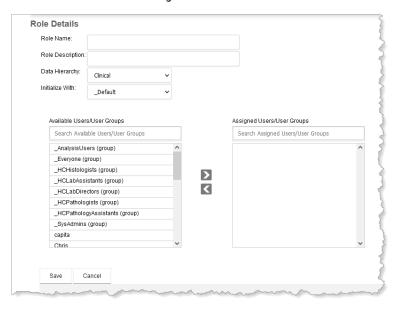
You can also choose another user role to initialize the new user role with. This allows you to initialize the new user roles with settings that are close to the desired ones and then adjust only those settings that are different.

Assigning Users to the User Role

To add a user to the user role, go to the Role Details page for that role where you see the list of available users and user groups on the left.

You can use the Search box at the top of the list to filter the list. Just type a few characters of the name or names you are looking for, and the list will adjust to include those names.

Select a user from the Available list and either drag it to the right column or use the < and > buttons to move users from the Available to the Assigned column or vice versa.



Assigning Command Permissions

After creating a new user role, you see the Command Permissions page where you can define what activities the user role can perform. (Or, click **Commands** next to a role on the Roles page.)

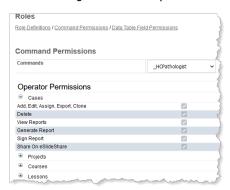
Note that these activities are divided into *Operator Permissions* (standard activities for users) and *Administrative Permissions* (activities usually reserved for administrators).

The permissions you see depend on which Aperio eSlide Manager applications are licensed on your Aperio eSlide Manager location. For example, you will not see entries for TMALab if TMALab has not been installed and licensed.

 Select the user role for which you want to define settings from the drop-down list at the top of the list of permission categories. To see the permissions for multiple user roles, select one user role from each drop-down list across the page.



2. Click the + sign next to each permission category to see what commands apply to that category.



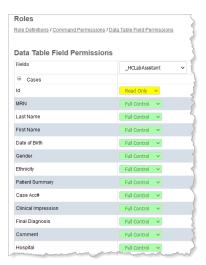
3. Review each setting and select or clear the check box for each activity, depending on what you want this user role to be able to do.

Assigning Data Field Permissions

Assigning data field permissions defines what data fields this user role can see and modify.

The data fields you see depend on which Aperio eSlide Manager applications are licensed on your Aperio eSlide Manager location.

- 1. Click **Data Table Field Permissions** next to a role on the Roles page.
- Select the user role for which you want to define settings from the drop-down list at the top of the list of permission categories. To see the permissions for multiple user roles, select one user role from each drop-down list across the page.
- 3. Click the + sign next to each permission category to see what data fields apply to that category (you only see the data fields that have been made visible in the data tables).



- 4. Review each setting and select **Read Only**, **No Access**, or **Full Control**, depending on what you want the user role to be able to do with this data field.
 - Read Only User can see but cannot modify this data field.
 - Full Control User can see and modify this data field.
 - No Access User cannot see this data field.

6

Creating Data Groups

This chapter discusses how to create data groups in Aperio eSlide Manager for organizing your data. User permissions are based on user roles and data groups.

Data groups allow you to define what data a user can see. If a user doesn't have access to a data group, the data in that group will not appear on the Aperio eSlide Manager page when that user logs in.

A data group can be a pathologist, sample type, project or department or whatever grouping makes sense to accommodate your workflow.

If you have multiple users using the same user role, but you want them to have access to different data, you can give them access to different data groups.

For example, Pathologist 1, Pathologist 2, and Pathologist 3 all use the Pathologist user role which, in our example, gives them the ability to: view cases but not change patient information, view and generate reports, score slides, and so on. Using data groups, you can give each pathologist access only to his or her own group of cases by assigning each pathologist's cases to a different data group and then giving each pathologist full access only to his or her data group.

Should you choose not to use data groups, all data will automatically be assigned to the Default data group (see below). Upon installation, an administrator has full control of the Default data group and a non-administrative user has no access to the Default data group. Access to the Default data group can be changed by the administrator.



When changing data on an Aperio eSlide Manager page, remember to click **Save** to save your changes or click **Cancel** to exit the page without saving your changes.

User Access to Data Groups

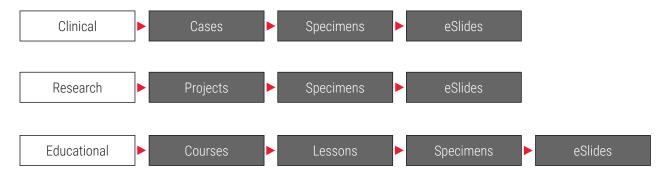
Data group access permissions are:

- Full Control User can add, edit or delete data in the group.
- Read Only User can only view data in the group.
- No Access User will not see the data in the group.

When the user adds new data, he or she can choose which data group to add the data to. If the user does not have access to a particular data group, that data group will not appear in the data group drop-down list.

Data Group Hierarchies

Aperio eSlide Manager organizes data in a hierarchy:



Data group permissions also follow this hierarchy. If a user is given Full Control to a Case in a clinical configuration, the user also has Full Control access to Specimens and eSlides associated with that Case.

When adding data to Aperio eSlide Manager, you must have Full Control permission to all levels of the data group. For example, if you add a new digital slide, you must have Full Control permission to the image that will be associated with that slide.

A user that may be required to enter data for all data groups must have Full Control access to all data groups. An administrator automatically has full control of all data groups.

The user role a user logs in with also must have the correct permissions to access all the data required by that user's job. See "Chapter 5: Defining User Roles" on page 30 for more on user roles.



Set up different data groups for users in different data hierarchies. For example, a user who uses the clinical hierarchy should have access to data groups that include only clinical data, while a user who uses the research hierarchy should have access to data groups that only include research data. This avoids confusion with users trying to assign digital slides or specimens that are already assigned in another data hierarchy.

The Default Data Group

The Default data group exists before you add any data groups. When you scan a slide, the resulting image is automatically added to the Default data group.

Although the administrator automatically has full control permissions to the Default data group, be aware that anyone who will be entering data and associating data in the Aperio eSlide Manager data tables must have Full Control permission to the Default data group.

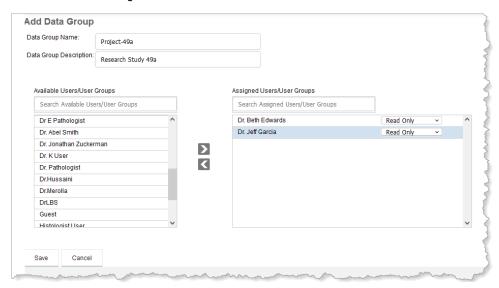
Adding a Data Group

- 1. Go to the Administrative menu and select Data Group Management to open the Data Groups window.
- 2. Click **Add** to add a new data group. You now see the Add Data Group page.
- 3. Enter the **Data Group Name**. This name will be displayed in the data group drop-down list viewed by the user upon data entry. Enter a **Data Group Description** as appropriate.

Assigning Users to the Data Group

To add a user to the data group, on the Add Data Group page, you see the list of available users and user groups on the left.

- Use the Search box at the top of the list to filter the list; type a few characters of the name or names you are looking for, and the list will adjust to include those names.
- Select a user from the Available list and drag it to the right column or use the < and > buttons to move users between the Available and Assigned columns.



In the drop-down list next to the assigned user in the right-hand pane, select the user's level of access to the data group (Read Only, Full Control, or No Access).

Creating User Groups

This chapter discusses what user groups are, how to create them, and how to assign users to them.

Aperio eSlide Manager controls access to data by setting permissions for user roles and data groups.

In many cases, multiple users should have the same data access and command permissions. For example, all pathologists may need to access the same data group and use the same commands. To make administration of Aperio eSlide Manager easier and more straightforward, you can create user groups to which multiple users can be added.

Note that this can result in complicated access rights as a user can belong to multiple user groups with different permissions. See "User Group Permissions Inheritance" on page 41 for details.



When changing data on an Aperio eSlide Manager page, remember to click **Save** to save your changes or click **Cancel** to exit the page without saving your changes.

System User Groups

Several system user groups are already defined, and cannot be deleted. These are used by various internal processes of Aperio eSlide Manager and the Aperio eSlide Manager Network clinical workflow solutions. System user group names begin with an underscore, such as _Everyone.

By default, all Aperio eSlide Manager users belong to _Everyone. Administrators can assign roles and data groups to _Everyone just as they can for any other user group.

Creating a User Group

To create a user group:

- 1. Go to the Administrative menu and select User Group Management to go to the User Groups page.
- 2. On the User Groups page, click Add.
- 3. On the User Group Details page, type the name of the user group and optionally a description.

Adding Users to a User Group

To add users to a user group:

- 1. You can use the Search box at the top of the Available or Assigned Users list to filter the list. Just type a few characters of the name or names you are looking for, and the list will adjust to include those names.
- 2. Select one or more users in the Available Users column and click the > button to move the users to the Assigned Users column. Or, simply drag the users over. Note that you cannot add a user group to another user group.

Working with User Groups

If you want to	Do this
Delete a user group	On the User Groups page, click Delete on the same line as the user group you want to delete. (Note that there is no Delete link on the line of system user groups, which cannot be deleted.)
	You cannot delete a user group that contains members.
Modify a user group	On the User Groups page, click Edit on the same line as the user group you want to edit. On the User Group Details page, you can change the name of the user group, its description, and
	add or remove users to or from the user group.

User Group Permissions Inheritance

Just as you do with users, you can assign user groups to specific roles and data groups.

A user can be given data access and command permissions in several ways:

- Directly by assigning the user to a data group;
- Directly by assigning the user to a user role that has been given specific command/operator permissions;
- Through a user group that has been assigned to a data group or user role.

Because of this, the user can have conflicting permissions. For example, the user can be a member of a user group that has Full Control access to the data group DemoData. However, the user group Group_Pathologists she is assigned to may only have Read Only access to that data group.

Here are the basic permissions inheritance rules:

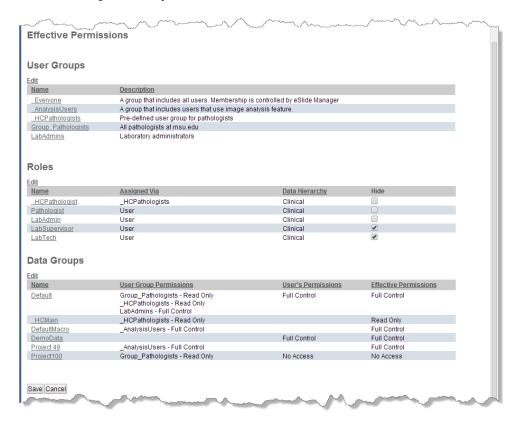
- The user gets the superset of all roles assigned to every user group he or she is a member of. So, when logging in, the user must select one of those roles.
- When there is a conflict in permissions between user groups the user is a member of, the user gets the most permissive setting.
- If you directly assign the user to a data group or user role, the permission setting for the user overrides any permission setting granted by membership in a user group whether that user group permission is more or less restrictive.

When the administrator is going to directly give a permission setting to a user that overrides a permission setting already applied to the user through membership in a user group, a warning displays, such as "WARNING: User [DR. BETH EDWARDS] is a member of the following user group(s): GROUP_PATHOLOGISTS. This action will override the user group access level for this user. Are you sure you want to proceed?"

To see the user's set of permissions:

- 1. Log in as an administrator, go to the Administrative menu and select User Management.
- 2. On the Users page, click the name of the user you want to see permission settings for or click **Edit** on the line for that user.

The User Details page shows the user's effective permissions that she inherited through her membership in user groups and those she was given directly:



In this example, the user was given Full Control access to the Default data group through her membership in the LabAdmin user group, but was given Read Only access by her membership in the Group_Pathologists user group. Her effective permission is Full Control, the less restrictive setting.

However, because permissions given directly to the user (not through a user group) override user group settings, she has No Access to the Project100 data group; although the Group_Pathologists user group gave the user Read Only access to the Project100 data group, she was explicitly given No Access when she was added to that data group.

Notice that the Roles section shows whether the user was assigned a role directly or inherited it through a user group.

Aperio eSlide Manager Privacy and Cybersecurity

In addition to the use of passwords to restrict user access to specific data (discussed in the next chapter), Aperio eSlide Manager also offers additional features that protect the privacy and security of your data.



This chapter discusses tools available to you to secure Aperio eSlide Manager data. It is your responsibility to decide what measures to put in place to secure your Aperio eSlide Manager installation.

User Authorization

In order to use any part of the Aperio eSlide Manager software, an individual must log into the system. A user logs in by entering a valid user name and password, which are verified against the Aperio eSlide Manager database. Once users have logged on, they remain logged on until they explicitly log off or until their session is timed out due to inactivity.

While users are logged on, everything they do is authenticated to ensure they are authorized. (In some cases, an individual may log in with different user roles to perform different activities.) In some cases, users may be authorized to *view* information but not to *update* it.

Guest Access

On the Aperio eSlide Manager login page, there is optionally a button which enables individuals to log in as a guest (that is, with the _Guest user role). Clicking this button signs the individual on as the guest user, at which point they are authorized to access "public" information only. If the individual attempts to access other information, they are prompted to log in as a different user.

For information on setting up the guest user and restricting data access permissions for that user, see "Appendix C: Setting up the Guest User" on page 90.

LDAP User Authentication

If your organization uses an LDAP server to centralize user authentication and user information, and the Aperio eSlide Manager LDAP interface has been installed and configured, Aperio eSlide Manager can use your LDAP server for user authentication and user information. See "Chapter 4: Adding Users" on page 27 to define whether a user will be authenticated by Aperio eSlide Manager or by the LDAP server. For information on defining the connection between Aperio eSlide Manager and your LDAP server, see the document Configuring the Aperio LDAP Interface.

Data Encryption

An important aspect of Aperio eSlide Manager is that it manages *specimen* information in addition to *image* information. Essentially, this is the difference between a thing and a picture of a thing. Most of the information useful in managing slides pertains to the specimen rather than to the digital image. Depending on the application, these data may be sensitive and may

include individually identifiable data governed by HIPAA. It is important that these data can only be *viewed* and *updated* by authorized users.

Patient Data Confidentiality

Aperio eSlide Manager provides a full security system that ensures that users can only access data they are authorized to see, thus protecting patient data from unauthorized access.

Digital slides and related metadata reside in the Aperio eSlide Manager database. Aperio eSlide Manager uses an administrator/user structure that restricts security-sensitive actions to an authorized administrator. The administrator can:

- Set up users with passwords. Users must log into Aperio eSlide Manager with their user name and password and be authenticated before they can access data.
- > Set up user roles that restrict access to certain Aperio eSlide Manager commands or data fields.
- Set up data groups that restrict access to data to specific users.
- Set users' access permissions to grant them full control access, read-only access or no access to the defined data groups.

SSL and Certificates

Aperio eSlide Manager Information Manager is a web-based system which uses standard web server software (Apache, from the Apache Software Foundation). Users of the system access Aperio eSlide Manager using standard web browsers such as Microsoft Internet Explorer, Firefox, Apple Safari, Opera, etc. Web browsers and web servers support a standard encryption technology called SSL (Secure Socket Layer). SSL was developed for e-commerce and financial applications, but is equally useful for applications which manage sensitive information such as Aperio eSlide Manager.

When a web application uses SSL encryption, the URLs all begin with https instead of http (you will notice this when you buy something online or access a financial website such as your bank). The "s" means "secure" (SSL is being used). Additionally, many web browsers display a "lock" icon when accessing a website which uses SSL encryption to indicate the communication between the browser and the website is secured.

Aperio eSlide Manager has the option of using SSL encryption. By default, SSL is enabled. For customers who will use Aperio eSlide Manager to manage clinical information or sensitive research information we recommend that SSL be enabled. There are some important considerations for enabling SSL encryption which are discussed in the following paragraphs; if you have questions about this please contact Leica Biosystems Technical Services.

Ordinarily, web applications use network port 80. This is the default for any http URLs. For example, the following URL will use network port 80:

http://spectrum.sitename.com/

By convention, secure web sites use network port 443. This is the default for any https: URLs. For example, the following URL will use network port 443:

https://spectrum.sitename.com/

When SSL is enabled, Aperio eSlide Manager automatically re-directs all users from insecure http: URLs to secure https: URLs. In the process, users will be routed from port 80 to port 443. Therefore in order to use Aperio eSlide Manager with SSL enabled, network port 443 must be "opened." If a visitor enters the following URL:

http://spectrum.sitename.com/

They will automatically be re-directed to the following URL:

https://spectrum.sitename.com/

There is no way for users to access an Aperio eSlide Manager system which has SSL enabled without using secure access.

There is one exception to the re-direction described above. If users visit an Aperio eSlide Manager system via the "public" directory, they will automatically be logged on as a guest, as described above. To continue the example above, they could enter the following URL (or click on a link):

http://spectrum.sitename.com/public/

For this case, they are not re-directed to a secure web site, since they will be accessing only public information anyway.

Some customers may choose to have only guest access to a public website. In that event local users will log into Aperio eSlide Manager and will use https: URLs with SSL data encryption, but public users will be auto-logged on to Aperio eSlide Manager as guests and will use http: URLs without SSL data encryption. In this configuration it is not necessary to "open" network port 443, since it will not be used by public visitors.

SSL is enabled on the Aperio eSlide Manager server by default. Leica Biosystems Technical Services can assist you if you need to disable or re-enable SSL.

Web applications which use SSL encryption must have a secure certificate associated with them. A certificate is a disk file which contains encrypted information that identifies the web application. It is used as a "key" to encrypt communication sessions between the web server and individual users' web browsers.

An internally-generated SSL certificate is used to secure communication between Aperio services. This certificate expires 3 years after installation. When this happens, the Aperio eSlide Manager system will no longer be usable. Contact Leica Biosystems Technical Services to regenerate and install certificates for Aperio services.

In addition to the internally-generated SSL certificate, it is recommended the Aperio WebServer be secured using an SSL certificate that is valid for the hostname it will be accessed from and be recognized by your intranet browsers. Your IT department can procure an SSL certificate for this purpose. Contact Leica Biosystems Technical Services to install this certificate.

As with the internally-generated SSL certificate, the SSL certificate provided by your IT department will also expire after a period of time (typically 1-3 years). Contact Leica Biosystems Technical Services to install the replacement Aperio WebServer certificate.

Note for Aperio eSlide Manager Sites that Use a Self-Generated SSL Certificate

If your Aperio eSlide Manager site is using SSL to protect data transactions and has a self-generated SSL certificate (that is, you created the SSL certificate yourself instead of purchasing one from a certificate authority), you need to install the certificate on the server in order for Aperio eSlide Manager Compliance to be able to create the Acrobat files that contain your audit reports and for Aperio eSlide Manager Reporting to be able to create the report Acrobat files. For details, see the Self-Generated SSL Certificate Installation and Setup for Reporting and Auditing Application Note.

Managing Privacy

If your Internet browser has its auto-complete feature enabled, your browser may display a white box that lists previously typed entries.

This can have security and privacy implications. If a single person uses the workstation, you may find the browser autocomplete feature convenient and time-saving.

However, if more than one person uses the same workstation to enter Aperio eSlide Manager data, patient names and private data may be displayed by the browser auto-complete feature, and this could violate your patient confidentiality policy.

Therefore, it is up to your Aperio eSlide Manager administrator to decide whether the Internet browser auto-complete feature should be turned off. Refer to the Internet browser help file to determine how to enable/disable this feature in the browsers used by your users.

Cybersecurity

There are a number of things your IT staff and administrators can do to protect Aperio servers on your network and the users who use them from cybersecurity threats.

This section discusses how Aperio products protect electronic protected health information (EPHI) and provide protections against cybersecurity threats. We also discuss the measures you can take to protect client workstations and Aperio servers on your network. This document gives information for IT network administrators, Aperio product administrators, and Aperio product end users.

Password, Login, and User Configuration Safeguards

- We recommend you set Windows password policy for client workstations to require the following:
 - A minimum of ten characters
 - At least one non-alphanumeric character
 - At least one numeric digit
 - At least one lowercase letter
 - Different from the previous five passwords used
 - Users to change their passwords every 90 days
 - If a user has five consecutive invalid login attempts, lock the user out for 30 minutes. If it is not practical to wait for 30 minutes to use the system, the user should contact the IT administrator to reset the user account.

Although these are recommendations for Windows passwords, note that Aperio eSlide Manager password requirements are also set by default to these requirements. For information on configuring Aperio eSlide Manager user passwords, see "Chapter 9: Password and Login Options" on page 49.

- We recommend you configure client workstations to time out screen displays after 15 minutes of inactivity and require users to log in again after that time.
- For security reasons, do not use user names "Admin," "Administrator," or "Demo" when adding users to the Aperio client workstations.

Physical Safeguards

We recommend you install and use a disk encryption utility to encrypt the data on client workstation hard disks to protect them.

- Be aware that workstations are susceptible to malware, viruses, data corruption and privacy breaches from physical media such as CDs, DVDs, or USB drives. To reduce the risk of data corruption or unauthorized setting changes, only use physical media that are known to be free from viruses or malware.
- Protect client workstations from unauthorized access by limiting physical access to them.

Administrative Safeguards

- We recommend using Active Directory to centralize user authentication both for security reasons and to make it easier to add and remove users from the system. Note that we also provide an LDAP interface to Aperio eSlide Manager to connect Aperio eSlide Manager to the LDAP directory service. See the Configuring the Aperio LDAP Interface document for information.
- Set up the users of the Aperio product with permissions that allow them to access only the portions of the system required for their work.
- We recommend that all users working with Aperio products be part of a specific Windows domain in which users or user groups have been defined with access permissions to images and other data used by this system, and that only these users and user groups have these access permissions.
- Follow your institution's security policy to protect data in the Aperio database.
- Protect the Aperio server and client workstations from unauthorized access by using standard IT techniques. Examples include:
 - · Firewalls We recommend enabling the Windows firewall on client workstations.
 - Secure VPNs for remote access of the Aperio server by client workstations
 - Allow lists, an administrative tool used to prevent unauthorized programs from running, should be implemented on Aperio servers and client workstations.

Protecting the Aperio Server

The Aperio server is the storage device that contains the scanned images. Here are some recommendations for your server:

- Use normal care in maintaining and using Aperio servers. Interrupting network connections or turning off the servers while they are processing data (such as when they are analyzing digital slides or generating an audit report) can result in data loss.
- Your IT department must maintain the servers and workstations, applying Windows and Aperio security patches and hot fixes that may be available for the system.
- Aperio eSlide Manager is installed with Microsoft SQL Express which does not provide data encryption. To encrypt your data at rest, we recommend using Microsoft Enterprise SQL Standard (2019 or later) or Enterprise SQL server which come with database encryption.
- We recommend putting all Aperio eSlide Manager services on a single server. If using a hub and spoke configuration, you must secure connection between spokes and the hub; we recommend that you protect data in transit by using SSL with strong security protocols such as Transport Layer Security (TLS) or that you use network-level encryption such as IPSec or SSH tunneling.

- You should select a server that can be configured to detect intrusion attempts such as random password attacks, automatically locking accounts used for such attacks, and notifying administrators of such events.
- Contact your IT department to make sure network configuration protects Private Health Information (PHI) and sensitive data in transit.
- We recommend implementing allow lists on the server to prevent unauthorized applications from running on it.
- If you are not using allow lists (which prevent any virus from executing), we strongly recommend installing anti-virus software on the server. Run antivirus scans at least every 30 days.
 - We also recommend that you configure the antivirus software to exclude .SVS, .SCN, .TIF, and .JPG file types as well as the file storage from "on access scanning" as these files can be very large and are accessed continually as they are being scanned and users are viewing the eSlides. Virus scans should be configured to run during non-peak hours as they are very CPU intensive and can interfere with scanning. (In rare circumstances, third-party applications such as virus or security software may prevent Aperio software from connecting to servers or devices. If you are having this problem, contact Leica Biosystems Technical Services for assistance.)
- We recommend you back up your servers, images, and the SQL database.
- We recommend encrypting the contents of the server hard disks.
- The file shares on the server should be protected from unauthorized access using accepted IT practices.
- You should enable Windows Event logging on your server to track user access and changes to data folders that contain patient information and images.

Off the Shelf Software

While conducting cybersecurity assessments, you may wish to consider which third party software components are used by Leica Biosystems software. Lists of all off-the-shelf software (OTS) used by Aperio eSlide Manager are maintained by Leica Biosystems. If you would like information on OTS used, contact your Leica Biosystems Sales or Customer Support representative and ask for the Software Bills of Materials for Aperio eSlide Manager.

9

Password and Login Options

This chapter discusses user password and login options that can be set by administrators for the entire site or for individual users.

The password and login options are on the System Settings page—that page also contains options for page display, scanning alerts, compliance module options, and reporting options (if the Compliance module is licensed). For information on those options, see:

- ▶ Thumbnail Display Settings "Chapter 11: System Settings Options" on page 64
- ▶ Global Image Share "Chapter 11: System Settings Options" on page 64
- Scan Alerts Settings "Chapter 15: Scanning Options" on page 81
- Compliance "Chapter 10: System and Data Audits" on page 56
- ▶ Report Generation Aperio eSlide Manager User's Guide



When changing data on an Aperio eSlide Manager page, remember to click **Save** to save your changes or click **Cancel** to exit the page without saving your changes.

LDAP Note

If your organization uses an LDAP server to centralize user authentication and user information, and the Aperio eSlide Manager LDAP interface has been installed and configured, user login and authentication will be handled for selected users by the LDAP server and the Aperio eSlide Manager login options will not be enforced for those users. For information on configuring the LDAP interface to Aperio eSlide Manager see the document *Configuring the Aperio LDAP Interface*.

Setting System-Wide Password Options

From the Administrative menu, select System Settings. The Settings page displays.

The settings on this page apply to all users of the system unless you override a setting for a specific user (see "Setting Password Options for Specific Users" on page 51).



In addition to the system-wide password settings discussed in this chapter, each individual user can use the My Settings command in the Administrative menu to change their password. See the Aperio eSlide Manager User's Guide for details.

The following password options are available. Note that to provide the best security, many of the password requirements are set by default to encourage your users to create complex passwords. When the user sets a password, reminder text shows them the requirements:

harmon and a second	- Mary Mary Mary Mary Mary Mary Mary Mary	and the same of th
Old Password:		
New Password:		(password must be at least 8 characters long, contain an uppercase, a
New Password.		lowercase, a numeric, and a special character (I, @, #, \$, %, ^, *, or _), and be different from previous 5 passwords)
Retype New Password:		
hammen with the same of the sa	and the same of th	White the same of

Option	Description
Minimum password length	The default length for passwords is eight characters. Set this to zero if you don't want to specify a minimum length.
Previous passwords remembered	When you force a user to change a password (or the user chooses to change their password), for added security you may wish to prevent them from choosing previously used passwords. This option causes Aperio eSlide Manager to remember the specified number of previously used passwords and prevents the user from choosing one of them. Set this to zero if you don't want to use this option.
Require lowercase letter	Select this check box to require the user to use one or more lowercase letters in their password.
Require uppercase letter	Select this check box to require the user to use one or more uppercase letters in their password.
Require number	Select this check box to require the user to use one or more numbers in their password.
Require special characters	For added security, select this check box to require the user to use at least one of these special characters in the password:
	! @ # \$ % ^ & * () _ + (space)
Maximum invalid login attempts	After the specified number of invalid login attempts, Aperio eSlide Manager locks the user's account and prevents them from logging in again. Set this to zero if you don't want to use this option.
	After the user makes the specified number of invalid login attempts, the next time they try to log in, they see an error message: "You have exceeded the number of invalid login attempts. Your account has been locked." The user's account is locked. (See "Unlocking a User Account" on page 52.)
Prevent simultaneous logins	To prevent a user from logging in while that user still has an active Aperio eSlide Manager session open, select the Prevent Multiple Simultaneous Logins check box. This option does not affect administrator or system user logins.
	Select this option to prevent a user from having multiple active Aperio eSlide Manager sessions. If the user tries to log in when they already have a session open, they see "The user is already logged in."
	Note that closing the Internet browser when logged into Aperio eSlide Manager does not log the user off—in this case, the session remains active until it times out. (See "Appendix A: Configuration Settings" on page 83 for information on adjusting the login timeout period.)
Maximum days between logins	After the specified number of days without logging in, Aperio eSlide Manager locks the user's account. When the user tries to log in, they will be told to contact an administrator to unlock their account (see "Unlocking a User Account" on page 52). Set this to zero if you don't want to use this option.

Option	Description
Password expiration time	After the specified number of days, the user's password expires. On or after the date specified, when the user tries to log in, they will be told they must change their password.
	Set this option to zero if you don't want to set an expiration time.
Password expiration warning time	The user will be warned the specified number of days before their password expires. Set this option to zero if you don't want to issue a warning.
Logging invalid login attempts	Choose where and if Aperio eSlide Manager will send notification of invalid login attempts by selecting an option from the Invalid Login Attempt Alerts Go To drop-down list.
	None – Do not log invalid login attempts.
	Administrator E-mail – Send notification to an administrator.
	Windows Event Log – Send notification to the standard Windows event log.
	For information on the Windows Event Log, see "Configuring and Using the Windows Event Log" on page 54.
SMTP alert settings	If you send invalid login attempts logs to the administrator, you need to fill in some information in the SMTP Alert Settings section of the System Settings page.
	• E-mail Recipient – The email address of the administrator to whom alerts will be emailed if Administrator E-mail is selected from the Invalid Login Attempt Alerts Go To drop-down list.
	 Aperio eSlide Manager E-Mail Address (From: field) – Some email servers require a "From:" email address for each message. Type a valid email address into this box. This does not have to be a real address, but must be in a valid email address format; for example: eSlideManagerAdmin@msu.edu. If you do not fill in this box, Aperio eSlide Manager will do its best to guess an appropriate email address, but this can cause problems if Aperio eSlide Manager guesses incorrectly—so, we strongly recommend entering something here.
	Outgoing SMTP E-Mail Server – The name of the SMTP email server that processes email for your organization. (You can get this from your network administrator.)
	SMTP User Name and SMTP Password – The user name and password used to log into your SMTP server. (You can get this from your network administrator.) Type the SMTP password again in Retype SMTP Password to make sure it is correct.

Setting Password Options for Specific Users

You can force a user to change their password the next time they log in or can set an expiration date on their account.

To see information on a user, go to the **Administrative** menu and click **User Management**. The Users page appears.

For each user, you can click **View Log** to see login information or click **Edit** to set password options. (See "Viewing the User Account Log" on page 53 for information on viewing logs.)

Editing User Account Settings

To edit a user's password options, click **Edit** next to that user's name on the Users page. The User Details page for that user appears.

In the User Details section, you can:

- Change or set the user name
- Change the user's password

Tip: You may want to set the user's initial password (for example, *changeme*) and also select the **Force user to change password at next login** check box. This provides the user with a one-time login, but then requires them to choose a password the first time they log in.

After logging in with the initial password, the user sees a window asking them to change their password, and sees text boxes to type in their new password.

- Set an expiration date for the user's account. On that date, the user's account will expire. If the user tries to log in on or after the expiration date, they will be told to contact an administrator.
 - To restore an expired account, the administrator can remove the expiration date on the account or change the date to a future date.
- See the status of a user's account. If the user account is locked, the administrator can unlock it. (See the next section, "Unlocking a User Account".)
- Force the user to change their password the next time they log in if the user forgets their password. The administrator sets a temporary password for the user and selects this option. This provides the user with a one-time login, but then requires them to choose a password the first time they log in.

Unlocking a User Account

If a user account has been locked (for example, the user has exceeded the number of invalid login attempts allowed), you can verify that the user account has been locked by going to the Users page:



The administrator can unlock it by going to the Users page and editing that user's account:



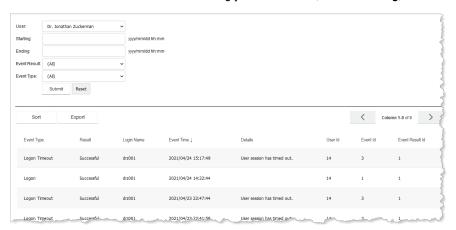
Click the Unlock link to unlock the account.



If a user's account is not locked but has expired, you can restore the account by removing the expiration date on this page or setting the expiration date to a future date.

Viewing the User Account Log

- 1. To view a user account log, go to the **Administrative** menu at the top of the page and select **User Management**.
- 2. On the line for the user whose account log you want to see, click View Log, and the user's account log page appears:



Note that you can select another user by using the User drop-down list at the top of the page.

By default, the list of all account events appears at the bottom of the page. To filter those events by date period or event type or result, use the options in the top pane of the page:

- Starting and Ending dates Choose a date range.
- **Event Result** Choose to display events that had a Successful or Failed outcome.
- **Event Type** Choose to display events having to do with Login, Logoff, or Login Timeouts.

Configuring and Using the Windows Event Log

By selecting **Windows Event Log** from the **Invalid Login Attempt Alerts Go To** drop-down list on the System Settings page, information will be written in the Windows Event Log file every time someone attempts to log into Aperio eSlide Manager but is unsuccessful in doing so.

If invalid logging happens frequently on your system, the default settings for the Windows Event Log may be not be adequate for use with Aperio eSlide Manager. If the message "Exception in database driver. The event log file is full." appears on the Login page, you will want to configure the Windows Event Log to increase its size and to overwrite the oldest entries with new entries.

The exact settings you should use depend on your installation, but we recommend increasing the maximum log size to at least 2MB (2048 KB) and selecting the Overwrite events as needed radio button. This allows the event log to overwrite the oldest items with the newest entries if the log fills up:

For information on configuring the Windows Event Log, see the documentation for your version of Windows.

Viewing the Windows Event Log

To view the Windows Event Log, click **Start** on the Windows task bar and select **All Programs > Administrative Tools > Event Viewer**.

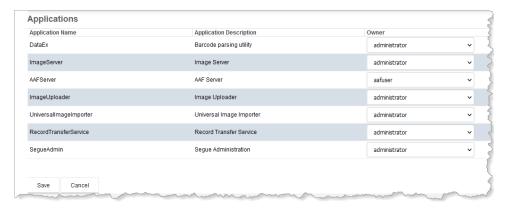
Aperio Application Password Protection

Several internal Aperio applications that pass data back and forth behind the scenes, such as Aperio Algorithm Framework and ImageServer, use passwords to communicate with other components of the Aperio system.

A specific user is designated the owner of the Aperio application, and the password for that user is maintained within the Aperio eSlide Manager database itself as the password of the application.

To set the owner of the Aperio applications that use this password protection method:

Go to the Aperio eSlide Manager Administrative menu and select Applications. The Applications page shows a list
of applications.



2. Choose a user from the **Owner** drop-down list. The application will then run logged in as that user and will use that user's password to log into other Aperio applications.

The default owner for Aperio applications is the global administrator because these applications need permissions and rights that the global administrator has by default. Although you can define a new user solely for use as application owner (for example, ImageServer_Owner), be sure to give that user a role that has access to all Aperio eSlide Manager data and all administrative rights. If there are any users other than the global administrator (user name administrator) who are the owners of multiple applications, make sure you do not have the **Prevent Multiple Simultaneous Logins** check box selected on the System Settings page.

10 System and Data Audits

Aperio eSlide Manager contains several features that assist your organization in complying with regulatory requirements such as FDA 21 CFR Part 11, HIPAA, and GLP. The optional Aperio eSlide Manager Compliance Module contains additional features that address specific regulatory requirements.

Aperio scanners and web management software are used around the clock at reference laboratories, academic medical centers, pharmaceutical companies, and clinical research organizations. Many of these have comprehensive regulatory compliance policies, with the Aperio software a central part of their overall compliant operation.

For more information on regulatory requirements, see:

- ► CLIA'88 Standards 493.1251 1256 Laboratory Requirements
- Commission on Laboratory Accreditation: Laboratory Accreditation Program, Anatomic Pathology Check-List

The responsibility of regulatory compliance rests with the individual practice, hospital, reference lab, or clinical trial, and is a business problem involving policies, procedures, training, etc. Although using the Aperio eSlide Manager Compliance module will not in itself make your site compliant with regulatory requirements, it can be an important part of your regulatory compliance process. Leica Biosystems is committed to assisting its customers to maintain regulatory compliance, and has implemented a strong set of security features in its software to assist with the secure management of healthcare data.

If you need additional help in these efforts, the Leica Biosystems Professional Services can assist you in developing and implementing a compliance process.

At the heart of most regulatory requirements is the concept of tracking changes in data, securing the access to the data, and verifying that changes to data are made by authorized personnel. See the following sections for information on features in these areas.

The Aperio eSlide Manager Compliance module offers the ability to track changes on the Aperio eSlide Manager site by creating an audit report and requiring and logging electronic signatures when certain data is modified. Aperio eSlide Manager Compliance is an optional module available for purchase.



When changing data on an Aperio eSlide Manager page, remember to click **Save** to save your changes or click **Cancel** to exit the page without saving your changes.

Installing Aperio eSlide Manager Compliance

Before entering a license key that enables the use of Aperio eSlide Manager Compliance, an additional installation program must be run. Contact Leica Biosystems Technical Services for assistance.

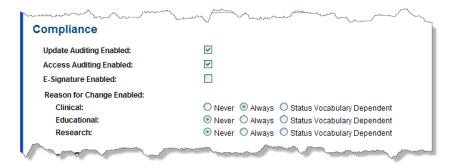
Note for Aperio eSlide Manager Sites that Use a Self-Generated SSL Certificate

If your Aperio eSlide Manager site is using SSL to protect data transactions and has a self-generated SSL certificate (that is, you created the SSL certificate yourself instead of purchasing one from a certificate authority), and you are using Aperio eSlide Manager Reporting to create audit reports, you need to install the certificate on the server in order for Aperio eSlide Manager Compliance to be able to create the Acrobat files that contain your audit reports. For details, see the Self-Generated SSL Certificate Installation and Setup for Reporting and Auditing Application Note.

Enabling Data Auditing and Electronic Signatures

To enable data auditing and electronic signatures:

- 1. Go to the Administrative menu and select System Settings.
- 2. On the System Settings page, go to the Compliance section:



- To enable auditing data changes, select the **Update Auditing Enabled** check box. Any changes to Aperio eSlide Manager data (new data, changes, deletions) will now be tracked and appear in the audit report (discussed in the next section).
- To enable auditing user viewing of data, select the **Access Auditing Enabled** check box. Any selected fields that are viewed by a user will now be tracked and appear in the audit report. (See "Customizing the Data Display" on page 22 for information on selecting which data to audit.)
- To enable e-signatures, select the E-signatures Enabled check box. If an Aperio eSlide Manager user changes
 the status field on a details page, Aperio eSlide Manager will now ask the user to enter his or her user name
 and password before making the change, and will track the user's change in the audit report. A history of
 e-signatures also appears on the details page.
- 3. To enable prompting the user for a reason for a change on the Aperio eSlide Manager page, select the **Reason for Change Enabled** radio button for each of the data hierarchies:
 - Never Never ask the user for a reason for the change.
 - Always Always ask the user for a reason for the change.
 - Status Vocabulary Dependent The intent of this option is that the user will not be prompted for reason for change during the initial setup of the case/project/course. Initial setup is defined as: the status field does not contain a value from the status vocabulary or it contains the first vocabulary item (which might be something like "Setup"). After the case/project/course is saved with the Status field containing a vocabulary item other than the first vocabulary item (such as "Ready for Review"), the case/project/course is considered set up and the user is now prompted for a reason for change when he/she modifies the case/project/course.

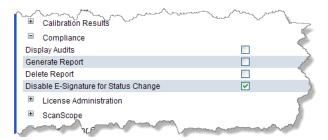
When the Compliance module is licensed, the date of the last change will appear at the top of the details page that was changed (the date is an active link to an audit report for that change). If reasons for change are enabled, the reason also appears on the page.



Disabling Electronic Signatures for Specific Users

With electronic signatures enabled, by default all Aperio eSlide Manager users will need to enter an electronic signature when changing a status field. If you wish to disable electronic signatures for a specific user role:

- 1. Go to the Administrative menu and select Role Management.
- 2. Click **Commands** on the line of the role you want to modify.
- 3. Select the user role you want to modify at the top of the Command Permissions page and scroll down to Administrative Permissions and the Compliance entry:

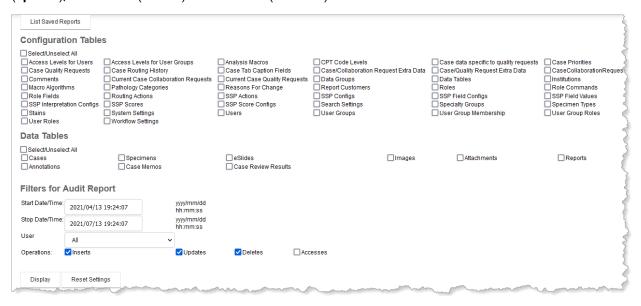


- Select the Disable E-Signature for Status Change check box.
- 5. Repeat for each user role for which you want to disable electronic signatures.

Configuring and Viewing a System Audit Report

- Go to the Administrative menu and select Audit Trails.
- 2. The user must be logged in with a role that has permission to view and configure the audit report to see the Audit Trails command on this menu.

3. On the Audit Configuration page, select the data tables you want to audit as well as the date range for the report and the users to be included in the report. Select whether you want to audit data added (Inserts), data changed (Updates), data deleted (Deletes) or data viewed (Accesses).

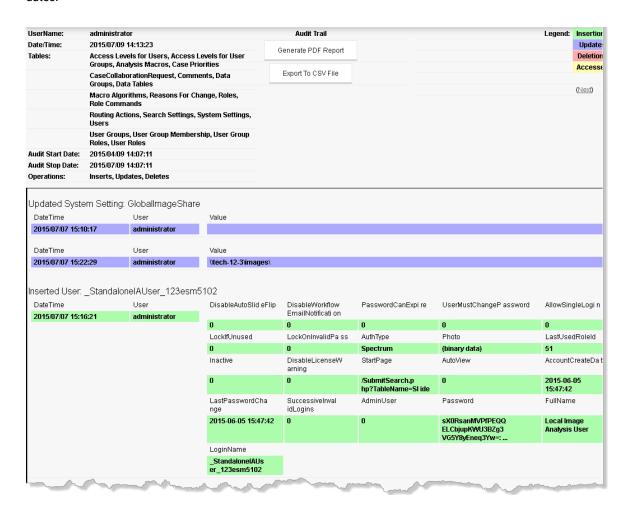


- To clear the settings on the page to start over, click Reset Settings.
- To see a list of reports you have previously generated or exported, click List Saved Reports.



On this page you can delete or open a report.

4. On the Audit Configuration page, click the **Display** button to view the audit report for the selected data, users, and dates:



Note that areas of the report are color coded to indicate data added (green for insertions), data updated (blue), data deleted (red), and data viewed (yellow).

Next and **Previous** links appear if your report is more than one page—click them to navigate the report. Links are included for items accessed—click them to see the details pages for those items.

- To export the report to a file:
 - a. Click **Export to CSV File** to create a file that can optionally be opened by Microsoft Excel (a .CSV file). See "Creating a Report in CSV Format" below.
 - If you have Aperio eSlide Manager Reporting enabled on your Aperio eSlide Manager site, click Generate PDF Report to create an Adobe Acrobat format report file. (See "Creating a Formatted Report" on page 61.)

Creating a Report in CSV Format

You can create a comma-separated values or tab-separated values file version of the audit report that Microsoft Excel can read.

- 1. On the audit report page, click Export to CSV File.
- On the new page you can name and save the report and choose whether it will be saved in comma-separated values format or tab-separated values format. (Your choice depends on the application you will be using to format the data.) You also see a list of previously saved reports.
 - Don't include the file extension .csv in the file name—it will automatically be added to the file name.
- 3. Click the Create & Save CSV File button.

Aperio eSlide Manager gathers the information to create the report. When it has gathered the data, you see a page that contains an **Open/Save** link and a **List Saved Files** link.

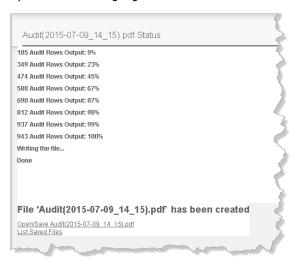
- 4. Click the **Open/Save** link. Depending on the settings in your browser, the report either opens directly in Microsoft Excel or you are given the option to save it to your disk.
- To see the list of previously saved reports, click List Saved Files.

Creating a Formatted Report

If you have Aperio eSlide Manager Reporting enabled, the Audit Report page displays an additional button, **Generate PDF Report**, which formats the audit report as an Adobe Acrobat file.

- 1. On the audit report page, click **Generate PDF Report**. You now see a list of saved reports and have the opportunity to change the name of the report before you save it.
 - Don't include the file extension .pdf in the file name—it will automatically be added to the file name.
- Click Create & Save PDF File.

Aperio eSlide Manager gathers the information to create the report. When it has gathered the data, you see:



Click the Open/Save link. Depending on the settings in your browser, the file either opens directly in Acrobat Reader or you are given the option to save it to your disk.



If generating the PDF report takes an unusually long time, try reducing the scope of the audit report by using the filters to specify a smaller date range or fewer data items.

4. To see the list of previously saved reports, click **List Saved Files**.

List Page Data Audit Reports

In addition to viewing an audit report on the entire Aperio eSlide Manager system, you can also see an audit report on individual Aperio eSlide Manager data such as cases, specimens, digital slides, TMA cores, and so on when you are logged in with a user role that has administrative permission **Compliance: Display Audits** enabled.

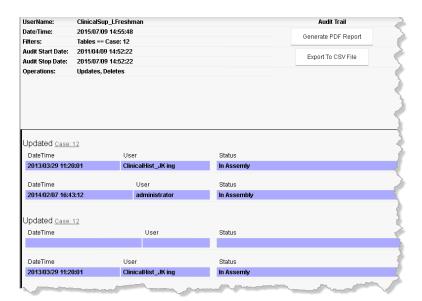
 Click the View Audits link at the top of a list page. For example, on the Cases list page select one or more cases and click View Audits:



On the next page, select the dates and time you want to audit, which user (or all users) you want to audit, and
whether you want to audit data added (Inserts), data changed (Updates), data deleted (Deletes) or data viewed
(Accesses).



3. Click **Display** to see a report. Note that this report includes links that take you to the details page for the selected item:



On the Audit Trail report page displayed, you can create the report as an Adobe Acrobat file or export it to a Microsoft Excel-compatible file. See "Configuring and Viewing a System Audit Report" on page 58 for details on these options.

Aperio eSlide Manager Calibration Report

As part of their regulatory compliance process, some laboratories and clinics require a written record of equipment calibration. See "Calibration Results Report" on page 81 for information on the Calibration results report.

System Settings Options

Administrators can set a number of Aperio eSlide Manager display options that affect the entire site.

The System Settings page contains general system settings and password options as well as Aperio WebViewer settings.

To go to the System Settings page:

- 1. Log into Aperio eSlide Manager as an administrator.
- 2. Go to the Administrative menu and select System Settings.



When changing data on an Aperio eSlide Manager page, remember to click **Save** to save your changes or click **Cancel** to exit the page without saving your changes.

Aperio WebViewer Settings

At the top of the System Settings page you see the WebViewer settings for:

- Defining sort order of digital slides in the WebViewer slide tray
- Selecting measurement display units



Aperio WebViewer Slide Tray Sort Order

The Aperio WebViewer slide tray groups digital slides by specimen.

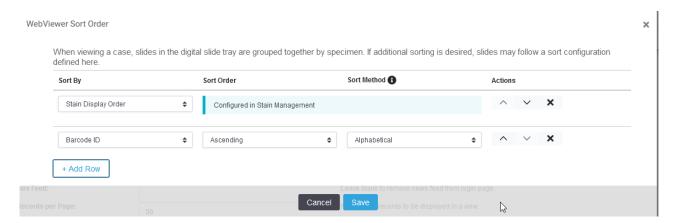
You can also define a multi-level sort here. For example, you can define a sort that first sorts by stain name and then sorts by block ID. In this case, you might have HER2 slides appear as a group within a specimen, and then those HER2-stained slides would appear sorted in block ID order.



For information on using the WebViewer slide tray and on how sorting affects the slide tray display, refer to the **Aperio WebViewer User's Guide** for your version of WebViewer.

To define a multi-level sort for the WebViewer slide tray:

1. Click **Edit** under the sort table. You see the WebViewer Sort Order window:



- 2. If there are no sort rows defined, click Add Row.
- 3. Select the first sort criteria from the **Sort By** drop-down list.
 - If you select **Stain Display Order**, you must go to the Stains Management page to configure the stain sort order. You can click the **Configured in Stain Management** link on this window to go to that page. For information on configuring the stain sort order, see "Stain Display Order" on page 71.
- 4. If you select a sort criteria other than Stain Display Order, you can choose these options for that criteria:
 - a. In the Sort Order column, select Ascending or Descending.
 - In the Sort Method column, select Natural or Alphabetical (see "About Natural and Alphabetical Sort Methods" below).
- 5. Click **Add Row** to define another, lower-level sort criteria.
- 6. To move the order of a sort criteria in the sort, use the up and down arrows in the **Action** column. For example, moving the second sort criteria row to the top position makes it the primary sort criteria that is used first in the sort.
- 7. To delete a sort criteria, click the X in the Action column.
- 8. When you have finished defining the sort, click **Save**.

About Natural and Alphabetical Sort Methods

Natural and alphabetical sort methods sort numbers differently.

Natural sort order is an ordering of strings in alphabetical order, except that multi-digit numbers are treated as if they were a single character.

An alphabetical sort uses a strict character sort.

For example, if you are sorting by Block ID, and you have Block 2, Block 3, Block 4, and Block 21:

- An alphabetical sort lists these as Block 2, Block 21 (two characters "2" and "1"), Block 3, and Block 4
- A natural sort lists these as Block 2, Block 3, Block 4, and Block 21 (one character "21").

Aperio WebViewer Measurement Units

To choose the unit of measure Aperio WebViewer uses when displaying measurements:

- Click Edit on the WebViewer Length Line.
- 2. Select Microns or Millimeters from the drop-down list, and click Save. The default value is Microns.



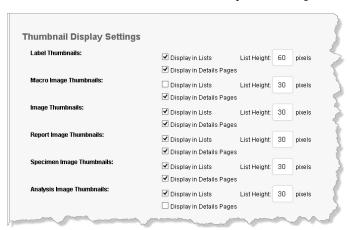
Selecting Thumbnail Display Options

Images in Aperio eSlide Manager are represented on list and detail pages by smaller versions of the image called thumbnails.

- A *list page* is a page which contains a summary of items, such as the page you see when you use the **All eSlides (as List)** command on the Aperio eSlide Manager main page.
- A details (or data) page is a page that contains details about a list item, such as the page you see when you select an individual case to see the Case Details page that contains information about that case.

To change the system display settings for thumbnails:

1. Go to the Administrative menu and select System Settings. The System Settings page appears:



Turn thumbnail display options on and off by selecting/clearing the check box next to the type of thumbnail. The
 Display in Lists check box turns thumbnail display on/off on the list pages such as the eSlides list. The Display in
 Details Pages check box turns thumbnail display on/off for data pages such as the Case Details page.

Set the height of the thumbnail by entering the number of pixels in the text box that follows List Height.

Additional Information

- The Image Thumbnails is the thumbnail of the area of interest that was scanned from the entire glass slide.
- The Macro Image Thumbnails is the thumbnail of the macro image captured during scanning.

- The Label Thumbnails is the thumbnail of the eSlide label (if it was captured during scanning).
- The Specimen Image Thumbnails is the thumbnail of the specimen gross image.
- The Analysis Image Thumbnails is the thumbnail of the image analysis mark-up image.
- The Report Image Thumbnails is the thumbnail of the image that was selected to include in reports. (Only used if you have the optional Aperio eSlide Manager Reporting module unlocked and if the report template you are using contains images.) For information on report images, see the Aperio eSlide Manager Reporting User's Guide.

Note that the thumbnail settings on this page do not override data table settings that limit access to thumbnails. See "Configuring Non-Data Fields" on page 24.

Defining the Number of Items to Display on a List Page

To define the number of items to display on a list page, type a number in the **Default Records per Page** text box.

Although the administrator can use this page to set the *default* number of items to display on a list page, the user can temporarily change the number of items to display whenever using a page by typing a new number in the **Display** field.

This is especially useful when a user wants to tag a large number of items or, alternatively, quickly view short lists.

Enabling Viewing of eSlide Label Images

For quality assurance, it is important that some Aperio eSlide Manager users be able to view the eSlide label along with the digital slide to verify that the correct digital slide is being worked with.

On the other hand, HIPAA requirements require that patient privacy be preserved, so Aperio eSlide Manager users who don't need to see the eSlide label should be prevented from doing so.

Enabling Label Viewing on the ImageServer – To enable any viewing of eSlide labels, you must set the *-label* flag in the ImageServer.ini file. To do so, use the Aperio eSlide Manager System Information utility on the DSR that contains Aperio eSlide Manager and select the ImageServer **Show label images** option. This is a prerequisite for setting additional label viewing options discussed below.

Enabling Label Viewing in Aperio eSlide Manager Pages – To enable viewing of eSlide labels on Aperio eSlide Manager list and detail pages:

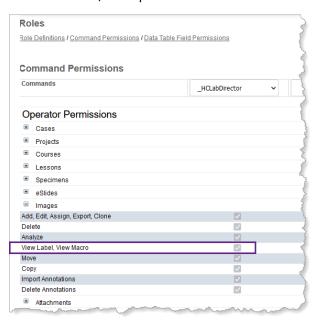
- 1. Log into Aperio eSlide Manager as an administrator with a user role that allows editing system settings.
- 2. Go to the **Administrative** menu and select **System Settings**.
- 3. Select the check boxes next to Label Thumbnails to enable label display in list and details pages.

Note that these options enable display of labels *only* on the Aperio eSlide Manager pages and only for users who have logged in using a role that permits viewing labels (see the section below),but not in client applications such as Aperio ImageScope.

Enabling Label Viewing for Specific Users (Labels in Aperio eSlide Manager and Aperio ImageScope) – To fine-tune label viewing for specific users:

- 1. Log into Aperio eSlide Manager as an administrator with a user role that allows editing user roles.
- 2. Go to the Administrative menu and select Role Management.
- 3. Create a user role or modify an existing one.

4. For that user role, select permission to view labels:



Selecting the Default Digital Slide Viewer

This option selects which digital slide viewer will be used by default to view an Aperio eSlide Manager image (generally a digital slide).

No matter what viewer is set as the default viewer, note the following:

- Users can override the default setting by pressing a specific key for the viewer they want to use. (See the *Aperio* eSlide Manager User's Guide for details.)
- Users can always open images in WebViewer by clicking on the line for a Case, Project, or Lesson on a list page, which opens all digital slides associated with that element in the WebViewer slide tray. This is true even if WebScope or Aperio ImageScope is set as the default viewer.

To select the default viewer:

- Log into Aperio eSlide Manager as an administrator.
- 2. Go to the Administrative menu and select System Settings.
- Select which viewer to use as the default from the Default Image Viewer drop-down list.

Selecting the Date Format

The System Settings page contains an option to select the specific date format you want users to use on Aperio eSlide Manager.

- 1. Log into Aperio eSlide Manager as an administrator.
- 2. Go to the Administrative menu and select System Settings.
- 3. In the Display Settings section, click on the **Date Format** drop-down list and select the format users will use.

Adding an RSS Feed to the Login Page

You can add an RSS feed to the Aperio eSlide Manager login page to provide daily news of interest to Aperio eSlide Manager users:

- 1. Log into Aperio eSlide Manager as an administrator.
- 2. Go to the Administrative menu and select System Settings.
- 3. In the **Login News Feed** text box, type a news feed source to use. (You must enter a valid RSS/Atom news feed.)

Tip: A search for "RSS news feeds" on the Internet will provide many choices of news feeds.

12 Managing Stains, Body Sites, and Comments Libraries

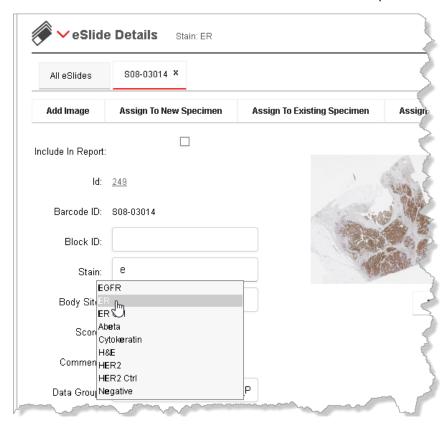
Several features are provided to allow you to manage stains, body sites, and comments



When changing data on an Aperio eSlide Manager page, remember to click **Save** to save your changes or click **Cancel** to exit the page without saving your changes.

Maintaining Stains and Body Sites Libraries

The stain and body site libraries define the stains and body sites that the Aperio eSlide Manager user can choose from when entering data on digital slides or specimens. As the user begins to type a stain or body site, a box appears from which the user can choose an item that contains the same characters. For example:



The choices shown have been defined in the stain or body site library.

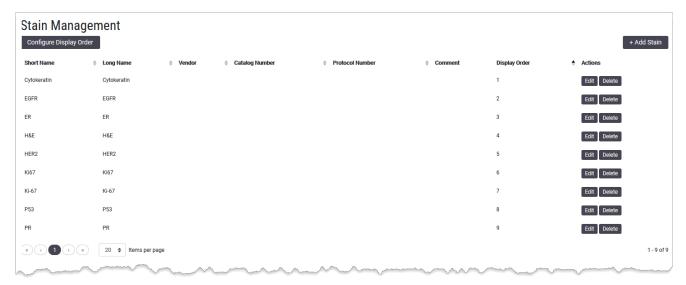
To create or maintain stains or body site library:

- Log into Aperio eSlide Manager as an administrator.
- 2. Go to the Administrative menu and select Stain Management or Body Sites.
 - To create your own stain or body site, click Add and type in the information on that stain or body site.
 - To delete a stain or body site, click **Delete** on the line for that stain or body site.
 - To modify a stain or body site, click **Edit** on the line for that stain or body site.

Stain Display Order

On the Stain Management page, the Display Order field dictates the order in which digital slides will appear in reports and in the Aperio WebViewer slide tray.. For example, if the HER2 stain has a Display Order value of 1, slides using that stain will be listed first. To change the display order, click **Edit** in the row for the stain and change the Display Order value.

Note that you can also define a more advanced multi-level stain sort by clicking the **Configure Display Order** button (see the next section).

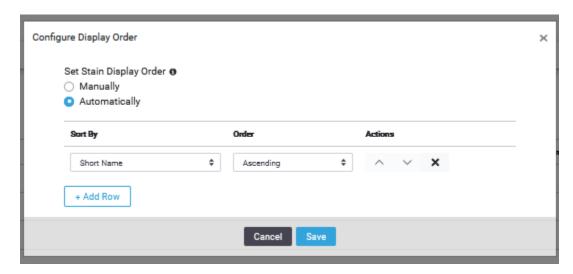




To define a WebViewer slide tray sort that uses elements in addition to stain definitions (for example, Block ID, barcode, and so on) in a multi-level sort, see "Aperio WebViewer Slide Tray Sort Order" on page 64. For information on using the WebViewer slide tray and on how sorting affects the slide tray display, refer to the **Aperio WebViewer User's Guide** for your version of WebViewer.

Selecting Stain Sort Order

To create a multi-level sort for the Stain Management page stains, click the **Configure Display Order** button at the top of the page. You see the Configure Display Order window.



The first selection on this window is **Set Stain Display Order**.

- Manually If you select Manually, you are choosing to determine stain order by editing the Display Order column on the Stain Management page.
- Automatically If you select Automatically, you are choosing to determine the stain order by using the options on this window to configure a multi-level sort.

To create an Automatic sort:

- 1. Select **Automatically** on the Configure Display Order window.
- 2. Select an element in the Sort By drop-down list (such as Short Name). All slides will first be sorted by this element.
 - a. Select the Order of the sort (Ascending or Descending).
- 3. To sort within that first sort choice, click the **Add Row** button.
 - a. Select an element in the **Sort By** drop-down list (such as **Vendor**). All slides are first sorted by the element in the first row of the sort, then by the element in the second row.
 - b. Select the Order of the sort (Ascending or Descending).

For example, if you have multiple PR stains, this sort will sort all PR stains together (short name), and then within that group, sort by the stain vendor.

Once you have defined multiple sort rows, you can use the up and down arrows to change the precedence of the sort row. You can also use the X button to delete a row.



Remember that Aperio WebViewer uses the stain order defined to sort digital slides within a specimen in the WebViewer slide tray if you select the stain as a sort criteria. See "Aperio WebViewer Slide Tray Sort Order" on page 64 for more information on defining the WebViewer slide tray sort.

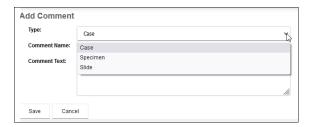
Maintaining a Comments Library

The Aperio eSlide Manager user can use predefined comments wherever a Comments field appears on Aperio eSlide Manager pages.

In addition to predefined comments that can be used in Comments fields, the administrator can also define comments that can be used for specific stain/body site combinations.

To create, edit, or delete predefined comments:

- 1. Go to the **Administrative** menu and select **Comments**. The Comments page appears.
- 2. To create a new comment, click Add. The Add Comment page appears.
- 3. Select the type of comment you want to create from the Type drop-down list (depending on the data hierarchy you logged in under and the features enabled on your Aperio eSlide Manager site, these might include case, project, slide, and so on), give it a name and type the actual comment in the Comment Text box.



To edit or delete a comment, use the **Edit** and **Delete** links on the Comments list page.

Note that slide-specific comments (comments that apply to specific stain/body site combinations) can only be created on the Slide Specific Processing Configuration page. See "Chapter 13: Slide-Specific Configuration" on page 74.

Selecting a Comment

In a Comments field, the Aperio eSlide Manager user can select any of the predefined comments appropriate for that field. For example, on a Case Details page, the user can select a comment of type Case.

13 Slide-Specific Configuration

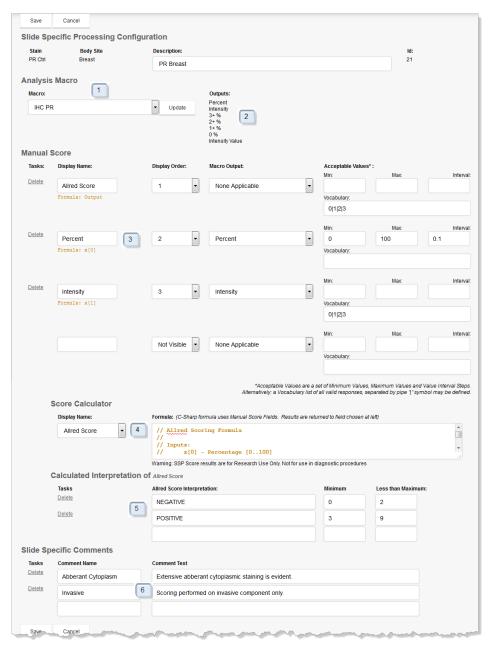
Slide-specific processing was designed to provide a quick and easy way for the pathologist to mark and analyze areas of interest on a digital slide all in one simple step. The keys to slide-specific processing are the stain and body site libraries.

Defining what analysis to perform for a specific stain/body site digital slide and how to calculate, display, and interpret the results is done by the Aperio eSlide Manager administrator on the Slide-Specific Processing Configuration page.

For example, here is a sample configuration page for breast tissue digital slides that are stained for PR analysis. The numbers on this illustration relate to the steps below the illustration.



When changing data on an Aperio eSlide Manager page, remember to click **Save** to save your changes or click **Cancel** to exit the page without saving your changes.



On this page, the administrator defines:

- The default algorithm to use for this type of digital slide (or selects no algorithm if manual scoring is desired)
- Which algorithm results or manual scores will appear on the digital slide portion of the Aperio eSlide Manager page.
- Defines how scores will be displayed on the Aperio eSlide Manager page.
- Optionally provides a formula that will be used to calculate scores.
- Provides information on how to interpret the scores.
- Optionally defines slide-specific comments that can be used on digital slide detail pages.

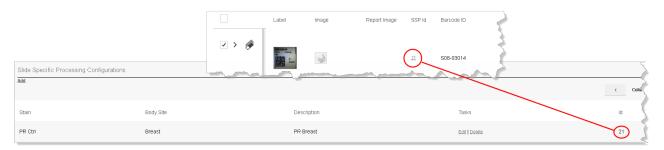
A detailed discussion of this page is beyond the scope of this guide. For details on slide-specific processing configuration, please see the eIHC User's Guide and the eIHC Guide to Aperio eSlide Manager Setup.

The Slide-Specific Configuration ID

Each slide-specific configuration you create has a unique ID.

The SsConfigld (SSP Id) field is displayed on the eSlides list for each digital slide that uses a body site/stain combination for which a slide-specific configuration has been created. (As with any field, the SSP Id field can only be seen on the page if the administrator made it visible on the Slides data table.)

For example, the digital slide below uses the Breast/PR body site/stain, and its SSP Id indicates that slide-specific configuration 21 exists for that combination and is used for this slide.



To view slide-specific configurations, go to the **Administrative** menu and select **Slide Specific Processing**. To see the slide-specific configuration attached to a specific slide, click the SSP Id for that digital slide.

Normally, once a slide-specific configuration has been set up, the administrator will not change it. However, if it *is* changed, the SSP Id shown for a digital slide is displayed in red:



This indicates that the slide-specific configuration used for this slide is not the current version, and that the older slide-specific configuration has been archived. The archived slide-specific configuration will continue to be used when you analyze or manually score this digital slide.

If you want the digital slide to use the *updated* slide-specific configuration for this body site/stain combination, then you need to reset the body site or stain for this digital slide to trigger use of the current slide-specific configuration, not the archived one. See below for details.

About Archived Slide-Specific Configurations

When you modify an existing slide-specific configuration, the previous version of the configuration is archived so that it can continue to be used by digital slides that are already linked to it. To see the archived slide-specific configuration used by a specific digital slide, click the red SSP Id on that digital slide's line on the eSlides page.

The archived slide-specific configuration is read-only so that it cannot be modified.

The SSP Id for the slide-specific configuration increments when you change and save it. The example above shows that archived slide-specific configuration 3 will continue to be used for this slide—the new version of that slide-specific configuration is now 4 (or the next available number if that number is being used by another slide-specific configuration).

Resetting a Digital Slide to Use the Current Slide-Specific Configuration

To reset the digital slide to use the current slide-specific configuration:

- 1. Open the details page for the digital slide by clicking the Ficon next to the digital slide on the eSlides page.
- Go to the eSlide Details section of the details page and choose a different stain and click Save.
 (If the Stain field does not appear on this page, ask the Administrator to enable it.) You will be warned that changing the definition will delete the current analysis/scoring data.
- 3. After saving the page, set the modified stain back to its original value and click **Save**. The digital slide will now use the current version of the slide-specific configuration for that body site/stain.

Now when you view the eSlides page, you see that the digital slide is using the current slide-specific configuration. Note that the SSP Id is not displayed in red, which means that the current version of the slide-specific configuration is being used, not an archived version.

Adding Image Analysis Macros

This chapter discusses administrator options for image analysis for research use.

In order to perform image analysis using an analysis algorithm, you must first fine-tune the algorithm settings to suit your needs and then save the algorithm settings as a *macro*. In order to make the macro available to Aperio eSlide Manager users who will use it to analyze digital slides, you must register the macro with Aperio eSlide Manager.

You will use the Aperio ImageScope viewing application to:

- View a digital slide
- Fine-tune the algorithm settings for that slide
- Save the settings as a macro and register the macro in the Aperio eSlide Manager database. This last step is done through Aperio ImageScope and no further action is necessary within Aperio eSlide Manager to make the macro available to users other than making sure users have access to the appropriate data groups the macros are associated with.

See the Aperio Image Analysis User's Guide or Aperio Image Analysis Workstation User's Guide for details on doing this.

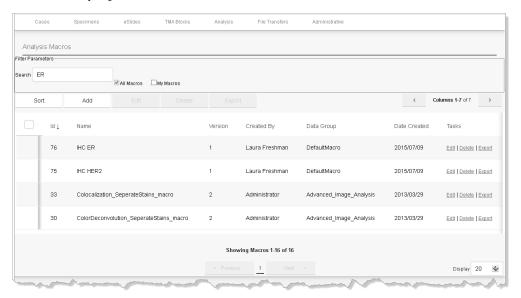


When changing data on an Aperio eSlide Manager page, remember to click **Save** to save your changes or click **Cancel** to exit the page without saving your changes.

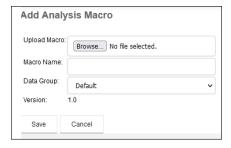
Adding Macros

In older versions of Aperio eSlide Manager, the macros were not installed by Aperio ImageScope into the Aperio eSlide Manager database, but were saved as separate xml files. An additional step was then required to register them with Aperio eSlide Manager. If you have macros that were created in the past that need to be registered with Aperio eSlide Manager, you can use the Aperio eSlide Manager **Add Macro** command to register them. If you create macros using the current version of Aperio ImageScope, you do not need to do this step.

1. Go to the **Analysis** menu at the top of the Aperio eSlide Manager page and select **Macros**. You see the list of macros that are already registered.



2. Click **Add** on the Analysis Macros page. The Add Analysis Macro page appears:

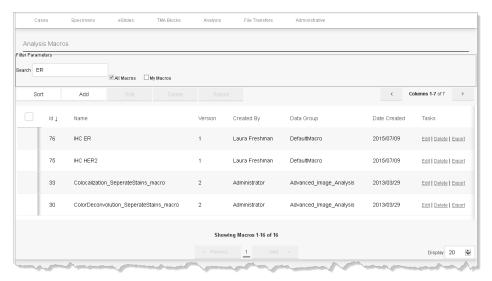


- 3. Click **Browse** to navigate to the macro file you want to register. It will be an .xml file.
- 4. Type a macro name in the Macro Name box using a name that will help you to identify the macro in the future.
- 5. Choose the data group you want to associate with this macro. (This determines which users will be able to use the macro, depending on their data group permissions.)
- 6. Click Save to save the macro. You return to the Analysis Macros page where you see your new macro listed.

Viewing the List of Registered Macros

To see the list of algorithm macros that are registered in Aperio eSlide Manager, go to the Analysis menu and select Macros.

The Analysis Macros page appears, listing all available macros.



For information on using this page to find and organize macros, see the Aperio eSlide Manager User's Guide.

Notes for Aperio eSlide Manager Multi-site Installations

The rules on which algorithm macros are available for multi-site users are:

- Algorithms and macros are only available to users who have data group permissions to use them. (This applies to users of all types of Aperio eSlide Manager installations.)
- When a multi-site user opens a digital slide in Aperio eSlide Manager, the algorithms and macros available to use on that image are only the algorithms and macros installed on the server on which that image is located.
- To share a macro among sites, you must install the algorithm from which that macro was derived on the sites where the image on which you want to use the algorithm is located.

For More Information on Image Analysis

Additional information on image analysis is available in other guides:

- For information on a specific image analysis algorithm, see the user's guide for that algorithm.
- For general information on using image analysis algorithms, see the *Aperio Image Analysis User's Guide*. If you are using the Aperio Image Analysis Workstation, see the *Aperio Image Analysis Workstation User's Guide*.
- For information on fine-tuning algorithm settings, saving them as a macro, and registering them with Aperio eSlide Manager, see the *Aperio Image Analysis User's Guide*.
- For information on performing batch image analysis, including using the Aperio eSlide Manager analysis job queue, see the Aperio eSlide Manager User's Guide.

15 Scanning Options

This chapter contains information on Aperio eSlide Manager options that relate to using an Aperio scanner.

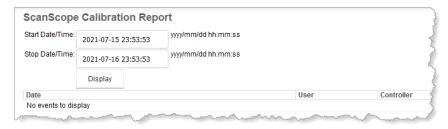


When changing data on an Aperio eSlide Manager page, remember to click Save to save your changes or click Cancel to exit the page without saving your changes.

Calibration Results Report

The Aperio scanner calibrates itself each time you scan a slide and sends the calibration information to Aperio eSlide Manager where you can access a complete report of calibrations. To view the calibration report:

- Log into Aperio eSlide Manager as an administrator or with a user role that has the Administrative Permissions
 Calibration Results: View setting enabled.
- Go to the Administrative menu and select Calibration Results.
- 3. On the ScanScope Calibration Report page, use the filtering options to select the range of dates you want information for and click **Display**.



Scan Permission

When you start the Console application to scan slides on the Aperio scanner, you are asked to log in. The Aperio eSlide Manager user who logs into the Console must have a user role that allows use of the scanner. This setting is in the Command Permissions section of the Roles page:



For more information on modifying user roles, see "Chapter 5: Defining User Roles" on page 30.

Email Notification of Terminated Autoscan

You can tell Aperio eSlide Manager to let you know if an automatic scan stopped unexpectedly.

- 1. Log into Aperio eSlide Manager as an administrator.
- 2. Go to the Administrative menu and select System Settings.
- 3. Scroll down to the Scan Alerts Settings area:



4. Type the email address of the person to whom you want to send alert email messages.

Use of this feature assumes that other Aperio eSlide Manager email settings on the System Settings page are configured and that the local email service is available. For information on the email settings on the System Settings page, see "Setting System-Wide Password Options" on page 49.



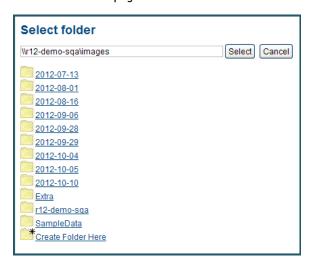
Configuration Settings

This appendix discusses how to change Aperio eSlide Manager configuration settings.

Defining Aperio eSlide Manager File Access

Aperio eSlide Manager's access to files on the network is provided by defining network shares on the Aperio eSlide Manager Servers List page. Network shares must be defined for the destination or source for any file access, such as copying files, moving files, importing digital slides, and so on.

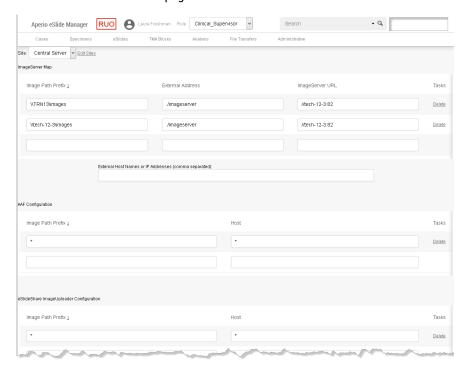
When you use an Aperio eSlide Manager command to access a file on the network (for example, to move or copy a file or add a digital slide image), the window that appears on which you specify the file location references the network shares defined on the Servers List page.



To access the Servers List page, open a browser and type "servers_list.php" after your Aperio eSlide Manager server name. For example, if your Aperio eSlide Manager server is named "eSlideManager," then type this in the browser address box:

http://eSlideManager/servers_list.php

You now see the Servers List page:



Note that the fields on this page are case-sensitive and must be lower case. You will define network shares in the ImageServer Map section. We recommend that you not change the fields in the other sections of this page, which are used for advanced configuration.

By default when you first install Aperio eSlide Manager, a definition exists for the images folder on your Aperio eSlide Manager server.

- Image Path Prefix This specifies the UNC path to the images directory. You may specify a path in UNC format such as \eSlideManager\Images or may type an asterisk, a wildcard symbol that tells Aperio eSlide Manager that any path is acceptable. You must set image folders to shareable. For information on doing so, contact your IT staff.
- External Address This information is used by Aperio eSlide Manager when creating URLs for the user's browser or .SIS files when it has determined that the user is accessing the server externally. The information in this field must correspond to a proxy entry in the httpd.conf file of the Aperio WebServer.
- ImageServer URL This information is used by Aperio eSlide Manager when creating URLs for the user's browser or .SIS files when it has determined that the user is accessing the server locally. Be sure to specify port 82, which is the port ImageServer listens on. If you want to reference an ImageServer that resides on a different server, supply that server name in the ImageServer URL; for example, //eSlide Manager2:82.
- External Host If you cannot directly access the ImageServer URL (for example, if the ImageServer is behind a firewall), include the server name on which the ImageServer resides in the External Host field. If the Aperio WebServer is configured with a non-standard port, it will need to be specified in the External Host Name field (for example, externalhostname.com:81).

After entering a network share, if you want to create more, press **Return** or click **Save** and a new set of text boxes appears.

To delete a network share, click the **Delete** link next to its definition.

Click Save after the last definition has been entered. Restart the ImageServer service after adding network shares.

Global Image Share Location

When you install Aperio eSlide Manager for the first time, you must define a location for storage of images for Aperio eSlide Manager applications (for example, this defines the location where the Genie Montage Maker stores montage images).

To do so:

- 1. Log in as an administrator.
- Go to the Administrative menu and select System Settings.
- 3. In the Global Image Share text box, type the location in which images are stored and click Save.



The location must be specified in UNC format (for example \\ESM\images, not C:\images). This location is on the same server as Aperio eSlide Manager and is the folder ImageServer uses to store and retrieve images. Note that even if you are using a multi-site Aperio eSlide Manager configuration that uses multiple ImageServers, this should point to the local ImageServer image folder on your Aperio eSlide Manager server. (You only need to do this on a new installation—when upgrading from a previous Aperio eSlide Manager installation, this location is filled in for you from existing configuration files.)

Initialization File User Configurable Settings



For assistance with configuring Aperio eSlide Manager settings, contact Leica Biosystems Technical Services.

Most Aperio eSlide Manager configuration settings are maintained in the Aperio eSlide Manager administrative pages. However, to change Aperio eSlide Manager configuration settings directly:

- 1. Using Windows Explorer, navigate to the directory Program Files\<Aperio master folder>\spectrum\conf and open the spectrum.ini file in a text editor such as Notepad.
- After making your changes (see the next section), go to the File menu and select Save. Then exit.

Note that you can always return to the default Aperio eSlide Manager settings by overwriting the spectrum.ini file in this directory with the copy contained in the spectrum\conf\recommended directory.

Commonly used settings are contained in the spectrum.ini file. These settings are:

- **DataServerHost** Defines the location on the network of the Aperio DataServer.
- **DataServerPort** Defines the port on which the DataServer listens. Usually 86.
- ▶ AllowGuest/GuestButton These settings enable and disable the user of a Guest login. See "Appendix C: Setting up the Guest User" on page 90 for details on setting up a guest user.
- DocumentUploadDirectory Defines the directory into which new document files will be uploaded when you use the Add Document command in Aperio eSlide Manager. Make sure you specify this location using UNC notation (for example, \\eSlideManager\UploadedDocs) instead of path notation (for example, C:\UploadedDocs).
- InstallationType Configures the Aperio eSlide Manager data organization for your type of organization.
 - Clinical The data table hierarchy naming convention is Case, Specimen, eSlide

- Research The data table hierarchy naming convention is Project, Specimen, eSlide
- Educational The data table hierarchy naming convention is Course, Lesson, Specimen, eSlide
- Genie The data table hierarchy name convention is Genie Projects, Genie Training Sets, and eSlides.

Note on Backing up Aperio eSlide Manager Data

Be aware of the data locations where your digital slide image files and uploaded documents are stored, as they may be located on different disks. Ensure that your backup procedures back up these directories to preserve your Aperio eSlide Manager data.

Aperio eSlide Manager provides automatic backup of the Aperio eSlide Manager database. This consists of all of the data stored in the Aperio eSlide Manager SQL database, but does not include data pointed to by the database, such as the image directories. For details on the automatic backup feature, see "Appendix B: Automatic Aperio eSlide Manager Database Backup" on page 87.

Changing the User Login Timeout Value

If an Aperio eSlide Manager administrator or user is logged on for a set period of time without any activity, the login session times out for that user, and the user is required to log in again. The default timeout period is 30 minutes, but can be changed by editing the DataServer.exe.config file in \<Aperio Master Folder>\DataServer and changing the AuthCacheTimeout value. This value is the timeout period length in minutes. After changing this value, you must restart the DataServer.

Setting up the Image Metadata Exporter

The Image Metadata Exporter is used to automatically send information on a digital slide from Aperio eSlide Manager to a predefined folder for pickup by an LIS or other data management system. Image Metadata Exporter is a licensed option to Aperio eSlide Manager.

When a slide is scanned, a comma-separated value (CSV) file containing the digital slide's barcode, image ID, and the location of the digital slide image is written to the LIS transfer folder. If the scanned digital slide does not have a barcode, this CSV file won't be created.

You must configure your LIS or data management system to look in that folder to pick up the digital slide data.

To enable this feature on Aperio eSlide Manager:

- Create a folder to which the digital slide data will be sent.
- 2. Log into Aperio eSlide Manager as an administrator.
- Go to the Administrative menu and select Systems Settings.
- 4. On the System Settings page, type a UNC path for the folder you created into the Slide Completion Export text box.

Automatic Aperio eSlide Manager Database Backup

To help our customers ensure their Aperio eSlide Manager database is secure, Leica Biosystems includes an automatic backup feature.



The automatic Aperio eSlide Manager database backup backs up the Aperio eSlide Manager database, which contains metadata associated with your digital slides (such as case information, annotations, and so on). This database contains pointers to your actual digital slide images, but does not contain the images themselves. For this reason, you must be sure to back up your \mages directory and other contents of your DSR as a separate process.

Backing up data is an important element of managing and protecting your data. Although you undoubtedly have your own backup strategy and plan in place, Leica Biosystems has instituted an automatic backup for the Aperio eSlide Manager database which can be a part of your overall backup plan.

The Aperio eSlide Manager database is maintained by Microsoft SQL Server and the automatic backup is created as a SQL Server backup file under the direction of the DataServer.

If you need to restore a backup, you will need to use the Microsoft SQL Server Management Studio or T-SQL statements, so we recommend that someone in your IT department or organization be familiar with managing SQL.

Including the Aperio eSlide Manager Backup in Your Data Protection Plan

Simply backing up data is not enough to protect it. If the server on which the Aperio eSlide Manager database resides also contains the backup file, and the server disk crashes, you lose your backup as well as your original data.

Therefore, your IT department should regularly make a copy of the AperioDbBackup<date>.bak file (for example, by writing it to CD) and then store that copy off site with your other backup data.

The Aperio eSlide Manager backup saves the Aperio eSlide Manager database information, which contains metadata associated with your digital slide images and points to those images, but does not save the actual image files themselves.

Additional Backups

Please be sure that your backup plan also backs up data not backed up by the automatic Aperio eSlide Manager database backup:

- The \Images directory or directories that contain your digital slides as well as other files pointed to by the Aperio eSlide Manager database such as documents and reports
- The Aperio eSlide Manager httpd.conf file, Aperio eSlide Manager server configuration data
- Configuration files in the \ScanScope directories, such as DataServer\DataServer.exe.config
- ► The \ScanScope\Controller directory, Controller configuration files
- DocumentUploadDirectory By default points to C:\UploadedDocs
- ImageUploadDirectory By default points to C:\UploadedImages

Default Backup Operation

Although you can change backup options, such as frequency and backup file location (see below), the default backup operates as follows:

1. Once a week (by default, on Sunday), a full backup is done. The first time this backup is done, a new file is created with the current date in the filename. For example:

```
AperioDbBackup2007-09-06.bak
```

- This file is created in the \backup folder of your Microsoft SQL Server installation. (Notice that this directory may also contain an undated AperioDbBackup.bak file—this is the file that was created when you upgraded from one software release to another. This file saves your original data before it is migrated into the new release. This file changes only when you install another release.)
- 2. Every two hours (default setting), differential backups will be written to the same AperioDbBackup<date>.bak file. (If you open this file in Microsoft SQL Server, you will see the multiple backups in the file.)
 - If the backup file is missing (for example, you have moved it or copied it to CD and then deleted it), a new backup file will be started and a differential backup will be done (with a full backup being done on the scheduled day).
- 3. To keep the amount of disk space used by the backup file to a reasonable size, the automatic backup will delete backup files that are older than seven days (default setting).

If You Manually Create an Aperio eSlide Manager Database Backup

DataServer notices if a full backup gets created outside of the automated process (for example, you manually create a backup using T-SQL statements). In this case, DataServer immediately creates a new full backup to guarantee backup integrity as an "unscheduled" backup breaks the chain of automated differential backups.

Setting Backup Options

All of the automatic backup settings can be modified by editing the DataServer.exe.config file using Notepad. This file is located in the Program Files\ScanScope\DataServer directory on the workstation on which your Aperio eSlide Manager database resides.

After making your changes, you must restart DataServer (see the *Aperio eSlide Manager User's Guide* for information on using the Service Manager to start/restart services.)

Look for this section in that file:

```
<backupConfiguration
   Schedule="Weekly"
   StartTime="15:00"
   WeekDaysToRun="Sunday"
   DiffBackupInterval="2"
   RetentionDays="7"
   BackupFolder=""
/>
```

Backup options include:

Option	Description	Values	Default
Schedule	How often to create a full backup	None, Daily, Weekly	Weekly
StartTime	Time of day to run a full backup	HH:MM (military format)	15:00
WeekDaysToRun	Days of the week to run if the Schedule is set to Weekly	Monday, Tuesday, Wednesday, Thursday, Friday, Saturday, Sunday	Sunday
DiffBackupInterval	An interval in hours defining when the differential backup will be run.	An integer value1 turns off the differential backup, allowing only full backups to be done.	2
RetentionDays	How many days to keep the backup file before deleting it and starting a new one.	Integer value1 turns off the cleanup feature, allowing your backup file to expand indefinitely. If the Schedule is set to Weekly, a value less than 7 is ignored and 7 is used.	7
BackupFolder	Location for backup file. This is a path on the DataServer machine—the account that runs the SQL Server instance must have permission to access this folder.	A text string.	None. If the value is not set then the backup file will be stored inside the default SQL server \backup folder.

C Setting up the Guest User

A guest user can be enabled for Aperio eSlide Manager and guest user access permissions adjusted for your security needs.

A guest user logs into Aperio eSlide Manager by clicking the **Guest Login** button on the Aperio eSlide Manager login page and typing the user name "quest."

The Aperio eSlide Manager Guest user was defined so guests can log into Aperio eSlide Manager with restricted privileges. The guest user can see information on the site that is available to the general public but does not have access to confidential information that is available to the administrator. The guest user cannot be deleted from Aperio eSlide Manager, but the Aperio eSlide Manager administrator can set the guest user data group permissions to adjust the type of information the guest user can see.

Enabling the Guest User

Guest user access is off by default for new Aperio eSlide Manager installations. Enable the guest user by editing the Aperio eSlide Manager configuration file, spectrum.ini, which is located in Program Files\<Aperio master folder>\spectrum\conf.

- Set AllowGuest to 1 to allow a guest user to log in, or set it to 0 to prevent guest user log in. Enabling this does not
 cause a Guest Login button to appear. If AllowGuest is enabled, the user can simply enter "guest" as the login user
 name to access the site as a guest.
- 2. Set GuestButton to 1 to display a **Guest Login** button or 0 to not display a **Guest Login** button. (AllowGuest must be set to 1 in order for GuestButton to enable the **Guest Login** button.)

Changing Guest User Data Group Permissions

Guest user permissions set the minimum access to a data group. Therefore, guest user permissions override all other user access permissions if the guest user permissions are higher. For example, if the guest user has Read Only data access to a data group and you have set the Dr. Beth user to No Access, Dr. Beth will actually have Read Only access because the guest user has Read Only access.

If the guest user has Full Control data access to a data group, all users will have Full Control access to that data group. It is important to keep this in mind when you are setting up permissions for the guest. The guest user cannot be deleted from Aperio eSlide Manager, but you can set the guest user data group access to *No Access* if you don't want a guest user to see any data on Aperio eSlide Manager (or simply set AllowGuest to 0 as explained in the previous section).

To change the data group permissions for the guest user on Aperio eSlide Manager:

- 1. Go to the **Administrative** menu and select **User Management**. The Users page appears.
- 2. Click Edit on the guest user line.
- 3. Choose an access level.

Guest user access levels for the defined data groups are:

- No Access The user will not see that data group upon data entry nor have access to any data belonging to this group.
- **Read Only** The user will be able to view data associated with that data group, but will not be able to add or edit data belonging to this group.
- Full Control The user will have the ability to add, edit or delete any data associated with this data group.

D

Custom Event Handling

Aperio eSlide Manager allows custom events to be added to your Aperio eSlide Manager site. An example of an event would be an action such as sending data to or getting data from a Laboratory Information System, changing the contents of a data field, and so on.

Aperio eSlide Manager data table pages contain an Events section where you can define an event to add to that specific data page. For example, adding an event to the Case data page causes a new button to appear on the Case Details page that is used to trigger the specified event.

The event handler program that can be triggered on the page must be custom built for you. You can contract with Leica Biosystems to design and create an event handler program. For information on custom work, contact your Leica Biosystems Sales representative.

After you work with Leica Biosystems to define what the special event is to do, and they have created the event handler program for you, here is how to install it on your Aperio eSlide Manager site:

- Copy the Event Handler files to the \Program Files\ScanScope\DataServer\EventHandlers folder on your Aperio
 eSlide Manager server.
- 2. Log into Aperio eSlide Manager as an administrator.
- Go to the Administrative menu and select Data Table Management.
- 4. Edit the specific data table for the details page you want to add the event to and go to the **Events** section at the bottom of that data table page.
- 5. Click **Add**. You see the Add Event page:



- 6. On the Add Event page, type a name for the event (for example, **Send Case Data to LIS**), type the file name of the event handler program (for example, lis.exe), and optionally type a description of the event.
- 7. Click Save. You now see the new event listed in the Events section of the data tables page:.

You can use the **Edit** and **Delete** links on the event line to modify or delete this event.

License Administration

This appendix contains information on Aperio eSlide Manager licensing.

Each DSR (Digital Slide Repository) containing an Aperio eSlide Manager database has a unique System ID. A license key is configured for a specific System ID and can only be used on that Aperio eSlide Manager system.

A license key which enables access tier and optional modules to be unlocked must be entered by an administrator on the License Administration page. (First-time license entry must be done by the Aperio eSlide Manager global administrator.) The appropriate license key will be sent to you by Leica Biosystems Technical Services.

Only one license is in effect at a time, but you can replace the existing license at any time with a new one that enables additional components you have purchased as well as your existing components.

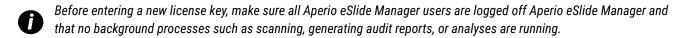
Installing the First System ID and License

If you are installing the software release for the first time (that is, you are not upgrading), you will need to install your System ID and install a license key if this has not already been done for you by a Leica Biosystems technician. Contact Leica Biosystems Technical Services for assistance.

Viewing License Status

The License Administration page displays information on licensing for your Aperio eSlide Manager site. Items listed on this page include:

- System ID The System ID can only be installed once and cannot be modified once installed.
- **System Description** This text describes your Aperio eSlide Manager site and can be any text you like. It can be changed at any time.
- License Key The currently installed license is displayed.
- Licensed Components Any modules that have been unlocked with a license are listed here.
- Algorithms Various image analysis algorithm groups are listed depending on your type of licensing.
- **System Information** Number of users defined, number of data groups defined, and database size are shown.



To see the License Administration page, go to the **Administrative** menu and select **License Administration**. The License Administration page appears:



You can change the System Description or enter another license by clicking the Edit button.

Expiring Licenses

Some licenses expire after a specific number of days. The license administration page lets you know how much time is left on such a license.

Algorithm Licensing

Two types of image analysis algorithms are licensed on Aperio eSlide Manager: eIHC algorithms and RUO (research use only) algorithms. Their licensing options differ slightly.

- eIHC algorithms are metered and may be run the number of times allowed by your license. (See the next section for more information on metering.)
- RUO algorithms use may be unlimited, metered, or for a number of months. You may try an RUO algorithm for 30 days from first use if a license is not installed.

Metered Licenses

Certain analysis algorithms are metered and may be run the number of times allowed by your license.

When the number of executions approaches the maximum number allowed by your license, a warning message will appear when an Aperio eSlide Manager user logs into Aperio eSlide Manager (if access warning messages have not been disabled for that user). After you have executed the algorithms the maximum number of times allowed, future executions will be disabled. At that point you can purchase a license allowing more algorithm executions—contact your Leica Biosystems Sales representative for information on purchasing an upgrade to a higher access tier.

What counts as one algorithm execution?

Algorithm execution counts are based on the parent digital slide. Therefore:

- Analysis of multiple TMA spots on a TMA slide counts as a single algorithm execution.
- Multiple algorithm executions on a single digital slide count as one execution, even if performed at different times and with different algorithms from the same group (see the previous section for a discussion of algorithm groups).

For example, analyzing one digital slide multiple times with different metered RUO algorithms counts as one execution, but analyzing one digital slide with a metered RUO algorithm and with an eIHC algorithm counts as two executions because the algorithms are from different groups.

If an algorithm analysis fails and does not return results (viewed in the Annotations window), the analysis is not included in the execution count.

Upgrading to a New License

For details on the specific access allowed by the licenses you have received from Leica Biosystems and for information on purchasing upgraded licenses, see your Leica Biosystems Sales representative.

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