Aperio LIS Connectivity

Overview

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Customer Resources

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

Disclaimers

- 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 eSlides or generating an audit report) can result in data loss.
- This manual is not a substitute for the detailed operator training provided by Leica Biosystems Imaging or for other advanced instruction. Leica Biosystems Imaging Field Representatives should be contacted immediately for assistance in the event of any instrument malfunction. Installation of hardware should only be performed by a certified Leica Biosystems Imaging Service Engineer.
- ImageServer is intended for use with eSlides created by scanning glass slides with the scanner. Educators will use Aperio software to view and modify eSlides in Composite WebSlide (CWS) format.
- The barcode decoding software used by Aperio scanners was provided by Honeywell International, Inc.

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Contents

1 Introduction

This document provides an overview of the Aperio LIS Connectivity solution, showing how it helps to integrate your Laboratory Information System (LIS) with Aperio eSlide Manager, a digital slide management system.

We discuss the features of Aperio LIS Connectivity, the benefits it provides, and how it optimizes the efficiency of your user workflow.

IT Managers may find this document helpful in explaining how Aperio LIS Connectivity fits into their network environment, and how it connects the LIS and Aperio eSlide Manager to provide an integrated solution.

About This Guide

- This chapter contains a product overview and introduction to Aperio LIS Connectivity.
- *"Chapter 2: System Design" on page 9* gives an in-depth look at the design of Aperio LIS Connectivity.
- *"Chapter 3: Product Capabilities" on page 14* gives more details on the capabilities of Aperio LIS Connectivity along with installation options.

References

For additional information on the Aperio LIS Connectivity environment, refer to:

- *Aperio eSlide Manager Administrator's Guide*, MAN-0044
- *Aperio Cybersecurity and Network Recommendations,* MAN-0355

Contact Us

Do you have questions or need assistance? Contact us at Leica Biosystems.com.

Product Overview

The Aperio eSlide Manager LIS Connectivity Solution ("Aperio LIS Connectivity") enables pathologists or other users of laboratory information systems to access digitally scanned slide images of a patient case from within the LIS system.

Aperio LIS Connectivity offers a tightly coupled integration between Aperio eSlide Manager and LIS systems that enables the launch of Aperio eSlide Manager digital viewers through the LIS interface. The integration also ensures that the viewer launching the images is always synchronized with the case open on the LIS. This gives the users of the LIS confidence that they are launching and viewing the appropriate results and images in the Aperio eSlide Manager digital viewer.

Figure A: Overview of the Integration System

Above is a simple representation of what the integration looks like. Aperio LIS Connectivity offers bi-directional messaging between the LIS and Aperio eSlide Manager.

Aperio LIS Connectivity is responsible for handling message transformations between the systems. In other words, Aperio LIS Connectivity accepts information from the LIS through HL7 2.x messages, internally transforms that using Leica-Aperio eSlide Manager specifications, and transmits the data to Aperio eSlide Manager to save in its database. Conversely, when physical slides are scanned by an Aperio scanner, the information is sent via Aperio LIS Connectivity to the LIS in a format that it understands.

There are two major components within the Aperio LIS Connectivity solution as shown in Figure B, the Integration Engine that accepts HL7 messages from the LIS, transforms them into Leica-Aperio eSlide Manager specifications and hands them to the Aperio eSlide Manager Sync Hub. Aperio eSlide Manager Sync Hub is responsible for taking inputs from the integration engine and updating the Aperio eSlide Manager database, to ensure synchronization between Aperio eSlide Manager and the LIS. In other words, all changes made to a patient order/case on the LIS will be routed to Aperio eSlide Manager via Aperio LIS Connectivity to avoid data mismatch between systems.

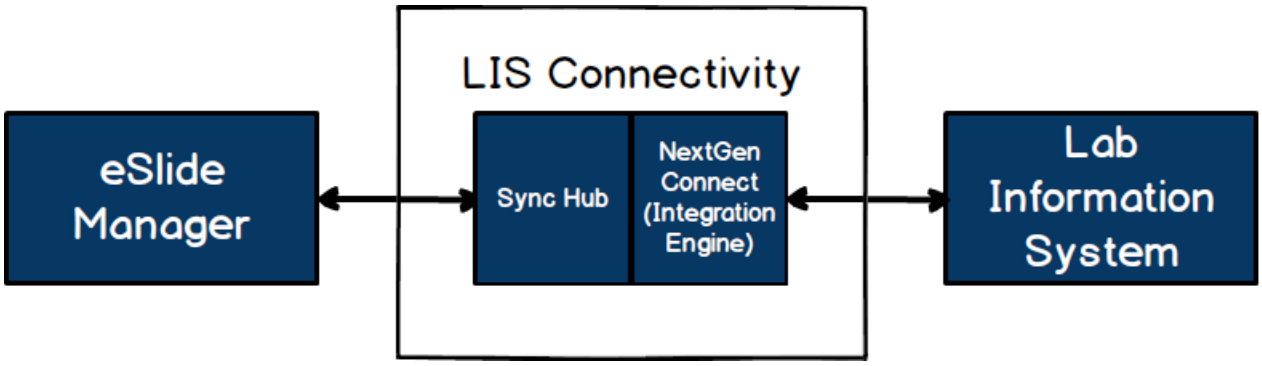

Figure B: Aperio LIS Connectivity Components

Figure C below shows how the integrated solution benefits workflow efficiency. As shown at the top of the illustration, the users previously used multiple subsystems to perform their routine diagnostic workflow, accessing the LIS separately and launching Aperio eSlide Manager as a separate application to view the digital images of the same case being viewed in the LIS. This lead to risks of mis-diagnosis and delayed diagnosis as launching two different subsystems disrupts the workflow.

Integrating these systems with Aperio LIS Connectivity enables a single system to view all the information by launching Aperio viewers from within the LIS. This enhances the user experience and avoids mis-diagnosis or delayed diagnosis by synchronizing the viewer with the case being viewed in the LIS. So, at any given time, the user accesses only a single patient case.

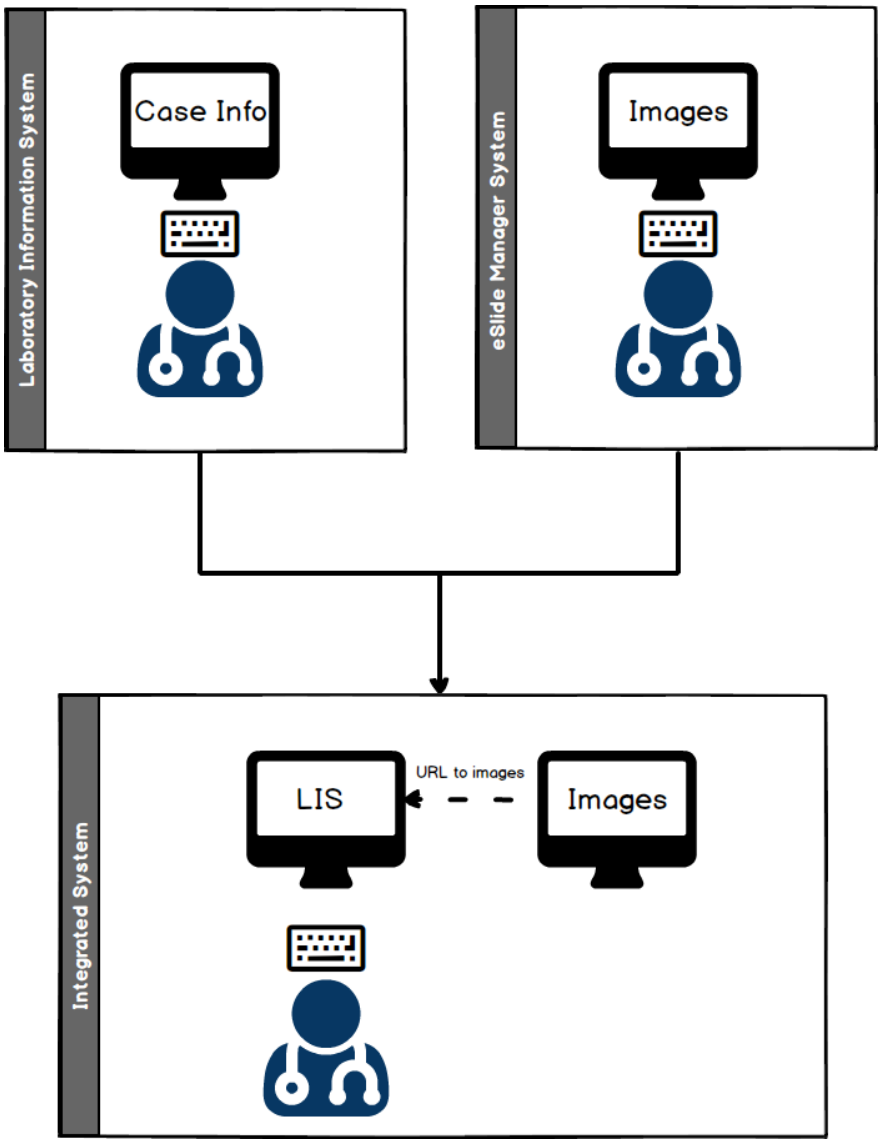

Figure C: Aperio LIS Connectivity Solution Benefit

Additional Features

Other benefits of Aperio LIS Connectivity include:

- To avoid unauthorized access, users accessing the system are authenticated and authorized through Aperio eSlide Manager credentials while accessing the digital slide viewer.
- Information exchange between systems is encrypted so that there is no misuse of patient information while information is being transfered between Aperio eSlide Manager and the LIS.
- Aperio LIS Connectivity installations are automated with minimal configuration, which saves time and enables a quicker start to optimized lab workflow.

2 System Design

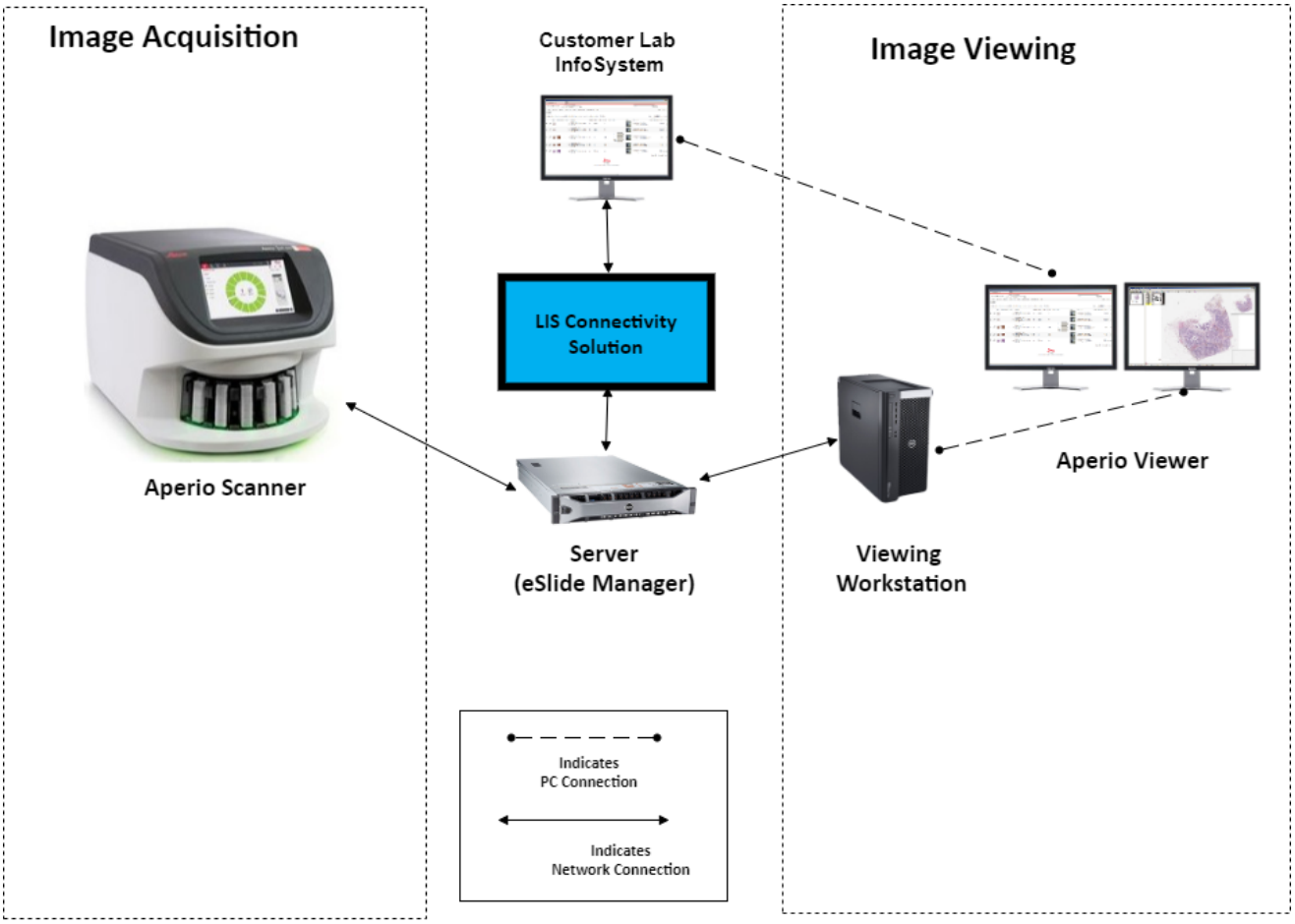

Figure D: Overall System Design

The illustration above shows how Aperio LIS Connectivity fits into your system.

Workflows

This section follows the different workflows supported by Aperio LIS Connectivity.

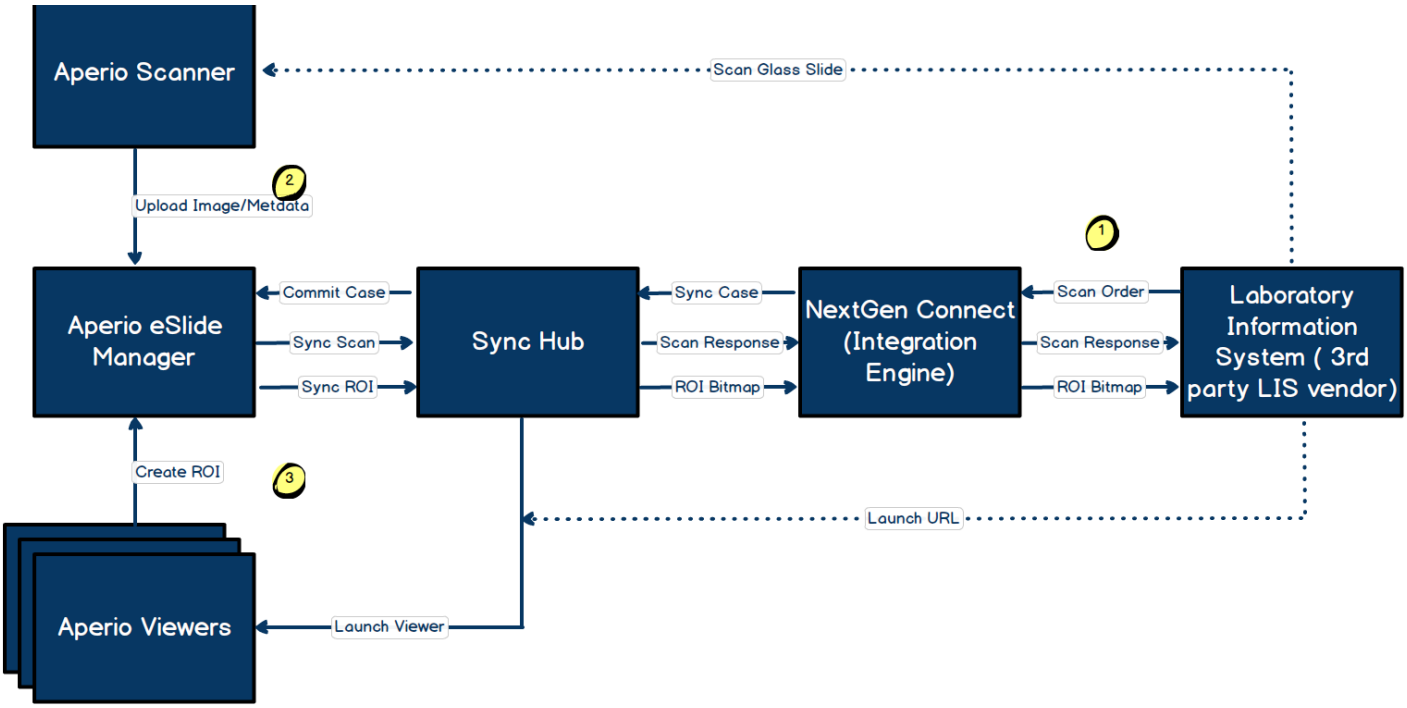

Figure D1: Order First Workflow

Order First Workflow focuses on initiating the scan order request from the LIS. The order goes through transformations and if all data and structure are submitted per the system specifications, the data from the order gets saved on Aperio eSlide Manager as Case, Specimen and/or slide orders.

The type of orders supported are New, Update or Cancel.

The order triggers a manual workflow step to scan the slide (which is handled by the lab technician as a manual process).

After a scan is complete, Aperio eSlide Manager triggers a response to the LIS. The response goes through the transformations and per the specifications gets routed to the LIS.

Note: The scan response only triggers if the slide has a valid barcode label and ID (also known as unique slide ID) that the Aperio scanner can recognize.

The response contains information about the digital image along with the ability to launch Aperio viewers (based on customer's choice of the viewer) to view the digital image. The LIS application is responsible to appropriately show the image information and for the trigger to launch the viewer.

The image information contains the URLs for every level of the hierarchy: Case, Specimen, Block and Slide based on that level's unique ID. The LIS may choose to use any or all URLs if they wish to launch images at different hierarchy levels.

The user launching the viewer from the LIS has the ability to draw a region of interest in the viewer as part of their reporting workflow. Aperio eSlide Manager, on drawing the report region on a digital image, shares the ROI information to the LIS application. The LIS can use the ROI image and information to fit its workflow.

Similarly to the “New” case order coming from the LIS, the workflow also supports updating an existing order or to cancel the information on a case. Aperio eSlide Manager supports this ability to ensure synchronization between Aperio eSlide Manager and a 3rd party LIS application.

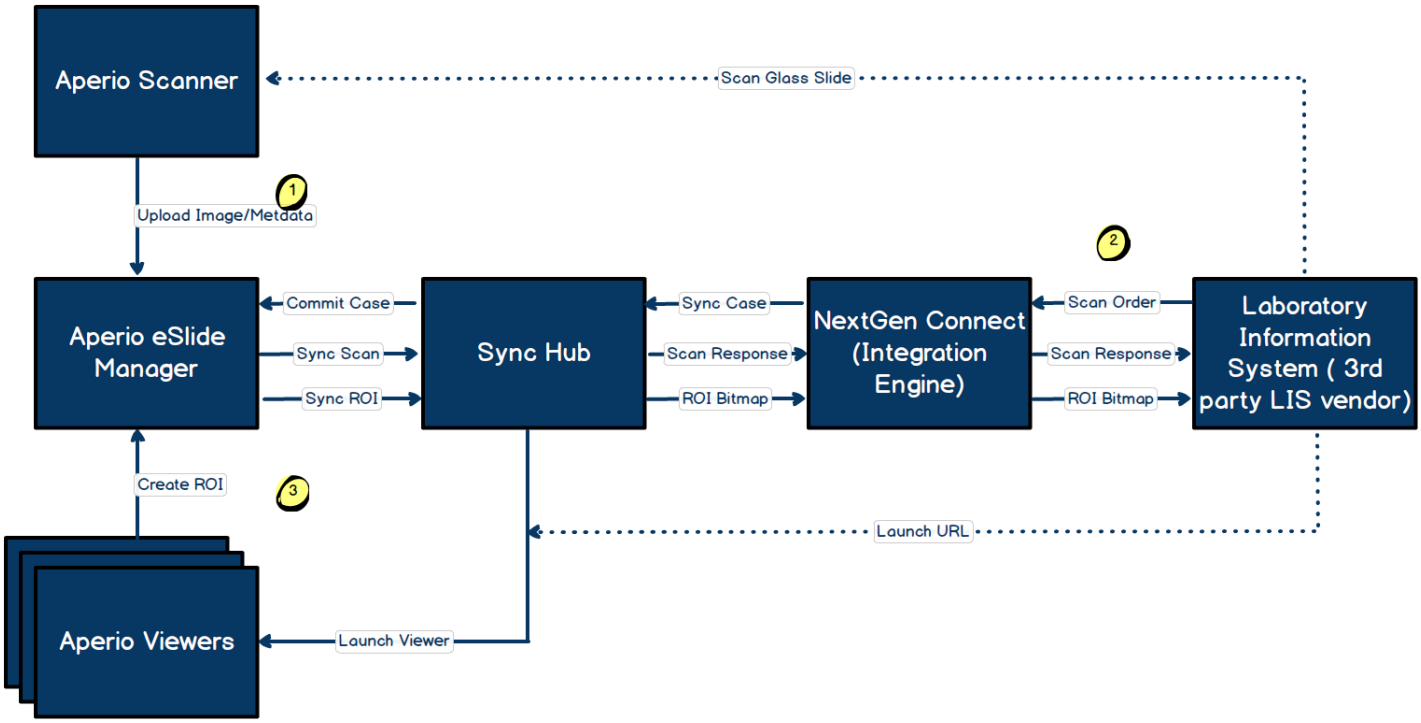

Figure D2: Scan First Workflow

Most of the Scan First Workflow follows the same steps as the Order First Workflow except that the scan of the physical slides happens as a first step and then the order is shared by the LIS. Aperio eSlide Manager associates the images to the incoming case as is done in the first workflow.

The other parts of this workflow like “Update” and “Cancel” follow the steps as mentioned in Figure D1. Note that Update and Cancel orders are separate work orders and should not be combined in a single order.

Detailed Design

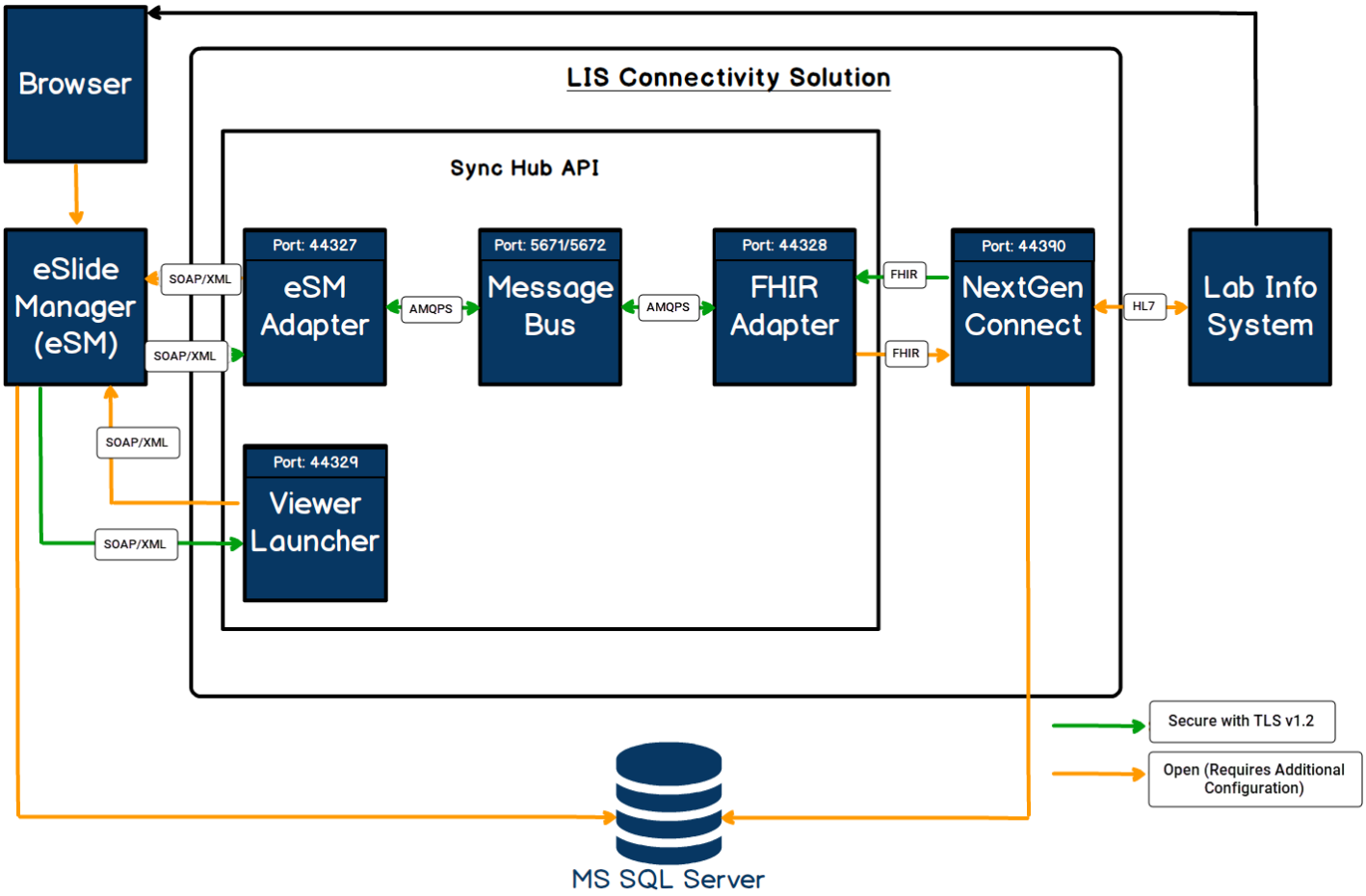

Figure E: Detailed System Design

The detailed design diagram above illustrates the components of Aperio LIS Connectivity, the mode of communication between the components, and the standard ports they use for transporting information.

NextGen Connect is a cross-platform interface engine that validates, accepts and relays portable messages between Sync Hub and the LIS.

All communication marked with green arrows are secure using TLS v1.2. All communication marked with orange arrows are configurable for cybersecurity. If the LIS vendor's LIS is not SSL compatible, we recommend the customer purchase a NextGen Connect (Mirth) license to secure the connection between NextGen Connect and the LIS. Please visit NextGen.com for details.

Protocol	Definition
HL7	Health Level Seven or HL7 refers to a set of international standards for transfer of clinical and administrative data between software applications used by various healthcare providers.
SOAP/XML	SOAP (abbreviation for Simple Object Access Protocol) is a messaging protocol specification for exchanging structured information in the implementation of web services in computer networks. SOAP provides a means for systems to package and exchange messages encoded in XML

Table 1: Protocol Definitions

Message Types

Aperio LIS Connectivity uses the message types as shown in the below diagram.

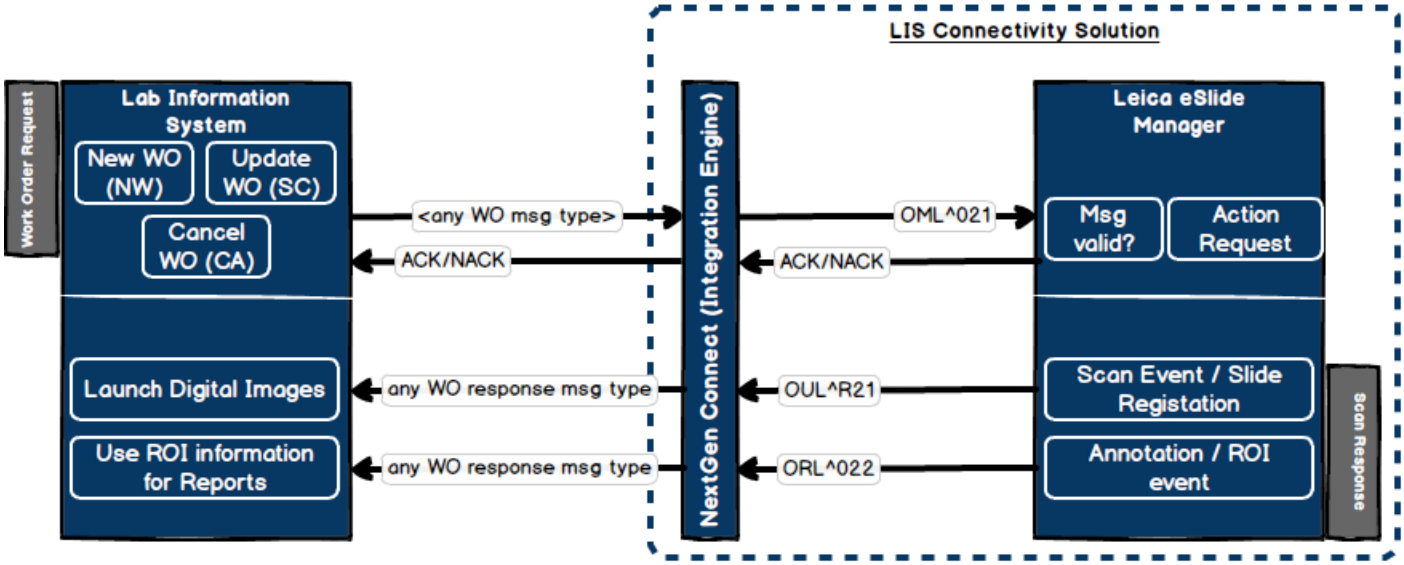

Figure F: Message Types

Message types shown above between the LIS and Integration Engine can be any Work Order (WO) HL7 message type but when they enter Aperio LIS Connectivity, the message types are Leica standard.

OML^021	Incoming Order from LIS converted into Aperio eSlide Manager specification (HL7)
ACK/NACK	Acknowledgment/Negative Acknowledgment
OUL^R21	Response shared by Leica once a digital slide is registered in Aperio eSlide Manager
ORL^022	ROI response shared by Leica when report region is drawn on the Viewer

3 Product Capabilities

This chapter gives additional information on Aperio LIS Connectivity features and installation details.

Integration Engine

Aperio LIS Connectivity uses NextGen Connect (Mirth) for message transformations between an LIS and Aperio eSlide Manager. Aperio LIS Connectivity supports version 3.8.1 of Mirth. A free version of Mirth is installed as part of Aperio LIS Connectivity deployment.

If the LIS vendor's LIS is not SSL compatible, we recommend the customer purchase a NextGen Connect license to secure the connection between NextGen Connect and the LIS. Please visit NextGen.com for details.

Supported HL7 Versions

Aperio LIS Connectivity supports all HL7 2.x versions. All communication sent and received by Aperio LIS Connectivity is through HL7 Lower Level Protocol (LLP). Incoming and outgoing IP addresses and ports can be configured.

Environment Description

Aperio LIS Connectivity is installed alongside Aperio eSlide Manager on one server and users connect through client machines. Pathologists who are remote can continue launching Aperio eSlide Manager and its WebViewer from their LIS depending on network security via VPN or DMZ configuration.

Aperio LIS Connectivity has logs created at every stage of the communication between the LIS and Aperio eSlide Manager to ensure traceability and auditability.

Licensing

Aperio LIS Connectivity uses a perpetual license mode and is dependent on the Aperio eSlide Manager license being available.

Additionally, if the LIS vendor's LIS is not SSL compatible, we recommend the customer purchase a NextGen Connect license to secure the connection between NextGen Connect and the LIS. Please visit NextGen.com for details.

Key Configurations

- The site can be configured to set the default Aperio viewer for launching digital images. The choices are Aperio ImageScope, Aperio ImageScope DX, or WebViewer.
- Aperio eSlide Manager can configured to be set up over SSL so that all communication between the integration engine and Aperio eSlide Manager is secure.
- An HL7 Mapper is used to map information between LIS HL7 fields to Leica-standard HL7 fields during implementation.
- Aperio LIS Connectivity supports organization of digital slides from one to four levels (Case/Specimen/Block/Slide) and a unique ID is required for each level.

Symbols

The following symbols may appear on your product label or in this user's guide:

	Consult instructions for use
	Manufacturer
	Date of manufacture (year - month - day)
	European Union Authorized Representative
	In vitro diagnostic device
	Serial number
	Catalog number
	Relative humidity range
	Biological risks
	Storage temperature range
	Electronic and electrical equipment waste disposal
	The exclamation point within an equilateral triangle is intended to alert you to the presence of important operating and maintenance (servicing) instructions. *Le point d'exclamation dans un triangle équilatéral vise à avertir l'utilisateur qu'il s'agit d'instructions d'utilisation et d'entretien importantes.*
	The lightning flash with arrowhead symbol within an equilateral triangle is intended to alert you to the presence of uninsulated "dangerous voltage" within the product's enclosure that may be of sufficient magnitude to constitute a risk of electric shock to persons. *Le symbole de l'éclair avec la pointe de flèche dans un triangle équilatéral vise à avertir l'utilisateur que le boîtier du produit présente une « tension dangereuse » non isolée d'une amplitude suffisante pour constituer un risque d'électrocution.*
	The flat surface with waves symbol within an equilateral triangle is intended to alert you to the presence of hot surfaces which could cause burn damage. *Le symbole d'une surface plane et de vagues dans un triangle équilatéral vise à avertir l'utilisateur de la présence de surfaces chaudes qui peuvent causer des brûlures.*
	The UV lamp within an equilateral triangle is intended to alert you to the presence of UV light within the product's enclosure that may be of sufficient magnitude to constitute a risk to the operator. *La lampe UV dans un triangle équilatéral vise à avertir l'utilisateur de la présence de rayonnement UV dans le boîtier du produit qui peut être d'une amplitude suffisante pour constituer un risque pour l'utilisateur.*

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