ACIST Medical Systems

ACIST Connect™ Case Study

Client Summary

ACIST Medical Systems (Acist) manufactures and supplies contrast imaging system technology for cardiology to over 75 countries. Acist is a part of the Bracco Group and is headquartered in Eden Prairie, Minnesota.

Project Overview

Noesis Labs LLC (Noesis) partnered with Acist to design, develop, test and deploy a Health Insurance Portability and Accountability Act (HIPAA) compliant medical device data system marketed as ACIST Connect™ (Connect). The Connect system pairs with Acist's HDi® intravenous ultrasound product to alleviate two important pain-points experienced by users of the existing product offering:

- Scheduling of studies which was previously only possible via the HDi console.
- Storage and sharing of study results which was previously accomplished via a manual data export from the HDi console to a CD or USB drive.

In addition to these issues Noesis designed the Connect system to provide many additional benefits around data retention, study reconciliation, data security, centralization, and automation.

Product Development Process

The development of the Connect system began with Noesis facilitating a deep dive into Acist's HDi product to understand the underlying architecture and identify potential integration paths. During this time, Noesis worked closely with Acist to develop a firm understanding of the HDi product, the desired functionality, and the technical, organizational, and environmental challenges that had to be met for the project to succeed. Noesis also provided guidance on the project scoping and feature prioritization at this early stage through candid assessments of technical challenges and general effort estimates.

"Noesis has been an exemplary development partner. From concept to full market release, Noesis's vast knowledge, flexibility, and clear communication made the ACIST Connect project a major success for the ACIST organization."

Adam Rondeau - Manager, Hospital Information Systems

Once a clear picture of important features and constraints emerged, Noesis initiated the process of researching specific technical solutions culminating in a formal proposal containing estimates

around scope, cost, staffing levels, risks, and schedule. Upon acceptance of the proposal the process of development began in earnest.

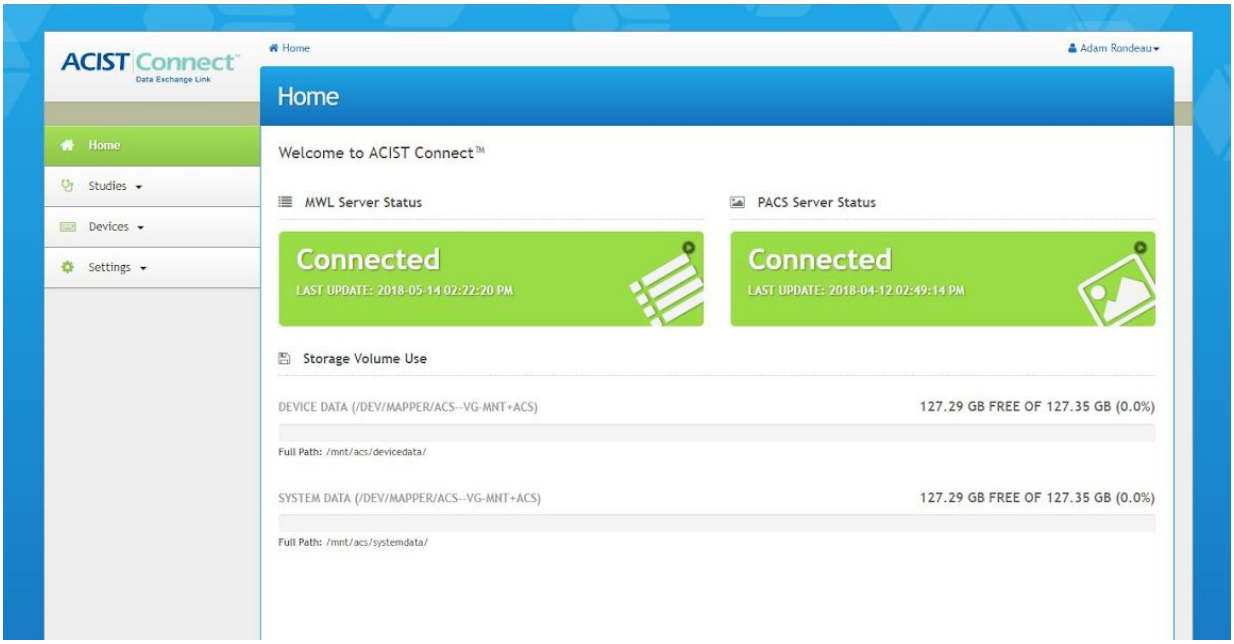
The team at Noesis commenced construction of a framework for what would become the Connect product and stood up a secure user acceptance testing (UAT) environment providing Acist an interactive window to the development progress. Working closely with representatives from Acist, Noesis continued development using an iterative development process that provided needed flexibility to accommodate the challenges and changing requirements involved in a greenfield project. As the Connect application began to mature, Noesis worked with an Acist quality assurance (QA) team to develop test plans, identify issues and regressions, squash bugs, and make the system more robust. The process culminated in the formal acceptance of the software by Acist followed by an organized knowledge and code transfer from Noesis including, dependency and licensing documentation, build tooling and process documentation, deployment documentation, and source code repository transfer. After delivery, Noesis provided support to ensure that Acist had every resource necessary to successfully manage, build, test, and deploy their new Connect system independently.

Product Details

The Connect system consists of a packaged Linux virtual machine (VM) configured and deployed on-site as an appliance running a suite of custom software. The VM provides boot-menu functionality for all necessary system configuration (network configuration, admin password reset, system reset, etc) but does not allow console login, which prevents unsupported system changes. Meanwhile, Acist maintains the ability to support the system via the use of a secure shell connection authenticated with a unique key generated per installation.

The entire VM creation process is automated including: OS customization/hardening, software build, installation, and configuration, and VM packaging. This eliminates the need to maintain a “gold” image and ensures every step of the product creation is repeatable and explicitly documented.

Once deployed, the Connect system hosts a web-based interface built using HTML5 and AngularJS. This interface provides role-based authentication and is the means by which the Connect system is configured and used. Several aspects of the web-based interface are reactive and changes in the system are immediately visible to all connected users (via websocket) without the need for a page refresh. Additionally, the web interface is also responsive, changing its layout to accommodate the client’s device (monitor, tablet, or phone).



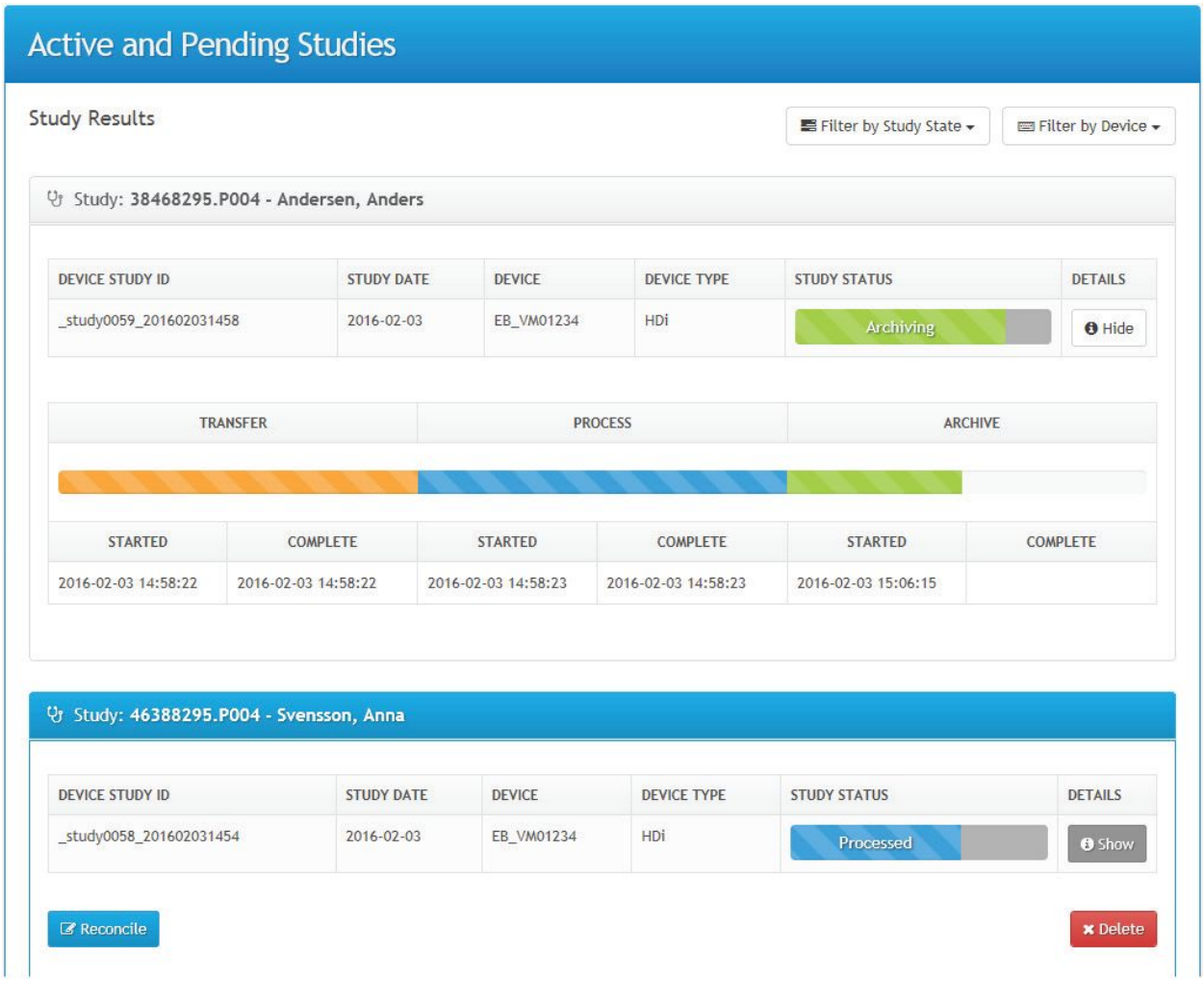
Acist Connect Home Screen

The Connect system's primary function is to provide connectivity between hospital systems and the Acist HDi device. To serve this purpose, the Connect can be configured to interface with a picture archiving and communication system (PACS). The connection to a PACS serves two purposes.

The first is allowing the Connect system to retrieve modality worklists (MWL) entered in the hospital's electronic medical records (EMR) software. Scheduled studies from a MWL are then made available to all connected HDi devices via an encrypted advanced programming interface (API) allowing medical staff to select their patient from a list of scheduled studies rather than manually entering information at the time of each study. This method provides several advantages including: lower error rate, time savings in the operating theater, and ability for study results to be correlated with previous patient records. Additionally, the Connect system is able to handle scheduling complexities such as complex character sets and patients with multiple name segments (both of which are encountered regularly in Acist's Japanese market) while shielding the HDi from those complexities.

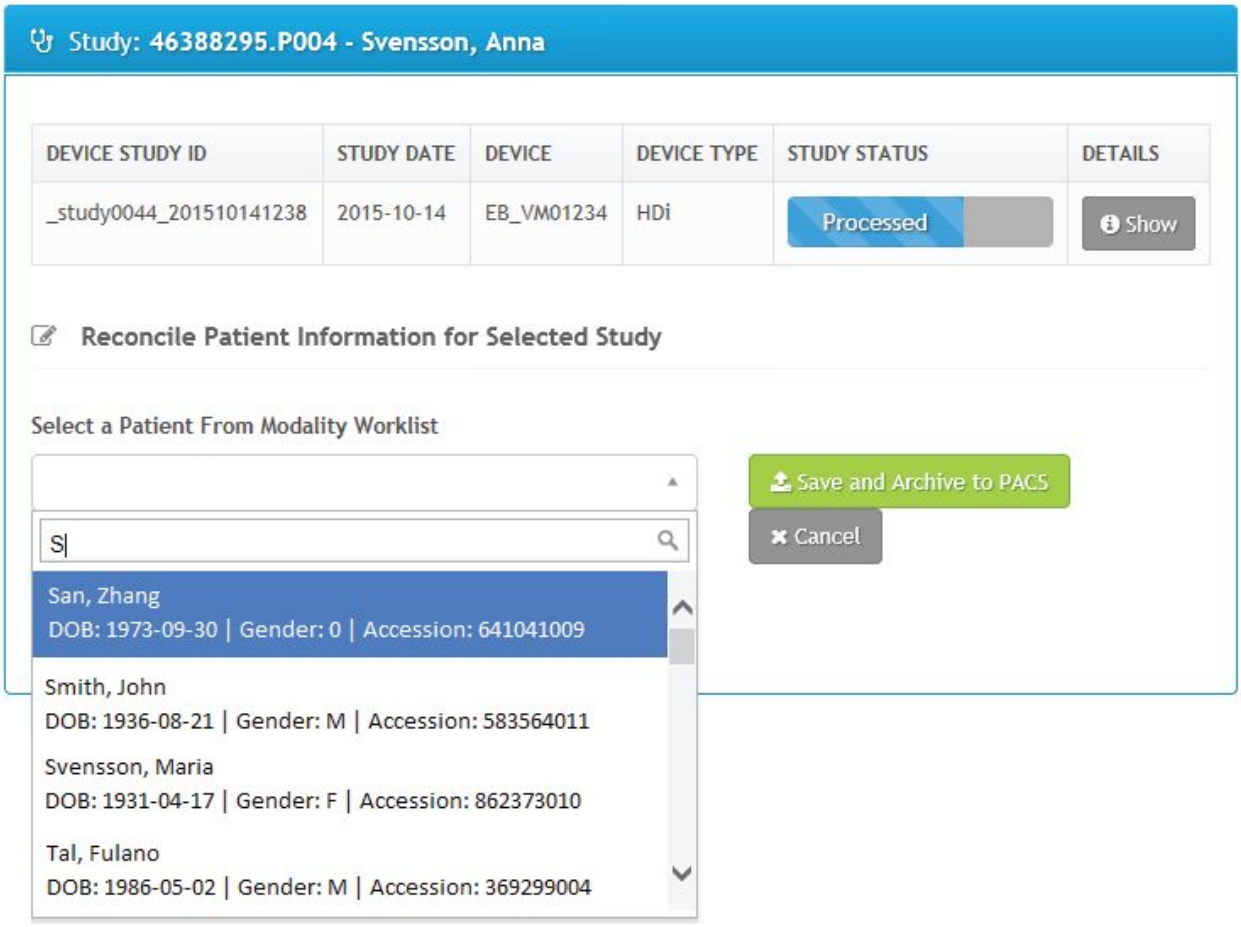
Modality Worklist Study Selection (HDi)

The second use of the Connect PACS integration is to support the archival of study results. Many hospitals utilize a PACS for centralized storage of study data and to link studies performed over time with the associated patient. With the introduction of the Connect system, the HDi gained the ability to securely export study results to a PACS using the Connect system as a proxy. This feature provides considerable advantages over the previous export to CD/USB method. First, and foremost, the export of study results to the Connect system is automated and secure, eliminating a timely and error prone manual export process. The automated export ensures that studies are archived quickly and accurately, alleviating concerns around the long-term storage of patient data on a potentially insecure medical device as well as the potential of filling the storage on the medical device. This process also eliminates concerns around storing patient medical data on CDs and USB devices which are notoriously difficult to track and less than ideal long-term storage mechanisms.



PACS Study Archival Status

In addition to its primary functionality, the Connect appliance provides several ancillary benefits. While most hospitals' PACS are configured to store compressed images, the Connect can be configured to maintain full quality study results even after exporting to a PACS, providing an excellent data source for clinical studies. Or, in the case that a PACS is not available in a facility the Connect can, itself, act as a centralized data store. Additionally, the Connect provides several options for PACS archival automation giving users an opportunity to manually reconcile ad-hoc, mismatched, or all study results before archival to a PACS. Users can also enable notifications in order to receive emails when new studies are pending reconciliation. Finally, because each HDi device is registered individually with the Connect system, it also acts as a device repository providing centralized management of HDi devices within a hospital.



Study Reconciliation

The Connect back-end software utilizes a MongoDB noSQL database for storage and was built with an event sourced architecture. This unique architecture ensures every action performed within the Connect system is logged providing a comprehensive audit log that can be used for troubleshooting or security audit purposes. It also provides the basis for a flexible reporting system that can be configured, even retroactively, to report on new metrics. Communication with both the web interface as well as the HDi device is supported by a representational state transfer (RESTful) API implemented with command/query responsibility segregation (CQRS). The combination of CQRS and a domain driven design helps clearly demarcate business logic, state altering operations, and read-only data representations. These clear demarcations significantly ease code maintenance and feature additions as the proper location of functionality can be quickly identified. Study transfers are achieved via encrypted rsync which allows efficient, secure, and reliable data transfer even in the case of network connectivity interruptions.

Reception and Maintenance

The Connect system was launched internationally in 2016 and has enabled Acist to compete in new market segments where hospital system integration is paramount. The product has won praise from clients for its ease of deployment, feature set, and reliability.

"Noesis Labs built a product that is an absolute dream to support and implement. Over two years since its release we have yet to identify a single software defect and our incident reports from the field are near zero.

In my career working with medical devices I have never worked with a piece of software that even comes close to the reliability and ease of use of ACIST Connect."

Ryan Gamst - Sr. Program Manager

Having facilitated thousands of HDi studies, the Connect system has proven to be extremely robust. Well over two years after initial deployment, the first Connect installations continue to perform flawlessly with minimal upkeep from either hospital IT staff or Acist.