



# Merge Unity™

## IHE INTEGRATION STATEMENT Integrating the Healthcare Enterprise (IHE)

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## INDICATIONS FOR USE: Merge Unity PACS

Merge Unity PACS is a medical image and information management system that allows viewing, selection, processing, printing, telecommunications, and media interchange of medical images from a variety of diagnostic imaging systems. Merge Unity PACS interfaces to various storage and printing devices using DICOM or similar interface standards.

Merge Unity PACS displays, stores, prints, and telecommunicates images from a number of medical modalities, including but not limited to MRI, CT, US, PET, DXA (bone densitometry), nuclear imaging, computed radiography, digital radiography, digitized films, digital photographs, mammographic images, and processed data from FDA-cleared third party image processing systems, including FDA-cleared systems for computer-aided detection and advanced image processing (e.g. 3-D processed images such as those produced by Voxar Corp.).

Lossy compressed mammographic images must not be used for primary diagnostic interpretation unless approved for use in digital mammography. Display monitors used for primary diagnostic interpretation of mammographic images must be approved for use in digital mammography.

## INDICATIONS FOR USE: Z3D

Z3D is intended to provide reading physicians, referring physicians, and other appropriate healthcare professionals tools to aid in interpreting medical images, including:

- Displaying DICOM compliant medical image volumes, such as CT, MRI, and PET.
- Reformatting images, including creation of MPRs, MIPs, MinIPs, color/monochrome 3D volume rendered images.
- Manipulating displayed images via control of slice thickness, slice interval, obliquity, perspective, rotation, window/level, crop, zoom, color/monochrome transformations, segmentation, sculpting, straightening the display of curved structures, and creating images perpendicular to a curvilinear path.
- Creating series of DICOM images and individually captured images that can be displayed and stored in a PACS.
- Measuring coronary calcium, which is intended for non-invasive identification and quantification of calcified atherosclerotic plaques in the coronary arteries using tomographic medical image data and clinically accepted calcium scoring algorithms.

**CAUTION:** Federal law restricts this device to sale by or on the order of a physician.

**CAUTION:** Unity PACS and Merge Z3D are not intended for diagnostic use on mobile device such as a phone or tablet.

The symbols glossary is provided electronically at <http://www.merge.com/Support/Resources.aspx>.

## CANADIAN DEVICE IDENTIFIER:

Device Name	Device Identifier
UNITY RIS/PACS	C-DRSW-00001
Merge Z3D	MERGE Z3D



### Manufacturer's Address

Merge Healthcare Incorporated  
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**DOCUMENT VERSION LOG:**

<b>Part</b>	<b>Date</b>	<b>Revision</b>	<b>Description</b>
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# 1. Overview

## 1.1 IHE – Integrating the Healthcare Enterprise

Integrating the Healthcare Enterprise (IHE) is an initiative designed to stimulate the integration of the information systems that support modern healthcare institutions. Its fundamental objective is to ensure that in the care of patients all required information for medical decisions is both correct and available to healthcare professionals.

IHE is a multi-year initiative undertaken by medical specialists, administrators, information technology professionals and manufacturers, sponsored in part by the Radiological Society of North America (RSNA) and the Healthcare Information and Management Systems Society (HIMSS), whose sole purpose is to improve the way computer systems in healthcare share information.

IHE is not a standards organization. Instead, it promotes coordinated use of existing standards such as DICOM and HL7 to develop workflow solutions for the healthcare enterprise.

## 1.2 Scope

This Integrating the Healthcare Enterprise (IHE) Integration Statement was developed as a high level statement for integration for products, which were intended to interoperate, based on IHE Integration Profiles. This document identifies the IHE Actors, IHE Integration Profiles and options Unity has implemented in our products.

This IHE Integration Statement does not guarantee successful interoperability of this product with other vendor's products. It is the user's responsibility to analyze thoroughly the application requirements and to specify a solution that integrates the Unity PACS with other vendor's software and systems.

## 1.3 Related Information

The following are Web sites with related information:

Web Site	Description
<a href="http://www.ihe.net/">http://www.ihe.net/</a>	For General Information on IHE
<a href="http://medical.nema.org/dicom.html">http://medical.nema.org/dicom.html</a>	For General Information on DICOM
<a href="http://www.hl7.org">http://www.hl7.org</a>	For General Information on HL7
<a href="http://www.hl7.org/special/Committees/ccow_sigvi.htm">http://www.hl7.org/special/Committees/ccow_sigvi.htm</a>	For General Information on CCOW

## 1.4 Glossary

### **Actors**

Information systems or components of information systems that produce, manage, or act on categories of information required by operational activities in the enterprise.

### **CCOW (Clinical Context Object Workgroup)**

A set of integration standards for the clinical desktop. The CCOW standard establishes the basis for ensuring secure and consistent access to patient information from heterogeneous sources through synchronizing and coordinating applications (such as those used for patient registration, order entry, and results reporting) so that they instinctively follow a specific context, including the identity of a user, a patient or a specific clinical observation.

### **DICOM (Digital Imaging and Communications in Medicine)**

The industry standard for transfer of radiologic images and other medical information between computers. DICOM enables digital communication between diagnostic and therapeutic equipment and systems from various manufacturers.

### **HL7 (Health Level 7)**

A communications standard that enables healthcare applications to exchange key sets of clinical and administrative data. Health Level 7 is one of several ANSI-accredited Standards Developing Organizations (SDOs) operating in the healthcare arena.

### **IHE (Integrating the Healthcare Enterprise)**

A set of standards to assist healthcare enterprises in achieving systems integration, enabling secure access to vital information for optimal patient care. Sponsored jointly by the Radiological Society of North America (RSNA) and the Healthcare Information and Management Systems Society (HIMSS).

### **Connectathon**

The annual IHE event at which systems are tested.

### **Transactions**

Interactions between actors that communicate the required information through standards-based messages.

## 2. Introduction

The goals of medical information systems are to improve the safety and quality of medical care, improve the efficiency of physicians and other medical personnel, and simultaneously lower costs. Since the formation of Unity, hospitals and imaging centers have achieved these goals using the Unity RIS/PACS solution. These benefits continue to expand with Unity's addition of advanced post-processing software, a full dictation and transcription system with voice recognition, and resource-based scheduling. The benefits that Unity's customers enjoy are in part related to a significant re-engineering of workflow provided by Unity products. This is facilitated by automated communication between Unity products and those of a wide variety of other vendors that produce radiology information systems, hospital information systems, and medical imaging equipment.

### 3. Unity's Dedication to Industry Standards

These interfaces use industry standards, DICOM, HL7, and CCOW. Unity is fully committed to industry standards and not only supports DICOM and HL7, but was the first company in the PACS industry to implement CCOW. The CCOW standard provides secure communication between disparate information systems so that physicians can access medical information on a patient on a single desktop with a single login.

Much of the functionality that IHE Integration Profiles are designed to achieve is currently provided by Unity internally and through HL7 and DICOM interfaces to medical information systems and imaging devices, the same standards-based tools used by IHE.

Table 1: IHE Integration Profiles and Related Unity Functionality

IHE Integration Profiles	Existing Unity Functionality
<p><b>Scheduled Workflow</b> Provides an efficient flow of information between systems involved in a typical imaging encounter, including consistency of patient information.</p>	<p>Support: Tested successfully at IHE Connectathon. Partial: Partially supported. Alternate Feature: Available using an alternate method without IHE support. Under Development: Currently being prepared for IHE support.</p> <p><input checked="" type="checkbox"/> <b>Partial</b> <input checked="" type="checkbox"/> <b>Under Development</b></p> <p>Unity currently has strong internal functionality to support this workflow, including HL7 interfaces to RIS and HIS systems, patient management, order management, modality worklist support for acquisition modalities (typically supported by RIS, not PACS), automated prefetching of prior exams from the PACS archive, and verification of demographic data from the information systems via HL7 and acquisition modalities via DICOM.</p> <p>Unity provides support for following functionality of the DSS/Order Filler Actor in Scheduled Workflow:</p> <ul style="list-style-type: none"> <li>• HL7 ADT</li> <li>• HL7 ORM</li> <li>• DICOM Modality Worklist SCP</li> <li>• Modality Performed Procedure Step SCP</li> </ul> <p>Unity provides support for following functionality of the Image Manager/Image Archive in Scheduled Workflow</p> <ul style="list-style-type: none"> <li>• HL7 ORM</li> <li>• DICOM Storage SCP</li> <li>• DICOM Query/Retrieve SCP</li> <li>• DICOM Storage Commitment SCP</li> <li>• Modality Performed Procedure Step SCP</li> </ul> <p>Unity will add support for this IHE workflow profile.</p>

<p><b>Patient Information Reconciliation</b></p> <p>A critical function that allows demographic information to be corrected, e.g., the emergency department patient that is initially labeled as a John Doe, but ultimately is identified by his correct name and medical record number</p>	<p><input checked="" type="checkbox"/> <b>Partial</b></p> <p><input checked="" type="checkbox"/> <b>Under Development</b></p> <p>Unity currently provides this functionality and will expand this functionality to IHE requirements.</p> <p>Unity provides support for following functionality of the DSS/Order Filler Actor in Patient Information Reconciliation:</p> <ul style="list-style-type: none"> <li>• HL7 ADT</li> <li>• DICOM Modality Worklist SCP</li> <li>• Modality Performed Procedure Step SCP</li> <li>• DICOM Query/Retrieve SCP</li> </ul>
<p><b>Consistent Presentation of Images</b></p> <p>Provides two types of functionality. First, it provides a method for technologists and radiologists to add value to raw images by appropriately adjusting image window and level, image orientation, cropping, and magnification as well as adding user notations. And second, the Grayscale Standard Display Function supports consistency of grayscale display for both softcopy and hardcopy.</p>	<p><input checked="" type="checkbox"/> <b>Support</b></p> <p><input checked="" type="checkbox"/> <b>Alternate Feature</b></p> <p>Unity has successfully tested at the IHE Connectathon as the following actor for Consistent Presentation of Images:</p> <ul style="list-style-type: none"> <li>• Image Manager</li> </ul> <p>Unity supports Grayscale Softcopy Presentation States for image display.</p> <p>Unity currently supports the ability to create, record, transmit, and display image display information, including user annotations, image window and level, orientation, cropping, and magnification.</p> <p>When acting as DICOM Storage SCU or Media Creator, Unity optionally generates Grayscale Presentation state and Key Object Selection Document objects that describe the current display parameters.</p> <p>Unity supports Grayscale Display Function on calibrated monitors, in particular, on Dominator reading stations.</p> <p>Unity will add support for other actors for this IHE workflow profile.</p>
<p><b>Presentation of Grouped Procedures</b></p> <p>Allows a single physical imaging exam, e.g. CT of chest, abdomen, and pelvis, to be split into separate exams for reading and billing.</p>	<p><input checked="" type="checkbox"/> <b>Alternate Feature</b></p> <p><input checked="" type="checkbox"/> <b>Under Development</b></p> <p>Unity currently supports this workflow by allowing studies to be split or combined and by allowing the technologist to create virtual series. Each of these virtual series can point to range of images and be assigned a set of display attributes, without the need to store more than one set of actual images. This IHE profile will be implemented by Unity.</p>

<p><b>Access to Radiology Information</b> provides a standard means for delivering radiology information, including reports and images.</p>	<p><input checked="" type="checkbox"/> <b>Support</b></p> <p>Unity has successfully tested at the IHE Connectathon as the following actor for Access to Radiology Information:</p> <ul style="list-style-type: none"> <li>• Image Manager</li> </ul> <p>Unity provides a complete dictation and transcription module with voice recognition, a report server, and interfaces that allow communication of these reports as well as display from external report servers. Unity allows access to exam images, reports, summary montages, and voice clips from thin clients, including web browsers and PDAs.</p> <p>Unity provides support for the following functionality of the Image Manager/Image Archive in Access to Radiology Information for the SOP Classes identified in <i>DICOM Network Interfaces - Conformance Statement for Unity PACS (UPAX-4466)</i>.</p> <ul style="list-style-type: none"> <li>• DICOM Storage SCP</li> <li>• DICOM Query/Retrieve SCP</li> </ul> <p>Unity will add support for other actors for this IHE workflow profile.</p>
<p><b>Key Image Notes</b> Provides a methodology to communicate a summary of the key findings to the referring doctor using selected images and text.</p>	<p><input checked="" type="checkbox"/> <b>Partial</b></p> <p><input checked="" type="checkbox"/> <b>Alternate Feature</b></p> <p><input checked="" type="checkbox"/> <b>Under Development</b></p> <p>This functionality is integral to the Unity PACS system through the montage, consisting of images selected by the radiologist and text notes that communicate the key findings of the case. This will be expanded to support this IHE profile. In addition, Unity allows radiologists to create a voice clip that summarizes the case.</p> <p>When acting as DICOM Storage SCU or Media Creator, Unity optionally generates Grayscale Presentation state and Key Object Selection Document objects that describe the current display parameters.</p>
<p><b>Simple Image and Numeric Reports</b> Allows the radiologists to create a summary for the referring clinician that includes key images and measurements and supports the growing use of specialized reporting packages and the use of digital dictation and voice recognition.</p>	<p><input checked="" type="checkbox"/> <b>Partial</b></p> <p><input checked="" type="checkbox"/> <b>Alternate Feature</b></p> <p><input checked="" type="checkbox"/> <b>Under Development</b></p> <p>Unity PACS supports all forms of Structured Reports, including Evidence Documents, as a Report Repository. The text and numeric portions of Structured Report contents are displayed to the user when viewing a study. Values can be automatically imported into the reading physician's report.</p> <p>Additional functionality is provided on the Unity PACS through the montage function, where radiologists can include measurements on images as well as short text reports. In addition, Unity's report generation module provides a complete reporting system including the use of report templates, voice recognition, and images. In addition, Unity's montage function supports this functionality. These functions will be adapted to support this IHE profile.</p>

<p><b>Post-Processing Workflow</b> Supports scheduling and tracking of post-processing workflow.</p>	<p><input checked="" type="checkbox"/> <b>Partial</b> <input checked="" type="checkbox"/> <b>Alternate Feature</b> <input checked="" type="checkbox"/> <b>Under Development</b></p> <p>Unity provides support for following functionality of the Image Manager/Image Archive in the Post-Processing Workflow</p> <ul style="list-style-type: none"> <li>• Query/Retrieve SCP</li> <li>• Modality Performed Procedure Step SCP</li> </ul> <p>Additionally, Unity has integrated post-processing including multiplanar reformatting, 3D display, and maximum intensity projection. This post-processing is supported at the technologist's and radiologist's workstations, with processed images added as new DICOM series to exams. Unity will add support for other actors for this IHE workflow profile.</p>
<p><b>Charge Posting</b> Supports the exchange of information related to charges.</p>	<p><input checked="" type="checkbox"/> <b>Partial</b> <input checked="" type="checkbox"/> <b>Under Development</b></p> <p>Unity supports charge capture and posting.</p> <p>Unity provides support for the following functionality of the DSS/Order Filler in Charge Posting</p> <ul style="list-style-type: none"> <li>• HL7 DFT^P03</li> </ul> <p>This IHE profile will be implemented by DR.</p>
<p><b>Evidence Documents</b></p>	<p><input checked="" type="checkbox"/> <b>Partial</b></p> <p>Unity provides support for all of the functionality of the Image Manager/Image Archive in the Evidence Documents workflow:</p> <ul style="list-style-type: none"> <li>• DICOM Storage SCP</li> <li>• DICOM Query/Retrieve SCP</li> <li>• DICOM Storage Commitment SCP</li> </ul> <p>This IHE profile will be implemented by DR.</p>

<b>Portable Data for Imaging</b>	<input checked="" type="checkbox"/> <b>Support</b> Unity has successfully passed IHE testing as the following actors for Portable Data for Imaging: <ul style="list-style-type: none"> <li>• Portable Media Creator (no options)</li> <li>• Image Display</li> <li>• Display (ITI TF)</li> </ul> Unity additionally supports the following actor for Portable Data for Imaging: <ul style="list-style-type: none"> <li>• Portable Media Importer</li> </ul> Image Display capability is not limited to IHE PDI compliant CDs, it applies to any DICOM Part 10 CD/DVD, for the SOP Classes and Transfer Syntaxes identified in <i>DICOM Media Storage - Conformance Statement for Unity</i> (UPAX-4467). Unity will add support for other actors for this IHE workflow profile.
<b>Structured Report Export</b>	<input checked="" type="checkbox"/> <b>Support</b> Unity has successfully tested at the IHE Connectathon as the following actor for Structured Report Export: <ul style="list-style-type: none"> <li>• Enterprise Report Repository</li> </ul>

While IHE provides protocols for handling a number of clinically important scenarios, it does not address a number of significant functions required for an efficient PACS system, including radiologist and modality-specific electronic hanging protocols and referring physician communication protocols (both addressed by US Patent #5,452,416). Therefore, adherence to IHE standards is beneficial and desirable, and Unity provides additional product functionality.

## 4. Unity IHE Implementation

Unity is highly committed to industry standards.

### 1.5 Current Implementation

Current IHE support

Unity has successfully passed IHE tests for the following

- Unity Report Manager implements an Enterprise Report Repository actor in the Simple Image and Numeric Report workflow.
- The CD Ambassador implements the actors Portable Media Creator, Image Display and Display (ITI TF) in the Portable Data for Imaging workflow.
- Unity DICOM Catapult implements the actor Image Manager/Image Archive in the Access to Radiology Information and Consistent Presentation of Data workflows.

### 1.6 Future Plans for Implementation

In Unity, IHE is an imperative long-term goal. Our initial goal is to provide additional Image Manager/Image Archive and Image Display functionality. To this end, but consistent with the implementation strategy described above, Unity expects to introduce these features to its product offerings in upcoming releases:

- DICOM Query/Retrieve – enhancements

Unity intends to continue pursuing support of IHE requirements, with the goal of implementing the following:

**Table 2: Future goals for implementing actors and profiles**

Actor:	Integration Profiles:
Image Manager/Image Archive	Scheduled Workflow Patient Information Reconciliation Consistent Presentation of Images Presentation of Grouped Procedures Access to Radiology Information Key Image Notes Post-Processing Workflow Reporting Workflow Evidence Documents NM Image Integration Profile

Actor:	Integration Profiles:
Image Display	Scheduled Workflow Consistent Presentation of Images Access to Radiology Information Key Image Notes Presentation of Grouped Procedures Post-Processing Workflow NM Image Integration Profile
DSS/Order Filler	Scheduled Workflow Patient Information Reconciliation Presentation of Grouped Procedures Charge Posting Post-Processing Workflow Reporting Workflow
Enterprise Report Repository	Simple Image and Numeric Report
External Report Repository Access	Access to Radiology Information Simple Image and Numeric Report
Report Repository	Access to Radiology Information Simple Image and Numeric Report
Report Manager	Simple Image and Numeric Report Reporting Workflow
Report Reader	Simple Image and Numeric Report Portable Data for Imaging
Portable Media Creator	Portable Data for Imaging
Display (ITI TF)	Portable Data for Imaging
Image Display	Portable Data for Imaging
Media Importer	Portable Data for Imaging
Portable Media Importer	Portable Data for Imaging

## 5. Conclusion

Unity is committed to industry standards and will add IHE compliance to its current implementation of the DICOM, HL7, and CCOW standards. As other vendors expand their support for IHE, customers and vendors will benefit, as there will be less need for customization of interfaces between medical information systems. Widespread adoption of IHE will allow customers to choose best-of-breed systems, knowing in advance that there will be a rich interface with other IHE compliant systems from other vendors.