

DICOM 6000 Interface

DICOM Conformance Statement

Software Version 1.1.6

MAN-01179 Revision 002

HOLOGIC®

Mammography

DICOM 6000 Interface

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Software Version 1.1.6

MAN-01179 Revision 002

HOLOGIC®

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1. Overview

The DICOM 6000 Interface implements the necessary DICOM services to receive images and ImageChecker CAD results from remote systems. It also supports sending images (received Digital Mammography For Processing and locally generated Digital Mammography For Presentation) to remote systems.

The following table provides an overview of the network services supported by the DICOM 6000 Interface.

SOP Classes	User of Service (SCU)	Provider of Service (SCP)
Transfer		
Digital Mammography X-Ray Image Storage – For Presentation	Yes	Yes
Digital Mammography X-Ray Image Storage – For Processing	Yes	Yes
Mammography CAD SR	No	Yes

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3. Introduction

Hologic, Inc. develops and markets a full line of mammography products including the DICOM 6000 Interface. This document describes the DICOM services used and provided by the DICOM 6000 Interface. It contains the requirements for DICOM interoperability between this product, other Hologic products, and products from other vendors. It also provides information necessary to configure other vendors' products to communicate with this product via DICOM.

In general, the DICOM 6000 Interface accepts digital mammography images and R2 ImageChecker computer-aided detection (CAD) results as a Service Class Provider (SCP) of the Storage Service Class, renders CAD findings on the images as overlays, and exports output images as a Service Class User (SCU) of the Storage Service Class. The system also serves as an SCP of the Verification Service Class.

The DICOM 6000 Interface only adds overlays for Digital Mammography For Presentation images. Digital Mammography For Processing images are sent to all configured destinations without modification.

3.1. Revision History

The information in this document applies to DICOM 6000 Interface software version 1.1.6.

3.2. Audience

This document is intended to aid in connecting the DICOM 6000 Interface to other components that make use of the DICOM standard for interconnecting networked imaging devices. The reader of this document should be familiar with the DICOM standard and PACS components that utilize the standard.

3.3. Remarks

A DICOM conformance statement – the structure and content of which are stipulated by the DICOM standard – is intended to aid in determining the suitability of interconnecting digital imaging devices. References to specific functionality in a conformance statement are not sufficient to guarantee interoperability between components. The following should be considered when evaluating interoperability:

- The DICOM conformance statement for the DICOM 6000 Interface provides a starting point for ascertaining whether the product can communicate with other systems.
- The only way to know for certain whether the DICOM 6000 Interface can interoperate with other systems is to perform connectivity testing.
- This document represents a best effort to document the functionality of commercial versions of the DICOM 6000 Interface and is not a functional specification of any Hologic component or product. Hologic reserves the right to make changes at any time to the functionality of the DICOM components described herein, and is committed to following the evolution of the DICOM standard.

3.4. Definitions, Terms and Abbreviations

This document uses the following acronyms.

AE	Application Entity
CAD	Computer-Aided Detection
DICOM	Digital Imaging and Communications in Medicine
IOD	Information Object Definition
PDU	Protocol Data Unit
SCP	Service Class Provider
SCU	Service Class User
SOP	Service Object Pair
SR	Structured Report
TCP/IP	Transmission Control Protocol/Internet Protocol
UID	Unique Identifier
VR	Value Representation

3.5. References

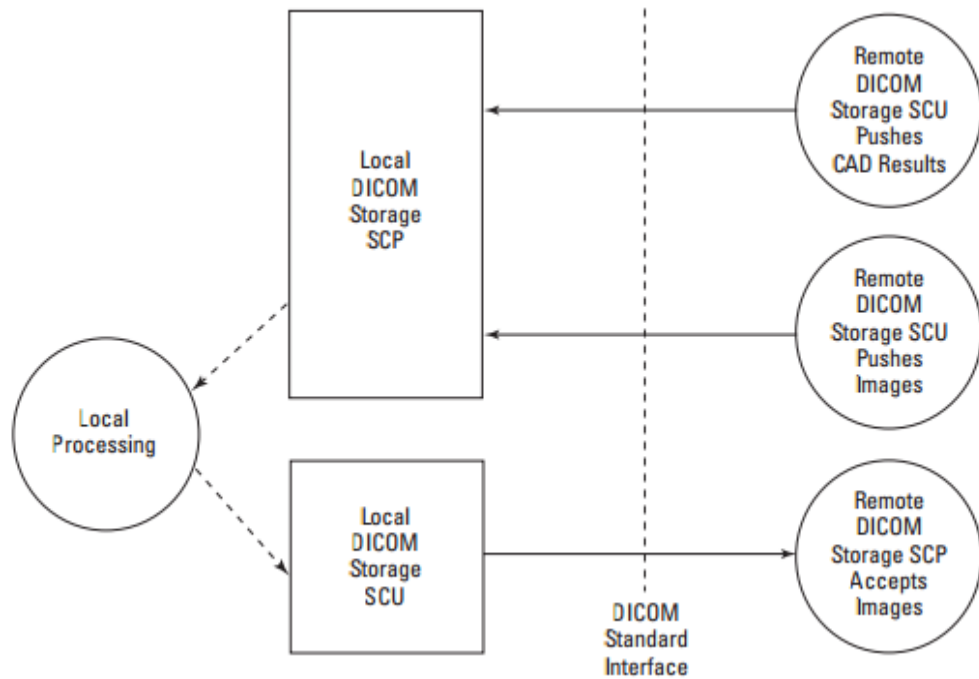
National Electrical Manufacturers Association DICOM Standard, PS 3.

4. Networking

4.1. Implementation Model

4.1.1. Application Data Flow

The following diagram depicts the Application Entities (AE) and their relationships to Real-World Activities.



Application Data Flow

The Local Processing is initiated at system startup. The Local DICOM Storage SCP and Local DICOM Storage SCU are executed at system startup and exist in one executable program using one AE title.

A Remote DICOM Storage SCU initiates a push of images to the Local DICOM Storage SCP. A different Remote DICOM Storage SCU initiates a push of CAD results to the Local DICOM Storage SCP. These received DICOM instances are stored in a local database and made available to the Local Processing. Upon completion of Processing, the output images are passed to the Local DICOM Storage SCU, which pushes the output images to a Remote DICOM Storage SCP.

DICOM instances that are accepted by the Local DICOM Storage SCP are stored temporarily, until Processing is completed.

4.1.2. Functional Definition of AE's

The Local DICOM Storage SCP AE supports the following functions:

- Accepts DICOM association requests
- Accepts DICOM storage requests
- Responds to DICOM verification requests
- Rejects DICOM association requests

The Local DICOM Storage SCU AE supports the following functions:

- Negotiates and establishes DICOM association with remote destination
- Stores DICOM Composite SOP Instance to remote destination

4.1.3. Sequencing of Real-World Activities

4.1.3.1. For Presentation Images and CAD Results

When For Presentation images or CAD results are pushed from a remote application:

- The Local DICOM Storage SCP AE responds to a DICOM association initiation, and selects a matching Presentation Context (Abstract Syntax and Transfer Syntax).
- The Local DICOM Storage SCP AE accepts an association and waits for a C-STORE request.
- Upon receiving a C-STORE request, the Local DICOM Storage SCP AE performs a license check, validates the image or CAD results, stores the image or CAD results object to the local database and disk, and queues the image or CAD results for processing.
- The Local DICOM Storage SCP AE sends a C-STORE response.
- Upon completion of processing, each output image is formatted into a DICOM Digital Mammography X-Ray Image – For Presentation.
- The Local DICOM Storage SCU AE initiates a DICOM association to a remote application.
- The Local DICOM Storage SCU AE waits for the association acceptance and sends a C-STORE request containing the output image.
- The Local DICOM Storage SCU AE waits for a C-STORE response.
- The Local DICOM Storage SCU AE closes the association.

The output images are stored under the same DICOM Study as the input images.

4.1.3.2. For Processing Images

When For Processing images are pushed from a remote application:

- The Local DICOM Storage SCP AE responds to a DICOM association initiation, and selects a matching Presentation Context (Abstract Syntax and Transfer Syntax).
- The Local DICOM Storage SCP AE accepts the association and waits for a C-STORE request.
- Upon receiving a C-STORE request, the Local DICOM Storage SCP AE performs a license check, validates the image, stores the image object to the local database and disk, and queues the image for transmission.
- The Local DICOM Storage SCP AE sends a C-STORE response.
- The Local DICOM Storage SCU AE initiates a DICOM association to a remote application.

- The Local DICOM Storage SCU AE waits for the association acceptance and sends a C-STORE request containing the For Processing image.
- The Local DICOM Storage SCU AE waits for a C-STORE response.
- The Local DICOM Storage SCU AE closes the association.

4.2. AE Specifications

4.2.1. Local DICOM Storage SCP

4.2.1.1. SOP Classes

This Application Entity provides Standard Conformance to the following DICOM SOP Classes as an SCP:

SOP Class Name	SOP Class UID
Digital Mammography X-Ray Image Storage – For Presentation	1.2.840.10008.5.1.4.1.1.1.2
Digital Mammography X-Ray Image Storage – For Processing	1.2.840.10008.5.1.4.1.1.1.2.1
Mammography CAD SR	1.2.840.10008.5.1.4.1.1.88.50
Verification SOP Class	1.2.840.10008.1.1

4.2.1.2. Association Policies

The Local DICOM Storage SCP accepts associations, but does not initiate them.

4.2.1.2.1. General

The maximum PDU size accepted is 28672. If during association negotiation the maximum sized PDU of the system negotiating with the application is larger than this value, the PDU size will be limited to this value. The Application Context Name is '1.2.840.10008.3.1.1.1'. These values are defined in the mergecom.pro file.

4.2.1.2.2. Number of Associations

The Local DICOM Storage SCP accepts up to six simultaneous associations.

4.2.1.2.3. Asynchronous Nature

Asynchronous mode is not supported. All operations are performed synchronously.

4.2.1.2.4. Implementation Identifying Information

The Implementation Class UID is '2.16.840.1' and the Implementation Version Name is 'MergeCOM3_350'. These values are defined in the mergecom.pro file.

4.2.1.3. Association Initiation Policy

The Local DICOM Storage SCP does not initiate associations.

4.2.1.4. Association Acceptance Policy

The Local DICOM Storage SCP accepts an association when it receives a valid association request, with at least one matching presentation context. An association request remains pending if the number of simultaneous associations has reached the maximum.

4.2.1.4.1. Push Images from Remote DICOM Storage SCU

4.2.1.4.1.1. Description and Sequencing of Activities

The Real-World Activity (i.e., Local Processing) is associated with a C-STORE SCP operation (i.e., Local DICOM Storage SCP Application Entity), and is triggered by images and CAD results pushed from Remote DICOM Storage SCU AE's. This results in the storage and processing of the received images and CAD results on the DICOM 6000 Interface. The C-STORE SCP operation will respond with a failure status if it is unable to store the images or CAD results.

4.2.1.4.1.2. Accepted Presentation Contexts

The Local DICOM Storage SCP accepts the Presentation Contexts shown in the following table:

Abstract Syntax Name	UID	Transfer Syntax Name	Syntax UID	Role	Extended Negotiation
Digital Mammography X-Ray Image Storage – For Presentation	1.2.840.10008.5.1.4.1.1.1.2	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	None
		Explicit VR Little Endian	1.2.840.10008.1.2.1	SCP	None
Digital Mammography X-Ray Image Storage – For Processing	1.2.840.10008.5.1.4.1.1.1.2.1	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	None
		Explicit VR Little Endian	1.2.840.10008.1.2.1	SCP	None
Mammography CAD SR	1.2.840.10008.5.1.4.1.1.88.50	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	None
		Explicit VR Little Endian	1.2.840.10008.1.2.1	SCP	None
Verification	1.2.840.10008.1.1	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	None
		Explicit VR Little Endian	1.2.840.10008.1.2.1	SCP	None

4.2.1.4.1.3. Presentation Context Acceptance Criterion

The Local DICOM Storage SCP accepts any of the Presentation Contexts listed in the Presentation Context Table.

4.2.1.4.1.4. Transfer Syntax Selection Policies

Transfer Syntax selection is based on the Transfer Syntax configuration item for the proposed SOP Class (or the default list applicable to all SOP Classes). The first Transfer Syntax from the proposed list that matches any of those configured (for a given SOP Class or for all SOP Classes) is selected for acceptance. If none of the proposed Transfer Syntaxes matches, the Presentation Context will be rejected.

4.2.1.4.1.5. SOP Specific Conformance

The Local DICOM Storage SCP provides Level 2 (Full) conformance to all of the accepted Storage SOP Classes. It does not provide Digital Signature support. No coercion of Attributes is performed. Mammography CAD SR instances with a value for Manufacturer (0008,0070) that does not contain 'R2 Technology, Inc.' or 'Hologic', case insensitive, are rejected.

All Type 1 attributes for the Digital Mammography X-Ray Image IOD are expected to be present with a valid value (not zero length). If not, the image instance may be rejected.

The following table lists the possible values for the Status (0000,0900) attribute of the C-STORE response:

Service Status	Further Meaning	Error Code	Reason
Success	Success	0000	Image or CAD results successfully stored.
Error	Invalid license or unsupported CAD SR	0001	License validation failed or non-R2 Mammography CAD SR received.
Error	Internal error	0110	Failed to update database records.
Error	Invalid data set	A900	Mandatory DICOM attribute missing.

4.2.2. Local DICOM Storage SCU

4.2.2.1. SOP Classes

This Application Entity provides Standard Conformance to the following DICOM SOP Classes as an SCU:

SOP Class Name	SOP Class UID
Digital Mammography X-Ray Image Storage – For Presentation	1.2.840.10008.5.1.4.1.1.1.2
Digital Mammography X-Ray Image Storage – For Processing	1.2.840.10008.5.1.4.1.1.1.2.1

4.2.2.2. Association Policies

The Local DICOM Storage SCU initiates associations, but does not accept them.

4.2.2.2.1. General

The maximum PDU size offered is 28672. The Application Context Name is '1.2.840.10008.3.1.1.1'. These values are defined in the mergecom.pro file.

4.2.2.2.2. Number of Associations

The Local DICOM Storage SCU initiates up to two simultaneous associations.

4.2.2.2.3. Asynchronous Nature

Asynchronous mode is not supported. All operations are performed synchronously.

4.2.2.2.4. Implementation Identifying Information

The Implementation Class UID is '2.16.840.1' and the Implementation Version Name is 'MergeCOM3_350'. These values are defined in the mergecom.pro file.

4.2.2.3. Association Initiation Policy**4.2.2.3.1. Local Processing****4.2.2.3.1.1. Description and Sequencing of Activities**

The Real-World Activity (i.e., Remote DICOM Storage SCP accepts images) is associated with a C-STORE SCU operation (i.e., Local DICOM Storage SCU Application Entity) and is triggered by the completion of Local Processing. This results in the sending of Digital Mammography images to a Remote DICOM Storage SCP.

4.2.2.3.1.2. Proposed Presentation Contexts

One of the following Abstract Syntaxes is proposed with each association request:

Abstract Syntax Name	UID	Transfer Syntax Name	Transfer Syntax UID	Role	Extended Negotiation
Digital Mammography X-Ray Image Storage – For Presentation	1.2.840.10008.5.1.4.1.1.	Implicit VR Little Endian	1.2.840.10008.1.2	SCU	None
	1.2	Explicit VR Little Endian	1.2.840.10008.1.2.1	SCU	None
Digital Mammography X-Ray Image Storage – For Processing	1.2.840.10008.5.1.4.1.1.	Implicit VR Little Endian	1.2.840.10008.1.2	SCU	None
	1.2.1	Explicit VR Little Endian	1.2.840.10008.1.2.1	SCU	None

4.2.2.3.1.3. SOP Specific Conformance

If a C-STORE response indicates success or warning (B000, B007, B006), the associated output images shall be permitted to be deleted.

If a C-STORE response indicates failure or an unrecognized status value, the failure will be logged, the association will be reattempted at a later time, and the associated output images shall not be deleted. After three successive failed attempts, no more attempts will be made, and the associated output images shall be permitted to be deleted. The retry interval is approximately 10 minutes. It and the number of times to retry are currently not configurable.

4.2.2.3.1.3.1. Digital Mammography X-Ray Image Objects

An output image that contains an overlay is identical to its corresponding input 'For Presentation' image except for the following attributes:

- (0008,0018) SOP Instance UID
- (0020,000E) Series Instance UID

The following attributes are added to each output image that contains an overlay if they are not present in the input image, or modified if they are present:

- (0008,103E) Series Description
- (6000,0010) Overlay Rows
- (6000,0011) Overlay Columns
- (6000,0022) Overlay Description
- (6000,0040) Overlay Type
- (6000,0050) Overlay Origin
- (6000,0100) Overlay Bits Allocated
- (6000,0102) Overlay Bit Position
- (6000,1500) Overlay Label
- (6000,3000) Overlay Data

If the '_R2' indicator is appended to the Series Description (0008,103E) attribute, it indicates that an R2 DICOM 6000 overlay has been added to the image. The DICOM 6000 Interface Service Tool Utility Indicator screen provides a way to control the presence or absence of the '_R2' indicator in the image header for each result produced by the DICOM 6000 Interface. The Series Description (0008,103E) attribute is not appended with the '_R2' indicator when an overlay is not added.

If (6000,eeee) attributes are present in the input image, they may be modified to accommodate the merging of the existing and new overlay data. More specifically, Overlay Rows (6000,0010), Overlay Columns (6000,0011), Overlay Type (6000,0040), Overlay Origin (6000,0050), and Overlay Data (6000,3000) may need to be modified.

All 'For Processing' images, and any 'For Presentation' images to which an overlay is not added are forwarded without any modification.

4.2.2.4. Association Acceptance Policy

The Local DICOM Storage SCU does not accept associations.

4.3. Network Interfaces

4.3.1. Physical Network Interface

The TCP/IP stack is inherited from the Windows XP Professional (Service Pack 2 or higher) operating system. For connectivity Hologic systems normally use 10/100/1000 Base-T Ethernet with RJ45 connector. DICOM is indifferent to the physical medium over which TCP/IP executes.

4.3.2. Additional Protocols

None

4.4. Configuration

The Configuration and Service Tool is used for DICOM configuration.

4.4.1. AE Title/Presentation Address Mapping

The default Listen Port for the Local DICOM Storage SCP is 7100. The AE Titles for the SCUs and SCPs are provided to the application from a database internal to the application.

The following fields are configurable for the Local DICOM Storage SCP:

- AE Title
- Port Number

The AE title for the Local DICOM Storage SCU is the same as that for the Local DICOM Storage SCP.

The following fields are configurable for each output device (Remote DICOM Storage SCP):

- AE Title
- IP Address
- Port Number
- User Label

5. Support of Character Sets

Latin alphabet no. 1 (ISO_IR 100) is supported.

6. Security Profiles

The DICOM 6000 Interface does not support any specific DICOM security measures. It is assumed that the Hologic systems are used within a secured environment. It is assumed that a secured environment includes at a minimum:

- Firewall or router protections to ensure that only approved external hosts have network access to the Hologic systems.
- Firewall or router protections to ensure that the Hologic systems only have network access to approved external hosts and services.
- Any communication with external hosts and services outside the locally secured environment use appropriate secure network channels such as a Virtual Private Network (VPN).
- Other network security procedures such as automated intrusion detection may be appropriate in some environments. Additional security features may be established by the local security policy and are beyond the scope of this conformance statement.

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