Gentuity HF-OCT Imaging System

DICOM Conformance Statement

2023-05-23

1 Overview

The Gentuity HF-OCT Imaging System implements the necessary DICOM services to export OCT images to:

- A Picture Archiving And Communication System (PACS) via the Ethernet interface
- General Purpose USB Media

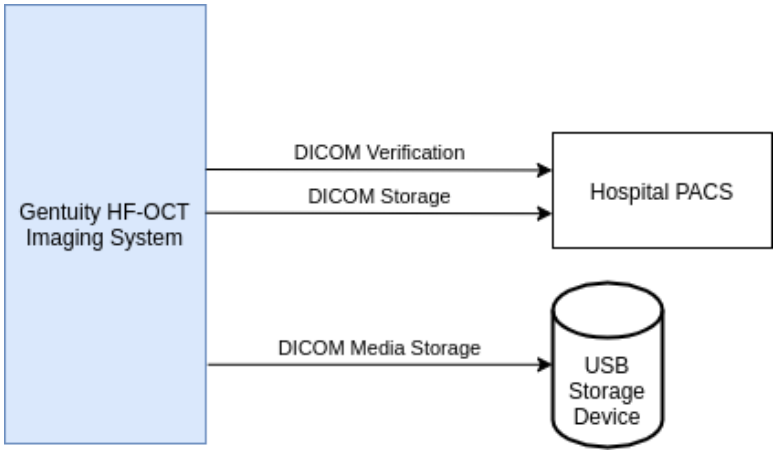

Figure 1.1 Overview of Implemented Services

1.1 Content and Transfer

Table 1.1 lists all Storage SOP Classes and the supported transfer mechanisms as well as the usage scenarios for those instances.

The "Transfer Syntax Set" column lists the sets of Transfer Syntaxes defined in Table 1.2 that are applicable to each SOP Class. The "DIMSE", "DICOM Web" and "Media Services" columns indicate the roles supported for each SOP Class.

The "Function" columns indicate how the instances are used by the system:

- Create: The system creates instances of the SOP Class. The type of the created SOP Class is indicated by one of the following abbreviations:
  - S: Standard SOP Class
  - SE: Standard Extended SOP Class
  - SP: Specialized SOP Class
  - P: Private SOP Class
- Display: The system displays the instances of the SOP Class to the user, either by displaying the SOP Instances natively or by applying instances of another suitable SOP Class to the image instances (e.g., a Presentation State or CAD SR).

- Process: The system processes the instances of the SOP Class to derive some further information that is made available to the user (e.g., a CAD processing algorithm, or a 3D Rendering).
- Archive: The system stores the instances of the SOP Class and makes them available again.

Table 1.1 Storage SOP Classes

SOP Classes		Transfer Syntax Set	DIMSE Services		DICOM Web Services		Media Services			Function			
			SCU	SCP	UA	OS	FSC	FSU	FSR	Create	Display	Process	Archive
Multi-frame True Color Secondary Capture Image Storage	1.2.840.10008.5.1.4.1.1.7.4	LL	Y	N	N	N	Y	N	N	S	N	N	N

Table 1.2 Supported Transfer Syntaxes

Transfer Syntax Set	Transfer Syntax Name	Transfer Syntax UID	DICOM Web Service Bulkdata Media Type
Lossless Compressed Transfer Syntax Set (LL)	JPEG Lossless, Non-Hierarchical, First-Order Prediction	1.2.840.10008.1.2.4.70	image/jpeg

1.1.1 Structured Reporting Root Template IDs - N/A

N/A

1.2 DIMSE Services

1.2.1 Verification

Table 1.3 lists support for the Verification SOP Class.

Table 1.3 Verification SOP Class

SOP Classes		Transfer Syntax		SCU	SCP
Verification	1.2.840.10008.↩ 1.1	Implicit VR Little Endian	1.2.840.10008.↩ 1.2	Y	N

1.2.2 Storage

For details on supported Storage SOP Classes see **Section 1.1** (p. 2).

1.2.3 Workflow Management - N/A

N/A

1.2.4 Query/Retrieve - N/A

N/A

1.2.5 Printing - N/A

N/A

1.3 DICOM Web Services - N/A

N/A

1.4 Media Services

The table below lists all supported Media Application Profiles.

Table 1.4 Supported Media Application Profiles

Media Storage Application Profile	FSC	FSR	FSU
USB			
STD-GEN-USB-JPEG	Y	N	N

1.5 Real Time Video Service - N/A

N/A

1.6 De-identification Profiles - N/A

N/A

1.7 Specific Character Sets

Table 1.5 Supported Specific Character Sets

Defined Term	IANA	Description
Single-Byte Character Sets without Code Extensions		
ISO_IR 100	ISO-8859-1	Latin Alphabet No.1 (West Europe)

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3 Introduction

3.1 Revision History

Revision	ECO #	Date	Product Version(s)	Revision Description
A	E04061		Gentuity HF-OCT Imaging System	Initial Release

3.2 Audience

This document is intended for the audience listed below. It is assumed that the reader has a working knowledge of the DICOM Standard.

The document structure was designed for easier access to relevant information for different user groups:

- Clinical Users, who want to get an overview of the implemented interoperability features of the system can see Section 4 Implementation Model.
- Personnel involved in Sales can use the information in Section 1 to assess the compatibility between different systems involved in a sales situation.
- System Integrators can use information in Section 6 during system installation and also information from Section 5 Service and Interoperability Description for details regarding the implemented services.
- Field Service Engineers can use the details from Section 5 Service and Interoperability Description and from Section 7 Network and Media Communication Details for troubleshooting.
- Hospital IT staff focusing on security can use the details provided in Section 8 Security regarding implemented Security features.
- Research Personnel may be interested in using information provided in Section 9 Information Object Definitions (IODs) or Section 10 Structured Report Content Encoding to get detailed imaging and measurement information.

3.3 Remarks

The scope of this DICOM Conformance Statement is to facilitate integration between the Gentuity HF-OCT Imaging System and other DICOM products. The Conformance Statement should be read and understood in conjunction with the DICOM Standard. DICOM by itself does not guarantee interoperability.

- The Conformance Statement does, however, facilitate a first-level comparison for interoperability between different applications supporting compatible DICOM functionality.
- This Conformance Statement should not replace validation with other DICOM equipment to ensure proper exchange of intended information. In fact, it is the user's responsibility to perform the following validation activities:

- The comparison of Conformance Statements from the Gentuity HF-OCT Imaging System and other DICOM conformant equipment is the first step towards assessing interconnectivity and interoperability between those systems.
- Test procedures should be defined and executed to validate the required level of interoperability with specific DICOM conformant equipment, as established by the healthcare facility.

The DICOM services utilized in this version of the Gentuity HF-OCT Imaging System were chosen in order to match as closely as possible other Intravascular OCT devices already on the market. However, this should not be understood to guarantee that the Gentuity HF-OCT Imaging System will be compatible with all the DICOM devices with which other Intravascular OCT devices already on the market are compatible. Furthermore, future versions of the Gentuity HF-OCT Imaging System may use different DICOM services which better relate to Intravascular OCT.

3.4 Terms and Definitions

Informal definitions are provided for the following terms used in this Conformance Statement. The DICOM Standard is the authoritative source for formal definitions of these terms.

Term	Definition
Abstract Syntax	The information agreed to be exchanged between applications, generally equivalent to a Service/Object Pair (SOP) Class. Examples: Verification SOP Class, Modality Worklist Information Model Find SOP Class, Computed Radiography Image Storage SOP Class.
Application Entity (AE)	A representation of the external behavior of an application process in terms of DICOM Network Services, Web Services and/or media exchange capabilities implemented in one or more roles. A single device may have multiple Application Entities.
Application Entity Title (AET)	The externally known name of an Application Entity, used to identify a DICOM application to other DICOM applications on the network.
Application Context	The specification of the type of communication used between Application Entities. Example: DICOM network protocol.
Association	A network communication channel set up between Application Entities.
Attribute	A unit of information in an Information Object Definition; a Data Element identified by a tag. The information may be a complex data structure (Sequence), itself composed of owner-level data elements. Examples: Patient ID (0010,0020), Accession Number (0008,0050), Photometric Interpretation (0028,0004), Procedure Code Sequence (0008,1032).
Data Element	A unit of information as defined by a single entry in the data dictionary. An encoded Information Object Definition (IOD) Attribute that is composed of, at a minimum, three fields: a Data Element Tag, a Value Length, and a Value Field. For some specific Transfer Syntaxes, a Data Element also contains a VR Field where the Value Representation of that Data Element is specified explicitly
Information Object Definition (IOD)	The specified set of Attributes that comprise a type of data object; does not represent a specific instance of the data object, but rather a class of similar data objects that have the same properties. Examples: MR Image IOD, CT Image IOD, Print Job I↩ OD. The Attributes within an IOD may be specified as Mandatory (Type 1), Required but possibly unknown (Type 2), or Optional (Type 3), and there may be conditions associated with the use of an Attribute (Types 1C and 2C).

Term	Definition
Media Application Profile	The specification of DICOM information objects and encoding exchanged on removable media (e.g., CDs).
Module	A set of Attributes within an Information Object Definition that are logically related to each other. Example: Patient Module includes Patient's Name, Patient ID, Patient' Birth Date, and Patient's Sex.
Negotiation	First phase of Association establishment that allows Application Entities to agree on the types of data to be exchanged and how that data will be encoded.
Origin Server	Refers to the program that can originate authoritative responses to HTTP requests for a given Target Resource. The term "server" refers to any implementation that receives a web service request message from a user agent.
Presentation Context	The set of DICOM Network Services used over an Association, as negotiated between Application Entities; includes Abstract Syntaxes and Transfer Syntaxes.
Private SOP Class	A SOP Class that is not defined in the DICOM Standard but is published in an implementation's Conformance Statement.
Protocol Data Unit (PDU)	A packet (piece) of a DICOM message sent across the network. Devices must specify the maximum size packet they can receive for DICOM messages.
Pullback	A single HF-OCT acquisition. Corresponds 1-to-1 with an Image Series.
Security Profile	A set of mechanisms, such as encryption, user authentication, or digital signatures, used by an Application Entity to ensure confidentiality, integrity, and/or availability of exchanged DICOM data.
Service Class Provider (SCP)	Role of an Application Entity that provides a DICOM network service; typically, a server that performs operations requested by another Application Entity (Service Class User). Examples: Picture Archiving and Communication System (image storage SCP, and image query/retrieve SCP), Radiology Information System (modality worklist SCP).
Service Class User (SCU)	Role of an Application Entity that uses a DICOM Network Service; typically, a client. Examples: imaging modality (image storage SCU, and modality worklist SCU), imaging workstation (image query/retrieve SCU).
Service/Object Pair Class (SOP Class)	The specification of the network or media transfer (service) of a particular type of data (object) ; the fundamental unit of a DICOM interoperability specification. Examples: Ultrasound Image Storage Service, Basic Grayscale Print Management.
Service/Object Pair Instance (SOP Instance)	An information object; a specific occurrence of information exchanged in a SOP Class. E.g., a specific X-ray image.
Specialized SOP Class	A SOP Class that is derived from the Standard that is specialized by additional type 1, 1C, 2, 2C, or 3 Attributes, by enumeration of specific permitted Values for Attributes, or by enumeration of specific permitted Templates. The additional Attributes may either be drawn from the Data Dictionary in PS3.6 or may be Private Attributes.
Standard SOP Class	A SOP Class defined in the Standard, and that is implemented and used without any modifications.
Standard Extended SOP Class	A SOP Class that is defined in the standard, and that is extended by additional type 3 Attributes. The additional Attributes may either be drawn from the DICOM Data Dictionary in PS3.6 or may be Private Attributes.
Tag	A 32-bit identifier for a Data Element, represented as a pair of four-digit hexadecimal numbers, the "group" and the "element". If the "group" number is odd, the tag is for a private (manufacturer-specific) data element. Examples: (0010,0020) [Patient ID], (07FE,0010) [Pixel Data], (0019,0210) [private data element].

Term	Definition
Transfer Syntax	The encoding used for exchange of DICOM information objects and messages. Examples: JPEG compressed (images), Little Endian Explicit Value Representation.
TLS-Secured Port	TCP port on which an implementation accepts TLS connections to exchange DICOM information.
Unique Identifier (UID)	A globally unique "dotted decimal" string that identifies a specific object or a class of objects; an ISO-8824 Object Identifier. Examples: Study Instance UID, SOP Class UID, SOP Instance UID.
User Agent	A client in a network protocol used in communications within a client-server distributed computing system. In particular, the Hypertext Transfer Protocol (HTTP) identifies the client software originating the request, using a user-agent header, even when the client is not operated by a user.
Value Representation (VR)	The format type of an individual DICOM data element, such as text, an integer, a person's name, or a code. DICOM information objects can be transmitted with either explicit identification of the type of each data element (Explicit VR), or without explicit identification (Implicit VR) ; with Implicit VR, the receiving application must use a DICOM data dictionary to look up the format of each data element.

3.5 Abbreviations

Abbreviations that are used in this DICOM Conformance Statement are listed here.

Term	Definition
AE	Application Entity
ACSE	Association Control Service Element
AET	Application Entity Title
CAD	Computer Aided Detection
CDA	Clinical Document Architecture
CID	Context Identifier
DCS	DICOM Conformance Statement
DHCP	Dynamic Host Configuration Protocol
DICOM	Digital Imaging and Communications in Medicine
ELE	Explicit VR Little Endian
FSC	File-Set Creator
FSU	File-Set Updater
FSR	File-Set Reader
HF-OCT	High Frequency Optical Coherence Tomography
IANA	Internet Assigned Numbers Authority
IHE	Integrating the Healthcare Enterprise
ILE	Implicit VR Little Endian
IOD	Information Object Definition
IPv4	Internet Protocol version 4
IPv6	Internet Protocol version 6

Term	Definition
ISO	International Organization for Standardization
MDS2	Manufacturers Disclosure Statement for Medical Device Security
NEMA	National Electrical Manufacturers Association
NTP	Network Time Protocol
OID	Object Identifier
OS	Origin Server
PDU	Protocol Data Unit
PHI	Protected Health Information
PPS	Performed Procedure Step
RTV	Real Time Video
SCP	Service Class Provider
SCU	Service Class User
SDP	Service Description Protocol
SOP	Service-Object Pair
TCP/IP	Transmission Control Protocol/Internet Protocol
TID	Template Identifier
UA	User Agent
UI	User Interface
UID	Unique Identifier
UL	Upper Layer
VR	Value Representation

3.6 References

[1] National Electrical Manufacturers Association (NEMA), Rosslyn, VA USA. PS3 / ISO 12052 Digital Imaging and Communications in Medicine (DICOM) Standard. `http://www.dicomstandard.org`.

[2] Integrating the Healthcare Enterprise (IHE). IHE Radiology Technical Framework. `http://www.ihe.net/Resources/technical_frameworks/#radiology`.

4 Implementation Model

This DICOM Conformance Statement covers the following products:

Product Name	Software Version(s)
Gentuity HF-OCT Imaging System	23.3.7

The generation of DICOM image files is done in the same way for both network exports and USB exports. For network exports, a DICOM verification is performed before generating each DICOM file.

DIMSE network communication is handled by dedicated executables provided by DCMTK, all of which operate as same Application Entity.

4.1 Application Entities and Data Flow

The network and media interchange application model for the Gentuity HF-OCT Imaging System is shown in Figure Gentuity HF-OCT Imaging System Application Data Flow Diagram.

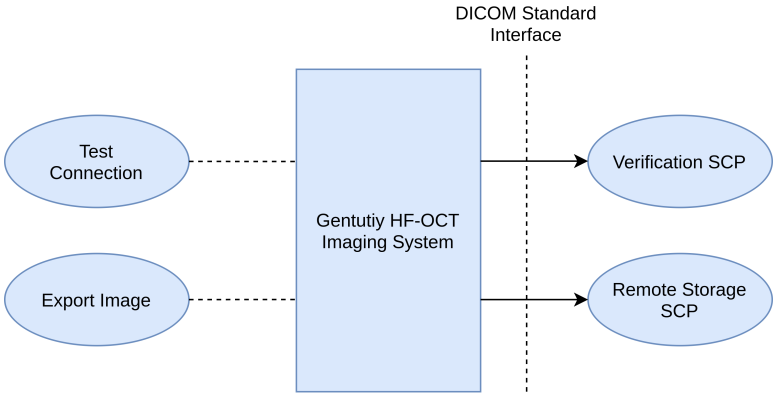

Figure 4.1 Gentuity HF-OCT Imaging System Application Data Flow Diagram

4.1.1 DIMSE Verification

A DIMSE Verification can be triggered in the following ways:

- By selecting the Test Connection button on the dialog to add or edit a network export server.
- By exporting a pullback to a network export server

As a troubleshooting aid, the system records the date and time of the most recent successful DIMSE Verification performed.

4.1.2 DIMSE Storage

A DIMSE Storage request is triggered by the user from the Patient List page. All pullbacks on the Gentuity HF-OCT Imaging System for the user-selected patients are transferred.

5 Service and Interoperability Description

5.1 Mapping of Services to Application Entities

Table 5.1 provides an overview of the Application Entities and the Services supported by each AE.

Table 5.1 Service to AE Mapping

Application Entity	Supported Services	Role				
		DIMSE		DICOM Media		
		SCU	SCP	FSC	FSU	FSR
Gentuity Client AE	Storage	Y	N	Y	N	N

5.2 Supported DIMSE Services

5.2.1 Basic Worklist Management Service - N/A

N/A

5.2.2 Modality Performed Procedure Step Service - N/A

N/A

5.2.3 Unified Worklist and Procedure Step Service - N/A

N/A

5.2.4 Instance Availability Notification Service - N/A

N/A

5.2.5 Storage Service

5.2.5.1 SCU of the Storage SOP Classes

As a Service Class User of the Storage Service Class, the Gentuity HF-OCT Imaging System uses the C-STORE-RQ message to request storage of DICOM objects by a remote SCP. See Section 1.1 Content and Transfer in the Overview for the list of supported SOP Classes.

For details regarding the content of SOP Instances that are created by the system, see Section 9, which describes the underlying IOD of the supported SOP Classes.

Storage requests are initiated only by the user (never automatically).

See section 9 for how pullbacks are divided into studies.

5.2.5.1.1 Transcoding of Transfer Syntaxes - N/A

N/A

5.2.5.2 SCP of the Storage SOP Classes - N/A

N/A

5.2.6 Storage Commitment Service - N/A

N/A

5.2.7 Query/Retrieve Service Class - N/A

N/A

5.2.8 Print Management Service - N/A

N/A

5.3 Supported DICOM Web Services - N/A

N/A

5.4 Media Service

5.4.1 File Set Creator (FSC)

Gentuity HF-OCT Imaging System supports creating the Basic Directory IOD as a File Set Creator as defined in Section 9.5.

For a list of supported Media Application Profiles, see Section 1.4 in the Overview.

For a list of supported SOP Classes, see Section 1.1 in the Overview.

The same Media Application Profile is used for all pullbacks exported to USB media:

- General Purpose USB Media Interchange with JPEG profile (STD-GEN-USB-JPEG)

5.4.2 File Set Reader (FSR) - N/A

N/A

5.4.3 File Set Updater (FSU) - N/A

N/A

5.5 Real Time Video Service - N/A

N/A

5.6 Cross Service Considerations - N/A

N/A

5.7 Specific Character Sets

For Specific Character Sets supported in addition to the default character repertoire, refer to Section 1.7 for the Values for Specific Character Set (0008,0005).

The Gentuity HF-OCT Imaging System avoids the use of characters in patient data that are not supported by ISO 8859-1:1987.

All console configurations use the same Specific Character Set.

6 Configuration

The Gentuity HF-OCT Imaging System allows the user to configure multiple Network Export servers via the settings shelf. Network interface configuration (such as DHCP or static IP address) is available to Gentuity service personnel only.

Throughout all subsections the following Values can be used in the "Configurable" column:

- USER: The parameter is configurable by the user.
- SERVICE: The parameter is configurable by service personnel.
- FIXED: The parameter is not configurable (it has a fixed Value). The Value is required for the configuration of the remote system.
- N/A: The parameter is not applicable for the local or the remote system.

6.1 General Configuration Parameters

Table 6.1 lists general configuration parameters applicable across all supported DICOM Services.

Table 6.1 General Configuration Parameters

Parameter	Configurable	Default Value	Comments
General Parameters			
Socket timeout	FIXED	60 seconds	
ACSE timeout	FIXED	30 seconds	

6.2 Configuration of DIMSE Services

The tables in the following subsections show the configuration parameters required for DIMSE Services.

6.2.1 Basic Worklist Management Service Configuration - N/A

N/A

6.2.2 Modality Performed Procedure Step Service Configuration - N/A

N/A

6.2.3 Unified Worklist and Procedure Step Service Configuration - N/A

N/A

6.2.4 Instance Availability Notification Service Configuration - N/A

N/A

6.2.5 Storage Service Configuration

Table 6.2 lists Storage Service configuration parameters:

Table 6.2 Storage Service Parameters

Local Configuration Parameters - Storage Service			
Parameter	**Configurable**	**Default Value**	**Comments**
Displayed Server Name	USER		Friendly name used to distinguish a particular Network Export Server configuration
Host Name of Network Export Server	USER		
Port	USER		
Called AE Title (SCP)	USER		
Calling AE Title (SCU)	USER	GENTUITYSYSTEM	
TLS Encryption Enabled	USER	Y	

6.2.6 Storage Commitment Service Configuration - N/A

N/A

6.2.7 Query/Retrieve Service Configuration - N/A

N/A

6.2.8 Print Management Service Configuration - N/A

N/A

6.3 Configuration of DICOM Web Services - N/A

N/A

6.4 Configuration of Media Storage Service

Table 6.3 lists configuration parameters for the Media Storage service:

Table 6.3 Media Storage Service Parameters

Local Configuration Parameters - Media Storage Service			
Parameter	**Configurable**	**Default Value**	**Comments**
Source Application Entity Title	FIXED	GDCM/ITK 4.11.1	
File-set ID	FIXED	GENTUITYHFOCT	

6.5 Configuration of Real Time Video Service - N/A

N/A

6.6 Configuration of Audit Trail - Syslog - N/A

N/A

7 Network and Media Communication Details

7.1 General

The cross interaction between the AEs is depicted in the diagrams below.

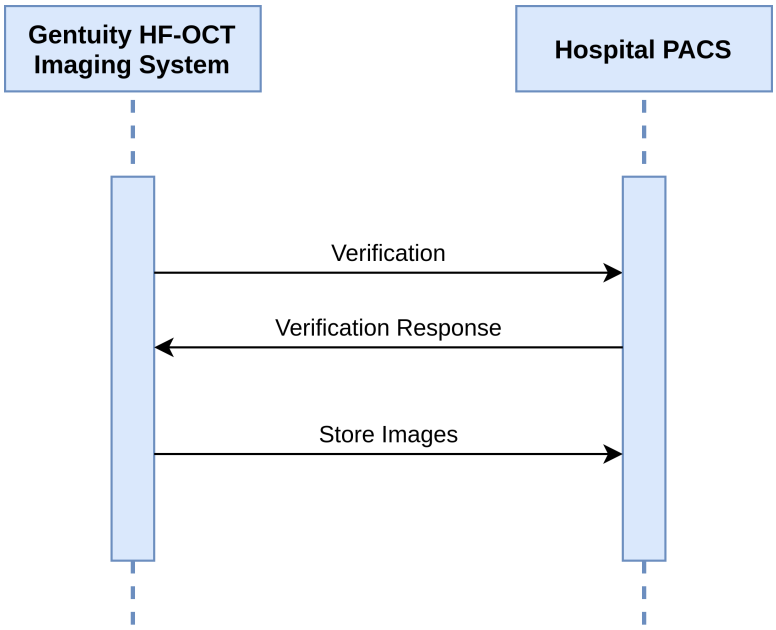

Figure 7.1 Real-World Activity and Cross AE interaction

7.1.1 General Association Parameters

Table 7.1 General Association Parameters

	Name	Value
Networking Services	Application Context Name	1.2.840.10008.3.1.1.1
	Implementation Class UID	1.2.276.0.7230010.3.0.3.6.7
	Implementation Version Name	OFFIS_DCMTK_367
	Maximum PDU length	16384 bytes
	Maximum number of simultaneous Associations as Association Initiator	1
Media Services	Implementation Class UID	1.2.826.0.1.3680043.2.1143.107.104.↩ 103.115.2.6.4.111.124.113
	Implementation Version Name	GDCM 2.6.4

7.2 Specifications

7.2.1 Gentuity HF-OCT Imaging System Application Entity

7.2.1.1 Sequencing of Real-World Activities for Gentuity HF-OCT Imaging System

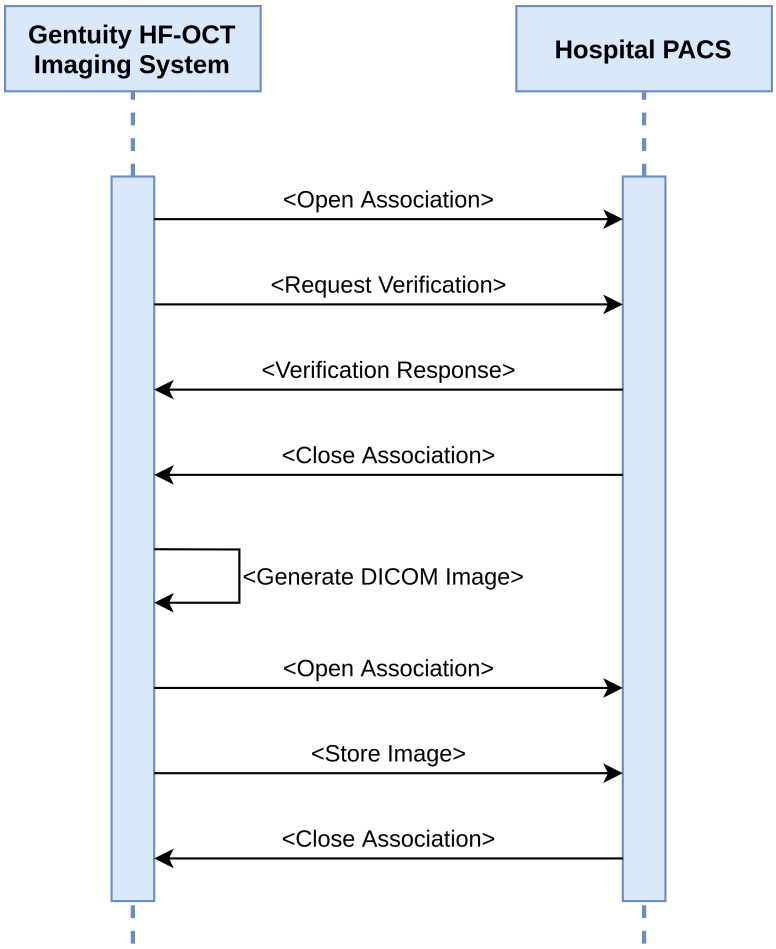

Figure 7.2 Sequencing of Real-World Activities

The figure above depicts the imaging sequence for the transfer of one pullback image file. When a network export is initiated by the user:

1. An association is opened
2. A C-ECHO verification request is sent awaiting a response. If a response is not received within 10 seconds, network export server is considered unreachable and the rest of the sequence is aborted.
3. After the verification response is received, the association is closed.
4. The system generates the DICOM image locally

5. A new association is opened
6. A C-STORE images storage request is sent
7. The association is closed

7.2.1.2 Association Parameters of Gentuity HF-OCT Imaging System - N/A

7.2.1.3 Association Initiation

This section details the Association policies of the Application Entity when it is initiating an Association.

7.2.1.3.1 Real-World Activity: Image Storage

If multiple pullbacks are selected for export, the sequence described above is repeated sequentially for each of the pullbacks.

If an association cannot be established, the operation is aborted, the failure is recorded in the application log and the user is notified that the transfer did not succeed.

Extended Negotiation

The Extended Negotiation parameters for all services that are supported by the Application Entity for the Real-World Activity Image Storage are described in Table 7.2.

Table 7.2 Extended Negotiation for Image Storage of Gentuity HF-OCT Imaging System - Association Initiation

SOP Class	Extended Negotiation	Support	Requested Value
Storage			
Networking Services	Level of support	N	**3**
	Level of Digital Signature support	N	**0**
	Element Coercion	N	**2**

Transfer Syntax Selection Policies

This section provides tables that describe the Transfer Syntax preference for different SOP Classes or SOP Class groups when there are multiple Transfer Syntaxes provided by the Association initiator for Real-World Activity Image Storage of Gentuity HF-OCT Imaging System.

Table 7.3 Transfer Syntax Selection Preference Order - Image SOP Classes for Gentuity HF-OCT Imaging System

Preference Order	Transfer Syntax	UID	Comments
1	JPEG Lossless, Non-Hierarchical, First-Order Prediction Transfer Syntax	1.2.840.10008.1.2.4.70	
2	Explicit VR Little-Endian Transfer Syntax	1.2.840.10008.1.2.1	

Preference Order	Transfer Syntax	UID	Comments
3	Explicit VR Big-Endian Transfer Syntax	1.2.840.10008.1.2.2	
4	Implicit VR Little-Endian Transfer Syntax	1.2.840.10008.1.2	

Table 7.4 Transfer Syntax Selection Preference Order - Non-Image SOP Classes for Gentuity HF-OCT Imaging System

Preference Order	Transfer Syntax	UID	Comments
1	Implicit VR Little-Endian Transfer Syntax	1.2.840.10008.↩ 1.2	

7.2.1.4 Association Acceptance - N/A

N/A

7.3 Status Codes

The following sections describe the Status Codes supported by the system for each implemented service as well as the reason for issuing specific Status codes or the associated behavior when receiving it.

7.3.1 General AE Communication and Failure Behavior and Handling

7.3.1.1 Communication Failure Behavior as Association Initiator

Table describes behavior of the AE if a communication failure occurs when it initiated an Association.

Table 7.5 DICOM Communication Failure Behavior as Association Initiator

Failure	Failure Behavior
Timeout	The Association is aborted using A-ABORT and command marked as failed and the reason is logged. Failures are reported to the user as a cumulative failure count.
Association aborted	The command is marked as failed and the reason is logged. Failures are reported to the user as a cumulative failure count.
Network Disconnect	The command is marked as failed and the reason is logged. A message indicating loss of network connectivity is reported to the user.

7.3.2 DIMSE Services

7.3.2.1 Basic Worklist Management Service - N/A

N/A

7.3.2.2 Modality Performed Procedure Step Service - N/A

N/A

7.3.2.3 Unified Worklist und Procedure Step Service - N/A

N/A

7.3.2.4 Instance Availability Notification Service - N/A

N/A

7.3.2.5 Storage Service

7.3.2.5.1 SCU of the Storage SOP Classes - C-STORE

Table 7.6 lists the Status Codes that the SCU of the Storage SOP Class supports for the C-STORE message and defines the application behavior when encountering the listed Status Codes.

Table 7.6 Status Codes C-STORE for the Storage SOP Classes - SCU

Service Status	Further Meaning	Status Code	Behavior
Success	Success	0000	Log the successful transfer then continue to next pullback selected for export.
Warning	Coercion of Data Elements	B000	Treat as a success. Log the status code then continue to next pullback selected for export.
	Data Set does not match SOP Class	B007	
	Elements Discarded	B006	
Failure	SOP Class not supported	0112	Treat as failure. Log the status code then continue to next pullback selected for export. Failures are reported to the user as a cumulative failure count.
	Invalid SOP Instance	0117	
	Duplicate Invocation	0210	
	Unrecognized Operation	0211	
	Mistyped Argument	0212	
	Not authorized	0214	
	Out of Resources	A700-A7FF	
	Data Set does not match SOP Class	A900-A9FF	
	Cannot Understand	C000-CFFF	
-	Other status codes	anything else	

7.3.2.5.2 SCP of the Storage SOP Classes - C-STORE - N/A

N/A

7.3.2.6 Storage Commitment Service - N/A

N/A

7.3.2.7 Query/Retrieve Service - N/A

N/A

7.3.2.8 Print Management Service - N/A

N/A

7.3.3 DICOM Web Services - N/A

N/A

8 Security

8.1 Introduction

The security section describes security features implemented by this product. It includes descriptions of non-DICOM network protocols, information to configure firewalls and application whitelists, lists of supported DICOM security profiles as well as Web Security features. Additionally, secured media storage, VPN, etc. are also specified in this security section.

8.2 External Network Requirements

Table 8.1 describes additional non-DICOM network protocols that are used by the Gentuity HF-OCT Imaging System.

Table 8.1 External Network Requirements

Profile	Actor	Transaction	Protocol Used	RFCs	Security Support	Reference
Basic Network Address Management	DHCP Client	Find and Use DHCP Server	DHCP	RFC2131; RFC2132; RFC2563	N/A	Annex C.2
		Maintain Lease	DHCP	RFC2131; RFC2132	N/A	Annex C.2
	DNS Client	Resolve Hostname	DNS	RFC1035; RFC2181	N	Annex C.2

8.3 TCP Port Configuration

See Section 6 Configuration for information on the usage of ports for DICOM and other protocols. This section contains helpful information for product administrators to configure firewalls, application whitelists, etc.

Details of the firewall configuration and required TCP and UDP ports are documented in the Cybersecurity Architecture Description. To obtain a copy of the document, send a request to `support@gentuity.com`.

8.4 DICOM Security Profiles Support - N/A

N/A

8.5 User Identity Negotiation Support - N/A

N/A

8.6 Web Services Security Features - N/A

N/A

8.7 Other Security Features - N/A

For more documentation of the security controls implemented in the Gentuity HF-OCT Imaging System, contact support@gentuity.com to request a copy of the Manufacturers Disclosure Statement for Medical Device Security (MDS2).

9 Annex A: Information Object Definitions (IODs)

This section describes all the SOP Instances natively created by Gentuity HF-OCT Imaging System, e.g., images created by an acquisition modality or evidence documents created on a review workstation (i.e., all SOP Classes that are marked in the "Created" column in Table 1.1). Details on Attribute coercion are defined in Section 5.2.5.2.

In the "Source" column, the following Values can be used:

- FIXED: The Value is pre-defined and cannot be modified.
- GENERATED: The Value is generated by the system.
- CONFIGURATION: The Value is copied from the system configuration.
- MWL: The Value is copied from a Modality Worklist entry.
- QUERY: The Value is determined by performing a query of any of the supported Query/Retrieve Services.
- USER: The Value is entered by the user.
- SCANNED: The Value is read from a barcode scanner or similar device.
- EMPTY: The Attribute is sent with a zero-length Value.
- SRC_INSTANCE: The Value is copied from previously created/received SOP Instances.

The "Presence" columns reflect the usage of the Module, Functional Group Macro, Attributes, or Value in the Gentuity HF-OCT Imaging System Implementation and is not necessarily the same as defined in the DICOM Standard. For the "Presence" column the following Values can be used:

- ALWAYS: the module, functional group macro, Attributes or Value is always present.
- CONDITIONAL: the presence of the module, functional group macro, Attributes or Value is dependent on a condition. The condition must be listed in the "Conditions" column.
- SRC_COPY: The presence of the Attributes and Values depends on the availability of these in the source instances, which are used for copying this information.
- EMPTY: The Attribute is present but without a Value (zero length).

9.1 Annex A.1 Information Shared Across Multiple IODs

9.1.1 Annex A.1.1 Common Modules

All SOP Instances generated by the system use the common modules listed in the Tables below or a subset of them, as defined in the IOD specific subsections below.

Table 9.1 Patient

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Patient's Name	(0010,0010)	USER	ALWAYS	CONDITIONAL			Entered by the operator in the New Patient Dialog box
Patient ID	(0010,0020)	USER	ALWAYS	CONDITIONAL			Entered by the operator in the New Patient Dialog box
Patient's Birth Date	(0010,0030)	USER	ALWAYS	CONDITIONAL			Entered by the operator in the New Patient Dialog box
Patient's Sex	(0010,0040)	FIXED	ALWAYS	EMPTY			This is not tracked by the software
Other Patient IDs Sequence	(0010,1002)	GENERATED	ALWAYS	ALWAYS			Internal Database ID
Type of Patient ID	(0010,0022)	FIXED	ALWAYS	ALWAYS	"TEXT"		

Table 9.3 General Study

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Study Instance UID	(0020,000D)	GENERATED	ALWAYS	ALWAYS			All pullbacks for a given patient performed within 8 hours of one another are given the same study UID, which is persisted in the device storage.
Study Date	(0008,0020)	GENERATED	ALWAYS	ALWAYS	Date that pullback was acquired		
Study Time	(0008,0030)	GENERATED	ALWAYS	ALWAYS	Time that pullback was acquired		
Referring Physician's Name	(0008,0090)	FIXED	ALWAYS	EMPTY			The user-specified physician is recorded as the performing physician
Study ID	(0020,0010)	FIXED	ALWAYS	EMPTY			
Accession Number	(0008,0050)	FIXED	ALWAYS	EMPTY			

Table 9.5 General Series

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Modality	(0008,0060)	FIXED	ALWAYS	ALWAYS	"OCT"		
Series Instance UID	(0020,000E)	GENERATED	ALWAYS	ALWAYS			Each pullback on the system corresponds 1-to-1 with a Series
Series Number	(0020,0011)	FIXED	ALWAYS	ALWAYS	1		
Laterality	(0020,0060)	FIXED	ALWAYS	EMPTY			The user is not able to specify which vessel is examined.
Series Date	(0008,0021)	GENERATED	ALWAYS	ALWAYS	Date that pullback was acquired		
Series Time	(0008,0031)	GENERATED	ALWAYS	ALWAYS	Time that pullback was acquired		
Performing Physician's Name	(0008,1050)	USER	ALWAYS	CONDITIONAL			
Series Description	(0008,103E)	USER	ALWAYS	CONDITIONAL			
Body Part Examined	(0018,0015)	FIXED	ALWAYS	ALWAYS	"CORONARYARTERY"		

Table 9.7 SC Equipment

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Conversion Type	(0008,0064)	FIXED	ALWAYS	ALWAYS	"SI"		
Secondary Capture Device Manufacturer	(0018,1016)	FIXED	ALWAYS	ALWAYS	"Gentuity"		
Secondary Capture Device Manufacturer's Model Name	(0018,1018)	GENERATED	ALWAYS	ALWAYS			
Secondary Capture Device Software Versions	(0018,1019)	GENERATED	ALWAYS	ALWAYS			

Table 9.9 General Image

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Instance Number	(0020,0013)	GENERATED	ALWAYS	ALWAYS			

Table 9.11 General Equipment

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Manufacturer	(0008,0070)	FIXED	ALWAYS	ALWAYS	"Gentuity"		
Institution Name	(0008,0080)	CONFIGURATION	ALWAYS	ALWAYS			
Institution Address	(0008,0081)	CONFIGURATION	ALWAYS	ALWAYS			
Manufacturer's Model Name	(0008,1090)	FIXED	ALWAYS	ALWAYS	"Gentuity HF-OCT Imaging System"		
Device Serial Number	(0018,1000)	GENERATED	ALWAYS	ALWAYS			
Software Versions	(0018,1020)	GENERATED	ALWAYS	ALWAYS			
Pixel Padding Value	(0028,0120)	FIXED	ALWAYS	ALWAYS	0		

Table 9.13 Image Pixel

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Pixel Data	(7FE0,0010)	GENERATED	ALWAYS	ALWAYS			
Recommended Display Frame Rate	(0008,2144)	GENERATED	ALWAYS	ALWAYS			
Frame Increment Pointer	(0028,0009)	GENERATED	ALWAYS	ALWAYS			

Table 9.15 Multi-frame

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Number of Frames	(0028,0008)	GENERATED	ALWAYS	ALWAYS			

Table 9.17 SOP Common Module

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
SOP Class UID	(0008,0016)	FIXED	ALWAYS	ALWAYS	"1.2.840.10008.5.1.4.1.1.7.4"		Multi-frame True Color Secondary Capture Image Storage
SOP Instance UID	(0008,0018)	GENERATED	ALWAYS	ALWAYS			
Instance Creation Date	(0008,0012)	GENERATED	ALWAYS	ALWAYS			
Instance Creation Time	(0008,0013)	GENERATED	ALWAYS	ALWAYS			
Timezone Offset From UTC	(0008,0201)	CONFIGURATION	ALWAYS	ALWAYS			