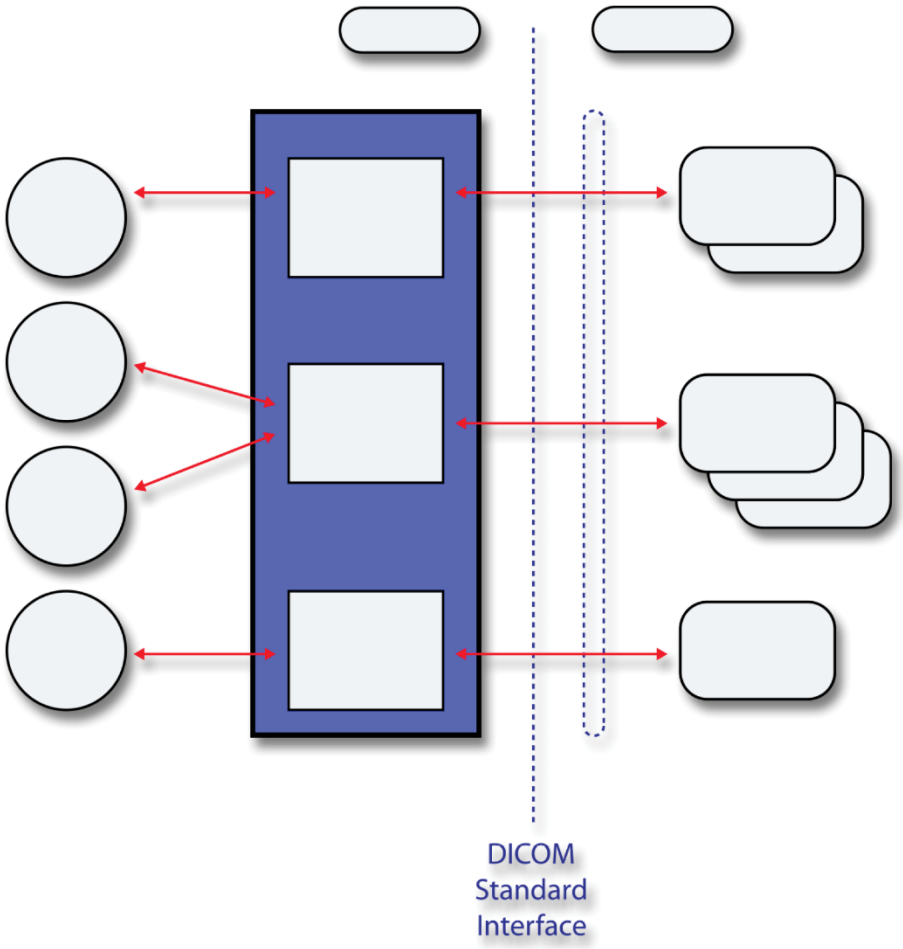
HOLOGIC®

Genius AI® Detection PRO



DICOM Conformance Statement

Software Version 3.1.0
RD-05208 Revision 001
June 2025

HOLOGIC®

HOLOGIC®

Genius AI® Detection PRO

Product Support: USA: 1.877.371.4372 Email: BreastHealth.Support@hologic.com

Therapixel SA
455 Promenade des Anglais
06200 Nice, France

Distributor:
Hologic Inc.
600 Technology Drive
Newark, DE 19702 USA

1 Overview

Genius AI Detection PRO software (later referenced as GAID PRO software) is an artificial intelligence (AI) based system for the processing of 2D and 3D mammograms. Its main functionalities are:

- Control of the image quality,
- Assessment of the breast density,
- Detection and characterization of lesions suspicious for breast cancer.

GAID PRO software receives input data from one or more remote AEs. GAID PRO software may query/retrieve prior mammograms from one or more remote AEs and send results to one or more remote AEs.

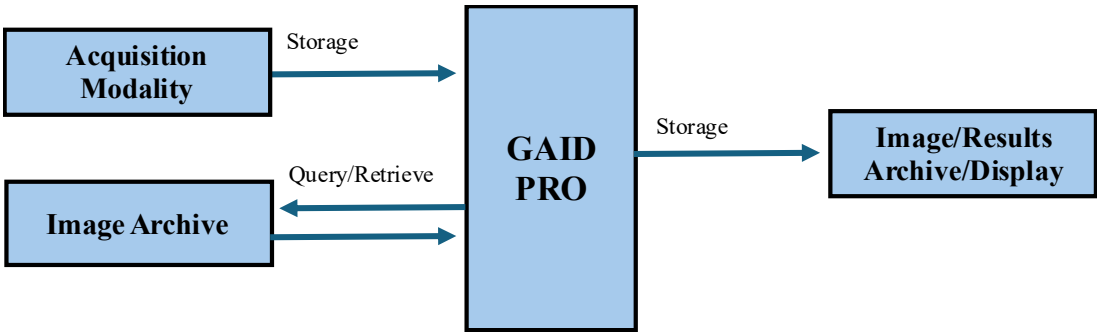


Figure 1-1 Overview of Implemented Services

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
Digital Mammography X-Ray Image Storage - For Presentation	1.2.840.10008.5.1.4.1.1.1.2	U; LL	N	Y	N	N	N	N	N	N	Y	Y	N
Digital Mammography X-Ray Image Storage - For Presentation	1.2.840.10008.5.1.4.1.1.1.2	L	N	Y	N	N	N	N	N	N	N	N	N
Secondary Capture Image Storage	1.2.840.10008.5.1.4.1.1.7	U; LL	Y	Y	N	N	N	N	N	S	N	N	N
Multi-frame True Color Secondary Capture Image Storage	1.2.840.10008.5.1.4.1.1.7.4	U; LL	Y	Y	N	N	N	N	N	S	N	N	N
Breast Tomosynthesis Image Storage	1.2.840.10008.5.1.4.1.1.13.1.3	U; LL	N	Y	N	N	N	N	N	N	Y	Y	N
Breast Tomosynthesis Image Storage	1.2.840.10008.5.1.4.1.1.13.1.3	L	N	Y	N	N	N	N	N	N	N	N	N
Mammography CAD SR Storage	1.2.840.10008.5.1.4.1.1.88.50	U	Y	Y	N	N	N	N	N	See Table 1-3			
Other SOP Classes		U; LL; L	N	Y	N	N	N	N	N	N	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 (Process 14)	1.2.840.10008.1.2.4.57	N/A
	JPEG Lossless, Non-Hierarchical, First-Order Prediction (Process 14 [Selection Value 1])	1.2.840.10008.1.2.4.70	N/A
	JPEG-LS Lossless	1.2.840.10008.1.2.4.80	N/A
	JPEG 2000 Image Compression (Lossless Only)	1.2.840.10008.1.2.4.90	N/A
	RLE Lossless	1.2.840.10008.1.2.5	N/A
Lossy Compressed Transfer Syntax Set (L)	JPEG Baseline (Process 1)	1.2.840.10008.1.2.4.50	N/A
	JPEG Extended (Process 2 & 4)	1.2.840.10008.1.2.4.51	N/A
	JPEG 2000 Image Compression	1.2.840.10008.1.2.4.91	N/A
Uncompressed Transfer Syntax Set (U)	Implicit VR Little Endian	1.2.840.10008.1.2	N/A
	Explicit VR Big Endian	1.2.840.10008.1.2.2	N/A
	Explicit VR Little Endian	1.2.840.10008.1.2.1	N/A

1.1.1 Structured Reporting Root Template IDs

Table 1-3 lists all Template IDs (TID) of Root Templates that are supported by the system. The "Function" column indicates how the system uses the content of the DICOM SR:

- CREATE: The system creates instances using the specified TID.
- RENDER: The system displays the content of the SR, without using the data for any processing.
- EXTRACT_DATA: The system can extract structured data from the content and use the data for subsequent processing (e.g., reporting).
- OVERLAY: The system uses the information in the SR to display information directly on the images (e.g., Mammography CAD markers).
- ARCHIVE: The system stores instances for later retrieval.

The "SOP Class UID" column indicates which of the SR Storage SOP Classes are used to encode the information or to store it. If multiple SOP Classes are supported the "Condition" column describes the conditions for using the different SOP Classes.

Table 1-3 Supported Root SR Template IDs (TIDs)

Name	Root TID	Function	SOP Classes		Condition
Mammography CAD Document Root	4000	CREATE	Mammography CAD SR Storage	1.2.840.10008.5.1.4.1.1.88.50	

1.2 DIMSE Services

1.2.1 Verification

Table 1-4 lists support for the Verification SOP Class.

Table 1-4 Verification SOP Class

SOP Classes		Transfer Syntax		SCU	SCP
Verification	1.2.840.10008.1.1	Explicit VR Little Endian	1.2.840.10008.1.2.1	Y	Y
		Explicit VR Big Endian	1.2.840.10008.1.2.2	Y	Y
		Implicit VR Little Endian	1.2.840.10008.1.2	Y	Y

1.2.2 Storage

For details on supported Storage SOP Classes see Section 1.1.

1.2.3 Workflow Management – N/A

1.2.4 Query/Retrieve

Table 1-5 lists all supported Query/Retrieve SOP Classes.

Table 1-5 Query/Retrieve SOP Classes

SOP Classes		Transfer Syntax		SCU	SCP
Study Root Query/Retrieve - Information Model - FIND	1.2.840.10008.5.1.4.1.2.2.1	Explicit VR Little Endian	1.2.840.10008.1.2.1	Y	N
		Explicit VR Big Endian	1.2.840.10008.1.2.2	Y	N
		Implicit VR Little Endian	1.2.840.10008.1.2	Y	N
Study Root Query/Retrieve - Information Model - MOVE	1.2.840.10008.5.1.4.1.2.2.2	Explicit VR Little Endian	1.2.840.10008.1.2.1	Y	N

SOP Classes		Transfer Syntax		SCU	SCP
		Explicit VR Big Endian	1.2.840.10008.1.2.2	Y	N
		Implicit VR Big Endian	1.2.840.10008.1.2	Y	N

1.2.5 Printing – N/A

1.3 DICOM Web Services – N/A

1.4 Media Services – N/A

1.5 Real-Time Video Service – N/A

1.6 De-identification Profiles – N/A

1.7 Specific Character Sets

Table 1-6 Supported Specific Character Sets

Defined Term	IANA	Description
Single-Byte Character Sets without Code Extensions		
ISO_IR 6	ISO-646 or US-ASCII	Default Repertoire
ISO_IR 100	ISO-8859-1	Latin Alphabet No.1 (West Europe)
ISO_IR 101	ISO 8859-2	Latin alphabet No. 2 (Central / Eastern Europe)
ISO_IR 109	ISO 8859-3	Latin alphabet No. 3 (South Europe)
ISO_IR 110	ISO 8859-4	Latin Alphabet No.4 (North Europe)
ISO_IR 144	ISO 8859-5	Cyrillic
ISO_IR 127	ISO 8859-6	Arabic
ISO_IR 126	ISO 8859-7	Greek
ISO_IR 138	ISO 8859-8	Hebrew
ISO_IR 148	ISO 8859-9	Latin5 / Turkish
ISO_IR 166	ISO 8859-11	Thai
Single-Byte Character Sets with Code Extension		
ISO 2022 IR 6		Default Repertoire
ISO 2022 IR 100		Latin Alphabet No. 1 (West Europe)
Multi-Byte Character Sets without Code Extensions		
ISO_IR 192	UTF-8	Unicode in UTF-8 Level 3
GB 18030	GB 18030	Chinese
GBK	GBK	Chinese

2 Table of Contents

3 Introduction

3.1 Revision History

Revision	Date	Product Version(s)	Change
Rev 001	2025-JUN-06	Genius AI Detection PRO software v3.1.0	Initial revision

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 0 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 0 during system installation and also information from Section 0 Service and Interoperability Description for details regarding the implemented services.
- Field Service Engineers can use the details from Section 0 Service and Interoperability Description and from Section 0 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 Annex A Information Object Definitions (IODs) or Annex 0 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 GAID PRO software and other DICOM products. The Conformance Statement should be read and understood in conjunction with the DICOM Standard [1]. 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 GAID PRO software 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.

3.4 Terms and Definitions

The following list includes DICOM Terms, that are used throughout this Conformance Statement:

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 lower-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 IOD. 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).
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's 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.
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].
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.

AE	Application Entity
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
GAID PRO	Genius AI Detection PRO software
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
ISO	International Organization for Standardization
MPPS	Modality Performed Procedure Step
MWL	Modality Worklist
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
QIDO-RS	Query based on ID for DICOM Objects by RESTful Services
RTV	Real-Time Video
SCP	Service Class Provider
SCU	Service Class User
SDP	Service Description Protocol
SOP	Service-Object Pair
SPS	Scheduled Procedure Step
SR	Structured Reporting
STOW-RS	STore Over the Web by RESTful Services
TCP/IP	Transmission Control Protocol/Internet Protocol
TID	Template Identifier
UA	User Agent
UI	User Interface
UID	Unique Identifier
UL	Upper Layer
UPS	Unified Procedure Step
UPS-RS	Unified Procedure Step by RESTful Services
VR	Value Representation
WADO-RS	Web Access to DICOM Objects by RESTful Services
WADO-URI	Web Access to DICOM Objects by URI

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 DICOM data interchange functionalities of the Genius AI Detection PRO software version 3.1.0. The following functions are supported:

- Reception (STORE-SCP) of SOP instances from external AE (promiscuous mode).
- Query/Retrieve to/from multiple external AE.
- Processing of SOP instances using artificial intelligence algorithms.
- Sending (STORE-SCU) of created SOP instances (processing results) to multiple external AE.

4.1 Application Entities and Data Flow

The network and media interchange application model for GAID PRO software is shown in Figure 4-1 GAID PRO Application Data Flow Diagram.

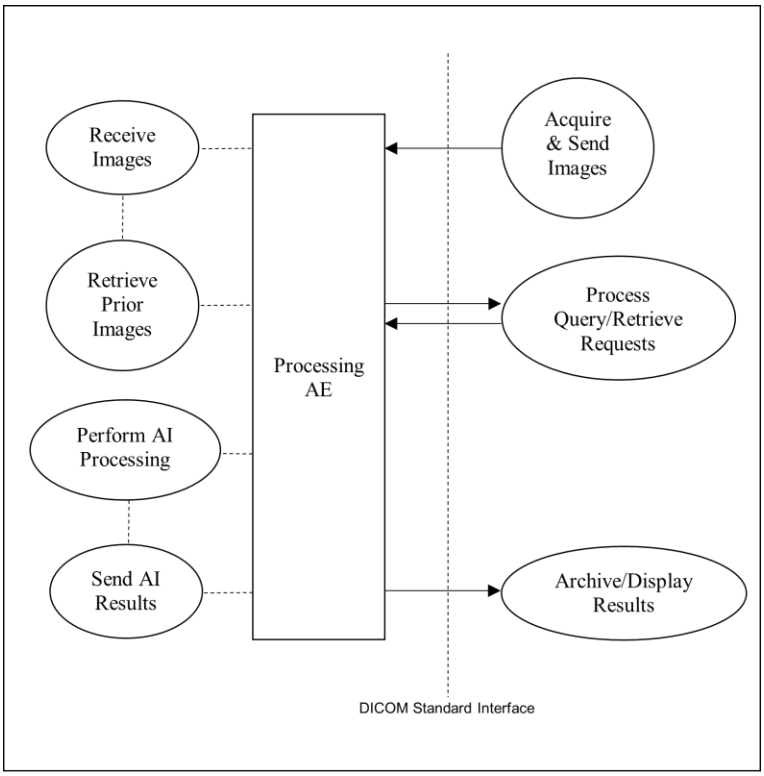


Figure 4-1 GAID PRO Application Data Flow Diagram

This section describes the organization of the supported Services into Application Entities based on the default configuration of the system. This may change based on the actual setup at the customer site. See Section 0 for details about the configurability of Services into AEs.

4.1.1 Functional Definition of PROCESSING AE

The PROCESSING AE implements the following DIMSE services:

- C-STORE (SCU and SCP), for reception of mammograms and sending results.
- C-FIND and C-MOVE (SCU), to query / retrieve prior mammograms.
- C-ECHO (SCU and SCP), to verify the availability of external AE.

The PROCESSING AE C-STORE (SCP) receives images from any external AE (promiscuous mode). For instance, a mammographic platform, upon acquisition of a mammogram, may send the acquired SOP Instances to the PROCESSING AE. Upon reception, the PROCESSING AE will:

- Filter the data, based on basic rules, to determine its eligibility for processing.
- Automatically initiate a Query / Retrieve to obtain the prior mammogram.
- Process the mammogram using artificial intelligence algorithms.
- Automatically send results (STORE SCU) to external AE in form of Mammography CAD SR or Secondary Capture Image.

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 Web		DICOM Media			Real-Time Video	
		SCU	SCP	Origin Server	User Agent	FSC	FSU	FSR	SCU	SCP
PROCESSING AE	Storage	Y	Y	N	N	N	N	N	N	N
	Query/Retrieve	Y	N	N	N	N	N	N	N	N
	Verification	Y	Y	N	N	N	N	N	N	N

5.2 Supported DIMSE Services

5.2.1 Basic Worklist Management Service – N/A

5.2.2 Modality Performed Procedure Step Service – N/A

5.2.3 Unified Worklist and Procedure Step Service – N/A

5.2.4 Instance Availability Notification Service – 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, GAID PRO software 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 Annex A, which describes the underlying IOD of the supported SOP Classes.

Processing results are stored automatically to one or more configured remote storage AEs using SOP Class(es) configured per remote storage AE.

5.2.5.1.1 Transcoding of Transfer Syntaxes – N/A

5.2.5.2 SCP of the Storage SOP Classes

As a Service Class Provider of the Storage Service Class, GAID PRO software receives the C-STORE-RQ message from remote SCUs. See Section 1.1 Content and Transfer in the Section 1 for the list of supported SOP Classes.
Table 5-2 defines the conformance levels of GAID PRO software.

Table 5-2 Levels of Conformance

Levels of Conformance	2
Level of Digital Signature Support	1

GAID PRO software does not coerce any Attributes upon receiving them from other systems.

Table 5-3 lists any limitations on displaying and processing instances, e.g., displaying and processing of the respective SOP Instances is prevented by an unsupported Value for an Attribute or the absence of that Attribute.

The "Effect" column describes what happens if the limitation is encountered. The following Values are used:

- ND: Display is not possible

- LD: Display is limited
- NP: Processing is not possible
- LP: Processing is limited
- OT: Other effects described in the "Comments" column

Table 5-3 Processing Limitations for Storage SCP

Limitation Case			Effect	Comments
Attribute Name	**Tag**	**Value**		
Digital Mammography X-Ray Image Storage - For Presentation (1.2.840.10008.5.1.4.1.1.1.2)				
Laterality	(0020,0062)	"B"	NP, ND	Processing and display are not permitted when laterality is equal to Both.
View Modifier Code Sequence.Code Value	(0054,0222).(0008,0100)	"R-102D2" OR "R-102D6" OR "R-102D7"	NP, ND	Processing and display are not permitted on Cleavage, Magnification, or Spot compression views.
Lossy Image Compression	(0028,2110)	"1"	NP, ND	Processing and display are not permitted on lossy compressed image data.
Breast Tomosynthesis Image Storage (1.2.840.10008.5.1.4.1.1.13.1.3)				
Laterality	(0020,9072)	"B"	NP, ND	Processing and display are not permitted when laterality is equal to Both.
View Modifier Code Sequence.Code Value	(0054,0222).(0008,0100)	"R-102D2" OR "R-102D6" OR "R-102D7"	NP, ND	Processing and display are not permitted on Cleavage, Magnification, or Spot compression views.
Lossy Image Compression	(0028,2110)	"1"	NP, ND	Processing and display are not permitted on lossy compressed image data.
All Other SOP Classes				
			NP, ND	Processing and display are not permitted on SOP instances of any other SOP Class.

Table 5-4 lists the actions performed upon receiving instances from a remote AE and the system behavior when certain conditions are encountered.

Table 5-4 Behavior when storing Instances

Action upon Receiving	Condition	System Behavior
Perform Transfer Syntax and Attribute Validation	Duplicate Instance	Ignore Instances
	Success	Store Instances in an internal database. Initiate processing if Instances' SOP Class matches those listed in Table 5-3. Delete Instances not matching SOP Class permitted for processing.
	Failure	Instances received using a lossy compression transfer syntax are not eligible for processing and are deleted immediately. Ignore Instances from processing.
Add to an existing study	Success	Store Instances in an internal database. Add Instances to processing if Instances' SOP Class matches those listed in Table 5-3. Delete Instances not matching SOP Class permitted for processing.

Table 5-5 describes how the SCP handles compression for stored instances.

The following Values are used in the "Behavior" column:

- AS_IS: Images are stored as received.
- CONFIGURATION: Images are compressed based on internal configuration settings.
- OTHER: All other conditions, which are further described in the "Comments" column.

The Transfer Syntax is used to describe the compression mechanism applied.

Table 5-5 Image Compression by Storage SCP

SOP Class		Behavior	Transfer Syntax		Comments
All SOP Classes		AS_IS			

Upon successful C-STORE, the SOP Instance is kept for the duration of the processing. When the processing is completed, the SOP Instance is deleted from the local storage. While GAID PRO software accepts all SOP classes, only those listed in Table 5-3 may be used for processing. Other SOP Classes are immediately deleted from the local storage upon receipt.

5.2.6 Storage Commitment Service – N/A

5.2.7 Query/Retrieve Service Class

5.2.7.1 SCU of the Study Root Q/R Information Model - FIND SOP Class

As a Service Class User of the Study Root Q/R - Information Model - FIND SOP Class, GAID PRO software uses the C-FIND-RQ message and supports the Query Keys listed in Table 5-6 for hierarchical queries.

In the "Matching Type" column the following Values can be used:

- SINGLE_VALUE: SCU can request Single Value matching on this Attribute.
- UID: SCU can request List of UID matching on this Attribute.
- WILDCARD: SCU can request Wildcard matching on this Attribute.
- RANGE: SCU can request Range matching on this Attribute.
- SEQUENCE: SCU can request Sequence matching on this Attribute.
- UNIVERSAL: SCU can request that the Attribute be a return Value (universal matching).

In the "Query Value Source" column the following Values can be used:

- FIXED: The query Value cannot be modified by the user or by configuration.
- GENERATED: The query Value is generated by the system (e.g., current date as the study date).
- CONFIGURATION: The query Value is dependent on system configuration.
- USER: The query Value is entered by the user.
- SCANNED: The query Value is read from a barcode scanner or similar device.
- EMPTY: The query Value is sent with a zero-length value to indicate it is a return key only.

In the "Display on UI" column the following Values can be used:

- D: the return Value is displayed on the main UI by default.
- C: the return Value is displayed on the main UI if configured.
- N: the return Value is never displayed.

Table 5-6 Supported C-FIND Attribute Matching for Study Root Q/R Model -SCU

Attribute Name	Tag	Matching Type	Query Value Source	Value	Display on UI	Comments
Study Level						
Study Date	(0008,0020)	RANGE	CONFIGURATION		N	
Patient ID	(0010,0020)	SINGLE_VALUE	GENERATED		N	
Issuer of Patient ID	(0010,0021)	SINGLE_VALUE	GENERATED, CONFIGURATION		N	Use of Issuer of Patient ID is optional
Series Level						
Modality	(0008,0060)	SINGLE_VALUE	FIXED	MG	N	
Study Instance UID	(0020,000D)	SINGLE_VALUE	GENERATED		N	

GAID PRO software does not support Extended Negotiation for Relational Queries.

The product issues C-FIND-CANCEL requests in the following scenarios:

- During system shutdown if requests are active.
- If C-FIND responses take longer than a configured time-out.

If the SCP ignores the cancellation request and continues sending C-FIND responses GAID PRO software will terminate the association by closing the network connection.

The Specific Character Set (0008,0005) value included in C-FIND requests is determined by configuration. See Section 6.1.

If the product receives from the SCP a C-FIND response containing unsupported values in Specific Character Set (0008,0005), characters in that character set will be treated as unknown characters as described in Section 6.1.2.3 in PS3.5.

5.2.7.2 SCU of the Patient Root Q/R Information Model - FIND SOP Class – N/A

5.2.7.3 SCU of the Study Root Q/R Information Model - MOVE SOP Class

A C-MOVE request is initiated to retrieve a study with matching Study Instance UID obtained via matching C-FIND response. A single study may be requested in a C-MOVE. C-MOVE-CANCEL is never sent. If the C-MOVE request has failed, the retry mechanism is initiated.

A C-STORE request is expected to be received within 30 minutes after C-MOVE has been successfully completed. If a C-STORE has not been received during that lapse of time, no C-MOVE is reissued and the retrieval of the study is abandoned.

5.2.7.4 SCU of the Patient Root Q/R Information Model - MOVE SOP Class – N/A

5.2.7.5 SCP of the Study Root Q/R Information Model - FIND SOP Class – N/A

5.2.7.6 SCP of the Patient Root Q/R Information Model - FIND SOP Class – N/A

5.2.7.7 SCP of the Study Root Q/R Information Model - MOVE SOP Class – N/A

5.2.7.8 SCP of the Patient Root Q/R - Information Model - MOVE SOP Class – N/A

5.2.8 Print Management Service – N/A

5.3 DICOM Web Services – N/A

5.4 Media Services – N/A

5.5 Real-Time Video Services – N/A

5.6 Cross Service Considerations

This section describes interaction between the implementation of different DICOM Services in this product. Details internal to an individual service are addressed in previous Service Sections.

Note: The DICOM Standard typically does not define cross-service requirements. Therefore, this section provides an implementation description and is not strictly required DICOM Conformance.

A sequence of C-FIND/C-MOVE are issued upon successful receipt of SOP Instances (via C-STORE) that are eligible for processing, to search for prior studies with matching Patient ID.

5.7 Specific Character Sets

See Section 1.7 for supported Values for Specific Character Set (0008,0005).

Generic configuration for Specific Character Sets is covered in Section 1.7. Service specific configuration for Specific Character Sets used in C-FIND requests is addressed in Section 6.1.

GAID PRO software displays a list of processed studies with the Patient's Name and Patient ID using a web interface. If characters from the Unicode (UTF-8) character set are used, support and display of specific characters is operating system and browser dependent.

GAID PRO software supports displaying character sets beyond the default character repertoire (ISO-IR 6) for all displayed attributes.

In case unsupported character sets are encountered, attributes may not be correctly rendered in the web display.

Created SOP Instances contain only ISO_IR 100 or ISO_IR 192 characters without Code Extensions.

6 Configuration

GAID PRO software provides a configuration web interface. Access to the configuration interface is restricted to authorized personnel using personal login and password provided by Hologic, or via LDAP when configured.

The configuration interface allows to:

- Configure the PROCESSING AE title and port,
- Declare external AE (title, host and port) to perform Q/R and store results (C-STORE).

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			
Timeout waiting for acceptance or rejection Response to an Association Open Request. (Application-Level timeout)	SERVICE	60s	
Timeout waiting for a response to an Association release request. (Application Level Timeout)	SERVICE	60s	
DIMSE timeout	SERVICE	60s	
Connection timeout	SERVICE	10s	When a connection with an external AE could not be established within the configured lapse of time, the connection is dropped.
C-MOVE operation timeout	SERVICE	1800s	A C-MOVE operation without progress (i.e., no change in sub-operations completion) during the configured lapse of time will be aborted.
TCP/IP Settings			
TCP/IP Send Buffer	FIXED	65535 Bytes	
TCP/IP Receive Buffer	FIXED	65535 Bytes	
DICOM Services Parameters			
Maximum number of simultaneous Associations accepted	FIXED	No specific limit.	
Specific Character Set	SERVICE	ISO_IR 100	Selection list that applies to C-FIND requests includes the character sets without code extensions in Table 1-7.

6.2 Configuration of DIMSE Services

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

In order to identify whether GAID PRO software is an SCP and / or an SCU, the following applies:

• SCP: The (Secured) Local Called AET and Remote Calling AET parameters are present.

• SCU: The (Secured) Local Calling AET and Remote Called AET parameters are present.

6.2.1 Basic Worklist Management Service Configuration – N/A

6.2.2 Modality Performed Procedure Step Service Configuration – N/A

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

6.2.4 Instance Availability Notification Service Configuration – 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**
Calling/Called AE Title (SCU and SCP)	SERVICE	GAIDPRO	The same configured value applies to local Store SCU and local Store SCP
Port (SCP)	SERVICE	104	
Address (IP or Host) (SCU and SCP)	SERVICE		Normally set by Service personnel during initial setup. Should be the GAID PRO hostname or IP address.
Supported Transfer Syntaxes as SCP	FIXED	See Table 1-2	
Supported Storage SOP Classes as SCP	FIXED	See Table 1-1	
Remote Configuration Parameters - Storage Service			
Parameter	**Configurable**	**Default Value**	**Comments**
Called AE Title (SCP)	SERVICE		Normally set by service personnel during initial setup.
Port (SCP)	SERVICE		Normally set by service personnel during initial setup.
Address (IP or Host) (SCP)	SERVICE		Normally set by service personnel during initial setup.

6.2.6 Storage Commitment Service Configuration – N/A

6.2.7 Query/Retrieve Service Configuration

Table 6-3 lists Query/Retrieve Service configuration parameters:

Table 6-3 Query/Retrieve Service Parameters

Local Configuration Parameters - Query/Retrieve Service			
Parameter	**Configurable**	**Default Value**	**Comments**
Calling AE Title (SCU)	SERVICE		All Local DICOM SCU use the same Calling AE Title and Address. See Table 6-2.
Remote Configuration Parameters - Query/Retrieve Service			
Parameter	**Configurable**	**Default Value**	**Comments**
Called AE Title (SCP)	SERVICE		Normally set by service personnel during initial setup.
Port (SCP)	SERVICE		Normally set by service personnel during initial setup.
Address (IP or Host) (SCP)	SERVICE		Normally set by service personnel during initial setup.

6.2.8 Print Management Service Configuration – N/A

6.3 Configuration of DICOM Web Services – N/A

6.4 Configuration of Media Storage Service – N/A

6.5 Configuration of Real-Time Video Service – N/A

6.6 Configuration of Audit Trail – Syslog – N/A

7 Network and Media Communication Details

7.1 General

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

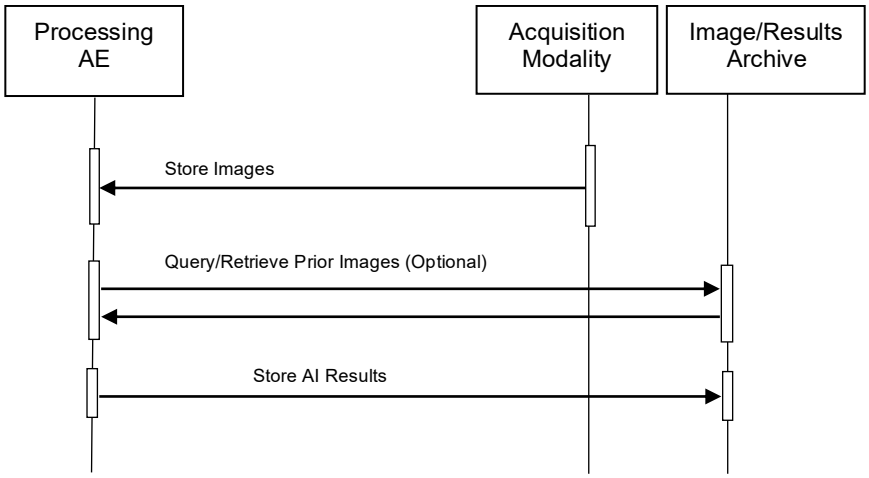


Figure 7-1 Real-World Activity and Cross AE interaction

7.1.1 General Association Parameters

Table 7-1 lists Association parameters applicable to all AEs on the system.

Table 7-1 General Association Parameters

	Name	Value
Networking Services	Application Context Name	1.2.840.10008.3.1.1.1
	Implementation Class UID	1.2.276.0.7230010.3.0.3.6.8
	Implementation Version Name	OFFIS_DCMTK_368
	Maximum PDU Length	16384
	ARTIM Timeout	30s
	Maximum number of simultaneous Associations as Association Initiator	4
	Maximum number of simultaneous Associations as Association Acceptor	Unrestricted
	Maximum number of outstanding asynchronous Transactions	0

7.2 Specifications

7.2.1 PROCESSING Application Entity

7.2.1.1 Sequencing of Real-World Activities for PROCESSING AE

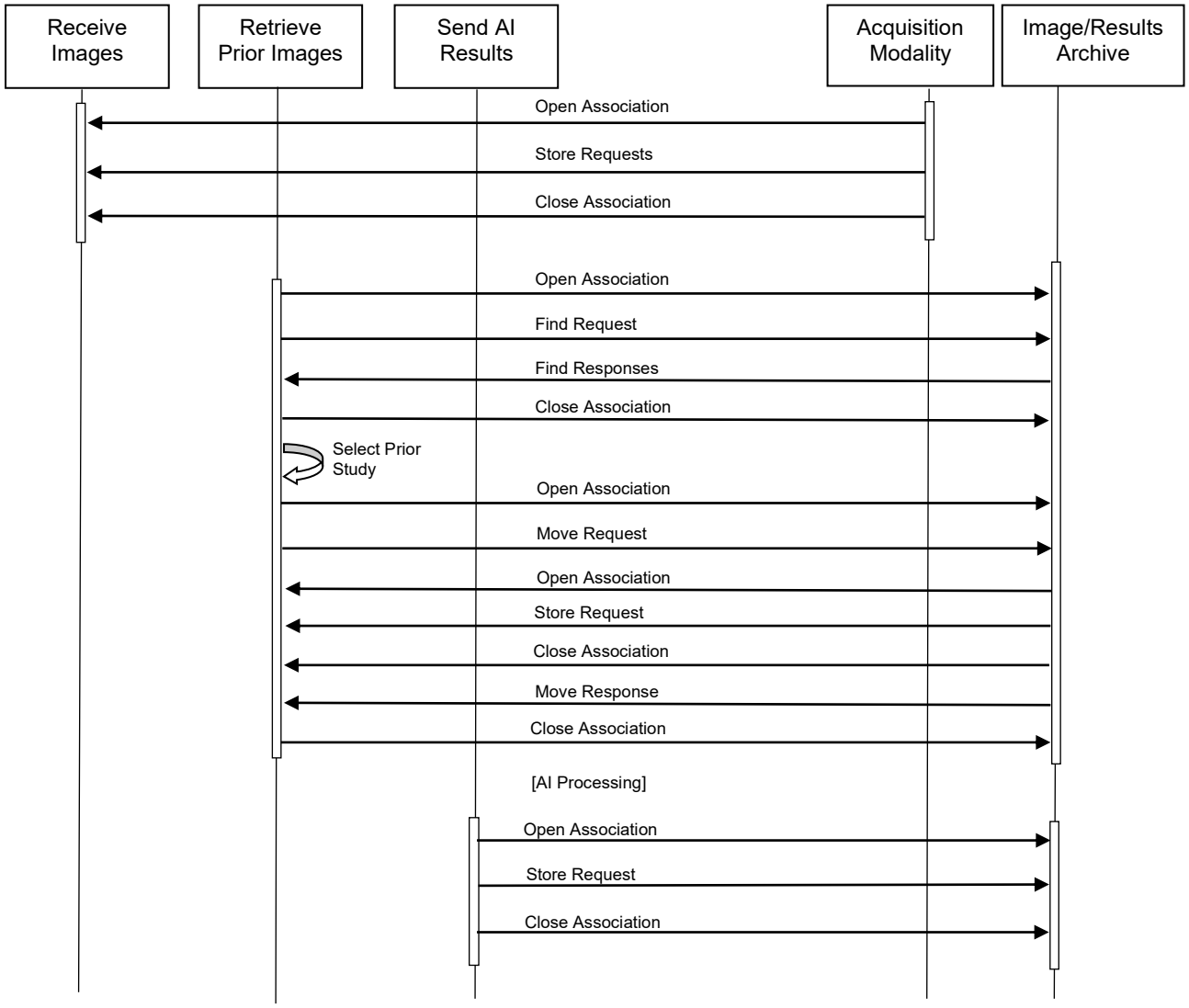


Figure 7-2 Sequencing of Real-World Activities for PROCESSING AE

The Acquisition Modality first opens an Association to the PROCESSING AE and triggers a Store Request. PROCESSING AE stores the SOP Instances and the Acquisition Modality closes the Association. If the SOP Instances are not supported, they are immediately deleted from the PROCESSING AE local storage (see Table 1-1 for the list of SOP Classes whose storage is supported). If the SOP Instances are supported, the PROCESSING AE initiates a C-FIND request to the Image/Results Archive immediately after the previous Association is closed to query for prior studies. If a matching prior is found (see Table 5-6 for the list of supported attribute matching for C-FIND), a C-MOVE is initiated from the PROCESSING AE to the Image/Results Archive. The Image/Results Archive subsequently opens an Association and sends a Store Request to the PROCESSING AE, which in turn stores the SOP Instances corresponding to the prior. The Image/Results Archive closes the Store Association, the PROCESSING AE closes the Move Association, and the processing is initiated by the PROCESSING AE.

When processing is complete, the PROCESSING AE initiates a C-STORE with the Image/Results Archive to send results in form of a Mammography CAD SR (see Section 0), or Secondary Capture Image (see Section A.3), or both depending on the configuration.

7.2.1.2 Association Parameters of PROCESSING AE – 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: Retrieve Prior Images

Query/Retrieve of prior mammograms is triggered automatically upon receipt (Store SCP) of a SOP Instance compatible with those listed in Table 1-1:

- A C-FIND is first initiated to list all available mammograms for a given patient identified by the Patient ID. The list of supported C-FIND attributes for Q/R is listed in Table 5-6.
- If a matching prior study is found, a C-MOVE is initiated.

In case the Association (either C-FIND or C-MOVE) cannot be established, a retry mechanism will be executed. The Association will be attempted 3 times with a 30s delay. If the Association could not be established after the retries, Q/R of prior mammograms is abandoned, and the processing continues without priors.

Extended Negotiation

The Extended Negotiation parameters for all services that are supported by the Application Entity for the Real-World Activity Retrieve Prior Images are described in Table 7-2.

Table 7-2 Extended Negotiation for Retrieve Prior Images of PROCESSING AE - Association Initiation

SOP Class	Extended Negotiation	Support	Requested Value
Query			
Applicable to all Query Retrieve - FIND SOP Classes mentioned under Section 0.	Relational queries	N	
	Date-time matching	N	
	Fuzzy semantic matching of person names	N	
	Timezone query adjustment	N	
	Enhanced Multi-Frame Image Conversion	N	
Retrieve			
Applicable to all Query Retrieve - MOVE SOP Classes mentioned under Section 0.	Relational retrieval	N	
	Enhanced Multi-Frame Image Conversion	N	
	Timezone query adjustment	N	

Role Negotiation - NA

7.2.1.3.2 Real-World Activity: Send AI Results

The PROCESSING AE automatically initiates a Store SCU with the Image/Results Archive when results are available. Results may be transmitted:

- As Mammography CAD SR (see Section 0)
- As Secondary Capture Image (see Section A.3)

The SOP Classes supported for Mammography CAD SR and Secondary Capture Image are listed in Table 1-1.

The only supported Transfer Syntax for the Mammography CAD SR and Secondary Capture Image SOP Classes is:

- Explicit VR Little Endian Transfer Syntax (1.2.840.10008.1.2.1)

In case the Association cannot be established, a retry mechanism will be executed. The Association will be attempted 3 times with a 30s delay. If the Association could not be established after the retries, the store attempt is abandoned, and no results are sent to the Image/Results Archive.

Extended Negotiation

The Extended Negotiation parameters for all services that are supported by the Application Entity for the Real-World Activity Send AI Results are described in Table 7-2.

Table 7-3 Extended Negotiation for Send AI Results of PROCESSING AE - Association Initiation

SOP Class	Extended Negotiation	Support	Requested Value
Storage			
Applicable to all Storage SOP Classes listed under Section 0.	Level of support	N	
	Level of Digital Signature support	N	
	Element Coercion	N	

Role Negotiation - NA

7.2.1.4 Association Acceptance

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

7.2.1.4.1 Real-World Activity: Receive Images

Any Application Entity may initiate an Association to the PROCESSING AE (so-called promiscuous mode). When the Association is closed, the PROCESSING AE will:

- Perform transfer syntax and attribute validation (see Table 5-4).
- Flag the study as being processed if SOP Instances are eligible after transfer syntax and attribute validation.
- Perform Q/R on prior mammograms when enabled.
- Start the processing.

Any subsequent SOP Instances received with Study Instance UID matching the study being processed will be added to the current processing.

Extended Negotiation

The Extended Negotiation parameters for all services that are requested by the Application Entity for the Real-World Activity Receive Images are described in Table 7-4.

Table 7-4 Extended Negotiation for Receive Images of PROCESSING AE - Association Acceptance

SOP Class	Extended Negotiation	Support	Requested Value
Storage			
Applicable to all Storage SOP Classes listed under Section 0.	Level of support	N	
	Level of Digital Signature support	N	
	Element Coercion	N	

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 per Presentation Context provided by the Association initiator for Real-World Activity Receive Images of the PROCESSING AE of the system.

Table 7-5 Transfer Syntax Selection Preference Order - Image SOP Classes for PROCESSING AE

Preference Order	Transfer Syntax	UID	Comments
1	JPEG Lossless, Nonhierarchical, First- Order Prediction (Processes 14 [Selection Value 1])	1.2.840.10008.1.2.4.70	
2	JPEG Lossless, Nonhierarchical (Processes 14)	1.2.840.10008.1.2.4.57	
3	JPEG-LS Lossless Image Compression	1.2.840.10008.1.2.4.80	
4	RLE Lossless	1.2.840.10008.1.2.5	
5	JPEG 2000 Image Compression (Lossless Only)	1.2.840.10008.1.2.4.90	

Preference Order	Transfer Syntax	UID	Comments
6	Explicit VR Little Endian	1.2.840.10008.1.2.1	
7	Explicit VR Big Endian	1.2.840.10008.1.2.2	
8	Implicit VR Little Endian	1.2.840.10008.1.2	
9	JPEG Baseline (Process 1)	1.2.840.10008.1.2.4.50	
10	JPEG Extended (Process 2 & 4)	1.2.840.10008.1.2.4.51	
11	JPEG 2000 Image Compression	1.2.840.10008.1.2.4.91	

Table 7-6 Transfer Syntax Selection Preference Order - Non-Image SOP Classes for PROCESSING AE

Preference Order	Transfer Syntax	UID	Comments
1	Explicit VR Little-Endian Transfer Syntax	1.2.840.10008.1.2.1	
2	Implicit VR little-Endian Transfer Syntax	1.2.840.10008.1.2	

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 7-7 describes behavior of the AE if a communication failure occurs when it initiated an Association.

Table 7-7 DICOM Communication Failure Behavior as Association Initiator

Failure	Failure Behavior
Timeout	The Association is aborted using A-ABORT and command marked as failed. The reason is logged and reported to the user in the audit database. Automatic retry of this service connection is started.
Association aborted	The command is marked as failed. The reason is logged and reported to the user in the audit database. Automatic retry of this service connection is started.
Network Disconnect	The command is marked as failed. The reason is logged and reported to the user in the audit database. Automatic retry of this service connection is started

7.3.1.2 Communication Failure Handling as Association Acceptor

Table 7-8 describes how the AE responds when it receives an Association request that leads to a failure in communication.

Table 7-8 DICOM Communication Failure Handling as Association Acceptor

Exception	Failure response
Failure during processing of an Association request	A-ABORT message is sent out and the connection is closed.
Unrecognized Called AE	AE responds with Association-RJ A message is logged: “Reason: Called AE Title Not Recognized”
Exceed limit for number of connections supported	Pending associations are queued until resources are available to process them. There is no explicit limit, but timeouts may occur under extreme load.

7.3.2 DIMSE Services

7.3.2.1 Basic Worklist Management Service – N/A

7.3.2.2 Modality Performed Procedure Step Service – N/A

7.3.2.3 Unified Worklist und Procedure Step Service – N/A

7.3.2.4 Instance Availability Notification Service – N/A

7.3.2.5 Storage Service

7.3.2.5.1 SCU of the Storage SOP Classes - C-STORE

Table 7-9 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 7-9 Status Codes C-STORE for the Storage SOP Classes - SCU

Service Status	Further Meaning	Status Code	Behavior
Success	Success	0000	Normal operation
Warning	Coercion of Data Elements	B000	Ignored
	Data Set does not match SOP Class	B007	Ignored
	Elements Discarded	B006	Ignored
Failure	SOP Class not supported	0112	Log & Retry mechanism
	Invalid SOP Instance	0117	Log & Retry mechanism
	Duplicate Invocation	0210	Log & Retry mechanism
	Unrecognized Operation	0211	Log & Retry mechanism
	Mistyped Argument	0212	Log & Retry mechanism
	Not authorized	0214	Log & Retry mechanism
	Out of Resources	A700-A7FF	Log & Retry mechanism
	Data Set does not match SOP Class	A900-A9FF	Log & Retry mechanism
	Cannot Understand	C000-CFFF	Log & Retry mechanism
-	Other status codes	anything else	Logged & Ignored

7.3.2.5.2 SCP of the Storage SOP Classes - C-STORE

Table 7-10 lists the Status Codes that the SCP of the Storage SOP Classes supports for the C-STORE message and defines conditions in which the listed Status Codes are sent.

Table 7-10 Status Codes C-STORE of the Storage SOP Classes - SCP

Service Status	Further Meaning	Status Codes	Related Fields	Condition (and Comments on Related fields)
Success	Success	0000		Normal operation
Warning	Coercion of Data Elements	B000		Not used.
	Data Set does not match SOP Class	B007		Not used.
	Elements Discarded	B006		Not used.
Refused	Refused: Out of Resources	A700		Logged o Returned when creation of the file storage for the DICOM object fails. This may be for a variety of reasons, including disk space exhaustion, file system permissions, or data corruption. o Also returned when the STORE SCP is shutting down and no longer accepting connections.

Service Status	Further Meaning	Status Codes	Related Fields	Condition (and Comments on Related fields)
Failure	Error: Data Set does not match SOP Class	A900		Logged. o Returned when the C-STORE request attributes do not appear to match the transferred object attributes for SOP Class UID or SOP Instance UID
	Error: Cannot understand	C000		Logged o Returned when the received DICOM object appears to be uninterpretable due to missing required attributes, such as Study Instance UID, Series Instance UID, SOP Instance UID or SOP Class UID. o Also returned if directory creation fails for storing the received object.

7.3.2.6 Storage Commitment Service – N/A

7.3.2.7 Query/Retrieve Service

7.3.2.7.1 SCU of the Query/Retrieve FIND SOP Classes - C-FIND

Table 7-11 lists the Status Codes that the SCU of any of the Query/Retrieve FIND SOP Classes supports for the C-FIND message and defines the application behavior when encountering the listed Status Codes.

Table 7-11 Status Codes C-FIND for Query/Retrieve FIND SOP Classes - SCU

Service Status	Further Meaning	Status Code	Behavior
Success	Matching is complete - No final identifier is supplied	0000	Normal behavior
Failure	Refused: Out of Resources	A700	Log & Retry mechanism
	Error: Data Set does not match SOP Class	A900	Log & Retry mechanism
	Error: Unable to process	C000-CFFF	Log & Retry mechanism
	SOP Class Not Supported	0122	Log & Retry mechanism
Cancel	Matching terminated due to cancel	FE00	Log & Retry mechanism
Pending	Matches are continuing - Current Match is supplied and any Optional Keys were supported in the same manner as Required Keys.	FF00	Collect matching response
	Matches are continuing - Warning that one or more Optional Keys were not supported for existence for this Identifier	FF01	Ignored
-	Other status codes	anything else	Logged & Ignored

7.3.2.7.2 SCU of the Query/Retrieve MOVE SOP Classes - C-MOVE

Table 7-12 lists the Status Codes that the SCU of any of the Query/Retrieve MOVE SOP Classes supports for the C-MOVE message and defines the application behavior when encountering the listed Status Codes.

Table 7-12 Status Codes C-MOVE for Query/Retrieve MOVE SOP Classes - SCU

Service Status	Further Meaning	Status Codes	Related Fields	Behavior
Success	Sub-operations Complete - No Failures	0000	(0000,1020) (0000,1021) (0000,1022) (0000,1023)	Normal operation.
Warning	Sub-operations Complete - One or more Failures	B000	(0000,1020) (0000,1022) (0000,1023)	Log & Retry mechanism
Failed	Out of Resources - Unable to calculate number of matches	A701	(0000,0902)	Log & Retry mechanism
	Out of Resources - Unable to perform sub-operations	A702	(0000,1020) (0000,1021) (0000,1022) (0000,1023)	Log & Retry mechanism
	Move Destination unknown	A801	(0000,0902)	Log & Retry mechanism
	Data Set does not match SOP Class	A900	(0000,0901) (0000,0902)	Log & Retry mechanism
	Unable to process	Cxxx	(0000,0901) (0000,0902)	Log & Retry mechanism
Cancel	Sub-operations terminated due to Cancel Indication	FE00	(0000,1020) (0000,1021) (0000,1022) (0000,1023)	Log & Retry mechanism
Pending	Sub-operations are continuing	FF00	(0000,1020) (0000,1021) (0000,1022) (0000,1023)	Logged & ignored.
-	Other status codes	anything else	-	Logged & ignored.

7.3.2.7.3 SCP of the Query/Retrieve FIND SOP Classes - C-FIND – N/A

7.3.2.7.4 SCP of the Query/Retrieve MOVE SOP Classes - C-MOVE – N/A

7.3.2.8 Print Management Service – N/A

7.3.3 DICOM Web Services – 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 GAID PRO software.

Table 8-1 External Network Requirements

Profile	Actor	Transaction	Protocol Used	RFCs	Security Support	Reference
Basic Time Synchronization	NTP Client	Maintain Time	NTP	RFC5905; RFC5906; RFC8633	Y	C.1.1
		Find NTP Servers	NTP	RFC5905; RFC5906; RFC8633	Y	C.1.1
Basic Network Address Management	DHCP Client	Find and Use DHCP Server	DHCP	RFC2131; RFC2132; RFC2563	Y	C.1.2
		Maintain Lease	DHCP	RFC2131; RFC2132	Y	C.1.2
	DNS Client	Resolve Hostname	DNS	RFC1035; RFC2181; RFC4033; RFC4034; RFC4035	Y	C.1.2

8.3 TCP Port Configuration

See Section 0 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.

TCP Port	Protocol	Actor(s)	Purpose
80	http	Application proxy / Load balancer	Redirect to https (port 443) or serving un-encrypted content.
443	https (http + TLS)	Application proxy / Load balancer	Serving TLS encrypted http content.
104 (SERVICE)	DICOM	STORE-SCP	DICOM access
22	Ssh	Service engineers	Secure servicing.

8.4 DICOM Security Profiles Support

8.4.1 Secure Use and User Identity Profiles

Table 8-2 lists the Secure Use and User Identity Profiles:

Table 8-2 Secure Use and User Identity Profiles

Profile	Creator/Sender	Consumer/Receiver	Reference
Online Electronic Storage Secure Use	N	N	C.2.1
Audit Trail Message Format	N	N	C.2.2
Audit Trail Message Transmission Profile - SYSLOG-TLS	N	N	C.2.3
Audit Trail Message Transmission Profile - SYSLOG-UDP	N	N	C.2.4

Profile	Creator/Sender	Consumer/Receiver	Reference
Basic User Identity Association	N	N	8.5
User Identity Plus Passcode Association	N	N	8.5
Kerberos Identity Negotiation Association	N	N	8.5
Generic SAML Assertion Identity Negotiation Association	N	N	8.5

8.4.2 Secure Transport Connection Profiles – N/A

8.4.3 Media Storage Security Profiles – N/A

8.4.4 Attribute Confidentiality Profiles – N/A

8.4.5 Digital Signature Profiles – N/A

8.4.6 Additional DICOM Security Profiles – N/A

8.5 User Identity Negotiation Support – N/A

8.6 Web Services Security Features

GAID PRO software does not expose any DICOM Web services. Standard (http-based) web services are exposed through a load-balancer / application proxy with https (TLS encryption) as the default entry point.

8.7 Other Security Features

8.7.1 Media Storage Security – N/A

8.7.2 Network Security – N/A

8.7.3 Other Security Features

User access to the configuration web user interface requires authentication. This may use an internal user database or external LDAP service for authentication. Passwords are only stored in secure hashed form.

Annexes

A Information Object Definitions (IODs)

This section describes all the SOP Instances natively created by GAID PRO software, 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).

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 GAID PRO software implementation and is not necessarily the same as defined in the DICOM Standard. For the "Presence" columns 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).

A.1 Information Shared Across Multiple IODs

A.1.1 Common Modules

All SOP Instances generated by the system use the common modules listed in

Table A-1 to Table A-4 or a subset of them, as defined in the IOD specific subsections below.

Table A-1 Patient Module

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Patient's Name	(0010,0010)	SRC_INSTANCE	ALWAYS	SRC_COPY			
Patient ID	(0010,0020)	SRC_INSTANCE	ALWAYS	SRC_COPY			
Issuer of Patient ID	(0010,0021)	SRC_INSTANCE	SRC_COPY	SRC_COPY			
Patient's Birth Date	(0010,0030)	SRC_INSTANCE	ALWAYS	SRC_COPY			
Patient's Sex	(0010,0040)	SRC_INSTANCE	ALWAYS	SRC_COPY			

Table A-2 General Study Module

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Study Date	(0008,0020)	SRC_INSTANCE	ALWAYS	SRC_COPY			
Study Time	(0008,0030)	SRC_INSTANCE	ALWAYS	SRC_COPY			
Accession Number	(0008,0050)	SRC_INSTANCE	ALWAYS	SRC_COPY			
Referring Physician's Name	(0008,0090)	SRC_INSTANCE	ALWAYS	SRC_COPY			
Study Description	(0008,1030)	SRC_INSTANCE	ALWAYS	SRC_COPY			
Study Instance UID	(0020,000D)	SRC_INSTANCE	ALWAYS	SRC_COPY			
Study ID	(0020,0010)	SRC_INSTANCE	ALWAYS	SRC_COPY			

Table A-3 General Equipment Module

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Manufacturer	(0008,0070)	FIXED	ALWAYS	ALWAYS	Therapixel		
Manufacturer's Model Name	(0008,1090)	FIXED	ALWAYS	ALWAYS	Genius AI Detection PRO		
UDI Sequence	(0018,100A)	GENERATED	CONDITIONAL	CONDITIONAL	One item	SC Image only	
>Unique Device Identifier	(0018,1009)	GENERATED	ALWAYS	ALWAYS			
>Device Description	(0050,0020)	GENERATED	ALWAYS	ALWAYS			
Software Versions	(0018,1020)	GENERATED	ALWAYS	ALWAYS			

Table A-4 SOP Common Module

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Specific Character Set	(0008,0005)	FIXED	ALWAYS	ALWAYS	ISO_IR 192 for SC Image, ISO_IR 100 for Mammography CAD SR		
Instance Creation Date	(0008,0012)	GENERATED	ALWAYS	ALWAYS			
Instance Creation Time	(0008,0013)	GENERATED	ALWAYS	ALWAYS			
SOP Class UID	(0008,0016)	FIXED	ALWAYS	ALWAYS	UID for • Multi-frame True Color Secondary Capture Image Storage • or Secondary Capture Image Storage or Mammography		

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
					CAD SR Storage		
SOP Instance UID	(0008,0018)	GENERATED	ALWAYS	ALWAYS			
Timezone Offset From UTC	(0008,0201)	GENERATED	CONDITIONAL	CONDITIONAL		SC Image only	
Instance Number	(0020,0013)	GENERATED	ALWAYS	ALWAYS			

A.1.2 Common Functional Group Macros – N/A

A.1.3 Common Private Modules

The table below lists private Attributes that are used in multiple IODs generated by the system. For documentation convenience and readability, they are organized in a module, although the concept of modules does not exist in the standard for private Attributes.

Note: By default, xx=10.

Table A-5 Private Module 1

Attribute Name	Tag	VR	VM	Identifiable Information	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Private Creator	(30F3,00xx)	LO	1	SAFE	FIXED	ALWAYS	ALWAYS	Therapixel		
Therapixel-InstitutionUid	(30F3,xx39)	LO	1	SAFE	GENERATED	ALWAYS	ALWAYS			ID of center for which report was generated
Therapixel-ReportUuid	(30F3,xx57)	LO	1	SAFE	GENERATED	ALWAYS	ALWAYS			Unique ID of source report
Therapixel-ReportDate	(30F3,xx59)	DA	1	SAFE	GENERATED	CONDITIONAL	ALWAYS		Mammography CAD SR only	Date reported generated in UTC
Therapixel-ReportTime	(30F3,xx61)	TM	1	SAFE	GENERATED	CONDITIONAL	ALWAYS		Mammography CAD SR only	Time report generated in UTC
Therapixel-SrExportFormat	(30F3,xx63)	LO	1	SAFE	GENERATED	CONDITIONAL	ALWAYS	Default=generic	Mammography CAD SR only	Structured Report content constraint
Therapixel-ExecutionStateCode	(30F3,xx64)	SS	1	SAFE		CONDITIONAL	ALWAYS		SC Image only	Processing execution code
Therapixel-TherapixelAddress	(30F3,xx76)	LO	1	SAFE		CONDITIONAL	ALWAYS		SC Image only	Therapixel address
Therapixel-DateOfFirstCeMark	(30F3,xx77)	DA	1	SAFE		CONDITIONAL	ALWAYS		SC Image only	Date of first CE mark

A.1.4 Coded Values – N/A

A.2 Mammography CAD SR IOD

Table A-6 defines the structure of Mammography CAD SR IOD.

Table A-6 Mammography CAD SR IOD

IE	Module Name	Presence (Module)	Condition	Reference
Patient	Patient Module	ALWAYS		Table A-1
Study	General Study Module	ALWAYS		Table A-2
Series	SR Document Series Module	ALWAYS		Table A-7
Equipment	General Equipment Module	ALWAYS		Table A-3
Document	SR Document General Module	ALWAYS		Table A-8
	SR Document Content Module	ALWAYS		Table A-9
	SOP Common Module	ALWAYS		Table A-4
	Private Module 1	ALWAYS		**Table** A-5

A.2.1 Mammography CAD SR IOD Specific Modules

The tables below list modules and Attributes for Mammography CAD SR IOD*:*

Table A-7 SR Document Series Module for Mammography CAD SR IOD

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Series Date	(0008,0021)	GENERATED	ALWAYS	ALWAYS			
Series Time	(0008,0031)	GENERATED	ALWAYS	ALWAYS			
Modality	(0008,0060)	FIXED	ALWAYS	ALWAYS	SR		
Series Description	(0008,103E)	CONFIGURATION	ALWAYS	ALWAYS	Genius AI Detection PRO Report		
Referenced Performed Procedure Step Sequence	(0008,1111)	EMPTY	ALWAYS	EMPTY			
Series Instance UID	(0020,000E)	GENERATED	ALWAYS	ALWAYS			
Series Number	(0020,0011)	CONFIGURATION	ALWAYS	ALWAYS	Default = 83200000		

Table A-8 SR Document General Module for Mammography CAD SR IOD

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Content Date	(0008,0023)	GENERATED	ALWAYS	ALWAYS			
Content Time	(0008,0033)	GENERATED	ALWAYS	ALWAYS			
Instance Number	(0020,0013)	GENERATED	ALWAYS	ALWAYS	Incremental counter starting from 1 (per Series)		
Performed Procedure Code Sequence	(0040,A372)	EMPTY	ALWAYS	EMPTY			

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Current Requested Procedure Evidence Sequence	(0040,A375)	GENERATED	ALWAYS	ALWAYS	One item		
>Referenced Series Sequence	(0008,1115)	GENERATED	ALWAYS	ALWAYS	One Item for each analyzed image		
>>Referenced SOP Sequence	(0008,1199)	GENERATED	ALWAYS	ALWAYS	One item		
>>>Referenced SOP Class UID	(0008,1150)	SRC_INSTANCE	ALWAYS	SRC_COPY	1.2.840.10008.5.1.4.1.1.13.1.3 or 1.2.840.10008.5.1.4.1.1.1.2		
>>> Referenced SOP Instance UID	(0008,1155)	SRC_INSTANCE	ALWAYS	SRC_COPY			
>>Series Instance UID	(0020,000E)	SRC_INSTANCE	ALWAYS	SRC_COPY			
>Study Instance UID	(0020,000D)	SRC_INSTANCE	ALWAYS	SRC_COPY			
Completion Flag	(0040,A491)	GENERATED	ALWAYS	ALWAYS	COMPLETE		
Verification Flag	(0040,A493)	GENERATED	ALWAYS	ALWAYS	UNVERIFIED		

Table A-9 SR Document Content Module for Mammography CAD SR IOD

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Value Type	(0040,A040)	FIXED	ALWAYS	ALWAYS	CONTAINER		
Concept Name Code Sequence	(0040,A043)	GENERATED	ALWAYS	ALWAYS			
>Code Value	(0008,0100)	FIXED	ALWAYS	ALWAYS	111036		
>Coding Scheme Designator	(0008,0102)	FIXED	ALWAYS	ALWAYS	DCM		
>Code Meaning	(0008,0104)	FIXED	ALWAYS	ALWAYS	Mammography CAD Report		
Continuity of Content	(0040,A050)	FIXED	ALWAYS	ALWAYS	SEPARATE		
Content Template Sequence	(0040,A504)	GENERATED	ALWAYS	ALWAYS			
>Mapping Resource	(0008,0105)	FIXED	ALWAYS	ALWAYS	DCMR		
>Template Identifier	(0040,DB00)	FIXED	ALWAYS	ALWAYS	4000		
Content Sequence	(0040,A730)	GENERATED	ALWAYS	ALWAYS	See Table B-1 for TID 4000 encoding		

A.2.2 Mammography CAD SR IOD Functional Group Macros - N/A

A.2.3 Mammography CAD SR IOD Private Modules – N/A

A.2.4 Mammography CAD SR IOD Coded Values

Refer to IOD specific tables.

A.3 Secondary Capture Image IOD

Table A-10 defines the structure of Secondary Capture Image IOD and Multi-frame True Color Secondary Capture Image IOD.

Table A-10 Secondary Capture Image IOD

IE	Module Name	Presence (Module)	Condition	Reference
Patient	Patient Module	ALWAYS		Table A-1
Study	General Study Module	ALWAYS		Table A-2
Series	General Series Module	ALWAYS		Table A-11
Equipment	General Equipment Module	ALWAYS		Table A-3
	SC Equipment Module	ALWAYS		Table A-12
Acquisition	General Acquisition Module	ALWAYS		Table A-13
Image	General Image Module	ALWAYS		Table A-14
	General Reference Module	ALWAYS		Table A-15
	Image Pixel Module	ALWAYS		Table A-16
	Multi-frame Module	CONDITIONAL	Multi-frame only	Table A-17
	SC Multi-frame Image Module	CONDITIONAL	Multi-frame only	Table A-18
	SC Multi-frame Vector Module	CONDITIONAL	Multi-frame only when Number of Frames > 1	Table A-19
	SOP Common Module	ALWAYS		Table A-4
	Private Module 1	ALWAYS		Table A-5

A.3.1 Secondary Capture Image IOD Specific Modules

The tables below list modules and Attributes for Secondary Capture Image IOD:

Table A-11 General Series Module for Secondary Capture Image IOD

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Series Date	(0008,0021)	GENERATED	ALWAYS	ALWAYS			
Series Time	(0008,0031)	GENERATED	ALWAYS	ALWAYS			
Modality	(0008,0060)				See Table A-12		
Series Description	(0008,103E)	CONFIGURATION	ALWAYS	ALWAYS	Genius AI Detection PRO Report		
Series Instance UID	(0020,000E)	GENERATED	ALWAYS	ALWAYS			
Series Number	(0020,0011)	CONFIGURATION	ALWAYS	ALWAYS	Default = “999999990”		

Table A-12 SC Equipment Module for Secondary Capture Image IOD

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Modality	(0008,0060)	CONFIGURATION	ALWAYS	ALWAYS	Default = OT		
Conversion Type	(0008,0064)	FIXED	ALWAYS	ALWAYS	SYN		
Secondary Capture Device Software Versions	(0018,1019)	GENERATED	ALWAYS	ALWAYS			

Table A-13 General Acquisition Module for Secondary Capture Image IOD

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Acquisition DateTime	(0008,002A)	EMPTY	ALWAYS	EMPTY			

Table A-14 General Image Module for Secondary Capture Image IOD

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Image Type	(0008,0008)	FIXED	ALWAYS	ALWAYS	DERIVED\SECONDARY		
Content Date	(0008,0023)	GENERATED	ALWAYS	ALWAYS	Date of GAID PRO report processing.		
Content Time	(0008,0033)	GENERATED	ALWAYS	ALWAYS	Time of GAID PRO report processing.		
Instance Number	(0020,0013)	GENERATED	ALWAYS	ALWAYS	Incremental counter starting from 1 (per Series)		
Patient Orientation	(0020,0020)	EMPTY	ALWAYS	EMPTY			
Image Laterality	(0020,0062)	GENERATED	ALWAYS	ALWAYS	L, R or B		
Burned in Annotation	(0028,0301)	FIXED	ALWAYS	ALWAYS	NO		

Table A-15 General Reference Module for Secondary Capture Image IOD

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Derivation Description	(0008,2111)	FIXED	ALWAYS	ALWAYS			

Table A-16 Image Pixel Module for Secondary Capture Image IOD

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Samples per Pixel	(0028,0002)	FIXED	ALWAYS	ALWAYS	3		
Photometric Interpretation	(0028,0004)	FIXED	ALWAYS	ALWAYS	RGB		
Planar Configuration	(0028,0006)	FIXED	ALWAYS	ALWAYS	0		
Rows	(0028,0010)	CONFIGURATION	ALWAYS	ALWAYS	Default = 960		
Columns	(0028,0011)	CONFIGURATION	ALWAYS	ALWAYS	Default = 960		

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Bits Allocated	(0028,0100)	FIXED	ALWAYS	ALWAYS	8		
Bits Stored	(0028,0101)	FIXED	ALWAYS	ALWAYS	8		
High Bit	(0028,0102)	FIXED	ALWAYS	ALWAYS	7		
Pixel Representation	(0028,0103)	FIXED	ALWAYS	ALWAYS	0		
Pixel Data	(7FE0,0010)	GENERATED	ALWAYS	ALWAYS	Processed views in 2x2 layout, results burned into images		

Table A-17 Multi-Frame Module for Multi-frame True Color Secondary Capture Image IOD

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Number of Frames	(0028,0008)	GENERATED	ALWAYS	ALWAYS			
Frame Increment Pointer	(0028,0009)	GENERATED	ALWAYS	ALWAYS	See Table A-18		

Table A-18 SC Multi-Frame Image Module for Multi-frame True Color Secondary Capture Image IOD

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Burned in Annotation	(0028,0301)	FIXED	ALWAYS	ALWAYS	NO		
Frame Increment Pointer	(0028,0009)	FIXED	ALWAYS	ALWAYS	(0018,2001)		

Table A-19 SC Multi-Frame Vector Module for Multi-frame True Color Secondary Capture Image IOD

Attribute Name	Tag	Source	Presence of Attribute	Presence of Value	Value	Conditions	Comments
Page Number Vector	(0018,2001)	GENERATED	ALWAYS	ALWAYS			

A.3.2 Secondary Capture Image IOD Functional Group Macros - N/A

A.3.3 Secondary Capture Image IOD Private Modules – N/A

A.3.4 Secondary Capture Image IOD Coded Values

Refer to IOD specific tables.

A.4 Basic Directory IOD – N/A

B Structured Report Content Encoding

This section provides the detailed content encoding for all TIDs supported by GAID PRO software.

Throughout the tables listed in Annex 0 the following codes are used for the "Source" and "Presence of Content Item" columns.

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.

In the "Presence of Content Item" 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 "Comments" 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).

B.1 Mammography CAD SR (TID 4000)

Table B-1 shows the encoding of content of a DICOM Mammography CAD SR (TID 4000).

Table B-1 Mammography CAD Document Root (TID 4000)

NL	Rel with Parent	VT	Concept Name	Source	Presence of Content Item	Values	TID	Comments
		CONTAINER	(111036, DCM, "Mammography CAD Report")	FIXED	ALWAYS		4000	
>	HAS CONCEPT MOD	CODE	(121049, DCM, "Language of Content Item and Descendants")	CONFIGURATION	ALWAYS	(eng, ISO639_2, “English”)	1204	
>>	HAS CONCEPT MOD	CODE	(121046, DCM, "Country of Language")	CONFIGURATION	ALWAYS	(US, ISO3166_1, "UNITED STATES")	1204	
>	CONTAINS	CONTAINER	(111028, DCM, "Image Library")	FIXED	ALWAYS	(Continuity of Content = “SEPARATE”)	4020	
>>	CONTAINS	IMAGE		SRC_INSTANCE	SRC_COPY	One Item per referenced image and referenced frame	4020	One Item per referenced image and referenced frame

NL	Rel with Parent	VT	Concept Name	Source	Presence of Content Item	Values	TID	Comments
>>>	HAS ACQ CONTEXT	CODE	(111027, DCM, "Image Laterality")	SRC_INSTANCE	SRC_COPY	See Table B-9	4020	(0020,0062) or (0020,9072)
>>>	HAS ACQ CONTEXT	CODE	(111031, DCM, "Image View")	SRC_INSTANCE	SRC_COPY	See Table B-10	4020	(0054,0220)
>>>>	HAS CONCEPT MOD	CODE	(111032, DCM, "Image View Modifier")	SRC_INSTANCE	SRC_COPY	See Table B-11	4020	(0054,0222)
>>>	HAS ACQ CONTEXT	TEXT	(111044, DCM, "Patient Orientation Row")	SRC_INSTANCE	SRC_COPY		4020	(0020,0020) Value 1
>>>	HAS ACQ CONTEXT	TEXT	(111043, DCM, "Patient Orientation Column")	SRC_INSTANCE	SRC_COPY		4020	(0020,0020) Value 2
>>>	HAS ACQ CONTEXT	DATE	(111060, DCM, "Study Date")	SRC_INSTANCE	SRC_COPY		4020	(0008,0020)
>>>	HAS ACQ CONTEXT	TIME	(111061, DCM, "Study Time")	SRC_INSTANCE	SRC_COPY		4020	(0008,0030)
>>>	HAS ACQ CONTEXT	DATE	(111018, DCM, "Content Date")	SRC_INSTANCE	SRC_COPY		4020	(0008,0023)
>>>	HAS ACQ CONTEXT	TIME	(111019, DCM, "Content Time")	SRC_INSTANCE	SRC_COPY		4020	(0008,0033)
>>>	HAS ACQ CONTEXT	NUM	(111026, DCM, "Horizontal Pixel Spacing")	SRC_INSTANCE	SRC_COPY	UNITS = (um, UCUM, ”micrometer”)	4020	(0018,1164) or (0028,0030) Value 1
>>>	HAS ACQ CONTEXT	NUM	(111066, DCM, "Vertical Pixel Spacing")	SRC_INSTANCE	SRC_COPY	UNITS = (um, UCUM, ”micrometer”)	4020	(0018,1164) or (0028,0030) Value 2
>	CONTAINS		See Table B-2					
>	CONTAINS		See Table B-7					
>	CONTAINS	CODE	(111065, DCM, "Summary of Analyses")	FIXED	ALWAYS	(111225, DCM, “Not Attempted”)	4000	

Table B-2 CAD PROCESSING AND FINDING SUMMARY (TID 4001, TID 4002)

NL	Rel with Parent	VT	Concept Name	Source	Presence of Content Item	Values	TID	Comments
		CODE	(111017, DCM, "CAD Processing and Findings Summary")	GENERATED	ALWAYS	See Table B-12	4001	
>	HAS PROPERTIES	TEXT	(111033, DCM, "Impression Description")	FIXED	ALWAYS	Case Score	4002	
>	HAS PROPERTIES	NUM	(111013, DCM, ”Certainty of impression”)	GENERATED	ALWAYS	UNITS = (%, UCUM, ”Percent”)	4002	
>	HAS PROPERTIES	TEXT	(111001, DCM, "Algorithm Name")	FIXED	ALWAYS	Genius AI Detection PRO	4019	

NL	Rel with Parent	VT	Concept Name	Source	Presence of Content Item	Values	TID	Comments
>	HAS PROPERTIES	TEXT	(111003, DCM, "Algorithm Version")	FIXED	ALWAYS	3.1.0	4019	
>	HAS PROPERTIES	NUM	(10001, 99THERAPIXEL, ”Breast Score”)	GENERATED	ALWAYS	UNITS = (%, UCUM, ”Percent”)	4002	
>>	HAS CONCEPT MOD	CODE	(G-C171, SRT, ”Laterality”)	FIXED	ALWAYS	(T-04030, SRT, ”Left breast”)	4002	
>>	HAS CONCEPT MOD	CODE	(121401, DCM, ”Derivation”)	FIXED	ALWAYS	(112187, DCM, ”Unspecified method of calculation”)	4002	
>	HAS PROPERTIES	NUM	(10001, 99THERAPIXEL, ”Breast Score”)	GENERATED	ALWAYS	UNITS = (%, UCUM, ”Percent”)	4002	
>>	HAS CONCEPT MOD	CODE	(G-C171, SRT, ”Laterality”)	FIXED	ALWAYS	(T-04020, SRT, ”Right breast”)	4002	
>>	HAS CONCEPT MOD	CODE	(121401, DCM, ”Derivation”)	FIXED	ALWAYS	(112187, DCM, ”Unspecified method of calculation”)	4002	
>	HAS PROPERTIES	NUM	(10003, 99THERAPIXEL, ”Case Complexity Index”)	GENERATED	ALWAYS	UNITS = ([arb’U], UCUM, ”arbitrary unit”)	4002	
>>	HAS CONCEPT MOD	CODE	(121401, DCM, ”Derivation”)	FIXED	ALWAYS	(112187, DCM, ”Unspecified method of calculation”)	4002	
>>	INFERRED FROM	TEXT	(112034, DCM, ”Calculation Description”)	GENERATED	ALWAYS	“Less”, “Medium”, or “More”	4002	
>	INFERRED FROM		See Table B-3					Repeat for each individual impression / recommendation included in the report. Not present if there are no single image findings to report.

Table B-3 INDIVIDUAL IMPRESSION / RECOMMENDATION (TID 4003)

NL	Rel with Parent	VT	Concept Name	Source	Presence of Content Item	Values	TID	Comments
		CONTAINER	(111034, DCM, ”Individual Impression / Recommendation”)	GENERATED	ALWAYS	Continuity of Content = ”SEPARATE”	4003	
>	HAS CONCEPT MOD	CODE	(111056, DCM, "Rendering Intent")	FIXED		(111150, DCM, ”Presentation Required:	4003	

						Rendering device is expected to present")		
>	CONTAINS							See Table B-4 for Breast composition (density), Table B-5 for Mammography breast density and Table B-6 for Calcification Cluster single image findings.

Table B-4 BREAST COMPOSITION CHARACTERISTICS (TID 4006, TID 4007)

NL	Rel with Parent	VT	Concept Name	Source	Presence of Content Item	Values	TID	Comments
		CODE	(111059, DCM, "Single Image Finding")	GENERATED	CONDITIONAL	(F-01710, SRT, "Breast composition")	4006	Present if breast composition was assessed.
>	HAS CONCEPT MOD	CODE	(111056, DCM, "Rendering Intent")	FIXED	ALWAYS	(111150, DCM, "Presentation Required: Rendering device is expected to present")	4006	
>	HAS PROPERTIES	TEXT	(111001, DCM, "Algorithm Name")	FIXED	ALWAYS	Genius AI Detection PRO	4019	
>	HAS PROPERTIES	TEXT	(111003, DCM, "Algorithm Version")	FIXED	ALWAYS	3.1.0	4019	
>	HAS PROPERTIES	CODE	(F-01710, SRT, "Breast composition")	GENERATED	ALWAYS	See Table B-13	4007	

Table B-5 MAMMOGRAPHY BREAST DENSITY CHARACTERISTICS (TID 4006)

NL	Rel with Parent	VT	Concept Name	Source	Presence of Content Item	Values	TID	Comments
		CODE	(111059, DCM, "Single Image Finding")	GENERATED	CONDITIONAL	(F-01796, SRT, "Mammography breast density")	4006	Present if Mammography breast density was detected.
>	HAS CONCEPT MOD	CODE	(111056, DCM, "Rendering Intent")	FIXED		(111150, DCM, "Presentation Required: Rendering device is expected to present")	4006	
>	HAS PROPERTIES	TEXT	(111001, DCM, "Algorithm Name")	FIXED	ALWAYS	Genius AI Detection PRO	4019	
>	HAS PROPERTIES	TEXT	(111003, DCM, "Algorithm Version")	FIXED	ALWAYS	3.1.0	4019	

>	HAS PROPERTIES	NUM	(111012, DCM, ”Certainty of Finding”)	GENERATED	ALWAYS	UNITS = (%, UCUM, ”Percent”)	4006	
>	HAS PROPERTIES	SCOORD	(111010, DCM, ”Center”)	GENERATED	ALWAYS	POINT	4021	
>>	R-SELECTED FROM	IMAGE		GENERATED	ALWAYS		4021	Image Library
>	HAS PROPERTIES	SCOORD	(111041, DCM, ”Outline”)	GENERATED	ALWAYS	CIRCLE	4021	
>>	R-SELECTED FROM	IMAGE		GENERATED	ALWAYS		4021	Image Library
>	HAS PROPERTIES	NUM	(10002, 99THERAPIXEL, ”Finding identifier”)	GENERATED	ALWAYS	UNITS = (1, UCUM, ”no units”)	4006	
>>	HAS CONCEPT MOD	CODE	(121401, DCM, ”Derivation”)	FIXED	ALWAYS	(112187, DCM, ”Unspecified method of calculation”)	4006	

Table B-6 CALCIFICATION CLUSTER CHARACTERISTICS (TID 4006)

NL	Rel with Parent	VT	Concept Name	Source	Presence of Content Item	Values	TID	Comments
		CODE	(111059, DCM, "Single Image Finding")	GENERATED	CONDITIONAL	(F-01775, SRT, ”Calcification Cluster”)	4006	Present if Calcification Cluster was detected.
>	HAS CONCEPT MOD	CODE	(111056, DCM, "Rendering Intent")	FIXED	ALWAYS	(111150, DCM, ”Presentation Required: Rendering device is expected to present”)	4006	
>	HAS PROPERTIES	TEXT	(111001, DCM, "Algorithm Name")	FIXED	ALWAYS	Genius AI Detection PRO	4019	
>	HAS PROPERTIES	TEXT	(111003, DCM, "Algorithm Version")	FIXED	ALWAYS	3.1.0	4019	
>	HAS PROPERTIES	NUM	(111012, DCM, ”Certainty of Finding”)	GENERATED	ALWAYS	UNITS = (%, UCUM, ”Percent”)	4006	
>	HAS PROPERTIES	SCOORD	(111010, DCM, ”Center”)	GENERATED	ALWAYS	POINT	4021	
>>	R-SELECTED FROM	IMAGE		GENERATED	ALWAYS		4021	Image Library
>	HAS PROPERTIES	SCOORD	(111041, DCM, ”Outline”)	GENERATED	ALWAYS	POLYLINE	4021	4 points, closed triangle
>>	R-SELECTED FROM	IMAGE		GENERATED	ALWAYS		4021	Image Library
>	HAS PROPERTIES	NUM	(10002, 99THERAPIXEL, ”Finding identifier”)	GENERATED	ALWAYS	UNITS = (1, UCUM, ”no units”)	4006	
>>	HAS CONCEPT MOD	CODE	(121401, DCM, ”Derivation”)	FIXED	ALWAYS	(112187, DCM, ”Unspecified method of calculation”)	4006	

Table B-7 SUMMARY OF DETECTIONS (TID 4000, TID 4015)

NL	Rel with Parent	VT	Concept Name	Source	Presence of Content Item	Values	TID	Comments
		CODE	(111064, DCM, "Summary of Detections")	GENERATED	ALWAYS	See Table B-14	4000	
>	INFERRED FROM	CONTAINER	(111063, DCM, "Successful Detections")	GENERATED	ALWAYS	Continuity of Content = ”SEPARATE”	4015	
>>	CONTAINS		See Table B-8					
>	INFERRED FROM	CONTAINER	(111025, DCM, ”Failed Detections”)	GENERATED	ALWAYS	Continuity of Content = ”SEPARATE”	4015	
>>	CONTAINS		See Table B-8					

Table B-8 DETECTION PERFORMED CHARACTERISTICS (TID 4017, TID 4019)

NL	Rel with Parent	VT	Concept Name	Source	Presence of Content Item	Values	TID	Comments
		CODE	(111022, DCM, "Detection Performed")	GENERATED	ALWAYS	(F-01796, SRT, ”Mammography breast density”) or (F-01775, SRT, ”Calcification Cluster”)	4017	
>	HAS PROPERTIES	TEXT	(111001, DCM, "Algorithm Name")	FIXED	ALWAYS	Genius AI Detection PRO	4019	
>	HAS PROPERTIES	TEXT	(111003, DCM, "Algorithm Version")	FIXED	ALWAYS	3.1.0	4019	
>	R-HAS PROPERTIES	IMAGE		GENERATED	ALWAYS		4017	Image Library, one item per analyzed image.

B.1.1 Code Sets

The following tables list specific code sets referenced from the Mammography CAD SR (TID 4000).

Table B-9 Mammography CAD SR - Side Codes

Coding Scheme Designator	Code Value	Code Meaning
SRT	T-04030	Left breast
SRT	T-04020	Right breast

Table B-10 Mammography CAD SR - Image View Codes

Coding Scheme Designator	Code Value	Code Meaning
SRT	R-10224	medio-lateral
SRT	R-10226	medio-lateral oblique
SRT	R-10228	latero-medial
SRT	R-10230	latero-medial oblique
SRT	R-10242	cranio-caudal
SRT	R-10244	caudo-cranial (from below)

Coding Scheme Designator	Code Value	Code Meaning
SRT	R-102D0	superolateral to inferomedial oblique
SRT	R-40AAA	inferomedial to superolateral oblique
SRT	R-102CF	exaggerated cranio-caudal
SRT	R-1024A	cranio-caudal exaggerated laterally
SRT	R-1024B	cranio-caudal exaggerated medially

Table B-11 Mammography CAD SR - Image View Modifier Codes

Coding Scheme Designator	Code Value	Code Meaning
SRT	R-102D1	Axillary Tail
SRT	R-102D3	Rolled Lateral
SRT	R-102D4	Rolled Medial
SRT	R-102CA	Rolled Inferior
SRT	R-102C9	Rolled Superior
SRT	R-102D5	Implant Displaced
SRT	R-102C2	Tangential
SRT	R-40AB3	Nipple in profile
SRT	P2-00161	Anterior compression
SRT	R-40ABE	Infra-mammary fold
SRT	R-40AB2	Axillary tissue

Table B-12 Mammography CAD SR – CAD Processing and Findings Summary Codes

Coding Scheme Designator	Code Value	Code Meaning
DCM	111241	All algorithms succeeded; without findings
DCM	111242	All algorithms succeeded; with findings
DCM	111243	Not all algorithms succeeded; without findings
DCM	111244	Not all algorithms succeeded; with findings
DCM	111245	No algorithms succeeded; without findings

Table B-13 Mammography CAD SR - Breast Composition Codes

Coding Scheme Designator	Code Value	Code Meaning
SRT	F-01711	Almost entirely fat
SRT	F-01712	Scattered fibroglandular densities
SRT	F-01713	Heterogeneously dense
SRT	F-01714	Extremely dense

Table B-14 Mammography CAD SR – Result Status Codes

Coding Scheme Designator	Code Value	Code Meaning
DCM	111222	Succeeded
DCM	111223	Partially Succeeded
DCM	111224	Failed
DCM	111225	Not Attempted

C Security Details

This section provides additional details about security features that are formally described in Section 8.

C.1 External Network Requirement Details

C.1.1 Basic Time Synchronization

Network time synchronization following RFC 8633 is handled by the VM host operating system (Ubuntu). Refer to the operating system documentation for further information.

C.1.2 Basic Network Address Management

Network addressing is handled by the VM host operating system (Ubuntu). It may be configured to use DHCP and / or DNSSEC by servicing agents. Refer to the operating system documentation for further information.

C.1.3 Application Configuration Management – N/A

C.1.4 DNS Service Discovery – N/A

C.2 DICOM Security Profile Details

C.2.1 Online Electronic Storage Secure Use

GAID PRO software allows access via:

- A web interface for which user access may be controlled by username and password.
- A DICOM interface which allows C-STORE actions from any source.
- Ssh interface using secure private keys for service purposes.

C.2.2 Audit Trail Messages – N/A

GAID PRO software does not generate DICOM compliant audit messages.

C.2.3 Audit Trail Message Transmission Profile - SYSLOG - TLS

See Section 6.6 Audit Trail Syslog Configuration for information about Syslog-TLS parameters.

C.2.4 Audit Trail Message Transmission Profile - SYSLOG - UDP

See Section 6.6 Audit Trail Syslog Configuration for information about Syslog-UDP parameters.

C.2.5 Secure Transport Connection Details – N/A

C.2.6 Attribute Confidentiality Details – N/A

The product does not support Attribute Confidentiality Profiles.

C.2.7 Digital Signature Details – N/A

The product does not support DICOM Digital Signatures.

C.2.8 Additional DICOM Security Profile Details – N/A

The product does not support any additional DICOM Security Profile.

D Mapping of Attributes – N/A

E Code Set Usage

Private codes used in Mammography CAD SR SOP Instances.

Code Value	Coding Scheme Designator	Code Meaning	Notes
10001	99THERAPIXEL	Breast Score	Breast-Level GAID PRO score.
10002	99THERAPIXEL	Finding identifier	Identifier used to relate findings present on different source images.
10003	99THERAPIXEL	Case Complexity Index	A value indicating the estimated complexity of reading the case.