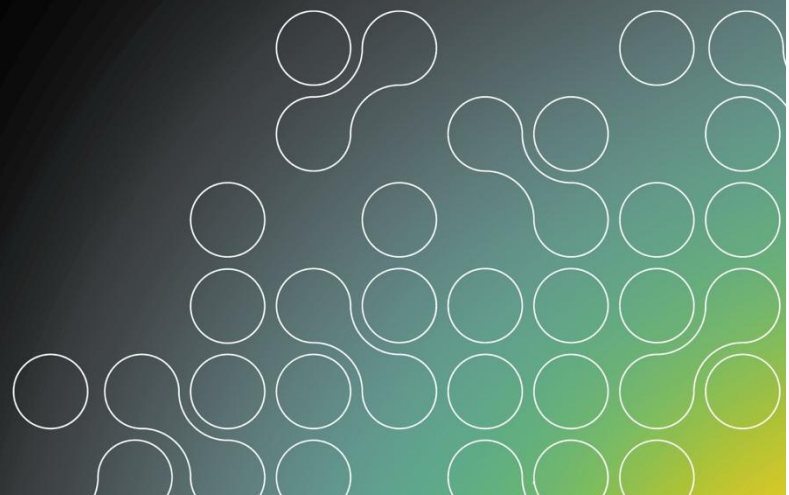


# DICOM Conformance Statement

For Volpara Scorecard 4.5,  
Volpara Live 2.4



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# 1 CONFORMANCE STATEMENT OVERVIEW

Volpara Scorecard and Volpara Live provide breast tissue analysis and quality assurance tools that assist radiologists in the analysis of digital mammograms.

Lunit implements the necessary DICOM services between Volpara Scorecard and Volpara Live and products from other vendors. The following table provides an overview of the network services supported by Volpara Scorecard and Volpara Live.

SOP CLASSES	USER OF SERVICE (SCU)	PROVIDER OF SERVICE (SCP)
TRANSFER		
Digital Mammography X-Ray Image Storage - For Processing	No	Yes
Secondary Capture Image Storage	Option (Note 2)	Yes (Note 1)
Mammography CAD SR	Option (Note 2)	

Notes:

1. The "Secondary Capture Image Storage" SCP capability is provided in order to process legacy Hologic Tomosynthesis raw projection images encoded as SC Images.
2. SCU functionality is only available as part of Volpara Scorecard and not Volpara Live.

## 2 CONTENTS

1	Conformance Statement Overview .....	3
2	Contents .....	4
3	Introduction .....	7
3.1	Audience .....	7
3.2	Remarks .....	7
3.3	Terms and Definitions .....	7
3.4	Basics of DICOM Communication .....	10
3.5	Abbreviations .....	11
3.6	References .....	12
4	Networking .....	13
4.1	Implementation Model .....	13
4.1.1	Application Data Flow .....	13
4.1.2	Functional Definition of AEs .....	13
4.1.3	Functional Definition of DICOM SCU .....	13
4.2	Sequencing of Real-World Activities .....	13
4.3	AE Specifications .....	14
4.3.1	DICOM SCP .....	14
4.3.2	CAD Integration SCP .....	17
4.3.3	DICOM SCU .....	20
4.4	Network Interfaces .....	25
4.4.1	Physical Network Interface .....	25
4.4.2	Additional Protocols .....	25
4.4.3	IPv4 and IPv6 Support .....	25
4.5	Configuration .....	25
4.5.1	AE Title/Presentation Address Mapping .....	25
4.5.2	Parameters .....	26
5	Media Interchange .....	27
6	Transformation of DICOM to CDA .....	27
7	Support of Character Sets .....	27
8	Security .....	27
8.1	Security Profiles .....	27
8.2	Association Level Security .....	28
8.3	Application Level Security .....	28
9	Annexes .....	29
9.1	IOD Contents .....	29
9.1.1	Created SOP Instances .....	29
9.1.2	Usage of Attributes from Received IODs .....	51
9.1.3	Attribute Mapping .....	54
9.1.4	Coerced/Modified Fields .....	54
9.2	Data Dictionary of Private Attributes .....	54
9.3	Coded Terminology and Templates .....	55

9.3.1	Context Groups.....	55
9.3.2	Template Specifications Groups .....	55
9.3.3	Mammography CAD SR .....	55
9.4	Grayscale Image Consistency .....	56
9.5	Standard Extended/Specialized/Private SOP Classes .....	56
9.6	Private Transfer Syntaxes .....	56

## Figures

Figure 1.	Mammography CAD SR structure .....	41
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## Tables

TABLE 4.1	SOP CLASSES FOR "DICOM SCP" .....	14
TABLE 4.2	DICOM APPLICATION CONTEXT .....	15
TABLE 4.3	DICOM IMPLEMENTATION CLASS AND VERSION FOR "DICOM SCP" .....	15
TABLE 4.4	ACCEPTABLE PRESENTATION CONTEXTS FOR "DICOM SCP" AND "RECEIVE DICOM IMAGE FROM A REMOTE DICOM STORAGE SCU" .....	16
TABLE 4.5	STORAGE C-STORE RESPONSE STATUS FOR ALL SOP CLASSES .....	16
TABLE 4.6	STORAGE C-STORE RESPONSE STATUS FOR "SECONDARY CAPTURE IMAGE STORAGE" .....	17
TABLE 4.7	ACCEPTABLE PRESENTATION CONTEXTS FOR "CAD INTEGRATION SCP" AND "RECEIVE MAMMOGRAPHY CAD STRUCTURED REPORT FROM A CAD SYSTEM" .....	19
TABLE 4.8	STORAGE C-STORE RESPONSE STATUS FOR ALL SOP CLASSES .....	19
TABLE 4.9	SOP CLASS(ES) FOR DICOM SCU .....	20
TABLE 4.10	DICOM APPLICATION CONTEXT .....	20
TABLE 4.11	DICOM IMPLEMENTATION CLASS AND VERSION FOR DICOM SCU .....	21
TABLE 4.12	ACCEPTABLE PRESENTATION CONTEXTS FOR "DICOM SCP" AND "RECEIVE DICOM IMAGE FROM A REMOTE DICOM STORAGE SCU" .....	21
TABLE 4.13	STORAGE C-STORE RESPONSE STATUS FOR ALL SOP CLASSES .....	22
TABLE 4.14	STORAGE C-STORE RESPONSE STATUS FOR "SECONDARY CAPTURE IMAGE STORAGE" .....	23
TABLE 4.18	PROPOSED PRESENTATION CONTEXTS FOR DICOM SCU .....	23
TABLE 4.19	DICOM COMMAND RESPONSE STATUS HANDLING BEHAVIOR.....	24
TABLE 4.20	DICOM COMMAND COMMUNICATION FAILURE BEHAVIOR.....	24
TABLE 4.21	AE TITLE CONFIGURATION TABLE .....	25
TABLE 9.1	SECONDARY CAPTURE IMAGE IOD MODULE TABLE .....	29
TABLE 9.2	MAMMOGRAPHY CAD SR IOD MODULE TABLE.....	31
TABLE 9.3	PATIENT MODULE OF ALL CREATED SOP INSTANCES .....	32
TABLE 9.4	GENERAL STUDY MODULE OF ALL CREATED SOP INSTANCES .....	32
TABLE 9.5	PATIENT STUDY MODULE OF ALL CREATED SOP INSTANCES .....	33
TABLE 9.6	GENERAL EQUIPMENT MODULE OF ALL CREATED SOP INSTANCES.....	33
TABLE 9.7	SOP COMMON MODULE OF CREATED SC IMAGE AND MAMMOGRAPHY CAD SOP INSTANCES .....	34
TABLE 9.8	TRUDENSITY, TRURADDOSE AND TRUPRESSURE RESULTS MACRO .....	34
TABLE 9.9	GENERAL SERIES MODULE OF CREATED SC IMAGE SOP INSTANCES .....	36
TABLE 9.10	SC EQUIPMENT MODULE OF CREATED SC IMAGE SOP INSTANCES .....	36
TABLE 9.11	GENERAL IMAGE MODULE OF CREATED SC IMAGE SOP INSTANCES .....	37
TABLE 9.12	IMAGE PIXEL MODULE OF CREATED SC IMAGE SOP INSTANCES.....	38
TABLE 9.13	SC IMAGE MODULE OF CREATED SC IMAGE SOP INSTANCES .....	38

TABLE 9.14 VOI LUT MODULE OF CREATED SC IMAGE SOP INSTANCES (MONOCHROME2 ONLY).....	38
TABLE 9.15 SR DOCUMENT SERIES MODULE OF CREATED MAMMOGRAPHY CAD SR SOP INSTANCES .....	39
TABLE 9.16 SR DOCUMENT GENERAL MODULE OF CREATED MAMMOGRAPHY CAD SR SOP INSTANCES .....	39
TABLE 9.17 SR DOCUMENT CONTENT MODULE OF CREATED MAMMOGRAPHY CAD SR SOP INSTANCES .....	40
TABLE 9.18 MAMMOGRAPHY CAD DOCUMENT ROOT (TID 4000).....	42
TABLE 9.19 LANGUAGE OF CONTENT AND DESCENDANTS (DTID 1204) .....	43
TABLE 9.20 MAMMOGRAPHY OVERALL CAD IMPRESSION/RECOMMENDATION (DTID 4001) .....	44
TABLE 9.21 CAD ANALYSES PERFORMED (TID 4016) .....	44
TABLE 9.22 CAD ANALYSIS PERFORMED (TID 4018) .....	45
TABLE 9.23 CAD ALGORITHM IDENTIFICATION (TID 4019).....	45
TABLE 9.24 CAD IMAGE LIBRARY ENTRY (TID 4020) .....	46
TABLE 9.25 MAMMOGRAPHY CAD IMPRESSION/RECOMMENDATION BODY (TID 4002) .....	48
TABLE 9.26 ATTRIBUTES REQUIRED IN ALL MAMMOGRAPHY IMAGES .....	51
TABLE 9.27 MANUFACTURER-SPECIFIC ATTRIBUTES REQUIRED IN MAMMOGRAPHY IMAGES .....	54

## 3 INTRODUCTION

### 3.1 Audience

This document is written for people who need to understand how Volpara Live and Volpara Scorecard will integrate into their healthcare facility. This includes both those responsible for overall imaging network policy and architecture, as well as integrators who need to have a detailed understanding of the DICOM features of the product. This document contains some basic DICOM definitions so that any reader may understand how Volpara software products implement DICOM features. However, integrators are expected to fully understand all the DICOM terminology, how the tables in this document relate to the product's functionality, and how that functionality integrates with other devices that support compatible DICOM features.

### 3.2 Remarks

The scope of this DICOM Conformance Statement is to facilitate integration between the virtual appliance and Volpara Scorecard and Volpara Live. This 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 is not supposed to replace validation with other DICOM equipment to ensure proper exchange of intended information. In fact, the user should be aware of the following important issues:

- The comparison of different Conformance Statements is just the first step towards assessing interconnectivity and interoperability between the product and other DICOM conformant equipment.
- Test procedures should be defined and executed to validate the required level of interoperability with specific compatible DICOM equipment, as established by the healthcare facility.

### 3.3 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.

**Abstract Syntax** - the information agreed to be exchanged between applications, generally equivalent to a Service/Object Pair (SOP) Class. *Examples:* Verification SOP Class, Modality Work List Information Model Find SOP Class, Computed Radiography Image Storage SOP Class.

**Application Entity (AE)** - an endpoint of a DICOM information exchange, including the DICOM network or media interface software, i.e., the software that sends or receives DICOM information objects or messages. A single device may have multiple Application Entities.

**Application Entity Title** - 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 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).

**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. The Attributes 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). Examples: MR Image IOD, CT Image IOD, Print Job IOD.

**Joint Photographic Experts Group (JPEG)** - a set of standardized image compression techniques, available for use by DICOM applications.

**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 Name, Patient ID, Patient Birth Date, and Patient 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.

**Presentation Context** - the set of DICOM network services used over an Association, as negotiated between Application Entities; includes Abstract Syntaxes and Transfer Syntaxes.

**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 work list 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 work list SCU), imaging workstation (image query/retrieve SCU).

**Service/Object Pair (SOP) Class** - the specification of the network or media transfer (service) of a particular type of data (object); the fundamental unit of DICOM interoperability specification. Examples: Ultrasound Image Storage Service, Basic Grayscale Print Management.

**Service/Object Pair (SOP) Instance** - an information object; a specific occurrence of information exchanged in an SOP Class. Examples: a specific x-ray image.

**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) [PixelData], (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.

**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.

**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.

## 3.4 Basics of DICOM Communication

This section describes terminology used in this Conformance Statement for the non-specialist. The key terms used in the Conformance Statement are highlighted in *italics* below. This section is not a substitute for training about DICOM, and it makes many simplifications about the meanings of DICOM terms.

*Two Application Entities* (devices) that want to communicate with each other over a network using DICOM protocol must first agree on several things during an initial network “handshake”. One of the two devices must initiate an *Association* (a connection to the other device), and ask if specific services, information, and encoding can be supported by the other device (*Negotiation*).

DICOM specifies a number of network services and types of information objects, each of which is called an *Abstract Syntax* for the Negotiation. DICOM also specifies a variety of methods for encoding data, denoted *Transfer Syntaxes*. The Negotiation allows the initiating Application Entity to propose combinations of Abstract Syntax and Transfer Syntax to be used on the Association; these combinations are called Presentation Contexts. The receiving Application Entity accepts the *Presentation Contexts* it supports.

For each Presentation Context, the Association Negotiation also allows the devices to agree on *Roles* - which one is the *Service Class User* (SCU - client) and which is the *Service Class Provider* (SCP - server). Normally the device initiating the connection is the SCU, i.e., the client system calls the server, but not always.

The Association Negotiation finally enables exchange of maximum network packet (*PDU*) size, security information, and network service options (called *Extended Negotiation* information).

The Application Entities, having negotiated the Association parameters, may now commence exchanging data. Common data exchanges include queries for work lists and lists of stored images, transfer of image objects and analyses (structured reports), and sending images to film printers. Each exchangeable unit of data is formatted by the sender in accordance with the appropriate *Information Object Definition*, and sent using the negotiated Transfer Syntax. There is a Default Transfer Syntax that all systems must accept, but it may not be the most efficient for some use cases. Each transfer is explicitly acknowledged by the receiver with a *Response Status* indicating success, failure, or that query or retrieve operations are still in process.

Two Application Entities may also communicate with each other by exchanging media (such as a CD-R). Since there is no Association Negotiation possible, they both use a Media Application Profile that specifies "pre-negotiated" exchange media format, Abstract Syntax, and Transfer Syntax.

## 3.5 Abbreviations

<b>AE</b>	Application Entity
<b>CAD</b>	Computer Aided Detection
<b>CDA</b>	Clinical Document Architecture
<b>CD-R</b>	Compact Disc Recordable
<b>CR</b>	Computed Radiography
<b>C-Store</b>	Composite Store
<b>CT</b>	Computed Tomography
<b>DICOM</b>	Digital Imaging and Communications in Medicine
<b>IOD</b>	Information Object Definition
<b>IPv6</b>	Internet Protocol version 6
<b>ISO</b>	International Organization for Standards
<b>JPEG</b>	Joint Photographic Experts Group
<b>LUT</b>	Look-Up Table
<b>MG</b>	Mammography (X-ray)
<b>NL</b>	Nesting Level
<b>PACS</b>	Picture Archiving and Communication System
<b>PDU</b>	Protocol Data Unit
<b>R</b>	Required (Key Attribute)
<b>RIS</b>	Radiology Information System
<b>SC</b>	Secondary Capture
<b>SCP</b>	Service Class Provider
<b>SCU</b>	Service Class User
<b>SOP</b>	Service-Object Pair

<b>SR</b>	Structured Reporting
<b>TCP/IP</b>	Transmission Control Protocol/Internet Protocol
<b>TID</b>	Template ID
<b>U</b>	Unique (Key Attribute)
<b>UL</b>	Upper Layer
<b>VOI</b>	Values of Interest
<b>VR</b>	Value Representation
<b>VT</b>	Value Type

## 3.6 References

NEMA PS3 - Digital Imaging and Communications in Medicine (DICOM) Standard, available free at <http://medical.nema.org>.

## 4 NETWORKING

### 4.1 Implementation Model

#### 4.1.1 Application Data Flow

The DICOM SCP is a standalone executable which is initialized on system startup.

#### 4.1.2 Functional Definition of AEs

The DICOM SCP supports the following functions:

- Accepts DICOM association requests.
- Accepts DICOM storage requests.
- Validates incoming DICOM images for Volpara image processing, checks for local disk space, stores incoming DICOM images on disk. Removes local copies of instances once image processing is complete and results are submitted.

#### 4.1.3 Functional Definition of DICOM SCU

The DICOM SCU supports the following functions:

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

### 4.2 Sequencing of Real-World Activities

When image processing is triggered by digital images pushed from a remote application:

1. The DICOM SCP responds to DICOM association initiation and selects a matching Presentation Context.
2. The DICOM SCP accepts an association and waits for a C-Store request.
3. Upon receiving a C-Store request, the DICOM SCP validates the incoming image and sends an appropriate C-Store response. (See Table 4.16 DICOM Command Response Status Handling Behavior for details.)

4. The DICOM SCP asynchronously begins the image processing action.
5. If Volpara Scorecard is configured:
  - a. Upon completion of image processing, the results are formatted into one or more DICOM SC Images, and one or more DICOM Mammography CAD SRs.
  - b. These are sent to the DICOM SCU which initiates associations to the configured remote applications.
  - c. The DICOM SCU sends C-Store requests containing the DICOM objects.

The DICOM SCU ends the association.

## 4.3 AE Specifications

### 4.3.1 DICOM SCP

#### 4.3.1.1 SOP Classes

This Application Entity provides Standard Conformance to the following SOP Classes:

Table 4.1 SOP Classes for "DICOM SCP"

SOP Class Name	SOP Class UID	SCU	SCP
Verification SOP Class	1.2.840.10008.1.1	No	Yes
Digital Mammography X-Ray Image Storage - For Processing	1.2.840.10008.5.1.4.1.1.1.2.1	No	Yes
Secondary Capture Image Storage	1.2.840.10008.5.1.4.1.1.7	No	Yes

#### 4.3.1.2 Association Policies

##### 4.3.1.2.1 General

The DICOM SCP accepts associations, but does not initiate associations.

The maximum PDU size accepted is 16384. If during association negotiation the maximum sized PDU of the system negotiating with the application is larger than this value, the PDU size will be limited to this value.

The DICOM standard application context name for DICOM 3.0 is always proposed:

Table 4.2 DICOM Application Context

DICOM application context for DICOM SCP	
Application Context Name	1.2.840.10008.3.1.1.1

#### 4.3.1.2.2 Number of Associations

The DICOM SCP places no hard limit from a DICOM perspective on concurrent Association count. But an increased number of associations may result in slow processing of images, in temporary Out Of Resource errors, or, in worst case, TCP/IP socket timeouts. See product user manual for details on how different numbers of associations may impact you.

#### 4.3.1.2.3 Asynchronous Nature

DICOM SCP does not support asynchronous communication (multiple outstanding transactions over a single Association).

#### 4.3.1.2.4 Implementation Identifying Information

Table 4.3 DICOM Implementation Class and Version for "DICOM SCP"

DICOM Implementation Class and Version for "DICOM SCP"	
Implementation Class UID	1.3.6.1.4.1.30071.8
Implementation Version Name	fo-dicom 4.0.2

#### 4.3.1.3 Association Initiation Policy

The DICOM SCP does not initiate Associations.

#### 4.3.1.4 Association Acceptance Policy

The DICOM SCP accepts an association when it receives a valid association request, with at least one matching presentation context, unless the DICOM SCP is specifically configured to be in promiscuous Called AE title mode. If the Called AE title of the association does not match the configured AE title of the DICOM SCP, the Association will be rejected. If the DICOM SCP is configured to only accept known Calling AE titles, and the Calling AE title given in the association is not configured as known, the Association will be rejected.

##### 4.3.1.4.1 Receive Images from a Remote DICOM Storage SCU

###### 4.3.1.4.1.1 Description and Sequencing of Activities

The Real-World Activity (Volpara Image Processing) is associated with a C-Store SCP operation, and is triggered by a push of images from a Remote DICOM Storage SCU. This results in the temporary storage of the DICOM images on the Volpara for Image Processing. The C-Store SCP operation will respond with a failure status if it is unable to store the images.

#### 4.3.1.4.1.2 Accepted Presentation Contexts

Table 4.4 Acceptable Presentation Contexts For "DICOM SCP" and "Receive DICOM Image from a Remote DICOM Storage SCU"

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Extended Negotiation
Name	UID	Name	UID		
Digital Mammography X-Ray Image Storage - For Processing	1.2.840.10008.5.1.4.1.1.1.2.1	JPEG-LS Lossless Image Compression	1.2.840.10008.1.2.4.80	SCP	None
		RLE Lossless	1.2.840.10008.1.2.5	SCP	None
		Explicit VR Little Endian	1.2.840.10008.1.2.1	SCP	None
		Implicit VR Little Endian	1.2.840.10008.1.2	SCP	None
Secondary Capture Image Storage	1.2.840.10008.5.1.4.1.1.7	JPEG-LS Lossless Image Compression	1.2.840.10008.1.2.4.80	SCP	None
		RLE Lossless	1.2.840.10008.1.2.5	SCP	None
		Explicit VR Little Endian	1.2.840.10008.1.2.1	SCP	None
		Implicit VR Little Endian	1.2.840.10008.1.2	SCP	None

When presented with multiple Transfer Syntaxes within one requested Presentation Context, the DICOM SCP accepts the supported syntaxes in the order of the list in the above table (i.e., it employs "SCP Priority").

DICOM SCP is configured to not accept any lossy Transfer Syntaxes.

#### 4.3.1.4.1.3 SOP Specific Conformance for all SOP Classes

Table 4.5 Storage C-Store Response Status for all SOP Classes

Service Status	Further Meaning	Error Code	Reason
Success	Success	0000	The DICOM Image was successfully received and stored by the Virtual Appliance.
Failure	Out of Resources	A700-A7FF	The Virtual Appliance was out of Memory, or Disk Space. The DICOM Image was not stored.
Failure	Data Set does not match SOP Class	A900-A9FF	The SOP Class given in the C-Store Request does not match the SOP Class in the received DICOM Image. The DICOM Image was not stored.

Service Status	Further Meaning	Error Code	Reason
Failure	Storage Cannot Understand	C000-CFFF	The SOP Class and/or SOP Instance UID in the received DICOM Image are missing. The DICOM Image was not stored.
Failure	SOP Class Not Supported	0122	The SOP Class was not "Digital Mammography X-Ray Image Storage - For Processing", or "Secondary Capture Image Storage" The DICOM Image was not stored.

#### 4.3.1.4.1.4 SOP Specific Conformance for "Secondary Capture Image Storage"

In addition, if a Secondary Capture Image is received that does not encode a tomosynthesis raw projection, the following code shall be returned:

Table 4.6 Storage C-Store Response Status for "Secondary Capture Image Storage"

Service Status	Further Meaning	Error Code	Reason
Failure	Processing Failure	0110	The SOP Class was "Secondary Capture Image Storage" but the image does not encode a tomosynthesis raw projection. The DICOM Image was not stored.

Constraints on Secondary Capture Image Storage DICOM Images are defined in section 9.1.2.

#### 4.3.1.4.1.5 SOP Specific Conformance for "Verification SOP Class"

The DICOM SCP provides standard conformance to the Verification SOP Class as an SCP. If the C-ECHO request was successfully received, a 0000 (Success) status code will be returned in the C-ECHO response.

## 4.3.2 CAD Integration SCP

CAD integration is available with Lunit INSIGHT® MMG, Lunit INSIGHT DBT, Transpara® and iCAD®.

### 4.3.2.1 SOP Classes

This Application Entity provides Standard Conformance to the following SOP Classes:

SOP Class Name	SOP Class UID	SCU	SCP
Mammography CAD SR Storage	1.2.840.10008.5.1.4.1.1.88.50	No	Yes

### 4.3.2.2 Association Policies

#### 4.3.2.2.1 General

The CAD Integration SCP accepts associations, but does not initiate associations.

The maximum PDU size accepted is 16384. If during association negotiation the maximum sized PDU of the system negotiating with the application is larger than this value, the PDU size will be limited to this value.

The DICOM standard application context name for DICOM 3.0 is always proposed:

DICOM application context for DICOM SCP	
Application Context Name	1.2.840.10008.3.1.1.1

#### 4.3.2.2.2 Number of Associations

The CAD Integration SCP places no hard limit from a DICOM perspective on concurrent Association count. But an increased number of associations may result in slow processing of images, in temporary Out Of Resource errors, or, in worst case, TCP/IP socket timeouts. See product user manual for details on how different numbers of associations may impact you.

#### 4.3.2.2.3 Asynchronous Nature

CAD Integration SCP does not support asynchronous communication (multiple outstanding transactions over a single Association).

#### 4.3.2.2.4 Implementation Identifying Information

DICOM Implementation Class and Version for “Volpara Transpara Integration SCP”	
Implementation Class UID	1.3.6.1.4.1.30071.8
Implementation Version Name	fo-dicom 4.0.2

### 4.3.2.3 Association Initiation Policy

The CAD Integration SCP does not initiate Associations.

### 4.3.2.4 Association Acceptance Policy

The CAD Integration SCP accepts an association when it receives a valid association request, with at least one matching presentation context, unless the CAD Integration SCP is specifically configured to be in promiscuous Called AE title mode. If the Called AE title of the association does not match the configured AE title of the CAD Integration SCP, the Association will be rejected. If the CAD Integration SCP is configured to only accept

known Calling AE titles, and the Calling AE title given in the association is not configured as known, the Association will be rejected.

#### 4.3.2.4.1 Receive Images from a Remote DICOM Storage SCU

##### 4.3.2.4.1.1 Description and Sequencing of Activities

The Real-World Activity (Extraction of CAD exam score) is associated with a C-Store SCP operation, and is triggered by a push a Mammography CAD Structured Report from a CAD system. This results in the temporary storage of the CAD exam score for Volpara Scorecard and Volpara Live to consume. The C-Store SCP operation will respond with a failure status if it is unable to store the images.

##### 4.3.2.4.1.2 Accepted Presentation Contexts

Table 4.7 Acceptable Presentation Contexts For "CAD Integration SCP" and "Receive Mammography CAD Structured Report from a CAD System"

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Extended Negotiation
Name	UID	Name	UID		
Mammography CAD SR Storage	1.2.840.10008.5.1.4.1.1.88.50	Explicit VR Little Endian	1.2.840.10008.1.2.1	SCP	None
		Implicit VR Little Endian	1.2.840.10008.1.2	SCP	None

When presented with multiple Transfer Syntaxes within one requested Presentation Context, the CAD Integration SCP accepts the supported syntaxes in the order of the list in the above table (i.e., it employs "SCP Priority").

##### 4.3.2.4.1.3 SOP Specific Conformance for all SOP Classes

Table 4.8 Storage C-Store Response Status for all SOP Classes

Service Status	Further Meaning	Error Code	Reason
Success	Success	0000	The DICOM Image was successfully received and stored by the Virtual Appliance.
Failure	Data Set does not match SOP Class	A900-A9FF	The SOP Class given in the C-Store Request does not match the SOP Class in the received DICOM Image. The DICOM Image was not stored.
-.//Failure	Storage Cannot Understand	C000-CFFF	The SOP Class and/or SOP Instance UID in the received DICOM Image are missing. The DICOM Image was not stored.

#### 4.3.2.4.1.4 SOP Specific Conformance for "Verification SOP Class"

The CAD Integration SCP provides standard conformance to the Verification SOP Class as an SCP. If the C-ECHO request was successfully received, a 0000 (Success) status code will be returned in the C-ECHO response.

### 4.3.3 DICOM SCU

#### 4.3.3.1 SOP Classes

This Application Entity provides Standard Conformance to the following SOP Class(es):

Table 4.9 SOP Class(es) for DICOM SCU

SOP Class Name	SOP Class UID	SCU	SCP
<b>Volpara Scorecard</b>			
Mammography CAD SR Storage	1.2.840.10008.5.1.4.1.1.88.50	Yes	No
Secondary Capture Image	1.2.840.10008.5.1.4.1.1.7	Yes	No

#### 4.3.3.2 Association Policies

##### 4.3.3.2.1 General

The maximum PDU size accepted is 16384. If during association negotiation the maximum sized PDU of the system negotiating with the application is larger than this value, the PDU size will be limited to this value.

The DICOM standard application context name for DICOM 3.0 is always proposed:

Table 4.10 DICOM Application Context

Application Context Name	1.2.840.10008.3.1.1.1
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##### 4.3.3.2.2 Number of Associations

The DICOM SCU places no hard limit from a DICOM perspective on concurrent Association count.

##### 4.3.3.2.3 Asynchronous Nature

DICOM SCU does not support asynchronous communication (multiple outstanding transactions over a single Association).

#### 4.3.3.2.4 Implementation Identifying Information

Table 4.11 DICOM Implementation Class and Version for DICOM SCU

Implementation Class UID	1.3.6.1.4.1.30071.8
Implementation Version Name	fo-dicom 4.0.2

#### 4.3.3.3 Association Initiation Policy

##### 4.3.3.3.1 "Remote DICOM Storage SCP Accepts Results"

The DICOM SCP does not initiate Associations.

##### 4.3.3.3.2 Association Acceptance Policy

The DICOM SCP accepts an association when it receives a valid association request, with at least one matching presentation context, unless the DICOM SCP is specifically configured to be in promiscuous Called AE title mode. If the Called AE title of the association does not match the configured AE title of the DICOM SCP, the Association will be rejected. If the DICOM SCP is configured to only accept known Calling AE titles, and the Calling AE title given in the association is not configured as known, the Association will be rejected.

##### 4.3.3.3.3 Receive DICOM Image from a Remote DICOM Storage SCU

###### 4.3.3.3.3.1 Description and Sequencing of Activities

The Real-World Activity (image processing) is associated with a C-Store SCP operation, and is triggered by a push of images from a Remote DICOM Storage SCU. This results in the temporary storage of the DICOM images on the Virtual Appliance for Image Processing. The C-Store SCP operation will respond with a failure status if it is unable to store the images.

###### 4.3.3.3.3.2 Accepted Presentation Contexts

Table 4.12 Acceptable Presentation Contexts For "DICOM SCP" and "Receive DICOM Image from a Remote DICOM Storage SCU"

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Extended Negotiation
Name	UID	Name	UID		
Digital Mammography X-Ray Image Storage - For Processing	1.2.840.10008.5.1.4.1.1.1.2.1	JPEG-LS Lossless Image Compression	1.2.840.10008.1.2.4.80	SCP	None
		RLE Lossless	1.2.840.10008.1.2.5	SCP	None
		Explicit VR Little Endian	1.2.840.10008.1.2.1	SCP	None

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Extended Negotiation
Name	UID	Name	UID		
		Implicit VR Little Endian	1.2.840.10008.1.2	SCP	None
Secondary Capture Image Storage	1.2.840.10008.5.1.4.1.1.7	JPEG-LS Lossless Image Compression	1.2.840.10008.1.2.4.80	SCP	None
		RLE Lossless	1.2.840.10008.1.2.5	SCP	None
		Explicit VR Little Endian	1.2.840.10008.1.2.1	SCP	None
		Implicit VR Little Endian	1.2.840.10008.1.2	SCP	None

When presented with multiple Transfer Syntaxes within one requested Presentation Context, the DICOM SCP accepts the supported syntaxes in the order of the list in the above table (i.e., it employs “SCP Priority”).

DICOM SCP is configured to not accept any lossy Transfer Syntaxes.

#### 4.3.3.3.3 SOP Specific Conformance for all SOP Classes

Table 4.13 Storage C-Store Response Status for all SOP Classes

Service Status	Further Meaning	Error Code	Reason
Success	Success	0000	The DICOM Image was successfully received and stored by the Virtual Appliance.
Failure	Out of Resources	A700-A7FF	The Virtual Appliance was out of Memory, or Disk Space. The DICOM Image was not stored.
Failure	Data Set does not match SOP Class	A900-A9FF	The SOP Class given in the C-Store Request does not match the SOP Class in the received DICOM Image. The DICOM Image was not stored.
Failure	Storage Cannot Understand	C000-CFFF	The SOP Class and/or SOP Instance UID in the received DICOM Image are missing. The DICOM Image was not stored.
Failure	SOP Class Not Supported	0122	The SOP Class was not “Digital Mammography X-Ray Image Storage - For Processing”, or “Secondary Capture Image Storage” The DICOM Image was not stored.

#### 4.3.3.3.4 SOP Specific Conformance for "Secondary Capture Image Storage"

In addition to the behavior described above, the DICOM SCP has the following additional behavior for incoming Secondary Capture Image Storage DICOM Images.

Table 4.14 Storage C-Store Response Status for "Secondary Capture Image Storage"

Service Status	Further Meaning	Error Code	Reason
Failure	Processing Failure	0110	The SOP Class was "Secondary Capture Image Storage" but the image does not encode a tomosynthesis raw projection. The DICOM Image was not stored.

Constraints on Secondary Capture Image Storage DICOM Images are defined in section 9.1.2.

#### 4.3.3.3.5 SOP Specific Conformance for "Verification SOP Class"

The DICOM SCP provides standard conformance to the Verification SOP Class as an SCP. If the C-ECHO request was successfully received, a 0000 (Success) status code will be returned in the C-ECHO response.

#### 4.3.3.3.6 Description and Sequencing of Activities

If Volpara Scorecard is configured, the DICOM SCU is invoked by the job control interface that is responsible for processing generated reports. A C-Store SCU operation on a new association is triggered for each generated report which initiates the sending of results to a Remote DICOM Storage SCP. If a transfer fails, the DICOM SCU will retry the send operation at a configurable interval, for a number of times.

#### 4.3.3.3.4 Proposed Presentation Contexts

Table 4.15 Proposed Presentation Contexts for DICOM SCU

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Extended Negotiation
Name	UID	Name List	UID List		
Volpara Reports					
Secondary Capture Image Storage	1.2.840.1000 8.5.1.4.1.1.7	Explicit VR Little Endian, Implicit VR Little Endian	1.2.840.10008.1.2.1, 1.2.840.10008.1.2	SCU	None
Mammography CADSR	1.2.840.1000 8.5.1.4.1.1.8 8.50	Explicit VR Little Endian, Implicit VR Little Endian	1.2.840.10008.1.2.1, 1.2.840.10008.1.2	SCU	None

When more than one Presentation Context is accepted for a SOP Class, the DICOM SCU accepts the first Presentation Context in the list returned by the SCP.

#### 4.3.3.3.4.1 SOP Specific Conformance for all SOP Classes

All Storage SOP Classes supported by DICOM SCU exhibit the same behavior, and are described together in this section.

Table 4.16 DICOM Command Response Status Handling Behavior

Service Status	Further Meaning	Error Code	Behavior
Success	Success	0000	The Remote SCP successfully stored the SOP Instance.
Warning	Warning	B000, B007, B006	Transmission is considered successful.
Error	Error	A7xx, A9xx, Cxxx	The DICOM Instance was not stored. Retransmission is not attempted.

The behavior of the DICOM SCU during communication failure is summarized in a table as follows:

Table 4.17 DICOM Command Communication Failure Behavior

Exception	Behavior
Timeout	The DICOM Instance was not stored. The Association will be reattempted at a later time. If errors continue, the Association will eventually stop reattempts.
Association rejected - Permanent	The DICOM Instance was not stored. The Association will not be reattempted at a later time.
Association rejected - Transient	The DICOM Instance was not stored. The Association will be reattempted at a later time. If errors continue, the Association will eventually stop reattempts.

#### 4.3.3.3.4.2 SOP Specific Conformance for Secondary Capture Image Storage Class

If configured, the Virtual Appliance can export a Secondary Capture Image instance, or "scorecard", that displays the TruDensity results in image form. See 9.1.1.1 Created SOP Instance(s) for Secondary Capture Image content details.

#### 4.3.3.3.4.3 SOP Specific Conformance for Mammography CAD SR Class

If licensed and configured, the Virtual Appliance can export a Mammography CAD SR instance that contains the TruDensity results in a structured report form. See 9.1.1.2 Created SOP Instance(s) for Mammography CAD SR content details.

#### 4.3.3.4 Association Acceptance Policy

The DICOM SCU does not accept associations.

## 4.4 Network Interfaces

### 4.4.1 Physical Network Interface

RJ45 Ethernet 10/100/1000.

### 4.4.2 Additional Protocols

None.

### 4.4.3 IPv4 and IPv6 Support

Volpara Scorecard and Volpara Live support only IPv4 Connections.

## 4.5 Configuration

### 4.5.1 AE Title/Presentation Address Mapping

#### 4.5.1.1 Local AE Titles

Volpara Scorecard and Volpara Live use one AE Title and TCP/IP Port. This configuration is managed by Lunit and can be changed on request.

Table 4.18 AE Title Configuration Table

Application Entity	Default AE Title	Default TCP/IP Port
DICOM SCP	VOLPARA1	11112
DICOM SCU	VOLPARA1	Not Applicable

#### 4.5.1.2 Remote AE Title/Presentation Address Mapping

##### 4.5.1.2.1 Remote Input Devices

Configuration of accepted Input Devices is handled by Lunit. It is generally set to a promiscuous mode for ease of installation and then locked down after the fact. This configuration can be changed on request.

##### 4.5.1.2.2 Remote Output Devices

Configuration of Output Destinations is handled by Lunit. This configuration can be changed on request.

## 4.5.2 Parameters

The following parameters are configurable for the DICOM SCP:

- AE Title
- Port number
- Unexpected SOP Classes can optionally be configured to be silently accepted and ignored by the DICOM SCP instead of actively rejected.
- Accepted Transfer Syntaxes can be configured, in terms of both preference and presence, per presentation context.

The following parameters are configurable for the DICOM SCU:

- AE Title
- Remote Hostnames or IPs
- Remote Ports
- Base Retransmission Delay
- Maximum Retransmission Delay
- Maximum Retransmission Duration
- Start Up Retransmission Scatter

## 5 MEDIA INTERCHANGE

None.

## 6 TRANSFORMATION OF DICOM TO CDA

None.

## 7 SUPPORT OF CHARACTER SETS

Volpara Scorecard and Volpara Live have no specific DICOM requirement on character sets and will not reject incoming C-Store requests based on character set. Consult your product user guide for more information.

## 8 SECURITY

Volpara Scorecard and Volpara Live do not support DICOM security profiles.

It is assumed that the Virtual Appliance is used within a secured environment. It is assumed that a secured environment includes at a minimum:

- Firewall or router protections to ensure that only approved external hosts have network access to the Virtual Appliance.
- Firewall or router protections to ensure that the Virtual Appliance only has network access to approved external hosts and services.
- Any communication with external hosts and services outside the locally secured environment use appropriate secure network channels, such as a Virtual Private Network (VPN).

Other network security procedures such as automated intrusion detection may be appropriate in some environments. Additional security features may be established by the local security policy and are beyond the scope of this conformance statement.

### 8.1 Security Profiles

Not applicable.

## 8.2 Association Level Security

Not applicable.

## 8.3 Application Level Security

Not applicable.

## 9 ANNEXES

### 9.1 IOD Contents

#### 9.1.1 Created SOP Instances

The following tables use several abbreviations. The abbreviations used in the “Presence of ...” column are as follows:

Abbreviation	Description
VNAP	Value Not Always Present (attribute sent zero length if no value is present)
ANAP	Attribute/Module Not Always Present
ALWAYS	Always Present
EMPTY	Attribute is sent without a value

Abbreviations to be used for the “Source” column are:

Abbreviation	Description
USER	The attribute source is from user input
AUTO	The attribute value is generated automatically
FIR	The attribute source is from the first mammography image received in the study
CONFIG	The attribute value is a configurable parameter

#### 9.1.1.1 Secondary Capture Image IOD

Table 9.1 Secondary Capture Image IOD module table

IE	Module	Reference	Usage	Presence of module
Patient	Patient	Table 9.3 Patient module of all created SOP instances	M	ALWAYS
	Clinical Trial Subject		U	NOT PROVIDED
Study	General Study	Table 9.4 General study module of all created SOP instances	M	ALWAYS
	Patient Study	Table 9.5 Patient study module of all created SOP instances	U	ALWAYS
	Clinical Trial Study		U	NOT PROVIDED

IE	Module	Reference	Usage	Presence of module
Series	General Series	Table 9.9 General Series module of created SC image SOP instances	M	ALWAYS
	Clinical Trial Series		U	NOT PROVIDED
Equipment	General Equipment	Table 9.6 General equipment module of all created SOP instances	U	ALWAYS
	SC Equipment	Table 9.10 SC Equipment module of created SC image SOP instances	M	ALWAYS
Image	General Image	Table 9.11 General Image module of created SC image SOP instances	M	ALWAYS
	Image Pixel	Table 9.12 Image Pixel module of created SC image SOP instances	M	ALWAYS
	Device		U	NOT PROVIDED
	Specimen		U	NOT PROVIDED
	SC Image	Table 9.13 SC Image module of created SC image SOP instances	M	ALWAYS
	Overlay Plane		U	NOT PROVIDED
	Modality LUT		U	NOT PROVIDED
	VOI LUT	Table 9.14 VOI LUT module of created SC image SOP instances (MONOCHROME2 only)	U	ALWAYS
	ICC Profile		U	NOT PROVIDED
SOP Common	SOP Common	Table 9.7 SOP common module of created SC image and mammography CAD SOP instances	M	ALWAYS
	Common Instance Reference		U	NOT PROVIDED

### 9.1.1.2 Mammography CAD SR Image IOD

Table 9.2 Mammography CAD SR IOD module table

IE	Module	Reference	Usage	Presence of module
Patient	Patient	Table 9.3 Patient module of all created SOP instances	M	ALWAYS
	Clinical Trial Subject		U	NOT PROVIDED
Study	General Study	Table 9.4 General study module of all created SOP instances	M	ALWAYS
	Patient Study	Table 9.5 Patient study module of all created SOP instances	U	ALWAYS
	Clinical Trial Study		U	NOT PROVIDED
Series	SR Document Series	Table 9.15 SR Document Series module of created mammography CAD SR SOP instances	M	ALWAYS
	Clinical Trial Series		U	NOT PROVIDED
Equipment	General Equipment	Table 9.6 General equipment module of all created SOP instances	M	ALWAYS
Document	SR Document General	Table 9.16 SR Document General module of created mammography CAD SR SOP instances	M	ALWAYS
	SR Document Content	Table 9.17 SR Document Content module of created mammography CAD SR SOP instances	M	ALWAYS

IE	Module	Reference	Usage	Presence of module
	SOP Common	Table 9.7 SOP common module of created SC image and mammography CAD SOP instances	M	ALWAYS

### 9.1.1.3 Common Modules

Table 9.3 Patient module of all created SOP instances

Attribute name	Tag	VR	Value	Presence of value	Source
Patient's Name	(0010,0010)	PN	Copied from source image	ALWAYS	FIR
Patient ID	(0010,0020)	LO	Copied from source image	ALWAYS	FIR
Patient's Birth Date	(0010,0030)	DA	Copied from source image	ALWAYS	FIR
Patient's Sex	(0010,0040)	CS	Copied from source image	ALWAYS	FIR
Any other attributes in this module, as determined on a per-SOP Class basis					FIR

Table 9.4 General study module of all created SOP instances

Attribute name	Tag	VR	Value	Presence of value	Source
Study Instance UID	(0020,000D)	UI	Copied from source image	ALWAYS	FIR
Study Date	(0008,0020)	DA	Copied from source image	ALWAYS (value required by Lunit)	FIR
Study Time	(0008,0030)	TM	Copied from source image	VNAP	FIR
Referring Physician's Name	(0008,0090)	PN	Copied from source image	VNAP	FIR
Study ID	(0020,0010)	SH	Copied from source image	VNAP	FIR
Accession Number	(0008,0050)	SH	Copied from source image	VNAP	FIR
Study Description	(0008,1030)	LO	Copied from source image	ANAP	FIR
Physician(s) of Record	(0008,1048)	PN	Copied from source image	ANAP	FIR
Any other attributes in this module, as determined on a per-SOP Class basis					FIR

Table 9.5 Patient study module of all created SOP instances

Attribute name	Tag	VR	Value	Presence of value	Source
Admitting Diagnoses Description	(0008,1080)	LO	Copied from source image	ANAP	FIR
Patient's Age	(0010,1010)	AS	Copied from source image	ANAP	FIR
Patient's Address	(0010,1040)	LO	Copied from source image	ANAP	FIR
Occupation	(0010,2180)	SH	Copied from source image	ANAP	FIR
Additional Patient's History	(0010,21B0)	LT	Copied from source image	ANAP	FIR
Admission ID	(0038,0010)	LO	Copied from source image	ANAP	FIR

Table 9.6 General equipment module of all created SOP instances

Attribute name	Tag	VR	Value	Presence of value	Source
Manufacturer	(0008,0070)	LO	"Matakina Technology"	ALWAYS	AUTO
Institution Name	(0008,0080)	LO	Copied from source image	ANAP	AUTO
Institution Address	(0008,0081)	ST	Copied from source image	ANAP	AUTO
Station Name	(0008,1010)	SH	Copied from source image	ALWAYS	AUTO
Institutional Department Name	(0008,1040)	LO	Copied from source image	ANAP	AUTO
Manufacturer's Model Name	(0008,1090)	LO	"Volpara Server"	ALWAYS	AUTO
Device Serial Number	(0018,1000)	LO	Serial Number of the Virtual Appliance	ALWAYS	AUTO
Software Versions	(0018,1020)	LO	Current Software version for the Virtual Appliance	ALWAYS	AUTO

Table 9.7 SOP common module of created SC image and mammography CAD SOP instances

Attribute name	Tag	VR	Value	Presence of value	Source
SOP Class UID	(0008,0016)	UI	See Section	ALWAYS	AUTO
SOP Instance UID	(0008,0018)	UI	Generated automatically by the system	ALWAYS	AUTO
Specific Character Set	(0008,0005)	CS	ISO_IR 100	ANAP	FIR
Instance Creation Date	(0008,0012)	DA	Date the SR was created	ALWAYS	AUTO
Instance Creation Time	(0008,0013)	TM	Time the SR was created	ALWAYS	AUTO

Table 9.8 TruDensity, TruRadDose and TruPressure results macro

Attribute name	Tag	VR	Value	Presence of value	Source
Private Creator	(0015,0010)	LO	MATAKINA_10	ALWAYS	AUTO
Reported Volpara Density Grade	(0015,1028)	LO	Volpara Density Grade (VDG) reported on SC Image. Will be equal to one of (0015,102A) or (0015,1035), depending on configuration. Volpara Private Attribute.	ALWAYS	AUTO
Volpara Density Grade - 4th Edition	(0015,102A)	SH	Calculated Volpara Density Grade expressed in BIRADS 4th edition (1-4), (or a-d if this reporting option is selected for 4th edition display). Volpara Private Attribute.	ANAP	AUTO
Volpara Reporting Edition	(0015,102C)	IS	Indicates which BIRADS edition was used in Reported Volpara Density Grade (0015,0028): 4 = 4th edition 5 = 5th edition Volpara Private Attribute.	ANAP	AUTO
Volpara Calculated Values	(0015,1032)	LT	Volpara calculated values in format "side\quantity\value" for each measure, concatenated, where side is one of "LEFT" "RIGHT" and quantity is one of "Volumetric Breast Density" "Breast Volume" "Fibroglandular Tissue Volume". Present if there are findings. Volpara Private Attribute.	ANAP	AUTO
Volpara Reported Density	(0015,1033)	DS	Density value reported on SC Image. Present if there are findings. Volpara Private Attribute.	ANAP	AUTO

Attribute name	Tag	VR	Value	Presence of value	Source
Volpara Density Grade - 5th Edition	(0015,1035)	SH	Calculated Volpara Density Grade expressed in BIRADS 5th edition (a-d). Volpara Private Attribute.	ANAP	AUTO
Volpara Reported Density Type	(0015,1036)	CS	Type of density that was reported to user. Enumerated values: AVERAGE MAXIMUM Present if there are findings. Volpara Private Attribute.	ANAP	AUTO
Volpara Density Reason Not Used Values	(0015,1070)	LT	Reasons why one or more images failed Volpara Density validation tests or Volpara Algorithm calculation in format "uid\side\view\reason\" for each image used in the calculation (concatenated), where side is one of "LEFT" "RIGHT" and view is one of "CC" "MLO". Present if density was calculated for the images. Zero-length if no failures occurred Volpara Private Attribute.	ANAP	AUTO
Volpara Creator Full Version	(0015,1075)	LO	Full identification of software used to create the DICOM Instance (including build number).	ALWAYS	AUTO
Volpara Image Type Values	(0015,1077)	LT	Type of images, in format "uid\side\view\type\" for each image used in the calculation (concatenated), where side is one of "LEFT" "RIGHT" view is one of "CC" "MLO" And type is one of "TOMO" "MAMMO" "UNKNOWN" Present if density was calculated for the images. Volpara Private Attribute.	ANAP	AUTO
Volumetric Breast Density - 4th edition	(0015,1038)	DS	Calculated using mean Density. Volpara Private Attribute.	ANAP	AUTO
Volumetric Breast Density - 5th edition	(0015,1034)	DS	Calculated using maximum Density. Volpara Private Attribute.	ANAP	AUTO

Attribute name	Tag	VR	Value	Presence of value	Source
Volpara Average Glandular Dose	(0015,1039)	DS	Patient-specific Average Glandular Dose per image in milligray (mGy), over all images used in density calculation. Calculated using Dance's method. Present if density was calculated for the images. Volpara Private Attribute.	ANAP	AUTO
Volpara Average Applied Pressure	(0015,1040)	DS	Average pressure in kilopascals (kPa) applied to patient anatomy for images used to calculate density. Present if Force present in images and contact area can be calculated. Volpara Private Attribute.	ANAP	AUTO
Volpara Density UDI	(0015,10B1)	LO	The Volpara Density UDI	ALWAYS	AUTO
Tyrer-Cuzick risk model version 8 (TC8) Risk Competing Mortality	(0015,10C1)	CS	Whether the system that provided the TC8 Risk score had Competing Mortality enabled. Enumerated values: TRUE FALSE Present if there is a TC8 risk score. Volpara Private Attribute.	ALWAYS	AUTO

#### 9.1.1.4 Secondary Capture Modules

Table 9.9 General Series module of created SC image SOP instances

Attribute name	Tag	VR	Value	Presence of value	Source
Modality	(0008,0060)	CS	"MG"	ALWAYS	AUTO
Series Instance UID	(0020,000E)	UI	Generated automatically by the system	ALWAYS	AUTO
Series Number	(0020,0011)	IS	Generated automatically by the system	ALWAYS	AUTO
Series Date	(0008,0021)	DA	The date at document generation	ALWAYS	AUTO
Series Time	(0008,0031)	TM	The time at document generation	ALWAYS	AUTO
Series Description	(0008,103E)	LO	"Mammography density Secondary Capture Series" or "Mammography density map Secondary Capture Series"	ALWAYS	AUTO
Body Part Examined	(0018,0015)	CS	"BREAST"	ALWAYS	AUTO

Table 9.10 SC Equipment module of created SC image SOP instances

Attribute name	Tag	VR	Value	Presence of value	Source
Conversion Type	(0008,0064)	CS	"WSD"	ALWAYS	AUTO
Modality	(0008,0060)	CS	"MG"	ALWAYS	AUTO

Table 9.11 General Image module of created SC image SOP instances

Attribute name	Tag	VR	Value	Presence of value	Source
Instance Number	(0020,0013)	IS	"1"	ALWAYS	AUTO
Patient Orientation	(0020,0020)	CS	Zero length	ALWAYS	AUTO
Content Date	(0008,0023)	DA	The date of document generation	ALWAYS	AUTO
Content Time	(0008,0033)	TM	The time of document generation	ALWAYS	AUTO
Image Type	(0008,0008)	CS	"ORIGINAL\SECONDARY"	ALWAYS	AUTO
Burned in Annotation	(0028,0301)	CS	"YES"	ALWAYS	AUTO
Referenced Image Sequence	(0008,1140)	SQ	The set of mammography images contributing to the density result	ALWAYS	AUTO
>Referenced SOP Class UID	(0008,1150)	UI	SOP Class UID of contributing instance (raw mammography or Hologic SC Image)	ALWAYS	AUTO
>Referenced SOP Instance UID	(0008,1155)	UI	SOP Instance UID of contributing instance	ALWAYS	AUTO
Recognizable Visual Features	(0028,0302)	CS	"NO"	ALWAYS	AUTO
Icon Image Sequence	(0088,0200)	SQ	Image containing the VDG score	ALWAYS	AUTO
>Samples per Pixel	(0028,0002)	US	1	ALWAYS	AUTO
>Photometric Interpretation	(0028,0004)	CS	MONOCHROME2	ALWAYS	AUTO
>Rows	(0028,0010)	US	64	ALWAYS	AUTO
>Columns	(0028,0011)	US	64	ALWAYS	AUTO
>Bits Allocated	(0028,0100)	US	8	ALWAYS	AUTO
>Bits Stored	(0028,0101)	US	8	ALWAYS	AUTO
>High Bit	(0028,0102)	US	7	ALWAYS	AUTO
>Pixel Representation	(0028,0103)	US	0	ALWAYS	AUTO
>Pixel Data	(7FE0,0010)	OW	Pixel data for icon image ("scorecard" image only)	ALWAYS	AUTO

Table 9.12 Image Pixel module of created SC image SOP instances

Attribute name	Tag	VR	Value	Presence of value	Source
Samples per Pixel	(0028,0002)	US	1	ALWAYS	AUTO
Photometric Interpretation	(0028,0004)	CS	"MONOCHROME2"	ALWAYS	AUTO
Rows	(0028,0010)	US	1165 minimum (more if additional outputs are configured for display)	ALWAYS	AUTO
Columns	(0028,0011)	US	1414	ALWAYS	AUTO
Bits Allocated	(0028,0100)	US	8	ALWAYS	AUTO
Bits Stored	(0028,0101)	US	8	ALWAYS	AUTO
High Bit	(0028,0102)	US	7	ALWAYS	AUTO
Pixel Representation	(0028,0103)	US	0	ALWAYS	AUTO
Pixel Data	(7FE0,0010)	OB	Image generated by software.	ALWAYS	AUTO

**SC Image Density Scorecards only:** If Scorecard is licensed, include Table 9.8 TruDensity, TruRadDose and TruPressure results macro.

Table 9.13 SC Image module of created SC image SOP instances

Attribute name	Tag	VR	Value	Presence of value	Source
No attributes provided from this module.					

Table 9.14 VOI LUT module of created SC image SOP instances (MONOCHROME2 only)

Attribute name	Tag	VR	Value	Presence of value	Source
Window Center	(0028,1050)	DS	"128" (MONOCHROME2 only)	ALWAYS	AUTO
Window Width	(0028,1051)	DS	"256" (MONOCHROME2 only)	ALWAYS	AUTO

### 9.1.1.5 Mammography CAD SR Modules

Table 9.15 SR Document Series module of created mammography CAD SR SOP instances

Attribute name	Tag	VR	Value	Presence of value	Source
Modality	(0008,0060)	CS	"SR"	ALWAYS	AUTO
Series Instance UID	(0020,000E)	UI	Generated automatically by the system	ALWAYS	AUTO
Series Number	(0020,0011)	IS	"1"	ALWAYS	AUTO
Series Date	(0008,0021)	DA	The date at document generation	ALWAYS	AUTO
Series Time	(0008,0031)	TM	The time at document generation	ALWAYS	AUTO
Series Description	(0008,103E)	LO	"Mammography density SR Series"	ALWAYS	AUTO
Referenced Performed Procedure Step Sequence	(0008,1111)	SQ	Zero Length	ALWAYS	AUTO

Table 9.16 SR Document General module of created mammography CAD SR SOP instances

Attribute name	Tag	VR	Value	Presence of value	Source
Instance Number	(0020,0013)	IS	"1"	ALWAYS	AUTO
Preliminary Flag	(0040,A496)	CS	"FINAL"	ALWAYS	AUTO
Completion Flag	(0040,A491)	CS	"COMPLETE"	ALWAYS	AUTO
Verification Flag	(0040,A493)	CS	"UNVERIFIED"	ALWAYS	AUTO
Content Date	(0008,0023)	DA	The date of document generation	ALWAYS	AUTO
Content Time	(0008,0033)	TM	The time of document generation	ALWAYS	AUTO
Performed Procedure Code Sequence	(0040,A372)	SQ	Zero length	ALWAYS	AUTO
Current Requested Procedure Evidence Sequence	(0040,A375)	SQ	Contains references to Series and Images used for the density calculation.	ALWAYS	AUTO

*If Volpara Scorecard is licensed, include Table 9.8.*

Table 9.17 SR Document Content module of created mammography CAD SR SOP instances

Attribute name	Tag	Req Type	Value	Presence of value	Source
Value Type	(0040,A040)		"CONTAINER"	ALWAYS	AUTO
Concept Name Code Sequence	(0040,A043)	1C	One sequence item - identifies the report type	ALWAYS	AUTO
>Code Value	(0008,0100)	1	"111036"	ALWAYS	AUTO
>Coding Scheme Designator	(0008,0102)	1	"DCM"	ALWAYS	AUTO
>Code Meaning	(0008,0104)	1	"Mammography CAD Report"	ALWAYS	AUTO
Continuity of Content	(0040,A050)	1	"SEPARATE"	ALWAYS	AUTO
Content Template Sequence	(0040,A504)	1C	One sequence item - identifies the root template	ALWAYS	AUTO
>Mapping Resource	(0008,0105)	1	"DCMR"	ALWAYS	AUTO
>Template Identifier	(0040,DB00)	1	"4000"	ALWAYS	AUTO
Content Sequence	(0040,A730)	1C	Sequence contains multiple Items according to TID 4000.	ALWAYS	AUTO
(Items)			Include Items for TID 4000 "Mammography CAD Document Root". See Figure 1 and Table 9.18 Mammography CAD document root (TID 4000).	ALWAYS	AUTO

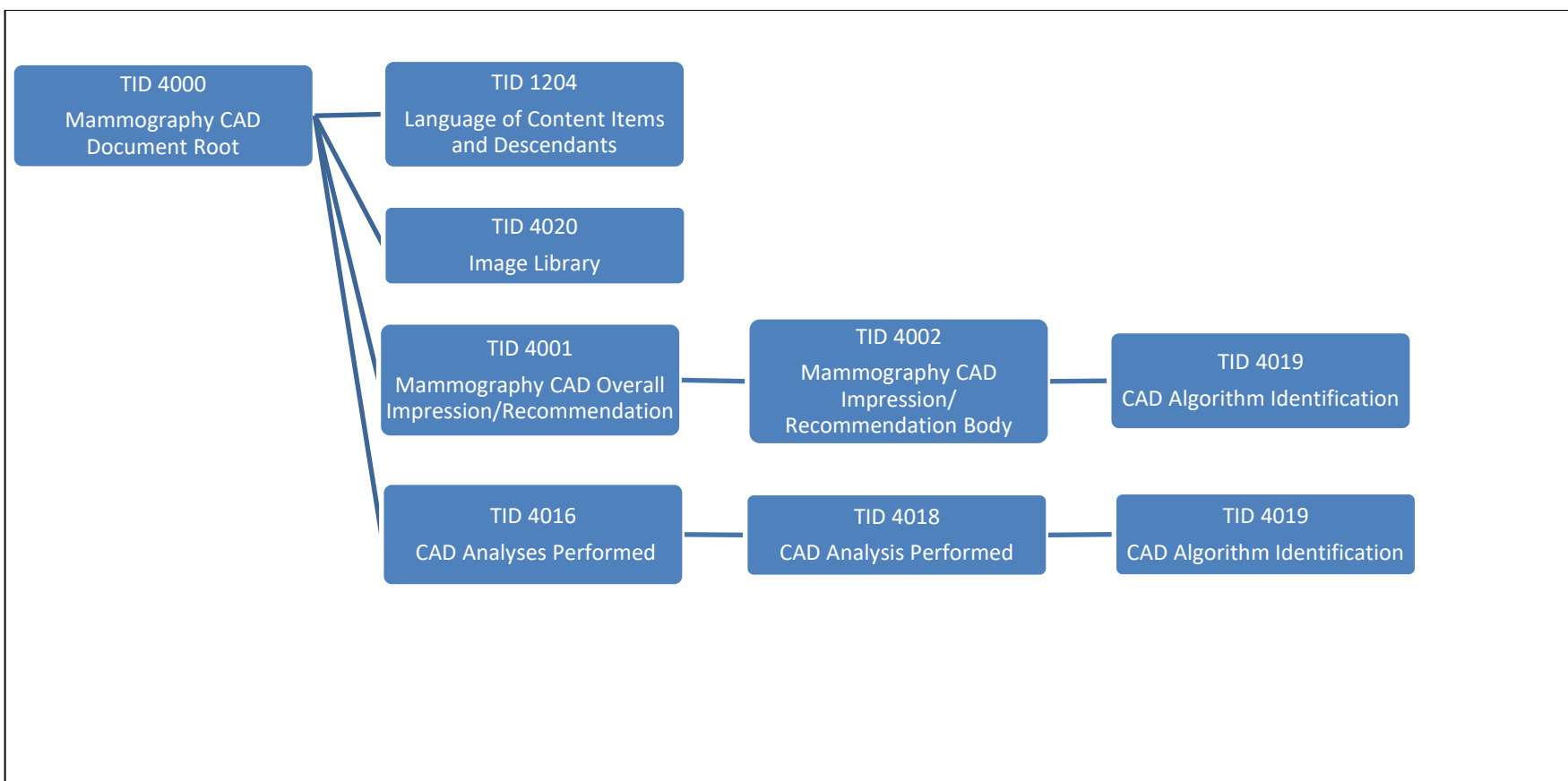


Figure 1. Mammography CAD SR structure

Table 9.18 Mammography CAD document root (TID 4000)

	NL	Rel with Parent	VT	Req Type	Concept name	Value	Presence of value
1			CONTAINER	M	EV (111036, DCM, "Mammography CAD Report")	-	ALWAYS
2	>	HAS CONCEPT MOD	INCLUDE	M	DTID 1204 "Language of Content Item and Descendants"	Refer to Table 9.19	ALWAYS
3	>	CONTAINS	CONTAINER	M	EV (111028, DCM, "Image Library")	-	ALWAYS
4	>>	CONTAINS	INCLUDE	M	DTID 4020 "CAD Image Library Entry"	Refer to Table 9.24 CAD image library entry (TID 4020)	ALWAYS
5	>	CONTAINS	INCLUDE	M	DTID 4001 "Mammography CAD Overall Impression/Recommendation"	Refer to Table 9.20 Mammography overall CAD impression/recommendation (DTID 4001)	
6	>	CONTAINS	CODE	M	EV (111064, DCM, "Summary of Detections")	111225, DCM, "Not Attempted"	ALWAYS

	NL	Rel with Parent	VT	Req Type	Concept name	Value	Presence of value
8	>	CONTAINS	CODE	M	EV (111065, DCM, "Summary of Analyses")	One of the following: 111222, DCM, "Succeeded" if a VDG density score was generated by Lunit, and all images yielded a density result. 111223, DCM, "Partially Succeeded" if a VDG density score was generated by Lunit, and one or more images did not yield a density result. 111224, DCM, "Failed" if a VDG density score was NOT generated by Lunit.	ALWAYS
9	>>	INFERRED FROM	INCLUDE	M	DTID 4016 "CAD Analyses Performed"	Refer to Table 9.21 CAD analyses performed (TID 4016)	ALWAYS

Table 9.19 Language of content and descendants (DTID 1204)

	NL	Rel with Parent	VT	Req Type	Concept name	Value	Presence of value
1		HAS CONCEPT MOD	CODE	M	EV (121049, DCM, "Language of Content Item and Descendants")	(en, RFC3066, "English")	ALWAYS
2	>	HAS CONCEPT MOD	CODE	U	EV (121046, DCM, "Country of Language")	(US, ISO3166_1, "UNITED STATES")	ALWAYS

Table 9.20 Mammography overall CAD impression/recommendation (DTID 4001)

	NL	Rel with Parent	VT	Req Type	Concept name	Value	Presence of value
1			CODE	M	EV (111017, DCM, "CAD Processing and Findings Summary") EV (111017, DCM, "CAD Processing and Findings Summary")	One of: 111242, DCM, "All algorithms succeeded; with findings" if a VDG score was generated 111244, DCM, "Not all algorithms succeeded; with findings" if a VDG was generated, but one or more images failed to yield a result. 111245, DCM, "Not algorithms succeeded; without findings" if a VDG was not generated (a "null report")	ALWAYS
2	>	HAS PROPERTIES	INCLUDE	U	DTID 4002 Mammography CAD Impression/ Recommendation Body	Refer to Table 9.25 Mammography CAD impression/recommendation body (TID 4002)	ANAP

Table 9.21 CAD analyses performed (TID 4016)

	NL	Rel with Parent	VT	Req Type	Concept name	Value	Presence of value
1			CONTAINER	MC	EV (111062, DCM, "Successful Analyses")	-	ANAP (present if value of parent is (111222, DCM, "Succeeded")
2	>	CONTAINS	INCLUDE	M	DTID 4018 "CAD Analysis Performed"	Refer to Table 9.22 CAD analysis performed (TID 4018)	ALWAYS
3			CONTAINER	MC	EV (111024, DCM, "Failed Analyses")	-	ANAP (present if value of parent is (111224, DCM, "Failed")

	NL	Rel with Parent	VT	Req Type	Concept name	Value	Presence of value
4	>	CONTAINS	INCLUDE	M	DTID 4018 "CAD Analysis Performed"	Refer to Table 9.22 CAD analysis performed (TID 4018)	ALWAYS

Table 9.22 CAD analysis performed (TID 4018)

	NL	Rel with Parent	VT	Req Type	Concept name	Value	Presence of value
1			CODE	M	EV (111004, DCM, "Analysis Performed")	P5-B3414,SRT, "Breast composition analysis"	ALWAYS
2	>	HAS PROPERTIES	INCLUDE	M	DTID 4019 CAD Algorithm Identification	Refer to Table 9.23 CAD algorithm identification (TID 4019)	ALWAYS
4	>	R-HAS PROPERTIES	IMAGE	MC		Reference to an IMAGE content item in the "Image Library" based on its node position. Repeat for every image the algorithm has processed.	ALWAYS

Table 9.23 CAD algorithm identification (TID 4019)

	NL	Rel with Parent	VT	Req Type	Concept name	Value	Presence of value
1			TEXT	M	EV (111001, DCM, "Algorithm Name")	"Volpara"	ALWAYS
2			TEXT	M	EV (111003, DCM, "Algorithm Version")	Algorithm Version	ALWAYS

Table 9.24 CAD image library entry (TID 4020)

	NL	Rel with Parent	VT	Req Type	Concept name	Value	Presence of value
1			IMAGE	M		Referenced SOP Sequence containing the SOP Class UID and SOP Instance UID copied from the source image header	ALWAYS
2	>	HAS ACQ CONTEXT	CODE	MC	EV (111027, DCM, "Image Laterality")	If Right Breast: T-04020, SRT, "Right breast"  If Left Breast: T-04030, SRT, "Left breast"	ALWAYS
3	>	HAS ACQ CONTEXT	CODE	MC	EV (111031, DCM, "Image View")	Copied from source image View Code Sequence	ALWAYS
4	>>	HAS CONCEPT MOD	CODE	MC	EV (111032, DCM, "Image View Modifier")	Copied from source image View Modifier Code Sequence	ANAP
5	>	HAS ACQ CONTEXT	TEXT	MC	EV (111044, DCM, "Patient Orientation Row")	Copied from source image (0020,0020) attribute value 1	ALWAYS
6	>	HAS ACQ CONTEXT	TEXT	MC	EV (111043, DCM, "Patient Orientation Column")	Copied from source image (0020,0020) attribute value 2	ALWAYS
7	>	HAS ACQ CONTEXT	DATE	MC	EV (111060, DCM, "Study Date")	Copied from source image Study Date (0008,0020) attribute value	ALWAYS
8	>	HAS ACQ CONTEXT	TIME	MC	EV (111061, DCM, "Study Time")	Copied from source image Study Time (0008 0030) if value is not empty	ANAP
9	>	HAS ACQ CONTEXT	DATE	MC	EV (111018, DCM, "Content Date")	Copied from source image Content Date (0008,0023) if value is not empty	ANAP

	NL	Rel with Parent	VT	Req Type	Concept name	Value	Presence of value
10	>	HAS ACQ CONTEXT	TIME	MC	EV (111019, DCM, "Content Time")	Copied from source image Study Time (0008,0033) if value is not empty	ANAP
11	>	HAS ACQ CONTEXT	NUM	MC	EV (111026, DCM, "Horizontal Pixel Spacing")	Converted from source image header (0018,1164) attribute value 1. UNITS = (mm, UCUM, "millimeter")	ANAP
12	>	HAS ACQ CONTEXT	NUM	MC	EV (111066, DCM, "Vertical Pixel Spacing")	Converted from source image header (0018,1164) attribute value 2. UNITS = (mm, UCUM, "millimeter")	ANAP
13	>	HAS ACQ CONTEXT	NUM	UC	EV (112011, DCM, "Positioner Primary Angle")	Copied from source image (0018,1510) Assumes UNITS = (deg, UCUM, "o")	ANAP
14	>	HAS ACQ CONTEXT	NUM	UC	EV (112012, DCM, "Positioner Secondary Angle")	Copied from source image (0018,1511) Assumes UNITS = (deg, UCUM, "o")	ANAP

Table 9.25 Mammography CAD impression/recommendation body (TID 4002)

	NL	Rel with Parent	VT	Req Type	Concept name	Value	Presence of value
5			TEXT	MC	EV (111033, DCM, "Impression Description")	"Volpara breast density findings"	ALWAYS
11			INCLUDE	M	DTID 4019 CAD Algorithm Identification	Refer to Table 9.23 CAD algorithm identification (TID 4019)	ALWAYS
<b>Left breast results</b>							
12			NUM	U	DCID 6142 Calculated Value	(112193, DCM, "Volume of breast") Present if 111017 (in TID 4000) is 111242 or 111244.	ANAP
13	>	HAS CONCEPT MOD	CODE	U	EV (G-C171, SRT, "Laterality")	(T-04030, SRT, "Left breast")	ALWAYS
14	>	HAS CONCEPT MOD	CODE	M	EV (121401, DCM, "Derivation")	(112189, DCM, "Three-dimensional method")	ALWAYS
12			NUM	U	DCID 6142 Calculated Value	(112192, DCM, "Volume of parenchymal tissue") Present if 111017 (in TID 4000) is 111242 or 111244.	ANAP
13	>	HAS CONCEPT MOD	CODE	U	EV (G-C171, SRT, "Laterality")	(T-04030, SRT, "Left breast")	ALWAYS
14	>	HAS CONCEPT MOD	CODE	M	EV (121401, DCM, "Derivation")	(112189, DCM, "Three-dimensional method")	ALWAYS
12			NUM	U	DCID 6142 Calculated Value	(112191, DCM, "Breast tissue density") Present if 111017 (in TID 4000) is 111242 or 111244.	ANAP
13	>	HAS CONCEPT MOD	CODE	U	EV (G-C171, SRT, "Laterality")	(T-04030, SRT, "Left breast")	ALWAYS
14	>	HAS CONCEPT MOD	CODE	M	EV (121401, DCM, "Derivation")	(112189, DCM, "Three-dimensional method")	ALWAYS

	NL	Rel with Parent	VT	Req Type	Concept name	Value	Presence of value
<b>Right breast results</b>							
12			NUM	U	DCID 6142 Calculated Value	(112193, DCM, "Volume of breast") Present if 111017 (in TID 4000) is 111242 or 111244.	ANAP
13	>	HAS CONCEPT MOD	CODE	U	EV (G-C171, SRT, "Laterality")	(T-04020, SRT, "Right breast")	ALWAYS
14	>	HAS CONCEPT MOD	CODE	M	EV (121401, DCM, "Derivation")	(112189, DCM, "Three-dimensional method")	ALWAYS
12			NUM	U	DCID 6142 Calculated Value	(112192, DCM, "Volume of parenchymal tissue") Present if 111017 (in TID 4000) is 111242 or 111244.	ANAP
13	>	HAS CONCEPT MOD	CODE	U	EV (G-C171, SRT, "Laterality")	(T-04020, SRT, "Right breast")	ALWAYS
14	>	HAS CONCEPT MOD	CODE	M	EV (121401, DCM, "Derivation")	(112189, DCM, "Three-dimensional method")	ALWAYS
12			NUM	U	DCID 6142 Calculated Value	(112191, DCM, "Breast tissue density") Present if 111017 (in TID 4000) is 111242 or 111244.	ANAP
13	>	HAS CONCEPT MOD	CODE	U	EV (G-C171, SRT, "Laterality")	(T-04020, SRT, "Right breast")	ALWAYS
14	>	HAS CONCEPT MOD	CODE	M	EV (121401, DCM, "Derivation")	(112189, DCM, "Three-dimensional method")	ALWAYS
<b>Bilateral results</b>							
12			NUM	U	DCID 6142 Calculated Value	(112191, DCM, "Breast tissue density") Present if 111017 (in TID 4000) is 111242 or 111244.	ANAP

	NL	Rel with Parent	VT	Req Type	Concept name	Value	Presence of value
13	>	HAS CONCEPT MOD	CODE	-	EV (G-C171, SRT, "Laterality")	(T-04080, SRT, "Both breasts")	ALWAYS
14	>	HAS CONCEPT MOD	CODE	-	EV (121401, DCM, "Derivation")	(112189, DCM, "Three-dimensional method")	ALWAYS
15	>	HAS CONCEPT MOD	TEXT	-	EV (112034, DCM, "Calculation Description")	"AVERAGE" or "MAXIMUM", as reported in (0015,1036) Volpara Reported Density Type (see Table 9.8 TruDensity, TruRadDose and TruPressure results macro).	ALWAYS
<b>Bilateral results—standard extended attributes</b>							
12			CODE	-	EV (F-01710, SRT, "Breast composition")	See DCID 6000 (DCID 6001) Overall Breast Composition. Values are: (F-01711,SRT,Almost entirely fat) (F-01712,SRT, Scattered fibroglandular densities) (F-01713,SRT, Heterogeneously dense) (F-01714,SRT, Extremely dense) Present if 111017 (in TID 4000) is 111242 or 111244.	ANAP
13	>	HAS CONCEPT MOD	CODE	-	EV (G-C171, SRT, "Laterality")	(T-04080, SRT, "Both breasts")	ALWAYS
14	>	HAS CONCEPT MOD	CODE	-	EV (121401, DCM, "Derivation")	(112189, DCM, "Three-dimensional method")	ALWAYS
15	>	HAS CONCEPT MOD	TEXT	-	EV (112034, DCM, "Calculation Description")	"AVERAGE" or "MAXIMUM", as reported in (0015,1036) Volpara Reported Density Type (see Table 9.8 TruDensity, TruRadDose and TruPressure results macro).	ALWAYS

## 9.1.2 Usage of Attributes from Received IODs

### 9.1.2.1 Attributes and Values Required for All Images

The following attributes and values are required to be present with values as described, in order for processing to take place.

Table 9.26 Attributes required in all mammography images

DICOM Tag	Required*	Description	Allowed/ Expected Value(s)	Constraint
(0008,0020)	N	Study Date		If present, copied onto the scorecard outputs.
(0008,0023)	N	Content Date		If present, copied onto the scorecard outputs.
(0008,0030)	N	Study Time		If present, copied onto the scorecard outputs.
(0008,0060)	Y	Modality		If not equal to "MG": The Image is not processed.
(0008,0070)	Y	Manufacturer		If ([manufacturer], [model]) combination is not one of the following: The image will not be processed.  Note: Additional scanners may be validated on a case-by-case basis: ([*], [Senograph, ADS, HOLOGIC, LORAD, Mammo-Clinical]) ([GE MEDICAL, HOLOGIC, LORAD, MEDI_FUTURE, MediFuture]), [*] ([GE HEALTHCARE], [Pristina]) ([FUJI], [AMULET, ASPIRE, FDR-1000AWS, Clearview, CR-IR363AWS]) ([Planmed, Anrad], [Nuance, SMAMII]) ([Sectra, Philips], [L50, MDM 1.5]) ([Philips], [Philips]) ([SIEMENS], [Novation, Inspiration]) ([SIEMENS], [*] where (0008,0008) contains "TOMO_PROJ" ([MetalTronica], [Helianthus, Helantius]) ([IMS], [Giotto]) ([TMM], [MGU-1000D])
(0008,1090)	Y	Manufacturer's Model Name		
(0008,0068)	Y	Presentation Intent Type	FOR PROCESSING	If not equal to "FOR PROCESSING" for mammo images: The image will not be processed.
(0010,0040)	Y	Patient's Sex	F	Image rejected if set to "M".

DICOM Tag	Required*	Description	Allowed/ Expected Value(s)	Constraint
(0018,0015)	Y	Body Part Examined	BREAST	If not equal to "BREAST": Image is not processed.
(0018,0060)	Y	KVP		If missing: Image is not processed.
(0018,11A0)	Y	Body Part Thickness		If missing: Image is not processed.
(0018,7050)	Y	Filter Material	Mo/Mo, Mo/Rh, Mo/W, Mo/Al, Mo/Ag, Rh/Mo, Rh/Rh, Rh/W, Rh/Al, Rh/Ag, W/Mo, W/Rh, W/W, W/Al, and W/Ag	Lunit will only produce process images with Target/Filter combinations specified.
(0018,7052)	N	Filter Thickness Minimum		One or both of these values is highly recommended. If absent, Lunit will use a default.
(0018,7054)	N	Filter Thickness Maximum		
(0018,9328)	C	Exposure Time in milliseconds		Either (0018,9332) or both (0018,9330) and (0018,9332) are required for TruDensity scatter calculations.
(0018,9330)	C	X-Ray Tube Current in milliamperes		
(0018,9332)	C	Exposure in milliamperes seconds		
(0020,0020)	Y	Patient Orientation		If 1st value is not one of "A" or "P" and 2nd value is not one of "L", "F", "R", "FL", "FR", or "HL": Image not processed.
(0020,0060)	Y	Laterality		See Image Laterality (0020,0062)

DICOM Tag	Required*	Description	Allowed/ Expected Value(s)	Constraint
(0020,0062)	Y	Image Laterality		If not equal to "L" or "R" and Laterality (0020,0060) is missing or invalid: Image not processed.
(0028,0030)	C	Pixel Spacing		See Imager Pixel Spacing (0018,1164)
(0028,0010)	Y	Rows		These Type 1 Image Module attributes are required for correct processing of the image pixels.
(0028,0011)	Y	Columns		
(0028,0101)	Y	Bits Stored		
(0028,0102)	Y	High Bit		
(0028,0004)	Y	Photometric Interpretation		
(0028,1300)	Y	Breast Implant Present		If equals to "YES" and View Modifier Code Sequence (0054,0222) is not present or does not contain a Value of "R-102D5": Image not processed.
(0054,0220)	Y	View Code Sequence		If Code Value not equal to "R-10226" (MLO) or "R-10242" (CC) for mammography images: Image not processed.
(0054,0222)	Y	View Modifier Code Sequence		See Breast Implant Present (0028,1300)

\* C = Conditional, N = Not required, Y = Required

### 9.1.2.2 Manufacturer-specific Requirements

The following attributes and values are required to be present for specific manufacturer and image types, in order for processing to take place.

Table 9.27 Manufacturer-specific attributes required in mammography images

Tag	Name	Description
<b>Hologic/LORAD</b>		
(0019,xx26)	Hologic Paddle ID Description	Images having values of "10CMC", or "7.5CMC" are not processed.
(7e01,xx02)	Hologic Codec Content Type	Used to determine if the image is a raw tomosynthesis image. Images having a value not equal to "HLXR" are not processed.
<b>Fuji</b>		
(0018,6000)	Sensitivity	
(0025,xx13)	Latitude	Fuji private attribute

### 9.1.3 Attribute Mapping

Various attributes are used in Secondary Capture, and Mammography CAD SR. Refer to Created SOP Instances. See Section 9.1.1 for more information.

### 9.1.4 Coerced/Modified Fields

Not applicable.

## 9.2 Data Dictionary of Private Attributes

The following private attributes are defined:

Name	Tag	VR	VM	Notes
MATAKINA_10	(0015,0010)	LO	1	Private Data Element Creator

Name	Tag	VR	VM	Notes
Reported Volpara Density Grade	(0015,1028)	LO	1	
Volpara Density Grade - 4th Edition	(0015,102A)	SH	1	
Volpara Reporting Edition	(0015,102C)	IS	1	
Volpara Calculated Values	(0015,1032)	LT	1	
Volpara Reported Density	(0015,1033)	DS	1	
Volpara Density Grade - 5th Edition	(0015,1035)	SH	1	
Volpara Reported Density Type	(0015,1036)	CS	1	
Volpara Average Glandular	(0015,1039)	DS	1	
Volpara Average Applied Pressure	(0015,1040)	DS	1	
Volpara Density Reason Not Used Values	(0015,1070)	LT	1	
Volpara Creator Full Version	(0015,1075)	LO	1	
Volpara Image Type Values	(0015,1077)	LT	1	
Volpara Density Production UDI	(0015,10B1)	LO	1	

## 9.3 Coded Terminology and Templates

### 9.3.1 Context Groups

Created Mammography CAD SR SOP Instances use the context groups that are associated with DICOM TID 4000 and related templates.

### 9.3.2 Template Specifications Groups

### 9.3.3 Mammography CAD SR

Created Mammography CAD SR SOP Instances use DICOM TID 4000 and related templates. An extension is used to report the overall VDG (BIRADS) score. This extension is described in Table 9.1 28

## 9.4 Grayscale Image Consistency

Not applicable.

## 9.5 Standard Extended/Specialized/Private SOP Classes

None.

## 9.6 Private Transfer Syntaxes

None.



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