

Breast Ring-array Ultrasound Imaging System

COCOLY*

DICOM Conformance Statement

Software Version 1.4.0

*COCOLY is a certified medical device only applicable in Japan.



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CONFORMANCE STATEMENT OVERVIEW

Breast Ring-array Ultrasound Imaging System COCOLY acquires the ultrasound data and reconstructs the slice and volume images to provide diagnostic images. It downloads worklists from information systems and save these images to network storage using the Digital Imaging and Communications in Medicine system, DICOM.

Table 1.1-1 provides an overview of the network services supported by COCOLY.

Table 1.1-1
NETWORK SERVICES

SOP Classes	User of Service (SCU)	Provider of Service (SCP)
Transfer		
US Image Storage	Yes	No
CT Image Storage	Yes	No
Workflow Management		
Modality Worklist Information Model – Find	Yes	No

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1. INTRODUCTION

1.1. AUDIENCE

This document is written for the people that need to understand how COCOLY 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. 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.

1.2. REMARKS

The scope of this DICOM Conformance Statement is to facilitate integration between COCOLY and other DICOM products. The Conformance Statement should be read and understood in conjunction with the DICOM Standard. DICOM by itself does not guarantee interoperability. This Conformance Statement is not supposed to replace validation with other DICOM equipment to ensure proper exchange of intended information.

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.

1.3. 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 Worklist Information Model Find SOP Class.

Application Entity (AE) – an end point 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).

COCOLY – The breast ring-array ultrasound imaging system of this conformance.

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: SC Image IOD.

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 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 (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 a 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) [Pixel Data], (0019,0210) [private data element]

Transfer Syntax – the encoding used for exchange of DICOM information objects and messages.

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.

1.4. ABBREVIATIONS

AE	Application Entity
CT	Computed Tomography
DICOM	Digital Imaging and Communications in Medicine
HIS	Hospital Information System
IOD	Information Object Definition
IPv4	Internet Protocol version 4
IPv6	Internet Protocol version 6
ISO	International Organization for Standards
MWL	Modality Worklist
PACS	Picture Archiving and Communication System
PDU	Protocol Data Unit
RIS	Radiology Information System.
SCP	Service Class Provider
SCU	Service Class User
SOP	Service-Object Pair
TCP/IP	Transmission Control Protocol/Internet Protocol
US	Ultrasound
VR	Value Representation

1.5. REFERENCES

NEMA PS3 Digital Imaging and Communications in Medicine (DICOM) Standard, available free at <https://www.dicomstandard.org/>

2. NETWORKING

2.1. IMPLEMENTATION MODEL

2.1.1. Application Data Flow

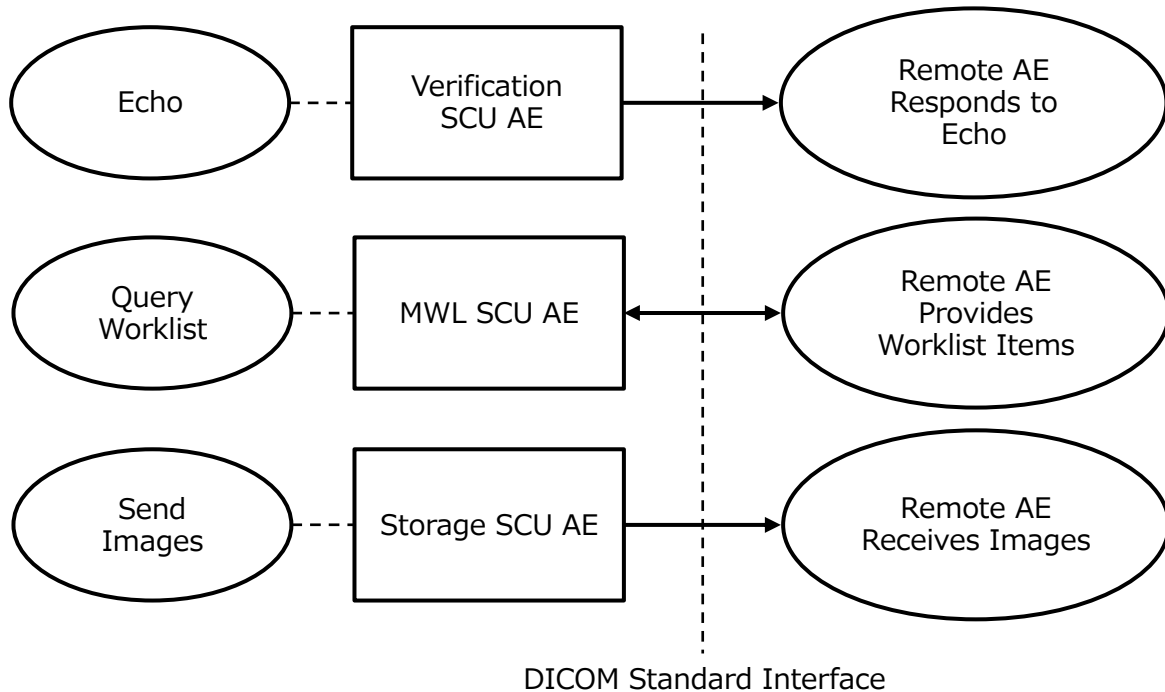


Figure 2.1-1
APPLICATION DATA FLOW DIAGRAM

- The Verification SCU AE sends a verification request to a remote AE.
In order to verify DICOM connection, C-Echo is issued to remote AE by executing the verify operation via service tool.
- The MWL SCU AE receives Worklist information from a remote AE.
Worklist information is acquired from Remote AE by executing the worklist operation in COCOLY.
- The Storage SCU AE sends images to a remote AE.
Images are transmitted to Remote AE by executing image transmission operation in COCOLY.

2.1.2. Functional Definition of AE's

2.1.2.1. Functional Definition of Storage Application Entity

When the image transmission operation is executed in COCOLY, Storage AE creates an IOD based on the image data, imaging information, and order information acquired by MWL (in the case of an independently issued inspection, the order information acquired by MWL does not exist, so COCOLY has Issue the required value), and starts image transfer.

2.1.2.2. Functional Definition of Workflow Application Entity

When the worklist operation is executed in COCOLY, Workflow AE creates an IOD based on the search conditions specified on the screen and the set search conditions, and C-FIND is executed for Remote AE.

2.1.3. Sequencing of Real World Activities

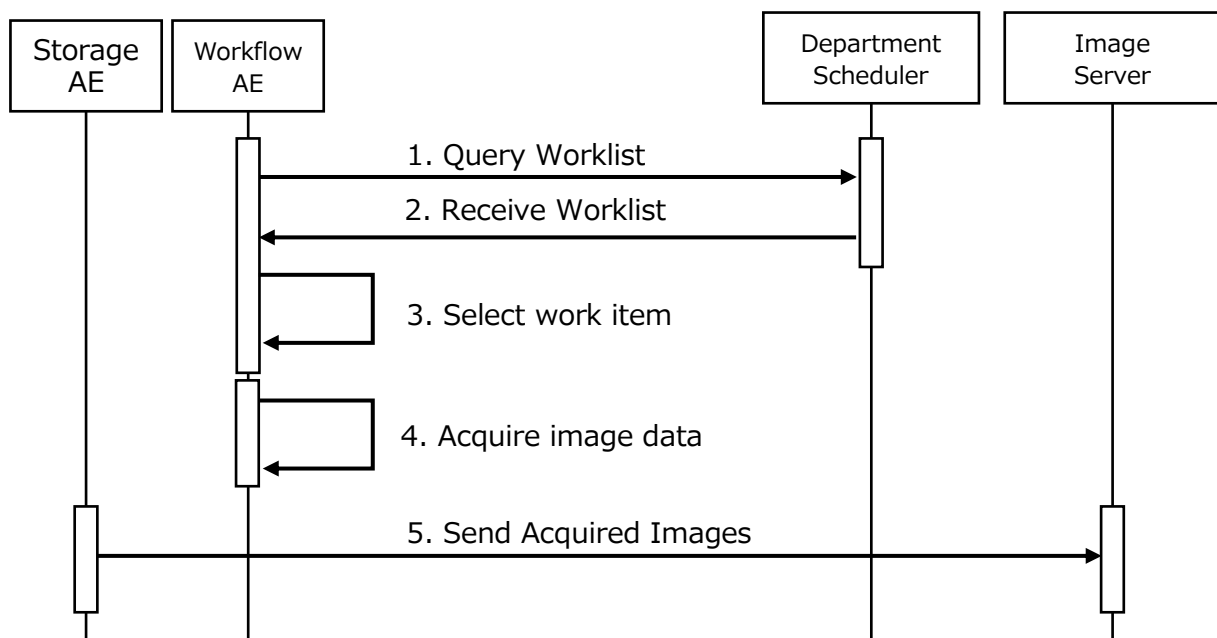


Figure 2.1-1
SEQUENCING CONSTRAINTS

Under normal scheduled workflow conditions the sequencing constraints illustrated in above Figure apply:

1. Query Worklist
2. Receive Worklist
3. Select work item from the Worklist
4. Acquire image data
5. Send Acquired images

2.2. AE SPECIFICATIONS

2.2.1. Verification SCU AE

2.2.1.1. SOP Classes

The Verification SCU AE provides Standard Conformance to the following SOP Classes:

Table 2.2-1

SOP CLASS FOR AE VERIFICARION

SOP Classes	SOP Class UID	SCU	SCP
Verification SOP Class	1.2.840.10008.1.1	Yes	No

2.2.1.2. Association Policies

2.2.1.2.1. General

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

Table 2.2-2

DICOM APPLICATION CONTEXT FOR AE VERIFICARION

Application Context Name	1.2.840.10008.3.1.1.1
--------------------------	-----------------------

2.2.1.2.2. Number of Associations

The Verification SCU AE initiates one Association at a time.

Table 2.2-3

NUMBER OF ASSOCIATIONS INITIATED FOR AE VERIFICARION

Maximum number of simultaneous Association	1
--	---

2.2.1.2.3. Asynchronous Nature

The Verification SCU AE does not support asynchronous mode.

2.2.1.2.4. Asynchronous Nature

The Verification SCU AE does not support asynchronous mode.

2.2.1.2.5. Implementation Identifying Information

The implementation information for this Application Entity is:

Table 2.2-4

DICOM IMPLEMENTATION CLASS AND VERSION FOR AE MWL

Implementation Class UID	1.2.392.200339.10339.1.1.4.0
Implementation Version Name	COCOLY_1.4.0

2.2.1.3. Association Initiation Policy

2.2.1.3.1. Activity – Send Echo

2.2.1.3.1.1. Description and Sequencing of Activities

By executing the verification operation in COCOLY, Verification SCU AE starts a new association for requesting C-Echo to Remote AE.

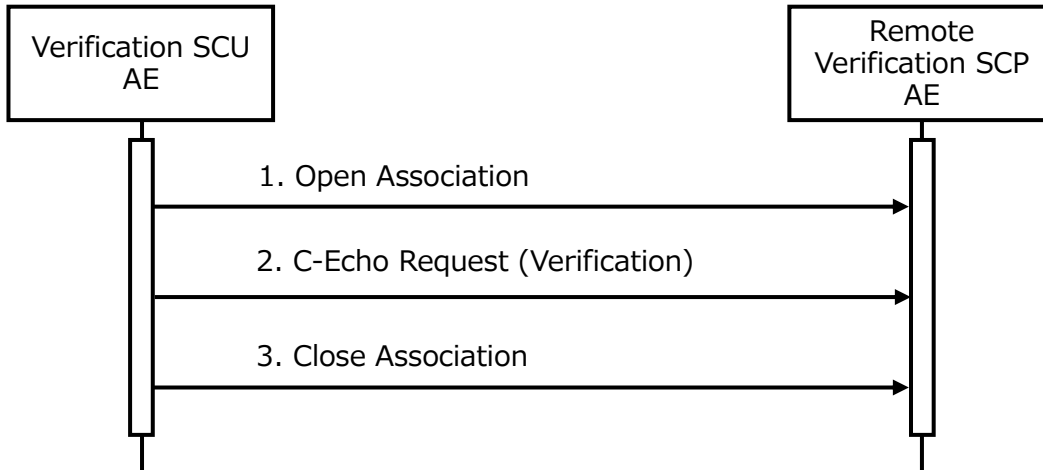


Figure 2.2-11
SEQUENCING OF ACTIVITY – SEND ECHO

A possible sequence of interactions between the Verification AE and a Verification SCP AE (e.g. image server or department scheduler device) is illustrated in above Figure:

1. The Verification SCU AE opens a new association with the Remote AE.
2. The Verification SCU AE sends C-Echo request to the Remote AE and the Remote AE replies with a C-ECHO response (status success).
3. The Verification SCU AE closes the association with the Remote AE.

2.2.1.3.1.2. Proposed Presentation Contexts

The Verification SCU AE supports the Presentation Contexts shown in the following table.

Table 2.2-5
PROPOSED PRESENTATION CONTEXTS FOR ACTIVITY SEND ECHO

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Ext. Neg.
Name	UID	Name List	UID List		
Verification	1.2.840.10008	Implicit VR	1.2.840.10008	SCU	None
	1.1	Little Endian	.1.2		

2.2.1.3.1.3. SOP Specific Conformance for Verification SOP Classes

The behavior of Verification SCU AE when encountering status codes in a C-ECHO response is summarized in the Table below:

**Table 2.2-6
VERIFICATION C-ECHO RESPONSE STATUS HANDLING BEHAVIOR**

Service Status	Further Meaning	Error Code	Behavior
Success	Success	0000	Status is displayed.
*	*	Any other status codes.	Use A-RELEASE to release the association. The error information is recorded in the log and the error information is displayed.

The behavior of Verification SCU AE during communication failure is summarized in the Table below:

**Table 2.2-7
STORAGE COMMUNICATION FAILURE BEHAVIOR**

Exception	Behavior
Timeout	The connection is disconnected.
Association aborted by the SCP or network layers	The error information is recorded in the log and the error information is displayed.

2.2.1.4. Association Acceptance Policy

The Verification SCU AE does not accept Associations.

2.2.2.Storage SCU AE

2.2.2.1. SOP Classes

The Storage SCU AE provides Standard Conformance to the following SOP Classes:

Table 2.2-8
SOP CLASS FOR AE STORAGE

SOP Classes	SOP Class UID	SCU	SCP
CT Image Storage	1.2.840.10008.5.1.4.1.1.2	Yes	No
Ultrasound Image Storage	1.2.840.10008.5.1.4.1.1.6.1	Yes	No

2.2.2.2. Association Policies

2.2.2.2.1. General

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

Table 2.2-9
DICOM APPLICATION CONTEXT FOR AE STORAGE

Application Context Name	1.2.840.10008.3.1.1.1
--------------------------	-----------------------

2.2.2.2.2. Number of Associations

The Storage SCU AE initiates one Association at a time for each destination to which a transfer request is being processed in the active job queue list. Only one job will be active at a time, the other remains pending until the active job is completed or failed.

Table 2.2-10
NUMBER OF ASSOCIATIONS INITIATED FOR AE STORAGE

Maximum number of simultaneous Association	1
--	---

2.2.2.2.3. Asynchronous Nature

The Storage SCU AE does not support asynchronous mode.

2.2.2.2.4. Implementation Identifying Information

The implementation information for this Application Entity is:

Table 2.2-11

DICOM IMPLEMENTATION CLASS AND VERSION FOR AE STORAGE

Implementation Class UID	1.2.392.200339.10339.1.1.4.0
Implementation Version Name	COCOLY_1.4.0

2.2.2.3. Association Initiation Policy

2.2.2.3.1. Activity – Send Images

2.2.2.3.1.1. Description and Sequencing of Activities

By executing the image transmission operation in COCOLY, Storage SCU AE starts a new association for requesting C-STORE to Remote AE.

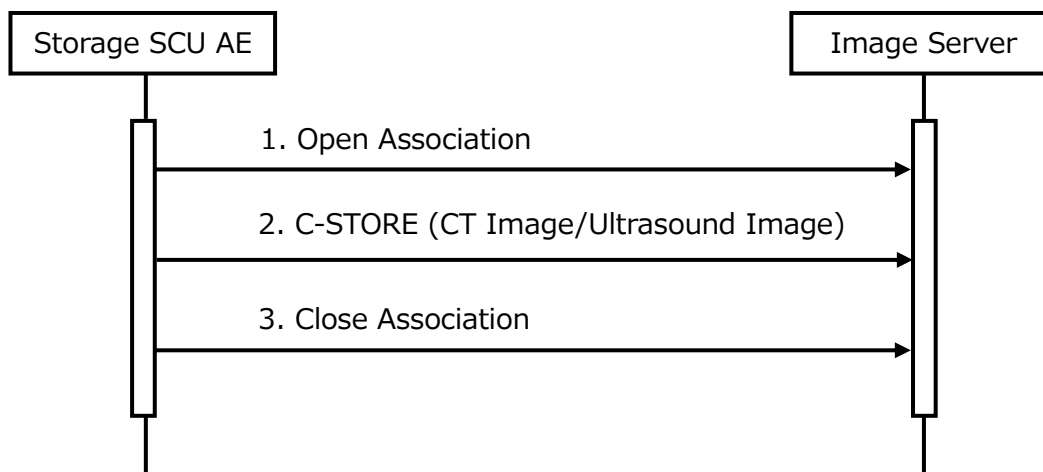


Figure 2.2-21

SEQUENCING OF ACTIVITY – SEND IMAGES

A possible sequence of interactions between the Storage AE and an Image Server (e.g. a storage or archive device supporting Storage SOP Classes as an SCP) is illustrated in above Figure:

4. The Storage SCU AE opens a new association with the Image Server.
5. Acquired images are transmitted to the Image Server using a C-STORE request and the Image Server replies with a C-STORE response (status success).
6. The Storage SCU AE closes the association with the Image Server.

2.2.2.3.1.2. Proposed Presentation Contexts

The Storage SCU AE will propose the Presentation Contexts shown in the following table.

**Table 2.2-12
PROPOSED PRESENTATION CONTEXTS FOR ACTIVITY SEND IMAGES**

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Ext. Neg.
Name	UID	Name List	UID List		
CT Image Storage	1.2.840.10008	Implicit VR	1.2.840.10008	SCU	None
	5.1.4.1.1.2	Little Endian	.1.2		
Ultrasound Image Storage	1.2.840.10008	Implicit VR	1.2.840.10008	SCU	None
	5.1.4.1.1.6.1	Little Endian	.1.2		

2.2.2.3.1.3. SOP Specific Conformance for Storage SOP Classes

The behavior of Storage SCU AE when encountering status codes in a Storage C-STORE response is summarized in the Table below:

**Table 2.2-13
STORAGE C-STORE RESPONSE STATUS HANDLING BEHAVIOR**

Service Status	Further Meaning	Error Code	Behavior
Success	Success	0000	End the transmission of image data.
Refused	Out of Resources	A700-A7FF	Use A-RELEASE to release the association. The error information is recorded in the log and the error information is displayed.
Error	Data Set does not match SOP Class	A900-A9FF	
Error	Cannot Understand	C000-CFFF	
Warning	Coercion of Data Elements	B000	
Warning	Data Set does not match SOP Class	B007	
Warning	Elements Discarded	B006	
*	*	Any other status codes.	

The behavior of Storage SCU AE during communication failure is summarized in the Table below:

Table 2.2-14
STORAGE COMMUNICATION FAILURE BEHAVIOR

Exception	Behavior
Timeout	The connection is disconnected.
Association aborted by the SCP or network layers	The error information is recorded in the log and the error information is displayed.

2.2.2.4. Association Acceptance Policy

The Storage SCU AE does not accept Associations.

2.2.3.MWL SCU AE

2.2.3.1. SOP Classes

The MWL SCU AE provides Standard Conformance to the following SOP Classes:

Table 2.2-15
SOP CLASS FOR AE MWL

SOP Classes	SOP Class UID	SCU	SCP
Modality Worklist Information Model - FIND	1.2.840.10008.5.1.4.31	Yes	No

2.2.3.2. Association Policies

2.2.3.2.1. General

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

Table 2.2-16
DICOM APPLICATION CONTEXT FOR AE MWL

Application Context Name	1.2.840.10008.3.1.1.1
--------------------------	-----------------------

2.2.3.2.2. Number of Associations

The MWL SCU AE initiates one Association at a time for a.

Table 2.2-17
NUMBER OF ASSOCIATIONS INITIATED FOR AE MWL

Maximum number of simultaneous Association	1
--	---

2.2.3.2.3. Asynchronous Nature

The MWL SCU AE does not support asynchronous mode.

2.2.3.2.4. Implementation Identifying Information

The implementation information for this Application Entity is:

Table 2.2-18
DICOM IMPLEMENTATION CLASS AND VERSION FOR AE MWL

Implementation Class UID	1.2.392.200339.10339.1.1.4.0
Implementation Version Name	COCOLY_1.4.0

2.2.3.3. Association Initiation Policy

2.2.3.3.1. Activity –Query Worklist

2.2.3.3.1.1. Description and Sequencing of Activities

By executing the worklist operation in COCOLY, MWL SCU AE starts a new association for requesting C-FIND to Remote AE.

Worklist search conditions are created based on the values set on the screen and the values set in the configuration file.

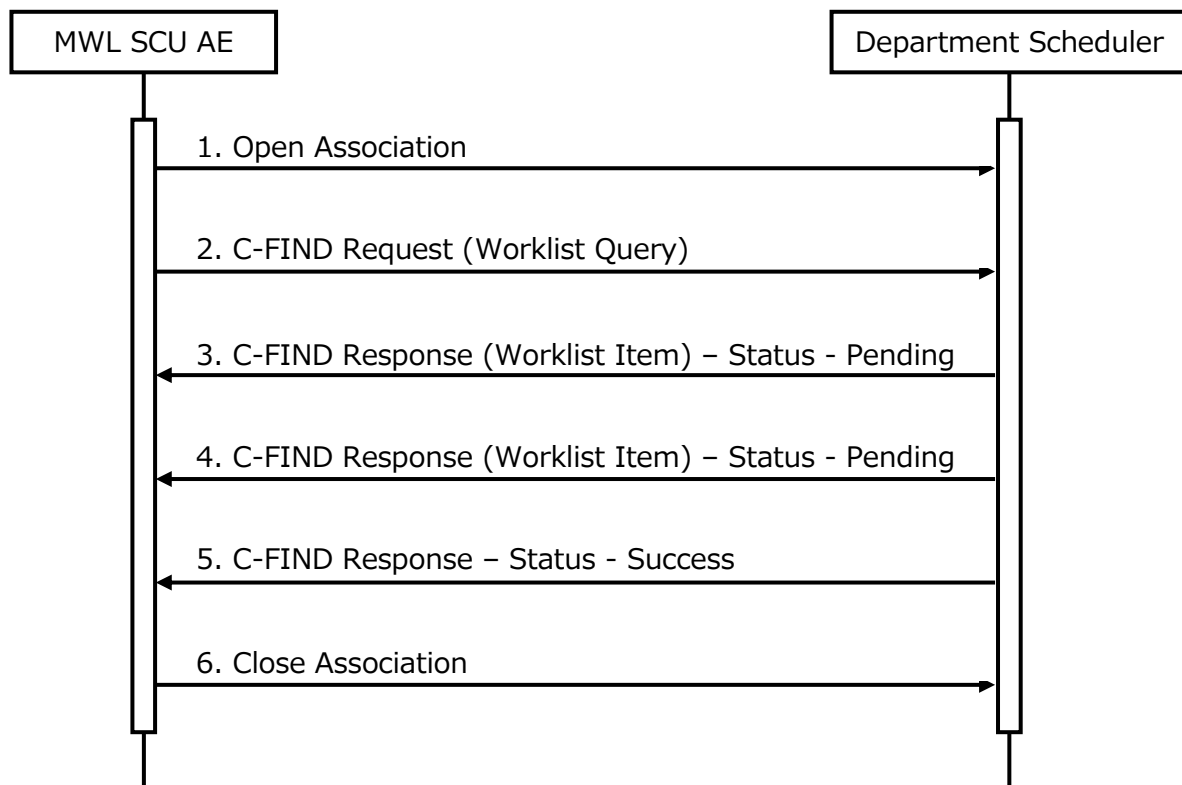


Figure 2.2-3
SEQUENCING OF ACTIVITY – QUERY WORKLIST

A possible sequence of interactions between the MWM SCU AE and a Department Scheduler (e.g. a device such as a RIS which supports the Modality Worklist SOP Class as an SCP) is illustrated in above Figure:

1. The MWM SCU AE opens an association with the Department Scheduler.
2. The MWM SCU AE sends a C-FIND request to the Department Scheduler containing the Worklist Query attributes.
3. The Department Scheduler returns a C-FIND response containing the requested attributes of the first matching Worklist Item.
4. The Department Scheduler returns another C-FIND response containing the requested attributes of the second matching Worklist Item.
5. The Department Scheduler returns another C-FIND response with status Success indicating that no further matching Worklist Items exist. This example assumes that only 2 Worklist items match the Worklist Query.
6. The MWM SCU AE closes the association with the Department Scheduler.

2.2.3.3.1.2. Proposed Presentation Contexts

The Storage SCU AE is capable of proposing the Presentation Contexts shown in the following table.

Table 2.2-19
PROPOSED PRESENTATION CONTEXTS FOR ACTIVITY WORKLIST UPDATE

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Ext. Neg.
Name	UID	Name List	UID List		
Modality Worklist Information Model - FIND	1.2.840.10008.5.1.4.31	Implicit VR Little Endian	1.2.840.10008.1.2	SCU	None

2.2.3.3.1.3. SOP Specific Conformance for MWL SOP Classes

The behavior of MWL SCU AE when encountering status codes in a Modality Worklist C-FIND response is summarized in the Table below:

Table 2.2-20**MODALITY WORKLIST C-FIND RESPONSE STATUS HANDLING BEHAVIOR**

Service Status	Further Meaning	Error Code	Behavior
Success	Success	0000	Finish getting the worklist. Display the contents of the acquired work list.
Refused	Out of Resources	A700-A7FF	Release the association using A-RELEASE. The error information is recorded in the log and the error information is displayed.
Error	Data Set does not match SOP Class	A900-A9FF	
Error	Cannot Understand	C000-CFFF	
Warning	Coercion of Data Elements	B000	
Warning	Data Set does not match SOP Class	B007	
Warning	Elements Discarded	B006	
*	*	Any other status codes.	

The behavior of MWL SCU AE during communication failure is summarized in the Table below:

Table 2.2-21**MODALITY WORKLIST COMMUNICATION FAILURE BEHAVIOR**

Exception	Behavior
Timeout	Disconnect the connection. The error information is recorded in the log and the error information is displayed.
Association aborted by the SCP or network layers	

Acquired images will always use the Study Instance UID specified for the Scheduled Procedure Step (if available). If an acquisition is unscheduled, a Study Instance UID will be generated locally.

The Table below provides a description of the MWL SCU AE Worklist Request Identifier and specifies the attributes that are copied into the images. Unexpected attributes returned in a C-FIND response are ignored.

Table 2.2-22
WORKLIST REQUEST IDENTIFIER

Attribute Name	Tag	VR	M	R	D
Scheduled Procedure Step Module					
Scheduled Procedure Step Sequence	(0040,0100)	SQ		x	
>Modality	(0008,0060)	CS	S	x	
>Scheduled Station AE Title	(0040,0001)	AE	S	x	
>Scheduled Procedure Step Start Date	(0040,0002)	DA	S	x	
>Scheduled Procedure Step Start Time	(0040,0003)	TM		x	
> Scheduled Performing Physician's Name	(0040,0006)	PN	*	x	
>Scheduled Procedure Step Description	(0040,0007)	LO		x	
>Scheduled Procedure Step ID	(0040,0009)	SH		x	
Requested Procedure Module					
Study Instance UID	(0020,000D)	UI		x	
Requested Procedure Description	(0032,1060)	LO		x	x
Requested Procedure ID	(0040,1001)	SH		x	
Imaging Service Request Module					
Accession Number	(0008,0050)	SH		x	x
Requesting Physician	(0032,1032)	PN		x	x
Requesting Service	(0032,1033)	LO		x	x
Visit Status Module					
Patient's Institution Residence	(0038,0400)	LO		x	
Patient Identification Module					
Patient's Name	(0010,0010)	PN		x	x
Patient ID	(0010,0020)	LO	S	x	
Patient Demographic Module					
Patient's Birth Date	(0010,0030)	DA		x	x
Patient's Sex	(0010,0040)	CS		x	
Patient's Size	(0010,1020)	DS		x	
Patient's Weight	(0010,1030)	DS		x	
Patient Comments	(0010,4000)	LT		x	
Patient Medical Module					
Medical Alerts	(0010,2000)	LO		x	
Pregnancy Status	(0010,21C0)	US		x	
Special Needs	(0038,0050)	LO		x	
Patient State	(0038,0500)	LO		x	

The above table should be read as follows:

Attribute Name : Attributes supported to build this product Worklist Request Identifier.

Tag: DICOM tag for this attribute.

VR: DICOM VR for this attribute.

M: Matching keys for (automatic) Worklist Update. A "S" will indicate that MWL SCU AE will supply an attribute value for Single Value Matching, a "R" will indicate Range Matching and a "*" will denote wildcard matching.

R: Return keys. An "x" will indicate that MWL SCU AE will supply this attribute as Return Key with zero length for Universal Matching.

D: Displayed keys. An "x" indicates that this worklist attribute is displayed to the user during a patient registration dialog. For example, Patient Name will be displayed when registering the patient prior to an examination.

2.2.3.4. Association Acceptance Policy

The MWL SCU AE does not accept Associations.

2.3. NETWORK INTERFACES

2.3.1. Physical Network Interface

COCOLY is indifferent to the physical medium over which TCP/IP is used.

2.3.2. Additional Protocols

None.

2.3.3. IPv4 and IPv6 Support

COCOLY only supports IPv4 connections.

2.4. CONFIGURATION

2.4.1. AE Title/Presentation Address Mapping

2.4.1.1. Local AE Titles

The AE Title of local applications is configured by editing the setup file. The AE Titles must be configured during installation.

Table 2.4-1
AE TITLE CONFIGURATION TABLE

Application Entity	Default AE Title	Default TCP/IP Port
Storage SCU	No Default	Not Applicable
MWL SCU	No Default	Not Applicable

2.4.1.2. Remote AE Title/Presentation Address Mapping

The AE Title, IP address and port numbers of remote applications are configured by editing the setup file.

2.4.2.Parameters

A large number of parameters related to the acquisition and general operation can be configured by editing the setup file. The Table below only shows those configuration parameters relevant to DICOM communication. See the Product's Service Manual for details on general configuration capabilities.

**Table 2.4-2
CONFIGURATION PARAMETERS TABLE**

Parameter	Configurable (Yes/No)	Default Value
General Parameter		
Supported Transfer Syntaxes	No	Implicit VR Little Endian
Maximum number of simultaneously initiated Associations	No	1
Storage SCU Parameters		
Time-out waiting for an acceptance or rejection response to an Association Request (Application Level Timeout)	Yes	30s
Time-out waiting for response to a P-DATA-TF (Application Level Timeout)	Yes	30s
Time-out waiting for a response to an Association release request (Application Level Timeout)	Yes	30s
Max PDU Send Size	Yes	65536 Bytes (64KB)
MWM SCU Parameters		
Time-out waiting for an acceptance or rejection response to an Association Request (Application Level Timeout)	Yes	30s
Time-out waiting for response to a P-DATA-TF (Application Level Timeout)	Yes	30s
Time-out waiting for a response to an Association release request (Application Level Timeout)	Yes	30s
Max PDU Send Size	Yes	65536 Bytes (64KB)

3. SUPPORT OF CHARACTER SETS

COCOLY supports the following character sets in addition to the default character sets.

- ISO 2022 IR 87

4. SECURITY

COCOLY does not support any defined DICOM security profiles.

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

- a. Firewall or router protections to ensure that only approved external hosts have network access to the product.
- b. Firewall or router protections to ensure that the product only has network access to approved external hosts and services.

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.

5. ANNEXES

5.1. IOD CONTENTS

5.1.1. Created SOP Instances

Table 5.1-1 specifies the attributes of a CT Image transmitted by the Storage SCU AE.

Table 5.1-2 specifies the attributes of a US Image transmitted by the Storage SCU AE.

The following tables use a number of abbreviations.

The abbreviations used in the "Presence of ..." column are:

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

The abbreviations used in the "Source" column:

MWL	the attribute value source Modality Worklist
USER	the attribute value source is from User input
AUTO	the attribute value is generated automatically
CONFIG	the attribute value source is a configurable parameter

5.1.1.1. CT Image IOD

COCOLY provides the CT Image IOD option only for Storage SCU AE, because it does not use X-ray.

The CT Image IOD consists of the modules of the following table and Additional Attribute as extended module. The Additional Attribute are described in Table 5.1-13.

**Table 5.1-1
IOD OF CREATE CT Image SOP INSTANCES**

IE	Module	Reference	Presence of Value
Patient	Patient	Table 5.1-3	ALWAYS
	Clinical Trial Subject	NA	Not Present
Study	General Study	Table 5.1-4	ALWAYS
	Patient Study	Table 5.1-5	ALWAYS
	Clinical Trial Study	NA	Not Present
Series	General Series	Table 5.1-6	ALWAYS
	Clinical Trial Series	NA	Not Present
Frame of Reference	Frame of Reference	Table 5.1-7	ALWAYS
	Synchronization	NA	Not Present
Equipment	General Equipment	Table 5.1-8	ALWAYS
Image	General Image	Table 5.1-9	ALWAYS
	General Reference	NA	Not Present
	Image Plane	Table 5.1-10	ALWAYS
	Image Pixel	Table 5.1-11	ALWAYS
	Contrast/Bolus	NA	Not Present
	Device	NA	Not Present
	Specimen	NA	Not Present
	CT Image	Table 5.1-14	ALWAYS
	Multi-energy CT Image	NA	Not Present
	Overlay Plane	NA	Not Present
	VOI LUT	NA	Not Present
	SOP Common	Table 5.1-12	ALWAYS
	Common Instance Reference	NA	Not Present

5.1.1.2. Ultrasound Image IOD

The Ultrasound Image IOD consists of the modules of the following table, plus Image Plane Module and Additional Attribute as extended module.

The Image Plane Module are described in Table 5.1-10.

The Additional Attribute are described in Table 5.1-13.

Table 5.1-2
IOD OF CREATE Ultrasound Image SOP INSTANCES

IE	Module	Reference	Presence of Value
Patient	Patient	Table 5.1-3	ALWAYS
	Clinical Trial Subject	NA	Not Present
Study	General Study	Table 5.1-4	ALWAYS
	Patient Study	Table 5.1-5	ALWAYS
	Clinical Trial Study	NA	Not Present
Series	General Series	Table 5.1-6	ALWAYS
	Clinical Trial Series	NA	Not Present
Frame of Reference	Frame of Reference	Table 5.1-7	ALWAYS
	Synchronization	NA	Not Present
Equipment	General Equipment	Table 5.1-8	ALWAYS
Image	General Image	Table 5.1-9	ALWAYS
	General Reference	NA	Not Present
	Image Pixel	Table 5.1-11	ALWAYS
	Contrast/Bolus	NA	Not Present
	Palette Color Lookup Table	NA	Not Present
	Specimen	NA	Not Present
	US Region Calibration	NA	Not Present
	US Image	Table 5.1-15	ALWAYS
	Overlay Plane	NA	Not Present
	VOI LUT	NA	Not Present
	ICC Profile	NA	Not Present
	SOP Common	Table 5.1-12	ALWAYS
	Common Instance Reference	NA	Not Present

5.1.1.3. Common Modules

Table 5.1-3

PATIENT MODULE OF CREATED SOP INSTANCES

Attribute Name	Tag	VR	Value	Presence of Value	Source
Patient's Name	(0010,0010)	PN		ALWAYS	MWL/ USER
Patient ID	(0010,0020)	LO		ALWAYS	MWL/ USER
Patient's Birth Date	(0010,0030)	DA		ALWAYS	MWL/ USER
Patient's Sex	(0010,0040)	CS		VNAP	MWL/ USER
Patient Comments	(0010,4000)	LT		ANAP	MWL

Table 5.1-4

GENERAL STUDY MODULE OF CREATED SOP INSTANCES

Attribute Name	Tag	VR	Value	Presence of Value	Source
Study Instance UID	(0020,000D)	UI		ALWAYS	MWL/ AUTO
Study Date	(0008,0020)	DA		VNAP	AUTO
Study Time	(0008,0030)	TM		VNAP	AUTO
Study ID	(0020,0010)	SH		VNAP	AUTO
Accession Number	(0008,0050)	SH		VNAP	MWL
Referring Physician's Name	(0008,0090)	PN		VNAP	MWL
Study Description	(0008,1030)	LO		ANAP	USER

Table 5.1-5
PATIENT STUDY MODULE OF CREATED SOP INSTANCES

Attribute Name	Tag	VR	Value	Presence of Value	Source
Patient's Age	(0010,1010)	AS		ANAP	MWL/ USER
Patient's Size	(0010,1020)	DS		ANAP	MWL
Patient's Weight	(0010,1030)	DS		ANAP	MWL

Table 5.1-6
GENERAL SERIES MODULE OF CREATED SOP INSTANCES

Attribute Name	Tag	VR	Value	Presence of Value	Source
Modality	(0008,0060)	CS	"CT" for CT Image IOD. "US" for US Image IOD	ALWAYS	AUTO
Series Instance UID	(0020,000E)	UI		ALWAYS	AUTO
Series Number	(0020,0011)	IS		ALWAYS	AUTO
Laterality	(0020,0060)	CS		ALWAYS	USER
Series Date	(0008,0021)	DA		ALWAYS	AUTO
Series Time	(0008,0031)	TM		ALWAYS	AUTO
Series Description	(0008,103E)	LO	Laterality description and user input.	ALWAYS	USER/ AUTO
Operators' Name	(0008,1070)	PN		ALWAYS	USER
Body Part Examined	(0018,0015)	CS	"BREAST"	ALWAYS	AUTO
Patient Position	(0018,5100)	CS	"HFP"	ALWAYS	AUTO

Table 5.1-7

FRAME OF REFERENCE MODULE OF CREATED SOP INSTANCES

Attribute Name	Tag	VR	Value	Presence of Value	Source
Frame of Reference UID	(0020,0052)	UI		ALWAYS	AUTO
Position Reference Indicator	(0020,1040)	LO		EMPTY	AUTO

Table 5.1-8

GENERAL EQUIPMENT MODULE OF CREATED SOP INSTANCES

Attribute Name	Tag	VR	Value	Presence of Value	Source
Manufacturer	(0008,0070)	LO	"Lily MedTech Inc."	ALWAYS	AUTO
Institution Name	(0008,0080)	LO		ANAP	CONFIG
Station Name	(0008,1010)	SH		ANAP	CONFIG
Institutional Department Name	(0008,1040)	LO		ANAP	CONFIG
Manufacturer's Model Name	(0008,1090)	LO		ALWAYS	CONFIG
Device Serial Number	(0018,1000)	LO		ALWAYS	CONFIG
Software Versions	(0018,1020)	LO		ALWAYS	CONFIG

Table 5.1-9

GENERAL IMAGE MODULE OF CREATED SOP INSTANCES

Attribute Name	Tag	VR	Value	Presence of Value	Source
Instance Number	(0020,0013)	IS		ALWAYS	AUTO
Patient Orientation	(0020,0020)	CS	"L¥F"	ALWAYS	AUTO
Content Date	(0008,0023)	DA		ALWAYS	AUTO
Content Time	(0008,0033)	TM		ALWAYS	AUTO

Table 5.1-10
IMAGE PLANE MODULE OF CREATED SOP INSTANCES

Attribute Name	Tag	VR	Value	Presence of Value	Source
Pixel Spacing	(0028,0030)	DS		ALWAYS	AUTO
Image Orientation (Patient)	(0020,0037)	DS	"1¥0¥0¥0¥0¥-1"	ALWAYS	AUTO
Image Position (Patient)	(0020,0032)	DS		ALWAYS	AUTO
Slice Thickness	(0018,0050)	DS		ALWAYS	AUTO
Slice Location	(0020,1041)	DS		ALWAYS	AUTO

Table 5.1-11
IMAGE PIXEL MODULE OF CREATED SOP INSTANCES

Attribute Name	Tag	VR	Value	Presence of Value	Source
Pixel Data	(7FE0,0010)	OW	Image data	ALWAYS	AUTO
Samples per Pixel	(0028,0002)	US	"1"	ALWAYS	AUTO
Photometric Interpretation	(0028,0004)	CS	"MONOCHROME2"	ALWAYS	AUTO
Rows	(0028,0010)	US	512	ALWAYS	AUTO
Columns	(0028,0011)	US	512	ALWAYS	AUTO
Bits Allocated	(0028,0100)	US	See section 5.1.1.4 for CT Image IOD.	ALWAYS	AUTO
Bits Stored	(0028,0101)	US		ALWAYS	AUTO
High Bit	(0028,0102)	US	See section 5.1.1.5 for US Image IOD.	ALWAYS	AUTO
Pixel Representation	(0028,0103)	US	"1" for CT Image IOD "0" for US Image IOD.	ALWAYS	AUTO
Pixel Aspect Ratio	(0028,0034)	IS	"1¥1"	ALWAYS	AUTO

Table 5.1-12
SOP COMMON MODULE OF CREATED SOP INSTANCES

Attribute Name	Tag	VR	Value	Presence of Value	Source
SOP Class UID	(0008,0016)	UI	"1.2.840.10008.5.1 .4.1.1.2" for CT Image IOD "1.2.840.10008.5.1 .4.1.1.6.1" for US Image IOD	ALWAYS	AUTO
SOP Instance UID	(0008,0018)	UI		ALWAYS	AUTO
Specific Character Set	(0008,0005)	CS	"¥ISO 2022 IR 87"	ALWAYS	AUTO

Table 5.1-13
ADDITIONAL ATTRIBUTE OF CREATED SOP INSTANCES

Attribute Name	Tag	VR	Value	Presence of Value	Source
Spacing Between Slices	(0018,0088)	DS		ANAP	USER

5.1.1.4. CT Image Module

Table 5.1-14
CT IMAGE MODULE OF CREATED SOP INSTANCES

Attribute Name	Tag	VR	Value	Presence of Value	Source
Image Type	(0008,0008)	CS	"ORIGINAL \neq PRIMARY"	ANAP	AUTO
Samples per Pixel	(0028,0002)	US	"1"	ALWAYS	AUTO
Photometric Interpretation	(0028,0004)	CS	"MONOCHROME2"	ALWAYS	AUTO
Bits Allocated	(0028,0100)	US	"16"	ALWAYS	AUTO
Bits Stored	(0028,0101)	US	"12"	ALWAYS	AUTO
High Bit	(0028,0102)	US	"11"	ALWAYS	AUTO
Rescale Intercept	(0028,1052)	DS	"0"	ALWAYS	AUTO
Rescale Slope	(0028,1053)	DS	"1"	ALWAYS	AUTO
KVP	(0018,0060)	DS		EMPTY	AUTO
Acquisition Number	(0020,0012)	IS		EMPTY	AUTO

5.1.1.5. US Image Module

Table 5.1-15
IOD OF CREATE Ultrasound Image SOP INSTANCE

Attribute Name	Tag	VR	Value	Presence of Value	Source
Image Type	(0008,0008)	CS	"ORIGINAL \neq PRIMARY"	ANAP	AUTO
Samples per Pixel	(0028,0002)	US	"1"	ALWAYS	AUTO
Photometric Interpretation	(0028,0004)	CS	"MONOCHROME2"	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

5.2. DATA DICTIONARY OF PRIVATE ATTRIBUTES

No Data Dictionary of Private attributes are supported.

5.3. CODED TERMINOLOGY AND TEMPLATES

No Coded Terminology and Templates are supported.

5.4. GRAYSCALE IMAGE CONSISTENCY

No Grayscale Image Consistency are supported.

5.5. STANDARD EXTENDED / SPECIALIZED / PRIVATE SOP CLASSES

No Specialized or Private SOP Classes are supported.

5.6. PRIVATE TRANSFER SYNTAXES

No Private Transfer Syntaxes are supported.