

Document #: 5021-19-F07

Revision: 3.0

Effective Date: Date of last approval

Page: 1 of 30

# Med X Change, Inc. 4Klearity

**DICOM Conformance Statement** 

## Document #: 5021-19-F07

Revision: 3.0

Effective Date: Date of last approval

Page: 2 of 30

## Contents

R	evisio	on His	story Table Error! Bookm	ark not defined
	8.2	Attri	ibute Mapping	26
	8.1	.2	Multi-frame True Color Secondary Capture IOD	25
	8.1	.1	Secondary Capture IOD	24
	8.1	IOD	Contents	24
8	An	nexure	es	24
	7.2	App	lication Level Security	23
	7.1	Sec	urity Profiles	23
7	Se	curity .		23
6	Su	pport o	of Character Sets	23
5	Me	edia Int	terchange	23
	4.4	Con	nfiguration	22
	4.3	Netv	work Interfaces	22
	4.2	2.4	Other AE	
	4.2	2.3	Commitment AE	
	4.2	2.2	Storage AE Specifications	
	4.2		Workflow AE Specifications	
	4.2	-	Specifications	
	4.1		Sequencing of Real Work Activities	
	4.1		Functional Definition of AE's	
	4.1	•	Application Data Flow	
•	4.1		lementation Model	
4			ng	
J	3.1		erences	
3			ns, Terms and Abbreviations	
	2.5		rning Regarding Connectivity	
	2.4		v to Use This Document	
	2.2		lience	
	2.1		neral informationpe	
2			ion	
1			V	
	_			

Document #: 5021-19-F07

Revision: 3.0

Effective Date: Date of last approval

Page: 3 of 30

#### 1 Overview

This document provides the details of the DICOM conformance statement for the Med X Change 4Klearity. This document is structured as suggested in the DICOM Standard (PS 3.2, 2011).

Table 1-1 – Network Services

SOP Classes	User of Service (SCU)	Provider of Service (SCP)
Transfer		
Secondary Capture Image	Yes	No
Storage		
Multi-frame Secondary	Yes	No
Capture Image Storage		
Video Endoscopic Image	Yes	No
Storage		
Video Photographic Image	Yes	No
Storage		
Workflow		
Modality Worklist Information	Yes	No
Model – FIND		
Storage Commitment Push	Yes	No
Model		
Other		
Verification	Yes	No

## 2 Introduction

## 2.1 General information

This document specifies the DICOM conformance statement of the Med X Change 4Klearity providing acquisition, study documentation, and archive capabilities.

#### 2.2 Scope

This document applies to Med X Change 4Klearity 7.10.0 (and higher).

#### 2.3 Audience

This document is intended for hospital staff, health system integrators, software designers, and implementers of the Med X Change 4Klearity. It is assumed that the reader has a working understanding of DICOM.

## 2.4 How to Use This Document

This statement consists of 5 important features that one should compare with other devices to determine connectivity:

1. **Implementation model**: The Implementation model describes the functional relationship between the device, the so-called "real-world activities" which initiate a certain DICOM

Document #: 5021-19-F07

Revision: 3.0

Effective Date: Date of last approval

Page: 4 of 30

functionality, and the DICOM services. A DICOM service is implemented on a device by a software process, which is called an "Application Entity" (AE). Each AE has a unique name called the AE Title, which is used to identify it to other AE's. The AE Title is configurable to avoid two devices with the same name on a network. The "bubble diagram" (Application Data Flow Diagram) shows the interaction of the AE with the outside world across the dashed line, i.e. the DICOM interface. The "sequencing of real world activities" describes the interaction using a time-scale, i.e. showing the sequence of events.

- 2. AE Specifications: Each AE supports one or more Service-Object-Pair (SOP) classes, which define the basic functionality. A SOP class consists of a combination of an Object or Information model with specific DICOM services. An example of such a SOP class is the VL Image Storage class, which consists of the combination of the DICOM C\_STORE command with the VL Image object. Each of these classes is uniquely identified by a unique identification number (UID), which is issued by the NEMA. In addition, the "role" of the AE is specified, i.e. User or Provider, which can be compared with acting as a Client or Server. In DICOM terms, this is called a Service Class User (SCU) or Service Class Provider (SCP). To interconnect with another device, the SOP classes as well as their role (SCU or SCP) have to be matched, i.e. a SCU has to match a SCP at another device with an identical SOP class. Make sure to compare the SOP Class UID itself, not the description because there are SOP classes which have the same name, but support a different (newer) Object, which is identified by a different SOP Class UID.
- 3. Presentation Context: Each SOP class supports a particular presentation context, which is the combination of the SOP class as specified in AE Specifications and the Transfer Syntax. The Transfer Syntax defines the encoding of the DICOM basic elements, i.e. its attributes and how the data is represented e.g. with a data type definition. The encoding of the data type as part of the message, or value representation (VR), can be done in two ways implicitly or explicitly. If a device supports explicit VR transfer syntax, it means that the transmitted data will include the VR information along with data and attribute tags. Implicit VR means that the VR information will not be included, and the receiving application must determine the VR type from the Attribute tag. For example, when receiving the Attribute "Patient Name" in explicit transfer syntax, there is an additional "Person Name" ("PN") field to identify the Value Representation. In the case of an implicit VR, this is assumed to be known by the receiver and not explicitly specified that this field has a type of "Person Name". Lastly, compression can be applied, such as JPEG, which is specified in the transfer syntax. The Transfer syntax of two devices has to match in order for them to communicate.
- 4. **Communication Profiles**: This section specifies the communication options. In practice, each device always supports application level interface to the OSI level 4 (Transport layer), i.e. TCP/IP stack. However, the physical media of two devices have to match for connectivity. Note that matching physical media can be achieved by standard off the shelf devices. For example, if one device supports standard Ethernet 100BaseT, it can be bridged to a Gigabit Ethernet, or whatever is supported.

Document #: 5021-19-F07

Revision: 3.0

Effective Date: Date of last approval

Page: 5 of 30

5. **Supported Attributes**: Many devices specify which DICOM attributes they require and/or store in their internal database. It is important to compare these against the source of the information, particularly if a device requires certain attributes to accomplish specific functionality such as 3-D viewing, image processing, etc. A mismatch could have the effect that certain functionality or applications might fail.

## 2.5 Warning Regarding Connectivity

The DICOM conformance statement provides a knowledgeable user with the information required in determining whether and to what extent independent DICOM implementations may be able to interoperate. However, the information contained in a DICOM conformance statement is not sufficient to ensure independent implementations will, in fact, be able to interoperate.

The user or system integrator must be aware of the following potential issues related to interoperability:

- Using only the information provided by this conformance statement does not guarantee
  interoperability of Med X Change equipment with non-Med X Change equipment. It is the
  user's (or system integrator's) responsibility to analyze thoroughly the application
  requirements and objectives to determine if they can be met by the connection of Med X
  Change equipment to non-Med X Change equipment.
- Med X Change equipment has been tested to assure that the actual implementation of the DICOM interface corresponds with this conformance statement. It is the responsibility of the user (or system integrator) to specify and carry out additional validation testing, which covers a broad spectrum of potential interactions between the independent implementations.
- Med X Change reserves the right to make changes to its products or to discontinue their delivery. Therefore, the user (or system integrator) should ensure that any future versions of Med X Change or non-Med X Change equipment are regression tested to verify that new software releases have not adversely impacted the ability to interoperate.

Med X Change provides this documentation "as is" without warranty of any kind, either expressed or implied, including, but not limited to, the implied warranties or merchantability and fitness for a particular purpose. Some states or countries do not allow disclaimers of express or implied warranties in certain transactions; therefore, this statement may not apply to you.

No part of this publication may be reproduced, transmitted, transcribed, recorded, or translated into any language in any form or by any means, electronic, magnetic, optical, chemical, physical, or otherwise without the express written permission of an authorized officer of Med X Change.

Med X Change reserves the right to correct this publication and to make changes to its contents without the obligation of informing anyone of these revisions or changes.

Revision: 3.0

Effective Date: Date of last approval

Page: 6 of 30

## 3 Definitions, Terms and Abbreviations

4Klearity DICOM Conformance Statement

Definitions, terms, and abbreviations used in this document are defined within the different parts of the DICOM standard. Abbreviations and terms are as follows:

AE DICOM Application Entity

AET Application Entity Title

ELE Explicit Little Endian

ILE Implicit Little Endian

EBE Explicit Big Endian

IBE Implicit Big Endian

IOD (DICOM) Information Object Definition

IM Information Model

ISO International Organization for Standardization

O Optional Key Attribute

PDU DICOM Protocol Data Unit

R Required Key Attribute

SC Secondary Capture

SCP DICOM Service Class Provider (DICOM server)

SCU DICOM Service Class User (DICOM client)

SOP DICOM Service-Object Pair

U Unique Key Attribute

VL Visible Light

## 3.1 References

[DICOM] Digital Imaging and Communications in Medicine (DICOM), NEMA PS 3.1-3.18, 2011

Revision: 3.0

Effective Date: Date of last approval

Page: 7 of 30

## 4 Networking

## 4.1 Implementation Model

## 4.1.1 Application Data Flow

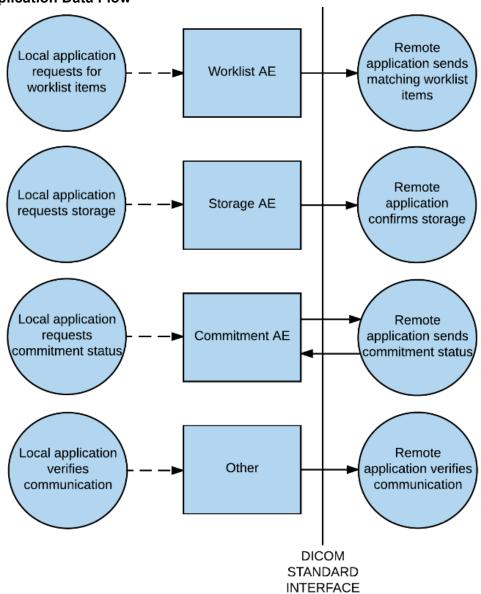


Figure 1 Application Data Flow

4Klearity exports images using DICOM Store Service. The following AE's describe the DICOM implementation of the 4Klearity:

 The Worklist AE queries an external workflow management system for work items to be performed on the 4Klearity.

Document #: 5021-19-F07

Revision: 3.0

Effective Date: Date of last approval

Page: 8 of 30

• The Storage AE is responsible for storing the information created by the system (image) to other applications either automatically or upon operator commands.

• The Storage Commitment AE is responsible for transferring the ownership of the exported media to the receiving application before the images and/or other objects are permanently deleted from the local physical storage at the unit.

## 4.1.2 Functional Definition of AE's

#### 4.1.2.1 Worklist AE

The Worklist AE acts as a SCU of the Basic Worklist Management Service Class. On user action, a query is performed to an external worklist manager and a set of worklist items matching the query is received. The received data is displayed on the user interface. A worklist item is selected for examination and all the data for that item along with the captures images is stored in the local database within the 4Klearity.

## 4.1.2.2 Storage AE

The Storage AE is responsible for exporting the images from the 4Klearity. Upon the Store, DICOM Instances are sent to the external application using DICOM Storage Service.

## 4.1.2.3 Storage Commitment AE

The storage commitment is performed after a DICOM item has been stored. After commitment is confirmed, the local item on the unit is automatically deleted.

## 4.1.2.4 Other AE

The device also supports sending C-ECHO to endpoints for testing communication between AEs.

## 4.1.3 Sequencing of Real Work Activities

A typical sequence is as follow:



Revision: 3.0

Effective Date: Date of last approval

Page: 9 of 30

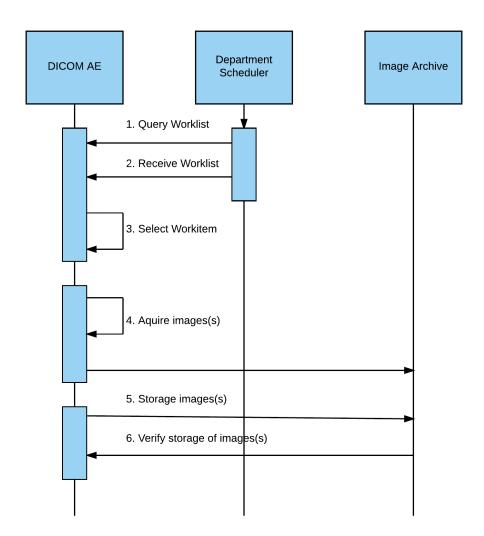


Figure 2 Sequence of Real World activities

- 1. A Worklist query is initiated manually by a user.
- 2. The worklist is received. Patient demographics and order information is stored in the local database and displayed to the user upon request.
- 3. For unscheduled exams, the patient information will be entered manually; otherwise the work item (worklist entry) will be selected.
- 4. Still images and videos are acquired.
- 5. The acquired data is sent to a DICOM destination automatically or initiated by the user.
- 6. Verify the data has been committed successfully.

Document #: 5021-19-F07

Revision: 3.0

Effective Date: Date of last approval

Page: 10 of 30

## 4.2 AE Specifications

## 4.2.1 Workflow AE Specifications

## 4.2.1.1 **SOP Classes**

This AE provides standard conformance to the following SOP classes.

Table 4-1 – SOP Classes for Worklist AE

SOP Class Name	SOP Class UID	SCU	SCP
Modality Worklist	1.2.840.10008.5.1.4.31	Yes	No
Query			

#### 4.2.1.2 Association Policies

#### 4.2.1.2.1 General

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

Table 4-2 - General DICOM for Worklist AE

Application Context Name	1.2.840.10008.3.1.1.1
Maximum PDU Size proposed	16384

## 4.2.1.2.2 Number of Associations

Table 4-3 – Number of Associations as association initiator for Worklist AE

Maximum number of simultaneous	1
associations	

The Workflow AE initiates association with an external AE in response to a user action in the application GUI.

#### 4.2.1.2.3 Asynchronous Nature

The Workflow AE does not support multiple outstanding transactions.

## 4.2.1.2.4 Implementation Identifying Information

Table 4-4 - DICOM Implementation Class and Version for Worklist AE

Implementation Class UID	1.2.276.0.7230010.3.0.9.9.1
Implementation Version Name	MED X CHANGE

## 4.2.1.3 Association Initiation Policies

## 4.2.1.3.1 Activity- Query Worklist

#### 4.2.1.3.1.1 Description and Sequence of Events

The worklist query is initiated automatically when the user visits the worklist and can also be initiated manually with filters applied. A search dialog is present on the GUI for entering the data as search criteria. When the query is initiated on user request/automatically, the data from the dialog will be inserted as matching keys into the query. On initiation of a request, 4Klearity will build an identifier for the C-FIND request; this will initiate an association to send the request and will wait for worklist responses. After retrieval of all responses, the application will access the

Document #: 5021-19-F07

Revision: 3.0

Effective Date: Date of last approval

Page: 11 of 30

internal worklist queue to display all the responses on the GUI and allow the user to select a specific patient/study for examination.

There is no mechanism to prevent system overflow. All worklist records retrieved will be displayed.

The 4Klearity will initiate an association to issue a C-FIND request according to the Modality Worklist Information Model.

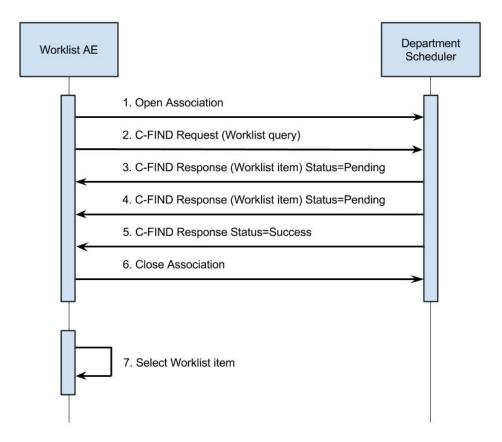


Figure 3 Sequence of Events – Worklist query

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

- 1. The Worklist AE opens an association with the Departmental Scheduler.
- 2. The Worklist AE sends a C-FIND request to the Departmental Scheduler containing the Worklist guery attributes.
- 3. The Departmental Scheduler returns a C-FIND response containing the requested attributes of the first matching worklist item.

Document #: 5021-19-F07

Revision: 3.0

Effective Date: Date of last approval

Page: 12 of 30

4. The Departmental Scheduler returns another C-FIND response contained the requested attributes of the second matching worklist item.

- 5. The Departmental Scheduler returns a final C-FIND response with Success status indicating that no further matching worklist items exist.
- 6. (This example assumes only 2 worklist items match the requested query).
- 7. The Worklist AE closes the association with the Departmental Scheduler.
- 8. The user selects a worklist item from the received responses and prepares to acquire new images for the selected item.

## 4.2.1.3.1.2 Proposed Presentation Contexts

The 4Klearity will propose Presentation Contexts as shown in the following table:

Table 4-5 – Proposed Presentation Contexts for Activity Query Worklist

Presentation Context Table						
Abstract Synt	ax	Transfer Syntax		Role	Ext Neg.	
Name	UID	Name	UID			
Modality	1.2.840.10008.5.1.4.31	ELE	1.2.840.10008.1.2.1	SCU	None	
Worklist Information		EBE	1.2.840.10008.1.2.2			
Model –		ILE	1.2.840.10008.1.2			
FIND						

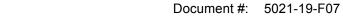
## 4.2.1.3.1.3 SOP Specific Conformance Statement for MWL SOP Class

The attributes listed below are sent with the Modality Worklist Query.

In the following table, an S in the M (Matching) column means single value matching, W means wild card matching, and R means Range matching. An X in the Q (Query) column indicates a matching key that the user can interactively set. An X in the D (Display) column means that item is displayed in the 4Klearity worklist, and an X in the IOD (Information Object Definition) column indicates the value that is returned in the response is used in the image instances created by the 4Klearity for that procedure.

Table 4-6 – Worklist Request Identifier

Module Name	Tag	VR	M	Q	D	IOD
Attribute Name						
Scheduled Procedure Step						
Scheduled Procedure Step Sequence	(0040,0100)	SQ				
Modality	(0008,0060)	CS	S	X	Х	X
Scheduled Procedure Step Start Date	(0040,0002)	DA	R	X	X	X
Scheduled Station AE Title	(0040,0001)	AE	S	X		
Scheduled Procedure Step Start Time	(0040,0003)	TM			Х	X
Scheduled Station Name	(0040,0010)	SH				X
Code Value	(0008,0100)	SH				
Code Meaning	(0008,0104)	LO				
Coding Scheme Designator	(0008,0102)	SH				



Revision: 3.0

Effective Date: Date of last approval

Page: 13 of 30

Requested Procedure						
Study Instance UID	(0020,000D)	UI				Х
Requested Procedure ID	(0040,1001)	SH			Χ	
Requested Procedure Description	(0032,1060)	LO			Χ	
Image Service Request						
Scheduled Performing Physician Name	(0040,0006)	PN			Χ	Χ
Accession Number	(0008,0050)	SH			Х	Х
Referring Physician Name	(0008,0090)	PN			Χ	Χ
Admission ID	(0038,0010	LO			Χ	Χ
Patient Identification						
Patient Name	(0010,0010)	PN			Χ	Χ
Patient ID	(0010,0020)	LO	S	X	Χ	Χ
Patient Demographic						
Patient Birth Date	(0010,0030)	DA			Χ	Χ
Patient Sex	(0010,0040)	CS			Χ	Χ

The response behavior is described as below.

Table 4-7 – MWL C-FIND Response Status Handling Behavior

	T	_	
Service	Further Meaning	Error	Behavior
Status		Code	
Success	Matching is complete	0000	The SCP has completed the matches.
			Worklist items are available for display or
			further processing.
Refused	Out of Resources	A700	The Association is released and the
			worklist query is marked as failed. The
			status meaning is logged and reported to
			the user if an interactive query. Any
			additional error information in the
			Response will be logged.
Failed	Identifier does not	A900	The Association is released and the
raileu		A900	
	match SOP Class		worklist query is marked as failed. The
			status meaning is logged and reported to
			the user if an interactive query. Any
			additional error information in the
			Response will be logged.
Failed	Unable to Process	C000 -	The Association is released and the
		CFFF	worklist query is marked as failed. The
			status meaning is logged and reported to
			the user if an interactive query. Any
			additional error information in the
			Response will be logged.
Pending	Matches are continuing	FF00	The worklist item contained in the
			Identifier is collected for further
			processing.
Pending	Matches are continuing	FF01	The worklist item contained in the

# Document #: 5021-19-F07

Revision: 3.0

Effective Date: Date of last approval

Page: 14 of 30

	Warning that one or more Optional Keys were not supported		Identifier is collected for later display or further processing. The status meaning is logged only once for each C-FIND operation.
*	*	Any other status	The Association is released and the worklist is marked as failed. The status meaning is logged and reported to the user if an interactive query. Any additional error information in the Response will be logged.

Document #: 5021-19-F07

Revision: 3.0

Effective Date: Date of last approval

Page: 15 of 30

The behavior of the Workflow AE during communication failure is summarized in the table below.

Table 4-8 – Modality Worklist Communication Failure Behavior

Exception	Behavior
Timeout	The Association is aborted using A-ABORT and the worklist query marked as failed. The reason is logged and reported to the user if an interactive query.
Association aborted by the SCP or network layers	The worklist query is marked as failed. The reason is logged and reported to the user if an interactive query.

## 4.2.2 Storage AE Specifications

## 4.2.2.1 SOP Classes

This AE provides standard conformance to the following SOP classes.

Table 4-9 – SOP classes for Storage AE

SOP Class Name	SOP Class UID	SCU	SCP
SC Image Storage	1.2.840.10008.5.1.4.1.1.7	Yes	No
Multi-frame True	1.2.840.10008.5.1.4.1.1.7.4	Yes	No
Color SC mage			
Storage			
Video Endoscopic	1.2.840.10008.5.1.4.1.1.77.1.1.1	Yes	No
Image Storage			
Video Photographic	1.2.840.10008.5.1.4.1.1.77.1.4.1	Yes	No
Image Storage			

## 4.2.2.2 Association Policies

## 4.2.2.2.1 General

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

Table 4-10 - General DICOM for Storage AE

Application Context Name	1.2.840.10008.3.1.1.1	
Maximum PDU Size proposed	16384	

## 4.2.2.2.2 Number of Associations

Table 4-11 – Number of Associations as association initiator for Storage AE

Maximum number of simultaneous	1
associations	

## 4.2.2.2.3 Asynchronous Nature

The Storage AE does not support asynchronous communication (multiple outstanding transactions over a single association).

Document #: 5021-19-F07

Revision: 3.0

Effective Date: Date of last approval

Page: 16 of 30

## 4.2.2.2.4 Implementation Identifying Information

Table 4-12 - DICOM Implementation Class and Version for STORE-SCP

Implementation Class UID	1.2.276.0.7230010.3.0.9.9.1
Implementation Version Name	MED_X_CHANGE

#### 4.2.2.3 Association Initiation Policies

## 4.2.2.3.1 Activity - Send Images

## 4.2.2.3.1.1 Description and Sequencing of Events

This activity is performed when the device is initiating the image transfer.

The user can select a patient case and request it to be sent to the configured destination. Each request is forwarded to the job queue and processed individually.

The Automatically Upload options allows the user to automatically send a patient case to a preconfigured destination. The option to enable or disable the Automatically Upload feature is configurable by the user from the GUI. When Automatically Upload option is enabled, the captured patient cases get automatically marked for storage. Each marked instance or marked set of instances stored in the database will be forwarded to the network job queue for a preconfigured target destination. The Automatically Upload option is triggered when the user closes the opened patient case. When the Automatically Upload feature is disabled, the user can manually send the patient cases to the destination from the GUI.

The Storage AE is invoked by the job control interface that is responsible for processing network storage tasks. The job consists of data describing the instances marked for storage, and the destination to which the instances will be sent. The Storage AE attempts to initiate a new association to issue a C-STORE request. If the Storage AE successfully establishes an association with a remote AE, it will transfer the image corresponding to the marked patient case via the open association. If the patient case consists of multiple images, then each of the images will be transferred over a new association.

If the C-STORE response from the remote application contains a status other than Success or Warning, then the association is released and the related job is switched to a failed state.

The converted DICOM images are converted directly before each association is completed, and are deleted upon closing the association (success or failure).



Revision: 3.0

Effective Date: Date of last approval

Page: 17 of 30

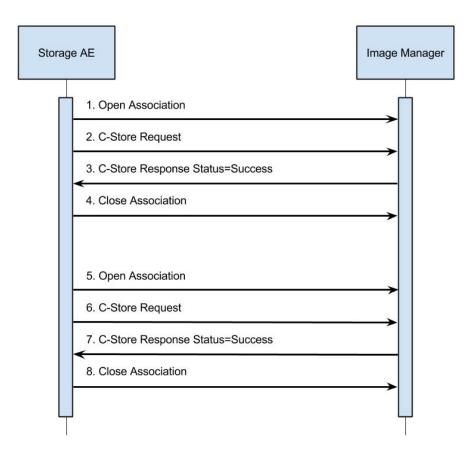


Figure 4 Sequence of Events - Store Request

A possible sequence of interactions between the Storage AE and an Image Manager (e.g. a storage device supporting the Storage SOP Class as an SCP) is illustrated in Figure 4.

- 1. The Storage AE opens an association with the Image Manager.
- 2. An acquired image is transmitted to the Image Manager using a C-STORE request.
- 3. The Image Manager replies with a C-STORE response (status success).
- 4. The Storage AE closes the association with the Image Manager.
- 5. The Storage AE opens a new association with the Image Manager.
- 6. Another acquired image is transmitted to the Image Manager using a C-STORE request.
- 7. The Image Manager replies with a C-STORE response (status success).
- 8. The Storage AE closes the association with the Image Manager.

Document #: 5021-19-F07

Revision: 3.0

Effective Date: Date of last approval

Page: 18 of 30

## **4.2.2.3.1.2 Proposed Presentation Contexts**

Table 4-13 – Proposed Presentation Context for Activity Send Images

	Prese	ntation Contex	t Table		
Abstract Syntax		Transfer Syntax		Role	Ext
Name	UID	Name	UID		Neg.
SC Image Storage	1.2.840.10008.5.1.4.1.1.7	JPEG Baseline (Process 1)	1.2.840.10008.1.2.4.50	SCU	None
		JPEG Process 1 Lossy	1.2.840.10008.1.2.4.70	SCU	None
		Explicit VR Little Endian	1.2.840.10008.1.2.1	SCU	None
		Implicit VR Endian	1.2.840.10008.1.2	SCU	None
Multi-frame True Color SC mage	1.2.840.10008.5.1.4.1.1.7. 4	MPEG4	1.2.840.10008.1.2.4.103	SCU	None
Storage		MPEG2	1.2.840.10008.1.2.4.100	SCU	None
Video Endoscopic	1.2.840.10008.5.1.4.1.1.77 .1.1.1	MPEG4	1.2.840.10008.1.2.4.103	SCU	None
Image Storage		MPEG2	1.2.840.10008.1.2.4.100	SCU	None
Video Photographic	1.2.840.10008.5.1.4.1.1.77 .1.4.1	MPEG4	1.2.840.10008.1.2.4.103	SCU	None
Image Storage		MPEG2	1.2.840.10008.1.2.4.100	SCU	None

For single frame images, 4Klearity proposes only JPEG Baseline.

## 4.2.2.3.1.3 SOP Specific Conformance for Storage SOP Classes

The Storage AE maintains a job queue for C-STORE commands. If some of the C-STORE commands in a job fail, then the job will need to be sent manually. Failed or successful jobs will never retry.

Table 4-14 - C-STORE Response Status Handling Behavior

Service Further Meaning Error Behavior	
----------------------------------------	--



Document #: 5021-19-F07

Revision: 3.0

Effective Date: Date of last approval

Page: 19 of 30

Status		Code	
Success	Matching is complete	0000	The SCP has successfully stored the SOP Instance. If all SOP Instances in a send job have status success then the job is marked as completed in the queue and reported to the user via the application.
Refused	Out of Resources	A700- A7FF	The Association is released and the send job is marked as failed. The status meaning and an error code is logged in the log file and the job failure is reported to the user via the application
Error	Data Set does not match SOP Class	A900- A9FF	The Association is released and the send job is marked as failed. The status meaning and an error code is logged in the log file and the job failure is reported to the user via the application.
Error	Cannot Understand	C000- CFFF	The Association is released and the send job is marked as failed. The status meaning and an error code is logged in the log file and the job failure is reported to the user via the application
Warning	Coercion of Data Elements	B000	Image transmission is considered successful but the status meaning and error code are logged in the log file
Warning	Data Set does not match SOP Class	B007	Image transmission is considered successful but the status meaning and error code are logged in the log file
Warning	Elements Discarded	B006	Image transmission is considered successful but the status meaning and error code are logged in the log file.
*	*	Any other status	The Association is released and the send job is marked as failed. The status meaning and an error code is logged in the log file.

## 4.2.3 Commitment AE

## 4.2.3.1 SOP Classes

This Commitment AE provides standard conformance to the following SOP classes.

Table 4-15 – SOP classes for Commitment AE

SOP Class Name	SOP Class UID	SCU	SCP
Storage Commitment	1.2.840.10008.1.20.1	Yes	Yes – For
Push Model			separate
			associations



Document #: 5021-19-F07

Revision: 3.0

Effective Date: Date of last approval

Page: 20 of 30

#### 4.2.3.2 Association Policies

#### 4.2.3.2.1 General

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

Table 4-16 - General DICOM for Commitment AE

Application Context Name	1.2.840.10008.3.1.1.1	
Maximum PDU Size proposed	16384	

#### 4.2.3.2.2 Number of Associations

Table 4-17 – Number of Associations as association initiator for Commitment AE

Maximum number of simultaneous	1
associations	

## 4.2.3.2.3 Asynchronous Nature

The Commitment AE does not support asynchronous communication (multiple outstanding transactions over a single association).

## 4.2.3.2.4 Implementation Identifying Information

Table 4-18 – DICOM Implementation Class and Version for STORE-SCP

Implementation Class UID	1.2.276.0.7230010.3.0.9.9.1
Implementation Version Name	MED_X_CHANGE

#### 4.2.3.3 Association Initiation Policies

## 4.2.3.3.1 Activity - Commitment

## 4.2.3.3.1.1 Description and Sequencing of Events

This activity is performed when a DICOM item has been stored successfully. At that time, a request for commitment will be sent to the configured Storage Commitment SCP server.

Responses for commitment can happen on the same association that initiated the requested, or on a separate association at a later time.

The unit is configured as an SCP server on port 105 for the incoming commitment response. There is no validation on AE Titles on this SCP server.

When an item is successfully marked as stored, it is automatically moved to the trash bin. The items can be restored from the trash bin, if needed.

## 4.2.3.3.1.2 Proposed Presentation Contexts

Revision: 3.0

Effective Date: Date of last approval

Page: 21 of 30

## 4Klearity DICOM Conformance Statement

Table 4-19 – Proposed Presentation Context for Activity Commitment

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Ext	
UID	Name	UID		Neg.	
1.2.840.10008.1.20.1	Implicit	1.2.840.10008.1.2	SCU	Non	
	VR			е	
	Endian				
	yntax UID	yntax Transfer Sy UID Name  1.2.840.10008.1.20.1 Implicit VR	yntax         Transfer Syntax           UID         Name         UID           1.2.840.10008.1.20.1         Implicit VR         1.2.840.10008.1.2	yntax         Transfer Syntax         Role           UID         Name         UID           1.2.840.10008.1.20.1         Implicit VR         1.2.840.10008.1.2         SCU	

## 4.2.3.3.1.3 SOP Specific Conformance for Storage Commitment SOP Class

## 4.2.4 Other AE

## 4.2.4.1 SOP Classes

This Other AE provides standard conformance to the following SOP classes.

Table 4-20 – SOP classes for Other AE

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

#### 4.2.4.2 Association Policies

## 4.2.4.2.1 General

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

Table 4-21 - General DICOM for Other AE

Application Context Name	1.2.840.10008.3.1.1.1
Maximum PDU Size proposed	16384

## 4.2.4.2.2 Number of Associations

Table 4-22 – Number of Associations as association initiator for Storage AE

Maximum number of simultaneous	1
associations	

## 4.2.4.2.3 Asynchronous Nature

The Other AE does not support asynchronous communication (multiple outstanding transactions over a single association).

Revision: 3.0

Effective Date: Date of last approval

Page: 22 of 30

## 4.2.4.2.4 Implementation Identifying Information

4Klearity DICOM Conformance Statement

Table 4-23 – DICOM Implementation Class and Version for Other AE

Implementation Class UID	1.2.276.0.7230010.3.0.9.9.1
Implementation Version Name	MED_X_CHANGE

## 4.2.4.3 Association initiation Policies

## 4.2.4.3.1 Activity – Verify Communications (SCU)

## 4.2.4.3.1.1 Description and Sequencing of Events

The Other AE sends DICOM verification requests when the user requests a test of validity of a DICOM connection through the GUI.

## 4.2.4.3.1.2 Proposed Presentation Contexts

The 4Klearity will propose Presentation Contexts as shown in the following table:

Table 4-24 – Proposed Presentation Contexts for Activity Verify Communication

Presentation Context Table						
Abstract Synt	ax	Transfer Syntax		Transfer Syntax Role Ext		Ext Neg.
Name	UID	Name UID				
Verification	1.2.840.10008	ELE	1.2.840.10008.1.2.1	SCU	None	
		ILE	1.2.840.10008.1.2			

## 4.2.4.3.1.3 SOP Specific Conformance – Verification SOP Class

The unit provides standard conformance to the Verification SOP Class as an SCU. If the C-ECHO request was successfully received by external verification SCP, a 0000 (Success) status code will be returned in the C-ECHO response. Otherwise, a C000 (Error – Cannot Understand) status code will be returned in the C-ECHO response.

#### 4.3 **Network Interfaces**

4Klearity uses TCP/IP as the underlying network implementation.

#### 4.4 Configuration

The following items are configurable:

## SCU parameters

- · Calling AE Title
- Called AE Title
- IP Address
- Port
- Diagnostic logging

## Worklist parameters

Worklist enabled Y/N

Document #: 5021-19-F07

Revision: 3.0

Effective Date: Date of last approval

Page: 23 of 30

## Query

- o Scheduled AE Title
- o Patient ID
- Modality
- Start date (range)

## Storage parameters

- · Storage enabled Y/N
- · Automatically Upload
- Upload Videos

## 5 Media Interchange

4Klearity does not support media interchange.

## 6 Support of Character Sets

4Klearity supports ISO-IR 100

## 7 Security

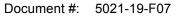
## 7.1 Security Profiles

4Klearity can be configured to use secure DICOM communication in conformance with the Basic TLS Secure Transport Connection Profile. The 4Klearity may communicate using the following Cipher Suites:

- TLS1\_TXT\_RSA\_WITH\_AES\_128\_SHA
- SSL3 TXT RSA DES 192 CBC3 SHA

## 7.2 Application Level Security

The following security and privacy requirements are defined for 4Klearity: The GUI contains a login function, including a password, and only authorized users will be able to login to the system.



Revision: 3.0

Effective Date: Date of last approval

Page: 24 of 30

## 8 Annexures

## 8.1 IOD Contents

## 8.1.1 Secondary Capture IOD

Table 8-1 – Secondary Capture IOD

Module	Attribute	Tag	Value and/or length, range, and
			origin
PATIENT	Patient Name	(0010,0010)	From MWL or entered by user
	Patient ID	(0010,0020)	From MWL or entered by user
	Patient Sex	(0010,0040)	From MWL or entered by user;
			M, F, O or empty
	Patient Birth Date	(0010,0030)	From MWL or entered by user
General Study	Study Instance UID	(0020,000D)	From MWL or automatically
			generated if creating an
			unscheduled case; not visible on
	Otrodo ID	(0000 0040)	UI Automotion III and a sector during the
	Study ID	(0020,0010)	Automatically generated; not visible on UI
	Study Date	(0008,0020)	From MWL or automatically
			created when the study is
	Otrodo Tirro	(0000 0000)	created
	Study Time	(0008,0030)	From MWL or automatically
			created when the study is created
	Accession Number	(0008,0050)	From MWL or entered by user
	Referring	(0008,0090)	From MWL or entered by the
	Physician's Name	(0000,0000)	user
	Admission ID	(0038,0010)	From MWL or entered by the
		(,,	user
General Series	Modality	(0008,0060)	From MWL or entered by the
	-		user
	Series Instance UID	(0020,000E)	Automatically generated
	Series Number	(0020,0011)	1
	Performing	(0008,1050)	From MWL or entered by the
	Physician Name		user
	Requested	(0032,1060)	
	Procedure		
0.000011	Description	(0000 0010)	Automorphis
General Image	Instance Number	(0020,0013)	Auto generated
	Patient Orientation	(0020,0020)	Empty, zero length
	Lossy Image Compression	(0028,2110)	01
	Lossy Image	(0028,2114)	ISO_10918_1
	Compression		
	Method		



Document #: 5021-19-F07

Revision: 3.0

Effective Date: Date of last approval

Page: 25 of 30

General Equipment	Conversion Type	(0008,0064)	WSD
	Manufacturer	(0008,0070)	MedXChange
	Station Name	(0008,1010)	From MWL; Not visible on UI
	Manufacturer Model	(0008,1090)	4Klearity
	Name		
	Software Versions	(0018,1020)	The version of the SCU
Image Pixel	Samples per Pixel	(0028,0002)	3
	Photometric	(0028,0004)	YBR_FULL_422
	Interpretation		
	Planar Configuration	(0028,0006)	0
	Rows	(0028,0010)	From Video
	Columns	(0028,0011)	From Video
	Bits Allocated	(0028,0100)	8
	Bits Stored	(0028,0101)	8
	High Bit	(0028,0102)	7
	Pixel	(0028,0103)	0
	Representation		
	Pixel Data	(7FE0,0010)	From Image
SOP Common	SOP Class UID	(0008,0016)	1.2.840.10008.5.1.4.1.1.7
Module			
	SOP Instance UID	(0008,0018)	Automatically generated
	Character Set	(0008,0005)	ISO_IR 100

## 8.1.2 Multi-frame True Color Secondary Capture IOD

Table 8-2 – Multi-frame True Color Secondary Capture IOD

Module	Attribute	Tag	Value and/or length, range, and origin
PATIENT	Patient Name	(0010,0010)	From MWL or entered by user
	Patient ID	(0010,0020)	From MWL or entered by user
	Patient Sex	(0010,0040)	From MWL or entered by user; M, F, O or empty
	Patient Birth Date	(0010,0030)	From MWL or entered by user
General Study	Study Instance UID	(0020,000D)	From MWL or automatically generated if creating an unscheduled case; not visible on UI
	Study ID	(0020,0010)	Automatically generated; not visible on UI
	Study Date	(0008,0020)	From MWL or automatically created when the study is created
	Study Time	(0008,0030)	From MWL or automatically created when the study is created
	Accession Number	(0008,0050)	From MWL or entered by user



Revision: 3.0

Effective Date: Date of last approval

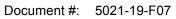
Page: 26 of 30

	Referring	(0008,0090)	From MWL or entered by the user
	Physician's Name	(0000,0090)	Trom www or entered by the user
	Admission ID	(0038,0010)	From MWL or entered by the user
General Series	Modality	(0008,0060)	From MWL or entered by the user
Ocheral Oches	Series Instance	(0020,000E)	Automatically generated
	UID	, ,	, ,
	Series Number	(0020,0011)	1
	Performing Physician Name	(0008,1050)	From MWL or entered by the user
	Requested	(0032,1060)	
	Procedure		
	Description		
General Image	Instance Number	(0020,0013)	Auto generated
	Patient Orientation	(0020,0020)	Empty, zero length
	Lossy Image	(0028,2110)	01
	Compression		
General Equipment	Manufacturer	(0008,0070)	MedXChange
	Station Name	(0008,1010)	From MWL; Not visible on UI
	Manufacturer	(0008,1090)	4Klearity
	Model Name		
	Software Versions	(0018,1020)	The version of the SCU
Image Pixel	Samples per Pixel	(0028,0002)	3
	Photometric	(0028,0004)	YBR_PARTIAL_420
	Interpretation		
	Planar	(0028,0006)	0
	Configuration		
	Rows	(0028,0010)	From Video
	Columns	(0028,0011)	From Video
	Bits Allocated	(0028,0100)	8
	Bits Stored	(0028,0101)	8
	High Bit	(0028,0102)	7
	Pixel	(0028,0103)	0
	Representation		
	Pixel Data	(7FE0,0010)	From Video
SOP Common	SOP Class UID	(0008,0016)	1.2.840.10008.5.1.4.1.1.7.4
Module			
	SOP Instance UID	(0008,0018)	Automatically generated
	Character Set	(0008,0005)	ISO_IR 100

## 8.1.3 Video Endoscopic Image Storage IOD

Table 8-3 – Video Endoscopic Image Storage IOD

Module	Attribute	Tag	Value and/or length, range, and
			origin
PATIENT	Patient Name	(0010,0010)	From MWL or entered by user
	Patient ID	(0010,0020)	From MWL or entered by user

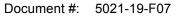


Revision: 3.0

Effective Date: Date of last approval

Page: 27 of 30

	Patient Sex	(0010,0040)	From MWL or entered by user; M,
	D (1 / D) (1 D /	(0040000)	F, O or empty
	Patient Birth Date	(0010,0030)	From MWL or entered by user
General Study	Study Instance	(0020,000D)	From MWL or automatically
	UID		generated if creating an
			unscheduled case; not visible on
			UI
	Study ID	(0020,0010)	Automatically generated; not
			visible on UI
	Study Date	(0008,0020)	From MWL or automatically
			created when the study is created
	Study Time	(0008,0030)	From MWL or automatically
			created when the study is created
	Accession Number	(0008,0050)	From MWL or entered by user
	Referring	(0008,0090)	From MWL or entered by the user
	Physician's Name		
	Admission ID	(0038,0010)	From MWL or entered by the user
General Series	Modality	(0008,0060)	From MWL or entered by the user
	Series Instance	(0020,000E)	Automatically generated
	UID		
	Series Number	(0020,0011)	1
	Performing	(0008,1050)	
	Physician Name		
	Code Value	(0008,0100)	
	Code Meaning	(0008,0104)	
	Coding Scheme	(0008,0102)	From MWL or entered by the user
	Designator		
	Requested	(0032,1060)	
	Procedure		
	Description		
General Image	Instance Number	(0020,0013)	Auto generated
	Patient Orientation	(0020,0020)	Empty, zero length
	Lossy Image	(0028,2110)	01
	Compression	,	
General Equipment	Manufacturer	(0008,0070)	MedXChange
	Station Name	(0008,1010)	From MWL; Not visible on UI
	Manufacturer	(0008,1090)	4Klearity
	Model Name	<b>,</b>	_
	Software Versions	(0018,1020)	The version of the SCU
Image Pixel	Samples per Pixel	(0028,0002)	3
<u> </u>	Photometric	(0028,0004)	YBR_PARTIAL_420
	Interpretation	`	
	Planar	(0028,0006)	0
	Configuration		
	Rows	(0028,0010)	From Video



Revision: 3.0

Effective Date: Date of last approval

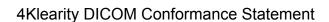
Page: 28 of 30

	Columns	(0028,0011)	From Video
	Bits Allocated	(0028,0100)	8
	Bits Stored	(0028,0101)	8
	High Bit	(0028,0102)	7
	Pixel	(0028,0103)	0
	Representation		
	Pixel Data	(7FE0,0010)	From Video
SOP Common	SOP Class UID	(0008,0016)	1.2.840.10008.5.1.4.1.1.7.4
Module			
	SOP Instance UID	(0008,0018)	Automatically generated
	Character Set	(0008 0005)	ISO IR 100

## 8.1.4 Video Photographic Image Storage IOD

Table 8-4 – Video Photographic Image Storage IOD

Module	Attribute	Tag	Value and/or length, range, and origin
PATIENT	Patient Name	(0010,0010)	From MWL or entered by user
	Patient ID	(0010,0020)	From MWL or entered by user
	Patient Sex	(0010,0040)	From MWL or entered by user; M, F, O or empty
	Patient Birth Date	(0010,0030)	From MWL or entered by user
General Study	Study Instance	(0020,000D)	From MWL or automatically
	UID	(	generated if MWL is not used; not visible on UI
	Study ID	(0020,0010)	Automatically generated; not visible on UI
	Study Date	(0008,0020)	From MWL or automatically created when the study is created
	Study Time	(0008,0030)	From MWL or automatically created when the study is created
	Accession Number	(0008,0050)	From MWL or entered by user
	Referring Physician's Name	(0008,0090)	From MWL or entered by the user
	Admission ID	(0038,0010)	From MWL or entered by the user
General Series	Modality	(0008,0060)	From MWL or entered by the user
	Series Instance UID	(0020,000E)	Automatically generated
	Series Number	(0020,0011)	1
	Performing Physician Name	(0008,1050)	From MWL or entered by the user
	Code Value	(0008,0100)	
	Code Meaning	(0008,0104)	
	Coding Scheme Designator	(0008,0102)	
	Requested	(0032,1060)	From MWL or entered by the user



Revision: 3.0

Effective Date: Date of last approval

Page: 29 of 30

T = .	1	
Description		
Instance Number	(0020,0013)	Auto generated
Patient Orientation	(0020,0020)	Empty, zero length
Lossy Image	(0028,2110)	01
Compression		
Manufacturer	(0008,0070)	MedXChange
Station Name	(0008,1010)	From MWL; Not visible on UI
Manufacturer	(0008,1090)	4Klearity
Model Name		
Software Versions	(0018,1020)	The version of the SCU
Samples per Pixel	(0028,0002)	3
Photometric	(0028,0004)	YBR_PARTIAL_420
Interpretation		
Planar	(0028,0006)	0
Configuration		
Rows	(0028,0010)	From Video
Columns	(0028,0011)	From Video
Bits Allocated	(0028,0100)	8
Bits Stored	(0028,0101)	8
High Bit	(0028,0102)	7
Pixel	(0028,0103)	0
Representation		
Pixel Data	(7FE0,0010)	From Video
SOP Class UID	(0008,0016)	1.2.840.10008.5.1.4.1.1.7.4
	,	
SOP Instance UID	(0008,0018)	Automatically generated
Character Set	(0008,0005)	ISO_IR 100
	Patient Orientation Lossy Image Compression Manufacturer Station Name Manufacturer Model Name Software Versions Samples per Pixel Photometric Interpretation Planar Configuration Rows Columns Bits Allocated Bits Stored High Bit Pixel Representation Pixel Data SOP Class UID	Description           Instance Number         (0020,0013)           Patient Orientation         (0020,0020)           Lossy Image         (0028,2110)           Compression         (0008,0070)           Manufacturer         (0008,1010)           Manufacturer         (0008,1090)           Model Name         (0018,1020)           Samples per Pixel         (0028,0002)           Photometric         (0028,0004)           Interpretation         (0028,0004)           Planar         (0028,0006)           Configuration         (0028,0010)           Rows         (0028,0010)           Columns         (0028,0101)           Bits Allocated         (0028,0101)           High Bit         (0028,0102)           Pixel         (0028,0103)           Representation         (7FE0,0010)           SOP Class UID         (0008,0016)

## 8.2 Attribute Mapping

The relationships between attributes received via Modality Worklist and stored in acquired images are summarized in the table below.

Table 8-5 – Attribute Mapping between Modality Worklist and Image IOD

			1
Field	MWL Tag	Image Tag	Interface
Patient Name	(0010,0010)	(0010,0010)	Υ
Patient ID	(0010,0020)	(0010,0020)	Υ
Patient Sex	(0010,0040)	(0010,0040)	Υ
Patient Birth Date	(0010,0030)	(0010,0030)	Υ
Study Instance UID	(0020,000D)	(0020,000D)	N
Study Date	(0040,0002)	(0008,0020)	Y
Study Time	(0040,0003)	(0008,0030)	Υ
Accession Number	(0008,0050)	(0008,0050)	Y
Referring	(0008,0090)	(0008,0090)	Y

Document #: 5021-19-F07

Revision: 3.0

Effective Date: Date of last approval

Page: 30 of 30

Physician's Name			
Modality	(0008,0060)	(0008,0060)	Υ
Performing	(0040,0006)	(0008,1050)	Υ
Physician Name			
Station Name	(0040,0010)	(0008,1010)	N
Admission ID	(0038,0010)	(0038,0010)	Υ
Code Value	(0008,0100)	(0008,0100)	Υ
Code Meaning	(0008,0104)	(0008,0104)	Υ
Coding Scheme	(0008,0102)	(0008,0102)	Υ
Designator			
Requested	(0032,1060)	(0032,1060)	Υ
Procedure			
Description			