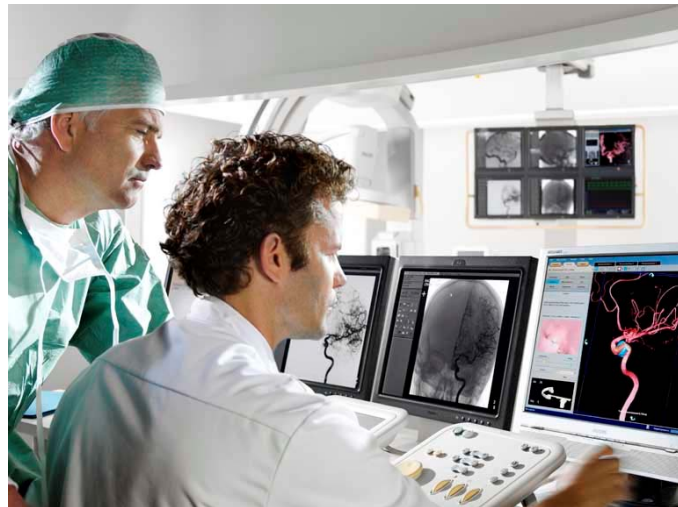

DICOM

Conformance Statement

EP Navigator R3.0



PHILIPS

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Document Number: XPS 031-090569.01

Date: 9 March 2010

1 DICOM CONFORMANCE STATEMENT OVERVIEW

EP Navigator is a system (consisting of both hardware and software included) for Cardiac Cathlab applications used along with Allura-Xper system. DICOM data (CT volume data) can be pushed from external workstation/PACS towards the EP Navigator system. The EP Navigator system stores the data in the local data repository. In order to be able to import DICOM data, the EP Navigator system provides DICOM storage as SCP.

A table of Supported Networking DICOM Service (SOP) Classes is provided with roles (User/Provider)

The EP Navigator system is designed to process CT images and use them for EP applications. In addition to that it can receive other data sets like MR, US, etc. However they are not used by the EP Navigator system, they are received to support multi-modality study import. Also the EP Navigator system can Query and Retrieve study info for a specific patient from a PACS. The EP Navigator system consists of Navigator work station with optional EP Cockpit snapshot functionality.

The EP Navigator system supports the following DICOM functionality.

- DICOM import functionality
- DICOM Query/Retrieve functionality.
- DICOM Verification functionality.
- Read DICOM CD or DVD Disks.

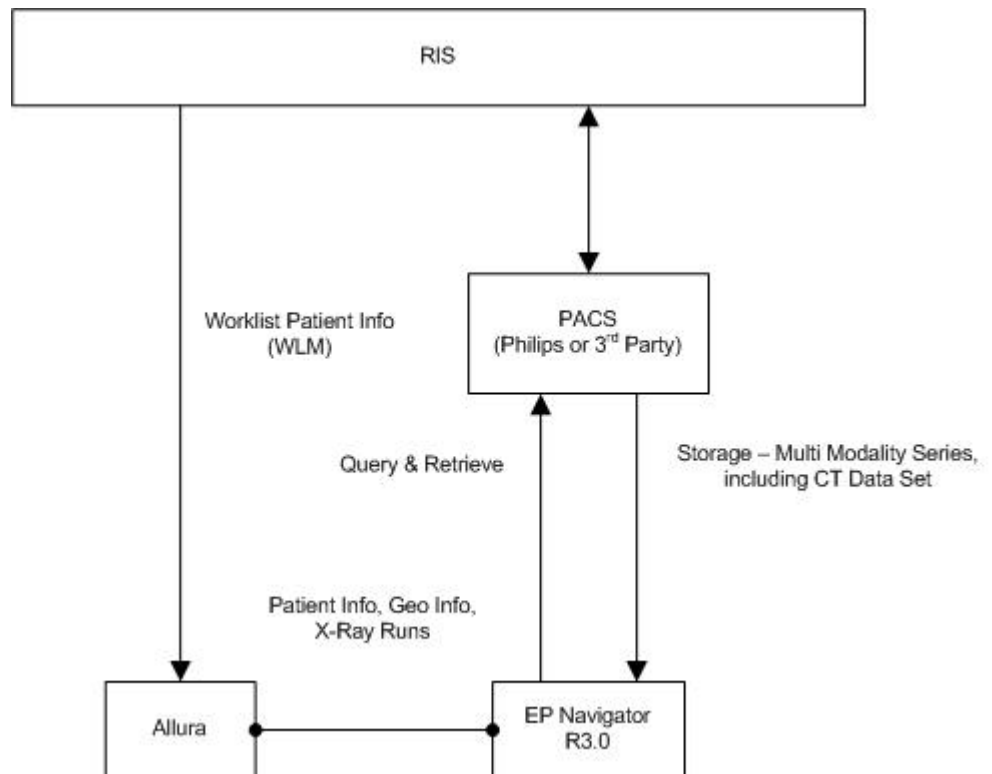


Figure 1: EP Navigator system context regarding DICOM connectivity interfaces

Note:

- EP Navigator Query/Retrieves or Imports CT data sets from PACS

Table 1: Network Services

SOP Class		User of Service (SCU)	Provider of Service (SCP)
Name	UID		
Other			
Verification SOP Class	1.2.840.10008.1.1	Yes	Yes
Query/Retrieve			
Patient Root Query/Retrieve Information Model - FIND SOP Class	1.2.840.10008.5.1.4.1.2.1.1	Yes	No
Patient Root Query/Retrieve Information Model - MOVE SOP Class	1.2.840.10008.5.1.4.1.2.1.2	Yes	No
Study Root Query/Retrieve Information Model - FIND SOP Class	1.2.840.10008.5.1.4.1.2.2.1	Yes	No
Study Root Query/Retrieve Information Model - MOVE SOP Class	1.2.840.10008.5.1.4.1.2.2.2	Yes	No
Transfer			
12-Lead ECG Waveform Storage SOP Class	1.2.840.10008.5.1.4.1.1.9.1.1	No	Yes
Computed Radiography Image Storage SOP Class	1.2.840.10008.5.1.4.1.1.1	No	Yes
CT Image Storage SOP Class	1.2.840.10008.5.1.4.1.1.2	No	Yes
General ECG Waveform Storage SOP Class	1.2.840.10008.5.1.4.1.1.9.1.2	No	Yes
Hemodynamic Waveform Storage SOP Class	1.2.840.10008.5.1.4.1.1.9.2.1	No	Yes
MR Image Storage SOP Class	1.2.840.10008.5.1.4.1.1.4	No	Yes
Multi-frame Grayscale Byte SC Image Storage SOP Class	1.2.840.10008.5.1.4.1.1.7.2	No	Yes
Multi-frame Grayscale Word SC Image Storage SOP Class	1.2.840.10008.5.1.4.1.1.7.3	No	Yes
Multi-frame Single Bit Secondary Capture Image Storage SOP Class	1.2.840.10008.5.1.4.1.1.7.1	No	Yes
Raw Data Storage SOP Class	1.2.840.10008.5.1.4.1.1.66	No	Yes
Secondary Capture Image Storage SOP Class	1.2.840.10008.5.1.4.1.1.7	No	Yes
Softcopy Presentation State Storage SOP Class	1.2.840.10008.5.1.4.1.1.11.1	No	Yes
Ultrasound Image Storage SOP Class	1.2.840.10008.5.1.4.1.1.6.1	No	Yes
Ultrasound Multi-frame Image Storage SOP Class	1.2.840.10008.5.1.4.1.1.3.1	No	Yes
X-Ray Angiographic Image Storage SOP Class	1.2.840.10008.5.1.4.1.1.12.1	No	Yes
X-Ray Radiofluoroscopic Image Storage SOP Class	1.2.840.10008.5.1.4.1.1.12.2	No	Yes

The services can be specified as a SCU, SCP or as an Option, which means that it is either configurable or that it can be purchased separately.

Table 2: Media Services

Media Storage Application Profile	Write Files (FSC / FSU)	Read Files (FSR)	Supported media
CD – R Disk			
General Purpose CD-R	NO / NO	YES	CD-R
CT/MR Studies on CD-R	NO / NO	YES	CD-R
DVD Disk			
General Purpose DVD-JPEG	NO / NO	YES	DVD-R. DVD+R, DVD+RW
CT/MR Studies on DVD Media	NO / NO	YES	DVD-R. DVD+R, DVD+RW

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3 INTRODUCTION

The introduction specifies product and relevant disclaimers as well as any general information that the vendor feels is appropriate.

3.1 Revision History

The revision history provides dates and differences of the different releases.

Table 3: Revision History

Document Version	Date of Issue	Author	Description
00	23 December 2009	PII Services/I OCC	Initial version based on EP Navigator 2.0
01	08 March 2010	PII Services/I OCC	Supported Query keys table updated with Series level attributes based on the Q/R Test observations. Default port number changed to 3028. Security section added

3.2 Audience

This Conformance Statement is intended for:

- (Potential) customers
- System integrators of medical equipment
- Marketing staff interested in system functionality
- Software designers implementing DICOM interfaces

It is assumed that the reader is familiar with the DICOM standard.

3.3 Remarks

The DICOM Conformance Statement is contained in chapter 4 through 8 and follows the contents and structuring requirements of DICOM PS 3.2.

This DICOM Conformance Statement by itself does not guarantee successful interoperability of Philips equipment with non-Philips equipment. The user (or user's agent) should be aware of the following issues:

- **Interoperability**
Interoperability refers to the ability of application functions, distributed over two or more systems, to work successfully together. The integration of medical devices into an IT environment may require application functions that are not specified within the scope of DICOM. Consequently, using only the information provided by this Conformance Statement does not guarantee interoperability of Philips equipment with non-Philips equipment.
It is the user's responsibility to analyze thoroughly the application requirements and to specify a solution that integrates Philips equipment with non-Philips equipment.
- **Validation**
Philips equipment has been carefully tested to assure that the actual implementation of the DICOM interface corresponds with this Conformance Statement.
Where Philips equipment is linked to non-Philips equipment, the first step is to compare the relevant Conformance Statements. If the Conformance Statements indicate that successful information exchange should be possible, additional

validation tests will be necessary to ensure the functionality, performance, accuracy and stability of image and image related data. It is the responsibility of the user (or user's agent) to specify the appropriate test suite and to carry out the additional validation tests.

- **New versions of the DICOM Standard**

The DICOM Standard will evolve in future to meet the user's growing requirements and to incorporate new features and technologies. Philips is actively involved in this evolution and plans to adapt its equipment to future versions of the DICOM Standard. In order to do so, Philips reserves the right to make changes to its products or to discontinue its delivery.

The user should ensure that any non-Philips provider linking to Philips equipment also adapts to future versions of the DICOM Standard. If not, the incorporation of DICOM enhancements into Philips equipment may lead to loss of connectivity (in case of networking) and incompatibility (in case of media).

3.4 Definitions, Terms and Abbreviations

DICOM definitions, terms and abbreviations are used throughout this Conformance Statement. For a description of these, see NEMA PS 3.3 and PS 3.4. The word Philips in this document refers to Philips Medical Systems.

The following acronyms and abbreviations are used in this document.

AE	Application Entity
ANSI	American National Standard Institute
AP	Application Profile
CD	Compact Disk
CD-R	CD Recordable
CR	Computed Radiography
CT	Computed Tomography
DICOM	Digital Imaging and Communications in Medicine
DIMSE	DICOM Message Service Element
DIMSE-C	DIMSE-Composite
DIMSE-N	DIMSE-Normalized
DVD-R	DVD Recordable
DVD-RW	DVD Rewritable
EBE	DICOM Explicit VR Big Endian
ELE	DICOM Explicit VR Little Endian
EP Navigator	Electro Physiology Navigator
FSC	File Set Creator
FSR	File Set Reader
FSU	File Set Updater
GUI	Graphic User Interface
ILE	DICOM Implicit VR Little Endian
IOD	Information Object Definition
ISIS	Information System – Imaging System
MOD	Magneto-Optical Disk
MPPS	Modality Performed Procedure Step
MR	Magnetic Resonance
NEMA	National Electrical Manufacturers Association
NM	Nuclear Medicine
PACS	Picture Archival and Communication System
PDU	Protocol Data Unit
RF	X-Ray Radiofluoroscopic
RIS	Radiology Information System
RT	Radiotherapy
RWA	Real-World Activity
SC	Secondary Capture
SCP	Service Class Provider

SCU	Service Class User
SOP	Service Object Pair
TCP/IP	Transmission Control Protocol/ Internet Protocol
TSM	Touch Screen Module
UID	Unique Identifier
US	Ultrasound
USMF	Ultrasound Multi-frame
WLM	Work list Management
XA	X-Ray Angiographic

Note:

The name “Electro-Physiology Work Spot” changed to “EP Navigator”. The term “EPW” in rest of the document refers to EP Navigator.

3.5 References

- [DICOM] Digital Imaging and Communications in Medicine, Part 1 – 18 (NEMA PS 3.1– PS 3.18), National Electrical Manufacturers Association (NEMA) Publication Sales 1300 N. 17th Street, Suite 1847 Rosslyn, Virginia. 22209, United States of America Internet: <http://medical.nema.org/>
Note that at any point in time the official standard consists of the most recent yearly edition of the base standard (currently 2008) plus all the supplements and correction items that have been approved as Final Text.

4 NETWORKING

This section contains the networking related services (vs. the media related ones).

4.1 Implementation model

The implementation model consists of three sections:

- The application data flow diagram, specifying the relationship between the Application Entities and the “external world” or Real-World Activities,
- A functional description of each Application Entity, and
- The sequencing constraints among them.

4.1.1 Application Data Flow

The EP Navigator system provides

- DICOM import functionality
- DICOM Query/ Retrieve functionality
- DICOM Verification functionality.

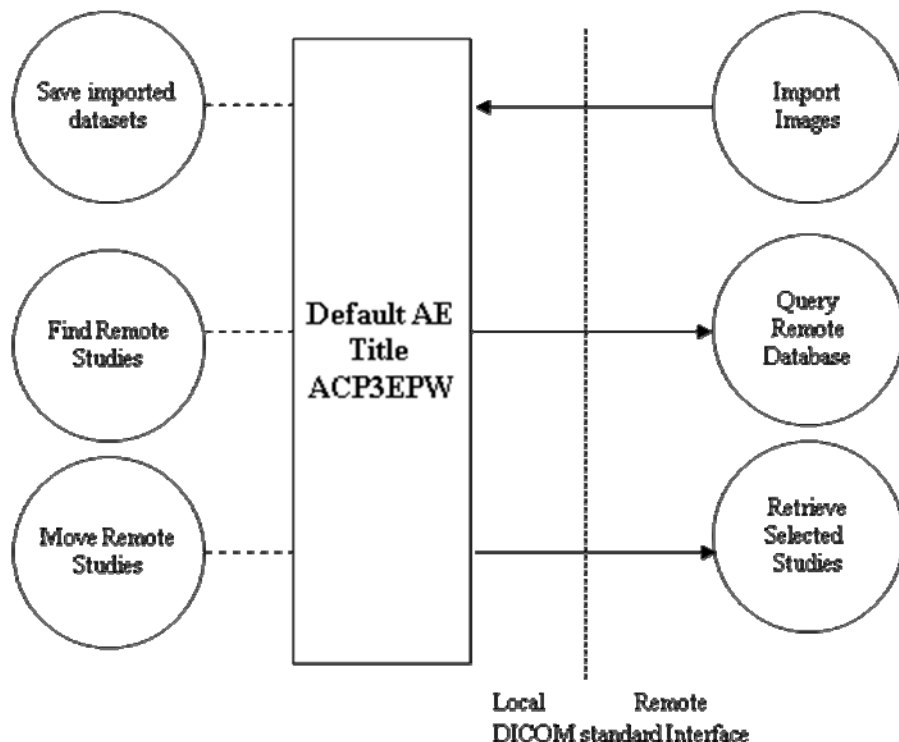


Figure 2: Application Data Flow Diagram

4.1.2 Functional Definition of AE's

This section contains a functional definition for each individual local Application Entity. This describes in general terms the functions to be performed by the AE, and the DICOM services used to accomplish these functions. In this sense, "DICOM services" refers not only to DICOM Service Classes, but also to lower level DICOM services, such as Association Services.

4.1.2.1 Functional Definition of ACP3EPW

This section describes in general terms the functions to be performed by the ACP3EPW Application Entity and the DICOM services used to accomplish these functions. ACP3EP Navigator provides the following DICOM services.

- DICOM Import
- DICOM Query/Retrieve
- DICOM Verification

4.1.3 Sequencing of Real World Activities

This section contains a description of sequencing as well as potential constraints of Real-World Activities, including any applicable user interactions, as performed by ACP3EPW Application Entity.

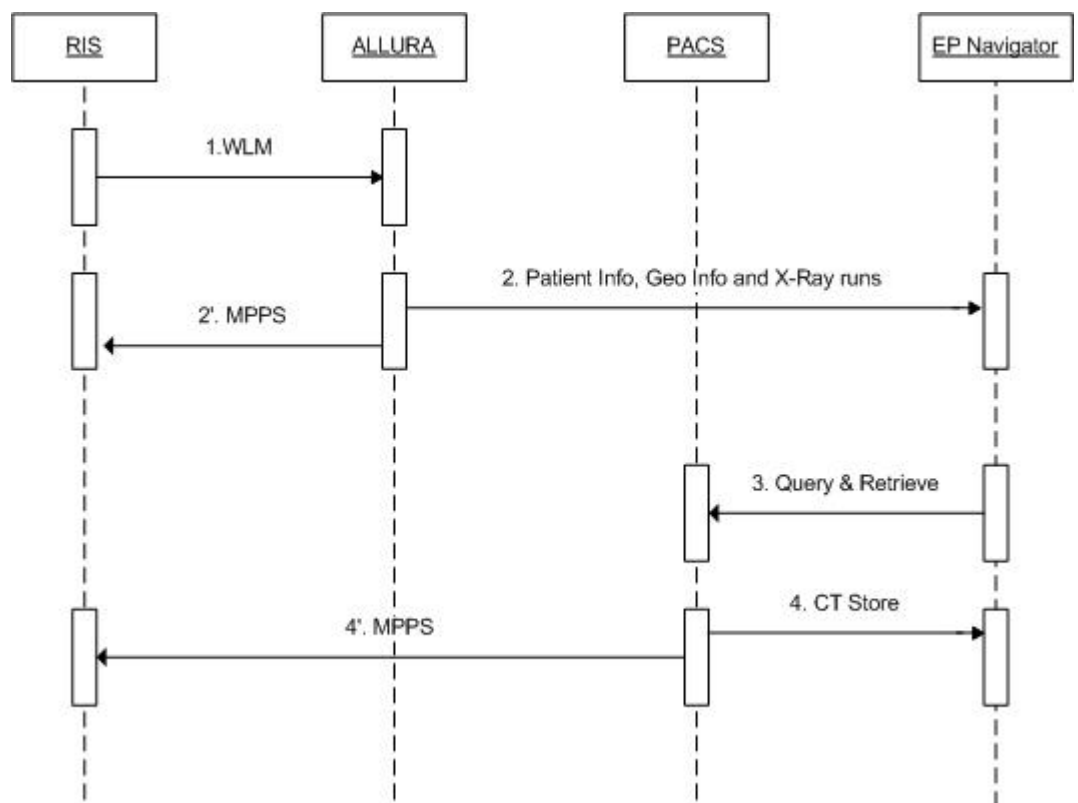


Figure 3: Sequencing of Real world Activities between EP Navigator system and PACS

Note:

- EP Navigator Query/Retrieves or Imports CT data sets from PACS

4.2 AE Specifications

The next section in the DICOM Conformance Statement is a set of application entity specifications. There are as many of these subsections as there are different AE's in the implementation.

4.2.1 ACP3EPW

Detail of this specific Application Entity is specified in this section.

4.2.1.1 SOP Classes

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

Table 4: SOP Classes for ACP3EPW

SOP Class Name	SOP Class UID	SCU	SCP
12-Lead ECG Waveform Storage SOP Class	1.2.840.10008.5.1.4.1.1.9.1.1	No	Yes
Computed Radiography Image Storage SOP Class	1.2.840.10008.5.1.4.1.1.1	No	Yes
CT Image Storage SOP Class	1.2.840.10008.5.1.4.1.1.2	No	Yes
General ECG Waveform Storage SOP Class	1.2.840.10008.5.1.4.1.1.9.1.2	No	Yes
Hemodynamic Waveform Storage SOP Class	1.2.840.10008.5.1.4.1.1.9.2.1	No	Yes
MR Image Storage SOP Class	1.2.840.10008.5.1.4.1.1.4	No	Yes
Multi-frame Grayscale Byte SC Image Storage SOP Class	1.2.840.10008.5.1.4.1.1.7.2	No	Yes
Multi-frame Grayscale Word SC Image Storage SOP Class	1.2.840.10008.5.1.4.1.1.7.3	No	Yes
Multi-frame Single Bit Secondary Capture Image Storage SOP Class	1.2.840.10008.5.1.4.1.1.7.1	No	Yes
Patient Root Query/Retrieve Information Model - FIND SOP Class	1.2.840.10008.5.1.4.1.2.1.1	Yes	No
Patient Root Query/Retrieve Information Model - MOVE SOP Class	1.2.840.10008.5.1.4.1.2.1.2	Yes	No
Raw Data Storage SOP Class	1.2.840.10008.5.1.4.1.1.66	No	Yes
Secondary Capture Image Storage SOP Class	1.2.840.10008.5.1.4.1.1.7	No	Yes
Softcopy Presentation State Storage SOP Class	1.2.840.10008.5.1.4.1.1.11.1	No	Yes
Storage Commitment Push Model SOP Class	1.2.840.10008.1.20.1	No	No
Study Root Query/Retrieve Information Model - FIND SOP Class	1.2.840.10008.5.1.4.1.2.2.1	Yes	No
Study Root Query/Retrieve Information Model - MOVE SOP Class	1.2.840.10008.5.1.4.1.2.2.2	Yes	No
Ultrasound Image Storage SOP Class	1.2.840.10008.5.1.4.1.1.6.1	No	Yes
Ultrasound Multi-frame Image Storage SOP Class	1.2.840.10008.5.1.4.1.1.3.1	No	Yes
Verification SOP Class	1.2.840.10008.1.1	No	Yes
X-Ray Angiographic Image Storage SOP Class	1.2.840.10008.5.1.4.1.1.12.1	No	Yes
X-Ray Radiofluoroscopic Image Storage SOP Class	1.2.840.10008.5.1.4.1.1.12.2	No	Yes

Note: Any SOP specific behavior is documented later in the conformance statement in the applicable SOP specific conformance section.

4.2.1.2 Association Policies

Each AE specification contains a description of the general association establishment and acceptance policies of the AE.

4.2.1.2.1 General

The DICOM standard application context has specified.

Table 5: DICOM Application Context

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

4.2.1.2.2 Number of Associations

The number of simultaneous associations that an Application Entity may support as a Initiator or Acceptor is specified.

Table 6: Number of Associations as an Association Initiator for ACP3EPW

Maximum number of simultaneous associations	10
---	----

Table 7: Number of Associations as an Association Acceptor for ACP3EPW

Maximum number of simultaneous associations	10
---	----

4.2.1.2.3 Asynchronous Nature

If the implementation supports negotiation of multiple outstanding transactions this is stated here, along with the maximum number of outstanding transactions supported.

Table 8: Asynchronous Nature as an Association Initiator for ACP3EPW

Maximum number of outstanding asynchronous transactions	1
---	---

4.2.1.2.4 Implementation Identifying Information

The value supplied for Implementation Class UID and version name are documented here.

Table 9: DICOM Implementation Class and Version for ACP3EPW

Implementation Class UID	1.3.46.670589.38.1.1.0
Implementation Version Name	EP Navigator 3.0

4.2.1.2.5 Communication Failure Handling

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

Table 10: Communication Failure Behavior

Exception	Behavior
ARTIM Timeout	Association setup fails. The reason is logged.

4.2.1.3 Association Initiation Policy

This describes the conditions under which the AE will initiate an association.

The behavior of the AE during association rejection is summarized in next table

Table 11: DICOM Association Rejection Handling

Result	Source	Reason/Diagnosis	Behavior
1 – rejected-permanent	1 – DICOM UL service-user	1 – no-reason-given	Association is not established. The error is logged.
		2 – application-context-name-not-supported	Association is not established. The error is logged.
		3 – calling-AE-title-not-recognized	Association is not established. The error is logged.

Result	Source	Reason/Diagnosis	Behavior
	2 – DICOM UL service-provider (ACSE related function)	7 – called-AE-title-not-recognized	Association is not established. The error is logged.
		1 – no-reason-given	Association is not established. The error is logged.
		2 – protocol-version-not-supported	Association is not established. The error is logged.
	3 – DICOM UL service-provider (presentation related function)	1 – temporary-congestion	Association is not established. The error is logged.
		2 – local-limit-exceeded	Association is not established. The error is logged.
2 – rejected-transient	1 – DICOM UL service-user	1 – no-reason-given	Association is not established. The error is logged.
		2 – application-context-name-not-supported	Association is not established. The error is logged.
		3 – calling-AE-title-not-recognized	Association is not established. The error is logged.
		7 – called-AE-title-not-recognized	Association is not established. The error is logged.
	2 – DICOM UL service-provider (ACSE related function)	1 – no-reason-given	Association is not established. The error is logged.
		2 – protocol-version-not-supported	Association is not established. The error is logged.
	3 – DICOM UL service-provider (presentation related function)	1 – temporary-congestion	Association is not established. The error is logged.
		2 – local-limit-exceeded	Association is not established. The error is logged.

The behavior of the AE on receiving an association abort is summarized in next table

Table 12: DICOM Association Abort Handling

Source	Reason/Diagnosis	Behavior
0 – DICOM UL service-user	0 – reason-not-specified	Application terminates the connection. Error is logged
2 – DICOM UL service-provider	0 – reason-not-specified	Application terminates the connection. Error is logged
	1 – unrecognized-PDU	Application terminates the connection. Error is logged
	2 – unexpected-PDU	Application terminates the connection. Error is logged
	4 – unrecognized-PDU parameter	Application terminates the connection. Error is logged
	5 – unexpected-PDU parameter	Application terminates the connection. Error is logged
	6 – invalid-PDU-parameter value	Application terminates the connection. Error is logged

The behavior of the AE for sending an association abort is summarized in next table.

Table 13: DICOM Association Abort Policies

Source	Reason/Diagnosis	Behavior
0 – DICOM UL service-user	0 – reason-not-specified	Application terminates the connection. Error is logged
2 – DICOM UL service-provider	0 – reason-not-specified	Application terminates the connection. Error is logged
	1 – unrecognized-PDU	Application terminates the connection. Error is logged
	2 – unexpected-PDU	Application terminates the connection. Error is logged
	4 – unrecognized-PDU parameter	Application terminates the connection. Error is logged

Source	Reason/Diagnosis	Behavior
	5 – unexpected-PDU parameter	Application terminates the connection. Error is logged
	6 – invalid-PDU-parameter value	Application terminates the connection. Error is logged

4.2.1.3.1 (Real-World) Activity – FIND As SCU

4.2.1.3.1.1 Description and Sequencing of Activities

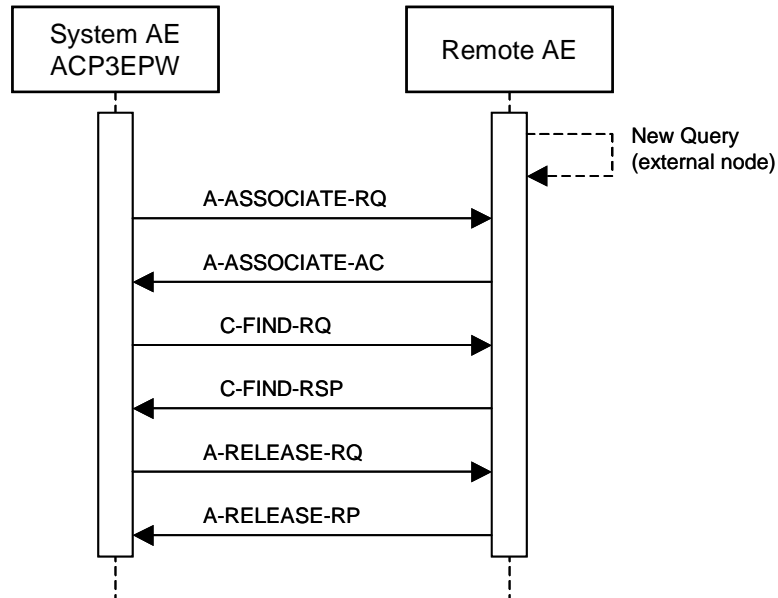


Figure 4: (Real World) Activity - FIND As SCU

The EP Navigator system can query patient study information on a remote system by finding matching patient information on the remote database.

The operator is able to query selected patient study information on a remote database to by means of query button provided in EP Navigator system.

The EP Navigator system initiates for each query request an association to the configured Remote AE and uses it to send the find (C_FIND) request and receive the associated responses.

The association is released after the find responses for the related request have been received.

4.2.1.3.1.2 Proposed Presentation Contexts

Table 14: Proposed Presentation Contexts for (Real-World) Activity – FIND As SCU

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Extended Negotiation
Name	UID	Name List	UID List		
Patient Root Query/Retrieve	1.2.840.10008.5.1.4.1.2.1.1	Explicit VR Big Endian	1.2.840.10008.1.2.2	SCU	None
		Explicit VR Little Endian	1.2.840.10008.1.2.1		

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Extended Negotiation
Name	UID	Name List	UID List		
Information Model - FIND SOP Class		Implicit VR Little Endian	1.2.840.10008.1.2		
Study Root Query/Retrieve Information Model - FIND SOP Class	1.2.840.10008.5.1.4.1.2.2.1	Explicit VR Big Endian	1.2.840.10008.1.2.2	SCU	None
		Explicit VR Little Endian	1.2.840.10008.1.2.1		
		Implicit VR Little Endian	1.2.840.10008.1.2		

The EP Navigator system is capable of proposing the Presentation Contexts shown in the above table

Extended negotiations are not supported by the EP Navigator system.

4.2.1.3.1.3 SOP Specific Conformance for Patient Root Query/Retrieve Information Model - FIND SOP Class

This section includes the SOP specific behavior, i.e. error codes, error and exception handling, time-outs, etc.

The behavior of an Application Entity SOP class is summarized as shown in next Table. The standard as well as the manufacturer specific status codes and their corresponding behavior is specified.

In Patient Root level model, if a query is made at the patient level and if SCP sends patient level responses to the EP Navigator system, then EP Navigator internally sends a Study level C_FIND_RQ supplying the Patient ID it just received from the C_FIND_RSP, querying for any studies for that patient in the remote database. If there are no studies received for the patient, then that patient details are not listed in the query results on the GUI of EP Navigator system.

4.2.1.3.1.3.1 Dataset Specific Conformance for Patient Root Q/R Information Model - FIND SOP Class SCU

This section includes the dataset specific behavior, i.e. error codes, error and exception handling, time-outs, etc.

Table 15: Supported Query Keys for C-FIND-RQ

Attribute Name	Tag	VR	Type Of Matching	Comment
Query/Retrieve Level	0008,0052	CS	Single Value	Patient
Q/R Patient level				
Patient ID	0010,0020	LO	Single Value, Wildcard and Universal	Patient Level
Patient's Name	0010,0010	PN	Single Value, Wildcard and Universal	Patient Level * Note 2
Patient's Birth Date	0010,0030	DA	Single Value	Patient Level
Q/R Study level (Patient Root)				
Patient ID	0010,0020	LO	Single Value	Study Level
Study Instance UID	0020,000D	UI	Universal	Study Level
Study Date	0008,0020	DA	Universal	Study Level
Study Time	0008,0030	TM	Universal	Study Level
Accession Number	0008,0050	SH	Universal	Study Level
Study ID	0020,0010	SH	Universal	Study Level
QR Series Level (Patient Root)				
Patient ID	0010,0020	LO	Single Value	Series Level
Modality	0008,0060	CS	Universal	Series Level
Performing Physician's Name	0008,1050	PN	Universal	Series Level

Attribute Name	Tag	VR	Type Of Matching	Comment
Protocol Name	0018,1030	LO	Universal	Series Level
Study Instance UID	0020,000D	UI	Single value	Series Level
Series Instance UID	0020,000E	UI	Universal	Series Level
Series Number	0020,0011	US	Universal	Series Level

Note: Though Universal matching is supported for Patient Name and Patient ID attributes at least one of these attributes should have value entered in their field (at least Wild card character) for a query

** Note 2: When maximum query hit limit is exceeded, a message "Query to PACS failed, Is PACS online?" appears.*

Table 16: C-FIND-RQ Status Response

Service Status	Code	Further Meaning	Description
Success	0000	Matching is complete	The find results are displayed.
Refused	A700	Out of Resources	No find results are displayed. The reason is logged.
Failed	A900	Identifiers does not match SOP class	No find results are displayed. The reason is logged.
	Cxxx	Unable to process	No find results are displayed. The reason is logged.
Cancel	FE00	Matching terminated due to Cancel Request	No find results are displayed. The reason is logged.
Pending	FF00	Matches are continuing – Current match is supplied and any optional keys were supported in the same manner as required keys.	The find command continues.
	FF01	Matches are continuing – Warning that one or more optional keys were not supported for existence and/or matching for this identifier	The find command continues.

Table 17: DICOM Command Communication Failure Behavior

Exception	Behavior
ARTIM Time-out	N/A
Reply Time-out	The query fails and the association is aborted. The reason is logged.
Association Time-out SCU	The association is released.
Association aborted	The query fails. The reason is logged.

4.2.1.3.1.4 SOP Specific Conformance for Study Root Query/Retrieve Information Model - FIND SOP Class

The behavior of an Application Entity SOP class is summarized as shown in next Table. The standard as well as the manufacturer specific status codes and their corresponding behavior is specified.

4.2.1.3.1.4.1 Dataset Specific Conformance for Study Root Q/R Information Model - FIND SOP Class SCU

This section includes the dataset specific behavior, i.e. error codes, error and exception handling, time-outs, etc.

Table 18: Supported Query Keys for C-FIND-RQ

Attribute Name	Tag	VR	Type Of Matching	Comment
Query/Retrieve Level	0008,0052	CS	Single Value	Study
Q/R Study level (Study Root)				
Study Instance UID	0020,000D	UI	Universal	
Study Date	0008,0020	DA	Universal	
Study Time	0008,0030	TM	Universal	
Accession Number	0008,0050	SH	Universal	
Patient's Name	0010,0010	PN	Single Value, Wildcard and Universal	
Patient ID	0010,0020	LO	Single Value, Wildcard and Universal	
Patient's Birth Date	0010,0030	DA	Single Value	
Study ID	0020,0010	SH	Universal	
QR Series Level (Study Root)				
Patient ID	0010,0020	LO	Single Value	
Modality	0008,0060	CS	Universal	
Performing Physician's Name	0008,1050	PN	Universal	
Protocol Name	0018,1030	LO	Universal	
Study Instance UID	0020,000D	UI	Single value	
Series Instance UID	0020,000E	UI	Universal	
Series Number	0020,0011	US	Universal	

Note: Though Universal matching is supported for Patient Name and Patient ID attributes at least one of these attributes should have value entered in their field (at least Wild card character) for a query.

Table 19: C-FIND-RQ Status Response

Service Status	Code	Further Meaning	Description
Success	0000	Matching is complete	The find results are displayed.
Refused	A700	Out of Resources	No find results are displayed. The reason is logged.
Failed	A900	Identifiers does not match SOP class	No find results are displayed. The reason is logged.
	Cxxx	Unable to process	No find results are displayed. The reason is logged.
Cancel	FE00	Matching terminated due to Cancel Request	No find results are displayed. The reason is logged.
Pending	FF00	Matches are continuing – Current match is supplied and any optional keys were supported in the same manner as required keys.	The find command continues.
	FF01	Matches are continuing – Warning that one or more optional keys were not supported for existence and/or matching for this identifier	The find command continues.

Table 20: DICOM Command Communication Failure Behavior

Exception	Behavior
ARTIM Time-out	N/A
Reply Time-out	The query fails and the association is aborted. The reason is logged.
Association Time-out SCU	The association is released.

Exception	Behavior
Association aborted	The query fails. The reason is logged.

4.2.1.3.2 (Real-World) Activity – MOVE As SCU

4.2.1.3.2.1 Description and Sequencing of Activities

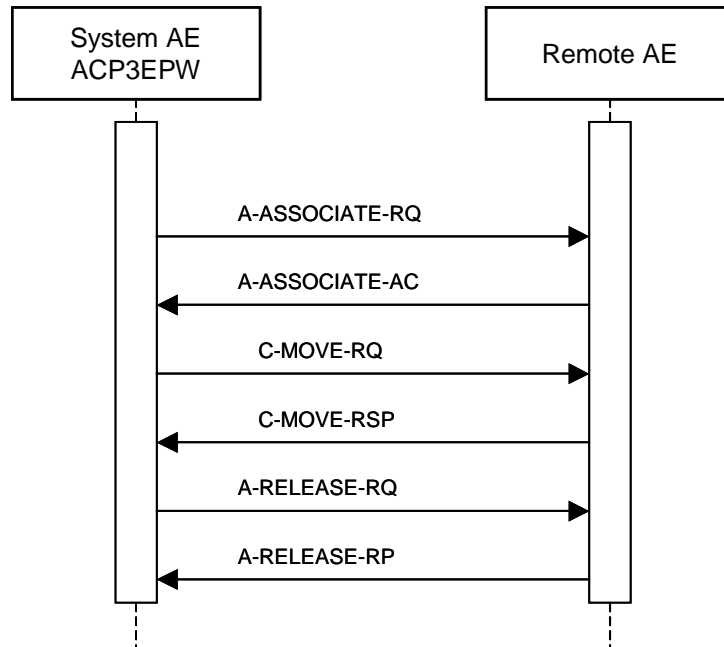


Figure 5: (Real World) Activity - MOVE As SCU

The EP Navigator system can retrieve patient study information from a remote system by supplying matching patient information from the remote database to its local database.

The operator is able to retrieve the matched patient study information from a remote database to local database by means of retrieve button provided by the EP Navigator system.

The EP Navigator system initiates for each retrieve request an association to the configured Remote AE and uses it to send the Retrieve (C_MOVE) request and receive the associated responses. The association is released after the Retrieve responses for the related request has been received.

4.2.1.3.2.2 Proposed Presentation Contexts

Table 21: Proposed Presentation Contexts for (Real-World) Activity – MOVE As SCU

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Extended Negotiation
Name	UID	Name List	UID List		
Patient Root	1.2.840.10008.5.1.4.1.2.1.2	Explicit VR Big Endian	1.2.840.10008.1.2.2	SCU	None

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Extended Negotiation
Name	UID	Name List	UID List		
Query/Retrieve Information Model - MOVE SOP Class		Explicit VR Little Endian	1.2.840.10008.1.2.1		
		Implicit VR Little Endian	1.2.840.10008.1.2		
Study Root Query/Retrieve Information Model - MOVE SOP Class	1.2.840.10008.5.1.4.1.2.2.2	Explicit VR Big Endian	1.2.840.10008.1.2.2	SCU	None
		Explicit VR Little Endian	1.2.840.10008.1.2.1		
		Implicit VR Little Endian	1.2.840.10008.1.2		

EP Navigator system is capable of proposing the Presentation Contexts shown in the above table

No extended negotiations as SCU are accepted by EP Navigator system.

4.2.1.3.2.3 SOP Specific Conformance for Patient Root Query/Retrieve Information Model - MOVE SOP Class

The behavior of an Application Entity SOP class is summarized as shown in next Table. The standard as well as the manufacturer specific status codes and their corresponding behavior is specified.

4.2.1.3.2.3.1 Dataset Specific Conformance for Patient Root Q/R Information Model - MOVE SOP Class SCU

This section includes the dataset specific behavior, i.e. error codes, error and exception handling, time-outs, etc.

Table 22: Identifiers for MOVE SCU

Attribute Name	Tag	VR	Comment
Patient Root Information Model			
Query/Retrieve Level	0008,0052	CS	
Q/R Patient level			
Patient ID	0010,0020	LO	
Q/R Study level (Patient Root)			
Patient ID	0010,0020	LO	
Study Instance UID	0020,000D	UI	

Table 23: C-MOVE-RQ Status Response

Service Status	Code	Further Meaning	Description
Success	0000	Sub-operations complete-No Failures	The move job is marked as completed. The association is released.
Refused	A701	Out of Resources-Unable to calculate number of matches	The move job is marked as failed. The association is released. The reason is logged.
	A702	Out of Resources – Unable to perform sub-operations	The move job is marked as failed. The association is released. The reason is logged.

Service Status	Code	Further Meaning	Description
	A801	Move Destination unknown	The move job is marked as failed. The association is released. The reason is logged.
Failed	A900	Identifier does not match SOP class	The move job is marked as failed. The association is released. The reason is logged.
	Cxxx	Unable to process	The move job is marked as failed. The association is released. The reason is logged.
Cancel	FE00	Sub-operations terminated due to Cancel Indication	The move job is marked as failed. The association is released. The reason is logged.
Warning	B000	Sub-operations complete – One or more Failures	The move job is marked as completed. The association is released.
Pending	FF00	Sub-operations are continuing.	The move job continues.

Table 24: DICOM Command Communication Failure Behavior

Exception	Behavior
ARTIM Time-out	The move job fails in case of association setup. The reason is logged.
Reply Time-out	The move job fails and the association is aborted. The reason is logged.
Association Time-out SCU	N/A
Association aborted	The move job fails. The reason is logged and.

4.2.1.3.2.4 SOP Specific Conformance for Study Root Query/Retrieve Information Model - MOVE SOP Class

The behavior of an Application Entity SOP class is summarized as shown in next Table. The standard as well as the manufacturer specific status codes and their corresponding behavior is specified.

4.2.1.3.2.4.1 Dataset Specific Conformance for Study Root Query/Retrieve Information Model - MOVE SOP Class SCU

This section includes the dataset specific behavior, i.e. error codes, error and exception handling, time-outs, etc.

Table 25: Identifiers for MOVE SCU

Attribute Name	Tag	VR	Comment
Study Root Information Model			
Query/Retrieve Level	0008,0052	CS	
Q/R Study level (Study Root)			
Study Instance UID	0020,000D	UI	

Table 26: C-MOVE-RQ Status Response

Service Status	Code	Further Meaning	Description
Success	0000	Sub-operations complete-No Failures	The move job is marked as completed. The association is released.
Refused	A701	Out of Resources-Unable to calculate number of matches	The move job is marked as failed. The association is released. The reason is logged.
	A702	Out of Resources – Unable to perform sub-operations	The move job is marked as failed. The association is released. The reason is logged
	A801	Move Destination unknown	The move job is marked as failed. The association is released. The reason is logged
Failed	A900	Identifier does not match SOP class	The move job is marked as failed. The association is released. The reason is logged.
	Cxxx	Unable to process	The move job is marked as failed. The association is released. The reason is logged
Cancel	FE00	Sub-operations terminated due to Cancel Indication	The move job is marked as failed. The association is released. The reason is logged
Warning	B000	Sub-operations complete – One or more Failures	The move job is marked as completed. The association is released.
Pending	FF00	Sub-operations are continuing.	The move job continues.

Table 27: DICOM Command Communication Failure Behavior

Exception	Behavior
ARTIM Time-out	The move job fails in case of association setup. The reason is logged
Reply Time-out	The move job fails and the association is aborted. The reason is logged
Association Time-out SCU	N/A
Association aborted	The move job fails. The reason is logged

4.2.1.4 Association Acceptance Policy

This describes the conditions under which the AE will initiate an association.

The behavior of the AE during association rejection is summarized in next table

Table 28: DICOM Association Rejection Handling

Result	Source	Reason/Diagnosis	Behavior
1 – rejected-permanent	1 – DICOM UL service-user	1 – no-reason-given	Association is not established. Error is logged.
		2 – application-context-name-not-supported	Association is not established. Error is logged.
		3 – calling-AE-title-not-recognized	Association is not established. Error is logged.
		7 – called-AE-title-not-recognized	Association is not established. Error is logged.
	2 – DICOM UL service-provider (ACSE related function)	1 – no-reason-given	Association is not established. Error is logged.
		2 – protocol-version-not-supported	Association is not established. Error is logged.
	3 – DICOM UL service-provider (presentation related function)	1 – temporary-congestion	Association is not established. Error is logged.
		2 – local-limit-exceeded	Association is not established. Error is logged.
2 – rejected-transient	1 – DICOM UL service-user	1 – no-reason-given	Association is not established. Error is logged.
		2 – application-context-name-not-supported	Association is not established. Error is logged.
		3 – calling-AE-title-not-recognized	Association is not established. Error is logged.
		7 – called-AE-title-not-recognized	Association is not established. Error is logged.
	2 – DICOM UL service-provider (ACSE related function)	1 – no-reason-given	Association is not established. Error is logged.
		2 – protocol-version-not-supported	Association is not established. Error is logged.
	3 – DICOM UL service-provider (presentation related function)	1 – temporary-congestion	Association is not established. Error is logged.
		2 – local-limit-exceeded	Association is not established. Error is logged.

The behavior of the AE on receiving an association abort is summarized in next table

Table 29: DICOM Association Abort Handling

Source	Reason/Diagnosis	Behavior
0 – DICOM UL service-user	0 – reason-not-specified	Application terminates the connection. Error is logged
2 – DICOM UL service-provider	0 – reason-not-specified	Application terminates the connection. Error is logged
	1 – unrecognized-PDU	Application terminates the connection. Error is logged
	2 – unexpected-PDU	Application terminates the connection. Error is logged
	4 – unrecognized-PDU parameter	Application terminates the connection. Error is logged
	5 – unexpected-PDU parameter	Application terminates the connection. Error is logged

Source	Reason/Diagnosis	Behavior
	6 – invalid-PDU-parameter value	Application terminates the connection. Error is logged

The behavior of the AE for sending an association abort is summarized in next table.

Table 30: DICOM Association Abort Policies

Source	Reason/Diagnosis	Behavior
0 – DICOM UL service-user	0 – reason-not-specified	Application terminates the connection. Error is logged
2 – DICOM UL service-provider	0 – reason-not-specified	Application terminates the connection. Error is logged
	1 – unrecognized-PDU	Application terminates the connection. Error is logged
	2 – unexpected-PDU	Application terminates the connection. Error is logged
	4 – unrecognized-PDU parameter	Application terminates the connection. Error is logged
	5 – unexpected-PDU parameter	Application terminates the connection. Error is logged
	6 – invalid-PDU-parameter value	Application terminates the connection. Error is logged

4.2.1.4.1 (Real-World) Activity – Verification as SCP

4.2.1.4.1.1 Description and Sequencing of Activities

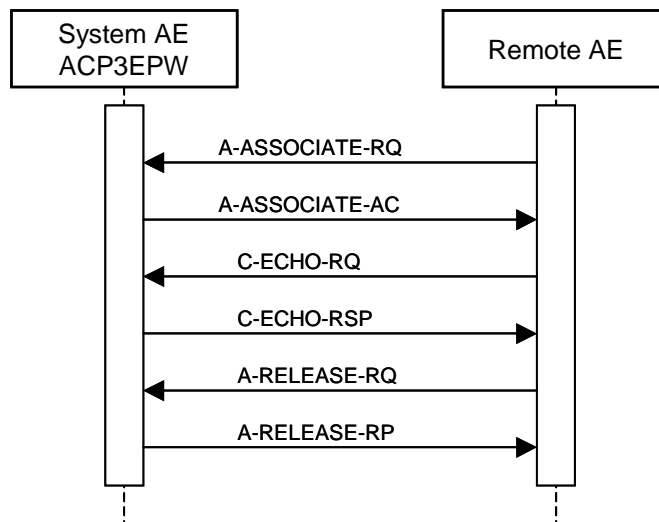


Figure 6: (Real World) Activity - Verification as SCP

The ACP3EPW accepts associations from Remote AEs that wish to verify application level communication using the C-ECHO command.

4.2.1.4.1.2 Accepted Presentation Contexts

Table 31: Acceptable Presentation Contexts for (Real-World) Activity – Verification as SCP

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Extended Negotiation
Name	UID	Name List	UID List		
Verification SOP Class	1.2.840.10008.1.1	Explicit VR Big Endian	1.2.840.10008.1.2.2	SCP	None
		Explicit VR Little Endian	1.2.840.10008.1.2.1		
		Implicit VR Little Endian	1.2.840.10008.1.2		

The ACP3EPW can accept the presentation contexts specified in the above table. Extended negotiations are not supported by EP Navigator system.

4.2.1.4.1.3 SOP Specific Conformance for Verification SOP Class

The ACP3EPW provides standard conformance to the Verification service class.

4.2.1.4.1.3.1 Dataset Specific Conformance for Verification C-ECHO SCP

This section includes the dataset specific behavior, i.e. error codes, error and exception handling, time-outs, etc.

Table 32: C-ECHO-RSP Status Response

Service Status	Code	Further Meaning	Description
Success	0000	Confirmation	Confirm the verification request

Table 33: DICOM Command Communication Failure Behavior

Exception	Behavior
ARTIM Time-out	The verification request fails. The reason is logged.
Reply Time-out	The verification request fails and association is aborted The reason is logged
Association Time-out SCU	The association is released.
Association aborted	The verification request fails. The reason is logged.

4.2.1.4.2 (Real-World) Activity – Image Import

4.2.1.4.2.1 Description and Sequencing of Activities

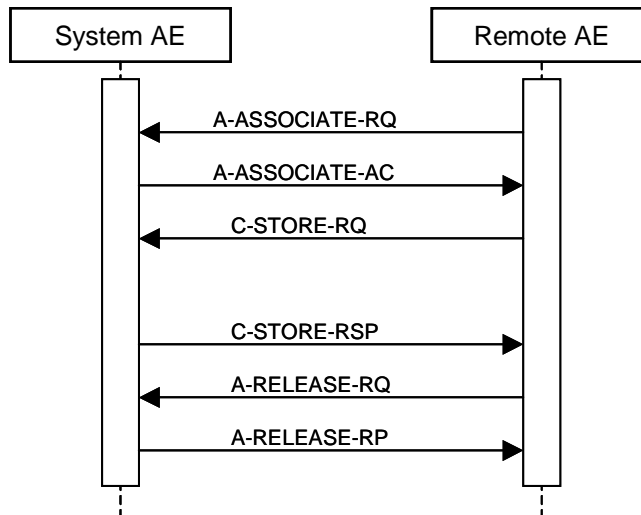


Figure 7: (Real World) Activity - Image Import

The Remote AE initiates an association request with A_ASSOCIATE_RQ to EP Navigator Application Entity, ACP3EPW for sending the patient study information or image data sets to EP Navigator. ACP3EPW accepts the association request by sending the response A_ASSOCIATE_AC to Remote AE.

Remote AE then sends the patient study information or image data sets with C_STORE_RQ for which the ACP3EPW responds for each image with C_STORE_RSP.

Association gets closed with the A_RELEASE_RQ from the Remote AE and A_RELEASE_RP back from ACP3EPW.

4.2.1.4.2.2 Accepted Presentation Contexts

Table 34: Acceptable Presentation Contexts for (Real-World) Activity – Image Import

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Extended Negotiation
Name	UID	Name List	UID List		
12-Lead ECG Waveform Storage SOP Class	1.2.840.10008.5.1.4.1.1.9.1.1	Explicit VR Big Endian	1.2.840.10008.1.2.2	SCP	None
		Explicit VR Little Endian	1.2.840.10008.1.2.1		
		Implicit VR Little Endian	1.2.840.10008.1.2		
Computed Radiography Image Storage SOP Class	1.2.840.10008.5.1.4.1.1.1	Explicit VR Big Endian	1.2.840.10008.1.2.2	SCP	None
		Explicit VR Little Endian	1.2.840.10008.1.2.1		
		Implicit VR Little Endian	1.2.840.10008.1.2		
CT Image Storage SOP Class	1.2.840.10008.5.1.4.1.1.2	Explicit VR Big Endian	1.2.840.10008.1.2.2	SCP	None
		Explicit VR Little Endian	1.2.840.10008.1.2.1		
		Implicit VR Little Endian	1.2.840.10008.1.2		
General ECG Waveform Storage SOP Class	1.2.840.10008.5.1.4.1.1.9.1.2	Explicit VR Big Endian	1.2.840.10008.1.2.2	SCP	None
		Explicit VR Little Endian	1.2.840.10008.1.2.1		
		Implicit VR Little Endian	1.2.840.10008.1.2		
Hemodynamic Waveform Storage SOP Class	1.2.840.10008.5.1.4.1.1.9.2.1	Explicit VR Big Endian	1.2.840.10008.1.2.2	SCP	None
		Explicit VR Little Endian	1.2.840.10008.1.2.1		

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Extended Negotiation
Name	UID	Name List	UID List		
MR Image Storage SOP Class	1.2.840.10008.5.1.4.1.1.4	Implicit VR Little Endian	1.2.840.10008.1.2	SCP	None
		Explicit VR Big Endian	1.2.840.10008.1.2.2		
		Explicit VR Little Endian	1.2.840.10008.1.2.1		
		Implicit VR Little Endian	1.2.840.10008.1.2		
Multi-frame Grayscale Byte SC Image Storage SOP Class	1.2.840.10008.5.1.4.1.1.7.2	Explicit VR Big Endian	1.2.840.10008.1.2.2	SCP	None
		Explicit VR Little Endian	1.2.840.10008.1.2.1		
		Implicit VR Little Endian	1.2.840.10008.1.2		
Multi-frame Grayscale Word SC Image Storage SOP Class	1.2.840.10008.5.1.4.1.1.7.3	Explicit VR Big Endian	1.2.840.10008.1.2.2	SCP	None
		Explicit VR Little Endian	1.2.840.10008.1.2.1		
		Implicit VR Little Endian	1.2.840.10008.1.2		
Multi-frame Single Bit Secondary Capture Image Storage SOP Class	1.2.840.10008.5.1.4.1.1.7.1	Explicit VR Big Endian	1.2.840.10008.1.2.2	SCP	None
		Explicit VR Little Endian	1.2.840.10008.1.2.1		
		Implicit VR Little Endian	1.2.840.10008.1.2		
Raw Data Storage SOP Class	1.2.840.10008.5.1.4.1.1.66	Explicit VR Big Endian	1.2.840.10008.1.2.2	SCP	None
		Explicit VR Little Endian	1.2.840.10008.1.2.1		
		Implicit VR Little Endian	1.2.840.10008.1.2		
Secondary Capture Image Storage SOP Class	1.2.840.10008.5.1.4.1.1.7	Explicit VR Big Endian	1.2.840.10008.1.2.2	SCP	None
		Explicit VR Little Endian	1.2.840.10008.1.2.1		
		Implicit VR Little Endian	1.2.840.10008.1.2		
Softcopy Presentation State Storage SOP Class	1.2.840.10008.5.1.4.1.1.11.1	Explicit VR Big Endian	1.2.840.10008.1.2.2	SCP	None
		Explicit VR Little Endian	1.2.840.10008.1.2.1		
		Implicit VR Little Endian	1.2.840.10008.1.2		
Ultrasound Image Storage SOP Class	1.2.840.10008.5.1.4.1.1.6.1	Explicit VR Big Endian	1.2.840.10008.1.2.2	SCP	None
		Explicit VR Little Endian	1.2.840.10008.1.2.1		
		Implicit VR Little Endian	1.2.840.10008.1.2		
Ultrasound Multi-frame Image Storage SOP Class	1.2.840.10008.5.1.4.1.1.3.1	Explicit VR Big Endian	1.2.840.10008.1.2.2	SCP	None
		Explicit VR Little Endian	1.2.840.10008.1.2.1		
		Implicit VR Little Endian	1.2.840.10008.1.2		
X-Ray Angiographic Image Storage SOP Class	1.2.840.10008.5.1.4.1.1.12.1	Explicit VR Big Endian	1.2.840.10008.1.2.2	SCP	None
		Explicit VR Little Endian	1.2.840.10008.1.2.1		
		Implicit VR Little Endian	1.2.840.10008.1.2		
X-Ray Radiofluoroscopic Image Storage SOP Class	1.2.840.10008.5.1.4.1.1.12.2	Explicit VR Big Endian	1.2.840.10008.1.2.2	SCP	None
		Explicit VR Little Endian	1.2.840.10008.1.2.1		
		Implicit VR Little Endian	1.2.840.10008.1.2		

The ACP3EPW Application Entity is capable of accepting the above mentioned Presentation Contexts from the Remote AE.

No Extended Negotiation as an ACP is accepted by the EP Navigator system.

4.2.1.4.2.3 SOP Specific Conformance for Storage SOP Classes

The behavior of an Application Entity SOP class is summarized as shown in next Table. The standard as well as the manufacturer specific status codes and their corresponding behavior are specified.

Table 35: C-STORE-RSP Status Response

Service Status	Code	Further Meaning	Description
Success	0000	Storage is complete	The image(s) will be stored in the EP Navigator database
Refused	A700	Out of Resources	The EP Navigator database is full. EP Navigator shall send a notification, log the condition and abort association.
Error	A900	Data set does not match the SOP class	The SOP class of the image(s) does not match the negotiated abstract syntax. EP Navigator shall send a notification. Log the condition and abort the association.
	C000	Cannot understand	The image(s) cannot be parsed. EP Navigator shall send a notification, log the condition, and abort the association.
Warning	B000	Coercion of Data Elements	NA
	B006	Elements discarded	NA
	B007	Data set does not match SOP class	NA

Table 36: DICOM Command Communication Failure Behavior

Exception	Behavior
ARTIM Time-out	The store job fails in case of association setup. The reason is logged.
Reply Time-out	The store job fails and association is aborted. The reason is logged.
Association Time-out SCU	The association is released.
Association aborted	The store job fails. The reason is logged.

4.3 Network Interfaces

4.3.1 Physical Network Interfaces

The EP Navigator 3.0 supports DICOM traffic on the physical hospital network interface.

Supported physical media includes:

IEEE 802.3-1995 (Fast Ethernet) 100Base-TX

IEEE 802.3-1995 10Base-TX

IEEE 802.3 1000BASE-T Gbit/s Ethernet over twisted pair at 1 Gbit/s (125 MB/s)

4.3.2 Additional Protocols

Not applicable.

4.4 Configuration

Any implementation's DICOM conformance may be dependent upon configuration, which takes place at the time of installation. Issues concerning configuration is addressed in this section.

4.4.1 AE Title/Presentation Address Mapping

An important installation issue is the translation from AE title to presentation address. How this is to be performed shall be described in this section.

Note: There does not necessarily have to be a one to one relationship between AE titles and Application Entities. If so, this should be made clear in the tables.

4.4.1.1 Local AE Titles

The local AE title mapping and configuration are specified.

Table 37: AE Title Configuration Table

Application Entity	Default AE Title	Default TCP/IP Port
ACP3EPW	ACP3EPW	3028

4.4.1.2 Remote AE Title/Presentation Address Mapping

The AE Title, Port Number and IP address of the Remote Applications can be configurable by the EP Navigator system.

4.4.2 Parameters

The specification of important operational parameters, their default value and range (if configurable) is specified here.

Table 38: Configuration Parameters table

Parameter	Configurable	Default Value
General Parameters		
Time-out waiting for acceptance or rejection Response to an Association Open Request. (Application Level timeout)	Yes	60 seconds
General DIMSE level time-out values	Yes	300 seconds
Time-out waiting for response to TCP/IP connect request. (Low-level timeout)	No	Based on OS
Time-out waiting for acceptance of a TCP/IP message over the network. (Low-level timeout)	No	Based on OS
Time-out for waiting for data between TCP/IP packets. (Low-level timeout)	No	Based on OS
Any changes to default TCP/IP settings, such as configurable stack parameters.	No	Based on OS
<Other configurable parameters>	No	
AE Specific Parameters		
Size constraint in maximum object size (see note 1)	No	
Maximum PDU size the AE can receive	No	Unlimited
Maximum PDU size the AE can send	No	Unlimited
AE specific DIMSE level time-out values	Yes	300 seconds
Number of simultaneous Associations by Service and/or SOP Class	No	1
<SOP Class support (e.g. Multi-frame vs single frame vs SC support), when configurable>	Yes	60 seconds
<Transfer Syntax support, e.g. JPEG, Explicit VR, when configurable>	Yes	
<Other configurable parameters>	Yes	ILE ELE EBE

5 MEDIA INTERCHANGE

5.1 Implementation Model

The implementation model shall identify the DICOM Application Entities in a specific implementation and relate the Application Entities to Real-World Activities.

5.1.1 Application Data Flow Diagram

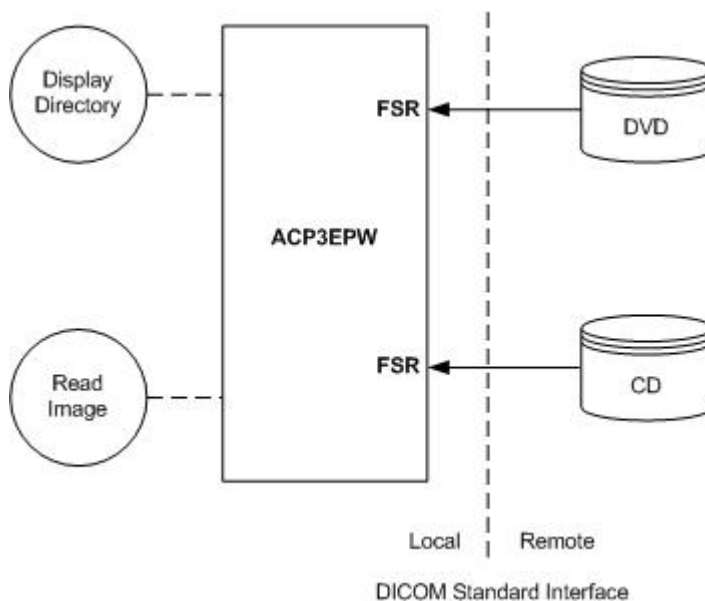


Figure 8: Application Data Flow Diagram

The EP Navigator System consists of one application entity: ACP3EPW.

The above figure shows the Media Interchange Application Data Flow.

The table below shows the Media interchange overview of the ACP3EPW Application Entity and the supporting roles for CD and DVD

Table 39: Media Services Table

Media Storage Application	Write Files (FSC / FSU)	Read Files (FSR)
General Purpose CD-R Interchange	NO / NO	YES
CT/MR Studies on the CD-R	NO / NO	YES
CT/MR Studies on the DVD Media	NO / NO	YES
General Purpose DVD Interchange with JPEG	NO / NO	YES

5.1.2 Functional Definitions of AE's

The Application Entity, ACP3EPW, can perform the CD-R and DVD media interchange service as SCU with the capabilities for:

RWA Display Directory (as FSR)
 RWA Read Images (as FSR)

5.1.3 Sequencing of Real World Activities

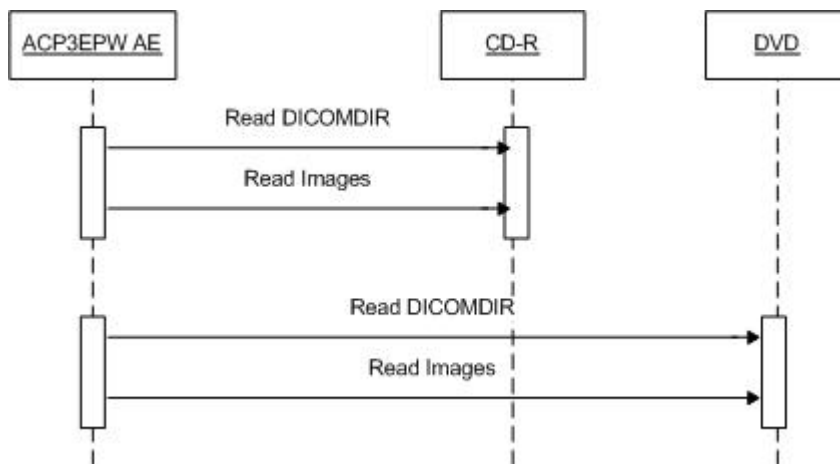


Figure 9: Sequencing of Real World Activity Read Images

5.1.4 File Meta Information for Implementation Class and Version

This next table specifies the list of values assigned to the File Meta Information attributes that pertain to the Implementation Class and Version.

Table 40: AE Related Application Profiles, Real-World Activities, and Roles

File Meta Information attributes	Value
Implementation Class UID	1.3.46.670589.38.1.1.0
Implementation Version Name	EP Navigator 3.0

5.2 AE Specifications

The next section in the DICOM Conformance Statement is a set of Application Entity specifications. There shall be one such specification for each Application Entity type.

5.2.1 ACP3EPW- Specification

The ACP3EPW Application Entity provides Standard Conformance to The DICOM media Storage Service and File Format ([DICOM] PS 3.10),

ACP3EPW Application Entity supports multi-patient and multi-study CD/DVD disks for Reading only.

Table 41: AE Related Application Profiles, Real-World Activities, and Roles

Supported Application Profile	Real-World Activity	Roles	SC Option
STD-GEN-CD	Display Directory	FSR	Interchange
	Read Images	FSR	Interchange
STD_CTMR_CD	Display Directory	FSR	Interchange

Supported Application Profile	Real-World Activity	Roles	SC Option
	Read Images	FSR	Interchange
STD_CT_MR_DVD	Display Directory	FSR	Interchange
	Read Images	FSR	Interchange
STD-GEN-DVD-JPEG	Display Directory	FSR	Interchange
	Read Images	FSR	Interchange

5.2.1.1 File Meta Information for the ACP3EPW

This section shall contain the values of the file Meta information that pertain to the Application Entity (see PS 3.10). These are:

- Source Application Entity Title
- Private Information Creator UID
- Private Information

5.2.1.2 Real-World Activities

5.2.1.2.1 Display Directory

When a CD/DVD is inserted in the CD/DVD drive of EP Navigator system, the CD/DVD application automatically detects the CD/DVD and the ACP3EPW Application Entity acts as FSR using the interchange option to read the DICOMDIR of the CD or DVD medium.

The displaying is structured according to the DICOM Composite Information Model: Patient, Study, Series, and Image.

5.2.1.2.1.1 Media Storage Application Profile

The ACP3EPW Application Entity supports the RWA Display Directory for the supported application profiles mentioned in the table above

5.2.1.2.1.1.1 Options

The mandatory DICOMDIR keys are required for the correct displaying of the directory information.

5.2.1.2.2 Read Images

When an image transfer from CD or DVD is initiated then the ACP3EPW Application Entity acts as FSR using the interchange option to import SOP instances from the CD or DVD medium.

EP Navigator supports the Study level imports. That means if a patient name on the CD/DVD has multiple Studies, the user shall be able to select a specific study and can import that.

If a study is imported successfully, then it will be visible in the "Local Storage". The imported study can be merged with the active patient in the EP Navigator system. If the imported data set is of CT image storage SOP class, then it will be visible in the EP Navigator "Data Selection" application. If the imported Study contains the SOP class other than CT image Storage, then it will not be displayed in the "Data Storage" application.

5.2.1.2.2.1 Media Storage Application Profile

The ACP3EPW Application Entity supports the RWA Read images for the supported application profiles mentioned in the table above

5.2.1.2.2.1.1 Options

The mandatory attributes of the DICOM images are required for the correct storage of the images in EP Navigator internal image data base.

5.3 Augmented and Private Application Profiles

None

5.3.1 Private Application Profiles

None

5.4 Media Configuration

CD/DVD import can be enabled or disabled by the Authorized Philips Service Personnel only.

6 SUPPORT OF CHARACTER SETS

Any support for character sets beyond the default character repertoire in Network and Media services shall be described here.

Table 42: Supported DICOM Character Sets of Electro Physiology Navigator - EP Navigator

Character Set Description	Defined Term	ESC Sequence	ISO Registration Number	Code Element	Character Set
Latin alphabet No. 1	ISO_IR 100	-	ISO-IR 6	G0	ISO 646
		-	ISO-IR 100	G1	Supplementary set of ISO 8859

7 SECURITY

7.1 Association Level Security

The EP Navigator rejects association requests from unknown applications, i.e. applications that offer an unknown "calling AE title". An application is known if – and only if – it is defined during configuration of the EP Navigator. The EP Navigator rejects association requests from applications that do not address its ACP3EPW AE, i.e. applications that offer a wrong "called AE title". The ACP3EPW AE title is defined during configuration of the EP Navigator.

7.2 Application Level Security

The EP Navigator allows the use of either a conventional (non-secure) DICOM communication or a secure DICOM communication based on the Transport Layer Security (TLS) protocol. If configured, the EP Navigator supports security measures for:

- secure authentication of a node
- integrity and confidentiality of transmitted data
- generation of audit trail records
- access control and user authentication.

7.2.1 DICOM Basic TLS Secure Transport Connection Profile

Secure communication is a "mode of operation" of the EP Navigator supported by the implementation of the DICOM Basic TLS Secure Transport Connection Profile. This functionality will be used by the nodes that can authenticate each other before they exchange DICOM information. For secure communication the TLS protocol v1.0 is used which provides message authentication, integrity, confidentiality, and replay protection. Confidentiality is optional and can be controlled by the encryption settings. The EP Navigator may communicate using the following Cipher Suites:

- TLS_RSA_WITH_NULL_SHA (Node authentication without encryption)
- TLS_RSA_WITH_3DES_SHA (Node authentication with encryption)

The EP Navigator supports X.509 certificates. The following TLS Certification checks will be done (TLS Handshake). The machine (either server or client) that will send its certificate will:

- Choose the certificate according to Common Name (CN) value in the Subject-field. This name is case-sensitive. All present certificates should have unique CN names.
- The server verifies
 - that the client certificate is a X.509 certificate which is not tampered with
 - that the client certificate is in the list of trusted certificates
 - that the client certificate is not expired (present time is between "Valid From" and "Valid To" fields of the X.509 certificate)
 - that the client certificate has the correct purpose (at least the Client Authentication purpose)
- The client verifies
 - that the server certificate is a X.509 certificate which is not tampered with
 - that the server certificate is in the list of trusted certificates

- that the server certificate is not expired (present time is between "Valid From" and "Valid To" fields of the X.509 certificate)
- that the server certificate has the correct purpose (at least Server Authentication purpose)

No verification is done on:

- revocation of certificates
- limiting the connection to a limited set of IP-addresses.

Node authentication with or without encryption is only possible when both nodes have:

- an access to their own private keys
- an access to a copy of the certificate of the other node containing its public key

The EP Navigator can only read certificates from the certificate stores of the HKEY_LOCAL_MACHINE registry key. It is the responsibility of the Hospital to setup and maintain the certificate stores. This includes the removal of revoked certificates and certificate updates prior to their expiration. Since neither X.500 directories, Lightweight Directory Access Protocol (LDAP) nor Certificate Revocation Lists (CRLs) are supported, the whole certificate chain needs to be replaced after a security breach. Figure below represents the message flow of TLS handshake supported by the EP Navigator.

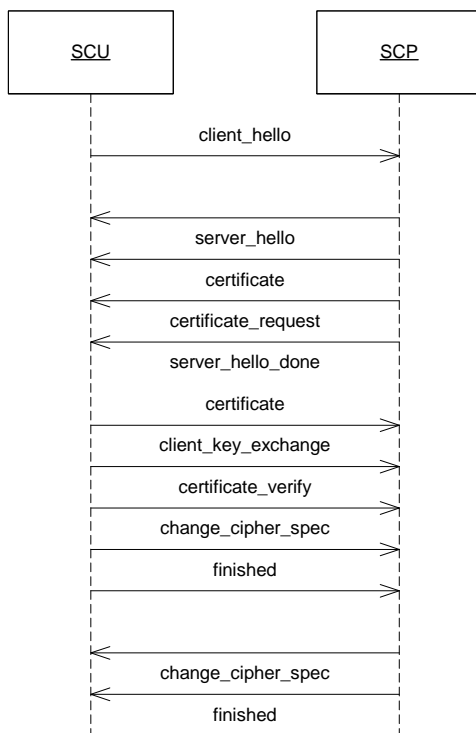


Figure 10 Message flow of TLS handshake

7.2.2 Generation of Audit Records

The EP Navigator can create audit messages according to the IHE Basic Security Integration Profile [IHE] to audit activities, to detect non-compliant behavior in the enterprise, and to facilitate detection of improper creation, access, modification and deletion of Protected Health Information (PHI). These messages may contain information that identifies the patient. The following messages will be created and sent to a central Audit Record Repository according to the Syslog protocol:

- ActorConfig (when security or networking configuration of the EP Navigator is modified via the field service functionality)
- ActorStartStop (when the EP Navigator starts or shuts down)
- DICOMInstancesDeleted (when an examination is deleted and it is not scheduled, prepared, or imported)
- DICOMInstancesUsed (when an examination is selected for acquisition)
- UserAuthenticated (when the user logs in or logs out)
- SecurityAlert (when an authentication of a secure node during TLS negotiation fails, e.g. Due to an invalid certificate)

If the central Audit Record Repository is not available, the audit trail record will be stored by the EP Navigator in a local buffer. Once the central Audit Record Repository is available again, the content of that buffer will be transferred to the central Audit Record Repository. The time that is part of the audit message will be the local time of the EP Navigator. This time will be synchronized with a Time Server. The Time Server and central Audit Record Repository are elements of the Hospital infrastructure

7.2.3 Basic Application Level Confidentiality Profile

Not Applicable.

8 ANNEXES OF APPLICATION "ACP3EPW (APPLICATION)"

8.1 IOD Contents

8.1.1 Created SOP Instance

This section specifies each IOD created (including private IOD's). It should specify the attribute name, tag, VR, and value. The value should specify the range and source (e.g. user input, Modality Worklist, automatically generated, etc.). For content items in templates, the range and source of the concept name and concept values should be specified. Whether the value is always present or not shall be specified.

Abbreviations used in the IOD tables for the column "Presence of Module" are:

ALWAYS	The module is always present
CONDITIONAL	The module is used under specified condition

Abbreviations used in the Module table for the column "Presence of Value" are:

ALWAYS	The attribute is always present with a value
EMPTY	The attribute is always present without any value (attribute sent zero length)
VNAP	The attribute is always present and its Value is Not Always Present (attribute sent zero length if no value is present)
ANAP	The attribute is present under specified condition – if present then it will always have a value
ANAPCV	The attribute is present under specified condition – if present then its Value is Not Always Present (attribute sent zero length if condition applies and no value is present)
ANAPEV	The attribute is present under specified condition – if present then it will not have any value

The abbreviations used in the Module table for the column "Source" are:

AUTO	The attribute value is generated automatically
CONFIG	The attribute value source is a configurable parameter
COPY	The attribute value source is another SOP instance
FIXED	The attribute value is hard-coded in the application
IMPLICIT	The attribute value source is a user-implicit setting
MPPS	The attribute value is the same as that use for Modality Performed Procedure Step
MWL	The attribute value source is a Modality Worklist
USER	The attribute value source is explicit user input

8.1.1.1 List of created SOP Classes

EP Navigator does not create any new SOP instances.

8.1.2 Usage of Attributes from Received IOD

Not Applicable.

8.1.3 Attribute Mapping

Not Applicable.

8.1.4 Coerced/Modified fields

Not Applicable.

8.2 Data Dictionary of Private Attributes

Not Applicable.

8.3 Coded Terminology and Templates

Not Applicable.

8.4 Grayscale Image consistency

Not Applicable.

8.5 Standard Extended/Specialized/Private SOPs

Not Applicable.

8.6 Private Transfer Syntaxes

Not Applicable.