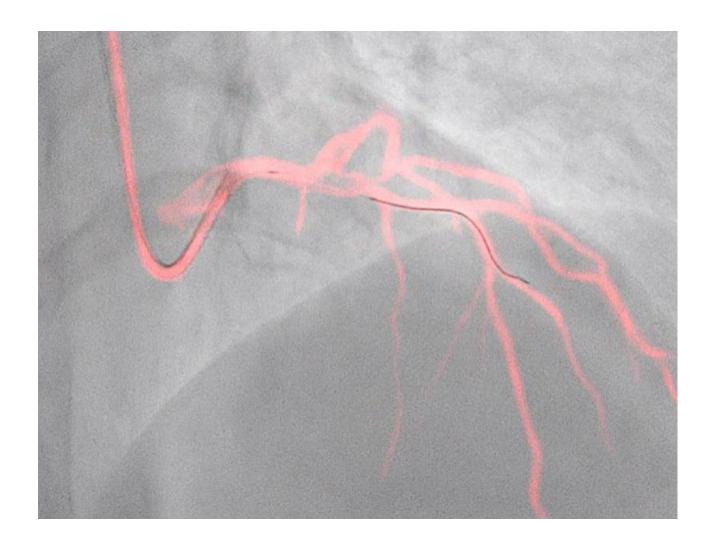
DICOM Conformance Statement

Dynamic Coronary Roadmap 1.0





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1. DICOM Conformance Statement Overview

Dynamic Coronary Roadmap is a software medical device intended to provide a real-time and dynamic angiographic roadmap of coronary arteries.

Dynamic Coronary Roadmap is to be used in combination with a Philips interventional X-ray system.

Dynamic Coronary Roadmap provides the clinical user with the possibility to create a screenshot or movie of the application, which is automatically archived on the configured PACS after creation.

The Dynamic Coronary Roadmap supports the following DICOM functionality:

Secure DICOM transfers: secure transfer of DICOM data between the clinical product and other DICOM compliant devices on the network. The data is sent as a DICOM compatible SC Image, either Single Frame for snapshots or Multiframe for movies.

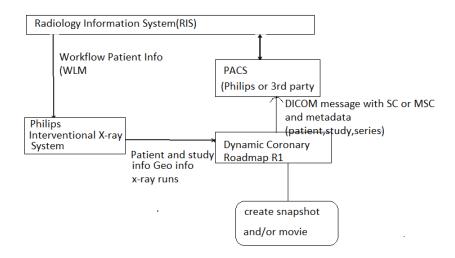


Figure 1: Dynamic Coronary Roadmap system context regarding DICOM connectivity interfaces

User of Provider of **SOP Class** Service Service **Display** UID Name (SCU) (SCP) Other Verification SOP Class 1.2.840.10008.1.1 Yes Yes* No **Transfer** Multiframe True Color Secondary Capture Image Storage 1.2.840.10008.5.1.4.1.1.7.4 Yes No No Secondary Capture Image Storage SOP Class 1.2.840.10008.5.1.4.1.1.7 Yes Nο No Workflow Management Storage Commitment Push Model SOP Class 1.2.840.10008.1.20.1 Yes No No

Table 1: Network Services

Note*: Verification as SCP is supported only part of asynchronous storage commitment.

2. Table of Contents

| | DICOM CONFORMANCE STATEMENT OVERVIEW | | | | |
|----------------------------|---|----------|--|--|--|
| | TABLE OF CONTENTS4 | | | | |
| | INTRODUCTION | | | | |
| 3.1. | REVISION HISTORY | _ | | | |
| 3.2. | AUDIENCE | | | | |
| 3.3. | REMARKS | | | | |
| 3.4. | DEFINITIONS, TERMS AND ABBREVIATIONS | | | | |
| 3.5. | REFERENCES | | | | |
| | NETWORKING | | | | |
| 4.1. | IMPLEMENTATION MODEL | | | | |
| 4.1.1. | Application Data Flow | | | | |
| 4.1.2. | Functional Definition of AE's | | | | |
| 4.1.3. | Sequencing of Real World Activities | | | | |
| 4.2. | AE SPECIFICATIONS | | | | |
| 4.2.1. | - J | | | | |
| 4.2.1. | | | | | |
| 4.2.1. | | | | | |
| 4.2.1. | | | | | |
| 4.2.1. | | | | | |
| 4.2.1. | , | | | | |
| 4.2.1. | , | | | | |
| 4.2.1. | (* * * * * * * * * * * * * * * * * * * | | | | |
| 4.2.1. | (······, ·····)g | | | | |
| 4.2.1. | , , , | | | | |
| 4.2.1.3 | , , | | | | |
| 4.3. | NETWORK INTERFACES | | | | |
| 4.3.1. | Physical Network Interfaces | | | | |
| 4.3.2. | Additional Protocols | | | | |
| 4.4. | CONFIGURATION | | | | |
| 4.4.1. | AE Title/Presentation Address Mapping | | | | |
| 4.4.1. | | | | | |
| 4.4.1. | | | | | |
| 4.4.2. | | | | | |
| | MEDIA INTERCHANGESUPPORT OF CHARACTER SETS | | | | |
| | SUPPORT OF CHARACTER SETS | | | | |
| 7. 7.1. | SECURITY PROFILES | | | | |
| | Security use Profiles | | | | |
| 7.1.1. 7.1.2. | Security Transport Connection Profiles | | | | |
| 7.1.2. 7.1.3. | Digital Signature Profiles | | | | |
| 7.1.3. 7.1.4. | Media Storage Security Profiles | | | | |
| 7.1. 4 . 7.1.5. | Attribute Confidentiality Profiles | | | | |
| 7.1.5. 7.1.6. | Network Address Management Profiles | | | | |
| 7.1.6. 7.1.7. | Time Synchronization Profiles | | | | |
| 7.1.7. 7.1.8. | Application Configuration Management Profiles | | | | |
| 7.1.6. 7.1.9. | Application Configuration Management Profiles | | | | |
| 7.1.9. | ASSOCIATION LEVEL SECURITY | | | | |
| 7.2. 7.3. | APPLICATION LEVEL SECURITY | | | | |
| | APPLICATION LEVEL SECURITYANNEXES OF APPLICATION "DYNAMIC CORONARY ROADMAP" | | | | |
| 8.1. | IOD CONTENTS | | | | |
| 8.1.1. | Created SOP Instance | | | | |
| 811 | | 20 26 | | | |

| 8.1.1.2. | Secondary Capture Image Storage SOP Class | 26 |
|----------|---|----|
| 8113 | Multiframe True Color Secondary Capture Image Storage SOP Class | 28 |

3. Introduction

3.1. Revision History

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

Table 2: Revision History

| | Document Version | Date of Issue | Status | Description |
|----|------------------|-------------------|------------|---------------|
| 00 | | 29-September-2016 | Authorized | Final Version |

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

Table 3: Definitions, Terms and Abbreviations

| Abbreviation/Term | Explanation | |
|-------------------|---|--|
| AE | Application Entity | |
| ANSI | American National Standard Institute | |
| AP | Application Profile | |
| DCR | Dynamic Coronary Roadmap | |
| DICOM | Digital Imaging and Communications in Medicine | |
| DIMSE | DICOM Message Service Element | |
| EBE | DICOM Explicit VR Big Endian | |
| ELE | DICOM Explicit VR Little Endian | |
| GUI | Graphic User Interface | |
| HIS | Hospital Information System | |
| HL7 | Health Level Seven | |
| ILE | DICOM Implicit VR Little Endian | |
| IOD | Information Object Definition | |
| ISIS | Information System – Imaging System | |
| NEMA | National Electrical Manufacturers Association | |
| PDU | Protocol Data Unit | |
| RIS | Radiology Information System | |
| RWA | Real-World Activity | |
| SC | Secondary Capture | |
| MFSC | Multiframe True Color Secondary Capture | |
| SCM | Study Component Management | |
| SCP | Service Class Provider | |
| SCU | Service Class User | |
| SOP | Service Object Pair | |
| TCP/IP | Transmission Control Protocol/Internet Protocol | |
| UID | Unique Identifier | |
| WLM | Worklist Management | |

3.5. References

[DICOM] Digital Imaging and Communications in Medicine, Parts 1-20 (NEMA PS 3.1- PS 3.20), National Electrical Manufacturers Association (NEMA)

Publication Sales 1300 N. 17th Street, Suite 1752 Rosslyn, Virginia. 22209, United States of America Internet: http://medical.nema.org/

4. Networking

This section contains the networking related services.

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 Dynamic Coronary Roadmap implements one network application entity: the Dynamic Coronary Roadmap Network AE. The following figure shows the networking application data flow as a functional overview of the application entity. On the left the local Real-World Activities are presented, whereas on the right the remote Real-World Activities are presented.

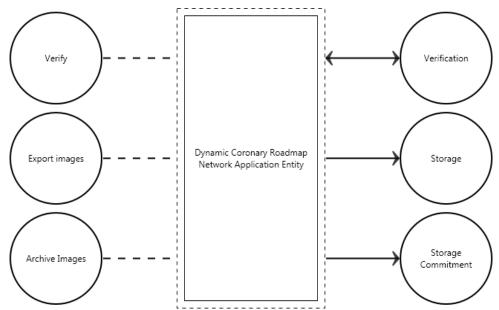


Figure 2: Application Data Flow Diagram

The Dynamic Coronary Roadmap incorporates the following functionality:

- Export current screen/view or screenshot or movie to a network DICOM node.
- Request a storage commitment for all exported images.

4.1.2. Functional Definition of AE's

Dynamic Coronary Roadmap incorporates the following functionality:

Export Images

The Dynamic Coronary Roadmap Network AE as Storage SCU implements the RWA Export Images to store movies and snapshots on a remote system, automatically using the relevant storage SOP classes.

Archive Images

The Dynamic Coronary Roadmap Network AE implements the RWA Archive Images to store (as Storage SCU) and, if configured, commit (as Storage Commitment SCU) images on the configured remote archive (e.g. PACS) using the Storage and Storage Commitment Push Model SOP class.

After sending a series of images to the archive, the Dynamic Coronary Roadmap System will request a storage commitment from this archive for all exported movies and snapshots. The storage commitment status is indicated in the Dynamic Coronary Roadmap application.

4.1.3. Sequencing of Real World Activities

Dynamic Coronary Roadmap is connected to the X-ray system. X-Ray system acquires images with a certain procedure and sends to Dynamic Coronary Roadmap. Based on the received x-ray images the Dynamic Coronary Roadmap allows to create DICOM objects (Secondary captures/ Multiframe captures) which are automatically archived to a configured PACS. I.e. it sends the C-STORE-RQ messages containing the image information.

When all images that it has stored, i.e. it sends the request for storage commit N-ACTION-RQ message.

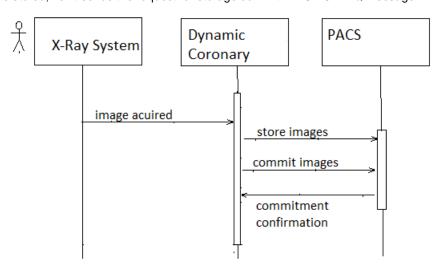


Figure 3: Sequence Diagram

4.2. AE Specifications

This 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. Dynamic Coronary Roadmap Network AE

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.

SCU **SOP Class Name SOP Class UID SCP** Verification SOP Class 1.2.840.10008.1.1 Yes Yes* Secondary Capture Image Storage SOP Class 1.2.840.10008.5.1.4.1.1.7 Yes No Multi-frame True Color Secondary Capture Image Storage 1.2.840.10008.5.1.4.1.1.7.4 Yes No Storage Commitment Push Model SOP Class 1.2.840.10008.1.20.1

Table 4: SOP Classes for Dynamic Coronary Roadmap Network AE

Note*: Verification as SCP is supported only part of asynchronous storage commitment.

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 is specified below.

Table 5: DICOM Application Context

| Description | Value |
|--------------------------|-----------------------|
| 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 an Initiator or Acceptor is specified here.

Table 6: Number of associations as an Association Initiator for this AE

| Description | Value |
|---|-------|
| Maximum number of simultaneous associations | 1 |

Table 7: Number of associations as an Association Acceptor for this AE

| Description | Value |
|---|-------|
| Maximum number of simultaneous associations | 1 |

4.2.1.2.3. Implementation Identifying Information

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

Table 8: DICOM Implementation Class and Version for Dynamic Coronary Roadmap Network AE

| Implementation Class UID | 1.3.46.670589.29.4411218.5524563.1.0 |
|-----------------------------|--------------------------------------|
| Implementation Version Name | PMS_CORTLS_1.0 |

4.2.1.3. Association Initiation Policy

The Application Entity will respond to a received Association rejection as shown in the next table.

Table 9: Association Rejection response

| Result | Source | Reason/Diagnosis | Behaviour |
|----------------------------|---|--|---|
| 1 – rejected- permanent | 1 – DICOM UL service-user | 1 – no-reason-given | "Cannot open association "message displayed on the system UI. |
| | | 2 – application-context-name-not supported | "Cannot open association "message displayed on the system UI. |
| | | 3 – calling-AE-title-not-recognized | "Cannot open association "message displayed on the system UI. |
| | | 7 – called-AE-title-not-recognized | "Cannot open association "message displayed on the system UI. |
| | 2 – DICOM UL service- provider (ACSE related | 1 – no-reason-given | "Cannot open association "message displayed on the system UI. |
| | function) | 2 – protocol-version-not-supported | "Cannot open association "message displayed on the system UI. |

| Result | Source | Reason/Diagnosis | Behaviour |
|----------------------------|---|--|---|
| | 3 – DICOM UL service- provider(Presentation related function) | 1 – temporary-congestion | "Cannot open association "message displayed on the system UI. |
| | | 2 – local-limit-exceeded | "Cannot open association "message displayed on the system UI. |
| 2 – rejected- transient | 1 – DICOM UL service-user | 1 – no-reason-given | "Cannot open association "message displayed on the system UI. |
| | 2 – DICOM UL service- provider (ACSE related function) | 2 – application-context-name-not-supported | "Cannot open association "message displayed on the system UI. |
| | | 3 – calling-AE-title-not-recognized | "Cannot open association "message displayed on the system UI. |
| | | 7 – called-AE-title-not-recognized | "Cannot open association "message displayed on the system UI. |
| | | 1 – no-reason-given | "Cannot open association "message displayed on the system UI. |
| | | 2 – protocol-version-not-supported | "Cannot open association "message displayed on the system UI. |
| | 3 – DICOM UL service- provider (Presentation | 1 – temporary-congestion | "Cannot open association "message displayed on the system UI. |
| | related function) | 2 – local-limit-exceeded | "Cannot open association "message displayed on the system UI. |

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

Table 10: Association Abort Handling

| Source | Reason/Diagnosis | Behavior when received | Sent when |
|---|------------------------------------|---|--|
| 0 – DICOM UL service-user (initiated abort) | 0- reason-not-specified | "Cannot open association "message displayed on the system UI. | SCU was unable to send the Response to SCP. |
| 2 – DICOM UL service-provider (initiated abort) | 0 - reason-not-specified | "Cannot open association "message displayed on the system UI. | SCU was unable to send the Response to SCP. |
| | 1 – unrecognized-PDU | "Cannot open association "message displayed on the system UI. | An unrecognized PDU type is received |
| | 2 – unexpected-PDU | "Cannot open association "message displayed on the system UI. | The received PDU type is not expected |
| | 4 – unrecognized-PDU- parameter | "Cannot open association "message displayed on the system UI. | An unrecognized Associate PDU item is received. |
| | 5 – unexpected-PDU- parameter | "Cannot open association "message displayed on the system UI. | One of the Associate PDU items is received more than once. • One of the Associate PDU items is received unexpectedly. |

| 6 – invalid-PDU-parameter- value | "Cannot open association "message displayed on the system UI. | One of the Associate PDU items is received more than once. • One of the Associate PDU items is not received. • There is mismatch in the application context names between the SCU and the SCP. • Unknown presentation context id is received. • Unknown abstract syntax is received. |
|-------------------------------------|---|--|
| | | The length or the format of a received PDU item is invalid. |

4.2.1.3.1. (Real-World) Activity – Verification as SCU

4.2.1.3.1.1. Description and Sequencing of Activities

The Dynamic Coronary Roadmap Network AE implements the Verification service class / Verification SOP class to verify application level communication.

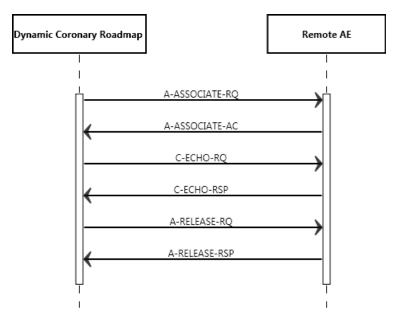


Figure 4: Data Flow Diagram - Verification as SCU

4.2.1.3.1.2. Proposed Presentation Contexts

The presentation contexts are defined in the next table.

Table 11: Proposed Presentation Contexts for (Real-World) Activity - Verification as SCU

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

4.2.1.3.1.3. SOP Specific Conformance for Verification SOP Class

The Dynamic Coronary Roadmap Network AE provides standard conformance to the DICOM Verification service class.

4.2.1.3.1.3.1. Dataset Specific Conformance for Verification C-ECHO SCU

Table 12: Status Response

| Service Status | Error Code | Further Meaning | Behavior |
|----------------|------------|-----------------|---|
| Success | 0000 | Confirmation | The SCP has successfully returned a verification response |

4.2.1.3.2. (Real-World) Activity – Image Export

4.2.1.3.2.1. Description and Sequencing of Activities

The Dynamic Coronary Roadmap implements the Storage service class as part of the Dynamic Coronary Roadmap to store selected images at an archive or other storage SCP. All actual selected images are exported using one and the same association.

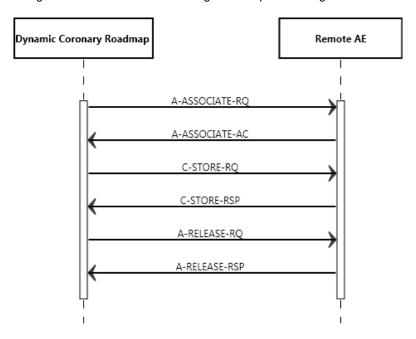


Figure 5: Data Flow Diagram - Store Image - Storage as SCU

4.2.1.3.2.2. Proposed Presentation Contexts

The presentation contexts are defined in the next table.

Table 13: Proposed Presentation Contexts for (Real-World) Activity – Image Export

| Presentation Context Table | | | | | |
|--|-----------------------------|---|--|------|-------------|
| Abstract Syntax | | Transfer Syntax | | | Extended |
| Name | UID | Name List | UID List | Role | Negotiation |
| Multi-frame True Color Secondary Capture Image Storage | 1.2.840.10008.5.1.4.1.1.7.4 | JPEG Baseline (Process 1) | 1.2.840.10008.1.2.4.50 | SCU | None |
| Secondary Capture Image Storage SOP Class | 1.2.840.10008.5.1.4.1.1.7 | Implicit VR Little Endian Explicit VR Big Endian | 1.2.840.10008.1.2 1.2.840.10008.1.2.2 | SCU | None |
| | | Explicit VR Little Endian | 1.2.840.10008.1.2.1 | | |
| | | JPEG Lossless, Non- Hierarchical, FOP (Process 14) | 1.2.840.10008.1.2.4.70 | | |

4.2.1.3.2.3. SOP Specific Conformance for Storage SOP Classes

4.2.1.3.2.3.1. Dataset Specific Conformance for C-STORE-RQ

Table 14: Status Response

| Service Status | Error Code | Further Meaning | Behavior |
|-------------------|------------|---|---|
| Success | 0000 | Successful stored | Export is successful. "Movie\snapshot archived "message displayed on the UI. |
| Failure | A7xx | Refused: Out of Resources | Export job failed. "Movie\snapshot archive failed "message is displayed on the UI and "The remote server returned a failure response: 0xA7000" message is displayed in the log viewer of SUT. |
| | А9хх | Error: Data Set does not match SOP Class | Export job failed. "Movie\snapshot archive failed "message is displayed on the UI and "The remote server returned a failure response: 0xA9000" message is displayed in the log viewer of SUT. |
| | Cxxx | Error: cannot understand | Export job failed. "Movie\snapshot archive failed "message is displayed on the UI and "The remote server returned a failure response: 0xC000" message is displayed in the log viewer of SUT. |
| Warning | B000 | Coercion of Data Elements | Export is successful. "Movie\snapshot archived "message displayed on the UI.and "Send message with a warning response 0xB000" message is displayed in the log viewer of SUT. |
| | B007 | Data Set does not match SOP Class | Export is successful. "Movie\snapshot archived "message displayed on the UI.and "Send message with a warning response 0xB007" message is displayed in the log viewer of SUT. |
| | B006 | Elements Discarded | Export is successful. "Movie\snapshot archived "message displayed on the UI.and "Send message with a warning response 0xB006" message is displayed in the log viewer of SUT. |

4.2.1.3.3. (Real-World) Activity – Storage Commitment Push Model as SCU

The Network AE supports asynchronous storage commitment. The Figure below shows the sequence diagram for the asynchronous storage commitment.

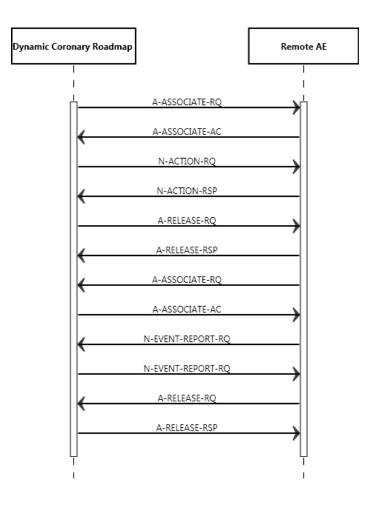


Figure 6: Data Flow Diagram -Storage Commitment as SCU

4.2.1.3.3.1. Proposed Presentation Contexts

The proposed presentation contexts for Storage Commitment Push Model as SCU are defined in Table 18.

Table 15: Proposed Presentation Contexts for (Real-World) Activity - Storage Commitment Push Model as SCU

| Presentation Context Table | | | | | |
|----------------------------|----------------------|---|---------------------|------|-------------|
| Abstract Syntax | | Transfer Syntax | | | Extended |
| Name | UID | Name List | UID List | Role | Negotiation |
| Storage Commitment Push | 1.2.840.10008.1.20.1 | Explicit VR Big Endian | 1.2.840.10008.1.2.2 | SCU | None |
| Model SOP Class | | Explicit VR Little Endian 1.2.840.10008.1.2.1 | | | |
| | | Implicit VR Little Endian | 1.2.840.10008.1.2 | | |

4.2.1.3.3.1. SOP Specific Conformance for Storage Commitment Push Model SOP Class

Dynamic Coronary Roadmap System conforms to the standard Storage Commitment model

4.2.1.3.3.1.1. Dataset Specific Conformance for Storage Commitment Push Model SOP Class N-EVENT-REPORT-SCP

Details regarding the Dataset Specific response behavior for Storage Commitment Attributes for N-EVENT-REPORT-RSP are described in this section.

Table 16: Status Response for N-EVENT-REPORT.

| Service Status | Error Code | Further Meaning | Behavior |
|-------------------|------------|------------------------------------|--|
| Success | 0000 | Operation complete | Storage commitment is successful. |
| Failure | xxxx | (any failure) | Storage commitment failed. And "Received a storage failure status for 'study instance UID of image of the image sent' "message is displayed in the log viewer. |
| | 0110 | Processing failure | Storage commitment failed. And "Received a storage failure status for 'study instance UID of image of the image sent' "message is displayed in the log viewer. |
| | 0112 | No such object instance | Storage commitment failed. And "Received a storage failure status for 'study instance UID of image of the image sent' "message is displayed in the log viewer. |
| | 0119 | Class / Instance conflict | Storage commitment failed. And "Received a storage failure status for 'study instance UID of image of the image sent' "message is displayed in the log viewer. |
| | 0122 | Referenced SOP class not supported | Storage commitment failed. And "Received a storage failure status for 'study instance UID of image of the image sent' "message is displayed in the log viewer. |
| | 0131 | Duplicate transaction | Storage commitment failed. And "Received a storage failure status for 'study instance UID of image of the image sent' "message is displayed in the log viewer. |
| | 0213 | Resource limitation | Storage commitment is successful. |

The communication status behavior of the N-EVENT-REPORT is listed in Table 18.

Table 17: DICOM Command Communication Failure Behavior for N-EVENT-REPORT.

| Exception | Behavior |
|--------------------------|---|
| Network Reply Time-out | The association is released. Continues with waiting for storage commitment. |
| Association Time-out SCU | The association is released. Continues with waiting for storage commitment. |
| Association aborted | Continues with waiting for storage commitment. |

4.2.1.3.3.1.2. Dataset Specific Conformance for Storage Commitment Push Model SOP Class N-ACTION-SCU

This chapter describes the Dataset Specific response behavior for Storage Commitment Attribute N-ACTION-RQ.

Table 18: Storage Commitment Attribute for N-ACTION-RQ

| Attribute Name | Tag | Comment |
|------------------------------|-----------|---------------------------|
| | | Storage Commitment Module |
| Transaction UID | 0008,1195 | |
| Referenced SOP Sequence | 0008,1199 | |
| >Referenced SOP Class UID | 0008,1150 | |
| >Referenced SOP Instance UID | 0008,1155 | |

The possible status responses for N-ACTION-RQ are shown in the Table 47.

Table 19: Status Response for A-ACTION-RQ.

| Service Status | Error Code | Further Meaning | Behavior |
|----------------|------------|----------------------------------|----------|
| Success | 0000 | Conformation. Operation complete | |
| Failure | XXXX | (any failure) | |

The possible communication failures are shown in the below 21.

Table 20: DICOM Command Communication Failure Behavior N-ACTION.

| Exception | Behavior |
|--------------------------|--|
| Reply Time-out | The association is released. The Archive Images job expects storage commitment report. |
| Association Time-out SCU | The association is released. The Archive Images job expects storage commitment report. |
| Association Aborted | The Archive Images job expects storage commitment report. |

4.2.1.3.4. (Real-World) Activity - Verification as SCP

4.2.1.3.4.1. Description and Sequencing of Activities

Note*: Verification as SCP is supported only part of asynchronous storage commitment.

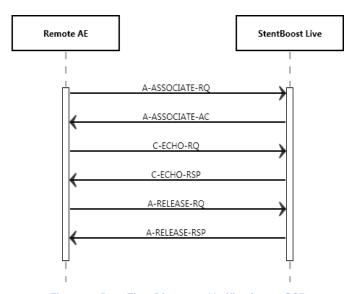


Figure 7: Data Flow Diagram - Verification as SCP

4.3. Network Interfaces

4.3.1. Physical Network Interfaces

The System provides only DICOM V3.0 TCP/IP Network Communication Support as defined in PS 3.8 of the standard.

TCP/IP is the only protocol stack supported.

Supported physical medium include:

IEEE 802.3-1995, 10BASE-T

IEEE 802.3-1995, 100BASE-TX (Fast Ethernet)

IEEE 802.3, 1000BASE-X (Fiber Optic Gigabit Ethernet).

The TCP/IP Stack is as supported by the underlying Operating System.

The API is the WinSock 2 interface as supported by the underlying Operating System.

4.3.2. Additional Protocols

No additional protocols are used.

4.4. Configuration

Any implementation's DICOM conformance may be dependent upon configuration, which takes place at the time of installation. Issues concerning configuration are 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 is described here.

4.4.1.1. Local AE Titles

The Field Service User Interface only allows one AE to be configured.

The following AE specific information must be available to configure a local AE:

- ae title
- port number (note that normally all local Dynamic Coronary Roadmap AE's will have a different port number)

4.4.1.2. Remote AE Title/Presentation Address Mapping

One or more remote AE's may be configured.

The following AE specific information must be available to configure a remote AE:

- ae title
- hostname or IP address
- port number

4.4.2. Parameters

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

Table 21: Configuration Parameters Table

| Parameter | Configurable | Default Value |
|--|--------------|---------------|
| General Parameter | | |
| Time-out waiting for acceptance or rejection Response to an Association Open Request (Application Level timeout) | Yes | |
| General Dimse level time-out values (Verification, Storage) | No | - |
| Time-out for response to TCP/IP connect request. (Low-level timeout) | OS | - |
| Time-out waiting for acceptance of a TCP/IP message over the network (Low-level timeout) | OS | - |
| Time-out for waiting for data between TCP/IP packets. (Low-level timeout) | OS | - |
| Any changes to default TCP/IP settings, such as configurable stack parameters. | OS | - |
| AE Specific Parameters | | |
| Size constraint in maximum object size | No | - |
| Maximum PDU size the AE can send and receive | Yes | 64234 |
| Association time-out SCP | Yes | |

| Parameter | Configurable Default Value |
|---|----------------------------|
| Association time-out SCU | Yes |
| AE specific DIMSE level time-out values | Yes |
| Number of simultaneous associations by service and/or SOP class | No |
| SOP Class support | No |
| Transfer Syntax support | No |
| Port Number | Yes |

5. Media Interchange

Not Applicable

6. Support of Character Sets

Any support for character sets in Network and Media services is described here.

Table 22: Supported DICOM Character Sets

| Character Set Description | Defined Term | ESC Sequence | ISO Registration Number | Code Element | Character Set |
|---------------------------|--------------|-----------------|----------------------------|-----------------|-------------------------------|
| Unicode in UTF-8 | ISO_ IR 192 | ESC 02/08 04/02 | ISO-IR 6 | G0 | ISO 646 |
| | | ESC 02/13 04/01 | ISO-IR 100 | G1 | Supplementary set of ISO 8859 |

7. Security

7.1. Security Profiles

7.1.1. Security use Profiles

Not applicable

7.1.2. Security Transport Connection Profiles

Secure communication is a "mode of operation" supported by the implementation of the DICOM Basic TLS Secure Transport Connection Profile [DICOM]. This functionality will be used by the nodes, which can authenticate each other before they exchange DICOM information. For secure communication Dynamic Coronary Roadmap 1.0 uses the protocols TLS 1.0, TLS 1.1, TLS 1.2 and SSL 3.0 which provides message authentication, integrity, confidentiality, and replay protection. Confidentiality is optional and can be controlled by the encryption settings. Within these protocols Dynamic Coronary Roadmap 1.0 supports the following Cipher Suites*:

- TLS_ECDHE_RSA_WITH_AES_256_CBC_SHA384_P256
- TLS_ECDHE_RSA_WITH_AES_256_CBC_SHA384_P384
- TLS_ECDHE_RSA_WITH_AES_128_CBC_SHA256_P256
- TLS ECDHE RSA WITH AES 128 CBC SHA256 P384
- TLS_ECDHE_RSA_WITH_AES_256_CBC_SHA_P256
- TLS_ECDHE_RSA_WITH_AES_256_CBC_SHA_P384
- TLS_ECDHE_RSA_WITH_AES_128_CBC_SHA_P256
- TLS_ECDHE_RSA_WITH_AES_128_CBC_SHA_P384
- TLS_DHE_RSA_WITH_AES_256_GCM_SHA384
- TLS_DHE_RSA_WITH_AES_128_GCM_SHA256
- TLS_DHE_RSA_WITH_AES_256_CBC_SHA
- TLS_DHE_RSA_WITH_AES_128_CBC_SHA
- TLS_RSA_WITH_AES_256_GCM_SHA384
- TLS_RSA_WITH_AES_128_GCM_SHA256
- TLS_RSA_WITH_AES_256_CBC_SHA256
- TLS_RSA_WITH_AES_128_CBC_SHA256
- TLS_RSA_WITH_AES_256_CBC_SHA
- TLS_RSA_WITH_AES_128_CBC_SHA
- TLS_ECDHE_ECDSA_WITH_AES_256_GCM_SHA384_P384
- TLS_ECDHE_ECDSA_WITH_AES_128_GCM_SHA256_P256
- TLS_ECDHE_ECDSA_WITH_AES_128_GCM_SHA256_P384
- TLS_ECDHE_ECDSA_WITH_AES_256_CBC_SHA384_P384
- TLS_ECDHE_ECDSA_WITH_AES_128_CBC_SHA256_P256
- TLS_ECDHE_ECDSA_WITH_AES_128_CBC_SHA256_P384
- TLS ECDHE ECDSA WITH AES 256 CBC SHA P256
- TLS_ECDHE_ECDSA_WITH_AES_256_CBC_SHA_P384
- TLS_ECDHE_ECDSA_WITH_AES_128_CBC_SHA_P256
- TLS_ECDHE_ECDSA_WITH_AES_128_CBC_SHA_P384
- TLS_DHE_DSS_WITH_AES_256_CBC_SHA256
- TLS_DHE_DSS_WITH_AES_128_CBC_SHA256
- TLS_DHE_DSS_WITH_AES_256_CBC_SHA
- TLS_DHE_DSS_WITH_AES_128_CBC_SHA
- TLS_RSA_WITH_3DES_EDE_CBC_SHA
- TLS_DHE_DSS_WITH_3DES_EDE_CBC_SHA
- TLS_RSA_WITH_NULL_SHA256**
- TLS_RSA_WITH_NULL_SHA**

^{*}not every cipher suite is supported by every protocol

^{**}NULL cipher, does not provide encryption. For authentication only

The Dynamic Coronary Roadmap 1.0 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 Dynamic Coronary Roadmap 1.0 reads certificates from the OS provided certificate stores. The client certificates are read from the currently logged in user store. The server certificates are read from the machine store. 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, neither Lightweight Directory Access Protocol (LDAP) nor Certificate Revocation Lists (CRLs) are supported, the whole certificate chain needs to be replaced after a security breach.

The following figure presents the message flow of TLS handshake supported.

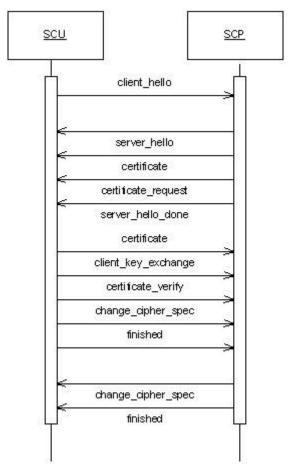


Figure 8: Message flow of TLS handshake

7.1.3. Digital Signature Profiles

Not applicable

7.1.4. Media Storage Security Profiles

Not applicable

7.1.5. Attribute Confidentiality Profiles

Not applicable

7.1.6. Network Address Management Profiles

Not applicable

7.1.7. Time Synchronization Profiles

Dynamic coronary roadmap 1.0 conforms to the IHE CT Profile. It is possible to synchronize time with the NTP Timeserver using serviceability. The NTP Timeserver is an element of Hospital Infrastructure.

7.1.8. Application Configuration Management Profiles

Not applicable

7.1.9. Audit Trail Profiles

The Audit Trail Component is a component of Dynamic Coronary Roadmap 1.0 and can create messages according to the ATNA, IHE defined standard. Actors are information systems or components of information systems that produce, manage, or act on categories of information required by operational activities in the enterprise. The Audit Trail Component allows security officers in an institution 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), where PHI data is considered as information records (Registration, Order, Study/Procedure, Reports and to a lesser degree Images/Presentation States), and not the flow of information between the systems. This includes information exported to and imported from every secured node in the "secured domain".

The messages will be created and sent to a syslog server according to the syslog protocol. The time that is used will be the local time of the system which is synchronized with the NTP Time Server. The timeserver and syslog server are elements of the Hospital infrastructure. The following messages will be created and sent to a central Audit Record Repository

- Application Activity
- Begin Transferring DICOM Instances
- DICOM Instances Transferred
- Security Alert
- User Authentication
- DICOM Instances Accessed

7.2. Association Level Security

The Dynamic coronary roadmap 1.0 accepts associations from unknown AEs but only for Storage commit N-Event-Report. If Dynamic coronary roadmap 1.0 is configured to use secure mode, then the incoming associations (for Dynamic coronary roadmap 1.0 as SCP) should follow secure mode.

7.3. Application Level Security

The Dynamic coronary roadmap 1.0 allows the use of either a conventional (non-secure) DICOM communication or a secure DICOM communication based on the Transport Layer Security (TLS) protocol and Security Sockets Layer (SSL) if configured, the Dynamic coronary roadmap 1.0 supports security

Measures for:

- Secure authentication of a node
- Integrity and confidentiality of transmitted data
- Replay protection
- Generation of audit trail records
- Access control and user authentication.

8. Annexes of application "Dynamic Coronary Roadmap"

8.1. IOD Contents

8.1.1. Created SOP Instance

This section specifies each IOD created by this application and specifies the content for each IOD created (including private IODs). For each attribute in the IOD the following information is supplied:

- Attribute name
- Tag
- VR Value representation
- Value specifies possible values
- Presence of value specifies if attribute is always present or only under specific conditions
- Source of value specifies the source of the value
- Comment gives additional information on the attribute

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.

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

Table 23: List of created SOP Classes

| SOP Class Name | SOP Class UID |
|---|-----------------------------|
| Secondary Capture Image Storage SOP Class | 1.2.840.10008.5.1.4.1.1.7 |
| Multiframe True Color Secondary Capture Image Storage SOP Class | 1.2.840.10008.5.1.4.1.1.7.4 |

8.1.1.2. Secondary Capture Image Storage SOP Class

Table 24 :IOD of Created Secondary Capture Image Storage SOP Class Instances

| Information Entity | Module | Presence Of Module |
|--------------------|----------------|--------------------|
| Patient | Patient Module | ALWAYS |

| Study | General Study Module | ALWAYS |
|-----------|--------------------------|--------|
| Series | General Series Module | ALWAYS |
| Emiliana | SC Equipment Module | ALWAYS |
| Equipment | General Equipment Module | ALWAYS |
| Image | General Image Module | ALWAYS |
| | Image Pixel Module | ALWAYS |
| | SOP Common Module | ALWAYS |

Table 25: Patient Module

| Attribute Name | Tag | VR | Value | Presence of Value | Source | Comment |
|----------------------|-----------|----|-------|-------------------|--------|-------------------------------|
| Patient's Name | 0010,0010 | PN | | ALWAYS | COPY | Obtained from X-Ray System |
| Patient ID | 0010,0020 | LO | | ALWAYS | COPY | Obtained from X-Ray System |
| Patient's Birth Date | 0010,0030 | DA | | ALWAYS | COPY | Obtained from X-Ray System |
| Patient's Sex | 0010,0040 | CS | | ALWAYS | COPY | Obtained from X-Ray System |

Table 26: General Study Module

| Attribute Name | Tag | VR | Value | Presence of Value | Source | Comment |
|----------------------------|-----------|----|-------|-------------------|--------|-------------------------------|
| Study Date | 0008,0020 | DA | | ALWAYS | COPY | Obtained from X-Ray System |
| Study Time | 0008,0030 | TM | | ALWAYS | COPY | Obtained from X-Ray System |
| Accession Number | 0008,0050 | SH | | ALWAYS | COPY | Obtained from X-Ray System |
| Referring Physician's Name | 0008,0090 | PN | | ALWAYS | COPY | Obtained from X-Ray System |
| Study Instance UID | 0020,000D | UI | | ALWAYS | COPY | Obtained from X-Ray System |
| Study ID | 0020,0010 | SH | | ALWAYS | COPY | Obtained from X-Ray System |

Table 27: General Series Module

| Attribute Name | Tag | VR | Value | Presence of Value | Source | Comment |
|---------------------|-----------|----|-------|-------------------|--------|-------------------------------|
| Modality | 0008,0060 | CS | XA | ALWAYS | FIXED | |
| Series Instance UID | 0020,000E | UI | | ALWAYS | AUTO | |
| Series Number | 0020,0011 | IS | | ALWAYS | COPY | Obtained from X-Ray System |

Table 28 : SC Equipment Module

| Attribute Name | Tag | VR | Value | Presence of Value | Source | Comment |
|-----------------|-----------|----|-------|-------------------|--------|---------|
| Modality | 0008,0060 | CS | OT | ALWAYS | FIXED | |
| Conversion Type | 0008,0064 | CS | WSD | ALWAYS | FIXED | |

Table 29: General Equipment Module

| Attribute Name | Tag | VR | Value | Presence of Value | Source | Comment |
|----------------|-----------|----|---------|-------------------|--------|---------|
| Manufacturer | 0008,0070 | LO | Philips | VNAP | FIXED | |

Table 30: General Image Module

| Attribute Name | Tag | VR | Value | Presence of Value | Source | Comment |
|----------------------|-----------|----|-------------------|----------------------|--------|---------|
| Instance Number | 0020,0013 | IS | | ALWAYS | AUTO | |
| Patient Orientation | 0020,0020 | CS | | EMPTY | FIXED | |
| Burned in Annotation | 0028,0301 | CS | NO | ALWAYS | FIXED | |
| Image Type | 8000,8000 | CS | DERIVED\SECONDARY | ALWAYS | AUTO | |

Table 31: Image Pixel Module

| Attribute Name | Tag | VR | Value | Presence of Value | Source | Comment |
|----------------------------|-----------|-------|-------|-------------------|--------|---------|
| Samples per Pixel | 0028,0002 | US | 3 | ALWAYS | FIXED | |
| Photometric Interpretation | 0028,0004 | CS | RGB | ALWAYS | FIXED | |
| Planar Configuration | 0028,0006 | US | 0 | ALWAYS | FIXED | |
| Rows | 0028,0010 | US | | ALWAYS | AUTO | |
| Columns | 0028,0011 | US | | ALWAYS | AUTO | |
| Bits Allocated | 0028,0100 | US | 8 | ALWAYS | FIXED | |
| Bits Stored | 0028,0101 | US | 8 | ALWAYS | FIXED | |
| High Bit | 0028,0102 | US | 7 | ALWAYS | FIXED | |
| Pixel Representation | 0028,0103 | US | 0 | ALWAYS | FIXED | |
| Pixel Data | 7FE0,0010 | OW/OB | | ALWAYS | AUTO | |

Table 32: SOP Common Module

| Attribute Name | Tag | VR | Value | Presence of Value | Source | Comment |
|------------------------|-----------|----|---------------------------|-------------------|--------|---------|
| Specific Character Set | 0008,0005 | CS | ISO_IR 192 | ALWAYS | FIXED | |
| Instance Creation Date | 0008,0012 | DA | | ALWAYS | AUTO | |
| Instance Creation Time | 0008,0013 | TM | | ALWAYS | AUTO | |
| SOP Class UID | 0008,0016 | UI | 1.2.840.10008.5.1.4.1.1.7 | ALWAYS | FIXED | |
| SOP Instance UID | 0008,0018 | UI | | ALWAYS | AUTO | |
| Instance Number | 0020,0013 | IS | | ALWAYS | AUTO | |

8.1.1.3. Multiframe True Color Secondary Capture Image Storage SOP Class

Table 33: IOD of Created Multiframe True Color Secondary Capture Image Storage SOP Class Instances

| Information Entity | Module | Presence Of Module |
|--------------------|--------------------------|--------------------|
| Patient | Patient Module | ALWAYS |
| Study | General Study Module | ALWAYS |
| Series | General Series Module | ALWAYS |
| Equipment | SC Equipment Module | ALWAYS |
| | General Equipment Module | ALWAYS |
| Image | General Image Module | ALWAYS |
| | Image Pixel Module | ALWAYS |
| | Cine Module | CONDITIONAL |

| Multi-Frame Module | ALWAYS |
|--------------------------------------|-------------|
| Multi-Frame Functional Groups Module | USER OPTION |
| SC Multi-frame Image Module | ALWAYS |
| SOP Common Module | ALWAYS |

Table 34: Patient Module

| Attribute Name | Tag | VR | Value | Presence of Value | Source | Comment |
|----------------------|-----------|----|-------|-------------------|--------|----------------------------|
| Patient's Name | 0010,0010 | PN | | ALWAYS | COPY | Obtained from X-Ray System |
| Patient ID | 0010,0020 | LO | | ALWAYS | COPY | Obtained from X-Ray System |
| Patient's Birth Date | 0010,0030 | DA | | ALWAYS | COPY | Obtained from X-Ray System |
| Patient's Sex | 0010,0040 | CS | F,M,O | ALWAYS | COPY | Obtained from X-Ray System |

Table 35: General Study Module

| Attribute Name | Tag | VR | Value | Presence of Value | Source | Comment |
|----------------------------|-----------|----|-------|-------------------|--------|-------------------------------|
| Study Date | 0008,0020 | DA | | ALWAYS | COPY | Obtained from X-Ray System |
| Study Time | 0008,0030 | TM | | ALWAYS | COPY | Obtained from X-Ray System |
| Accession Number | 0008,0050 | SH | | ALWAYS | COPY | Obtained from X-Ray System |
| Referring Physician's Name | 0008,0090 | PN | | ALWAYS | COPY | Obtained from X-Ray System |
| Study Instance UID | 0020,000D | UI | | ALWAYS | COPY | Obtained from X-Ray System |
| Study ID | 0020,0010 | SH | | ALWAYS | COPY | Obtained from X-Ray System |

Table 36: General Series Module

| Attribute Name | Tag | VR | Value | Presence of Value | Source | Comment |
|---------------------|-----------|----|-------|-------------------|--------|----------------------------|
| Modality | 0008,0060 | CS | XA | ALWAYS | FIXED | |
| Series Instance UID | 0020,000E | UI | | ALWAYS | AUTO | |
| Series Number | 0020,0011 | IS | | ALWAYS | COPY | Obtained from X-Ray System |

Table 37 : SC Equipment Module

| Attribute Name | Tag | VR | Value | Presence of Value | Source | Comment |
|-----------------|-----------|----|-------|-------------------|--------|---------|
| Modality | 0008,0060 | CS | XA | ALWAYS | FIXED | |
| Conversion Type | 0008,0064 | CS | WSD | ALWAYS | FIXED | |

Table 38: General Equipment Module

| Attribute Name | Tag | VR | Value | Presence of Value | Source | Comment |
|----------------|-----------|----|---------|-------------------|--------|---------|
| Manufacturer | 0008,0070 | LO | Philips | VNAP | FIXED | |

Table 39: General Image Module

| Attribute Name | Tag | VR | Value | Presence of Value | Source | Comment |
|----------------------|-----------|----|-------------------|-------------------|--------|---------|
| Content Date | 0008,0023 | DA | | ALWAYS | AUTO | |
| Content Time | 0008,0033 | TM | | ALWAYS | AUTO | |
| Instance Number | 0020,0013 | IS | | ALWAYS | AUTO | |
| Patient Orientation | 0020,0020 | CS | | ALWAYS | FIXED | |
| Burned in Annotation | 0028,0301 | CS | NO | ALWAYS | FIXED | |
| Image Type | 8000,8000 | CS | DERIVED\SECONDARY | ALWAYS | AUTO | |

Table 40: Image Pixel Module

| Attribute Name | Tag | VR | Value | Presence of Value | Source | Comment |
|----------------------------|-----------|-------|--------------|-------------------|--------|---------|
| Samples per Pixel | 0028,0002 | US | 3 | ALWAYS | FIXED | |
| Photometric Interpretation | 0028,0004 | CS | YBR_FULL_422 | ALWAYS | AUTO | |
| Planar Configuration | 0028,0006 | US | 0 | ANAP | FIXED | |
| Rows | 0028,0010 | US | | ALWAYS | AUTO | |
| Columns | 0028,0011 | US | | ALWAYS | AUTO | |
| Bits Allocated | 0028,0100 | US | 8 | ALWAYS | FIXED | |
| Bits Stored | 0028,0101 | US | 8 | ALWAYS | FIXED | |
| High Bit | 0028,0102 | US | 7 | ALWAYS | FIXED | |
| Pixel Representation | 0028,0103 | US | 0 | ALWAYS | FIXED | |
| Pixel Data | 7FE0,0010 | OW/OB | | ALWAYS | AUTO | |

Table 41: Cine Module

| Attribute Name | Tag | VR | Value | Presence of Value | Source | Comment |
|----------------|-----------|----|-------|-------------------|--------|---------|
| Frame Time | 0018,1063 | DS | | ALWAYS | AUTO | |

Table 42: Multi-Frame Module

| Attribute Name | Tag | VR | Value | Presence of Value | Source | Comment |
|-------------------------|-----------|----|----------|-------------------|--------|---------|
| Number of Frames | 0028,0008 | DS | | ALWAYS | AUTO | |
| Frame Increment Pointer | 0028,0009 | AT | 00181063 | ALWAYS | FIXED | |

Table 43:Multi-Frame Functional Groups Module

| Attribute Name | Tag | VR | Value | Presence of Value | Source | Comment |
|------------------|-----------|----|-------|-------------------|--------|---------|
| Content Date | 0008,0023 | DA | | ALWAYS | AUTO | |
| Content Time | 0008,0033 | TM | | ALWAYS | AUTO | |
| Instance Number | 0020,0013 | IS | | ALWAYS | AUTO | |
| Number of Frames | 0028,0008 | IS | | ALWAYS | AUTO | |

Table 44: SC Multi-Frame Image Module

| Attribute Name | Tag | VR | Value | Presence of Value | Source | Comment |
|-------------------------|-----------|----|----------|-------------------|--------|---------|
| Frame Increment Pointer | 0028,0009 | AT | 00181063 | ALWAYS | FIXED | |

| Burned In Annotation | 0028.0301 | CS | NO | ALWAYS | FIXED |
|------------------------|-----------|----|-----|--------|-------|
| Duffied in Affiliation | 0020,0301 | 00 | INO | ALWAIS | TIALD |

Table 45: SOP Common Module

| Attribute Name | Tag | VR | Value | Presence of Value | Source | Comment |
|------------------------|-----------|----|-----------------------------|-------------------|--------|---------|
| Specific Character Set | 0008,0005 | CS | ISO_IR 192 | ALWAYS | FIXED | |
| Instance Creation Date | 0008,0012 | DA | | ALWAYS | AUTO | |
| Instance Creation Time | 0008,0013 | TM | | ALWAYS | AUTO | |
| SOP Class UID | 0008,0016 | UI | 1.2.840.10008.5.1.4.1.1.7.4 | ALWAYS | FIXED | |
| SOP Instance UID | 0008,0018 | UI | | ALWAYS | AUTO | |
| Instance Number | 0020,0013 | IS | | ALWAYS | AUTO | |