

DICOM Conformance Statement

StentBoost Live R1.0



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1. DICOM Conformance Statement Overview

StentBoost Live is a software medical device intended to provide enhanced visualization of stents in coronary vessels. StentBoost Live is to be used in combination with a Philips Interventional X-ray system.

StentBoost Live provides the clinical user with the possibility to create a DICOM compatible snapshot movies, which is automatically archived on the configured PACS after creation.

The StentBoost Live 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, Single Frame for snapshots and MSC Multiframe capture for movies.

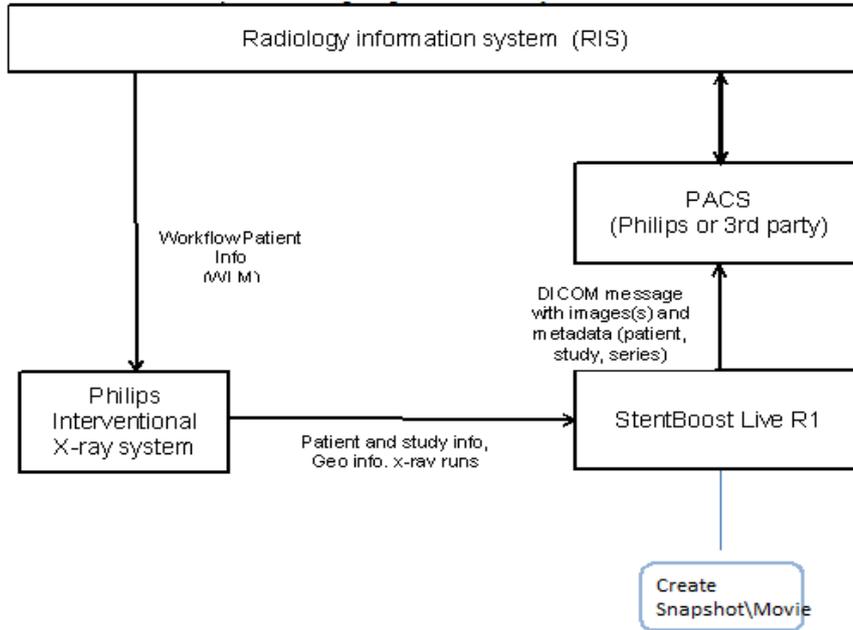


Figure 1: StentBoost Live system context regarding DICOM connectivity interfaces

Table 1: Network Services

SOP Class		User of Service (SCU)	Provider of Service (SCP)	Display
Name	UID			
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	No	No
Workflow Management				
Storage Commitment Push Model SOP Class	1.2.840.10008.1.20.1	Yes	No	No

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

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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-August-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
fDICOM	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 StentBoost Live implements one network application entity: the StentBoost Live 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.

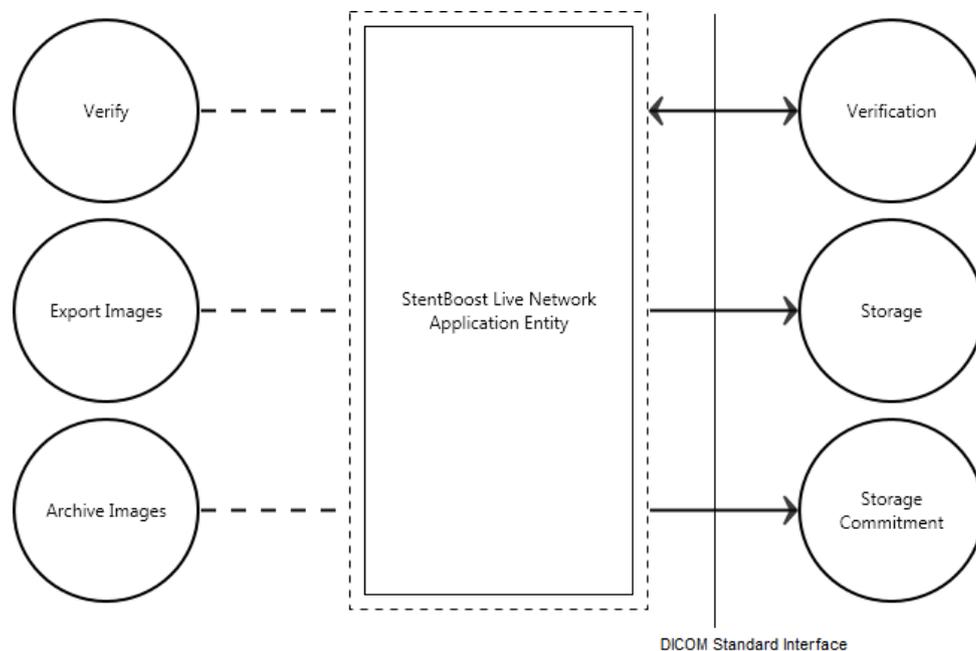


Figure 2: Application Data Flow Diagram

The StentBoost Live 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

StentBoost Live incorporates the following functionality:

Export Images

The StentBoost Live 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 StentBoost Live 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 StentBoost Live System will request a storage commitment from this archive for all exported movies and snapshots. The transfer status of the Snapshot and Movies is visible in the StentBoost Live application.

4.1.3. Sequencing of Real World Activities

StentBoost Live is connected to the X-ray system. X-Ray system acquires images with a certain procedure and sends to StentBoost Live. Based on the received x-ray images the StentBoost Live 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.

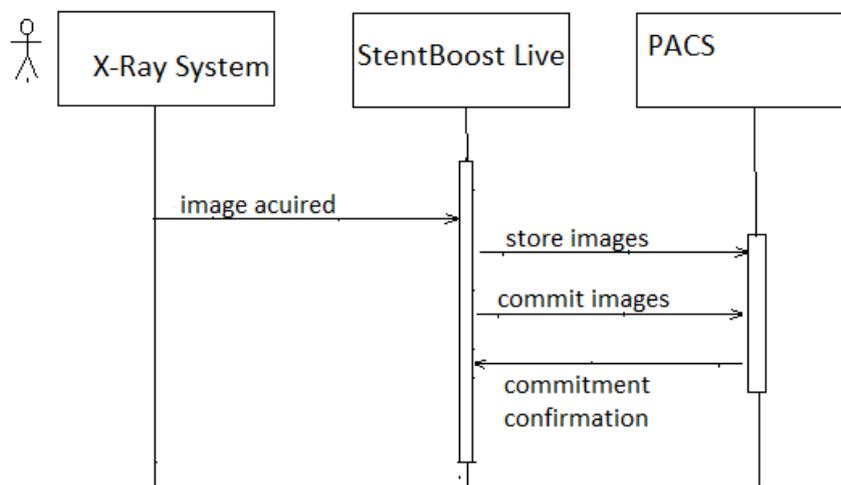


Figure 3: Sequence Diagram

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. StentBoost Live 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.

Table 4: SOP Classes for StentBoost Live Network AE

SOP Class Name	SOP Class UID	SCU	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 SOP Class	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	Yes	No

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 Stent Boost Live 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	Behavior
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 function)	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 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.

Result	Source	Reason/Diagnosis	Behavior
2 – rejected-transient	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 function)	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 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.

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 Stent Boost Live Network AE implements the Verification service class / Verification SOP class to verify application level communication.

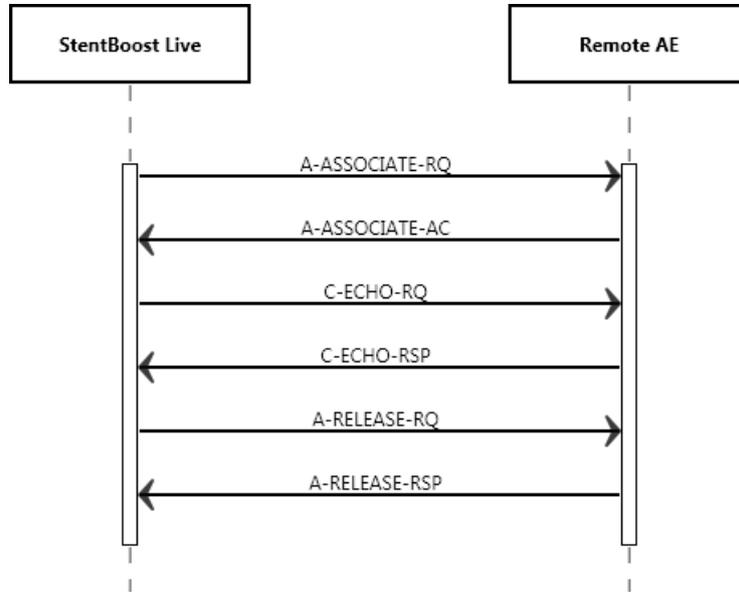


Figure 4: Data Flow Diagram – Verification as SCU

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		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	SCU	None
		Explicit VR Little Endian	1.2.840.10008.1.2.1		
		Implicit VR Little Endian	1.2.840.10008.1.2		

4.2.1.3.1.3. SOP Specific Conformance for Verification SOP Class

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

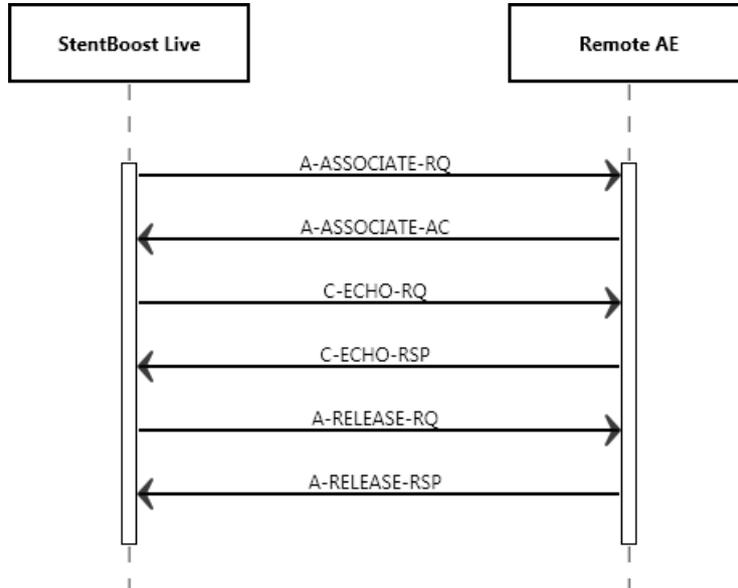


Figure 5: Data Flow Diagram – Store Image – Storage as SCU

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		Role	Extended Negotiation
Name	UID	Name List	UID List		
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	1.2.840.10008.1.2	SCU	None
		Explicit VR Big Endian	1.2.840.10008.1.2.2		
		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		

Note: In case during the PACS configuration test is found that the PACS does not support the JPEGBaseline (Process 1) transfer syntax for the Multi-frame True Color Secondary Capture Image Storage SOP class, then the “create Movie” function will not be enabled in the StentBoost Live application.

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	A700	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.
	A900	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.
	C000	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.

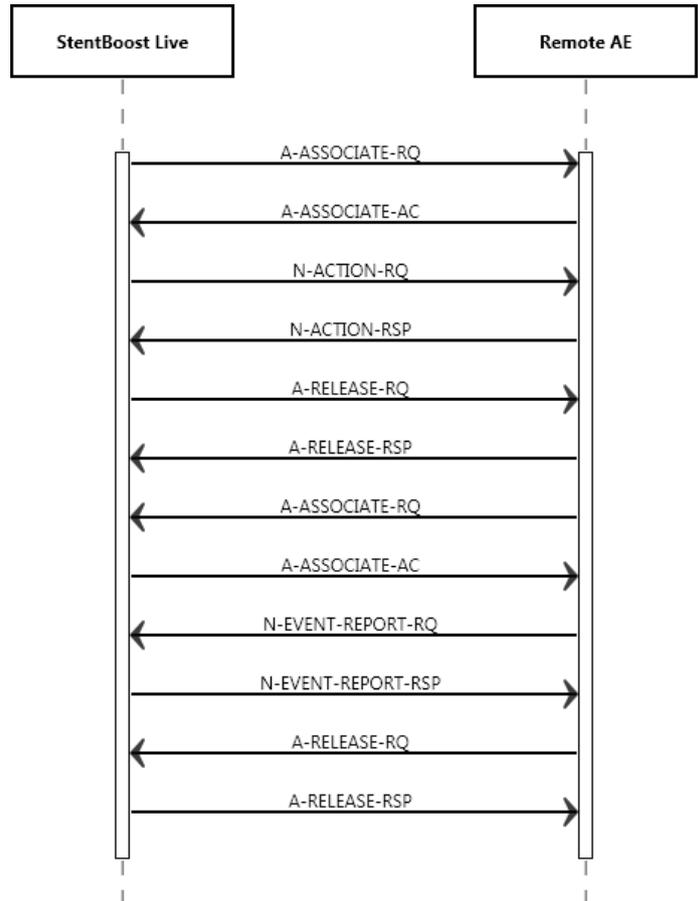


Figure 6: Data Flow Diagram -Storage Commitment as SCU

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		Role	Extended Negotiation
Name	UID	Name List	UID List		
Storage Commitment Push Model SOP Class	1.2.840.10008.1.20.1	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		

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

StentBoost Live 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	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 failed. And "Received a storage failure status for 'study instance UID of image of the image sent' "message is displayed in the log viewer.

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.

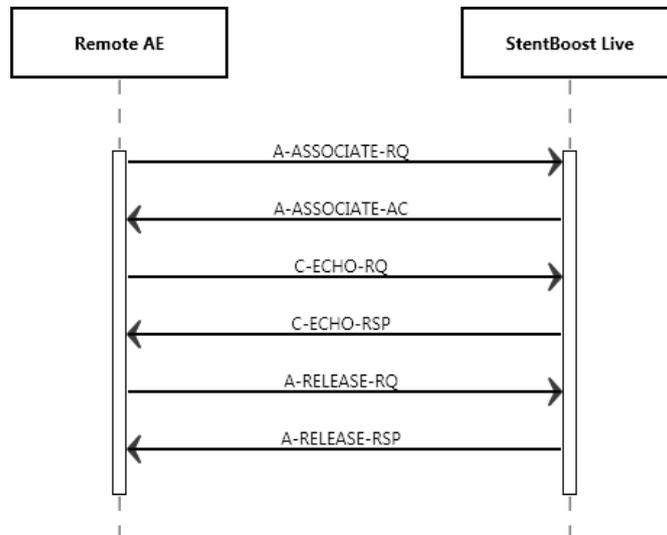


Figure 7: Data Flow Diagram – Verification as SCP

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 DICOM standard. 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 Stent Boost Live 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	
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	

Parameter	Configurable	Default Value
Port Number	Yes	241

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 StentBoost Live 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 StentBoost Live 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 StentBoost Live 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 StentBoost Live 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.

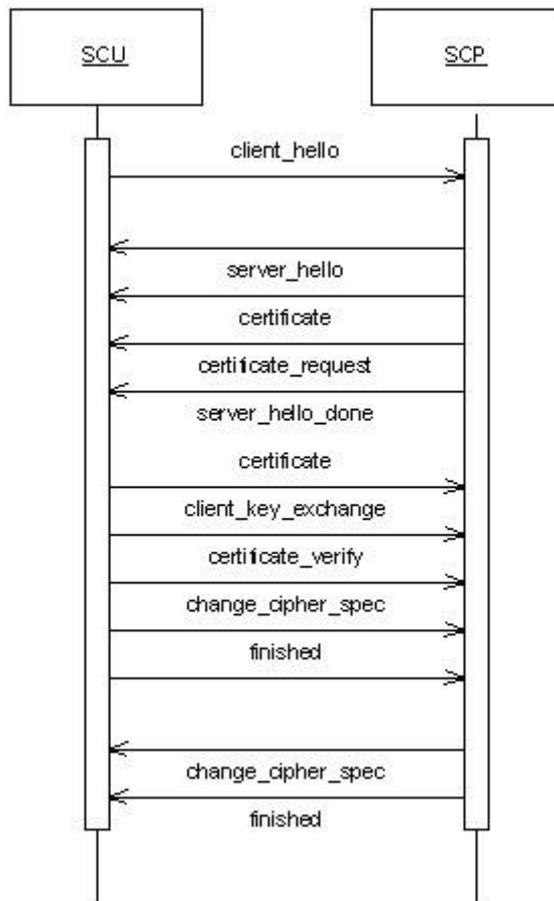


Figure 8: Message flow of TLS handshake

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

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

7.3. Application Level Security

The StentBoost Live 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 StentBoost Live 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 “StentBoost Live”

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
Equipment	SC Equipment Module	ALWAYS
	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 : General Equipment Module

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

Table 29 : 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 30: General Image Module

Attribute Name	Tag	VR	Value	Presence of Value	Source	Comment
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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	0008,0008	CS	DERIVED\SE CONDARY	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	AUTO	
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	ANAP	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	0008,0008	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	

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	