
DICOM

Conformance Statement

StentBoost / Integris 3D-RA
SW Release 4.2.2



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1 DICOM CONFORMANCE STATEMENT OVERVIEW

The Overview consists of an overview of the Network and Media Services used by the 3D-RA Release 4.2.

The first column specifies the SOP classes exactly as named in PS 3.6-2004.

Table 1: Network Services

SOP Class		User of Service (SCU)	Provider of Service (SCP)
Name	UID		
Transfer			
Secondary Capture Image Storage	1.2.840.10008.5.1.4.1.1.7	Yes	No
X-Ray Angiographic Image Storage	1.2.840.10008.5.1.4.1.1.12.1	Yes	No
Print Management			
Basic Film Session	1.2.840.10008.5.1.1.1	Yes	No
Basic Film Box	1.2.840.10008.5.1.1.2	Yes	No
Basic Grayscale Image Box	1.2.840.10008.5.1.1.4	Yes	No
Basic Grayscale Print Management (Meta)	1.2.840.10008.5.1.1.9	Yes	No
Printer	1.2.840.10008.5.1.1.16	Yes	No

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

Note: Verification SCP (C-ECHO) is not included in the table above because it is required for any Acceptor of an Association. The Verification SCU details are covered in the details of the conformance statement.

A table of Supported Media Storage Application Profiles (with roles) is provided.

Table 2: Media Services

Media Storage Application Profile	Write Files (FSC or FSU)	Read Files (FSR)
Compact Disk - Recordable		
General Purpose CD-R	Yes	Yes

Note: "File Set Reader (FSR) functionality will be supported by 3DRA for specialized non-DICOM information only"

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3 INTRODUCTION

3.1 Revision History

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

Table 3: Revision History

Document Version	Date of Issue	Author	Description
00	09 Augustus 2004	PMS MIT-IO	DICOM Conformance Statement. Draft version of document
01	17 Augustus 2004	PMS MIT-IO	Revision of the DICOM Conformance Statement following supplement 64. (Ref. DICOM 2003 supplement 64 Version 18).

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 3.2-2004.

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

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

responsibility of the user (or user's agent) to specify the appropriate test suite and to carry out the additional validation tests.

- **New versions of the DICOM Standard**

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

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

3.4 Definitions, Terms and Abbreviations

DICOM definitions, terms and abbreviations are used throughout this Conformance Statement. For a description of these, see NEMA PS 3.3-2004 and PS 3.4-2004. The word Philips in this document refers to Philips Medical Systems.

In this document, the term '3D-RA Release 4.2' has been used to refer to the 3DRA application as well the StentBoost application.

Protected Health Information

Protected Health Information is considered as information records, and not the flow of information between the systems [IHE]

Time Server

A system unit that knows, maintains and distributes the correct time in the enterprise [IHE]

The following acronyms and abbreviations are used in this document.

AE	Application Entity
ALWAYS	Always Present
ANAP	Attribute Not Always Present
AUTO	the attribute value is generated automatically
CD	Compact Disc
CD-R	CD-Recordable
CD-RW	CD-Rewritable
CONFIG	the attribute value source is a configurable parameter
DICOM	Digital Imaging and Communications in Medicine
DIMSE	DICOM Message Service Element
EBE	DICOM Explicit VR Big Endian
ELE	DICOM Explicit VR Little Endian
EMPTY	Attribute is sent without a value
FSC	File-set Creator
FSR	File-set Reader
FSU	File-set Updater
GUI	Graphic User Interface
HL7	Health Level Seven
IHE	Integrating the Healthcare Enterprise
ILE	DICOM Implicit VR Little Endian
IOD	Information Object Definition
NEMA	National Electrical Manufacturers Association

PDU	Protocol Data Unit
PHI	Protect Health Information
RIS	Radiology Information System
RWA	Real-World Activity
SC	Secondary Capture
SCP	Service Class Provider
SCU	Service Class User
SOP	Service Object Pair
TCP/IP	Transmission Control Protocol/Internet Protocol
TLS	Transport Layer Security protocol
UID	Unique Identifier
USER	the attribute value source is from User input
VNAP	Value Not Always Present
XA	X-Ray Angiographic

3.5 References

- [DICOM] Digital Imaging and Communications in Medicine (DICOM), Part 1 – 16 (NEMA PS 3.1-2004 – PS 3.16-2004), National Electrical Manufacturers Association (NEMA) Publication Sales 1300 N. 17th Street, Suite 1847 Rosslyn, Virginia. 22209, United States of America
- [IHE] Integrating the Healthcare Enterprise Technical Framework Revision 5.4: Radiological Society of North America (RSNA), Inc. 820 Jorie Boulevard, Oak Brook, IL, United States of America
- [TLS] Transport Layer Security protocol RFC 2246:Transport Layer Security protocol (TLS) v1.0.
- [SYSLOG] Syslog Protocol RFC 3164:The BSD Syslog Protocol

4 NETWORKING

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

4.1 Implementation model

The 3D-RA Release 4.2 system of Philips Medical System is a 3D Imaging generating system. The System contains:

- A DICOM Image export function to transfer DICOM Secondary Capture Images and private Reconstructed X-ray Images
- DICOM Print
- DICOM Verification
- DICOM Media Storage function to store DICOM Secondary Capture Images to CD-R and CD-RW media
- Support of Secure communication

The above DICOM Image Export and print functions are described in this document.

4.1.1 Application Data Flow

The 3D-RA Release 4.2 behaves as a system with four Application Entity (AE). The related Implementation Model is shown in Figure 1.

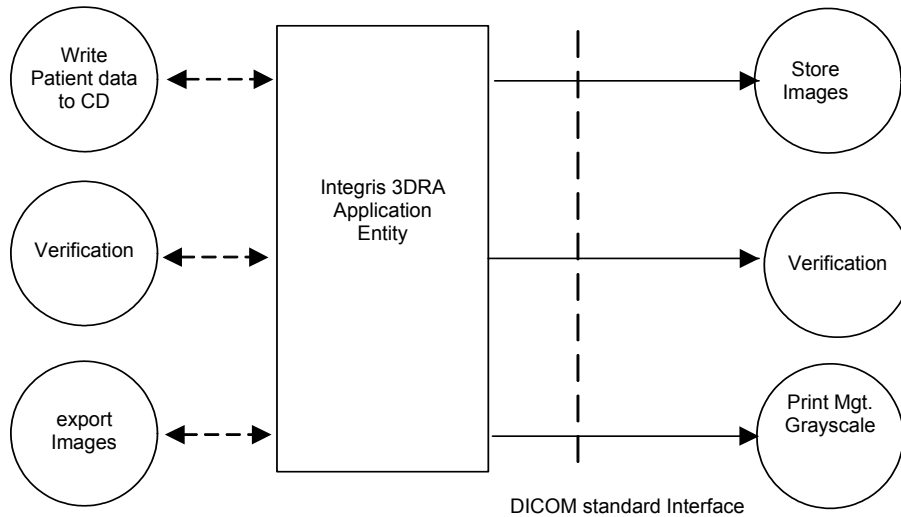


Figure 1: Application Data Flow Diagram

The images to be sent are selected from one or more examinations of a patient. At export request the images will be converted into DICOM format and sent out to a remote destination. While writing images to CD, each snapshot of the selected patient will be converted to DICOM media format and written on media.

4.1.2 Functional Definition of AE

The 3D-RA Release 4.2 DICOM Image Export AE acts as a Service Class User (SCU) of the Storage Service Class. When the export is initiated, the AE will open an association to the remote system. The selected images and related image data are converted into a DICOM message to be sent to the remote system. By writing images to CD the 3D-RA Release 4.2 acts as a File-Set Creator.

4.1.3 Sequencing of Real World Activities

When the examination is completed the created images can be exported via a network to the open domain.

Figure 2 gives an overview of the 3DRA system in a DICOM network.

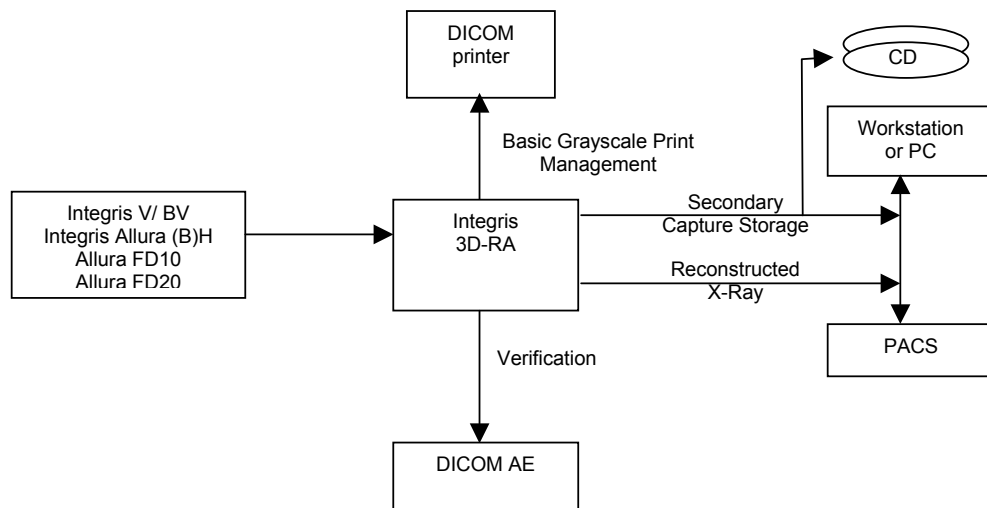


Figure 2: 3DRA in a DICOM network

4.2 AE Specifications

4.2.1 3D-RA Release 4.2

4.2.1.1 SOP Classes

The 3D-RA Release 4.2 DICOM Storage Application Entity provides Standard Conformance to the following DICOM V3.0 SOP Classes as an SCU:

Table 4: SOP Classes for 3D-RA Release 4.2

SOP Class Name	SOP Class UID	SCU	SCP
Secondary Capture Image Storage SOP Class	1.2.840.10008.5.1.4.1.1.7	Yes	No
Reconstructed X-ray SOP Class	1.3.46.670589.2.4.1.1	Yes	No
Verification	1.2.840.10008.1.1	Yes	No
Basic Grayscale Print Management Meta SOP Class	1.2.840.10008.5.1.1.9	Yes	No
> Basic Film Session SOP Class	1.2.840.10008.5.1.1.1	Yes	No
> Basic Film Box SOP Class	1.2.840.10008.5.1.1.2	Yes	No
> Basic Grayscale Image Box SOP Class	1.2.840.10008.5.1.1.4	Yes	No
> Printer SOP Class	1.2.840.10008.5.1.1.16	Yes	No

4.2.1.2 Association Policies

4.2.1.2.1 General

3D-RA Release 4.2 uses a PDU size of 16k.
The DICOM standard application context is specified as.

Table 5: DICOM Application Context

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

4.2.1.2.2 Number of Associations

The number of simultaneous associations that an Application Entity may support as a SCU is specifies, also any rules governing simultaneity of associations. 3D-RA Release 4.2 will establish one association at a time

Table 6: Number of Associations as an Association Initiator for 3D-RA Release 4.2

Maximum number of simultaneous associations	1
---	---

4.2.1.2.3 Asynchronous Nature

3D-RA Release 4.2 does not support asynchronous operations and will not perform asynchronous window negotiation

Table 7: Asynchronous Nature as an Association Initiator for 3D-RA Release 4.2

Maximum number of outstanding asynchronous transactions	0
---	---

4.2.1.2.4 Implementation Identifying Information

The value supplied for Implementation Class UID shall be documented here. If a version name is supplied, this fact shall be documented here. Policies defining the values supplied for version name may be stated here.

Table 8: DICOM Implementation Class and Version for 3D-RA Release 4.2

Implementation Class UID	1.3.46.670589.7.8.2.1
Implementation Version Name	3DRA_rel_4.2.1

4.2.1.3 Association Initiation Policy

3D-RA Release 4.2 initiates associations as a result of the following local Real-World activities.

4.2.1.3.1 (Real-World) Activity – Verify

4.2.1.3.1.1 Description and Sequencing of Activities

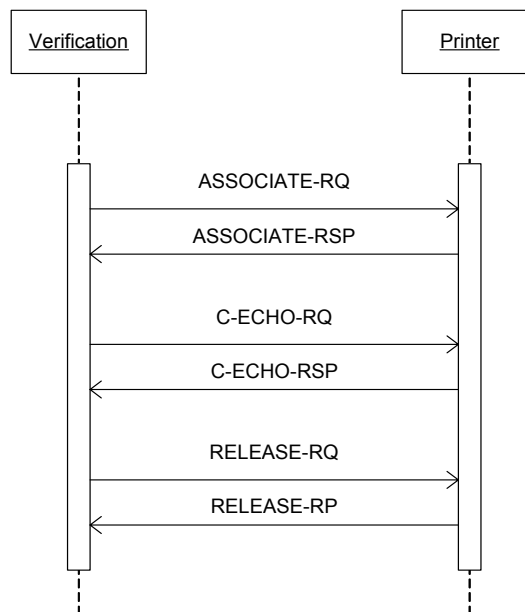


Figure 3: Real world activity Verify

3D-RA Release 4.2 will issue verification requests in response to UI mediated requests from the user to test validity of DICOM connection. This is only true for DICOM printer nodes.

4.2.1.3.1.2 Proposed Presentation Contexts

The 3D-RA Release 4.2 will propose the following presentation contexts:

Table 9: Proposed Presentation Contexts for (Real-World) Activity – Verify

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Extended Negotiation
Name	UID	Name List	UID List		
Verification	1.2.840.10008.1.1	ILE ELE EBE	1.2.840.10008.1.2 1.2.840.10008.1.2.1 1.2.840.10008.1.2.2	SCU	None

4.2.1.3.1.3 SOP Specific Conformance for SOP Classes

The 3D-RA Release 4.2 provides Standard Conformance to the DICOM Verification Service Class

4.2.1.3.2 (Real-World) Activity – Send Image

4.2.1.3.2.1 Description and Sequencing of Activities

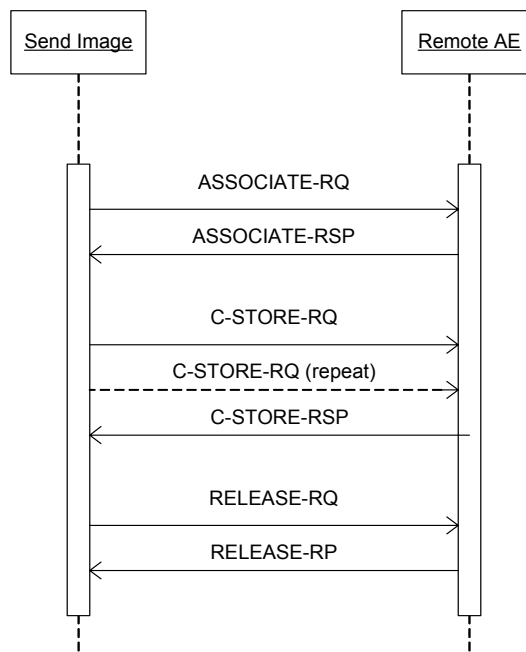


Figure 4: Real world activity Send Image

After selection of an image file, the file will be sent when initiating the Send command. The 3D-RA Release 4.2 initiates one association to the pre-configured peer system and uses it to send the selected images and runs via C-STORE requests (and receives the associated C-STORE responses). The association is released by 3D-RA Release 4.2 after successful transfer of the images or when an error occurs. The 3D-RA Release 4.2 handles each send request one after another.

4.2.1.3.2.2 Proposed Presentation Contexts

The 3D-RA Release 4.2 will propose the following presentation contexts:

Table 10: Proposed Presentation Contexts for (Real-World) Activity – Send Image

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Extended Negotiation
Name	UID	Name List	UID List		
Secondary Capture Image Storage - STORE	1.2.840.10008.5.1.4.1.1.7	ILE ELE EBE	1.2.840.10008.1.2 1.2.840.10008.1.2.1 1.2.840.10008.1.2.2	SCU	None

4.2.1.3.2.3 SOP Specific Conformance for SOP Classes

A not succeeded transfer is indicated on the console with an error messages:

Table 11: DICOM Command Response Status Handling Behavior C-STORE

Service Status	Further Meaning	Error Code	Behavior
Success	Complete succesfull	0000	Message in console
Refused		A7xx	Message in console
Error		A9xx Cxxx	Message in console
Warning		B00x	Message in console

4.2.1.3.2.4 Secondary Capture SCU Conformance

Table 5 lists the applied Conditional (DICOM Type 1C and 2C) and Optional (DICOM Type 3) attributes in the Secondary Capture Image IOD.

Table 12: Applied Conditional and Optional Attributes of the SC Image IOD

IE	Module	Conditional Attributes	Optional Attributes
Patient	Patient	-	-
Study	General Study	-	-
Series	General Series	Code Value, Code Scheme Designator, Scheduled Procedure Step ID, Requested Procedure ID	Series Date, Series Time, Performing Physician's Name, Referenced Study Component Sequence, Code Meaning, Performed Procedure Step Start Date, Performed Procedure Step Start Time, Performed Procedure Step ID, Performed procedure Step Description, Request Attributes Sequence, Scheduled Procedure Step Description, Scheduled Action Item Code Sequence,
Equipment	General Equipment SC Equipment	- -	Institution Name, Station Name, Manufacturer's Model Name, Software Version(s)
Image	General Image Image Pixel SC Image Module VOI LUT SOP Common	- - Window Width Specific Character Set	Image Type Date of Secondary Capture, Time of Secondary Capture Window Center

The availability of attributes depends on the image obtained via the private link from the 3D-RA.

4.2.1.3.3 (Real-World) Activity – Print Images

4.2.1.3.3.1 Description and Sequencing of Activities

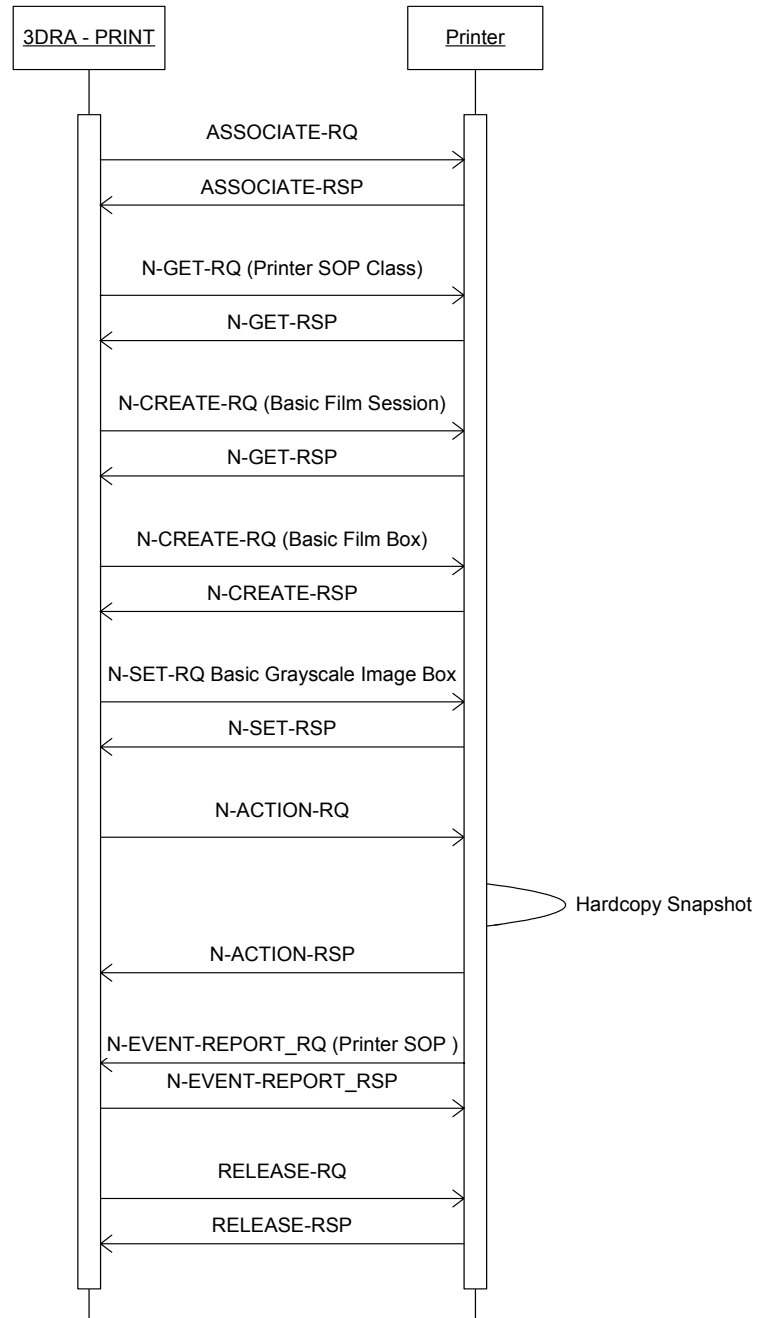


Figure 5: Real world activity Printer

The operator is able to select one or more images from the internal database (via the Data Handling facility) and perform the Print operation on them.

The operator will select the print destination (out of choice list of configured printers) and some print parameters.
 As a result, the 3D-RA Release 4.2 will initiate an association to the selected printer and uses it to send the Print Service Elements of the Print SOP Classes.

4.2.1.3.3.2 Proposed Presentation Contexts

The 3D-RA Release 4.2 will propose the following presentation contexts for Print:

Table 13: Proposed Presentation Contexts for (Real-World) Activity – Print Images

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Extended Negotiation
Name	UID	Name List	UID List		
Basic Grayscale Print Management Meta SOP Class	1.2.840.10008.5.1.1.9	ILE ELE EBE	1.2.840.10008.1.2 1.2.840.10008.1.2.1 1.2.840.10008.1.2.2	SCU	None

4.2.1.3.3.3 SOP Specific Conformance for SOP Classes

The 3D-RA Release 4.2 provides standard conformance to the Basic Grayscale Print Management Meta SOP Class.

The applied order of Print Service Elements (DIMSE's) is specified in Table 8. A description and the applied optional (i.e. non-mandatory attributes as Print SCU) attributes in these Service Elements are specified too. Note that the Service Elements order is not specified by the DICOM standard.

An explicit N-DELETE Request on the created instances is not done by the 3D-RA Release 4.2; these are deleted implicitly when releasing the association.

The full list of (Mandatory and Optional) attributes applies in these Service Elements are:

Table 14: Applied order of Print Service Elements and its optional attributes

Service Element of SOP Class	Description and applied optional attributes
N-GET of the Printer SOP Class	Purpose is to retrieve printer information.
N-CREATE of the Basic Film Session SOP Class	3D-RA Release 4.2 specifies the DICOM Printer about some general presentation parameters, applicable for all films in the Film Session. Applied optional attributes are: Number of Copies, Medium Type
N-CREATE of the Basic Film Box SOP Class	3D-RA Release 4.2 specifies the DICOM Printer about some general presentation parameters, applicable for all images in the Film Box. Applied optional attributes are: Film Orientation, Film Size ID, Magnification Type, Max. Density, Configuration Information, Trim.
N-SET of the Basic Grayscale Image Box SOP Class	3D-RA Release 4.2 will send the images to be printed.
N-ACTION of the Basic Film Box SOP Class	3D-RA Release 4.2 triggers the DICOM Printer to print, this actual print action is done at film box level. No (optional) attributes are present.

The table below specifies the supported Service Elements, which may be generated by the Printer at any time during the association.

Table 15: Applied sequence of Print Service Elem. and its optional attributes

Service Element of SOP Class	Note
N-EVENT-REPORT of the Printer SOP Class	May be sent at any moment by the Printer SCP (i.e. the DICOM Printer). 3D-RA Release 4.2 will respond.

The Status Codes of DIMSE Responses (Success, Warning, Failure) as returned by the printer will also be logged (for service purposes) and are mapped onto window messages.

The following implementation remarks are important to achieve successful printing:

The 3D-RA Release 4.2 will release the association after the last print command has been given and a N-ACTION-RSP message from the printer SOP has been received.

Table 16: DICOM Command Response Status Handling Behavior

Service Status	Further Meaning	Error Code	Behavior
Success	Matching is complete	0000	e.g. The SCP has successfully returned all matching information.
Warning		<>0000	Continue Job + UI Message
Error	Failure	<>0000	Stop Job + UI Message

4.2.1.3.3.4 SOP Specific Conformance for Basic Film Session SOP Classes

Table 17: Basic Film Session Presentation Module

Attribute Name	Tag	VR	Value	Presence of Value	Source
Number of Copies	2000,0010	IS	1-9	ALWAYS	USER
Print Priority*	2000,0020	CS	HIGH, MED, LOW	ALWAYS	CONFIG
Medium Type*	2000,0030		BLUE FILM, CLEAR FILM, PAPER, CURRENT	ALWAYS	CONFIG
Film Destination*	2000,0040		MAGAZINE, PROCESSOR, BIN_I (with I > 0)	ALWAYS	CONFIG

* Note: the Image Display Format, and Film Size ID are selectable.

Table 18: Printer SOP Class - N-EVENT-Report - Printer Module

Attribute Name	Tag	VR	Value	Presence of Value	Source
Printer Status Info	2110,0020	CS	Conditionally sent by the Printer. The 3D-RA Release 4.2 will react on notification, and will show corresponding messages on the UI for the events WARNING and FAILURE	ANAP	AUTO
Film destination	2000,0040	CS		ANAP	AUTO
Printer Name	2110,0030	LO		ANAP	AUTO

4.2.1.3.3.5 SOP Specific Conformance for Basic Film Box SOP Classes

Table 19: Basic Film Box Presentation Module

Attribute Name	Tag	VR	Value	Presence of Value	Source
Image Display Format *	2010,0010	ST	1,1; 1,2; 2,2; 2,3	ALWAYS	USER
Film Orientation	2010,0040	CS	PORTRAIT	ALWAYS	AUTO
Film Size ID *	2010,0050	CS			
Magnification Type*	2010,0060	CS	BILINEAR, CUBIC, NONE, REPLICATE	ALWAYS	CONFIG
Max Density*	2010,0130	US	1-350	ALWAYS	CONFIG
Trim	2010,0140	CS	NO	ALWAYS	AUTO
Configuration Information	2010,0150	ST		ALWAYS	CONFIG
Smoothing Type	2010,0080	CS		ALWAYS	AUTO
Border Density	2010,0100	CS	BLACK	ALWAYS	AUTO
Empty Image Density	2010,0110	CS	BLACK	ALWAYS	AUTO
Min. Density	2010,0120	US	0-349 (printer dependent)	ALWAYS	AUTO
Referenced Film Session Sequence	2010,0500	SQ	Parent Film Session	ALWAYS	AUTO
>Referenced SOP Class UID	0008,1150	UI	1.2.840.10008.5.1.1.1	ALWAYS	AUTO
>Referenced SOP Instance UID	0008,1155	UI		ALWAYS	AUTO

* Note: the Image Display Format, and Film Size ID are selectable.

Table 20: Basic Film Box SOP Class - N-ACTION RQ - Sop Common Module

Attribute Name	Tag	VR	Value	Presence of Value	Source
No data attributes present					

4.2.1.3.3.6 SOP Specific Conformance for Basic Grayscale Image Box SOP Class

Table 21: Basic Grayscale Image Box SOP Class - N-SET-RQ - Pixel Presentation Module

Attribute Name	Tag	VR	Value	Presence of Value	Source
Image Position	2020,0010	US		ALWAYS	AUTO
Polarity	2020,0020	CS	NORMAL	ALWAYS	AUTO
Preformatted Grayscale Image Sequence	2020,0110	SQ		ALWAYS	AUTO
>Samples per Pixel	0028,0002	US		ALWAYS	AUTO
>Photometric Interpretation	0028,0004	CS		ALWAYS	AUTO
>Rows	0028,0010	US		ALWAYS	AUTO
>Columns	0028,0011	US		ALWAYS	AUTO
>Bits Allocated	0028,0100	US		ALWAYS	AUTO
>Bits Stored	0028,0101	US		ALWAYS	AUTO
>High Bit	0028,0102	US		ALWAYS	AUTO
>Pixel Representation	0028,0103	US		ALWAYS	AUTO
>Pixel Data	7FE0,0010	OW		ALWAYS	AUTO

4.2.1.3.3.7 SOP Specific Conformance for Printer SOP Class

Table 22: Printer SOP Class - N-GET-RQ - Printer Module

Attribute Name	Tag	VR	Value	Presence of Value	Source
Manufacturer	0008,0070	LO		ALWAYS	AUTO
Manufacturer Model Name	0008,1090	LO		ALWAYS	AUTO
Device Serial Number	0018,1000	LO		ALWAYS	AUTO
Software Versions	0018,1020	LO		ALWAYS	AUTO
Date of Last Calibration	0018,1200	DA		ALWAYS	AUTO
Time of Last Calibration	0018,1201	TM		ALWAYS	AUTO
Printer Status	2110,0010	CS		ALWAYS	AUTO
Printer Status Info	2110,0020	CS		ALWAYS	AUTO
Printer Name	2110,0030	LO		ALWAYS	AUTO

4.2.1.4 Association Acceptance Policy

The 3D-RA Release 4.2 Application Entity does not accept associations.

4.3 Network Interfaces

4.3.1 Physical Network Interface

The 3D-RA Release 4.2 provides DICOM V3.0 TCP/IP Network Communication Support as defined in Part 8 of the DICOM Standard

The 3D-RA Release 4.2 uses the TCP/IP program stack of the Windows 2000 work station is used for the image transport.

The 3D-RA Release 4.2 supports Ethernet (ISO 8802-3), 10 and 100-BaseT for the Image and Printer Interface.

4.4 Configuration

The 3D-RA Release 4.2 AE titles are configurable the default values are:

4.4.1 AE Title/Presentation Address Mapping

4.4.1.1 Local AE Titles

The local AE title mapping and configuration shall be specified. The following table shall be used:

Table 23: AE Title Configuration Table

Application Entity	Default AE Title	Default TCP/IP Port
Import Provider	3DRAimport	3110
Remote Print	3DRAprint	3110
Remote Store SC	3DRAexport	3110
Remote Store Reconstr. X-ray SC	3DRAexportvol	3110
Echo	3DRAecho	3110

4.4.1.2 Remote AE Title/Presentation Address Mapping

For remote applications that act as Service Class Provider the following additional information must be provided:

Table 24: Remote AE Title Configuration Table

Application Entity	Description	Default TCP/IP Port
Import Provider	Hostname IP-Adress Port number	3010
Remote Print	Hostname IP-Adress Port number	3010
Remote Store SC	Hostname IP-Adress Port number t	3010
Remote Store Reconstr. X-ray SC	Hostname IP-Adress Port number	3010
Echo	Hostname IP-Adress Port number	3010

5 MEDIA INTERCHANGE

5.1 Implementation Model

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

5.1.1 Application Data Flow Diagram

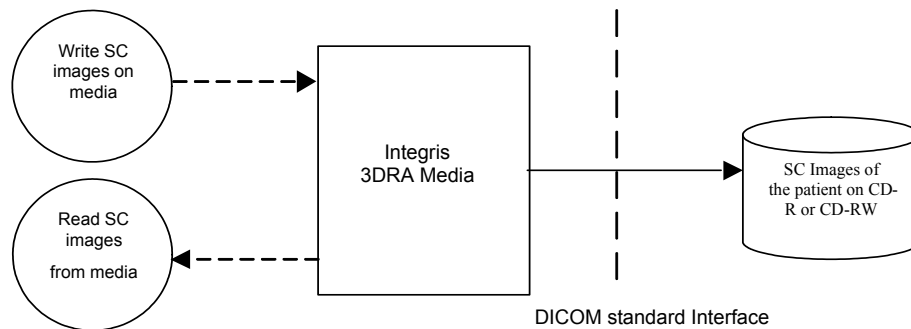


Figure 6: Application Data Flow Diagram

5.1.2 Functional Definitions of AE's

The next part of the Conformance Statement contains a functional definition for each local Application Entity. This describes in general terms the functions to be performed by the AE, and the DICOM services used to accomplish these functions. In this sense, "DICOM services" refers not only to DICOM service classes, but also to lower level DICOM services, such as the Media File System and mapping to particular media formats.

5.1.3 File Meta Information for Implementation Class and Version

The Implementation Class UID and Implementation Version Name in the File Meta Header is:

Table 25: DICOM Implementation Class and Version for 3D-RA Release 4.2 Media

Implementation Class UID	1.3.46.670589.7.8.2.1
Implementation Version Name	3DRA_rel_4.2.1

5.2 AE Specifications

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

5.2.1 3D-RA Release 4.2 Media - Specification

The 3D-RA Release 4.2 provides Standard Conformance to the DICOM Media Storage Service and File Format (PS 3.10) and the Media Storage Application Profiles.

The supported Application Profile, their Roles and the Service Class options, all defined in DICOM terminology, are listed in Table 26.

Table 26: AE Related Application Profiles, Real-World Activities, and Roles

Application Profile	Identifier	Real World Activity	Role	SC Option
General Purpose CD-R Image Interchange Profile	STD-GEN-CD	Write image(s) on CD-R disk	FSC	Interchange
	STD-GEN-CD	Write image(s) on CD-RW disk	FSC	Interchange

Note: Secondary Capture images only

5.2.1.1.1 (Real World) Activity DICOM Recording

After one or more patients are selected, the operator can choose to store the data onto a portable medium (CD-R or CD-RW). All Secondary Capture images belonging to all the selected patients will be stored on the portable medium in DICOM media format.

Though the entire patient data can extend to more than one CD, the DICOM Secondary Capture images are stored in the first CD itself. Hence, if the user wants to read the secondary capture images at a DICOM File-Set-Reader (FSR), he/she only needs the first CD of the series.

Table 27: SOP Classes and Transfer Syntaxes

IOD	SOP Class	Transfer Syntax and UID	FSC	FSR	FSU
Basic Directory	1.2.840.10008.1.3.10	ELE 1.2.840.10008.1.2.1	YES	YES	YES
SC Image Storage	1.2.840.10008.5.1.4.1.1.7	ELE 1.2.840.10008.1.2.1	YES	YES*	NO

* File Set Reader (FSR) functionality will be supported by 3DRA for specialized non-DICOM information only.

5.2.1.1.2 SOP FSC Conformance (Secondary Capture)

All Attributes from Table 5 and in addition all Type 1 attributes in the File Meta Information are written to the image files.

5.2.1.1.3 SOP FSC Conformance (Basic Directory)

3DRA will not delete any snapshots, which are already written to the File Set.

6 SUPPORT OF CHARACTER SETS

The 3D-RA Release 4.2 supports Extended Character Set "ISO_IR 100" which is the Latin alphabet No 1, supplementary set.

7 SECURITY

7.1 Security Measures

The 3D-RA Release 4.2 allows the use of either a conventional (non-secure) DICOM communication or a secure DICOM communication based on the Transport Layer Security (TLS) protocol 3D-RA Release 4.2. If configured, the 3D-RA Release 4.2 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.

7.1.1 DICOM Basic TLS Secure Transport Connection Profile

Secure communication is a "mode of operation" of the 3D-RA Release 4.2 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 the TLS protocol v1.0 is used which provides message authentication, integrity, confidentiality, and replay protection. Confidentiality is optional and can be controlled by the encryption settings.

The 3D-RA Release 4.2 may communicate using the following Cipher Suites:

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

The 3D-RA Release 4.2 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 3D-RA Release 4.2 can only read certificates from the certificate stores of the HKEY_LOCAL_MACHINE registry key. It is the responsibility of the Hospital to setup and maintain the certificate stores. This includes the removal of revoked certificates and certificate updates prior to their expiration. Since neither X.500 directories, Lightweight Directory Access Protocol (LDAP) nor Certificate Revocation Lists (CRLs) are supported, the whole certificate chain needs to be replaced after a security breach.

The following figure presents the message flow of TLS handshake supported by the 3D-RA Release 4.2.

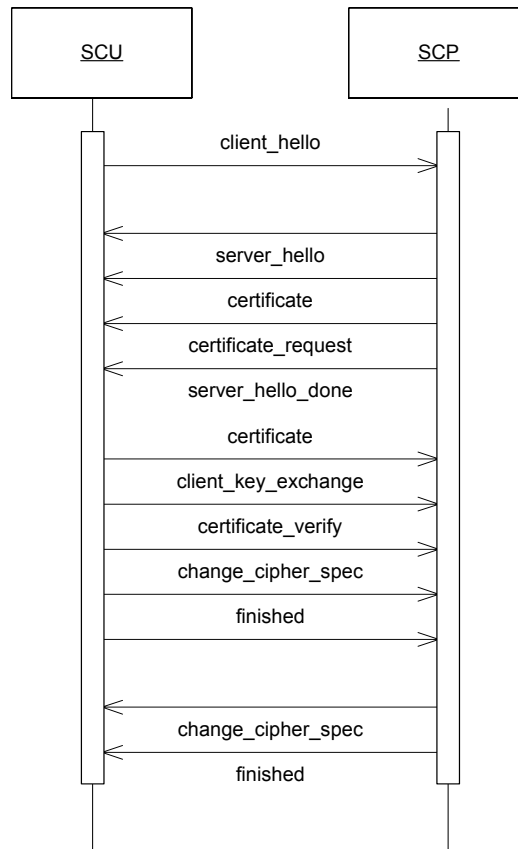


Figure 7: Message flow of TLS handshake

7.1.2 Generation of Audit Records

The 3D-RA Release 4.2 can create audit messages according to the IHE Basic Security Integration Profile [IHE] to audit activities, to detect non-compliant behavior

in the enterprise, and to facilitate detection of improper creation, access, modification and deletion of Protected Health Information (PHI). These messages may contain information that identifies the patient. The following messages will be created and sent to a central Audit Record Repository according to the Syslog protocol[SYSLOG]:

- ActorConfig (when security or networking configuration of the 3D-RA Release 4.2 is modified using the service screen)
- ActorStartStop (when the 3D-RA Release 4.2 starts or shuts down)
- BeginStoringInstances (when an exportable item is transferred from the 3D-RA Release 4.2 to a remote network node)
- DICOMInstancesDeleted (when a patient or an exportable item is deleted)
- DICOMInstancesUsed (when patient details are viewed in 3D-RA Release 4.2)
- Export (when a secondary capture is printed on a film/paper, and when a patient has been stored on CD)
- Import (when patient data is read from CD)
- SecurityAlert (when an authentication of a secure node during TLS negotiation [TLS] fails, e.g. Due to an invalid certificate)
- UserAuthenticated (when the user logs in)

If the central Audit Record Repository is not available, the audit trail record will be stored by the 3D-RA Release 4.2 in a local buffer. Once the central Audit Record Repository is available again, the content of that buffer will be transferred to the central Audit Record Repository. The time that is part of the audit message will be the local time of the 3D-RA Release 4.2. This time will be synchronized with a Time Server. The Time Server and central Audit Record Repository are elements of the Hospital infrastructure.

8 ANNEXES

8.1 IOD Contents

8.1.1 Created SOP Instances

This section specifies each IOD created (including private IOD's). It specifies the attribute name, tag, VR, and value. The value should specify the range and source (e.g. user input, automatically generated, etc.).

Recommended abbreviations to be used for the tables are:

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

Recommended abbreviations to be used for the source of the data values in the tables are:

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

8.1.1.1 Secondary Capture IOD

Table 28: Applied Modules in the SC Image IOD for the 3D-RA Release 4.2

IE	Module	Reference	Presence of Value
Patient	Patient	Table 30	ALWAYS
Study	General Study	Table 31	ALWAYS
Series	General Series	Table 36	ALWAYS
Equipment	General Equipment	Table 32	ALWAYS
Image	SC Image Equipment	Table 37	ALWAYS
	General Image	Table 34	ALWAYS
	Image Pixel	Table 33	ALWAYS
	SC Image	Table 38	ALWAYS
	VOI LUT	Table 35	ALWAYS
	SOP Common	Table 39	ALWAYS

8.1.1.2 XA reconstructed X-Ray SOP Class (private) IOD

Table 29: Applied Modules in the XA reconstructed X-RAY Private Image IOD for the 3D-RA Release 4.2

IE	Module	Reference	Presence of Value
Patient	Patient	Table 30	ALWAYS
Study	General Study	Table 31	ALWAYS
Series	General Series	Table 40	ALWAYS
Frame of Reference	Frame of Reference	Table 43	ALWAYS
Equipment	General Equipment	Table 32	ALWAYS

Image	General Image	Table 34	ALWAYS
	Image Plane	Table 41	ALWAYS
	Image Pixel	Table 33	ALWAYS
	VOI LUT	Table 42	ALWAYS
	SOP Common	Table 44	ALWAYS

8.1.1.3 Common Modules

Table 30: Patient Module of created SOP Instance

Attribute Name	Tag	CS	Value	Presence of value	Source
Patient's Name	0010,0010	PN		ALWAYS	AUTO
Patient ID	0010,0020	LO		ALWAYS	AUTO
Patient's Birth Date	0010,0030	DA		ALWAYS	AUTO
Patient's Sex	0010,0040	CS		ALWAYS	AUTO

Table 31: General Study Module of created SOP Instance

Attribute Name	Tag	CS	Value	Presence of value	Source
Study Date	0008,0020	DA		ALWAYS	AUTO
Study Time	0008,0030	TM		ALWAYS	AUTO
Accession Number	0008,0050	SH		ALWAYS	AUTO
Referring Physician's Name	0008,0090	PN		ALWAYS	AUTO
Study Instance UID	0020,000D	UI		ALWAYS	AUTO
Study ID	0020,0010	SH		ALWAYS	AUTO

Table 32: General Equipment Module

Attribute Name	Tag	CS	Value	Presence of value	Source
Manufacturer	0008,0070	LO	Philips Medical Systems (Netherlands)	ALWAYS	AUTO
Institution Name	0008,0080	LO		ALWAYS	AUTO
Station Name	0008,1010	SH		ALWAYS	AUTO
Manufacturer's Model Name	0008,1090	LO	Dell	ALWAYS	AUTO
Software Version(s)	0018,1020	LO		ALWAYS	AUTO

Table 33: Image Pixel Module

Attribute Name	Tag	CS	Value	Presence of value	Source
Samples per Pixel	0028,0002	US	1	ALWAYS	AUTO
Photometric Interpretation	0028,0004	CS	MONOCHROME2	ALWAYS	AUTO
Rows	0028,0010	US	512	ALWAYS	AUTO
Columns	0028,0011	US	512	ALWAYS	AUTO
Bits Allocated	0028,0100	US	8	ALWAYS	AUTO
Bits Stored	0028,0101	US	8	ALWAYS	AUTO
High Bit	0028,0102	US	7	ALWAYS	AUTO
Pixel Representation	0028,0103	US	0000	ALWAYS	AUTO
Pixel Data	7FE0,0010	OW/OB		ALWAYS	AUTO

Table 34: General Image Module

Attribute Name	Tag	CS	Value	Presence of value	Source
Image Type	0008,0008	CS	DERIVED SECONDARY	ALWAYS	AUTO
Instance Number	0020,0013	IS		ALWAYS	AUTO
Patient Orientation	0020,0020	CS	(Empty string)	ALWAYS	AUTO

8.1.1.4 SC Image Storage SOP Class**Table 35: Voi Lut Module**

Attribute Name	Tag	CS	Value	Presence of value	Source
Window Center	0028,1050	DS	127.5	ALWAYS	AUTO
Window Width	0028,1051	DS	255	ALWAYS	AUTO

Table 36: General Series Modules

Attribute Name	Tag	CS	Value	Presence of value	Source
Series Date	0008,0021	DA		ALWAYS	AUTO
Series Time	0008,0031	TM		ALWAYS	AUTO
Performing Physician's Name	0008,1050	PN		ANAP	AUTO
Referenced Study Component Sequence	0008,1111	SQ		ALWAYS	AUTO
>Referenced SOP Class UID	0008,1150	UI	Uniquely identifies the referenced Modality Performed Procedure SOP Class. 1.2.840.10008.3.1.2.3.3	ALWAYS	AUTO
>Referenced SOP Instance UID	0008,1155	UI		ALWAYS	AUTO
Patient Position	0018,5100	CS		ANAP	AUTO
Series Instance UID	0020,000E	UI		ALWAYS	AUTO
Series Number	0020,0011	IS		ALWAYS	AUTO
Performed Procedure Step Start Date	0040,0244	DA		ANAP	AUTO
Performed Procedure Step Start Time	0040,0245	TM		ANAP	AUTO
Performed Procedure Step ID	0040,0253	SH		ANAP	AUTO
Performed Procedure Step Description	0040,0254	LO		ANAP	AUTO
Request Attributes Sequence	0040,0275	SQ		ANAP	AUTO
>Scheduled Procedure Step Description	0040,0007	LO		ANAP	AUTO
>Scheduled Action Item Code Sequence	0040,0008	SQ		ANAP	AUTO
>>Code Value	0008,0100	SH		ANAP	AUTO
>>Coding Scheme Designator	0008,0102	SH		ANAP	AUTO
>>Coding Scheme Version	0008,0103	SH		ANAP	AUTO
>>Code Meaning	0008,0104	LO		ANAP	AUTO
>Scheduled Procedure Step ID	0040,0009	SH		ANAP	AUTO
>Requested Procedure ID	0040,1001	SH		ANAP	AUTO

Table 37: Sc Image Equipment Module

Attribute Name	Tag	CS	Value	Presence of value	Source
Conversion Type	0008,0064	CS	WSD	ALWAYS	AUTO
Modality	0008,0060	CS	XA	ALWAYS	AUTO

Table 38: Sc Image Module

Attribute Name	Tag	CS	Value	Presence of value	Source
Date of Secondary Capture	0018,1012	DA		ALWAYS	AUTO
Time of Secondary Capture	0018,1014	TM		ALWAYS	AUTO

Table 39: Sop Common Module

Attribute Name	Tag	CS	Value	Presence of value	Source
Specific Character Set	0008,0005	CS	ISO_IR 100	ALWAYS	AUTO
SOP Class UID	0008,0016	UI	1.2.840.10008.5.1.4.1.1.7	ALWAYS	AUTO
SOP Instance UID	0008,0018	UI		ALWAYS	AUTO

8.1.1.5 XA reconstructed X-Ray SOP Class (private)**Table 40: General Series Modules**

Attribute Name	Tag	CS	Value	Presence of value	Source
Series Date	0008,0021	DA		ALWAYS	AUTO
Series Time	0008,0031	TM		ALWAYS	AUTO
Modality	0008,0060	CS	XA	ALWAYS	AUTO
Performing Physician's Name	0008,1050	PN		ALWAYS	AUTO
Series Instance UID	0020,000E	UI		ALWAYS	AUTO
Series Number	0020,0011	IS	1	ALWAYS	AUTO
Performed Procedure Step Start Date	0040,0244	DA		ALWAYS	AUTO
Performed Procedure Step Start Time	0040,0245	TM		ALWAYS	AUTO
Performed Procedure Step ID	0040,0253	SH		ALWAYS	AUTO
Performed Procedure Step Description	0040,0254	LO		ALWAYS	AUTO
Request Attributes Sequence	0040,0275	SQ		ALWAYS	AUTO
>Scheduled Procedure Step Description	0040,0007	LO		ALWAYS	AUTO
>Scheduled Procedure Step ID	0040,0009	SH		ALWAYS	AUTO
>Requested Procedure ID	0040,1001	SH		ALWAYS	AUTO
Patient Position	0018,5100	CS	HFP, HFS, FFP, FFS, HFDR, FFDR, HFDL and FFD	ALWAYS	AUTO

Table 41: Image Plane Modules

Attribute Name	Tag	CS	Value	Presence of value	Source
Slice Thickness	0018,0050	DS		ALWAYS	AUTO
Image Position (Patient)	0020,0032	DS		ALWAYS	AUTO
Image Orientation (Patient)	0020,0037	DS		ALWAYS	AUTO
Pixel Spacing	0028,0030	DS		ALWAYS	AUTO
Slice Location	0020,1041	DS		ALWAYS	AUTO

Table 42: Voi Lut Module

Attribute Name	Tag	CS	Value	Presence of value	Source
Window Center	0028,1050	DS	32767.5	ALWAYS	AUTO
Window Width	0028,1051	DS	65535	ALWAYS	AUTO

Table 43: Frame of Reference Module

Attribute Name	Tag	CS	Value	Presence of value	Source
Frame of Reference UID	0020,0052	UI		ALWAYS	AUTO
Position Reference Indicator	0020,1040	LO		ALWAYS	AUTO

Table 44: Sop Common Module

Attribute Name	Tag	CS	Value	Presence of value	Source
Specific Character Set	0008,0005	CS	ISO_IR 100	ALWAYS	AUTO
SOP Class UID	0008,0016	UI	1.3.46.760589.2.4.1.1	ALWAYS	AUTO
SOP Instance UID	0008,0018	UI		ALWAYS	AUTO

8.1.2 Usage of Attributes from Received IOD's

Each application that depends on certain fields to function correctly should specify which ones are required for it to perform its intended function.

8.1.3 Attribute Mapping

When attributes are used by different SOP Classes (e.g. Modality Worklist, Storage and Modality Performed Procedure Step) this mapping shall be specified. For devices that specify other external protocols (such as HL7) mapping of their fields into the DICOM attributes is not required but highly recommended.

8.1.4 Coerced/Modified fields

An SCU might coerce certain attributes, e.g. the Patient's Name. An SCP might provide a different value of an attribute than was received. These changes shall be specified here. An example is Patient's Name, which could be modified using available information from either an internal database or obtained from an Information System/Information Manager. Another example is the generation of a new SOP Instance UID for an existing instance. The conditions influencing such coercion should be specified.

8.2 Data Dictionary of Private Attributes

Not applicable

8.3 Coded Terminology and Templates

Not applicable

8.4 Grayscale Image consistency

Any support for the DICOM Grayscale Standard Display Function will be specified in this section.

8.5 Standard Extended/Specialized/Private SOPs

Table 45: Mapping between UI elements and DICOM attributes

DICOM Attribute name	Tag	UI element	Note
Patient's Name	(0010,0010)	Patient Name	
Patient Sex	(0010, 0040)	Patient Sex	
Patient's Birth Date	(0010, 0030)	Patient Birthdate	
Patient ID	(0010, 0020)	Patient Id	
Study ID	(0020, 0010)	Exam Id	The User Interface "Exam ID" can be Study ID, Accession Number, Requested Procedure ID or the Study Instance UID, depending on the configuration setting.
Accession Number	(0008,0050)	Exam Id	
Study Instance UID	(0020,000D)	Exam Id	
Requested Procedure ID	(0040,1001)	Exam Id	
Study Date	(0008, 0020)	Exam Date	
Series Date	(0008, 0021)	Run Date	
Series Time	(0008, 0031)	Run Time	
Series Number	(0020, 0011)	Run Number	

8.6 Private Transfer Syntaxes

Not applicable.