

AGFA HEALTHCARE DICOM Conformance Statement



IMPAX HeartStation 1.5

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Conformance Statement Overview

IMPAX HeartStation will create and consume DICOM Waveform and DICOM Encapsulated PDF objects. The following services are supported by HeartStation:

Table 1.1-1: Network Services Supported

DICOM SOP Class Name	User of Service (SCU)	Provider of Service (SCP)
Transfer		
12-lead ECG Waveform Storage	No	Yes
Encapsulated PDF Storage	Yes	Yes
Workflow Management		
Modality Worklist Information Model - FIND	Yes	No

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1 INTRODUCTION

1.1 Revision Record

DICOM Conformance Statement IMPAX HeartStation 1.5		
Revision Number	Date	Reason for Change
1.0	August 29, 2012	Initial version for HeartStation 1.5

1.2 Purpose and Intended Audience of this Document

This document is a DICOM Conformance Statement for the DICOM Services of the HeartStation product. It is written according to part PS 3.2 of Digital Imaging and Communications in Medicine (DICOM) 3.0, NEMA PS 3.1-3.16, 2008.

The user of this document is involved with system integration and/or software design. We assume that the reader is familiar with the terminology and concepts that are used in the DICOM 3.0 standard and the IHE Technical Framework.

Readers not familiar with DICOM 3.0 terminology should first read the appropriate parts of the DICOM standard itself, prior to reading this conformance statement.

1.3 General Remarks

1.3.1 Integration and Validation Activities

The integration of any device into a system of interconnected devices goes beyond the scope of the DICOM 3.0 standard and this conformance statement when *interoperability* is desired. The responsibility for analyzing the applications requirements and developing a solution that integrates the Agfa equipment with other vendors' systems is the user's responsibility and should not be underestimated.

In some circumstances it might be necessary to perform a validation to make sure that functional interoperability between the Agfa equipment and non-Agfa devices works as expected. The user should ensure that any non-Agfa provider accepts responsibility for any validation required for their connection with the Agfa equipment.

1.3.2 Future Evolution

As the DICOM 3.0 standard evolves to meet the user's growing requirements and to incorporate new features and technologies, Agfa will follow the evolution of the standard. This evolution of the standard may require changes to devices that have implemented DICOM 3.0. The user should ensure that any non-Agfa provider, who connects with Agfa devices, also plans for future evolution of the DICOM standard. A refusal to do so may result in the loss of functionality and/or connectivity between the different products.

1.4 Acronyms and Abbreviations

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

AE	DICOM Application Entity
DICOM	Digital Imaging and Communications in Medicine
GUI	Graphical User Interface
IHE	Integrating the Healthcare Enterprise
IOD	(DICOM) Information Object Definition
PACS	Picture Archive and Communications System
SCU	DICOM Service Class User (DICOM client)
SCP	DICOM Service Class Provider (DICOM server)
SOP	DICOM Service-Object Pair
UID	Unique Identifier
UTF-8	Unicode Transformation Format - 8
VR	Value Representation

1.5 Related Documents

- ACR-NEMA Digital Imaging and Communications in Medicine (DICOM) V3.0.2008
- IHE Radiology Technical Framework Revision 5.5 – Final Text, November 20, 2003
- Health Level Seven standard version 2.3.1

2 NETWORKING

2.1 Implementation Model

2.1.1 Application Data Flow Diagram

The Application Data Flow Diagram in Figure 2.1-1 depicts the DICOM data flow to and from HeartStation. The tail of the arrow between HeartStation and the remote real world activity indicates the party that initiates the association negotiation.

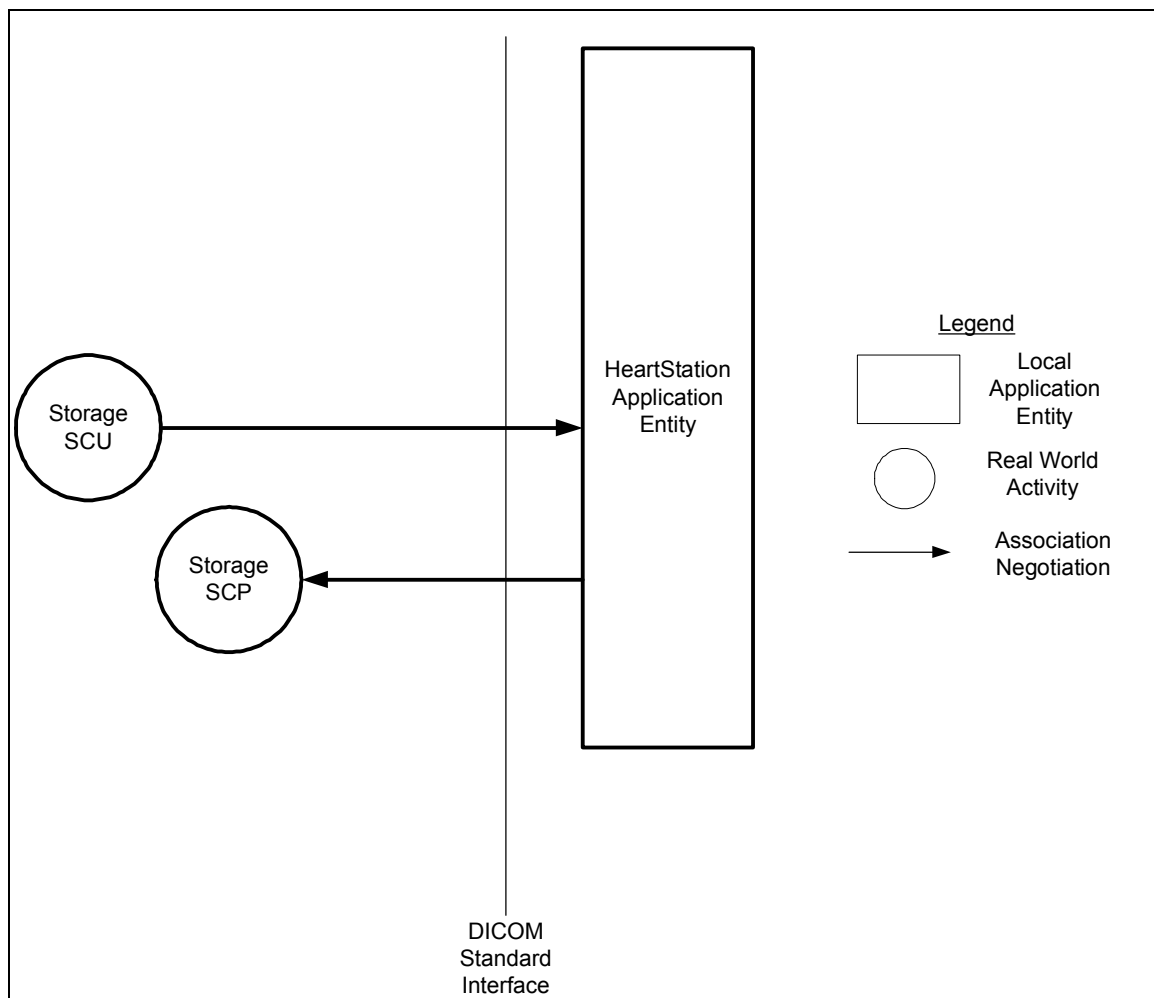


Figure 2.1-1: Functional Overview – Application Data Flow

2.1.2 Functional Definitions of AE's

This section will provide a brief description of the various application entities that are included as a part of HeartStation.

2.1.2.1 Functional Capability of SCP

The HeartStation SCP is capable of receiving 12-lead ECG Waveform Storage and Encapsulated PDF Storage requests.

2.1.2.2 Functional Capability of SCU

The HeartStation SCU is capable of sending Encapsulated PDF Storage messages.
The HeartStation SCU is capable of sending Modality Worklist Queries.

2.2 AE Specifications

2.2.1 HeartStation Specification

2.2.1.1 SOP Classes Supported

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

Table 2.2-1: SOP Classes for HeartStation

SOP Class Name	SOP Class UID	SCU	SCP
12-lead ECG Waveform Storage	1.2.840.10008.5.1.4.1.1.9.1.1	No	Yes
Encapsulated PDF Storage	1.2.840.10008.5.1.4.1.1.104.1	Yes	Yes
Modality Worklist Information Model - FIND	1.2.840.10008.5.1.4.31	Yes	No

2.2.1.2 Association Establishment Policies

2.2.1.2.1 General

The DICOM standard Application context shall be specified.

Table 2.2-2: DICOM Application Context

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

2.2.1.2.2 Number of Associations

The maximum number of simultaneous associations accepted by HeartStation is not constrained. There is no inherent limit to the number of associations other than limits imposed by the computer operating system.

2.2.1.2.3 Asynchronous Nature

HeartStation allows a single outstanding operation on any association. Therefore, HeartStation does not support asynchronous operations window negotiation, other than the default as specified by the DICOM specification.

2.2.1.2.4 Implementation Identifying Information

HeartStation will respond with the following implementation identifying parameters:

Table 2.2-3: DICOM implementation Class and Version for Verification

SCP Identification Parameters	
Implementation Class UID	1.2.40.0.13.1.1
Implementation Version Name	dcm4che-1.4.28
SCU Identification Parameters	
Implementation Class UID	1.2.40.0.13.1.1
Implementation Version Name	dcm4che-1.4.28

2.2.1.3 Association Initiation Policies

2.2.1.3.1 Activity – SCU

2.2.1.3.1.1 Description and Sequencing of Activity

HeartStation will act as an SCU to store an Encapsulated PDF Storage objects.
HeartStation will act as an SCU to perform Modality Worklist queries.

2.2.1.3.1.2 Proposed Presentation Contexts

Table 2.2-4: Presentation Contexts Proposed

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Extended Negotiation
Name	UID	Name List	UID List		
Encapsulated PDF Storage	1.2.840.10008.5.1.4.1.1.104.1	Implicit VR Little Endian	1.2.840.10008.1.2	SCU	None
		Explicit VR Little Endian	1.2.840.10008.1.2.1		
Modality Worklist Information Model - FIND	1.2.840.10008.5.1.4.31	Implicit VR Little Endian	1.2.840.10008.1.2	SCU	None
		Explicit VR Little Endian	1.2.840.10008.1.2.1		

2.2.1.3.2 SOP Specific Conformance for Encapsulated PDF IOD Storage

HeartStation creates an Encapsulated PDF object with the following DICOM attributes. All attributes conform to the Encapsulated PDF IOD class specification.

Table 2.2-5: Encapsulated PDF IOD Storage Attributes

Module	Attribute Name	Tag	Value
Patient	Patient's Name	(0010,0010)	ECG patient first and last names
	Patient ID	(0010,0020)	ECG patient id
	Patient's Birth Date	(0010,0030)	ECG birth date
	Patient's Sex	(0010,0040)	ECG patient gender
General Study	Study Instance UID	(0020,000D)	Generated by HeartStation using the following components: AGFA prefix: 1.2.124.113532
	Study Date	(0008,0020)	ECG acquisition date
	Study Time	(0008,0030)	ECG acquisition time
	Referring Physician's Name	(0008,0090)	From ECG or unvalued
	Study ID	(0020,0010)	From ECG, or unvalued
	Accession Number	(0008,0050)	From HIS, or unvalued
Encapsulated Document Series	Modality	(0008,0060)	"DOC"
	Series Instance UID	(0020,000E)	Created using the following components: AGFA prefix: 1.2.124.113532
	Series Number	(0020,0011)	"1"
	Series Description	(0008,103E)	"ECG Report - Embedded PDF"
General Equipment	Manufacturer	(0008,0070)	"Agfa"
SC Equipment	Conversion Type	(0008,0064)	"SD"
Encapsulated Document	Instance Number	(0020,0013)	"1"
	Content Date	(0008,0023)	Same value as Study Date
	Content Time	(0008,0033)	Same value as Study Time
	Acquisition DateTime	(0008,002A)	From ECG
	Burned In Annotation	(0028,0301)	"YES"
	Document Title	(0042,0010)	"ECG Report"
	> Concept Code Name Sequence	(0040,A043)	-
	>> Code Value	(0008,0100)	"ECG Report"
	>> Coding Scheme Designator	(0008,0102)	"ECG Report"
	>> Code Meaning	(0008,0104)	"1.1"
	>> Code Scheme Version	(0008,0103)	"1"
	MIME Type of Encapsulated Document	(0042,0012)	"application/pdf"
	Encapsulated	(0042,0011)	Encapsulated Document
	Verification Flag	(0040,A493)	If ECG was confirmed, then value is VERIFIED, if ECG was not confirmed value is "UNVERIFIED"
SOP Common	SOP Class UID	(0008,0016)	"1.2.840.10008.5.1.4.1.1.104.1"
	SOP Instance UID	(0008,0018)	Generated by HeartStation using the following components: AGFA prefix: 1.2.124.113532
	Instance Creation Date	(0008,0012)	Date ECG is acquired
	Instance Creation Time	(0008,0013)	Time ECG is acquired
SOP Common	Specific Character Set	(0008,0005)	"ISO_IR 100"

2.2.1.3.3 SOP Specific Conformance for Modality Worklist Queries

HeartStation provides standard conformance to the DICOM Modality Worklist Information Model Class as an SCU. The DICOM attributes that are utilized by HeartStation when issuing a DICOM Modality Worklist request are listed in Table 2.2-6. Queries are only by Patient ID (0010,0020)

Table 2.2-6: Attributes for the Modality Worklist Information Model

Attribute	Tag
Accession Number	(0008,0050)
Admission ID	(0038,0010)
Current Patient Location	(0038,0300)
Patient's Birth Date	(0010,0030)
Patient's Name	(0010,0010)
Patient's Sex	(0010,0040)
Patient's Race	(0010,2160)
Patient's State	(0038,0500)
Patient ID	(0010,0020)
Requested Procedure Description	(0032,1060)
Requested Procedure Code	(0032,1064)
Requesting Physician	(0032,1032)
Scheduled Procedure Step Start Date	(0040,0002)
Scheduled Procedure Step Start Time	(0040,0003)
Scheduled Procedure Step Status	(0040,0020)
Placer Order Number	(0040,2016)
Filler Order Number	(0040,2017)

2.2.1.3.4 Activity – SCP

2.2.1.3.4.1 Description and Sequencing of Activity

HeartStation will act as an SCP to receive 12-lead ECG Waveform Storage and Encapsulated PDF Storage objects.

2.2.1.3.5 Proposed Presentation Contexts

Table 2.2-7: Presentation Contexts Proposed

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Extended Negotiation
Name	UID	Name List	UID List		
12-lead ECG Waveform Storage	1.2.840.10008.5.1.4.1.1.9.1.1	Implicit VR Little Endian Explicit VR Little Endian	1.2.840.10008.1.2 1.2.840.10008.1.2.1	SCP	None
Encapsulated PDF Storage	1.2.840.10008.5.1.4.1.1.104.1	Implicit VR Little Endian Explicit VR Little Endian	1.2.840.10008.1.2 1.2.840.10008.1.2.1	SCP	None

2.2.1.3.6 SOP Specific Conformance for Encapsulated PDF IOD Storage

HeartStation accepts an Encapsulated PDF object and uses the following DICOM attributes. All attributes conform to the Encapsulated PDF IOD class specification.

Table 2.2-8: Encapsulated PDF IOD Storage Attributes

Module	Attribute Name	Tag	Notes
Patient	Patient's Name	(0010,0010)	
	Patient ID	(0010,0020)	
	Patient's Birth Date	(0010,0030)	Optional
	Patient's Sex	(0010,0040)	Optional
Patient Demographics	Patient's Height	(0010,1020)	Optional
	Patients Weight	(0010,1030)	Optional
General Study	Referring Physician's Name	(0008,0090)	Optional
	Accession Number	(0008,0050)	Optional
General Series	Performing Physicians' Name	(0008,1050)	Optional
Encapsulated Document	Acquisition DateTime	(0008,002A)	
SOP Common	SOP Class UID	(0008,0016)	"1.2.840.10008.5.1.4.1.1.104.1"
	Specific Character Set	(0008,0005)	Must be "ISO_IR 100"

2.2.1.3.7 SOP Specific Conformance for 12-lead ECG Waveform Storage

HeartStation accepts a 12-lead ECG Waveform Storage object and uses the following DICOM attributes.

Table 2.2-9: 12-lead ECG Waveform Storage Attributes

Module	Attribute Name	Tag	Notes
Patient	Patient's Name	(0010,0010)	
	Patient ID	(0010,0020)	
	Patient's Birth Date	(0010,0030)	Optional
	Patient's Sex	(0010,0040)	Optional
Patient Demographics	Patient's Height	(0010,1020)	Optional
	Patients Weight	(0010,1030)	Optional
	Patient's Age	(0010,1010)	Optional
General Study	Referring Physician's Name	(0008,0090)	Optional
	Accession Number	(0008,0050)	Optional
General Series	Performing Physicians' Name	(0008,1050)	Optional
	Operators' Name	(0008,1070)	Optional
General Equipment	Manufacturer	(0008,0070)	Optional
	Institution Address	(0008,0081)	Optional
	Institution Name	(0008,0080)	Optional
	Station Name	(0008,1010)	Optional
	Manufacturer's Model Name	(0008,1090)	Optional
	Device Serial Number	(0018,1000)	Optional
	Software Versions	(0018,1020)	Optional

Module	Attribute Name	Tag	Notes
SOP Common	SOP Class UID	(0008,0016)	"1.2.840.10008.5.1.4.1.1.9.1.1"
	Specific Character Set	(0008,0005)	Must be "ISO_IR 100"
Waveform Identification	Acquisition DateTime	(0008,002A)	
Waveform Module	Waveform Sequence	(5400,0100)	
	>Waveform Originality	(003A,0004)	
	>Number of Waveform Channels	(003A,0005)	
	>Number of Waveform Samples	(003A,0010)	
	>Sampling Frequency	(003A,001A)	
	>Waveform Data	(5400,1010)	
	>Channel Definition Sequence	(003A,0200)	
	>>Channel Sensitivity	(003A,0210)	
	>>Channel Sensitivity Units Sequence	(003A,0211)	
	>>>Code Value	(0008,0010)	Must be on of mV, nV, or V
	>>Filter Low Frequency	(003A,0220)	
	>>Filter High Frequency	(003A,0221)	
	>>Notch Filter Frequency	(003A,0222)	
	>>Channel Baseline	(003A,0213)	
Waveform Annotation	Waveform Annotation Sequence	(0040,B020)	
	Measurements are obtained from the following sequence structure		
	>Concept Name Code Sequence	(0040,A043)	On sequence per measurement
	>>Code Meaning	(0008,0104)	P Duration, P Axis, PP Interval, PR Interval, QRS Axis, QRS Duration, QTc Interval, QT Interval, RR Interval, T Axis
	>Numeric Value	(0040,A30A)	Value of measurement
	Statements are obtained from the following sequence structure		
	>Concept Name Code Sequence	(0040,A043)	On sequence per statement, up to 10 supported
	>Unformatted Text Value	(0070,0006)	Statement text

2.3 Network Interfaces

HeartStation provides DICOM V3.0 TCP/IP Network Communication Support as defined in PS 3.8 of the DICOM Standard. HeartStation inherits its TCP/IP stack from the computer system upon which it executes.

2.3.1 Physical Medium Support

HeartStation is indifferent to the physical medium over which TCP/IP executes; it inherits the medium from the computer system upon which it is being executed.

2.4 Configuration

HeartStation configuration parameters that affect its DICOM conformance are described in this section.

2.4.1 Configuration Parameters

The following table lists all of the DICOM parameters that can be configured via the HeartStation.

Table 2.4-1: Configuration Parameter Table

Parameter	Configurable (Yes/No)	Default Value
General Parameters		
Listening Port	Yes	10104
Maximum number of simultaneous Associations	Yes	10
Time-out waiting for A-ASSOCIATE RQ on open TCP/IP connection (ARTIM timeout)	Yes	5s
Time-out waiting on an open association for the next message (DIMSE timeout)	Yes	No timeout
Time-out waiting for acceptance or rejection Response to an Association Open Request. (Application Level timeout)	No	No timeout
Time-out waiting on an open association for the next message after sending A-RELEASE RSP or A-ABORT RQ (Closing timeout)	Yes	500ms
Maximum PDU size the AE can receive	Yes	16352
Maximum PDU size the AE can send	No	65535
Pack Command and Data PDVs in one PDU	Yes	False
Support for the Basic TLS Secure Transport Connection Profile	Yes	Off
Accepted TLS Ciphers	Yes	-
Storage Server AE Parameters		
Accepted Called AETs	Yes	Any
MWL SCU AE Parameters		
Accepted Called AE Title	Yes	MWLQuery
MWL SCP IP address	Yes	0.0.0.0
DICOM MWL Port	Yes	3320
Accepted Calling AE Title	Yes	SERVERNAME
Supported SOP Class	No	Modality Worklist Information Model – FIND
Transfer Syntax	Yes	ExplicitVRLittleEndian, ImplicitVRLittleEndian

3 SUPPORT FOR EXTENDED CHARACTER SETS

HeartStation supports ISO_IR 100 (ISO 8859-1 Latin 1) as an extended character set.

4 SECURITY

4.1 Security Profiles

HeartStation supports secure DICOM communication in conformance with the Basic TLS Secure Transport Connection Profile. At default configuration, the TLS option is deactivated.

4.2 Association Level Security

HeartStation can be configured to accept Association Requests from only a limited list of Calling AE Titles.

4.3 Application Level Security

HeartStation web module can be configured to require user authentication in order to access the user interface functionalities.