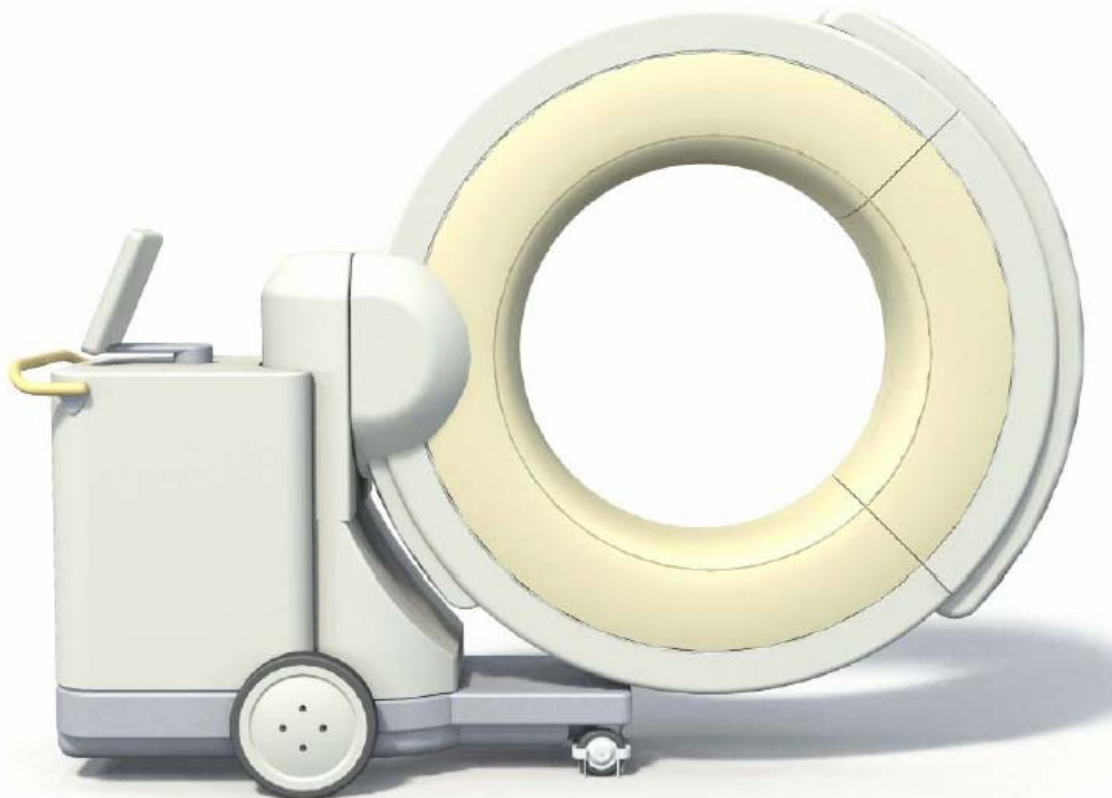

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O-Arm 1000 Imaging System DICOM Conformance Statement

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1 Conformance Statement Overview

The O-arm Imaging System of Medtronic Navigation, Inc is a 2D and 3D imaging generating system. The system supports downloading worklist from an information system, and sending locally created images across the network to another system. It is also supports saving images to CD.

The following table provides an overview of the network services supported by O-arm Imaging System.

NETWORK SERVICES

SOP Classes	User of Service (SCU)	Provider of Service (SCP)
Transfer		
CT Image Storage	Yes	No
X-Ray Angiographic Image Storage	Yes	No
X-Ray Radiofluoroscopic Image Storage	Yes	No
Workflow Management		
Modality Worklist	Yes	No

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3 Introduction

3.1 Scope and Field

The scope of this DICOM Conformance Statement is to facilitate data exchange between equipment of Medtronic Navigation, Inc and with equipment of other vendors. This document specifies the compliance to the DICOM standard. It contains a short description of the applications involved and provides technical information about the data exchange capabilities of the equipment. The main elements describing these capabilities are: the supported DICOM Service Object Pair (SOP) Classes, Roles, Information Object Definitions (IOD), Service Elements and Transfer Syntaxes. The field of application is the integration of the Medtronic Navigation, Inc equipment into an environment of medical devices. This Conformance Statement should be read in conjunction with the DICOM standard and its addenda.

3.2 Intended Audience

This Conformance Statement is intended for:

- (potential) clients,
- marketing staff interested in data exchange functionality,
- system integrators and Customer Support Engineers of medical equipment,
- software engineers implementing DICOM interfaces.

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

3.3 Contents and Structure

The DICOM Conformance Statement is contained in section 2 through 7 and follows the contents and structuring requirements of NEMA. Additionally, the sections following 7 (if present) specify the details of the applied IODs and Service Elements.

3.4 Used definitions, terms and abbreviations

DICOM definitions, terms and abbreviations are used throughout this Conformance Statement. For a description of these, see NEMA PS 3.3-2006 and PS 3.4-2006. The word Medtronic in this document refers to Medtronic Navigation, Inc.

3.5 References

[DICOM] Digital Imaging and Communications in Medicine (DICOM), NEMA PS 3.4-2006

3.6 Important note to the reader

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

Medtronic Navigation, Inc. (Littleton) MNL**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 a networked 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 Medtronic equipment with non-Medtronic equipment. It is the user's responsibility to analyze thoroughly the application requirements and to specify a solution that integrates Medtronic equipment with non-Medtronic equipment.

Validation

Medtronic equipment has been carefully tested to assure that the actual implementation of the DICOM interface corresponds with this Conformance Statement. Where Medtronic equipment is linked to non-Medtronic 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 the future to meet the user's growing requirements and to incorporate new features and technologies. Medtronic is actively involved in this evolution and plans to adapt its equipment to future versions of the DICOM Standard. In order to do so, Medtronic reserves the right to make changes to its products or to discontinue its delivery. The user should ensure that any non-Medtronic provider linking to Medtronic equipment also adapts to future versions of the DICOM Standard. If not, the incorporation of DICOM enhancements into Medtronic equipment may lead to loss of connectivity (in case of networking) and incompatibility (in case of media).

3.7 Acronyms and Abbreviations

The following acronyms and abbreviations are used in the document.

- ACC American College of Cardiology
- AE Application Entity
- ACR American College of Radiology
- ANSI American National Standard Institute
- BOT Basic Offset Table
- CD-R CD Recordable
- CD-M CD Medical
- DCI Digital Cardio Imaging
- DCR Dynamic Cardio Review
- DICOM Digital Imaging and Communication in Medicine
- DIMSE DICOM Message Service Element
- DIMSE-C DICOM Message Service Element-Composite

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- DIMSE-N DICOM Message Service Element-Normalized
- ELE Explicit VR Little Endian
- EBE Explicit VR Big Endian
- FSC File Set Creator
- GUI Graphic User Interface
- HIS Hospital Information System
- HL7 Health Level Seven
- ILE Implicit VR Little Endian
- IOD Information Object Definition
- ISIS Information System - Imaging System
- MPPS Modality Performed Procedure Step
- NEMA National Electrical Manufacturers Association
- PACS Picture Archiving and Communication System
- PDU Protocol Data Unit
- RIS Radiology Information System
- RWA Real World Activity
- SC 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

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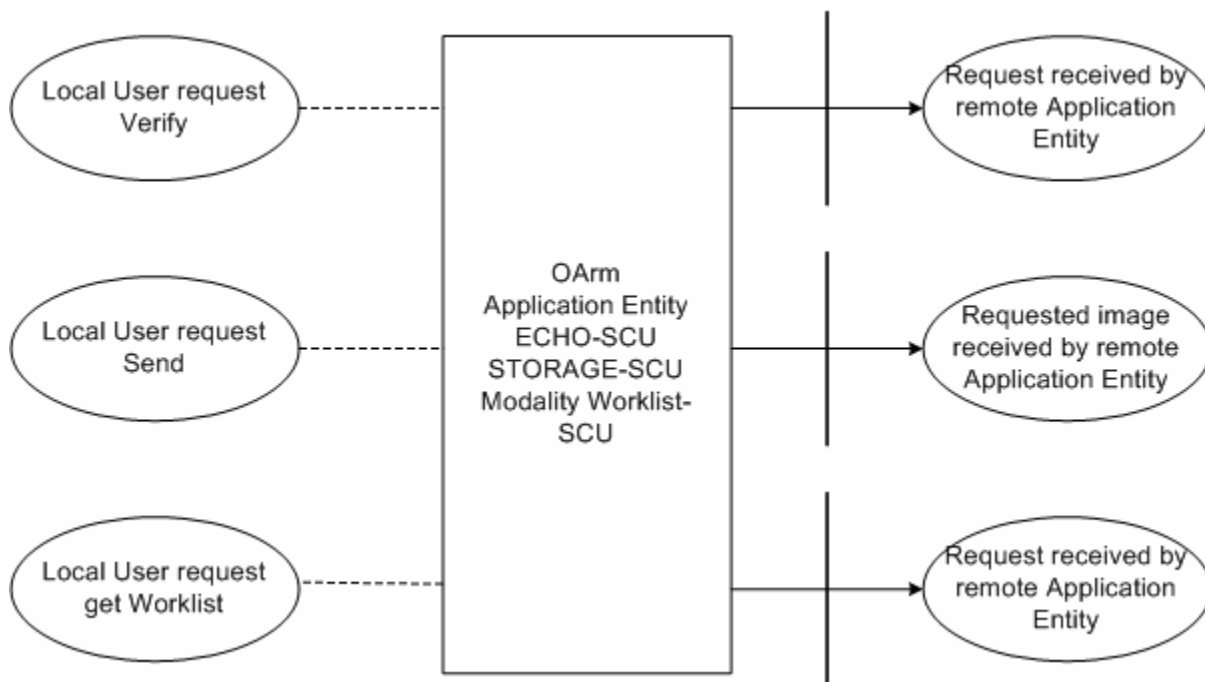
4 Networking

4.1 Implementation Model

4.1.1 Application Data Flow Diagram

The product target Operating System is Windows XP Professional.

The O-Arm DICOM network implementation acts as SCU for the verification, storage, and modality worklist network service.



4.1.2 Functional Definition of AE's

4.1.2.1 ECHO-SCU

ECHO-SCU is activated through the user interface when a user requests to verify a connection to the remote AE when configuring the list of remote AEs. It is also activated once per user request when user requests to send images to a remote AE.

4.1.2.2 STORAGE-SCU

STORAGE-SCU is activated through the user interface when a user selects instances from the local images and requests to send them to a remote AE (selected from a pre-configured list).

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4.1.2.3 Modality Worklist –SCU

Modality Worklist–SCU is activated through the user interface when user requests worklist from an information system. The query dialog allows user to enter specific criteria for the worklist query. All information retrieved is displayed in the list. The user can select items from the list and import them into the local database.

4.1.3 Sequencing of Real-World Activities

All SCU activities are sequentially initiated in the user interface, and another activity may not be initiated until the prior activity has completed. The application requires successful response to Verification request before Storage request can be made. If multiple images are selected for storage, the storage requests are sent sequentially, if one fails, no attempts are made to send storage requests for the subsequent images.

4.2 AE Specifications

4.2.1 O-arm Application Entity Specification

4.2.1.1 SOP Classes

The O-arm Application Entity provide standard conformance to the following SOP Classes as a SCU:

Supported DICOM SOP Classes

SOP Class Name	SOP Class UID
Verification	1.2.840.10008.1.1
CT Image Storage	1.2.840.10008.5.1.4.1.1.2
X-Ray Angiographic Image Storage	1.2.840.10008.5.1.4.1.1.12.1
X-Ray Radiofluoroscopic Image Storage	1.2.840.10008.5.1.4.1.1.12.2
Modality Worklist Information Model – FIND	1.2.840.10008.5.1.4.31

4.2.1.2 Association Establishment Policies

4.2.1.2.1 General

4.2.1.2.2 Number of Associations

The O-arm AE supports a single association at a time.

4.2.1.2.3 Asynchronous Nature

The asynchronous operations are not supported.

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4.2.1.2.4 Implementation Identifying Information

Implementation Class UID 1.2.826.0.1.3680043.1.1.4.2.175.2

Implementation Version Name DCMOBJ4.2.175.2

4.2.1.3 Association Initiation Policy

4.2.1.3.1 Activity -Verification

4.2.1.3.1.1 Description and Sequencing of Activities

When a user configures the DICOM Store Server he can try to connect to the configured server and verify the connection.

When a user selects the DICOM Store Server as the destination for sending images, the application first tries to verify the connection before sending images.

4.2.1.3.1.2 Proposed Presentation Context

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Extended Negotiation
Name	UID	Name	UID		
Verification SOP Class	1.2.840.10008.1.1	Explicit Little Endian	1.2.840.10008.1.2.1	SCU	None
		Implicit Little Endian	1.2.840.10008.1.2		
		JPEG Lossless	1.2.840.10008.1.2.4.57		
		RLE	1.2.840.10008.1.2.5		
		JPEG lossy	1.2.840.10008.1.2.4.51		

4.2.1.3.2 Activity – Image Storage

4.2.1.3.2.1 Description and Sequencing of Activities

When a user requests to send images, the O-arm AE first performs verification. If verification is successful, the application negotiates an association, sends all the images over it, and then closes it.

4.2.1.3.2.2 Proposed Presentation Context

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Extended Negotiation
Name	UID	Name	UID		
CT Image Storage	1.2.840.10008.5.1.4.1.1.2	Explicit Little Endian	1.2.840.10008.1.2.1	SCU	None
		Implicit	1.2.840.10008.1.2		

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		Little Endian			
		JPEG Lossless	1.2.840.10008.1.2.4.57		
		RLE	1.2.840.10008.1.2.5		
		JPEG lossy	1.2.840.10008.1.2.4.51		
X-Ray Angiographic Image Storage	1.2.840.10008.5.1.4.1.1.1 2.1	Explicit Little Endian	1.2.840.10008.1.2.1	SCU	None
		Implicit Little Endian	1.2.840.10008.1.2		
		JPEG Lossless	1.2.840.10008.1.2.4.57		
		RLE	1.2.840.10008.1.2.5		
		JPEG lossy	1.2.840.10008.1.2.4.51		
X-Ray Radiofluoroscopic Image Storage	1.2.840.10008.5.1.4.1.1.1 2.2	Explicit Little Endian	1.2.840.10008.1.2.1	SCU	None
		Implicit Little Endian	1.2.840.10008.1.2		
		JPEG Lossless	1.2.840.10008.1.2.4.57		
		RLE	1.2.840.10008.1.2.5		
		JPEG lossy	1.2.840.10008.1.2.4.51		

4.2.1.3.2.3 SOP Specific Conformance for SOP Classes

The following tables use a number of abbreviations. The abbreviations used in the "Presence of Value" column 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

CT Image Storage

Attribute Name	Tag ID	Value/ Remarks	Presence of value
Specific Character Set	0008,0005	ISO_IR 100	ALWAYS

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Image Type	0008, 0008	Derived, Primary, Axial	ALWAYS
SOP Class UID	0008, 0016	1.2.840.10008.5.1.4.1.1.2 (CT)	ALWAYS
SOP Instance UID	0008, 0018	Device generated	ALWAYS
Study Date	0008, 0020	<yyyymmdd>	ALWAYS
Series Date	0008, 0021	<yyyymmdd>	ALWAYS
Image Date	0008, 0023	<yyyymmdd>	ALWAYS
Study Time	0008, 0030	<hhmmss.frac>	ALWAYS
Series Time	0008, 0031	<hhmmss.frac>	ALWAYS
Image Time	0008, 0033	<hhmmss.frac>	ALWAYS
Accession Number	0008, 0050	From Modality Worklist or User Input	VNAP
Modality	0008, 0060	CT	ALWAYS
Manufacturer	0008, 0070	Medtronic	ALWAYS
Institution Name	0008, 0080	Configurable by admin user	VNAP
Referring Physician	0008, 0090	From Modality Worklist or empty	VNAP
Station Name	0008,1010	Configurable by admin user	
Study Description	0008, 1030	User input	ANAP
Performing Physician	0008, 1050	From Modality Worklist or User Input	ANAP
Patient Name	0010, 0010	From Modality Worklist or User Input	VNAP
Patient ID	0010, 0020	From Modality Worklist or User Input	VNAP
Patient Date of Birth	0010, 0030	From Modality Worklist or User Input	VNAP
Sex	0010, 0040	From Modality Worklist or User Input	VNAP
Slice Thickness	0018, 0050	Device generated	ALWAYS
KVp	0018, 0060		VNAP
Exposure Time	0018, 1150		VNAP
X-ray Tube Current - mA	0018, 1151		VNAP
Exposure	0018, 1152		VNAP
Patient Position	0018, 5100		VNAP
Study Instance UID	0020,000D	From Modality Worklist or device generated	ALWAYS
Series Instance UID	0020,000E	Device generated	ALWAYS
Study ID	0020, 0010	Device generated	ALWAYS
Series Number	0020, 0011	Device generated	ALWAYS
Acquisition Number	0020, 0012		VNAP
Image Number	0020, 0013	Device generated	ALWAYS
Image Position (Patient)	0020,0032	Device generated based on user input	ALWAYS
Image Orientation (Patient)	0020,0037	Device generated based on user input	ALWAYS
Dicom Frame Of Reference UID	0020, 0052	Device generated	ALWAYS
Series in Study	0020,1000	Device generated	ALWAYS
Position Reference Indicator	0020, 1040		VNAP
Samples Per Pixel	0028, 0002	1	ALWAYS
Photometric Interpretation	0028, 0004	MONOCHROME2	ALWAYS
Number Of Frames	0028, 0008	1	
Rows	0028, 0010	Device generated	ALWAYS
Columns	0028, 0011	Device generated	ALWAYS

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Pixel Spacing	0028,0030	Device generated	ALWAYS
Bits Allocated	0028, 0100	16	ALWAYS
Bits Stored	0028, 0101	Configured by Administrator <=16	ALWAYS
High Bit	0028, 0102	Bits Stored -1	ALWAYS
Pixel Representation	0028, 0103	0	ALWAYS
Window Center	0028, 1050	Device generated	ALWAYS
Window Width	0028, 1051	Device generated	ALWAYS
Rescale Intercept	0028, 1052	0	ALWAYS
Rescale Slope	0028, 1053	1	ALWAYS

**X-Ray Angiographic Image Storage
 X-Ray Radiofluoroscopic Image Storage**

Attribute Name	Tag ID	Value/ Remarks	Presence of value
Specific Character Set	0008,0005	ISO_IR 100	ALWAYS
Image Type	0008, 0008	ORIGINAL : PRIMARY : SINGLE PLANE	ALWAYS
SOP Class UID	0008, 0016	1.2.840.10008.5.1.4.1.1.12.1(XA) 1.2.840.10008.5.1.4.1.1.12.2(RF)	ALWAYS
SOP Instance UID	0008, 0018	Device generated	ALWAYS
Study Date	0008, 0020	<yyyymmdd>	ALWAYS
Series Date	0008, 0021	<yyyymmdd>	ALWAYS
Image Date	0008, 0023	<yyyymmdd>	ALWAYS
Study Time	0008, 0030	<hhmmss.frac>	ALWAYS
Series Time	0008, 0031	<hhmmss.frac>	ALWAYS
Image Time	0008, 0033	<hhmmss.frac>	ALWAYS
Accession Number	0008, 0050	From Modality Worklist or User Input	VNAP
Modality	0008, 0060	XA RF	ALWAYS
Manufacturer	0008, 0070	Medtronic	ALWAYS
Institution Name	0008, 0080	Configurable by admin user	ANAP
Referring Physician	0008, 0090	From Modality Worklist or empty	VNAP
Station Name	0008,1010	Configurable by admin user	
Study Description	0008, 1030	User input	ANAP
Performing Physician	0008, 1050	From Modality Worklist or User Input	ANAP
Patient Name	0010, 0010	From Modality Worklist or User Input	VNAP
Patient ID	0010, 0020	From Modality Worklist or User Input	VNAP
Patient Date of Birth	0010, 0030	From Modality Worklist or User Input	VNAP
Sex	0010, 0040	From Modality Worklist or User Input	VNAP
Slice Thickness	0018, 0050	Device generated	ALWAYS
KVp	0018, 0060		VNAP
Exposure Time	0018, 1150		VNAP
X-ray Tube Current - mA	0018, 1151		VNAP
Exposure	0018, 1152		VNAP
Radiation Setting	0018, 1155	SC	ALWAYS
Positioner Primary Angle	0018, 1510		VNAP
Positioner Secondary Angle	0018, 1511		VNAP

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Study Instance UID	0020,000D	From Modality Worklist or device generated	ALWAYS
Series Instance UID	0020,000E	Device generated	ALWAYS
Study ID	0020, 0010	Device generated	ALWAYS
Series Number	0020, 0011	Device generated	ALWAYS
Image Number	0020, 0013	Device generated	ALWAYS
Patient Orientation	0020, 0020	User Specified	ALWAYS
Laterality	0020, 0062		
Series in Study	0020,1000	Device generated	ALWAYS
Samples Per Pixel	0028, 0002	1	ALWAYS
Photometric Interpretation	0028, 0004	MONOCHROME2	ALWAYS
Number Of Frames	0028, 0008	1	ALWAYS
Rows	0028, 0010	Device generated	ALWAYS
Columns	0028, 0011	Device generated	ALWAYS
Pixel Spacing	0028,0030	Device generated	ALWAYS
Bits Allocated	0028, 0100	16	ALWAYS
Bits Stored	0028, 0101	Configured by Administrator <=16	ALWAYS
High Bit	0028, 0102	Bits Stored -1	ALWAYS
Pixel Representation	0028, 0103	0	ALWAYS
Pixel Intensity Relationship	0028, 1040	LIN	ALWAYS
Window Center	0028, 1050	Device generated	ALWAYS
Window Width	0028, 1051	Device generated	ALWAYS

4.2.1.3.3 Activity – Get Worklist

4.2.1.3.3.1 Description and Sequencing of Activities

The request for the worklist is initiated by the user interaction. The user is presented with dialog for entering search criteria. When query is started the data from dialog is used as matching keys for the query.

For each modality selected in the search criteria the application initiates an Association, sends request and waits for response.

Application merges all the responses for the selected modalities into one list and displays the combined list. User can select items from the list and import them into the local database.

4.2.1.3.3.2 Proposed presentation Context

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Ext. Neg.
Name	UID	Name	UID		

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Modality Worklist Information Model- FIND	1.2.840.10008.5.1.4.31	Explicit Little Endian	1.2.840.10008.1.2.1	SCU	None
		Implicit Little Endian	1.2.840.10008.1.2		
		JPEG Lossless	1.2.840.10008.1.2.4.57		
		RLE	1.2.840.10008.1.2.5		
		JPEG lossy	1.2.840.10008.1.2.4.51		

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4.2.1.3.3.3 SOP Specific conformance for Modality Worklist

The following tables describe the query Search Key Attributes.

Attribute Name	Tag	Value
Scheduled Procedure Step		
Scheduled Procedure Step Sequence	(0040,0100)	
>Modality	(0008,0060)	From UI or empty
>Scheduled Station AE Title	(0040,0001)	Own or empty
>Scheduled Procedure Step Start Date	(0040,0002)	Range from UI or empty
Patient Identification		
Patient's Name	(0010,0010)	From UI or empty
Patient ID	(0010,0020)	From UI or empty
Imaging Service Request		
Accession Number	(0008,0050)	From UI or empty

The following table describes Return Key Attributes.

An "x" in the **D** column indicates the attribute is displayed when browsing the Worklist results.

A tag in the **IOD** column will indicate that the related attribute is included into the SOP Instances of the IOD's created during processing of this worklist request. If this attribute represents an editable field in UI, the value is used as default for this field. If there is no editable field that corresponds to the attribute the value is used as is.

Module Name Attribute Name	Tag	D	IOD
Scheduled Procedure Step			
Scheduled Procedure Step Sequence	(0040,0100)	X	
>Modality	(0008,0060)	X	
>Scheduled Station AE Title	(0040,0001)	X	
>Scheduled Procedure Step Start Date	(0040,0002)	X	

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>Scheduled Procedure Step Start Time	(0040,0003)	X	
>Scheduled Performing Physician's Name	(0040,0006)	X	(0008,1050)
>Scheduled Procedure Step Description	(0040,0007)	X	
>Scheduled Action Item Code Sequence	(0040,0008)	X	
>>Code Value	(0008,0100)	X	
>>Coding Scheme Designator	(0008,0102)	X	
>>Coding Meaning	(0008,0104)	X	
>Scheduled Procedure Step ID	(0040,0009)	X	
>Scheduled Station Name	(0040,0010)	X	
Requested Procedure			
Study Instance UID	(0020,000D)	X	(0020,000D)
Requested Procedure ID	(0040,1001)	X	(0040,1001)
Requested Procedure description	(0032,1060)	X	(0032,1060)
Requested Procedure Code Sequence	(0032,1064)	X	
>Code Value	(0008,0100)	X	
>Coding Scheme Designator	(0008,0102)	X	
>Coding Meaning	(0008,0104)	X	
Imaging Service Request			
Accession Number	(0008,0050)	X	(0008,0050)
Referring Physician's Name	(0008,0090)	X	(0008,0090)
Requesting Physician	(0032,1032)	X	
Patient Identification			
Patient's Name	(0010,0010)	X	(0010,0010)
Patient ID	(0010,0020)	X	(0010,0020)
Patient Demographic			
Patient's Birth Date	(0010,0030)	X	(0010,0030)
Patient's Sex	(0010,0040)	X	(0010,0040)

4.2.1.4 Association Acceptance Policy

The O-Arm Imaging System Application Entity does not accept associations.

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4.3 Network Interfaces

4.3.1 Physical network Interface

The application inherits TCP/IP support from the underlying operating system.

4.3.2 Additional Protocols

When host names rather than IP addresses are used in the configuration properties to specify addresses for remote AEs, the application is dependent on the name resolution mechanism of the underlying operating system.