

☐ Product System (PS)

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Model Name: INNOSIGHT	Marketing Description :	

Model Name	InnoSight
DICOM Conformance Statement	

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History of Revision				
Version	Date	Authors	Department	Description
0	2017/2/17	FB Liu	HR13	First Release
1	2017/2/17	FB Liu	HR13	Modify worklist query condition
2	2017/10/20	FB Liu	HR13	Modify Model Name to InnoSight

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1. Definitions

AE	DICOM Application Entity
DICOM	Digital Imaging and Communications in Medicine
SCU	Service Class User, client
SCP	Service Class Provider, server
SOP	Service Operation Pair
UID	Unique Identifier
VR	Value Representation
FSC	File-Set Creator
FSU	File-Set Updater
MWL	Modality Worklist
US	Ultrasound

2. Implementation model

The system implements DICOM services to download worklist from MWL server and export exams with acquired images and cines to a DICOM storage server or USB device.

3. Networking

3.1 Application Data Flow Diagram

The local storage AE sends exams with acquired images and cines to one remote AE (Storage server). The Ultrasound system starts to send or export exams when “End Exam” is pressed or “Export exam to DICOM” is selected by user.

The worklist AE receives worklist information from remote AE (Worklist server). The Ultrasound System queries a remote AE for worklist items that matches the query request when “searching icon” is pressed by user.

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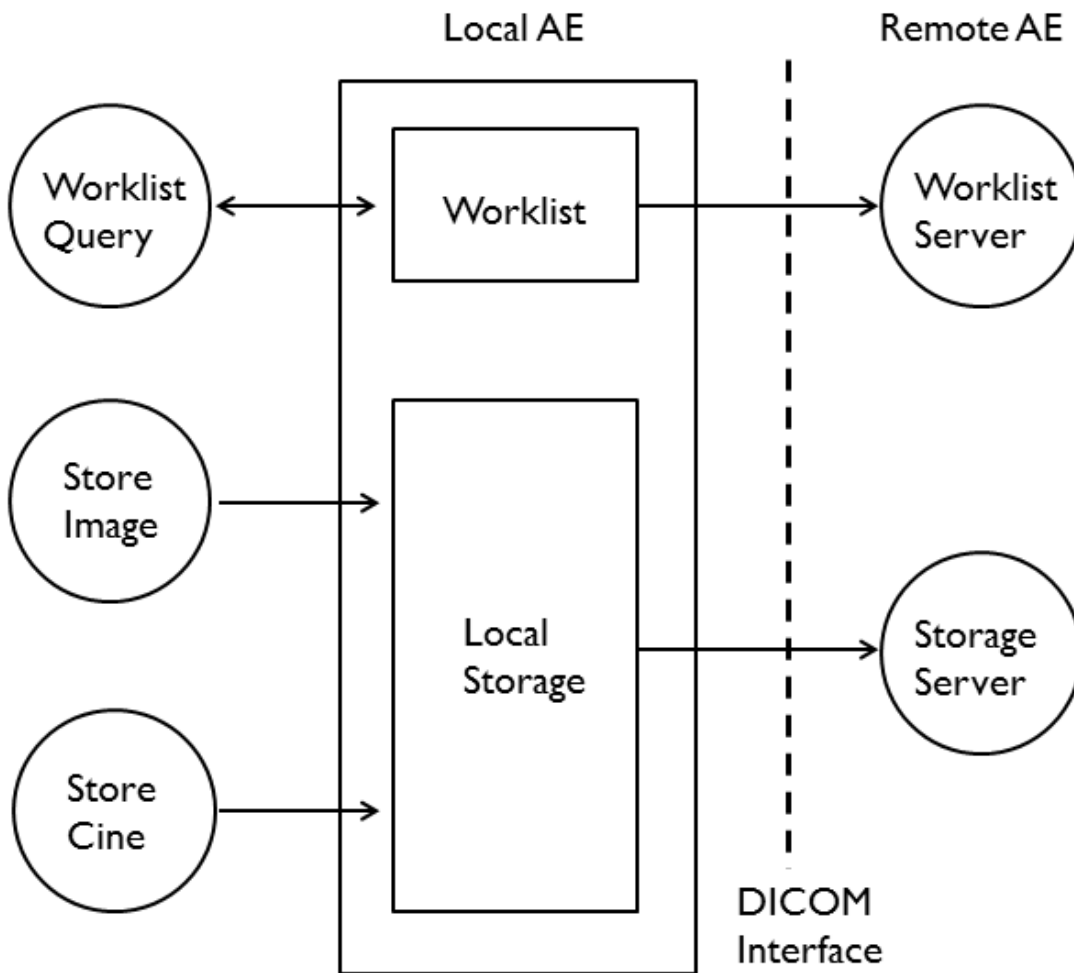


Figure 1 Application data flow diagram

3.2 Functional Definitions of AEs

The system has a single AE that performs all the required DICOM related tasks.

- The local storage AE initiates DICOM associations to send images to storage devices using the Ultrasound Image Storage SOP Class. The AE manages image transfer failures. A failed transfer will be re-attempted when network is re-connected.
- The worklist AE receives items from worklist server with studies matching the search criteria by sending C-FIND request. The search criteria contain Name, ID, Accession# and Start Date. The worklist server will transfer all matching items to the Ultrasound system, and the received items will be displayed in the “Query Worklist” page.

3.3 Sequencing of Real-World Activities

- Send exam to storage server

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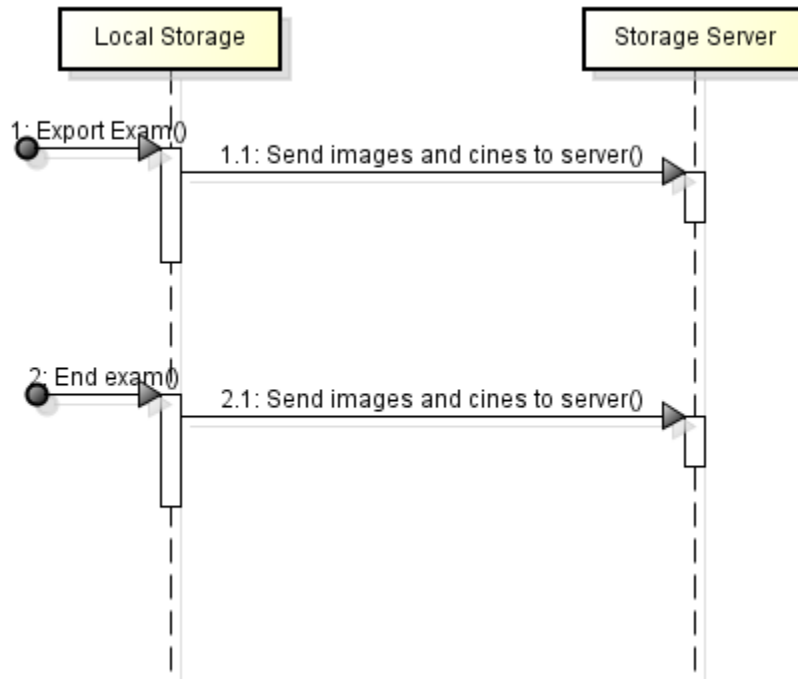


Figure 2 Send exam to storage server

● Query worklist

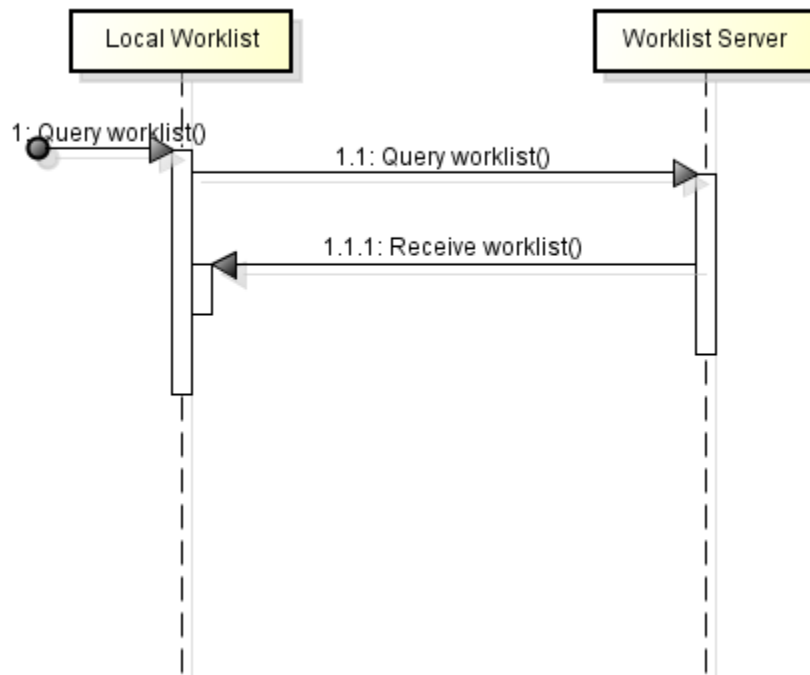


Figure 3 Query worklist

3.4 AE Specifications

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3.4.1 Storage Application Entity Specification

3.4.1.1 SOP classes

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

Table 1 Supported DICOM SOP Classes

SOP Class Name	SOP Class UID
Ultrasound Image Storage	1.2.840.10008.5.1.4.1.1.6.1
Ultrasound Multi-frame Image Storage	1.2.840.10008.5.1.4.1.1.3.1

3.4.1.2 Association Establishment Policies

3.4.1.2.1 General

The DICOM standard application context name for DICOM 3.0 is proposed:

Table 2 DICOM Application Context Name

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

The maximum length PDU for an association initiated by the system is configurable by a company authorized service representative. The default value is 64k (64234) bytes. The Maximum Length PDU negotiation is included in all association establishment requests.

3.4.1.2.2 Number of Associations

The AE will only open one association at a time.

3.4.1.2.3 Asynchronous Nature

The AE does not support asynchronous mode. All associations use the default synchronous mode for operations.

3.4.1.2.4 Implementation Identifying Information

Table 3 Implementation Identifying Information

Implementation Class UID	1.2.826.0.1.3680043.9.6741.5.2
Implementation Version Name	MergeCOM3_5_2_0

The Version Name indicated above is subject to change.

3.4.1.2.5 Association Initiation by Real-World Activity

The AE will attempt to establish a new association with a remote storage device due to three Real- World Activities.

- Export exam to DICOM
- End exam

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● Failed transfer

All these Real-World Activities result in a **Store** activity, which will generate an identical association initiation and image transfer process. An association is established when one of the actions shown below occurs.

- The user selects DICOM Store (“Export exam to DICOM”) from image review. An association is opened, all images/cines for the exam are transferred and then the association is closed.
- The user selects DICOM Store (“Export exam to DICOM”) from Exam List. An association is opened, all images/cines for the exam are transferred and then the association is closed.
- The user presses “End Exam”. An association is opened, all images/cines for the exam are transferred and then the association is closed.
- The network connection is re-established or a network error condition is cleared. Any images/cines that did not get transferred while there was no network connection will be transferred again. An association is opened, the image(s)/cine(s) transferred, and then the association is closed for the exam.

3.4.1.2.6 Presentation Context

The AE will negotiate associations in the order shown in Table 4. The first acceptable syntax will be used.

Table 4 Store - Presentation Context Table

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Extended Negotiation
Name	UID	Name List	UID List		
Ultrasound Image Storage	1.2.840.10008.5.1.4.1.1.6.1	Explicit VR Little Endian	1.2.840.10008.1.2.1	SCU	None
		Implicit VR Little Endian	1.2.840.10008.1.2		
		Explicit VR Big Endian	1.2.840.10008.1.2.2		
Ultrasound Multi-frame Image Storage	1.2.840.10008.5.1.4.1.1.3.1	Explicit VR Little Endian	1.2.840.10008.1.2.1	SCU	None
		Implicit VR Little Endian	1.2.840.10008.1.2		

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		Endian			
		Explicit VR	1.2.840.10008.1.		
		Big Endian	2.2		

3.4.2 Worklist Application Entity Specification

3.4.2.1 SOP classes

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

Table 5 Supported DICOM SOP Classes

SOP Class Name	SOP Class UID
MWL Information Model - FIND	1.2.840.10008.5.1.4.31
Modality Performed Procedure Step	1.2.840.10008.3.1.2.3.3

3.4.2.2 Association Establishment Policies

3.4.2.2.1 General

The DICOM standard application context name for DICOM 3.0 is proposed:

Table 6 DICOM Application Context Name

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

The maximum length PDU for an association initiated by the system is configurable by a company authorized service representative. The default value is 64k (64234) bytes. The Maximum Length PDU negotiation is included in all association establishment requests.

3.4.2.2.2 Number of Associations

The AE will only open one association at a time.

3.4.2.2.3 Asynchronous Nature

The AE does not support asynchronous mode. All associations use the default synchronous mode for operations.

3.4.2.2.4 Implementation Identifying Information

Table 7 Implementation Identifying Information

Implementation Class UID	1.2.826.0.1.3680043.9.6741.5.2
Implementation Version Name	MergeCOM3_5_2_0

The Version Name indicated above is subject to change.

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3.4.2.2.5 Association Initiation by Real-World Activity

The AE will attempt to establish a new association with a remote worklist device due to the Real-World Activities.

- Query worklist

The Real-World Activity results in a **Query** activity, which will generate an identical association initiation and worklist query/transfer process. An association is established when the action occurs.

- The user presses "searching icon" in the "Query Worklist" page. An association is opened and the search criterion is transferred. The worklist server returns studies matching the search criteria and then the association is closed.

3.4.2.2.6 Presentation Context

The AE will negotiate associations in the order shown in Table 8. The first acceptable syntax will be used.

Table 8 Worklist - Presentation Context Table

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Extended Negotiation
Name	UID	Name List	UID List		
MWL Information Model - FIND	1.2.840.10008.5.1.4.31	Explicit VR Little Endian Implicit VR Little Endian Explicit VR Big Endian	1.2.840.10008.1.2.1 1.2.840.10008.1.2 1.2.840.10008.1.2.2	SCU	None
Modality Performed Procedure Step	1.2.840.10008.3.1.2.3.3	Explicit VR Little Endian Implicit VR Little Endian Explicit VR Big Endian	1.2.840.10008.1.2.1 1.2.840.10008.1.2 1.2.840.10008.1.2.2	SCU	None

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3.4.2.3 Worklist Matching Keys

Table 9 Worklist – Matching Keys

Attribute Name	Tag	Type
Patient's Name	(0010,0010)	2
Patient ID	(0010,0020)	2
Accession Number	(0008,0050)	2
Date	(0040,0002)	2C

3.4.3 Verification Application Entity specification

3.4.3.1 SOP classes

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

Table 10 Supported DICOM SOP Classes

SOP Class Name	SOP Class UID
Verification	1.2.840.10008.1.1

3.4.3.2 Association Establishment Policies

3.4.3.2.1 General

The DICOM standard application context name for DICOM 3.0 is proposed:

Table 11 DICOM Application Context Name

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

The maximum length PDU for an association initiated by the system is configurable by a company authorized service representative. The default value is 64k (64234) bytes. The Maximum Length PDU negotiation is included in all association establishment requests.

3.4.3.2.2 Number of Associations

The AE will only open one association at a time.

3.4.3.2.3 Asynchronous Nature

The AE does not support asynchronous mode. All associations use the default synchronous mode for operations.

3.4.3.2.4 Implementation Identifying Information

Table 12 Implementation Identifying Information

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Implementation Class UID	1.2.826.0.1.3680043.9.6741.5.2
Implementation Version Name	MergeCOM3_5_2_0

The Version Name indicated above is subject to change.

3.4.3.2.5 Association Initiation by Real-World Activity

The AE will attempt to establish a new association with a remote storage device due to the Real-World Activities.

- Connection test

The Real-World Activity results in a **Verify** activity, which will generate an identical association initiation and verification process. An association is established when one of the actions shown below occurs.

- The user presses "Test" button in DICOM server setting pages. An association is opened and an echo request is transferred. AE reads message from network and then closes the association (For remote storage and worklist devices).
- The user enters the scan page from settings. An association is opened and an echo request is transferred. AE reads message from network and then closes the association (For remote storage device).
- For a default duration in scan page. An association is opened and an echo request is transferred. AE reads message from network and then closes the association (For remote storage device).

3.4.3.2.6 Presentation Context

The AE will negotiate associations in the order shown in Table 13. The first acceptable syntax will be used.

Table 13 Verify - Presentation Context Table

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Extended Negotiation
Name	UID	Name List	UID List		
Verification	1.2.840.10008.1.1	Explicit VR	1.2.840.10008.1.	SCU	None
		Little Endian	2.1		
	Implicit VR	1.2.840.10008.1.			
	Little Endian	2			
	Explicit VR	1.2.840.10008.1.			
	Big Endian	2.2			

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3.4.3.3 Request Message Table

Table 14 Association Negotiation Request message contents for each DICOM device

Device Type	SOP Classes Requested
Storage SCP	US Image Storage US Multi-frame Storage Verification
MWL SCP	Modality Worklist Verification

4. Media Storage

4.1 Application Data Flow Diagram

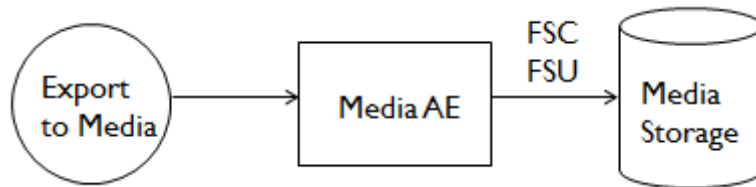


Figure 4 Data flow diagram for media storage

4.2 Functional Definitions of AE

The media AE exports the selected exam to the selected media destination.

4.3 AE Specifications

4.3.1 Implementation Identifying Information

Table 15 Implementation Identifying Information

Implementation Class UID	1.2.826.0.1.3680043.9.6741.5.2
Implementation Version Name	MergeCOM3_5_2_0

The Version Name indicated above is subject to change.

4.3.2 Real-World Activity

- The user selects DICOM Export (“Export exam (DICOM) to external storage”) from image review. A corresponding DICOMDIR is created and written to the media.
- The user selects DICOM Export (“Export exam (DICOM) to external storage”) from Exam List. A corresponding DICOMDIR is created and written to the media.

4.3.3 Options

Table 16 SOP classes and transfer syntaxes

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Information Object Definition	SOP Class UID	Transfer Syntax	Transfer Syntax UID
Media Storage Directory Storage	1.2.840.10008.1.3.10	Explicit VR Little Endian	1.2.840.10008.1.2.1
Ultrasound Image Storage	1.2.840.10008.5.1.4.1.1.6.1	Explicit VR Little Endian	1.2.840.10008.1.2.1
Ultrasound Multi-frame Image Storage	1.2.840.10008.5.1.4.1.1.3.1	Explicit VR Little Endian	1.2.840.10008.1.2.1

The (DICOMDIR) Directory includes Directory Records of PATIENT, STUDY, SERIES, IMAGE

Table 17 Patient Directory Record

Attribute Name	Tag	Type	Description
Patient's Name	(0010,0010)	2	Patient name in the form FIRST MIDDLE LAST based on the value entered in the Name field on the New Patient screen. Always sent even if zero length.
Patient ID	(0010,0020)	2	As entered in the ID field on the New Patient screen. Always sent even if zero length.

Table 18 Study Directory Record

Attribute Name	Tag	Type	Description
Study Instance UID	(0020,000D)	1	System generated
Study Date	(0008,0020)	1	Date when study was started
Study Time	(0008,0030)	2	Time when study was started

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Table 19 Series Directory Record

Attribute Name	Tag	Type	Description
Modality	(0008,0060)	1	Always "US"
Series Instance UID	(0020,000E)	1	System generated
Series Number	(0020,0011)	2	A number unique with the study

5. SOP Specific Conformance to Ultrasound Image Storage SOP Class

The AE uses the Ultrasound Image IOD Modules as shown in the tables below. Table 20 shows the modules used and Table 20 through 32 show the specific details of the attributes used in those modules. The only DIMSE service applicable to the combined IOD modules is C-STORE.

Table 20 Ultrasound Image IOD Modules Used

Information Entity	Module Name	Reference
Patient	Patient	See Table 21
Study	General Study	See Table 22
	Patient Study	See Table 23
Series	General Study	See Table 24
Equipment	General Equipment	See Table 25
Image	General Image	See Table 26
	Image Pixel	See Table 27
	Multi-frame Present	See Table 28
	US Image	See Table 29
	SOP Common	See Table 30

Table 21 Patient Module Attributes

Attribute Name	Tag	Type	Description
Patient's Name	(0010,0010)	2	Patient name in the form FIRST MIDDLE LAST based on the value entered in the Name field on the New Patient screen. Always sent even if zero length.
Patient ID	(0010,0020)	2	As entered in the ID field on the New Patient screen. Always sent even if zero length.
Patient's Birth Date	(0010,0030)	2	As entered in the DOB field on the New Patient screen. Always sent even if zero

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			length.
Patient's Sex	(0010,0040)	2	Set based on the Sex field on the New Patient screen. "Male" for Male, "Female" for Female.

Table 22 General Study Module Attributes

Attribute Name	Tag	Type	Description
Study Instance UID	(0020,000D)	1	System generated
Study ID	(0020,0010)	2	ID for the Study
Study Date	(0008,0020)	1	Date when study was started
Study Time	(0008,0030)	2	Time when study was started
Accession Number	(0008,0050)	2	As entered in the Accession field on the Patient Information screen. Always sent even if zero length.
Referring Physician's Name	(0008,0090)	2	Name of the patient's

Table 23 Patient Study Module Attributes

Attribute Name	Tag	Type	Description
Patient's Size	(0010,1020)	3	
Patient's Weight	(0010,1030)	3	

Table 24 General Series Module Attributes

Attribute Name	Tag	Type	Description
Modality	(0008,0060)	1	Always "US"
Protocol Name	(0018,1030)	3	Protocol name
Series Instance UID	(0020,000E)	1	System generated
Series Number	(0020,0011)	2	A number unique with the study

Table 25 General Equipment Module Attributes

Attribute Name	Tag	Type	Description
Manufacturer	(0008,0070)	2	Name of Manufacturer
Station Name	(0008,1010)	3	

Table 26 General Image Module Attributes

Attribute Name	Tag	Type	Description
Image Type	(0008,0008)	3	Always "ORIGINAL\PRIMARY" and protocol name

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Content Date	(0008,0023)	2C	
Content Time	(0008,0033)	2C	

Table 27 Image Pixel Module Attributes

Attribute Name	Tag	Type	Description
Samples per Pixel	(0028,0002)	1	A value of 3 for "RGB"
Photometric Interpretation	(0028,0004)	1	Always "RGB"
Planar Configuration	(0028,0006)	1C	Always 0000H
Rows	(0028,0010)	1	Always 706
Columns	(0028,0011)	1	Always 960
Pixel Spacing	(0028,0030)	1C	Physical distance between the center of each pixel (unit: mm)
Bits Allocated	(0028,0100)	1	Always 0008H
Bits Stored	(0028,0101)	1	Always 0008H
High Bit	(0028,0102)	1	Always 0007H
Pixel Representation	(0028,0103)	1	Always 0000H
Pixel Data	(7FE0,0010)	1	Data of image pixels

Table 28 Multi-frame Module Attributes

Attribute Name	Tag	Type	Description
Number of frames	(0028,0008)	1	Number of frames

Table 29 US Image Module Attributes

Attribute Name	Tag	Type	Description
Image Type	(0008,0008)	3	Always "ORIGINAL\PRIMARY" and protocol name
Samples per Pixel	(0028,0002)	1	A value of 3 for "RGB"
Photometric Interpretation	(0028,0004)	1	Always "RGB"
Planar Configuration	(0028,0006)	1C	Always 0000H
Bits Allocated	(0028,0100)	1	Always 0008H
Bits Stored	(0028,0101)	1	Always 0008H
High Bit	(0028,0102)	1	Always 0007H
Pixel Representation	(0028,0103)	1	Always 0000H

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Table 30 SOP Common Module Attributes

Attribute Name	Tag	Type	Description
SOP Class UID	(0008,0016)	1	1.2.840.10008.5.1.4.1.1.6.1 or 1.2.840.10008.5.1.4.1.1.3.1
SOP Instance UID	(0008,0018)	1	System generated