TOSHIBA

No. MIIUS0024EA

DICOM
CONFORMANCE STATEMENT
FOR
DIAGNOSTIC ULTRASOUND SYSTEM

MODEL SSA-530A Famio V1.00
(DICOM KIT USDI-530A)

TOSHIBA MEDICAL SYSTEMS CORPORATION

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1 Introduction

This document is a DICOM Conformance Statement for Toshiba's diagnostic ultrasound system Famio, model SSA-530A. It is intended to provide the reader with the knowledge of how to integrate this product within a DICOM compliant hospital network. It details the DICOM Service Classes, Information Objects, and Communication Protocols which are supported by this product as follows:

- Verification Service Class (SCU)
- Storage Service Class (SCU)

If the reader is unfamiliar with DICOM, it is recommended that they read the DICOM Specification (referenced below) prior to reading this conformance statement. Also note that this document is formatted according to the DICOM Specification, Part 2: Conformance.

1.1 References

ACR-NEMA Digital Imaging and Communications in Medicine, DICOM V3.0.

1.2 Definitions

- **Association Establishment** - An Association Establishment is the first phase of communication between two DICOM Application Entities. The AEs use the Association Establishment to negotiate how data will be encoded and the type of data to be exchanged.
- **Called Application Entity Title** - The Called AE Title defines the intended receiver of an Association.
- **Calling Application Entity Title** - The Calling AE Title defines the requestor of an Association.
- **DICOM Message Service Element (DIMSE)** - A DIMSE defines the services and protocols utilized by an Application Entity to exchange messages.
- **Information Object Definition (IOD)** - An IOD is a data model which is an abstraction of real-world information. This data model defines the nature and attributes relevant to the class of realworld objects represented.
- **Service Class Provider (SCP)** - A Service Class Provider plays the "server" role to perform operations and invoke notifications during an Association. An example of a Storage Service Class Provider would be an image storage device. In this case, the image storage device is storing the image that was sent by a Service Class User.
- **Service Class User (SCU)** - A Service Class User plays the "client" role to invoke operations and perform notifications during an Association. An example of a Storage Service Class User would be an image acquisition device. In this case, the image acquisition device will create and send a DICOM image by requesting that a Service Class Provider store that image.
- **Service/Object Pair (SOP) Class** - A SOP Class is defined by the union of an Information Object Definition and a set of DIMSE Services. A DICOM Application Entity may support one or more SOP Classes. Each SOP Class is uniquely identified by a SOP Class UID.
- **SOP Instance** - A specific occurrence of a Information Object.
- **Transfer Syntax** - The Transfer Syntax is a set of encoding rules that allow DICOM Application Entities to negotiate the encoding techniques (e.g., data element structure, byte ordering, compression) they are able to support. The Transfer Syntax is negotiated during Association Negotiation.
- **Unique Identifier (UID)** - A Unique Identifier is a globally unique, ISO compliant, ASCII-numeric string. It guarantees uniqueness across multiple countries, sites, vendors, and equipment.

- **Application Profile** - A Media Storage Application Profile defines a selection of choices at the various layers of the DICOM Media Storage Model which are applicable to a specific need or context in which the media interchange is intended to be performed.
- **DICOM File Service** - The DICOM File Service specifies a minimum abstract view of files to be provided by the Media Format Layer. Constraining access to the content of files by the Application Entities through such a DICOM File Service boundary ensures Media Format and Physical Media independence.
- **DICOM File** - A DICOM File is a File with a content formatted according to the requirements of this Part of the DICOM Standard. In particular, such files shall contain the File Meta Information and a properly formatted Data Set.
- **DICOMDIR File** - A unique and mandatory DICOM File within a File-set which contains the Media Storage Directory SOP Class. This File is given a single component File ID, DICOMDIR.
- **File** - A File is an ordered string of zero or more bytes, where the first byte is at the beginning of the file and the last byte is at the end of the File. Files are identified by a unique File ID and may by written, read, and/or deleted.
- **File ID** - Files are identified by a File ID which is unique within the context of the File-set they belong to. A set of ordered File ID Components (up to a maximum of eight) forms a File ID.
- **File ID Component** - A string of one to eight characters of a defined character set.
- **File Meta Information** - The File Meta Information includes identifying information on the encapsulated Data Set. It is a mandatory header at the beginning of every DICOM File.
- **File-set** - A File-set is a collection of DICOM Files (and possibly non-DICOM Files) that share a common naming space within which File IDs are unique.
- **File-set Creator** - An Application Entity that creates the DICOMDIR File and zero or more DICOM Files.
- **File-set Reader** - An Application Entity that accesses one or more files in a File-set.
- **File-set Updater** - An Application Entity that accesses Files, creates additional Files, or deletes existing Files in a File-set. A File-set Updater makes the appropriate alterations to the DICOMDIR file reflecting the additions or deletions.
- **DICOM File Format** - The DICOM File Format provides a means to encapsulate in a File the Data Set representing a SOP Instance related to a DICOM Information Object.
- **Media Format** - Data structures and associated policies which organizes the bit streams defined by the Physical Media format into data file structures and associated file directories.
- **Media Storage Model** - The DICOM Media Storage Model pertains to the data structures used at different layers to achieve interoperability through media interchange.
- **Physical Media** - A piece of material with recording capabilities for streams of bits. Characteristics of a Physical Media include form factor, mechanical characteristics, recording properties and rules for recording and organizing bit streams in accessible structures.

1.3 Acronyms, Abbreviations, and Symbols

The following acronyms and abbreviations are used in this document.

- ACC American College of Cardiology
- ACR American College of Radiology
- ASCII American Standard Code for Information Interchange
- AE Application Entity
- ANSI American National Standards Institute
- CEN TC251 Comite Europeen de Normalisation - Technical Committee 251 – Medical Informatics
- DICOM Digital Imaging and COmmunications in Medicine
- DIMSE DICOM Message Service Element
- DIMSE-C DICOM Message Service Element-Composite
- DIMSE-N DICOM Message Service Element-Normalized
- FSC File-Set Creator
- FSR File-Set Reader
- FSU File-Set Updater
- HIS Hospital Information System
- HL7 Health Level 7
- IE Information Entity
- IOD Information Object Definition
- ISO International Standard Organization
- JIRA Japan Industries Association of Radiological Systems
- NEMA National Electrical Manufacturers Association
- PDU Protocol Data Unit
- RIS Radiology Information System
- SCP Service Class Provider
- SCU Service Class User
- SOP Service Object Pair
- TCP/IP Transmission Control Protocol/Internet Protocol
- UID Unique Identifier

2 Implementation Model

2.1 Verification

The Verification service class defines an application level class of service which allows the service engineer to verify the ability of an application on a Remote DICOM device to respond to DICOM messages. The DICOM Service Tool application supports the Verification service and acts as the SCU. The response to Verification requests from remote applications is handled by the Verification SCP application.

2.1.1 Application Data Flow Diagram

Network AE implementation acts as the SCU for the Verification service.

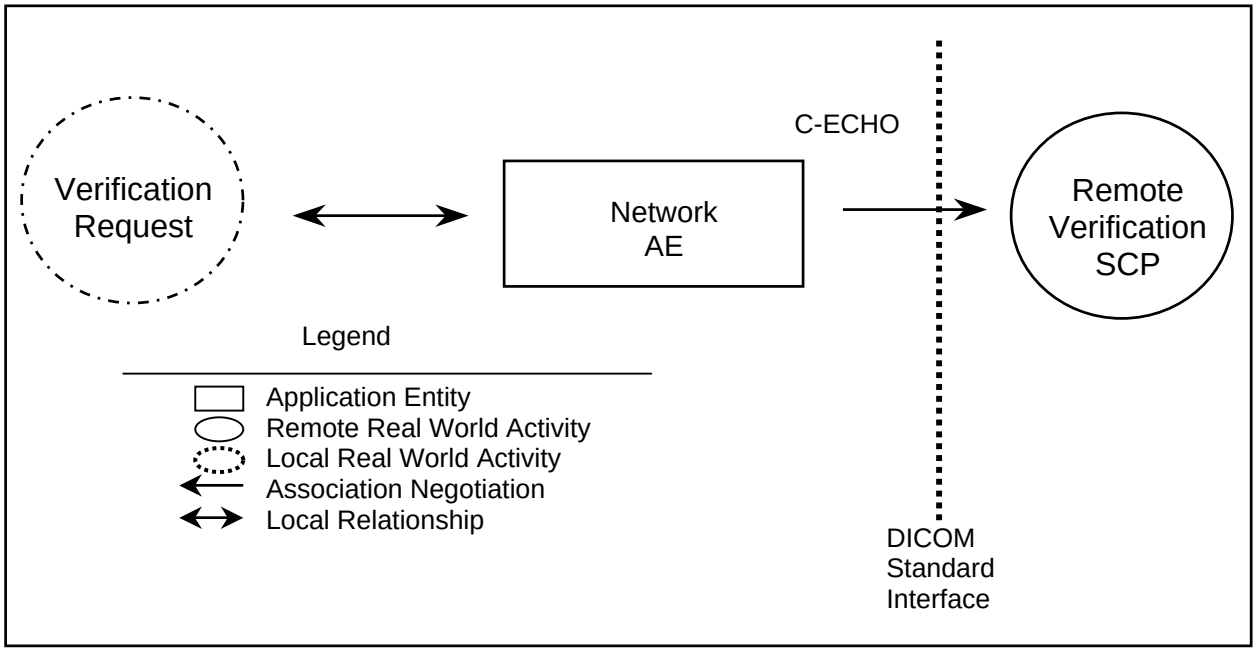

Figure 1

2.1.2 Functional Definitions of Application Entities

Network AE is used to verify that Remote DICOM devices are active on the network. It therefore performs the following tasks:

- Establishes DICOM association with the Remote DICOM device.
- Performs Verification of the presence of the Remote DICOM device on the network.

2.1.3 Sequence of Real World Activities

2.1.3.1 Features

- Operator requests Verification of activation of the Remote DICOM device.
- Network AE acts as the SCU for Verification.

2.1.3.2 Operation

Step 1: Select the Remote DICOM device

Step 2: Request Verification of activation of the Remote DICOM device

2.2 Image Storage

Network AE establishes an association for Storage of DICOM Composite Information Objects in the Remote Real World Activity.

2.2.1 Application Data Flow Diagram

Network AE implementation acts as the SCU for the Storage service.

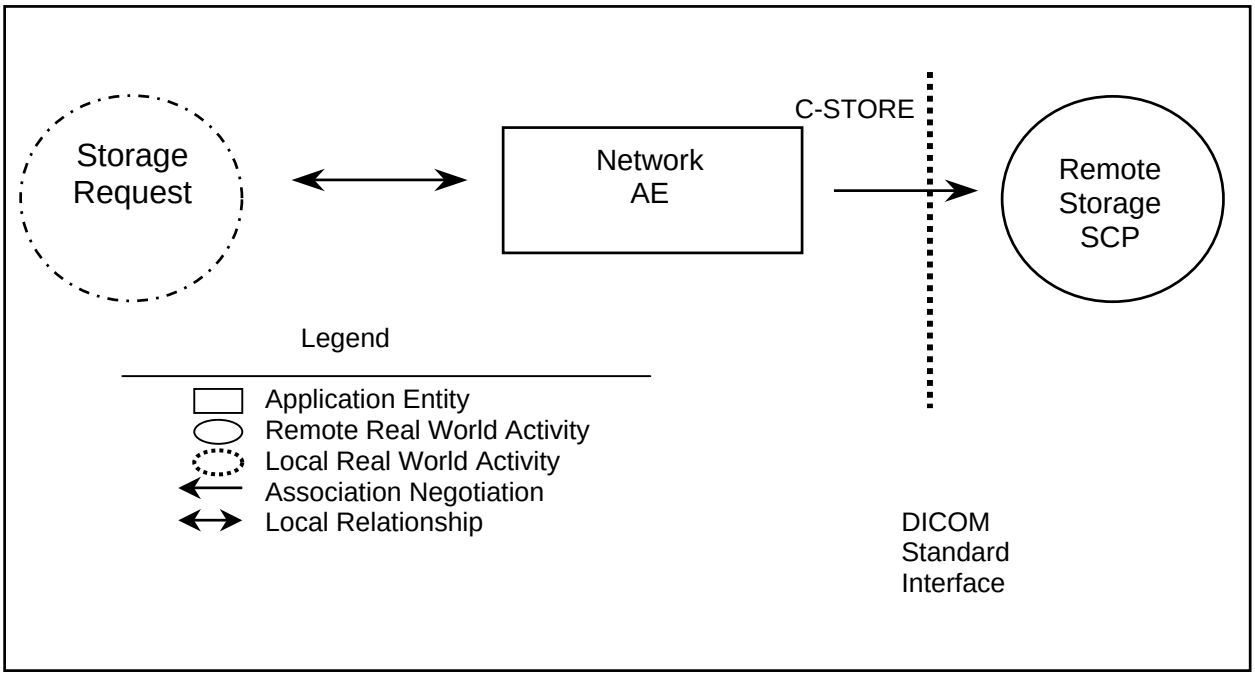

Figure 2

2.2.2 Functional Definitions of Application Entities

Network AE is used to transmit images to a Remote DICOM device.
It therefore performs the following tasks:

- Builds DICOM US Image Information Objects.
- Establishes DICOM association with the Remote DICOM device.
- Stores DICOM US Information Objects on the Remote DICOM device.

2.2.3 Sequence of Real World Activities

2.2.3.1 Features

- The operator requests transfer of an image to a server after selecting the target image from the File List.
- Network AE transfers an image immediately and automatically after capture to the server when the feature is set up in advance.
- Storage requests are placed in a queue and are executed in the background.
- When the image transmit fails, Network AE displays an error message and asks the operator to attempt it or to cancel.
- Network AE acts as the SCU for Storage.

2.2.3.2 Operation

The operations for image transfer are described below:

Operation 1

Step 1: Select the image to be transferred.

Step 2: Request transfer.

Operation 2

Network AE transfers an image immediately and automatically after capture to the server when the feature is set up in advance.

3 AE Specifications

3.1 Network AE Specification

Network Activity: Network AE (initiation) provides Standard Conformance to the following DICOM SOP Classes as an SCU:

Table 1

SOP Class Name	SOP Class UID
Verification	1.2.840.10008.1.1
Ultrasound Image Storage	1.2.840.10008.5.1.4.1.1.6.1

3.1.1 Network AE Association Establishment Policies

3.1.1.1 General

The configuration of the DICOM application defines the Application Entity Titles, the port numbers, and of course the host name and net address.
The Application Entity will utilize the following Application Context Name:

Table 2

DICOM V3.0 Application Context	1.2.840.10008.3.1.1.1

3.1.1.2 Number of Associations

Network AE (initiation) initiates several associations at a time, one for each transfer request being processed.

3.1.1.3 Asynchronous Nature

Network AE (initiation) does not support asynchronous communication (multiple outstanding transactions over a single association).

3.1.2 Association Initiation by Real World Activity

Network AE initiates an association when the following activity is chosen by the operator:

- Verification
  Verify that a Remote DICOM device is present on the network.
- Storage
  Create and store a US image to a Remote DICOM device.

3.1.2.1 Real World Activity – Verification SCU

3.1.2.1.1 Associated Real World Activity

The associated Real World Activity is a C-ECHO request initiated by Network AE. If the process successfully establishes an association with a Remote DICOM device, it will send the C-ECHO request via the open association to verify that the Remote DICOM device is responding to DICOM messages.

3.1.2.1.2 Proposed Presentation Contexts

Network AE supports the following Presentation Contexts for Verification.

Table 3

Presentation Context Table					
Abstract Syntax		**Transfer Syntax**			**Extended**
Name	**UID**	**Name List**	**UID List**	**Role**	**Negotiation**
Verification	1.2.840.10008.1.1	Implicit VR Little Endian	1.2.840.10008.1.2	SCU	None

3.1.2.1.2.1 SOP Specific Conformance Statement

The Application conforms to the definition of a Verification SCU in accordance with the DICOM Standard..

3.1.2.2 Real World Activity – Image Storage SCU

3.1.2.2.1 Associated Real World Activity

The associated Real World Activity is a C-STORE request that has been initiated. If the C-STORE response from the remote Application contains an error status, the association is aborted.

3.1.2.2.2 Proposed Presentation Contexts

Network AE supports the following Presentation Contexts for Storage.

Table 4

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

3.1.2.2.2.1 SOP Specific Conformance Statement

The Application conforms to the definition of a Storage SCU in accordance with the DICOM Standard..

4 Communications Profiles

4.1 Supported Communication Stacks

This system provides DICOM V3.0 TCP/IP Network Communication Support as defined in Part 8 of the DICOM Standard.

4.2 OSI Stack

Not applicable to this product.

4.3 TCP/IP Stack

This system uses the TCP/IP stack from the computer system on which it is running.

4.3.1 API

Not applicable to this product.

4.3.2 Physical Media Support

This system is indifferent to the physical medium over which TCP/IP executes; it inherits the medium from the computer system on which it is running.

4.4 Point to Point Stack

Not applicable to this product.

5 Configuration

The Configuration Utility allows the service engineer to set and maintain configuration parameters of local and Remote DICOM application entities.

The parameters are as follows:

Table 5

Parameter			Default
Local	AE Title		Famio
	Port Number		104
	Host Name		Famio
	Alias		Famio
	Max PDU Receive Size [byte]		4096. (The Value range is 4K to 64K Bytes. If service engineer sets smaller than 4K Bytes, Famio sets 16K Bytes automatically.)
	IP Address		192.168.0.2
	Institution Name		Toshiba Hospital
Remote	**Storage 1**	AE Title	Server1
		Port Number	104
		Host Name	Server1
		Alias	Server1
		Max PDU Send Size [byte]	4096. (The Max PDU Send Size depends on the value specified by the Remote AE in the Association Information. The value range is 4K to 64K Bytes.)
		IP Address	192.168.0.3
		Auto Archive	OFF
		Default Archive	None
	Storage 2	AE Title	Server2
		Port Number	104
		Host Name	Server2
		Alias	Server2
		Max PDU Send Size [byte]	4096. (The Max PDU Send Size depends on the value specified by the Remote AE in the Association Information. The value range is 4K to 64K Bytes.)
		IP Address	192.168.0.4
		Auto Archive	OFF
		Default Archive	None

6 Support of Extended Character Sets

This Product supports the following character sets:

- ISO-IR 100 (Latin alphabet No. 1) Supplementary set of ISO 8859

7 DIMSE and Attributes - Verification SCU

7.1 DIMSE

Table 6

SOP Class	DIMSE Service Element	Usage SCU *1	Usage
Verification	C-ECHO	M	Used

*1: M = Mandatory, C = Conditional, U = User option

8 DIMSE and Attributes - Ultrasound Image Storage SCU

8.1 DIMSE

Table 7

SOP Class	DIMSE Service Element	Usage SCU *1	Usage
Ultrasound Image Storage	C-STORE	M	Used

*1: M = Mandatory

8.2 Entity Module Definitions

The information modules for the Ultrasound Workstation are defined below.

Table 8

Information Entity	Module	Reference	Usage*1
Patient	Patient Module	8.3.1	M
Study	General Study Module	8.3.2	M
Study	Patient Study Module	8.3.3	U
Series	General Series Module	8.3.4	M
Frame of Reference	Frame of Reference Module	Not Used	U
Frame of Reference	US Frame of Reference Module	Not Used	C
Equipment	General Equipment Module	8.3.5	M
Image*2	General Image Module	8.3.6	M
Image	Image Pixel Module	8.3.7	M
Image	Palette Color Lookup Table	Not Used	C
Image	Contrast/bolus Module	Not Used	C
Image	US Region Calibration Module	8.3.8	U
Image	US Image Module	8.3.9	M
Image	Overlay Plane Module	Not Used	U
Image	VOI LUT Module	Not Used	U
Image	SOP Common Module	8.3.10	M
Curve*2	Curve Identification Module	Not Used	M
Curve	Curve Module	Not Used	M

Curve	Audio Module	Not Used	U
Curve	SOP Common	Not Used	M

*1 M = Mandatory, C = Conditional, U = User option
*2 The Image and Curve IEs are mutually exclusive.

8.3 Attributes

8.3.1 Patient Module

Table 9

Attribute Name	Tag	Type	Attribute Description
Patient's Name	(0010, 0010)	2	Length = 0 when no entry is made
Patient ID	(0010, 0020)	2	Length = 0 when no entry is made
Patient's Birth Date	(0010, 0030)	2	Length = 0 when no entry is made
Patient's Sex	(0010, 0040)	2	Length = 0 when no entry is made
Ethnic Group	(0010, 2160)	3	Not set when no entry is made
Patient Comments	(0010, 4000)	3	Not set when no entry is made

8.3.2 General Study Module

Table 10

Attribute Name	Tag	Type	Attribute Description
Study Instance UID	(0020, 000D)	1	Always set
Study ID	(0020, 0010)	2	Always set
Study Date	(0008, 0020)	2	Always set
Study Time	(0008, 0030)	2	Always set
Referring Physician's Name	(0008, 0090)	2	Always set
Accession Number	(0008, 0050)	2	Length = 0 when no entry is made
Study description	(0008, 1030)	3	Not set when no entry is made
Name of Physician(s) Reading Study	(0008, 1060)	3	Not set when no entry is made

8.3.3 Patient Study Module

Table 11

Attribute Name	Tag	Type	Attribute Description
Patient's Age	(0010, 1010)	3	Not set when no entry is made
Patient's Size	(0010, 1020)	3	Not set when no entry is made
Patient's Weight	(0010, 1030)	3	Not set when no entry is made

8.3.4 General Series Module

Table 12

Attribute Name	Tag	Type	Attribute Description
Modality	(0008, 0060)	1	Always set ("US")
Series Instance UID	(0020, 000E)	1	Always set
Series Number	(0020, 0011)	2	Always set
Series Date	(0008, 0021)	3	Always set
Series Time	(0008, 0031)	3	Always set
Operator's Name	(0008, 1070)	3	Not set when no entry is made
Protocol Name	(0018, 1030)	3	Not set when no entry is made

8.3.5 General Equipment Module

Table 13

Attribute Name	Tag	Type	Attribute Description
Manufacturer	(0008, 0070)	2	Always set
Institution Name	(0008, 0080)	3	Always set
Station Name	(0008, 1010)	3	Always set
Institutional Department Name	(0008, 1040)	3	Always set
Manufacturer's Model Name	(0008, 1090)	3	Always set
Device Serial Number	(0018, 1000)	3	Always set
Software Version	(0018, 1020)	3	Always set

8.3.6 General Image Module

Table 14

Attribute Name	Tag	Type	Attribute Description
Image Number	(0020, 0013)	2	Always set
Content Date	(0008, 0023)	2C	Always set
Content Time	(0008, 0033)	2C	Always set
Image Type	(0008, 0008)	3	Always set
Acquisition Date	(0008, 0022)	3	Always set
Acquisition Time	(0008, 0032)	3	Always set
Patient Orientation	(0020, 0020)	2C	Always set (Length = 0)

8.3.7 Image Pixel Module

Table 15

Attribute Name	Tag	Type	Attribute Description
Samples per Pixel	(0028, 0002)	1	Always set (1)
Photometric Interpretation	(0028, 0004)	1	Always set ("MONOCHROME2”)
Rows	(0028, 0010)	1	Always set (480)
Columns	(0028, 0011)	1	Always set (640)
Bits Allocated	(0028, 0100)	1	Always set (8)
Bits Stored	(0028, 0101)	1	Always set (8)
High Bit	(0028, 0102)	1	Always set (7)
Pixel Representation	(0028, 0103)	1	Always set (0)
Pixel Data	(7FE0, 0010)	1	Always set

8.3.8 US Region Calibration Module

8.3.8.1 US Region Calibration Module B-mode

Table 16

Attribute Name	Tag	Type	Attribute Description
Sequence of Ultrasound Regions	(0018, 6011)	1	Always set
>Region Location Min x0	(0018, 6018)	1	Always set
>Region Location Min y0	(0018, 601A)	1	Always set
>Region Location Max x1	(0018, 601C)	1	Always set
>Region Location Max y1	(0018, 601E)	1	Always set
>Physical Units X Direction	(0018, 6024)	1	Always set
>Physical Units Y Direction	(0018, 6026)	1	Always set
>Physical Delta X	(0018, 602C)	1	Always set
>Physical Delta Y	(0018, 602E)	1	Always set
>Region Spatial Format	(0018, 6012)	1	Always set
>Region Data Type	(0018, 6014)	1	Always set
>Region Flags	(0018, 6016)	1	Always set

8.3.8.2 US Region Calibration Module M-mode

Table 17

Attribute Name	Tag	Type	Attribute Description
Sequence of Ultrasound Regions	(0018, 6011)	1	Always set
>Region Location Min x0	(0018, 6018)	1	Always set
>Region Location Min y0	(0018, 601A)	1	Always set
>Region Location Max x1	(0018, 601C)	1	Always set

>Region Location Max y1	(0018, 601E)	1	Always set
>Physical Units X Direction	(0018, 6024)	1	Always set
>Physical Units Y Direction	(0018, 6026)	1	Always set
>Physical Delta X	(0018, 602C)	1	Always set
>Physical Delta Y	(0018, 602E)	1	Always set
>Region Spatial Format	(0018, 6012)	1	Always set
>Region Data Type	(0018, 6014)	1	Always set
>Region Flags	(0018, 6016)	1	Always set

8.3.9 US Image Module

Table 18

Attribute Name	Tag	Type	Attribute Description
Sample Per Pixel	(0028, 0002)	1	Always set (1)
Photometric Interpretation	(0028, 0004)	1	Always set ("MONOCHROME2")
Bits Allocated	(0028, 0100)	1	Always set (8)
Bits Stored	(0028, 0101)	1	Always set (8)
High Bit	(0028, 0102)	1	Always set (7)
Pixel Representation	(0028, 0103)	1	Always set (0)
Image Type	(0008, 0008)	2	Always set
Ultrasound Color Data Present	(0028, 0014)	3	Always set (0)
Transducer Type	(0018, 6031)	3	Not set when entry is not made

8.3.10 SOP Common Module

Table 19

Attribute Name	Tag	Type	Attribute Description
SOP Class UID	(0008, 0016)	1	Always set
SOP Instance UID	(0008, 0018)	1	Always set
Specific Character Set	(0008, 0005)	1C	Always set ("ISO_IR 100")

E