**DICOM
CONFORMANCE STATEMENT
FOR
DIAGNOSTIC ULTRASOUND SYSTEM
APLIO MODEL SSA-770A**

TOSHIBA CORPORATION

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1 INTRODUCTION

This document is a DICOM Conformance Statement for Toshiba's Diagnostic Ultrasound System APLIO MODEL SSA-770A. It is intended to provide the reader with the knowledge of how to integrate this product within a DICOM compliant hospital archive. It details the DICOM Service Classes, Information Objects, and Communication Protocols which are supported by this product as follows:

- MOD Medium Storage Service Class (FSC/FSR/FSU)

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

1.1 REFERENCE

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

1.2 DEFINITIONS

- **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 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 Componen**t: A string of one to eight characters of a defined character set.
- **File Meta Informatio**n: 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-se**t: 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 Creato**r: An Application Entity that creates the DICOMDIR File (see section 8.6) and zero or more DICOM Files.
- **File-set Reade**r: An Application Entity that accesses one or more files in a File-set.
- **File-set Update**r: 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 Forma**t: 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 Forma**t: 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 Mode**l: The DICOM Media Storage Model pertains to the data structures used at different layers to achieve interoperability through media interchange.
- **Physical Medi**a: 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

  - **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 real-world objects represented.

  - **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.

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
- RIS   Radiology Information System
- SOP   Service Object Pair
- UID   Unique Identifier

2 IMPLEMENTATION MODEL

2.1 MOD MEDIUM

The DICOM archive application serves as an interface with the MOD offline medium device. It incorporates the offline media directory into the browser and copies SOP Instances to a medium or retrieves SOP Instances from a medium to local storage. The DICOM Archive application supports Standard MOD media. The FSU role updates new SOP Instances only to media with preexisting File-sets conforming to the Application Profiles supported. The contents of DICOMDIR will be temporarily stored in the Archive Database.
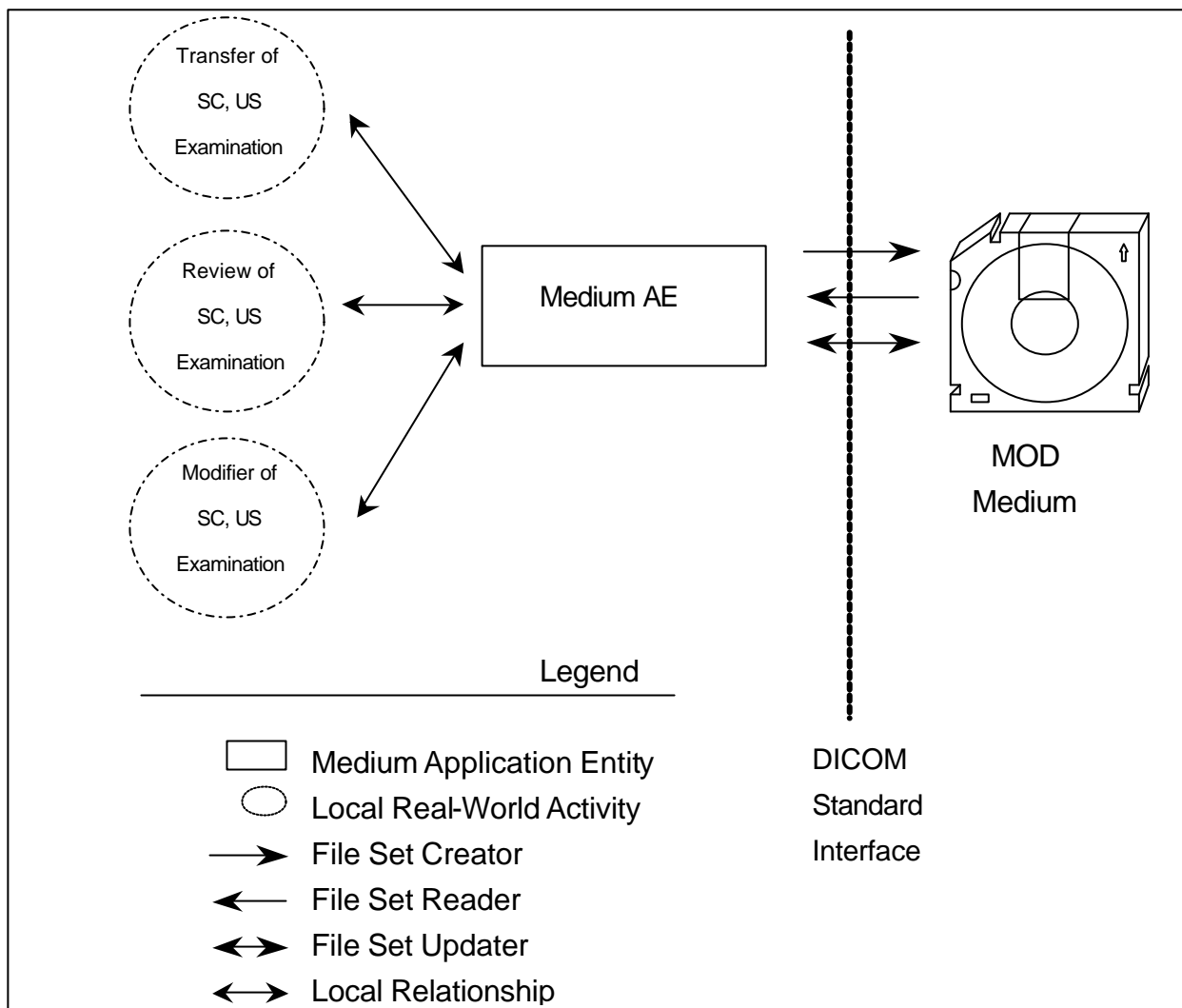
2.1.1 APPLICATION DATA FLOW DIAGRAM

Figure 1

2.1.2 FUNCTIONAL DEFINITIONS OF AE$_S$

Medium AE is used to create/read/modify studies/images to/from an offline DICOM MOD Medium. It therefore performs the following tasks:

- Builds DICOM SC, US Information Objects.
- CREATES a DICOMDIR file that represents the contents of the DICOM SC, US Information Objects to be recorded.
- RECORDS DICOM SC, US Information Objects from local storage to a MOD medium.
- READS the DICOMDIR file that represents the contents of the data as recorded.
- DISPLAYS the ordered list of studies/images, identifying information, or icon images.
- READS the selected studies/images from a MOD medium and displays them on the monitor of the DICOM Reader.
- READS the File-set of the MOD medium and writes it to the local storage of DICOM Reader.
- MODIFIES the DICOMDIR file and the studies/images.

2.1.3 SEQUENCING OF REAL WORLD ACTIVITIES

The DICOM Archive application will not perform updates before the directory information of DICOMDIR is read completely.

2.1.3.1 FEATURES

- Operator requests storage of study/images to a MOD medium after selecting studies from the Study List.
- Operator requests immediate and automatic storage of an image after capture.
- Operator requests retrieval of study/images from a MOD medium to the local disk.
- Storage requests are placed in a queue and are executed in the background.

2.1.3.2 OPERATIONS

The operations for manual image transfer/modification are described below:

Operation-1

      Step-1: Display the image to be transferred/modified.

      Step-2: Request transfer/modification.

Operation-2

      Step-1: Select the study to be transferred/modified.

      Step-2: Request transfer/modification.

2.1.4 FILE META INFORMATION FOR INPLEMENTATION CLASS UID AND VERSION NAME

Medium File Meta Information will specify the following Implementation Identifying Information

Table 1

System	Implementation Class UID	Implementation Version Name	File Meta Information Version
APLIO SSA-770A	1.2.392.200036.9116.7.8.10. 46.6.1.1	TM_APLIO_1.0	Version 1

3   AE SPECIFICATIONS

3.1 MEDIUM AE SPECIFICATION

Medium Activity : Medium AE provides Conformance to DICOM Interchange of the Media Storage Service Class. The Application Profiles and roles are listed in the following table.

Table 2

Application Profiles Supported	Real-World Activity	Roles	SC Option
AUG-US-ID-MF-MOD128 (128MB 90mm MOD)	Transfer of SC, US Examination	FSC	Interchange
AUG-US-ID-MF-MOD230 (230MB 90mm MOD)	Modifier of SC, US Examination	FSU	Interchange
AUG-US-ID-MF-MOD540 (540MB 90mm MOD)	Review of SC, US Examination	FSR	Interchange
AUG-US-ID-MF-MOD650 (650MB 90mm MOD)			
AUG-US-ID-MF-MOD12 (1.2GB 90mm MOD)			

3.1.1   FILE META INFORMATION FOR THE APPLICATION ENTITY

The Source Application Entity Title is set by the user in the configuration file.

3.1.2 REAL WORLD ACTIVITY - REMOVABLE MEDIA

A DICOM conformant Magneto-Optical Disk (MOD) is created when a non-conformant MOD is inserted into APLIO and one or more DICOM Exams are transferred to the MOD. When Exams are first transferred, their files are added to the MOD in DICOM Part 10 format and a valid DICOMDIR is created and saved to the MOD. APLIO can add images to an existing DICOM conformant MOD and update its DICOMDIR. APLIO can be a File-set Reader and a File-set Updater.

4   AUGMENTATED AND PRIVATE APPLICATION PROFILES

4.1 AUGMENTED APPLICATION PROFILES

Augmented Application Profiles cover from Standard Application Profiles in addition to dealing with SC IOD.

Table 3

Augmented Application Profiles	Standard Application Profiles
AUG-US-ID-MF-MOD128	STD-US-ID-MF-MOD128
AUG-US-ID-MF-MOD230	STD-US-ID-MF-MOD230
AUG-US-ID-MF-MOD540	STD-US-ID-MF-MOD540
AUG-US-ID-MF-MOD650 [1]	STD-US-ID-MF-MOD650
AUG-US-ID-MF-MOD12 [1]	STD-US-ID-MF-MOD12

[1] AUG-US-ID-MF-MOD650 and AUG-US-ID-MF-MOD12 are replaced from 130mm MOD to 90mm MOD

4.2 SOP CLASS AUGMENTATIONS

Aforementioned Application Profiles sport following SOP Class UID and Transfer Syntax.

Table 4

Information Object Definition	SOP Class UID	Transfer Syntax	Transfer Syntax UID
Secondary Capture Image Storage	1.2.840.10008.5.1.4.1.1.7	Explicit VR Little Endian Uncompressed	1.2.840.10008.1.2.1

4.3 DIRECTORY AUGMENTATIONS

Not applicable to this product

4.4 OTHER AUGMENTATIONS

Not applicable to this product

4.5 PRIVATE APPLICATION PROFILES

Not applicable to this product

5 EXTENSIONS/SPECIALIZATIONS/PRIVATIZATIONS

Not applicable to this product.

6 CONFIGURATION

Not applicable to this product.

7 SUPPORT OF EXTENDED CHARACTER SETS

ISO-IR 100 (Latin 1 alphabet No.1) Supplementary set of ISO8859

8 MOD STORAGE INFORMATION OBJECT DEFINITION

8.1 ENTRY MODULE DEFINITIONS

Table 5

Object	Module/Key	Reference	Usage[1]
DICOM File Meta Information		8.1.1.1 / 8.1.1.2	M
Basic Directory Information Object	File-set Identification Module	8.1.2.1	M
	Directory Information Module	8.1.2.2	U
Definition of Specific Directory Records	PATIENT keys	8.1.3.1	M
	STUDY keys	8.1.3.2	M
	SERIES keys	0	M
	IMAGE keys	8.1.3.4	M

[1] M=Mandatory, C=Conditional, U=User option

8.1.1 DICOM FILE META INFORMATION

8.1.1.1 DICOM FILE META INFORMATION OF DIRECTORY IOD

Table 6

Attribute Name	Tag	Type	Attribute Description
File Preamble	No Tag	1	Always set
DICOM Prefix	No Tag	1	Always set ("DICM")
Group Length	(0002, 0000)	1	Always set
File Meta Information Version	(0002, 0001)	1	Always set (0001H)
Media Storage SOP Class UID	(0002, 0002)	1	Always set ("1.2.840.10008.1.3.10")
Media Storage SOP Instance UID	(0002, 0003)	1	Always set
Transfer Syntax UID	(0002, 0010)	1	Always set
Implementation Class UID	(0002, 0012)	1	Always set
Implementation Version Name	(0002,0013)	3	Always set ("TM_APLIO_1.0")

8.1.1.2   DICOM FILE META INFORMATION IMAGE IOD

Table 7

Attribute Name	Tag	Type	Attribute Description
File Preamble	No Tag	1	Always set
DICOM Prefix	No Tag	1	Always set ("DICM")
Group Length	(0002, 0000)	1	Always set
File Meta Information Version	(0002, 0001)	1	Always set (0001H)
Media Storage SOP Class UID	(0002, 0002)	1	Always set
Media Storage SOP Instance UID	(0002, 0003)	1	Always set
Transfer Syntax UID	(0002, 0010)	1	Always set
Implementation Class UID	(0002, 0012)	1	Always set
Implementation Version Name	(0002, 0013)	3	Always set ("TM_APLIO_1.0")

8.1.2 BASIC DIRECTORY INFORMATION OBJECT

8.1.2.1   FILE-SET IDENTIFICATION MODULE

Table 8

Attribute Name	Tag	Type	Attribute Description
File-set ID	(0004, 1130)	2	Always set

8.1.2.2   DIRECTORY INFORMATION MODULE

Table 9

Attribute Name	Tag	Type	Attribute Description
Offset of the First Directory Record of the Root Directory Entity	(0004, 1200)	1	Always set
Offset of the Last Directory Record of the Root Directory Entity	(0004, 1202)	1	Always set
File-set Consistency Flag	(0004, 1212)	1	Always set
Directory Record Sequence	(0004, 1220)	2	Set if present in image object.
>Offset of the Next Directory Record	(0004, 1400)	1C	Set if present in image object.
>Record In-use Flag	(0004, 1410)	1C	Always set (FFFFH)
>Offset of Referenced Lower-Level Directory Entity	(0004, 1420)	1C	Set if present in image object.
>Directory Record Type	(0004, 1430)	1C	Always set "PATIENT", "STUDY", "SERIES", "IMAGE", "CURVE", or "PRIVATE"
>Referenced File ID	(0004, 1500)	1C	Contains the filename in media for the Directory Records of Type IMAGE and PRIVATE
>Referenced SOP Class UID in File	(0004, 1510)	1C	For the Directory Record Types IMAGE and PRIVATE
>Referenced SOP Instance UID in File	(0004, 1511)	1C	For the Directory Record Types IMAGE and PRIVATE
>Referenced Transfer Syntax UID in	(0004, 1512)	1C	For the Directory Record Types

File			IMAGE and PRIVATE
> Record Selection Keys	see below		

8.1.3 DEFINITION OF SPECIFIC DIRECTORY RECORDS

8.1.3.1 PATIENT KEYS

Table 10

Attribute Name	Tag	Type	Attribute Description
Specific Character Set	(0008,0005)	1C	Always set ("ISO_IR 100")
Patent's Name	(0010, 0010)	2	Set if present in image object.
Patient ID	(0010, 0020)	1	Always set
Patient's Birth Date	(0010,0030)	3	Set if present in image object.
Patient's Sex	(0010,0040)	3	Set if present in image object.
Patient's Age	(0010,1010)	3	Set if present in image object.
Patient's Size	(0010,1020)	3	Set if present in image object.
Patient's Weight	(0010,1030)	3	Set if present in image object.
Patient's Address	(0010,1040)	3	Set if present in image object.
Patient Comment	(0010,4000)	3	Set if present in image object.

8.1.3.2 STUDY KEYS

Table 11

Attribute Name	Tag	Type	Attribute Description
Specific Character Set	(0008,0005)	1C	Always set ("ISO_IR 100")
Study Date	(0008, 0020)	1	Always set
Study Time	(0008, 0030)	1	Always set
Accession Number	(0008, 0050)	2	Set if present in image object.
Referring Physician's Name	(0008,0090)	3	Set if present in image object.
Study Description	(0008, 1030)	2	Set if present in image object.
Admitting Diagnosis Description	(0008,1080)	3	Set if present in image object.
Study Instance UID	(0020, 000D)	1C	Always set
Study ID	(0020, 0010)	1	Generates automatically, if not present. Value = "-"

8.1.3.3 SERIES KEYS

Table 12

Attribute Name	Tag	Type	Attribute Description
Specific Character Set	(0008,0005)	1C	Always set ("ISO_IR 100")
Series Date	(0008,0021)	3	Set if present in image object.
Modality	(0008, 0060)	1	Always set
Institution Name	(00080080)	3	Set if present in image object.
Institution Address	(00080081)	3	Set if present in image object.
Performing Physician's Name	(0008,1050)	3	Set if present in image object.
Operator's Name	(0008,1070)	3	Set if present in image object.
Series Instance UID	(0020, 000E)	1	Always set
Series Number	(0020, 0011)	1	Always set

8.1.3.4   IMAGE KEYS

Table 13

Attribute Name	Tag	Type	Attribute Description
Specific Character Set	(0008,0005)	1C	Always set ("ISO_IR 100")
Image Type	(0008, 0008)	3	Always set
SOP Class UID	(0008,0016)	3	Always set
SOP Instance UID	(0008,0018)	3	Always set
Image Date	(0008,0023)	3	Set if present in image object.
Image Time	(0008,0033)	3	Set if present in image object.
Instance Number	(0020, 0013)	1	Always set
Rows	(0028, 0010)	3	Always set
Columns	(0028, 0011)	3	Always set
Calibration Image	(0050,0004)	3	Always set
Pixel Spacing	(0028, 0030)	3	Set if present in image object.
Icon Image Sequence	(0088,0200)	3	Always set
>Samples per Pixel	(0028,0002)		1
>Photometric Interpretation	(0028,0004)		"MONOCHROME2"
>Rows	(0028,0010)		64
>Columns	(0028,0011)		64
>Bits Allocated	(0028,0100)		8
>Bits Stored	(0028,0101)		8
>High Bit	(0028,0102)		7
>Pixel Representation	(0028,0103)		0 (Unsigned)
>Pixel Data	(7FE0,0010)		Icon Image pixel data

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