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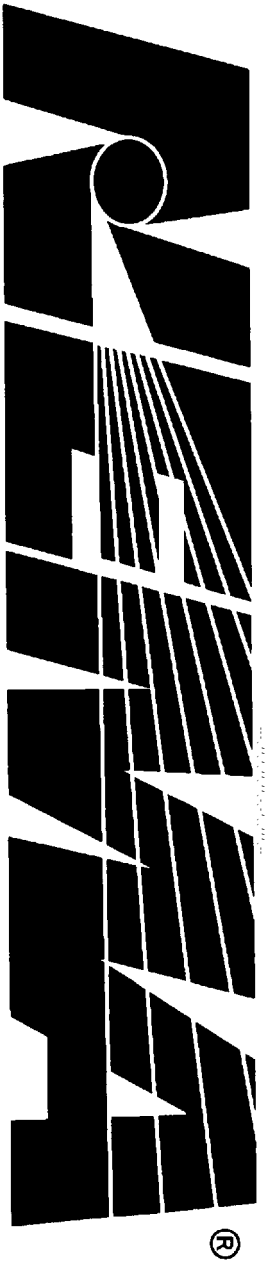
DICOM

Part 11

Media Storage Application Profiles



DICOM®

Digital Imaging and Communications in Medicine

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Digital Imaging and Communications in Medicine (DICOM)

Part 11: Media Storage Application Profiles

Published by

National Electrical Manufacturers Association
1300 N. 17th Street
Rosslyn, Virginia 22209 USA

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FOREWORD

The American College of Radiology (ACR) and the National Electrical Manufacturers Association (NEMA) formed a joint committee to develop a Standard for Digital Imaging and Communications in Medicine. The ACC (American College of Cardiology) joined this standardization effort with a particular interest in the definition of Digital Media Storage Standards. This DICOM Standard was developed according to NEMA procedures.

This standard is developed in liaison with other standard organizations including CEN TC251 in Europe and JIRA in Japan, with review also by other organizations including IEEE, HL7 and ANSI in the USA.

The DICOM Standard is structured as a multi-part document using the guidelines established in the following document:

ISO/IEC Directives, 1989 part 3 - Drafting and Presentation of International Standards.

This document is part of the DICOM Standard which consists of the following parts:

PS 3.1: Introduction and Overview
PS 3.2: Conformance
PS 3.3: Information Object Definitions
PS 3.4: Service Class Specifications
PS 3.5: Data Structures and Encoding
PS 3.6: Data Dictionary
PS 3.7: Message Exchange
PS 3.8: Network Communication Support for Message Exchange
PS 3.9: Point-to-Point Communication Support for Message Exchange
PS 3.10: Media Storage and File Formats for Media Interchange
PS 3.11: Media Storage Application Profiles
PS 3.12: Media Formats and Physical Media for Media Interchange
PS 3.13: Print Management Point-to-Point Communication Support
PS 3.14: Grayscale Standard Display Function
PS 3.15: Security Profiles

These parts are independent but related documents. Their development level and approval status may differ.

PS 3.7, PS 3.8, and PS 3.9 focus on the communication of digital image data across point-to-point and network interfaces. PS 3.10, PS 3.11, and PS 3.12 address the open interchange of digital image data on removable storage media. Their development takes into account past and current related efforts:

- The ACR-NEMA Standard for Magnetic Tape (PS1) has defined a generic means to store on a 9 track magnetic tape one or more Data Sets formatted per the ACR-NEMA V2.0 Standard
- A Japanese effort called IS&C (Image Save and Carry) has also used an ACR-NEMA V2.0-based format to store images on a 130 millimeter (5 1/4 inch) Magneto-Optical Disk with an IS&C specific media organization format
- European effort initiated by the University of Geneva in Switzerland has defined PAPYRUS, an ACR-NEMA V2.0-based format to store one or more images grouped as folders in files irrespective of

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the physical media and its file organization format. The new PAPYRUS V3.0 is intended to be a specific Application Profile compatible with this part

As both network communication and media interchange share a number of common characteristics, the following parts of DICOM developed for network communication are leveraged for media interchange:

PS 3.2: Conformance
PS 3.3: Information Object Definitions
PS 3.4: Service Class Specifications
PS 3.5: Data Set Structures and Encoding
PS 3.6: Data Dictionary

PS 3.10, *Media Storage and File Formats for Media Interchange*, lays a foundation for two other parts of the DICOM Standard by specifying a general model for the storage of medical imaging information on removable media. PS 3.12, *Media Formats and Physical Media,* defines a number of standard Physical Media and corresponding Media Formats suitable for medical image information exchange. This part, PS 3.11, *Media Storage Application Profiles,* enables interoperability by specifying standard sets of elements from the various other parts of the DICOM Standard related to a specific clinical need. Conformance to DICOM in the area of media interchange is defined by PS 3.2 and is based on the Application Profiles defined by this part.

PS 3.11 and PS 3.12 will be expanded through the addition of Application Profile and media definition annexes as clinical needs and physical media technologies evolve.

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1 Scope and field of application

This part of the DICOM Standard specifies application specific subsets of the DICOM Standard to which an implementation may claim conformance. Such a conformance statement applies to the interoperable interchange of medical images and related information on storage media for specific clinical uses. It follows the framework, defined in PS 3.10, for the interchange of various types of information on storage media.

This part is related to other parts of the DICOM Standard in that:

- PS 3.2, *Conformance*, specifies the general rules for assuring interoperability, which are applied for media interchange through the Application Profiles of this part
- PS 3.3, *Information Object Definitions*, specifies a number of Information Object Definitions (e.g., various types of images) which may be used in conjunction with this part. It also defines a medical Directory structure to facilitate access to the objects stored on media
- PS 3.4, *Service Class Specifications*, specifies the Media Storage Service Class upon which Application Profiles are built
- PS 3.5, *Data Structure and Encoding*, addresses the encoding rules necessary to construct a Data Set which is encapsulated in a file as specified in PS 3.10
- PS 3.6, Data Dictionary, contains an index by Tag of all Data Elements related to the Attributes of Information Objects defined in PS3.3. This index includes the Value Representation and Value Multiplicity for each Data Element
- PS 3.10, Media Storage and File Formats for Media Interchange, standardizes the overall open Storage Media architecture used by this part, including the definition of a generic File Format, a Basic File Service and a Directory concept
- PS 3.12, Media Formats and Physical Media, defines a number of standard Physical Media and corresponding Media Formats. These Media Formats and Physical Media selections are referenced by one or more of the Application Profiles of this part. PS 3.12 is intended to be extended as the technologies related to Physical Medium evolve

2 Normative References

The following standards contain provisions which, through reference in this text, constitute provisions of this Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this Standard are encouraged to investigate the possibilities of applying the most recent editions of the standards indicated below.

ISO/IEC Directives, 1989 part 3 - Drafting and presentation of international standards.

ISO 7498-1, Information Processing Systems - Open Systems Interconnection - Basic Reference Model.

ISO 8859, Information Processing - 8-bit single-byte coded graphic character sets - part 1: Latin Alphabet No. 1.

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3 Definitions

For the purposes of this standard the following definitions apply.

3.1 REFERENCE MODEL DEFINITIONS

This part of the Standard is based on the concepts developed in ISO 7498-1 and makes use of the following terms defined in it:

a) Application Entity
b) Service or Layer Service
c) Transfer Syntax

3.2 DICOM INTRODUCTION AND OVERVIEW DEFINITIONS

This part of the Standard makes use of the following terms defined in PS 3.1 of the DICOM Standard:

- Attribute

3.3 DICOM CONFORMANCE

This part of the Standard makes use of the following terms defined in PS 3.2 of the DICOM Standard:

a) Conformance Statement
b) Standard SOP Class
c) Standard Extended SOP Class
d) Specialized SOP Class
e) Private SOP Class
f) Standard Application Profile
g) Augmented Application Profile
h) Private Application Profile

3.4 DICOM INFORMATION OBJECT DEFINITIONS

This part of the Standard makes use of the following terms defined in PS 3.3 of the DICOM Standard:

a) Information Object Definition
b) Basic Directory IOD
c) Basic Directory Information Model

3.5 DICOM DATA STRUCTURE AND ENCODING DEFINITIONS

This part of the standard makes use of the following terms defined in PS 3.5 of the DICOM Standard:

a) Data Element
b) Data Set

3.6 DICOM MESSAGE EXCHANGE DEFINITIONS

This part of the Standard makes use of the following terms defined in PS 3.7 of the DICOM Standard:

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a) Service Object Pair (SOP) Class
b) Service Object Pair (SOP) Instance
c) Implementation Class UID

3.7 DICOM MEDIA STORAGE AND FILE FORMAT DEFINITIONS

This part of the standard makes use of the following terms defined in PS 3.10 of the DICOM Standard:

a) Application Profile
b) DICOM File Format
c) DICOM File Service
d) DICOM File
e) DICOMDIR File
f) File
g) File ID
h) File Meta Information
i) File-set
j) Media Storage Model

3.8 MEDIA STORAGE APPLICATION PROFILES

This part of the DICOM Standard uses the following definitions:

3.8.1 Application Profile Class

A group of related Application Profiles defined in a single annex to this part.

4 Symbols and abbreviations

The following symbols and abbreviations are used in this part of the standard.

ACC	American College of Cardiology
ACR	American College of Radiology
AP	Application Profile
ASCII	American Standard Code for Information Interchange
AE	Application Entity
ANSI	American National Standards Institute
CEN TC 251	Comite Europeen de Normalisation - Technical Committee 251 - Medical Informatics
DICOM	Digital Imaging and Communications in Medicine
FSC	File-set Creator
FSR	File-set Reader
FSU	File-set Updater
HL7	Health Level 7
IEEE	Institute of Electrical and Electronics Engineers

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IS&C	Image Save and Carry
ISO	International Standards Organization
ID	Identifier
IOD	Information Object Definition
JIRA	Japan Industries Association of Radiation Apparatus
NEMA	National Electrical Manufacturers Association
OSI	Open Systems Interconnection
SOP	Service-Object Pair
TCP/IP	Transmission Control Protocol/Internet Protocol
UID	Unique Identifier
VR	Value Representation

5 Conventions

Words are capitalized in this document to help the reader understand that these words have been previously defined in Section 3 of this document and are to be interpreted with that meaning.

6 Purpose of an Application Profile

An Application Profile is a mechanism for selecting an appropriate set of choices from the parts of DICOM for the support of a particular media interchange application. Application Profiles for commonly used interchange scenarios, such as inter-institutional exchange of x-ray cardiac angiographic examinations, or printing ultrasound studies from recordable media, are meant to use the flexibility offered by DICOM without resulting in so many media and format choices that interchange is compromised.

Media interchange applications claim conformance to one or more Media Storage Application Profiles. Two implementations that conform to identical Application Profiles and support complementary File-set roles (e.g. an FSC interchanging media with an FSR) are able to exchange SOP Instances (pieces of DICOM information) on recorded media within the context of those Application Profiles.

A DICOM Application Profile specifies:

a. which SOP Classes and options must be supported, including any required extensions, specializations, or privatizations
b. for each SOP Class, which Transfer Syntaxes may be used
c. what information should be included in the Basic Directory IOD
d. which Media Storage Service Class options may be utilized
e. which roles an application may take: File-set Creator, File-set Reader, and/or File-set Updater
f. which physical media and corresponding media formats must be supported

and any additional conformance requirements.

The result of making the necessary choices means that the Application Profile can be thought of as a vertical path through the various parts of DICOM that begins with choices of information to be exchanged

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and ends at the physical medium. Figure 6-1 shows the relationship between the concepts used in an Application Profile and the parts of DICOM.

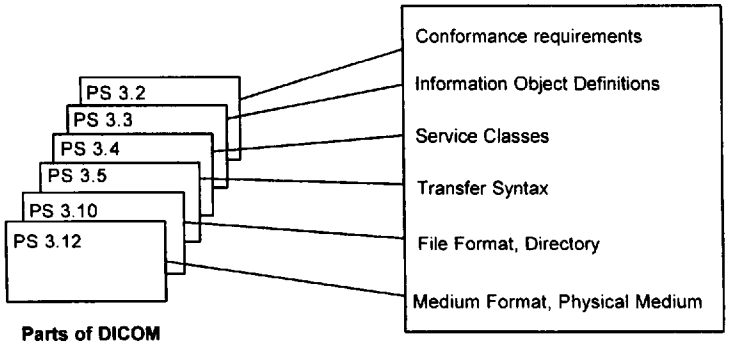

Figure 6-1
RELATIONSHIP BETWEEN AN APPLICATION PROFILE AND PARTS OF DICOM

An Application Profile is organized into the following major parts:

a. The name of the Application Profile, or the list of Application Profiles grouped in a related class
b. A description of the clinical context of the Application Profile
c. The definition of the Media Storage Service Class with the device Roles for the Application Profile and associated options
d. Informative section describing the operational requirements of the Application Profile
e. Specification of the SOP Classes and associated IODs supported and the Transfer Syntaxes to be used
f. The selection of Media Format and Physical Media to be used
g. If the Directory Information Module is used, the description of the minimum subset of the Information Model required
h. Other parameters which need to be specified to ensure interoperable media interchange

The structure of DICOM and the design of the Application Profile mechanism is such that extension to additional SOP Classes and new exchange media is straightforward.

7 Conformance requirements

Implementations may claim conformance to one or more PS 3.11 Application Profiles in a Conformance Statement as outlined in PS 3.2.

NOTE : Additional specific conformance requirements for an Application Profile may be listed in the Application Profile definition.

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8 Structure of application profile

Application Profiles specific to various clinical areas are defined in the annexes to this part. Each Annex defines an Application Profile Class related to a single area of medical practice, e.g., cardiology, or to a single functional context, e.g., image transfer to a printer system. Several specific Application Profiles may be defined in each Application Profile class, and an identification scheme is established to label each specific Application Profile.

An example of an Application Profile structure is provided in below. The section identifier "X" should be replaced by the identifier of the annex.

CLASS AND PROFILE IDENTIFICATION - SECTION X.1

Section X.1 of the Application Profile defines the class and specific Application Profiles in that class.

This section assigns an identifier to each Application Profile of the form ttt-x...x-y...y, where "ttt" indicates the type of Application Profile, "x...x" is an abbreviation of a significant term for the clinical context and "y...y" is a significant term for a distinguishing feature of the specific Application Profile. The "ttt" type term shall be one of STD, AUG, or PRI, indicating whether the Application Profile is a Standard, Augmented, or Private Application Profile respectively (see PS 3.2). Neither "x...x" nor "y...y" is restricted in length or content.

Note: Conformance Statements may use the earlier prefix of APL which is equivalanet to STD. This use is deprecated and may be retired in future versions of the standard.

CLINICAL CONTEXT - SECTION X.2

Section X.2 of the Application Profile shall describe the clinical need for the interchange of medical images and related information on storage media, and its context of application. This section shall not require any specific functionality of the Application Entities exchanging information using media interchange beyond their capabilities in the roles of File-set Creator, File-set Reader, and File-set Updater.

NOTE: This Section does not, for example, place any graphical presentation or performance requirements on workstations which read DICOM interchange media. Such requirements are beyond the scope of a DICOM Media Storage Application Profile. The requirements which fall within the scope of an Application Profile are the specific functional storage media interchange capabilities associated with the defined roles.

ROLES AND SERVICE CLASS OPTIONS SECTION X.2.1

Section X.2.1 describes the Service Class Options used and the contextual application of the roles of File-set Creator, File-set Reader, and File-set Updater.

GENERAL CLASS PROFILE - SECTION X.3

Section X.3 defines characteristics of the Application Profile Class that are constant across all specific Application Profiles in the class.

SOP CLASSES AND TRANSFER SYNTAXES - SECTION X.3.1

Section X.3.1 lists the SOP Classes and Transfer Syntaxes common to all specific Application Profiles in the class, if any. This section specifies which SOP Classes are mandatory and optional for the roles of *FSC, FSR, and FSU, including any required groupings or SOP options.*

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PHYSICAL MEDIA AND MEDIA FORMATS - SECTION X.3.2

Section X.3.2 defines the physical media and corresponding media formats common to all specific Application Profiles in the class, if any.

This section also specifies any file service functionality beyond the DICOM File Service required by the clinical application to be supplied by the Media Format Layer.

DIRECTORY INFORMATION IN DICOMDIR - SECTION X.3.3

Section X.3.3 specifies the type of Directory Records that shall be supported and any additional associated keys. It also defines any extensions to or specializations of the Basic Directory Information Object Definition, if any.

OTHER PARAMETERS - SECTION X.3.4

Section X.3.4 is optional; if present, it should define any other parameters common to all specific Application Profiles in the class which may need to be specified in order to ensure interoperable media interchange.

SPECIFIC APPLICATION PROFILES - SECTION X.4 AND FOLLOWING

Sections X.4.and following, each define the unique characteristics of a specific Application Profile. If there are any Application Profile specific changes to IODs, Transfer Syntax, DICOMDIR, or other general class requirements, they should be described for each Application Profile that specifies such changes.

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Annex A Basic Cardiac X-ray Angiographic Application Profile (Normative)

A.1 CLASS AND PROFILE IDENTIFICATION

This Annex defines an Application Profile Class for Basic Cardiac X-ray Angiographic clinical applications.

The identifier for this class shall be STD-XABC. This annex is concerned only with cardiac angiography.

The specific Application Profile in this class is shown in the Table A.1-1.

NOTE: This table contains only a single Application Profile. It is expected that additional Application Profiles may be added to PS 3.11.

Table A.1-1
BASIC CARDIAC XA PROFILE

Application Profile	Identifier	Description
Basic Cardiac X-Ray Angiographic Studies on CD-R Media	STD-XABC-CD	It handles single frame or multi-frame digital images up to 512x512x8 bits; biplane acquisitions are encoded as two single plane information objects.

A.2 CLINICAL CONTEXT

This Application Profile Class facilitates the interchange of primary digital X-ray cine runs, typically acquired as part of cardiac catheterization procedures. Typical media interchanges would be from in-lab acquisition equipment to either a display workstation or to a data archive system, or between a display workstation and a data archive system (in both directions). This context is shown in figure A.2-1 below.

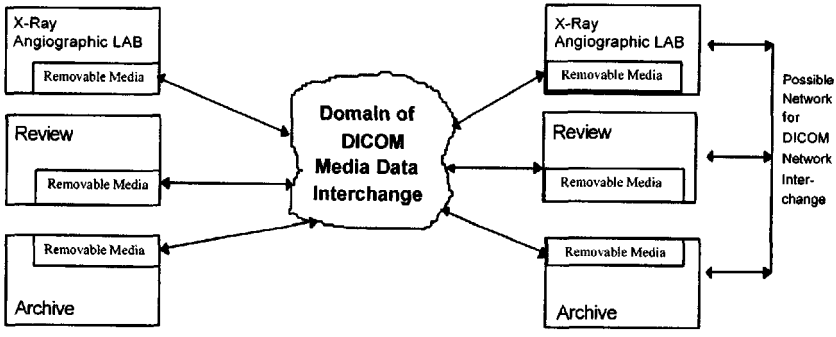

Figure A.2-1
CLINICAL CONTEXT DIAGRAM

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The operational use of media interchange is potentially both intra-institutional and inter-institutional.

A.2.1 Roles and service class options

This Application Profile Class uses the Media Storage Service Class defined in PS 3.4 with the Interchange Option.

The Application Entity shall support one or more of the roles of File-set Creator, File-set Reader, and File-set Updater, defined in PS 3.10.

A.2.1.1 FILE SET CREATOR

The Application entity acting as a File-Set Creator generates a File Set under the STD-XABC Application Profile Class. Typical entities using this role would include X-ray angiographic lab equipment, and archive systems which generate a patient record for transfer to another institution. File Set Creators shall be able to generate the Basic Directory SOP Class in the DICOMDIR File with all types of Directory Records related to the SOP Classes stored in the File-set.

FSC shall offer the ability to either finalize the disc at the completion of the most recent write session (no additional information can be subsequently added to the disc) or to allow multi-session (additional information may be subsequently added to the disk).

NOTE: A multiple volume (a logical volume that can cross multiple physical media) is not supported by this Application Profile Class. If a set of Files, e.g., a Study, cannot be written entirely on one CD-R, the FSC will create multiple independent DICOM File-sets such that each File-set can reside on a single CD-R media controlled by its individual DICOMDIR file. The user of the FSC can opt to use written labels on the discs to indicate that there is more than one disc for this set of files (e.g., a study).

A.2.1.2 FILE SET READER

The role of File Set Reader is used by Application Entities which receive a transferred File Set. Typical entities using this role would include display workstations, and archive systems which receive a patient record transferred from another institution. File Set Readers shall be able to read all the SOP Classes defined for the specific Application Profile for which a Conformance Statement is made, using all the defined Transfer Syntaxes.

A.2.1.3 FILE SET UPDATER

The role of File Set Updater is used by Application Entities which receive a transferred File Set and update it by the addition of information. Typical entities using this role would include analytic workstations, which, for instance, may add to the File-set an information object containing a processed (e.g., edge-enhanced) image. Stations which update patient information objects would also use this role. File-set Updaters do not have to read the images. File-set Updaters shall be able to generate one or more of the SOP Instances defined for the specific Application Profile for which a conformance statement is made, and to read and update the DICOMDIR file.

FSU shall offer the ability to either finalize the disc at the completion of the most recent write session (no additional information can be subsequently added to the disc) or to allow multi-session (additional information may be subsequently added to the disk).

NOTE: If the disc has not been closed out, the File-set Updater shall be able to update information assuming there is enough space on the disc to write a new DICOMDIR file, the information, and the fundamental CD-R control structures. CD-R control structures are the structures that are inherent to the CD-R standards, see PS 3.12.

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A.3 STD-XABC-CD BASIC CARDIAC PROFILE

A.3.1 SOP classes and transfer syntaxes

This Application Profile is based on the Media Storage Service Class with the Interchange Option (see PS 3.4).

SOP Classes and corresponding Transfer Syntaxes supported by this Application Profile are specified in the Table A.3-1.

Table A.3-1
STD-XABC-CD SOP CLASSES AND TRANSFER SYNTAXES

Information Object Definition	Service Object Pair Class UID	Transfer Syntax and UID	FSC Requirement	FSR Requirement	FSU Requirement
Basic Directory	1.2.840.10008.1.3.10	Explicit VR Little Endian Uncompressed 1.2.840.10008.1.2.1	Mandatory	Mandatory	Mandatory
X-Ray Angiographic Image	1.2.840.10008.5.1.4.1.1.12.1	JPEG Lossless Process 14 (selection value 1) 1.2.840.10008.1.2.4.70	Mandatory	Mandatory	Optional
Detached Patient Management	1.2.840.10008.3.1.2.1.1	Explicit VR Little Endian Uncompressed 1.2.840.10008.1.2.1	Optional	Optional	Optional

Notes: 1. This application profile does not allow the use of the X-Ray Angiographic Bi-Plane Image Object. Biplane acquisitions must therefore be transferred as two single plane SOP instances. A future Application Profile that permits X-Ray Angiographic Bi-Plane Image Object transfer is under development.

2. This Applicaton Profile includes only the XA Image and Detached Patient Management SOP Instances. It does not include Standalone Curve, Modality LUT, VOI LUT, or Overlay SOP Instances.

A.3.2 Physical media and media formats

Basic Cardiac Application Profiles in the STD-XABC class require the 120 mm CD-R physical media with the ISO/IEC 9660 Media Format, as defined in PS 3.12.

A.3.3 Directory information in DICOMDIR

Conformant Application Entities shall include in the DICOMDIR File a Basic Directory IOD containing Directory Records at the Patient and subsidiary levels appropriate to the SOP Classes in the File-set.

Note: DICOMDIRs with no directory information are not allowed by this Application Profile.

A.3.3.1 ADDITIONAL KEYS

Table A.3-2 specifies the type of Directory Records that shall be supported and the additional associated keys. Refer to the Basic Directory IOD in PS 3.3.

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Table A.3-2
STD-XABC-CD ADDITIONAL DICOMDIR KEYS

Key Attribute	Tag	Directory Record Type	Type	Notes
Date of Birth	(0010,0030)	PATIENT	2	
Sex	(0010,0040)	PATIENT	2	
Institution Name	(0008,0080)	SERIES	2	
Institution Address	(0008,0081)	SERIES	2	
Performing Physician	(0008,1050)	SERIES	2	
Icon Image Sequence	(0088,0200)	IMAGE	1	
Image Type	(0008,0008)	IMAGE	1	
Calibration Image	(0050,0004)	IMAGE	2	
Referenced Image Sequence	(0008,1140)	IMAGE	1C	Required if the SOP Instance referenced by the Directory Record has an Image Type (0008,0008) of BIPLANE A or BIPLANE B.
>Referenced SOP Class UID	(0008,1150)	IMAGE	1C	Required if Referenced Image Sequence (0008,1140) is present
>Referenced SOP Instance UID	(0008,1155)	IMAGE	1C	Required if Referenced Image Sequence (0008,1140) is present

A.3.3.2 ICON IMAGES

Directory Records of type IMAGE shall include Icon Images. The icon pixel data shall be supported with Bits Allocated (0028,0100) equal to 8 and Row (0028,0010) and Column (0028,0011) attribute values of 128.

Notes: 1. This icon size is larger than that recommended in PS 3.10 because the 64x64 icon would not be clinically useful for identifying and selecting x-ray angiographic images.

2. For multi-frame images, it is recommended that the icon image be derived from the frame identified in the Directory Frame Number attribute (0028,6010), if defined for the image SOP Instance. If the Directory Frame Number is not present, a frame approximately one-third of the way through the multi-frame image should be selected. The process to reduce a 512x512 image to a 128x128 image is beyond the scope of this standard.

A.3.4 Other parameters

This section defines other parameters common to all specific Application Profiles in the STD-XABC class which need to be specified in order to ensure interoperable media interchange.

A.3.4.1 IMAGE ATTRIBUTE VALUES

The attributes listed in Table A.3-3 used within the X-Ray Angiographic Image files shall take the values specified.

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Table A.3-3
STD-XABC-CD- REQUIRED IMAGE ATTRIBUTE VALUES

Attribute	Tag	Value
Modality	(0008,0060)	XA
Rows	(0028,0010)	512 (see below)
Columns	(0028,0011)	512 (see below)
Bits Allocated	(0028,0100)	8
Bits Stored	(0028,0101)	8

When creating or updating a File-set, Rows or Columns shall not exceed a value of 512. When reading a File-set, an FSR or FSU shall accept a value of at least 512 for Rows or Columns.

Overlay data, if present, shall be encoded in Overlay Data (60XX,3000).

A.3.4.1.1 ATTRIBUTE VALUE PRECEDENCE

The values of attributes contained in a Detached Patient Management SOP Instance referenced by a Directory Record of type PATIENT shall take precedence over the values of those attributes contained in a SOP Instance referenced by a subsidiary Directory Record. The DICOMDIR Directory Records of type PATIENT shall have key attribute values in accordance with this precedence.

Note: This allows patient identification and demographic information to be updated without changing the composite Image IOD files. The DICOMDIR file is critical in establishing the link between the updated information and the image. As an example, at the time an Image file was written, the patient's name was incorrect, or inconsistent with the Hospital Information System records. Subsequently, a Detached Patient Management file with the corrected name is added to the File-set. If the FSR supports the Detached Patient Management SOP Class, then the FSR should use the information from this SOP Class rather than the information in the Image file.

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Annex B (Normative) - 1024 X-ray Angiographic Application Profile

B.1 CLASS AND PROFILE IDENTIFICATION

This Annex defines a class of Application Profiles for 1024 X-ray Angiographic clinical applications. The identifier for this class shall be STD-XA1K. It is the intent of this profile to be backward compatible with the Basic Cardiac X-ray Angiographic Application Profile (STD-XABC-CD) in PS 3.11 Annex A.

The specific Application Profiles in this class are shown in the Table B.1-1.

Table B.1-1 - 1024 X-ray Angiographic Profiles

Application Profile	Identifier	Description
1024 X-Ray Angiographic Studies on CD-R Media	STD-XA1K-CD	It handles single frame or multi-frame X-ray digital images up to 1024x1024x12 bits; biplane acquisitions are encoded as two single plane information objects. Secondary Capture images are supported.

B.2 CLINICAL CONTEXT

This class of Application Profiles facilitates the interchange of primary digital X-ray cine runs, typically acquired as part of angiographic procedures. Typical media interchanges would be from in-lab acquisition equipment to either a display workstation or to a data archive system, or between a display workstation and a data archive system (in both directions).

Additionally, images derived from or related to primary digital X-ray cine runs, such as quantitative analysis images, reference images, multi-modality images and screen capture images, may be interchanged via this Profile.

The operational use of the media interchange is potentially both intra-institutional and inter-institutional.

Note: An FSC conforming to the Basic 512 Cardiac Angiographic Profile and General Purpose CD-R Profile supporting the SC Image Media Storage SOP Class could, if the restrictions in this profile were observed, create images that were readable by an FSR supporting the profile. Conversely, SC Images written by an FSC conforming to this profile, would be readable by an FSR conforming to the Basic 512 Cardiac Angiographic Profile and the General Purpose CD-R Profile supporting the SC Image Media Storage SOP Class.

B.2.1 Roles and Service Class Options

This Application Profile Class uses the Media Storage Service Class defined in PS 3.4 with the Interchange Option.

The Application Entity shall support one or more of the roles of File-set Creator, File-set Reader, and File-set Updater, defined in PS 3.10.

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B.2.1.1 File Set Creator

The Application entity acting as a File-Set Creator generates a File Set under the STD-XA1K Application Profile Class. Typical entities using this role would include X-ray angiographic lab equipment, and archive systems which generate a patient record for transfer to another institution. File Set Creators shall be able to generate the Basic Directory SOP Class in the DICOMDIR File with all types of Directory Records related to the SOP Classes stored in the File-set.

An FSC shall offer the ability to either finalize the disc at the completion of the most recent write session (no additional information can be subsequently added to the disc) or to allow multi-session (additional information may be subsequently added to the disc).

Note: A multiple volume (a logical volume that can cross multiple physical media) is not supported by this Application Profile Class. If a set of Files, e.g., a Study, cannot be written entirely on one CD-R, the FSC will create multiple independent DICOM File-sets such that each File-set can reside on a single CD-R medium controlled by its individual DICOMDIR file. The user of the FSC can opt to use written labels on the discs to reflect that there is more than one disc for this set of files (e.g., a Study).

B.2.1.2 File Set Reader

The role of File Set Reader shall be used by Application Entities which receive a transferred File Set. Typical entities using this role would include display workstations, and archive systems which receive a patient record transferred from another institution. File Set Readers shall be able to read all the defined SOP Instances defined for the specific Application Profiles to which a conformance claim is made, using all the defined Transfer Syntaxes.

B.2.1.3 File Set Updater

The role of File Set Updater shall be used by Application Entities which receive a transferred File Set and update it by the addition of processed information. Typical entities using this role would include analytic workstations, which for instance may add to the File Set an information object containing a processed (e.g., edge-enhanced) image frame. Stations which update patient information objects would also use this role. File-set Updaters shall be able to read and update the DICOMDIR file. File-set Updaters do not have to read the image information object. File-set Updaters shall be able to generate one or more of the SOP Instances defined for the specific Application Profiles to which a conformance claim is made, and to read and update the DICOMDIR file.

An FSU shall offer the ability to either finalize the disc at the completion of the most recent write session (no additional information can be subsequently added to the disc) or to allow multi-session (additional information may be subsequently added to the disc).

Note: If the disc has not been finalized, the File-set Updater will be able to update information assuming there is enough space on the disc to write a new DICOMDIR file, the information, and the fundamental CD-R control structures. CD-R control structures are the structures that are inherent to the CD-R standards; see PS 3.12

B.3 STD-XA1K-CD APPLICATION PROFILE CLASS REQUIREMENTS

B.3.1 SOP Classes and Transfer Syntaxes

This Application Profile is based on the Media Storage Service Class with the Interchange Option (see PS 3.4).

SOP Classes and corresponding Transfer Syntaxes supported by this Application Profile are specified in Table B.3-1.

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Table B.3-1
STD-XA1K-CD SOP Classes and Transfer Syntaxes

Information Object Definition	Service Object Pair Class UID	Transfer Syntax and UID	FSC Requirement	FSR Requirement	FSU Requirement
Basic Directory	1.2.840.10008.1.3.10	Explicit VR Little Endian Uncompressed 1.2.840.10008.1.2.1	Mandatory	Mandatory	Mandatory
X-Ray Angiographic Image	1.2.840.10008.5.1.4.1.1.12.1	JPEG Lossless Process 14 (selection value 1) 1.2.840.10008.1.2.4.70	Mandatory	Mandatory	Optional
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	Optional	Mandatory	Optional
Standalone Overlay	1.2.840.10008.5.1.4.1.1.8	Explicit VR Little Endian Uncompressed 1.2.840.10008.1.2.1	Optional	Optional	Optional
Standalone Curve	1.2.840.10008.5.1.4.1.1.9	Explicit VR Little Endian Uncompressed 1.2.840.10008.1.2.1	Optional	Optional	Optional
Detached Patient Management	1.2.840.10008.3.1.2.1.1	Explicit VR Little Endian Uncompressed 1.2.840.10008.1.2.1	Optional	Mandatory	Optional

B.3.2 Physical Media And Media Formats

1024 X-Ray Angiographic Application Profiles in the STD-XA1K class require the 120mm CD-R physical media with the ISO/IEC 9660 Media Format, as defined in PS3.12.

B.3.3 Directory Information in DICOMDIR

Conformant Application Entities shall include in the DICOMDIR File a Basic Directory IOD containing Directory Records at the Patient and subsidiary levels appropriate to the SOP Classes in the File-set.

Note: DICOMDIRs with no directory information are not allowed by this Application Profile.

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B.3.3.1 Additional Keys

Table B.3-2 specifies the type of Directory Records that shall be supported and the additional associated keys. Refer to the Basic Directory IOD in PS3.3.

Table B.3-2
STD-XA1K Additional DICOMDIR Keys

Key Attribute	Tag	Directory Record Level	Type	Notes
Date of Birth	(0010,0030)	PATIENT	2	
Sex	(0010,0040)	PATIENT	2	
Institution Name	(0008,0080)	SERIES	2	
Institution Address	(0008,0081)	SERIES	2	
Performing Physician	(0008,1050)	SERIES	2	
Icon Image Sequence	(0088,0200)	IMAGE	1	
Image Type	(0008,0008)	IMAGE	1C	Required if the SOP Instance referenced by the Directory Record is an XA Image.
Calibration Image	(0050,0004)	IMAGE	2	
Referenced Image Sequence	(0008,1140)	IMAGE	1C	Required if the SOP Instance referenced by the Directory Record is an XA Image and has an Image Type (0008,0008) value 3 of BIPLANE A or BIPLANE B.
>Referenced SOP Class UID	(0008,1150)	IMAGE	1C	Required if Referenced Image Sequence (0008,1140) is present
>Referenced SOP Instance UID	(0008,1155)	IMAGE	1C	Required if Referenced Image Sequence (0008,1140) is present

B.3.3.2 Icon Images

Directory Records of type IMAGE shall include Icon Images. The icon pixel data shall be Bits Allocated and Bits Stored (0028,0101)attribute values of 8 with Row (0028,0010) and Column (0028,0011) attribute values of 128 and Photometric Interpretation (0028,0004) attribute value of MONOCHROME2.

Notes: 1. It is recommended that the Icon Images be encoding using VR OB encoding. The use of OW, allowed by the STD-XABC-CD Basic Cardiac profile defined in PS 3.11 Annex A, is deprecated, and may be retired in future versions of the standard.

2. This icon size is larger than that recommended in PS 3.10 because the 64x64 icon would not be clinically useful for identifying and selecting x-ray angiographic images.

3. For multi-frame images, it is recommended that the icon image be derived from the frame identified in the Directory Frame Number attribute (0028,6010), if defined for the image SOP Instance. If the Directory Frame Number is not present, a frame approximately one-third of the way through the multi-frame image should be selected. The process to reduce any image to a 128x128 image is beyond the scope of this standard.

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B.3.4 Other Parameters

This section defines other parameters common to all specific Application Profiles in the STD-XA1K class which need to be specified in order to ensure interoperable media interchange.

B.3.4.1 Image Attribute Values

The attributes listed in Table B.3-3 used within the X-Ray Angiographic Image files have the specified values.

Table B.3-3
STD-XA1K-CD Required XA Image Attribute Values

Attribute	Tag	Value
Modality	(0008,0060)	XA
Rows	(0028,0010)	up to 1024 (see below)
Columns	(0028,0011)	up to 1024 (see below)
Bits Stored	(0028,0101)	8, 10, and 12 bits only

Notes: 1. An FSC or FSU, when creating or updating a File-set, Rows or Columns will not exceed a value of 1024. When reading a File-set, an FSR or FSU will accept all values of up to 1024 for Rows or Columns.

2. Photometric Interpretation, Pixel Representation, High Bit, Bits Allocated and Samples per Pixel are defined in the XA IOD.

The attributes listed in Table B.3-4 used within the Secondary Capture Image files have the specified values.

Table B.3-4
STD-XA1K-CD Required SC Image Attribute Values

Attribute	Tag	Value
Rows	(0028,0010)	up to 1024 (see below)
Columns	(0028,0011)	up to 1024 (see below)
Samples per Pixel	(0028,0002)	1
Photometric Interpretatation	(0028,0004)	MONOCHROME2
Bits Allocated	(0028,0100)	8 bits only
Bits Stored	(0028,0101)	8 bits only
High Bit	(0028,0102)	7
Pixel Representation	(0028,0103)	0000H (unsigned)

Notes: 1. An FSC or FSU, when creating or updating a File-set, Rows or Columns will not exceed a value of 1024. When reading a File-set, an FSR or FSU will accept all values of up to 1024 for Rows or Columns.

2. It is recommend that Referenced Image Sequence (0008,1140) be present if the SC Image is significantally related to XA images and frames stored on the same media, and if present, it should contain references to those images and frames.

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Overlay Group 60XX shall not be present in Secondary Capture Images, and Standalone Overlays shall not be referenced by or to Secondary Capture Images used in this profile.

B.3.4.2 Multiframe JPEG Format

The JPEG encoding of pixel data shall use Interchange Format (with table specification) for all frames.

B.3.4.3 Attribute Value Precedence

The values of attributes contained in a Detached Patient Management SOP Instance referenced by a DICOMDIR PATIENT Directory Record shall take precedence over the values of those attributes contained in a SOP Instance referenced by a subsidiary Directory Record. The DICOMDIR Directory Records shall have key attribute values in accordance with this precedence.

Note: This allows patient identification and demographic information to be updated without changing the composite Image IOD files. The DICOMDIR file thus is critical in establishing the link between the updated information and the image. As an example, at the time an Image file was written, the patient's name therein was incorrect, or inconsistent with the Hospital Information System records. Subsequently, a Detached Patient Management file with the corrected name is added to the file-set. The FSR should use the name from the Patient file rather than the name in the Image file.

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Annex C Ultrasound Application Profile (Normative)

C.1 CLASS AND PROFILE IDENTIFICATION

This Annex defines Application Profiles for Ultrasound Media Storage applications. Each Application Profile has a unique identifier used for conformance claims. Due to the variety of clinical applications of storage media in Ultrasound, a family of application profiles are described in this section to best tailor an application choice to the specific needs of the user. The identifier used to describe each profile is broken down into three parts: a prefix, mid-section, and suffix. The prefix describes the overall Application Profile Class and is common for all ultrasound application profiles. The mid section describes the specific clinical application of the profile. The suffix is used to describe the actual media choice the profile will use.

The prefix for this class of application profiles is identified with the STD-US identifier.

Note: Conformance Statements may use the earlier prefix of APL which is equivalent to STD. This use is deprecated and may be retired in future versions of the standard.

The midsection is broken down into three subclasses which describes the clinical use of the data. These classes are: Image Display (ID identifier), Spatial Calibration (SC identifier), and Combined Calibration (CC identifier). All three subclasses can be applied to either single frames (SF) images or single and multi-frames (MF) images. The SC subclass enhances the ID class by adding the requirement for region specific spatial calibration data with each IOD. The CC subclass enhances the SC subclass by requiring region specific pixel component calibration.

The suffix, xxxx, is used to describe the actual media choice used for the conformance claim. Any of the above mentioned classes can be stored onto one of eight pieces of media described in the Table C.3-3.

The specific Application Profiles are shown in the following table.

Table C.1-1
APPLICATION PROFILE IDENTIFIERS

Application Profile	Single Frame	Single & Multi-Frame
Image Display	STD-US-ID-SF-xxxx	STD-US-ID-MF-xxxx
Spatial Calibration	STD-US-SC-SF-xxxx	STD-US-SC-MF-xxxx
Combined Calibration	STD-US-CC-SF-xxxx	STD-US-CC-MF-xxxx

The ID Application Profile Classes are intended to be used for the transfer of ultrasound images for display purposes.

The SC Application Profile Classes are intended to be used for the transfer of ultrasound images with spatial calibration data for quantitative purposes (see section C.4).

The CC Application Profile Classes are intended to be used for the transfer of ultrasound images with spatial and pixel component calibration data for more advanced quantitative purposes (see section C.5).

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C.2 CLINICAL CONTEXT

These classes of Application Profiles facilitate the interchange of ultrasound data on media. Typical interchanges would be between ultrasound systems, between an ultrasound system and a display workstation, between display workstations, or between an ultrasound system and a data archive. This context is shown in Figure C.2-1.

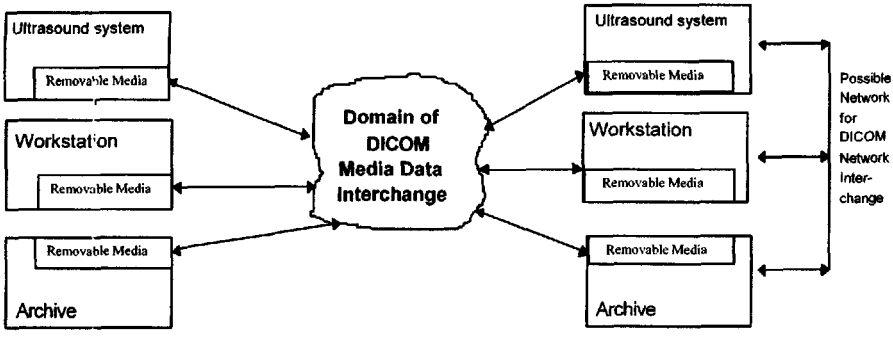

Figure C.2-1
CLINICAL CONTEXT

The operational use of the media transfer is potentially both intra-institutional and inter-institutional.

C.2.1 Roles

C.2.1.1 FILE SET CREATOR

The role of File Set Creator shall be used by Application Entities which generate a File Set under the STD-US class of Application Profiles. Typical entities using this role would include ultrasound imaging equipment, workstations, and archive systems which generate a patient record for transfer. File Set Creators shall be able to generate the DICOMDIR directory file, single and/or multi frame Ultrasound Information Object files, and depending on the subclass, region specific calibration in the defined Transfer Syntaxes.

C.2.1.2 FILE SET READER

The role of File Set Reader shall be used by Application Entities which receive a transferred File Set. Typical entities using this role would include ultrasound systems, display workstations, and archive systems which receive a patient record from a piece of media. File Set Readers shall be able to read the DICOMDIR directory file and all Information Objects defined for the specific Application Profiles, using the defined Transfer Syntaxes.

C.2.1.3 FILE SET USER

The role of File Set Updater shall be used by Application Entities which receive a transferred File Set and updates it by the addition or deletion of objects to the media. Typical entities using this role would include ultrasound systems adding new patient records to the media and workstations which may add an information object containing a processed or modified image.

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C.3 GENERAL CLASS PROFILE

C.3.1 Abstract and Transfer Syntaxes

Application Profiles in this class, STD-US, shall support the appropriate Information Object Definitions (IOD) and Transfer Syntaxes for the Media Storage SOP Class in the following table. In the role of FS-Updater or FS-Creator the application can choose one of the three possible transfer Syntaxes to create an IOD. In the role of FS-Reader an application shall support all transfer Syntaxes defined for the STD-US application profile.

Table C.3-1
ABSTRACT AND TRANSFER SYNTAXES

Information Object Definition	SOP Class UID	Transfer Syntax	Transfer Syntax UID
DICOM Media Storage Directory	1.2.840.10008.1.3.10	Explicit VR Little Endian Uncompressed	1.2.840.10008.1.2.1 (see *PS 3.10 section 8.6*)
Ultrasound Image Storage	1.2.840.10008.5.1.4.1.1.6.1	Explicit VR Little Endian Uncompressed	1.2.840.10008 1.2.1
		RLE Lossless Image Compression	1.2.840.10008.1.2.5
		JPEG Lossy, Baseline Sequential with Huffman Coding (Process 1)	1.2.840.10008.1.2.4.50
Ultrasound Multi-frame Image Storage	1.2.840.10008.5.1.4.1.1.3.1	Explicit VR Little Endian Uncompressed	1.2.840.10008.1.2.1
		RLE Lossless Image Compression	1.2.840.10008.1.2.5
		JPEG Lossy, Baseline Sequential with Huffman Coding (Process 1)	1.2.840.10008.1.2.4.50

C.3.1.1 Ultrasound Single and Multi-frame Pixel Formats Supported

The STD-US application profile requires that all ultrasound image objects only be stored using the values described in PS 3.3 US Image Module and the specializations used for the Ultrasound Single and Multi-Frame IODs.

In the role of FS-Updater or FS-Creator the application can choose any of the supported Photometric Interpretations described in PS 3.3 US Image Module to create an IOD. In the role of FS-Reader, an application shall support all Photometric Interpretations described in PS 3.3 US Image Module.

Table C.3-2 describes restrictions on the use of various Transfer Syntaxes with the supported Photometric Interpretations for both single and multi-frame images.

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Table C.3-2
DEFINED PHOTOMETRIC INTERPRETATION AND TRANSFER SYNTAX PAIRS

Photometric Interpretation Value	Transfer Syntax	Transfer Syntax UID
MONOCHROME2	Uncompressed RLE Lossless Image Compression	1.2.840.10008.1.2.1 1.2.840.10008.1.2.5
RGB	Uncompressed RLE Lossless Image Compression	1.2.840.10008.1.2.1 1.2.840.10008.1.2.5
PALETTE COLOR	Uncompressed RLE Lossless Image Compression	1.2.840.10008.1.2.1 1.2.840.10008.1.2.5
YBR_FULL	RLE Lossless Image Compression	1.2.840.10008.1.2.5
YBR_FULL_422	Uncompressed JPEG Lossy	1.2.840.10008.1.2.1 1.2.840.10008.1.2.4.50
YBR_PARTIAL_422	Uncompressed JPEG Lossy	1.2.840.10008.1.2.1 1.2.840.10008.1.2.4.50

C.3.2 Physical Media And Media Formats

An ultrasound application profile class may be supported by any one of the media described in Table C.3-3.

Table C.3-3
MEDIA CLASSES

Media	Media Classes	Media Format	PS 3.12
1.44MB Floppy Disc	FLOP	DOS	Annex B
128MB 90mm MOD	MOD128	DOS, unpartitioned (removable media)	Annex C
230MB 90mm MOD	MOD230	DOS, unpartitioned (removable media)	Annex G
540MB 90mm MOD	MOD540	DOS, unpartitioned (removable media)	Annex H
650MB 130mm MOD	MOD650	DOS, unpartitioned (removable media)	Annex D
1.2GB 130mm MOD	MOD12	DOS, unpartitioned (removable media)	Annex E
2.3GB 130mm MOD	MOD23	DOS, unpartitioned (removable media)	Annex I
CD-R	CDR	ISO/IEC 9660	Annex F

C.3.3 DICOMDIR

The Directory shall include Directory Records of PATIENT, STUDY, SERIES, IMAGE corresponding to the information object files in the File Set. All DICOM files in the File Set incorporating SOP Instances (Information Objects) defined for the specific Application Profile shall be referenced by Directory Records. At the image level each file contains a single ultrasound image object or a single ultrasound multi-frame image object as defined in PS 3.3 of the standard.

NOTE: For all media selected in this Application Profile Class, STD-US, the following applies as defined in PS 3.12.

All implementations should include the DICOM Media Storage Directory in the DICOMDIR file. There should only be one DICOMDIR file on a single media. The DICOMDIR file should be found in the root directory of the media. For the case of double-sided MOD media, there shall be a DICOMDIR on each side of the media.

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On a single media the patient ID key at the patient level shall be unique for each patient directory record.

C.3.3.1 Additional Keys

File Set Creators and Updaters are only required to generate mandatory elements specified in PS 3.10. At each directory record level any additional data elements can be added as keys, but is not required by File Set Readers to be able to use them as keys.

C.3.3.2 File Component IDs

Note: File Component IDs should be created using a random number filename to minimize File Component ID collisions as described in PS 3.12. The FS-Updater should check the existence of a Component ID prior to creating that ID. Should an ID collision occur, the FS-Updater should try another ID.

C.4 SPATIAL CALIBRATION (SC) CLASS REQUIREMENTS

All implementations conforming to the Application Profile Class SC shall include the US Region Calibration Module with the exception of pixel component organization data element (0018,6044) and other data elements which are conditional on that data element.

C.5 COMBINED CALIBRATION (CC) CLASS REQUIREMENTS

All implementations conforming to the Application Profile Class CC shall include the US Region Calibration Module including the pixel component organization data element (0018,6044) and other data elements which are conditional on that data element.

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Annex D (Normative) - General Purpose CD-R Image Interchange Profile

D.1 PROFILE IDENTIFICATION

This Annex defines an Application Profile Class potentially inclusive of all defined Media Storage SOP Classes. This class is intended to be used for the interchange of Composite Image and Standalone SOP Instances via CD-R media for general purpose applications.Objects from multiple modalities may be included on the same media.

A detailed list of the Media Storage SOP Classes that may be supported is defined in PS 3.4.

Table D.1-1 STD-GEN-CD Profile

Application Profile	Identifier	Description
General Purpose CD-R Image Interchange	STD-GEN-CD	Handles interchange of Composite Image SOP Instances and SOP Instances which conform to the model defined for Stand-alone SOP Classes, such as Curves, Overlays and LUTs.

The identifier for this General Purpose Image Exchange profile shall be STD-GEN-CD.

Equipment claiming conformance to this Application Profile shall list the subset of Media Storage SOP Classes that it supports in its Conformance Statement.

Note: Since it is not required to support all Media Storage Classes the user should carefully consider the subset of supported Media Storage SOP Classes in the Conformance Statements of such equipment to establish effective object interchange.

D.2 CLINICAL CONTEXT

This Application Profile facilitates the interchange of images and related data on CD-R media. Typical interchange would be between acquisition devices, archives and workstations.

This Application Profile facilitates the creation of a multi-modality medium for image interchange, useful for clinical, patient record, teaching and research applications, within and between institutions.

This profile is intended only for general purpose applications. It is not intended as a replacement for specific Application Profiles that may be defined for a particular clinical context. The latter may support compression transfer syntaxes, limitations on the form and content of SOP Class instances, and specific media choices that preclude the use of the General Purpose Interchange Profile.

Note: The creation of a CD-R is considerably more complex than the reading thereof. Therefore the clinical context for this Application profile is likely to be asymmetric, with a sophisticated File Set Creator and relatively simple File Set Readers.

D.2.1 Roles and Service Class Options

This Application Profile uses the Media Storage Service Class defined in PS3.4 with the Interchange Option.

The Application Entity shall support one or more of the roles of File Set Creator (FSC), File Set Reader (FSR), and File Set Updater (FSU), defined in PS 3.10.

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D.2.1.1 File Set Creator

The role of File Set Creator shall be used by Application Entities which generate a File Set under this Image Interchange Class of Application Profiles.

File Set Creators shall be able to generate the Basic Directory SOP Class in the DICOMDIR file with all the subsidiary Directory Records related to the Image SOP Classes stored in the File Set.
The Application Entity acting as a File Set Creator generates a File Set under the STD-GEN-CD Application Profile.

FSC shall offer the ability to either finalize the physical volume at the completion of the most recent write session (no additional information can be subsequently added to the volume) or to allow multi-session (additional information may be subsequently added to the volume).

Note: A multiple volume (i.e. a logical volume that can cross multiple physical media) is not supported by this class of Application profile. If a set of Files, e.g., a Study, cannot be written entirely on one physical volume, the FSC will create multiple independent DICOM File Sets such that each File Set can reside on a single physical volume controlled by its individual DICOMDIR file. The user of the FSC can opt to use written labels on the physical volumes to indicate that there is more than one physical volume for this set of files (e.g., a study).

D.2.1.2 File Set Reader

The role of File Set Reader shall be used by Application Entities which receive a transferred File Set under the Image Interchange Class of Application Profiles. Typical entities using this role would include image generating systems, display workstations, and archive systems which receive a patient record; e.g. transferred from another institution.

File Set Readers shall be able to read the DICOMDIR directory file and all the SOP Instance files defined for this Application Profile, for which a Conformance Statement is made, using the defined Transfer Syntax.

D.2.1.3 File Set Updater

The role of File Set Updater is used by Application Entities which receive a transferred File Set under the Image Exchange Class of Application Profiles and update it by the addition (or deletion) of images or information to (or from) the medium. Typical entities using this role would include image generating systems and workstations which process or modify images.

File Set Updaters shall be able to generate one or more of the SOP Instances defined for this Application Profile, for which a Conformance Statement is made, and to read and update the DICOMDIR file.

FSU shall offer the ability to either finalize the physical volume at the completion of the most recent write session (no additional information can be subsequently added to the volume) or to allow multi-session (additional information may be subsequently added to the volume).

Note: If the volume has not been finalized, the File Set Updater will be able to update information assuming there is enough space on the volume to write a new DICOMDIR file, the information, and the fundamental volume control structures. Volume control structures are the structures that are inherent to the standards of the physical volume, see PS 3.12.

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D.3 STD-GEN-CD PROFILE

D.3.1 SOP Classes and Transfer Syntaxes

This Application Profile is based on the Media Storage Service Class with the Interchange Option (see PS 3.4).

Table D.3-1
STD-GEN-CD SOP Classes and Transfer Syntaxes

Information Object Definition	Service Object Pair Class UID	Transfer Syntax and UID	FSC Requirement	FSR Requirement	FSU Requirement
Basic Directory	1.2.840.10008.1.3.10	Explicit VR Little Endian Uncompressed 1.2.840.10008.1.2.1	Mandatory	Mandatory	Mandatory
Composite Image & Stand-alone Storage	*Refer to: PS 3.4 for SOPs UID definitions*	Explicit VR Little Endian Uncompressed 1.2.840.10008.1.2.1	Defined in Conformance Statement	Defined in Conformance Statement	Optional
Detached Patient Management	1.2.840.10008.3.1.2.1.1	Explicit VR Little Endian Uncompressed 1.2.840.10008.1.2.1	Optional	Defined in Conformance Statement (See D.3.3.2)	Optional

The SOP Classes and corresponding Transfer Syntax supported by this Application Profile are specified in the Table D.3-1. The supported Storage SOP Class(es) shall be listed in the Conformance Statement using a table of the same form.

D.3.2 Physical Medium And Medium Format

The STD-GEN-CD application profile requires the 120 mm CD-R physical medium with the ISO/IEC 9660 Media Format, as defined in PS3.12.

D.3.3 Directory Information in DICOMDIR

Conformant Application Entities shall include in the DICOMDIR File the Basic Directory IOD containing Directory Records at the Patient and the subsidiary Study and Series levels, appropriate to the SOP Classes in the File Set.

All DICOM files in the File Set incorporating SOP Instances defined for the specific Application Profile shall be referenced by Directory Records.

Note: DICOMDIRs with no directory information are not allowed by this Application Profile.

All implementations shall include the DICOM Media Storage Directory in the DICOMDIR file. There shall only be one DICOMDIR file per File Set. The DICOMDIR file shall be in the root directory of the medium. The Patient ID at the patient level shall be unique for each patient directory record in one File Set.

D.3.3.1 Additional Keys

File Set Creators and Updaters are required to generate the mandatory elements specified in PS 3.3.

Table D.3-2 specifies the additional associated keys. At each directory record level other additional data elements can be added, but it is not required that File Set Readers be able to use them as keys. Refer to the Basic Directory IOD in PS 3.3.

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Table D.3-2
STD-GEN-CD Additional DICOMDIR Keys

Key Attribute	Tag	Directory Record Type	Type	Notes
Image Type	(0008,0008)	IMAGE	1C	Required if present in image object.
Referenced Image Sequence	(0008,1140)	IMAGE	1C	Required if present in image object.
>Referenced SOP Class UID	(0008,1150)	IMAGE	1C	Required if Referenced Image Sequence (0008,1140) is present
>Referenced SOP Instance UID	(0008,1155)	IMAGE	1C	Required if Referenced Image Sequence (0008,1140) is present.

Note: The requirements with respect to the mandatory DICOMDIR keys in PS 3.3 imply that either these attributes are present in the Image IOD, or they are in some other way supplied by the File-set Creator. These attributes are (0010,0020) Patient ID, (0008,0020) Study Date, (0008,0030) Study Time, (0020,0010) Study ID, (0020,0011) Series Number, and (0020,0013) Image Number.

D.3.3.2 Attribute value precedence

If an FSR supports the Detached Patient Management SOP Class, the values of attributes contained in a Detached Patient Management SOP Instance referenced by a Directory Record of type PATIENT, shall take precedence over the values of those attributes contained in the SOP Instance referenced by a subsidiary Directory Record. The DICOMDIR Directory Records of type PATIENT shall have key attributes values in accordance with this precedence.

Note: 1. This allows patient identification and demographic information to be updated without changing the composite Image IOD files. The DICOMDIR file thus is critical in establishing the link between the updated information and the image. As an example, at the time an Image file was written, the patient's name therein was incorrect, or inconsistent with the Hospital Informations System records. Subsequently, a Detached Patient Management file with the corrected name is added to the File Set. The FSR should use the information from the Detached Patient Management SOP Class, rather than the information in the Image file.

2. The support for the Detached Patient Management SOP Class as indicated in Table D.3-1, is to be defined in the Conformance Statement, and is not mandatory for all FSRs of this profile. Applications which require the ability to read updated patient identifying information, such as an FSR that may forward an updated SOP Instance elsewhere, may need to support this mechanism. Applications such as standalone viewers may choose not to support this mechanism, in which case the user should be made aware, for example by a screen message or in the documentation, that updated identifying information may exist on the media that is not visible.

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Annex E (Normative) - CT and MR Image Application Profiles

E.1 PROFILE IDENTIFICATION

This Annex defines Application Profiles for Computed Tomography and Magnetic Resonance Imaging interchange and storage on high capacity rewriteable magneto-optical disks (MOD) and CD-R uncompressed and with lossless compression.

Table E.1-1 - STD-CTMR Profiles

Application Profile	Identifier	Description
CT/MR Studies on 650MB MOD	STD-CTMR-MOD650	Handles single frame 8, 12 or 16 bit grayscale and 8 bit palette color, uncompressed and lossless compressed images.
CT/MR Studies on 1.2GB MOD	STD-CTMR-MOD12	Handles single frame 8, 12 or 16 bit grayscale and 8 bit palette color, uncompressed and lossless compressed images.
CT/MR Studies on 2.3GB MOD	STD-CTMR-MOD23	Handles single frame 8, 12 or 16 bit grayscale and 8 bit palette color, uncompressed and lossless compressed images.
CT/MR Studies on CD-R	STD-CTMR-CD	Handles single frame 8, 12 or 16 bit grayscale and 8 bit palette color, uncompressed and lossless compressed images.

E.2 CLINICAL CONTEXT

These Application Profiles facilitate the interchange and storage of primary CT and MR images as well as related Secondary Capture Images with certain defined attributes, including grayscale and palette color images. CT, MR and SC images may co-exist within the same File-set.

Typical interchanges would be between acquisition devices, archives and workstations, within and between institutions.

E.2.1 Roles and Service Class Options

These Application Profiles uses the Media Storage Service Class defined in PS 3.4 with the Interchange Option.

The Application Entity shall support one or more of the roles of File-set Creator, File-set Reader, and File-set Updater, defined in PS 3.10.

E.2.1.1 File Set Creator

The Application entity acting as a File-Set Creator generates a File Set under a STD-CTMR Application Profile. Typical entities using this role would include CT or MR equipment, and archive systems which

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generate a patient record for transfer to another institution. File Set Creators shall be able to generate the Basic Directory SOP Class in the DICOMDIR File with all types of Directory Records related to the SOP Classes stored in the File-set.

Note: A multiple volume (a logical volume that can cross multiple physical media) is not supported by this class of Application profile. If a set of Files, e.g., a Study, cannot be written entirely on one physical volume, the FSC will create multiple independent DICOM File-sets such that each File-set can reside on a single physical volume controlled by its individual DICOMDIR file. The user of the FSC can opt to use written labels on the physical volumes to indicate that there is more than one physical volume for this set of files (e.g., a study).

E.2.1.2 File Set Reader

The role of File Set Reader is used by Application Entities which receive a transferred File Set. Typical entities using this role would include display workstations, and archive systems which receive a patient record transferred from another institution. File Set Readers shall be able to read all the SOP Classes defined for the specific Application Profile for which a Conformance Statement is made, using all the defined Transfer Syntaxes.

E.2.1.3 File Set Updater

The role of File Set Updater is used by Application Entities which receive a transferred File Set and update it by the addition of information. Typical entities using this role would include analytic workstations, which, for instance, may add to the File-set an information object containing a processed image. Stations which update patient information objects would also use this role. File-set Updaters do not have to read the images. File-set Updaters shall be able to generate one or more of the SOP Instances defined for the specific Application Profile for which a conformance statement is made, and to read and update the DICOMDIR file.

Note: The File-set Updater will be able to update information assuming there is enough space on the volume to write a new DICOMDIR file and the information.

E.3 STD-CTMR PROFILES

E.3.1 SOP Classes and Transfer Syntaxes

These Application Profiles are based on the Media Storage Service Class with the Interchange Option (see PS 3.4).

SOP Classes and corresponding Transfer Syntaxes supported by these Application Profiles are specified in the Table E.3-1.

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Table E.3-1
STD-CTMR SOP Classes and Transfer Syntaxes

Information Object Definition	Service Object Pair Class UID	Transfer Syntax and UID	FSC Require-ment	FSR Require-ment	FSU Require-ment
Basic Directory	1.2.840.10008.1.3.10	Explicit VR Little Endian Uncompressed 1.2.840.10008.1.2.1	Mandatory	Mandatory	Mandatory
CT Image	1.2.840.10008.5.1.4.1.1.2	JPEG Lossless Process 14 (selection value 1) 1.2.840.10008.1.2.4.70	Optional	Mandatory	Optional
CT Image	1.2.840.10008.5.1.4.1.1.2	Explicit VR Little Endian Uncompressed 1.2.840.10008.1.2.1	Optional	Mandatory	Optional
MR Image	1.2.840.10008.5.1.4.1.1.4	JPEG Lossless Process 14 (selection value 1) 1.2.840.10008.1.2.4.70	Optional	Mandatory	Optional
MR Image	1.2.840.10008.5.1.4.1.1.4	Explicit VR Little Endian Uncompressed 1.2.840.10008.1.2.1	Optional	Mandatory	Optional
SC Image (grayscale)	1.2.840.10008.5.1.4.1.1.7	JPEG Lossless Process 14 (selection value 1) 1.2.840.10008.1.2.4.70	Optional	Mandatory	Optional
SC Image (grayscale)	1.2.840.10008.5.1.4.1.1.7	Explicit VR Little Endian Uncompressed 1.2.840.10008.1.2.1	Optional	Mandatory	Optional
SC Image (palette color)	1.2.840.10008.5.1.4.1.1.7	JPEG Lossless Process 14 (selection value 1) 1.2.840.10008.1.2.4.70	Optional	Optional	Optional
SC Image (palette color)	1.2.840.10008.5.1.4.1.1.7	Explicit VR Little Endian Uncompressed 1.2.840.10008.1.2.1	Optional	Optional	Optional
Detached Patient Management	1.2.840.10008.3.1.2.1.1	Explicit VR Little Endian Uncompressed 1.2.840.10008.1.2.1	Optional	Defined in Conformance Statement (See E.3.4.1.1)	Optional

E.3.2 Physical Medium And Medium Format

The STD-CTMR-MOD650 application profile requires the 130 mm 650MB R/W MOD physical medium with the PCDOS Media Format, as defined in PS 3.12.

The STD-CTMR-MOD12 application profile requires the 130 mm 1.2GB R/W MOD physical medium with the PCDOS Media Format, as defined in PS 3.12.

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The STD-CTMR-MOD23 application profile requires the 130 mm 2.3GB R/W MOD physical medium with the PCDOS Media Format, as defined in PS 3.12.

The STD-CTMR-CD application profile requires the 120 mm CD-R physical medium with the ISO 9660 Media Format, as defined in PS 3.12.

E.3.3 Directory Information in DICOMDIR

Conformant Application Entities shall include in the DICOMDIR File a Basic Directory IOD containing Directory Records at the Patient and subsidiary levels appropriate to the SOP Classes in the File-set. All DICOM files in the File-set incorporating SOP Instances defined for the specific Application Profile shall be referenced by Directory Records.

Note: DICOMDIRs with no directory information are not allowed by this Application Profile.

E.3.3.1 Additional Keys

File Set Creators and Updaters are required to generate the mandatory elements specified in PS 3.3, Annex F of the standard. Table E.3-2 specifies the additional associated keys. At each directory record level other additional data elements can be added, but it is not required that File Set Readers be able to use them as keys. Refer to the Basic Directory IOD in PS 3.3.

E.3.3.2 Localizer Related Attributes

Directory Records of type IMAGE shall include the mandatory attributes from the Frame of Reference and Image Plane modules, if present in the composite image object, as specified in PS3.3 and included in Table E.3-2, in order to allow the image to be referenced to a localizer image or other orthogonal image. The Rows (0028,0010) and Columns (0028,0011) attributes are required in order to facilitate annotation of such a localizer.

Note: The Frame of Reference module is specified in PS 3.3 as mandatory for the CT and MR composite information objects, but not for Secondary Capture objects.

E.3.3.3 Icon Images

Directory Records of type SERIES or IMAGE may include Icon Images. The icon pixel data shall be as specified in PS 3.3 Icon Image Key Definition, and restricted such that Photometric Interpretation (0028,0004) shall be MONOCHROME2 or PALETTE COLOR, Bits Allocated (0028,0100) and Bits Stored (0028,0101) shall be equal to 8, and Rows (0028,0010) and Columns (0028,0011) shall be equal to 64.

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E.3.4 Other Parameters

This section defines other parameters in the STD-CTMR profiles which need to be specified in order to ensure interoperable information interchange.

Table E.3-2
STD-CTMR Additional DICOMDIR Keys

Key Attribute	Tag	Record Type	Type	Notes
Referenced Image Sequence	(0008,1140)	IMAGE	1C	Required if present in image object.
>Referenced SOP Class UID	(0008,1150)	IMAGE	1C	Required if Referenced Image Sequence (0008,1140) is present.
>Referenced SOP Instance UID	(0008,1155)	IMAGE	1C	Required if Referenced Image Sequence (0008,1140) is present.
Image Position (Patient)	(0020,0032)	IMAGE	1C	Required if present in image object.
Image Orientation (Patient)	(0020,0037)	IMAGE	1C	Required if present in image object.
Frame of Reference UID	(0020,0052)	IMAGE	1C	Required if present in image object.
Rows	(0028,0010)	IMAGE	1	
Columns	(0028,0011)	IMAGE	1	
Pixel Spacing	(0028,0030)	IMAGE	1C	Required if present in image object.

Notes: 1. The Basic Directory Information Object definition in PS 3.3 defines the following attributes as Type 1 or 2: for PATIENT directory records: (0010,0010) Patient's Name; for STUDY directory records: (0008,0050) Accession Number, (0008,0020) Study Date, (0008,1030) Study Description; for SERIES directory records: (0008,0060) Modality. Hence these are not redefined here.

2. The Basic Directory Information Object definition in PS 3.3 allows for the optional inclusion of Icon Images at the IMAGE or SERIES level. These remain optional for this profile, and the choice of whether or not to include Icon Images for every image or series, or in a more selective manner, is left up to the implementor. E.3.3.3 describes restrictions that apply to Icon Images that are included in this profile.

E.3.4.1 Image Attribute Values

The attributes listed in Table E.3-3 used within CT Image files, those listed in Table E.3-4 used within MR Image files, those listed in Table E.3-5 used within grayscale SC Image files, and those listed in Table E.3-6 used within color SC Image files, shall take the values specified, which are more specific than, but must be consistent with, those specified in the definition of the CT, MR and SC Image Information Object Definitions in PS 3.3.

Table E.3-3 STD-CTMR
Required Image Attribute Values for CT Images

Attribute	Tag	Value

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Modality	(0008,0060)	CT
Photometric Interpretation	(0028,0004)	MONOCHROME2

Table E.3-4 STD-CTMR
Required Image Attribute Values for MR Images

Attribute	Tag	Value
Modality	(0008,0060)	MR
Photometric Interpretation	(0028,0004)	MONOCHROME2
Bits Stored	(0028,0101)	8,12 to 16
High Bit	(0028,0102)	(0028,0101) Bits Stored - 1

Note: The definition of the MR Composite Image Object in PS 3.3 does not restrict (0028,0101) Bits Stored or (0028,0102) High Bit.

Table E.3-5 STD-CTMR
Required Image Attribute Values for Grayscale SC Images

Attribute	Tag	Value
Samples Per Pixel	(0028,0002)	1
Photometric Interpretation	(0028,0004)	MONOCHROME2
Bits Allocated	(0028,0100)	8 or 16
Bits Stored	(0028,0101)	(0028,0100) Bits Allocated
High Bit	(0028,0102)	(0028,0101) Bits Stored - 1

Table E.3-6 STD-CTMR
Required Image Attribute Values for Color SC Images

Attribute	Tag	Value
Samples Per Pixel	(0028,0002)	1
Photometric Interpretation	(0028,0004)	PALETTE COLOR
Bits Allocated	(0028,0100)	8
Bits Stored	(0028,0101)	8
High Bit	(0028,0102)	7

E.3.4.1.1 Attribute Value Precedence

If an FSR supports the Detached Patient Management SOP Class, the values of attributes contained in a Detached Patient Management SOP Instance referenced by a Directory Record of type PATIENT, shall take precedence over the values of those attributes contained in the SOP Instance referenced by a subsidiary Directory Record. The DICOMDIR Directory Records of type PATIENT shall have key attributes values in accordance with this precedence.

Note: 1. This allows patient identification and demographic information to be updated without changing the composite Image IOD files. The DICOMDIR file thus is critical in establishing the link between the

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updated information and the image. As an example, at the time an Image file was written, the patient's name therein was incorrect, or inconsistent with the Hospital Informations System records. Subsequently, a Detached Patient Management file with the corrected name is added to the File Set. The FSR should use the information from the Detached Patient Management SOP Class, rather than the information in the Image file.

2. The support for the Detached Patient Management SOP Class as indicated in Table E.3-1, is to be defined in the Conformance Statement, and is not mandatory for all FSRs of this profile. Applications which require the ability to read updated patient identifying information, such as an FSR that may forward an updated SOP Instance elsewhere, may need to support this mechanism. Applications such as standalone viewers may choose not to support this mechanism, in which case the user should be made aware, for example by a screen message or in the documentation, that updated identifying information may exist on the media that is not visible.

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Annex F (Normative) - Waveform Diskette Interchange Profile

F.1 PROFILE IDENTIFICATION

This Annex defines a class of Application Profiles for interchange of Waveform SOP Instances via 1.44 MB Diskette (floppy disk) media.

The identifier for this class shall be STD-WVFM.

The specific Application Profiles in this class are shown in the Table F.1.

Table F.1 - Waveform Application Profiles

Application Profile	Identifier	Description
12-lead ECG Interchange on Diskette	STD-WVFM-ECG-FD	Uncompressed ECG waveform data
Hemodynamic Waveform Interchange on Diskette	STD-WVFM-HD-FD	Uncompressed hemodynamic waveform data

F.2 CLINICAL CONTEXT

This Application Profile facilitates the interchange of waveforms and related data on floppy disk media.

This primary clinical context for this profile is the transfer of waveforms, such as electrocardiograms, from non-networked equipment (mobile or remote acquisition units) to archive or display equipment.

F.2.1 Roles and Service Class Options

This class of Application Profile uses the Media Storage Service Class defined in PS3.4 with the Interchange Option.

The Application Entity shall support one or more of the roles of File Set Creator (FSC), File Set Reader (FSR), and File Set Updater (FSU), defined in PS 3.10.

The role of File Set Creator shall be used by Application Entities which generate a File Set under this Class of Application Profiles. FSCs shall be able to generate the Waveform SOP Instances defined for this Application Profile, and the Basic Directory SOP Instance in the DICOMDIR file with all the subsidiary Directory Records related to the Waveform SOP Instances stored in the File Set.

The role of File Set Reader shall be used by Application Entities which receive a transferred File Set under this Class of Application Profiles. File Set Readers shall be able to read the DICOMDIR directory file and all the SOP Instance files defined for this Application Profile, using the defined Transfer Syntax.

The role of File Set Updater is used by Application Entities which receive a transferred File Set under this Class of Application Profiles, and update it by the addition (or deletion) of waveforms or ancillary information to (or from) the medium. FSUs shall be able to read and update the DICOMDIR file, and optionally to generate the Waveform SOP Instances defined for this Application Profile.

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F.4 STD-WVFM-ECG-FD PROFILE

F.4.1 SOP Classes and Transfer Syntaxes

This Application Profile is based on the Media Storage Service Class with the Interchange Option (see PS 3.4).

The SOP Classes and corresponding Transfer Syntax supported by this Application Profile are specified in the Table F.4.1-1. The supported Storage SOP Classes shall be listed in the Conformance Statement using a table of the same form.

Table F.4.1-1 STD-WVFM-ECG-FD SOP Classes and Transfer Syntaxes

Information Object Definition	Service Object Pair Class UID	Transfer Syntax and UID	FSC Requirement	FSR Requirement	FSU Requirement
Basic Directory	1.2.840.10008.1.3.10	Explicit VR Little Endian Uncompressed 1.2.840.10008.1.2.1	Mandatory	Mandatory	Mandatory
12-lead ECG Waveform Storage	1.2.840.10008.5.1.4.1.1.9.1.1	Explicit VR Little Endian Uncompressed 1.2.840.10008.1.2.1	Mandatory	Mandatory	Optional

F.4.2 Physical Medium And Medium Format

The STD-WVFM-ECG-FD application profile requires the 1.44 MB Diskette physical medium with the PC File System Media Format, as defined in PS3.12 Annex B.

F.4.3 Directory Information in DICOMDIR

Conformant Application Entities shall include in the DICOMDIR File the Basic Directory IOD containing Directory Records at the Patient and the subsidiary Study and Series levels, appropriate to the SOP Classes in the File Set. All DICOM files in the File Set incorporating SOP Instances defined for the specific Application Profile shall be referenced by Directory Records.

F.5 STD-WVFM-HD-FD PROFILE

F.5.1 SOP Classes and Transfer Syntaxes

This Application Profile is based on the Media Storage Service Class with the Interchange Option (see PS 3.4).

The SOP Classes and corresponding Transfer Syntax supported by this Application Profile are specified in the Table F.5.1-1. The supported Storage SOP Classes shall be listed in the Conformance Statement using a table of the same form.

Table F.5.1-1 STD-WVFM-HD-FD SOP Classes and Transfer Syntaxes

Information Object Definition	Service Object Pair Class UID	Transfer Syntax and UID	FSC Requirement	FSR Requirement	FSU Requirement
Basic Directory	1.2.840.10008.1.3.10	Explicit VR Little Endian Uncompressed 1.2.840.10008.1.2.1	Mandatory	Mandatory	Mandatory

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Hemodynamic Waveform Storage	1.2.840.10008.5.1.4.1.1.9.2.1	Explicit VR Little Endian Uncompressed 1.2.840.10008.1.2.1	Mandatory	Mandatory	Optional

F.5.2 Physical Medium And Medium Format

The STD-WVFM-HD-FD application profile requires the 1.44 MB Diskette physical medium with the PC File System Media Format, as defined in PS3.12 Annex B.

F.5.3 Directory Information in DICOMDIR

Conformant Application Entities shall include in the DICOMDIR File the Basic Directory IOD containing Directory Records at the Patient and the subsidiary Study and Series levels, appropriate to the SOP Classes in the File Set. All DICOM files in the File Set incorporating SOP Instances defined for the specific Application Profile shall be referenced by Directory Records.

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