DICOM Conformance Statement

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1. Conformance Statement Overview

AMRA® Profiler 4 imports DICOM objects generated by MRI scanners. From these images, volume representations of the patient is created for further automatic and manual processing and analysis.
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Table 1.1 Media services

Media Storage Application Profile	Write Files (FSC or FSU)	Read Files (FSR)
DVD		
General Purpose DVD-RAM	No	Yes
Compact Disk – Recordable		
General Purpose CD-R	No	Yes
ZIP archive		
General Purpose ZIP archive	Yes	No

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2. Introduction

2.1. Revision History

Document Version	Date of Issue	Description
1.0	Sept. 30, 2021	First version
1.1	Nov. 8, 2021	Updates in section 8.1.2: Added support for Real World Value Mapping. Added optional attributes to aid deduplication of image data. Other minor corrections and clarifications.
1.2	Apr. 19, 2022	Updates in section 8.1.2: Added alternative tags to use for input of Patient height. Other minor corrections.
1.3	Aug. 23, 2022	Updated with new AMRA logo.
1.4	Sep. 13, 2022	Updates in section 8.1.2: Added required tag Device Serial Number.
1.5	Oct. 12, 2022	Updates in section 8.1.2: Updated Patient's Age to a required tag.
1.6	Dec. 19, 2022	Updates in section 8.1.2: Remarks for Patient's Name and Patient ID updated.
1.7	Apr. 12, 2023	Updates in section 8.1.2: Added optional Patient's Birth Date tag.
1.8	Jan. 1, 2025	Rename of Ambra to Inteleshare.
1.9	Jan. 14, 2026	Updates in section 8.1.2: Added required tag Software Versions. Changed tag Manufacturer's model name to required and updated the description. Changed description for tag Device Serial Number. Added Flip Angle and Repetition Time as required tags.

2.2. Audience

This document is written for the people that need to understand how AMRA® Profiler 4 will integrate into their healthcare facility. This includes both those responsible for overall imaging network policy and architecture, as well as integrators who need to have a detailed understanding of the DICOM features of the product. This document contains some basic DICOM definitions so that any reader may understand how this product implements DICOM features. However, integrators are expected to fully understand all the DICOM terminology, how the tables in this document relate to the product's functionality, and how that functionality integrates with other devices that support compatible DICOM features.

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2.3. Remarks

The scope of this DICOM Conformance Statement is to facilitate integration between AMRA® Profiler 4 and other DICOM products. The Conformance Statement should be read and understood in conjunction with the DICOM Standard. DICOM by itself does not guarantee interoperability. The Conformance Statement does, however, facilitate a first-level comparison for interoperability between different applications supporting compatible DICOM functionality.

This Conformance Statement is not supposed to replace validation with other DICOM equipment to ensure proper exchange of intended information. In fact, the user should be aware of the following important issues:

- The comparison of different Conformance Statements is just the first step towards assessing interconnectivity and interoperability between the product and other DICOM conformant equipment.
- Test procedures should be defined and executed to validate the required level of interoperability with specific compatible DICOM equipment, as established by the healthcare facility.

2.4. Terms and Definitions

Informal definitions are provided for the following terms used in this Conformance Statement. The DICOM Standard is the authoritative source for formal definitions of these terms.

Term	**Definition**
Application Entity (AE)	An end point of a DICOM information exchange, including the DICOM network or media interface software; i.e., the software that sends or receives DICOM information objects or messages. A single device may have multiple Application Entities.
Media Application Profile	The specification of DICOM information objects and encoding exchanged on removable media (e.g., CDs).

2.5. Abbreviations

Abbreviation	**Explanation**
AE	Application Entity
AMRA	AMRA Medical
C	Conditionally required (Key Attribute)
DICOM	Digital Imaging and Communications in Medicine
FSC	File-Set Creator
FSU	File-Set Updater
FSR	File-Set Reader
IOD	Information Object Definition
ISO	International Organization for Standards
JPEG	Joint Photographic Experts Group
MR	Magnetic Resonance Imaging

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Abbreviation	Explanation
O	Optional (Key Attribute)
PACS	Picture Archiving and Communication System
R	Required (Key Attribute)
SC	Secondary Capture
SOP	Service-Object Pair
U	Unique (Key Attribute)
VR	Value Representation
ZIP	A file format used to compress data

2.6. References

NEMA PS3 Digital Imaging and Communications in Medicine (DICOM) Standard, available for free at http://medical.nema.org/.

3. Networking

Not applicable.

4. Media Interchange

4.1. Implementation Model

4.1.1. Application Data Flow

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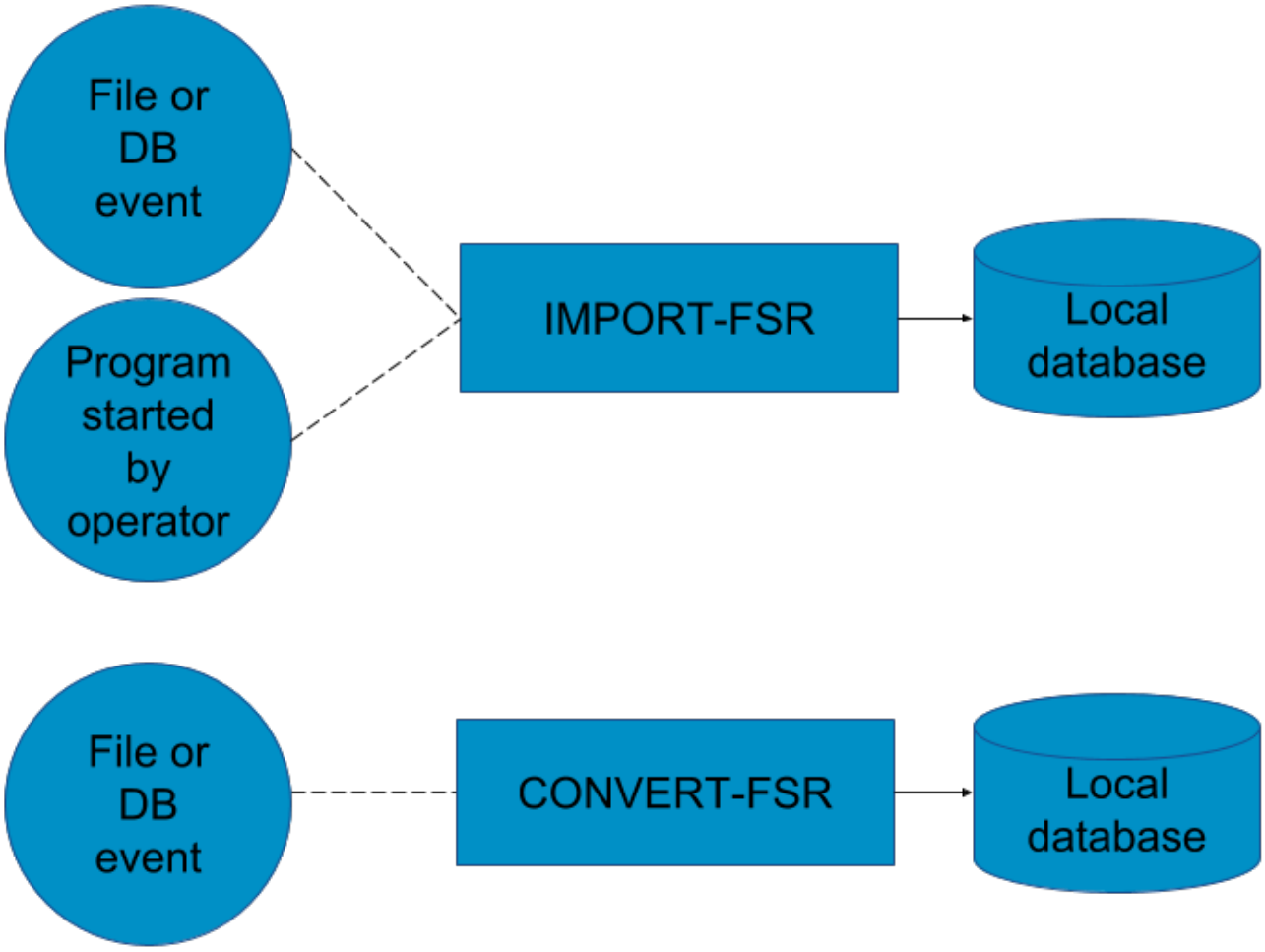

The application is a suite of tools written in Python containing both headless server software and tools that provide a user interface. DICOM is only used for import of data, internally the application uses a proprietary data format. The import module provides media support as a File Set Reader.

Conceptually the application may be modeled as the following AEs:

- IMPORT-FSR which loads a PS3.10 compliant File Set, with or without a DICOMDIR, either from the local file system or from PS3.12 compliant media according to one of the General Purpose Media Application Profiles of PS3.11 (CD-R or DVD-RAM) and stores it in the local database along with a small set of basic parsed data.
- CONVERT-FSR which converts File Sets stored in the local database to an internal, proprietary data format.

In effect, the application is media-neutral, since the user is required to point out a DICOMDIR file or a ZIP File Media on any available file system.

The following DICOM Transfer Syntaxes are supported:

Transfer Syntax UID	**Transfer Syntax Name**
1.2.840.10008.1.2	Implicit VR Endian
1.2.840.10008.1.2.1	Explicit VR Little Endian
1.2.840.10008.1.2.1.99	Deflated Explicit VR Little Endian

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Transfer Syntax UID	Transfer Syntax Name
1.2.840.10008.1.2.2	Explicit VR Big Endian
1.2.840.10008.1.2.4.70	JPEG Lossless, Nonhierarchical, First-Order Prediction (Processes 14 [Selection Value 1])
1.2.840.10008.1.2.4.80	JPEG-LS Lossless Image Compression
1.2.840.10008.1.2.4.90	JPEG 2000 Image Compression (Lossless Only)
1.2.840.10008.1.2.5	RLE Lossless

Compressed Transfer Syntaxes are not supported, which limits the Media Application Profiles supported.

4.1.2. Functional Definition of AEs

IMPORT-FSR

IMPORT-FSR is activated by an event generated by the file system or an event generated by the database. It can also be activated manually by a human operator running an application. The IMPORT-FSR AE is used to import a File Set to the local database. The following tags are read and stored in order to facilitate searchability.

Attribute Name	Tag	Attribute Description
Patient's Name	(0010,0010)	Patient's full name.
Patient ID	(0010,0020)	Primary identifier for the patient.
Patient Birth Date	(0010,0030)	Date of birth of the named patient.
Patient's Sex	(0010,0040)	Sex of the named patient.
Patient's Age	(0010,1010)	Age of the patient.
Patient's Weight	(0010,1030)	Weight of the patient, in kilograms.
Patient's Size	(0010,1020)	Height of the patient, in meters.
Study Instance UID	(0020,000D)	Unique identifier for the Study.
Study Date	(0008,0020)	Date when the Study started.
Study Time	(0008,0030)	Time when the Study started.

CONVERT-FSR

CONVERT-FSR is activated by an event generated by the file system or an event generated by the database. It is used to convert a relevant subset of a File Set to a proprietary data format.

4.2. AE Specifications

4.2.1. Import FSR

IMPORT-FSR provides standard conformance to the Media Storage Services Class.

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Application Profiles Supported	Real World Activities	Role
STD-GEN-CD	Load File Set	FSR
STD-GEN-DVD-RAM	Load File Set	FSR
STD-GEN-ZIP	Load File Set	FSR

File Meta Information for the Application Entity

Not applicable, since MEDIA-FSR is not an FSC or FSU.

Real World Activities

Load File Set

IMPORT-FSR is activated by either a file system event, an event from the database or manually triggered by a command issued by an operator. A file path is given as an argument in all cases. The behaviour then differs depending on the file path:

- If the file path leads to DICOMDIR or a folder containing a DICOMDIR, all the referenced instances will be archived and stored in the local database.
- If the file path leads to a ZIP archive or a TAR GZIP archive containing a File Set, the archive will be stored in the local database.
- If the file path leads to another type of file (including a single instance), to a folder without a DICOMDIR or to a non existing file, the application will ignore the input.

4.2.2. Convert FSR

File Meta Information for the Application Entity

Not applicable, since CONVERT-FSR is not an FSC or FSU.

Real World Activities

Convert Study

CONVERT-FSR is activated when an analysis is run for a given Study.

4.3. Augmented and Private Application Profiles

AMRA® Profiler 4 supports one augmented application profile, described below.

4.3.1. Augmented Application Profiles

Augmented Application Profile STD-GEN-ZIP

The STD-GEN-ZIP is an augmentation of the STD-GEN-BD application profile, as defined in the DICOM standard. The Profile is augmented by the way this profile enables a compressed storage of a set of DICOM images.

SOP Class Augmentations

The SOP Classes listed below are supported by this application profile.

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SOP Class Name	SOP Class UID
MR Image Storage	1.2.840.10008.5.1.4.1.1.4

Directory Augmentations

The name of the ZIP file shall be structured in the following way:

Part 1	Separator	Part 2
File-set ID (0004,1130)	.	zip

Examples of valid ZIP file names:

- my_examination.zip
- 2017-06-16.zip

Thus, the file ending must be zip, the separator between Part 1 and Part 2 must be a dot (.) and Part 1 shall be compliant with File-set ID (0004,1130) as defined in the DICOM standard.

A DICOMDIR file may be present in the ZIP archive. It shall be treated in the same way as defined in the standard. If no DICOMDIR file is present, this is equivalent to a DICOMDIR file that specifies all files contained in the ZIP archive.

Other Augmentations

All DICOM files in the ZIP archive that contains the Study Instance UID (0020,000D) tag must have the same value for this tag. If two files with different values for the Study Instance UID tag are found, the ZIP archive is considered invalid and cannot be processed.

4.4. Media Configuration

No specific media configuration exists in AMRA® Profiler 4.

5. Transformation of DICOM to CDA

Not applicable.

6. Support of Character Sets

6.1. Overview

6.2. Character Sets

In addition to the default character repertoire, the Defined Terms for Specific Character Set in the table below are supported.

Character Set Description	Defined Term
Latin alphabet No.1	ISO_IR 100
Unicode in UTF-8	ISO_IR 192

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6.3. Character Set Configuration

Whether or not characters are displayed correctly depends on the presence of font support in the underlying operating system. Typically, it may be necessary for the user to add one of the "all Unicode" fonts to their system configuration in order to correctly display characters that would not typically be used in the default locale.

7. Security

Not applicable.

8. Annexes

8.1. IOD Contents

8.1.1. Created SOP Instances

None.

8.1.2. Usage of Attributes From Received IODs

Attribute Name	Tag	Optionality	Remarks
Acquisition Date	(0008,0022)	R	Used to connect results with an exact time point when the scan was performed.
Acquisition Time	(0008,0032)	O	Used to connect results with an exact time point when the scan was performed.
Additional Patient History	(0010,21B0)	C	Required if the Patient Size or Study Comments tag do not contain the patient height information. Typically, this field can be used to input height on GE MRI consoles. See applicable Service User Guide for specification on how height shall be input, since this is a free text field.
Device Serial Number	(0018,1000)	R	Used to track which scanner the image data is acquired with. Enables relevant feedback from AMRA to the imaging facility if an issue occurs repeatedly or if a scanner is updated or modified after certification.

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Attribute Name	Tag	Optionality	Remarks
Echo Time	(0018,0081)	R	Some measurements can not be calculated if missing. In milliseconds.
Flip Angle	(0018,1314)	R	Some measurements can not be calculated if missing. In degrees.
Frame of Reference UID	(0020,0052)	R	Required in order to merge whole body scan.
Image Position (Patient)	(0020,0032)	R	Required to merge images into volumes. In millimeters.
Image Orientation (Patient)	(0020,0037)	R	Required to merge images into volumes.
Image Type	(0008,0008)	C	Used to detect signal type of images. Required if this information is not present in Series Description.
Instance Number	(0020,0013)	O	Used to aid deduplication.
In-Plane Phase Encoding Direction	(0018,1312)	R	Required for certain calculations.
Magnetic Field Strength	(0018,0087)	R	Required for certain calculations.
Manufacturer	(0008,0070)	R	Used internally for manufacturer dependent choices.
Manufacturer's model name	(0008,1090)	R	Used to detect hardware configuration changes after the scanner certification.
Patient ID	(0010,0020)	R	Presented in product output to identify a patient. Sender is responsible for de-identification, if needed. Can be modified on upload if Inteleshare web portal is used.
Patient's Name	(0010,0010)	O	Can be presented in product output to identify a patient. Sender is responsible for de-identification, if needed. Can be modified on upload if Inteleshare web portal is used.

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Attribute Name	Tag	Optionality	Remarks
Patient's Birth Date	(0010,0030)	O	Can be presented in product output to identify a patient. Sender is responsible for de-identification, if needed. Can be modified on upload if Inteleshare web portal is used.
Patient's Age	(0010,1010)	R	Presented in product output, relevant for patient assessment.
Patient's Sex	(0010,0040)	R	Used to calculate informatics measurements as well as to present normative data for measured values. Can be modified on upload if Inteleshare web portal is used.
Patient's Size	(0010,1020)	C	Used to calculate several measurements as well as to present normative data for measured values. Can be modified on upload if Inteleshare web portal is used. In meters. Required if height information is not present in Additional Patient History or Study Comments tag.
Patient's Weight	(0010,1030)	R	Used to calculate several measurements as well as to present normative data for measured values. Can be modified on upload if Inteleshare web portal is used. In kilograms.
Pixel Spacing	(0028,0030)	R	Required for correct image interpretation. In millimeters.
Protocol Name	(0018,1030)	O	Used for documentation purposes only.
Real World Value Intercept	(0040,9224)	C	Required if necessary for correct image interpretation. Note: Only one mapping per image supported.

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Attribute Name	Tag	Optionality	Remarks
Real World Value Slope	(0040,9225)	C	Required if necessary for correct image interpretation. Note: Only one mapping per image supported.
Repetition Time	(0018,0080)	R	Some measurements can not be calculated if missing. In milliseconds.
Rescale Intercept	(0028,1052)	C	Required if necessary for correct image interpretation and Real World Value Intercept is not available.
Rescale Slope	(0028,1053)	C	Required if necessary for correct image interpretation and Real World Value Slope is not available.
Series Description	(0008,103E)	R	Used to determine whether the series should be processed. Can also include signal type of images.
Series Date	(0008,0021)	C	Used to detect and exclude overlapping image stacks. May be de-identified, but differences to Series Date of other series' should be intact. Required if Series Number is missing.
Series Instance UID	(0020,000E)	R	Used to confirm data integrity. May be encrypted with a deterministic cipher.
Series Number	(0020,0011)	C	Used to detect and exclude overlapping image stacks. Required if Series Date or Series Time is missing.
Series Time	(0008,0031)	C	Used to detect and exclude overlapping image stacks. May be de-identified, but differences to Series Time of other series' should be intact. Required if Series Number is missing.
Slice Number	(2001,100A)	O	Used to aid deduplication.
Slice Thickness	(0018,0050)	C	Required for correct image interpretation of single-slice series.

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Attribute Name	Tag	Optionality	Remarks
Software Versions	(0018,1020)	R	Used to detect software changes after the scanner certification.
SOP Class UID	(0008,0016)	R	Used for data integrity checks.
Study Comments	(0032,4000)	C	Required if the Patient Size or Additional Patient History tags do not contain the patient height information. Typically, this field can be used to input height on Philips MRI consoles. See applicable Service User Guide for specification on how height shall be input, since this is a free text field.
Study Instance UID	(0020,000D)	R	Subsets of the same study can be imported separately, e.g. whole body scan not imported at the same time as liver scan. May be encrypted with a deterministic cipher.

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