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TYPE OF DOCUMENT: **CONFORMANCE STATEMENT**

TITLE: **MDR™
(Medical Digital Recorder™)
DICOM Conformance Statement**

This document is provided as a reference regarding DICOM conformance of the Medical Digital Recorder™ (MDR™).

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NAI Tech Products
Div. McDonough Medical Products

12919 Earhart Avenue
Auburn, CA. 95602 U.S.A.

Tel: (866) DICOMBX (342-6629)
(Toll Free)

Fax: (530) 887-1108

Web: www.dicombox.com

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0.0 INTRODUCTION

This document describes the NAI Tech Products Medical Digital Recorder™ (MDR™) conformance to the ACR-NEMA DICOM (Digital Imaging and Communications in Medicine) standard and satisfies the DICOM requirements for vendor conformance specification.

0.1 DICOM Background

The DICOM information exchange specification provides a definite structure of commands and information that allow for the interoperability of medical imaging devices.

Developed by the American College of Radiology (ACR) and the National Electrical Manufacturers Association (NEMA), the DICOM standard strives to promote communication of image information through the use of a standardized set of command classes and information semantics.

0.1.1 DICOM Classes of Information

The DICOM standard defines classes of information that are common to many modalities of medical imaging. However, to meet the specific needs of information content for such a diverse range of information, the DICOM specification defines structures for a multitude of medical data.

To alleviate the need for applications to implement every aspect of the DICOM specification, a list of conformance tables for every service class was created to define the minimum set of information necessary for data exchanges.

0.1.2 Subset of DICOM Used by the MDR™

A requirement of the DICOM specification is to maintain a compliance document that outlines a subset of DICOM services and data classes that are supported by an application. The purpose of this document is to define a subset of DICOM for the exchange of medical information with the NAI Tech Products Medical Digital Recorder™.

0.1.3 DICOM Version Number

This document is written with respect to the ACR-NEMA DICOM version number 3.0.



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0.2 Acronyms and Abbreviations

The following acronyms and abbreviations may be used in this document.

Table 0.2 – List of Acronyms and Abbreviations

Acronym	Definition
ACR	American College of Radiology
AE	Application Entity
CD/DVD	Note: The MDR™ can be configured with CD only, DVD only, or a combination CD/DVD drive.
CD-R	Compact Disk - Recordable
CD-RW	Compact Disk - Rewritable
DICOM	Digital Imaging and Communications in Medicine
DVD+R	Digital Video Disk - Recordable
DVD+RW	Digital Video Disk - Rewritable
FSC	File Set Creator
FSR	File Set Reader
GB	Giga bytes
IOD	Information Object Definition
ISO	International Standards Organization
MB	Mega bytes
MDR™	Medical Digital Recorder™ (NAI Tech Products)
NEMA	National Electrical Manufacturers Association
SCP	Service Class Provider
SCU	Service Class User
SOP	Service Object Pair
UID	Unique Identifier
VR	Value Representation

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0.3 References

Table 0.3 – References

Reference	Description	Source
ACR and DICOM 3.0	The Digital Imaging and Communications in Medicine (DICOM) standard	National Electrical Manufacturers Association (NEMA) Publication Sales 1300 N. 17th Street, Suite 1847 Rosslyn, VA 22209 USA
P/N 005-00126-00, Rev. X.X (see note below)	NAI Tech Products Medical Digital Recorder™ (MDR™) Operator Manual	NAI Tech Products 12919 Earhart Avenue Auburn, CA 95602
Note: Revision number of above MDR™ Operator Manual is subject to change with new software releases.		

1.0 IMPLEMENTATION MODEL

The Medical Digital Recorder™ (MDR™) creates CD or DVD media with various DICOM SOP instances. The MDR™ can process various IODs.

SOP Instances are received via the network as requests from a DICOM AE, acting as a Service Class User (SCU), requesting one of various Storage Service Classes.

1.1 Application Data Flow Diagram: MDR™ Real-World Relationship

Figure 1.1 depicts the MDR™ real-world relationship Application Data Flow Diagram.

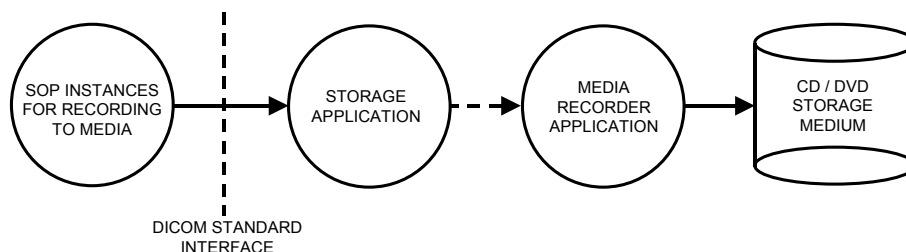


Figure 1.1 – Application Data Flow Diagram: MDR™ Real-World Relationship

The Storage Application acts as a Service Class Provider (SCP) for various Storage SOP classes.

The MDR™ has local storage utilizing an internal hard-disk drive, which may contain various SOP instances obtained by the Storage Application via the network.



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The Media Recorder Application can initialize media by acting as an FSC to create a new DICOM file-set on any of the following 120mm media:

- CD-R DVD+R (see note below)
- CD-RW DVD+RW (see note below).

Note: The MDR™ is modular in design and may be configured with CD only, DVD only, or a CD/DVD combination drive.

The MDR™ initializes the DICOM file-set and writes the specified SOP instances onto the media. The SOP instances written will be limited to instances that match the criteria of the Application Profile that is supported and utilized.

1.2 Functional Definition of Application Entities

This device has two Application Entities (AEs):

- Media Recorder Application
- Storage Application.

Table 1.2 lists the functions of each of the above AEs:

Table 1.2 – Application Entities and Functions

Type of Application Entity (AE)	Function
Media Recorder Application	Initialize a piece of CD/DVD media, and write a new DICOM file-set onto the media. Display a directory listing of the file-set on a piece of CD/DVD media.
Storage Application	Act as a Service Class Provider for various DICOM Storage Service Classes, enabling the MDR™ to receive SOP Instances via the network.

1.3 Sequencing Requirements

Real world activities are sequenced as required by the definition of the service classes. No additional sequencing activity is necessary.

1.4 File Meta Information

- Implementation Class UID: 1.2.840.113742.2.20030619
- Implementation Version Name: NAI 4.09

Note: The Implementation Class UID and the Implementation Version Name are subject to change with new software releases.



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2.0 APPLICATION ENTITY SPECIFICATIONS

2.1 Media Recorder Application

The Media Recorder Application provides standard conformance to DICOM Interchange Option of the Media Storage Service Class. The supported Application Profiles and roles are listed in Table 2.1.

Table 2.1 – Supported Application Profiles, Activities, and Roles for Media Recorder

Application Profile Supported	Real World Activity	Role	Service Class Option
STD-GEN-CD STD-GEN-DVD-RAM	Create CD/DVD	FSC	Interchange
STD-GEN-CD STD-GEN-DVD-RAM	Display Directory	FSR	Interchange

2.1.1 File Meta Information for the Application Entity

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

2.1.2 Real-World Activities for this Application Entity

2.1.2.1 Real-World Activity: Create CD/DVD

The Media Recorder Application acts as an FSC, using the interchange option when requested to record media.

The Media Recorder Application will do the following:

- SOP Instances received by the storage application are written to the media, and
- A corresponding DICOMDIR is created and written to the media.

2.1.2.2 Real-World Activity: Display Directory

The Media Recorder Application acts as an FSR to read and display the contents of a directory on the media located in the CD/DVD drive. The Media Recorder Application will display the contents of the directory when the "Disk Contents" soft-key is depressed.



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2.2 Storage Application

In order to receive SOP Instances via the network, the Storage Application provides standard conformance as a Service Class Provider for the SOP Classes as shown in Table 2.2.

Table 2.2 – SOP Classes Supported by the MDR™ Storage Application as a Service Class Provider

SOP Class	SOP Class UID	Transfer Syntax	Transfer Syntax UID
Verification Service Class	1.2.840.10008.1.1	Implicit VR Little Endian	1.2.840.10008.1.2
		Explicit VR Big Endian	1.2.840.10008.1.2.2
		Explicit VR Little Endian	1.2.840.10008.1.2.1
Secondary Capture	1.2.840.10008.5.1.4.1.1.7	Implicit VR Little Endian	1.2.840.10008.1.2
		Explicit VR Big Endian	1.2.840.10008.1.2.2
		Explicit VR Little Endian	1.2.840.10008.1.2.1
		JPEG Lossy	1.2.840.10008.1.2.4.50
Multi-Frame Grayscale Byte Secondary Capture	1.2.840.10008.5.1.4.1.1.7.2	Implicit VR Little Endian	1.2.840.10008.1.2
		Explicit VR Big Endian	1.2.840.10008.1.2.2
		Explicit VR Little Endian	1.2.840.10008.1.2.1
		JPEG Lossy	1.2.840.10008.1.2.4.50
Multi-Frame True Color Secondary Capture	1.2.840.10008.5.1.4.1.1.7.4	Implicit VR Little Endian	1.2.840.10008.1.2
		Explicit VR Big Endian	1.2.840.10008.1.2.2
		Explicit VR Little Endian	1.2.840.10008.1.2.1
		JPEG Lossy	1.2.840.10008.1.2.4.50



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Table 2.2 – SOP Classes Supported by the MDR™ Storage Application as a Service Class Provider

SOP Class	SOP Class UID	Transfer Syntax	Transfer Syntax UID
Ultrasound	1.2.840.10008.5.1.4.1.1.6.1	Implicit VR Little Endian	1.2.840.10008.1.2
		Explicit VR Big Endian	1.2.840.10008.1.2.2
		Explicit VR Little Endian	1.2.840.10008.1.2.1
		JPEG Lossy	1.2.840.10008.1.2.4.50
Ultrasound Multi-Frame	1.2.840.10008.5.1.4.1.1.3.1	Implicit VR Little Endian	1.2.840.10008.1.2
		Explicit VR Big Endian	1.2.840.10008.1.2.2
		Explicit VR Little Endian	1.2.840.10008.1.2.1
		JPEG Lossy	1.2.840.10008.1.2.4.50
Ultrasound (Retired)	1.2.840.10008.5.1.4.1.1.6	Implicit VR Little Endian	1.2.840.10008.1.2
		Explicit VR Big Endian	1.2.840.10008.1.2.2
		Explicit VR Little Endian	1.2.840.10008.1.2.1
		JPEG Lossy	1.2.840.10008.1.2.4.50
Ultrasound Multi-Frame (Retired)	1.2.840.10008.5.1.4.1.1.3	Implicit VR Little Endian	1.2.840.10008.1.2
		Explicit VR Big Endian	1.2.840.10008.1.2.2
		Explicit VR Little Endian	1.2.840.10008.1.2.1
		JPEG Lossy	1.2.840.10008.1.2.4.50



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Table 2.2 – SOP Classes Supported by the MDR™ Storage Application as a Service Class Provider

SOP Class	SOP Class UID	Transfer Syntax	Transfer Syntax UID
Computed Radiography	1.2.840.10008.5.1.4.1.1.1	Implicit VR Little Endian	1.2.840.10008.1.2
		Explicit VR Big Endian	1.2.840.10008.1.2.2
		Explicit VR Little Endian	1.2.840.10008.1.2.1
		JPEG Lossy	1.2.840.10008.1.2.4.50
Nuclear Medicine (Retired)	1.2.840.10008.5.1.4.1.1.5	Implicit VR Little Endian	1.2.840.10008.1.2
		Explicit VR Big Endian	1.2.840.10008.1.2.2
		Explicit VR Little Endian	1.2.840.10008.1.2.1
		JPEG Lossy	1.2.840.10008.1.2.4.50
X-Ray Angiography	1.2.840.10008.5.1.4.1.1.12.1	Implicit VR Little Endian	1.2.840.10008.1.2
		Explicit VR Big Endian	1.2.840.10008.1.2.2
		Explicit VR Little Endian	1.2.840.10008.1.2.1
		JPEG Lossy	1.2.840.10008.1.2.4.50
X-Ray Radiofluoroscapy	1.2.840.10008.5.1.4.1.1.12.2	Implicit VR Little Endian	1.2.840.10008.1.2
		Explicit VR Big Endian	1.2.840.10008.1.2.2
		Explicit VR Little Endian	1.2.840.10008.1.2.1
		JPEG Lossy	1.2.840.10008.1.2.4.50



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3.0 Augmented and Private Profiles

3.1 Augmented Profiles

This device supports no Augmented Profiles.

3.2 Private Profiles

No Private Profiles are supported by this device.

4.0 Extensions, Specializations, Privatizations of SOP Classes and Transfer Syntaxes

None.

5.0 Configuration

The MDR™ has only one available configuration using a 120mm CD/DVD read-write drive. For supported profiles, see Table 2.1.

6.0 Support of Extended Character Sets

The MDR™ will support only the ISO_IR 100 (ISO 8859-1:1987 Latin alphabet No. 1 supplementary set) as an extended character set.

7.0 Codes and Controlled Terminology

The SOP classes supported by this implementation do not support the use of Codes and Controlled Terminology.