

DICOM Conformance Statement for ExactVu™ 2.0



Revision 1.5

Revision History

Date	Author	Revision	Description of Change
20 October	J. Li	1.0	Initial revision
23 October	J. Li	1.1	Add the attributes list for the images sent by storage SCU
8 November 2017	J. Li	1.2	Remove 0010,0021 from the attribute list in section 4.3.4.2.3. The attribute used to be in a retired Study Acquisition Module, and now only used for query.
14 November 2017	S. Smith	1.3	Reformatted for consistency with ExactVu IFU styles and formats. Made minor wording changes.
15 November 2017	S. Smith	1.4	Corrected error with graphic in logo Minor wording changes based on feedback from Marketing Implemented review comments: • Added attributes to section 2.4.3.2.2
20 December 2017	J. Li	1.5	Changed the Support of Character Sets from ISO_IR 100 to ISO_IR 101

Conformance Statement Overview

This is a DICOM Conformance Statement for ExactVu 2.0. ExactVu provides the capability to store ultrasound studies to a PACS server, and read MR images from a USB storage device, or a CD/DVD through a USB port. It supports the following DICOM SOP classes:

SOP Class Name	SOP Class UID	Service Class Role
Verification(Echo)	1.2.840.10008.1.1	SCU
US Image Storage	1.2.840.10008.5.1.4.1.1.6.1	SCU
Raw Data Storage	1.2.840.10008.5.1.4.1.1.66	SCU
Storage Commitment Push Model	1.2.840.10008.1.20.1	SCU

ExactVu serves as DICOM File-Set Reader (FSR); however, it only reads MR studies with DICOMDIR for its *FusionVu* functionality.

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Introduction

1.1 Audience

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This DICOM Conformance Statement is intended for following audiences:

- Hospital or clinical practice staff or Exact Imaging customers
- System integrator of medical equipment
- DICOM Software engineer or designer
- Marketing or Sales personnel with DICOM knowledge

1.2 Scope and field of Application

It is the intent of this document to provide an unambiguous specification for DICOM implementations of ExactVu. This specification includes a DICOM Conformance Statement and is necessary to ensure proper processing and interpretation of ExactVu medical data exchanged using DICOM.

The reader of this DICOM Conformance Statement should be aware that ExactVu uses private data elements to hold its raw data. The reader is advised to ignore these elements as they are private tags only.

The use of the DICOM Conformance Statement, in conjunction with the DICOM Standards, is intended to facilitate communication with the ExactVu high resolution micro-ultrasound system. However, **by itself**, **it is not sufficient to ensure that inter-operation will be successful**.

The reader of this DICOM Conformance Statement should be aware of the following important issues:

- Test procedures should be defined and conducted to validate the desired level of connectivity
- The DICOM standard will evolve over time to meet future real-world requirements

1.3 Definition, Terms and Abbreviation

Definitions, terms and abbreviations used in this document are defined within the different parts of the DICOM standard. Abbreviations and terms used are as follows:

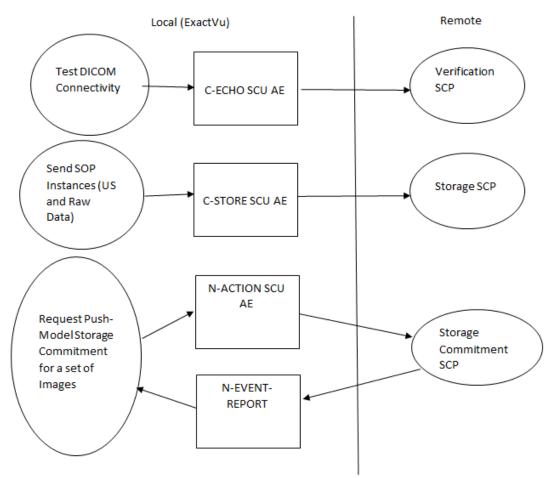
Term	Definition
EVυ	High-resolution micro-ultrasound device from Exact Imaging Inc.
AE	DICOM Application Entity
ASCE	Association Control Service Element
FSR	File-Set Reader
IOD	Information Object Definition
ISO	International Standard Organization
PDU	Protocol Data Unit
SCU	Service Class User
SCP	Service Class Provider
SOP	Service-Object Pair
GSPS	Grayscale Softcopy Presentation State
TCP/IP	Transmission Control Protocol/Internet Protocol

UID Unique Identifier

2 Networking

2.1 Implementation Model

ExactVu implements DICOM verification SCU, Storage SCU and Storage Commitment SCU. Below is the application data flow diagram.





2.2 Functional Definition of Application Entities

All communications and image transfer with remote application is accomplished using the DICOM protocol over a network using the TCP/IP protocol stack.

2.2.1 Verification

The DICOM verification SCU (i.e., connectivity test) is available for test and validation purposes of remote AEs. ExactVu opens an association and sends C-ECHO request to verify specified DICOM SCP node. Upon receiving the response from SCP, or in case of failure, it closes the connection.

2.2.2 Storage and Storage Commitment

DICOM Storage SCU and Storage Commitment SCU are available to send studies to remote AEs. When the user selects a study or studies to export to PACS, ExactVu wraps the images of a study as DICOM standard ultrasound or raw data SOP instances, document according to 2.3.4.2.3 and Appendix A, and sends the SOP instances to the Storage SCP.

It will then request to SCP a Push-Model Storage Commitment for the set of the SOP instances if the Storage Commitment is configured to use. As a Storage Commitment SCU, ExactVu establishes an association to send a Storage Commitment request (N-ACTION) to the remote AE, gets the response status and the association is done. It then waits 30 seconds for an association from the SCP to get the commitment status for every SOP instance sent from the SCP with an N-EVENT-REPORT.

2.3 AE Specifications

2.3.1 SOP Classes

ExactVu AE provides the Standard Conformance to the following DICOM Standard SOP Classes as SCU.

SOP Class Name	SOP Class UID	Service Class Role
Verification(Echo)	1.2.840.10008.1.1	SCU
US Image Storage	1.2.840.10008.5.1.4.1.1.6.1	SCU
Raw Data Storage	1.2.840.10008.5.1.4.1.1.66	SCU
Storage Commitment Push Model	1.2.840.10008.1.20.1	SCU

2.3.2 Transfer Syntaxes

Transfer Syntax	UID
Implicit VR Little Endian	1.2.840.10008.1.2
Explicit VR Little Endian	1.2.840.10008.1.2.1

2.3.3 Association Establishment Policies

2.3.3.1 General

ExactVu always proposes the DICOM Application Context Name listed in the table below during the establishment of all associations. The maximum PDU size is 64234 bytes.

Name	UID
DICOM 3.0 Application Context	1.2.840.10008.3.1.1.1

2.3.3.2 Number of Associations

This version of implementation supports one simultaneous association for initiator and acceptor.

2.3.3.3 Asynchronous Nature

This version of implementation only supports a single outstanding transaction over an existing association. As such, it does not support asynchronous communication.

2.3.3.4 Implementation Identifying Information

ExactVu uses the MergeCOM-3 Advanced DICOM Toolkit. It uses the following implementation identifying parameters:

Implementation Class UID	2.16.840.1
Implementation Version	
MergeCOM3_5_4_0	

2.3.4 Association Initiation Policy

ExactVu initiates associations for the following real-world activities:

- Verification(C-ECHO) SCU
- Storage(C-STORE) SCU
- Storage Commitment Push Model SCU

2.3.4.1 (Real-World) Activity - Verification SCU

2.3.4.1.1 Description and Sequence

ExactVu initiates a verification request when the user tests DICOM connectivity from the UI or prior to sending a study. The association is closed when a response from SCP is received or in case of failure.

2.3.4.1.2 Proposed Presentation Contexts

Abstract Synto	xc	Transfer Syntax		Role	Extended Negotiation
Name	UID	Name	UID		
Verification 1.2.8	1.2.840.10008.1.1	Implicit VR Little Endian	1.2.840.10008.1.2	SCU	None
		Explicit VR Little Endian	1.2.840.10008.1.2.1	SCU	None
		Explicit VR Big Endian	1.2.840.10008.1.2.2	SCU	None

2.3.4.1.3 SOP Specific Conformance Statement for SOP Verification Class

ExactVu provides standard conformance for DICOM communication verification.

2.3.4.2 (Real-World) Activity - Storage SCU

2.3.4.2.1 Description and Sequence

ExactVu initiates a C-STORE association as SCU when attempting to send SOP Instances to remote AEs. The transfer syntaxes that can be proposed are normally determined using the table in section 2.3.4.2.2.

2.3.4.2.2 Proposed Presentation Contexts

Abstract Syntax		Transfer Syntax		Role	Extended Negotiation
Name	UID	Name	UID		
Ultrasound Image	1.2.840.10008.5.1.4.1.1.6.1	Implicit VR Little Endian	1.2.840.10008.1.2	SCU	None
Storage		Explicit VR Little Endian	1.2.840.10008.1.2.1	SCU	None
Raw Data Storage	1.2.840.10008.5.1.4.1.1.66	Explicit VR Big Endian	1.2.840.10008.1.2.2	SCU	None

2.3.4.2.3 SOP Specific Conformance Statement for SOP Classes

ExactVu provides standard conformance to the DICOM Standard Storage Service Class as SCU for all storage SOP classes listed in the table in section 2.3.4.2.2. ExactVu sends the following attributes in C_STORE_RQ. All the mandatory attributes are sent. ExactVu also uses private attributes (refer to Appendix A).

8000	0005	Specific Character Set
8000	0008	Image Type
0008	0016	SOP Class UID
8000	0018	SOP Instance UID
8000	0020	Study Date
8000	0021	Series Date
8000	0022	Acquisition Date
8000	0023	Content Date
8000	0030	Study Time
8000	0031	Series Time
8000	0032	Acquisition Time
8000	0033	Content Time
8000	0050	Accession Number
8000	0060	Modality
8000	0070	Manufacturer
0008	0080	InstitutionName
8000	0090	Name of the patient's referring physician
8000	0201	Time zone offset from UTC
8000	103E	Series Description
8000	1090	Manufacturer's Model Name
0010	0010	Patient's Name
0010	0020	Patient ID
0010	0021	Issuer of Patient ID

0010 0040 Patient's Sex 0020 000D Study Instance UID 0020 000E Series Instance UID 0020 0010 Study ID 0020 0011 Series Number 0020 0013 Instance Number 0020 0013 Instance Number 0028 0002 Samples per Pixel 0028 0004 Photometric Interpretation 0028 0006 Planar Configuration 0028 0010 Rows 0028 0011 Columns 0028 0010 Rist Allocated 0028 0100 Bits Allocated 0028 0102 High Bit 0028 0102 High Bit 0028 0103 Pixel Representation 0728 0103 Pixel Representation	0010	0030	Patient's Birth Date
0020000ESeries Instance UID00200010Study ID00200011Series Number00200013Instance Number00280002Samples per Pixel00280004Photometric Interpretation00280006Planar Configuration00280010Rows00280011Columns00280030Pixel Spacing00280100Bits Allocated00280101Bits Stored00280102High Bit00280103Pixel Representation	0010	0040	Patient's Sex
00200010Study ID00200011Series Number00200013Instance Number00280002Samples per Pixel00280004Photometric Interpretation00280006Planar Configuration00280010Rows00280011Columns00280030Pixel Spacing00280101Bits Allocated00280101High Bit00280103Pixel Representation	0020	000D	Study Instance UID
00200011Series Number00200013Instance Number00280002Samples per Pixel00280004Photometric Interpretation00280006Planar Configuration00280010Rows00280011Columns00280030Pixel Spacing00280100Bits Allocated00280101Bits Stored00280102High Bit00280103Pixel Representation	0020	000E	Series Instance UID
00200013Instance Number00280002Samples per Pixel00280004Photometric Interpretation00280006Planar Configuration00280010Rows00280011Columns00280030Pixel Spacing00280100Bits Allocated00280101Bits Stored00280102High Bit00280103Pixel Representation	0020	0010	Study ID
00280002Samples per Pixel00280004Photometric Interpretation00280006Planar Configuration00280010Rows00280011Columns00280030Pixel Spacing00280100Bits Allocated00280101Bits Stored00280102High Bit00280103Pixel Representation	0020	0011	Series Number
00280004Photometric Interpretation00280006Planar Configuration00280010Rows00280011Columns00280030Pixel Spacing00280100Bits Allocated00280101Bits Stored00280102High Bit00280103Pixel Representation	0020	0013	Instance Number
00280006Planar Configuration00280010Rows00280011Columns00280030Pixel Spacing00280100Bits Allocated00280101Bits Stored00280102High Bit00280103Pixel Representation	0028	0002	Samples per Pixel
0028 0010 Rows 0028 0011 Columns 0028 0030 Pixel Spacing 0028 0100 Bits Allocated 0028 0101 Bits Stored 0028 0102 High Bit 0028 0103 Pixel Representation	0028	0004	Photometric Interpretation
00280011Columns00280030Pixel Spacing00280100Bits Allocated00280101Bits Stored00280102High Bit00280103Pixel Representation	0028	0006	Planar Configuration
00280030Pixel Spacing00280100Bits Allocated00280101Bits Stored00280102High Bit00280103Pixel Representation	0028	0010	Rows
00280100Bits Allocated00280101Bits Stored00280102High Bit00280103Pixel Representation	0028	0011	Columns
00280101Bits Stored00280102High Bit00280103Pixel Representation	0028	0030	Pixel Spacing
00280102High Bit00280103Pixel Representation	0028	0100	Bits Allocated
0028 0103 Pixel Representation	0028	0101	Bits Stored
	0028	0102	High Bit
7FE0 0010 Pixel Data	0028	0103	Pixel Representation
	7FE0	0010	Pixel Data

2.3.4.3 (Real-World) Activity – Storage Commitment Push Model SCU

2.3.4.3.1 Description and Sequence

ExactVu supports synchronous mode for Storage Commitment Push Model SCU after the previous C-STORE SCU operation for a study: ExactVu sends an N-ACTION-RQ request with the SOP instances that need to be committed to the remote AE, then listens to its local port (which needs to be configured together with the local IP or hostname on the SCP) for N-EVENT-REPORT-RQ to receive the commitment result of SOP instances. The timeout for waiting is for 30 seconds. The presentation contexts are defined in section 2.3.4.3.2.

2.3.4.3.2 Proposed Presentation Contexts

Abstract Synta	x	Transfer Syntax		Role	Extended Negotiation
Name	UID	Name	UID		
Storage Commitment Push Model	1.2.840.10008.1.20.1	Implicit VR Little Endian	1.2.840.10008.1.2	SCU	None
		Explicit VR Little Endian	1.2.840.10008.1.2.1	SCU	None
		Explicit VR Big Endian	1.2.840.10008.1.2.2	SCU	None

2.3.4.3.3 SOP Specific Conformance Statement for SOP Verification Class

The associated real-world activity with the Storage Commitment Push Model service is the communication by the ExactVu to remote AE so that the SCU requests the SCP to commit to permanently store SOP Instances that have been sent to it. Once the all the SOP instances in a study are committed on the SCP, ExactVu can mark the study as successfully archived and it can be

deleted from local storage.

2.3.5 Association Acceptance Policy

As a Storage Commitment Push Model SCU, ExactVu waits for association from the SCP. It may reject Association attempts with rejected-transient and no-reason-given whenever any of the following error happens:

- Invalid association
- No pending request for the association
- Unexpected system error
- The association has been aborted by the remote AE

2.4 Network Interfaces

2.4.1 Physical Network Interfaces

ExactVu uses the MergeCOM-3 Advanced DICOM Toolkit to communicate over the TCP/IP protocol stack on any physical interconnection media supporting the TCP/IP stack. The Toolkit inherits the TCP/IP stack from the host operating system upon which it executes, i.e., Windows 7 for ExactVu.

2.4.2 Additional Protocols

Not applicable.

2.5 Configuration

Any implementation's DICOM conformance may be dependent upon configuration, which takes place at the time of installation.

2.5.1 AE Title/Presentation Address Mapping

AE Titles on ExactVu can be configured from Preferences/Network Settings page. The parameters and default values are specified as following:

Service Class Name	Remote Server (IP or Host Name)	Remote Port	Remote AE	Local AE	Local Port
Storage		104			Not applicable
Storage Commitment Push Model		104			105

Note:

- 1. Empty items in the above table means there is no default value.
- 2. The parameters specified in the above table are on the ExactVu side, which acts as an SCU. These parameters must match the corresponding parameters set in the DICOM server, i.e., the SCP. This means:
 - The remote server (SCP) and its port should be able to be connected to ExactVu.

- The remote AE should be correctly set in the SCP.
- The local AE from ExactVu should be allowed for the service class in the SCP.
- The local port (and the local computer name or address) for Storage Commitment Push Mode should be known for the service class in the SCP.

3 Media Interchange

3.1 Implementation Model

ExactVu implements DICOM File-Set Reader.

3.1.1 Application Data Flow Diagram

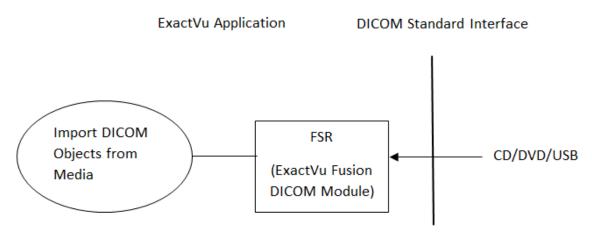


Figure 2: DICOM File-Set Reader Flow Diagram

3.1.2 Functional Definitions of AEs

ExactVu imports images and Presentation States from a removable media storage. The real-world activity "Import DICOM Objects from Media" is performed when the user requests to read a MR study list and/or images from a CD/DVD or USB storage device.

3.1.3 Sequencing of Real World Activities

When the user selects to display MRI study list from a USB based CD/DVD drive, or from a USB storage device, ExactVu acts as a FSR to read the DICOMDIR from the DICOM file set on the media, i.e., CD/DVD or USB storage device, and build a study list to display to the user. When the user selects a MRI study to load, ExactVu reads MR images and Presentation States.

3.2 AE Specifications

Application Profile	Identifier	Role	Real World Activity	Service Class
CT/MR Studies on CD-R	STD-CTMR-CD	FSR	Read Images and Presentations	Interchange
CT/MR Studies on CD-R	STD-CTMR-DVD	FSR	Read Images and Presentations	Interchange

Application Profile	Identifier	Role	Real World Activity	Service Class
General Purpose CD-R Interchange	STD-GEN-CD	FSR	Read Images and Presentations	Interchange
General Purpose USB Interchange	STD-GEN-USB	FSR	Read Images and Presentations	Interchange

4 Support of Character Sets

The following table lists the character sets used in ExactVu.

Character Set Description	Defined Term	ISO Registration Number	Code Element	Character Set	AE Role
Latin alphabet No. 2	ISO 2022 IR 101	ISO_IR 101	G2	Supplementary set of ISO 8859	Storage SCU, FSR
Default repertoire	ISO 2022 IR 6	ISO_IR 6	G0	ISO 646	FSR

5 Security

ExactVu does not support any specific security measures. It is assumed that ExactVu is used within a secured environment. It is assumed that a secured environment includes at a minimum:

- Firewall or router protections to ensure that only approved external hosts have network access to ExactVu
- Firewall or router protections to ensure that ExactVu only has network access to approved external hosts and services
- Any communication with external hosts and services outside the locally secured environment use appropriate secure network channels (e.g. such as a Virtual Private Network (VPN))
- Other network security procedures such as automated intrusion detection may be appropriate in some environments
- Additional security features may be established by the local security policy and are beyond the scope of this DICOM Conformance Statement

Appendix A Private Attributes

Data Dictionary of Private Attribute

ExactVu adds EVuPrivateInfo and EvuPrivateBinary private module to indicate private information and data.

Private Group "EvuPrivateInfo"

Attribute Name	Tag	VR	VM	Use
Private Creator ID	7171,0010	LO	1	"EVuPrivateInfo". Reserve element numbers 1000-10FF of group 7171 in the SOP instance
	7171,102B	LT	2	Private referenced proprietary image (SOP class and instance UID)

Private Group "EvuPrivateBinary"

Attribute Name	Tag	VR	VM	Use
Private Creator ID	9191,0010	LO	1	"EVuPrivateInBinary". Reserve element numbers 1000-10FF of group 9191 in the SOP instance
	9191,10E1	OW	1	Private raw data for ExactVu proprietary data