



## **Biim Ultrasound, AS**

**Title:** DICOM Conformance Statement, Biim Ultrasound  
App Version 1

**Document:** D00085 Rev C

		<b>DICOM Conformance Statement, Biim Ultrasound App Version 1</b>	<b>Page 1 of 10</b>
The information contained in this document is the sole property of Biim Ultrasound, AS. Any reproduction in whole or in part without written permission of Biim Ultrasound is prohibited. <i>User responsible for verifying revision if printed.</i>			

## Table of Contents

<b>1</b>	<b>Purpose and Scope .....</b>	<b>3</b>
<b>2</b>	<b>Conformance statement overview.....</b>	<b>3</b>
<b>3</b>	<b>Definitions.....</b>	<b>3</b>
<b>4</b>	<b>Reference Documents.....</b>	<b>4</b>
<b>5</b>	<b>Networking.....</b>	<b>4</b>
<b>5.1</b>	<b>Implementation Model.....</b>	<b>4</b>
<b>5.1.1</b>	<b>Application Data Flow .....</b>	<b>4</b>
<b>5.1.2</b>	<b>Functional Definition of AEs .....</b>	<b>5</b>
<b>5.1.3</b>	<b>Sequencing of Real-World Activities .....</b>	<b>5</b>
<b>6</b>	<b>AE Specifications.....</b>	<b>5</b>
<b>6.1</b>	<b>Store AE – Specification .....</b>	<b>5</b>
<b>6.1.1</b>	<b>SOP Classes .....</b>	<b>5</b>
<b>6.1.2</b>	<b>Association Establishment Policies.....</b>	<b>5</b>
<b>7</b>	<b>Communication.....</b>	<b>6</b>
<b>7.1</b>	<b>TCP/IP Stack.....</b>	<b>6</b>
<b>8</b>	<b>Configuration.....</b>	<b>7</b>
<b>8.1</b>	<b>Local Device Settings.....</b>	<b>7</b>
<b>8.2</b>	<b>Remote Device Settings.....</b>	<b>7</b>
<b>9</b>	<b>Support of Character Sets .....</b>	<b>7</b>
<b>10</b>	<b>Security .....</b>	<b>7</b>
<b>10.1</b>	<b>Secure Connection Profile.....</b>	<b>7</b>
<b>11</b>	<b>Information Object Definition .....</b>	<b>8</b>
<b>11.1</b>	<b>Patient Module of Created SOP Instances .....</b>	<b>8</b>
<b>11.2</b>	<b>Study Module of Created SOP Instances .....</b>	<b>8</b>
<b>11.3</b>	<b>General Series Module of Created SOP Instances.....</b>	<b>8</b>
<b>11.4</b>	<b>Equipment Module of Created SOP Instances.....</b>	<b>9</b>
<b>11.5</b>	<b>Image Pixel Module of Created SOP Instances .....</b>	<b>9</b>
<b>11.6</b>	<b>Image Pixel Module of Created SOP Instances .....</b>	<b>10</b>

## 1 PURPOSE AND SCOPE

The purpose of this document is to provide the DICOM conformance statement for the Biim Ultrasound App Version 1. The document assumes that the reader has a basic understanding of DICOM standard and functionality.

## 2 CONFORMANCE STATEMENT OVERVIEW

The Biim Ultrasound App Version 1 implements the necessary DICOM services to save acquired ultrasound images to the digital image archives.

The Biim Ultrasound App Version 1 product is based on NEMA DICOM version number 3.0 – 2007.

Table 1 Networking Services provides an overview of the networking services supported by the Biim Ultrasound App Version 1.

**Table 1 Networking Services**

Networking SOP Classes	User of Service (SCU)	Provider of Service (SCP)
Transfer		
Ultrasound Image Storage	Yes	No
General		
Verification	Yes	No

## 3 DEFINITIONS

Table 2 contains definition of terms used or referenced in this document.

**Table 2. Definitions and Acronyms**

Term	Definition
AE	DICOM Application Entity
AES	Advanced Encryption Standard
AET	Application Entity Title
DICOM	Digital Imaging and Communications in Medicine
FDA	Food and Drug Administration

Term	Definition
IEC	International Electrotechnical Commission
JPEG	Joint Photographic Experts Group
NEMA	National Electrical Manufacturers Association
SCP	DICOM Service Class Provider (server)
SCU	DICOM Service Class User (client)
SOP	Service – Object Pair
TLS	Transport Layer Security
UID	Unique Identifier
US	Ultrasound
VR	Value Representation

#### 4 REFERENCE DOCUMENTS

NEMA DICOM Standard Version 3.0 – 2007.

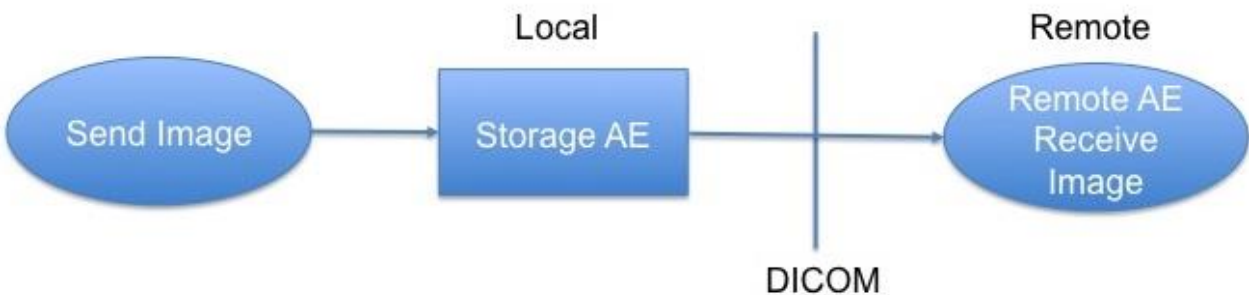
#### 5 NETWORKING

##### 5.1 Implementation Model

##### 5.1.1 Application Data Flow

Figure 1 Application Data Flow Diagram describes application data flow when sending ultrasound images. Storage AE sends images to a single remote AE. Each set of images will be sent separately using their own association to Remote AE. Images will have been captured and saved by a user function like “Save Image”. Sending of the images will have been initiated by a user activity “Send to DICOM”. There is a standard DICOM interface between Storage AE and Remote AE.

**Figure 1 Application Data Flow Diagram**



## 5.1.2 Functional Definition of AEs

### 5.1.2.1 Functional Definition of the Storage Application Entity

The Biim Ultrasound App Version 1 sends images to the Remote AE by opening an association first. Then it sends the images in the loop. The user can select multiple images and the Biim Ultrasound App Version 1 loops through all images selected for sending. Then the Biim Ultrasound App Version 1 closes the association.

### 5.1.3 Sequencing of Real-World Activities

The following steps are repeated for sending images:

- A-Associate
- C-ECHO command
- C-STORE Image instance (loop through all images)
- A-Release

The Biim Ultrasound App Version 1 offers the possibility to check the DICOM connection by using the verify application entity procedure. It has the following steps:

- A-Associate
- C-ECHO command
- A-Release

## 6 AE SPECIFICATIONS

### 6.1 Store AE – Specification

#### 6.1.1 SOP Classes

The Store AE provides conformance to the DICOM V3.0 SOP Classes that have been listed in Table 3 Store AE SOP Class Support.

**Table 3 Store AE SOP Class Support**

SOP Class Name	SOP Class UID	Conformance
Ultrasound Image Storage	1.2.840.10008.5.1.4.1.1.6.1	Standard
Verification	1.2.840.10008.1.1	Standard

#### 6.1.2 Association Establishment Policies

##### 6.1.2.1 General

The Biim Ultrasound App Version 1 always proposes a standard application context name for DICOM 3.0:

	DICOM Conformance Statement, Biim Ultrasound App Version 1	Page 5 of 10
The information contained in this document is the sole property of Biim Ultrasound, AS. Any reproduction in whole or in part without written permission of Biim Ultrasound is prohibited. <i>User responsible for verifying revision if printed.</i>		

**Table 4 DICOM Application Context for AE Storage**

Application Context Name	1.2.840.10008.3.1.1.1
--------------------------	-----------------------

Maximum PDU size offered to SCP: 16 384 bytes

#### 6.1.2.2 Number of Associations

The Biim Ultrasound App Version 1 opens always one Association to the destination when a connection is requested.

**Table 5 Maximum number of Association for AE Storage**

Maximum number of simultaneous associations	1
---	---

#### 6.1.2.3 Asynchronous Nature

The Biim Ultrasound App Version 1 uses synchronous communication. It has only one transaction ongoing simultaneously.

#### 6.1.2.4 Implementation Identifying Nature

Implementation Class UID	1.2.276.0.7230010.3.0.3.6.1
Implementation Version Name	biim L 12-4

#### 6.1.2.5 Proposed Presentation Contexts

**Table 6 Proposed Presentation Contexts for Store and Verification**

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Extended Negotiation
Name	UID	Name List	UID List		
Verification	1.2.840.10008.1.1	Implicit VR Little Endian	1.2.840.10008.1.2	SCU	None
Ultrasound Image Storage	1.2.840.10008.5.1.4.1.1.6.1	Implicit VR Little Endian	1.2.840.10008.1.2	SCU	None
		Explicit VR Little Endian	1.2.840.10008.1.2.1		
		JPEG Baseline	1.2.840.10008.1.2.4.50		

## 7 COMMUNICATION

### 7.1 TCP/IP Stack

The Biim Ultrasound App Version 1 product uses TCP/IP communication that is supported by the underlying operating system. The system supports all physical interfaces that are available in the device. The Biim Ultrasound App Version 1 does not configure or control the network interfaces.

		DICOM Conformance Statement, Biim Ultrasound App Version 1	Page 6 of 10
The information contained in this document is the sole property of Biim Ultrasound, AS. Any reproduction in whole or in part without written permission of Biim Ultrasound is prohibited. <i>User responsible for verifying revision if printed.</i>			

## 8 CONFIGURATION

The Biim Ultrasound App Version 1 allows the user to update the DICOM configuration at any time. The user can save different sets with defined names representing each configuration set. Each set contains local and remote device parameters.

### 8.1 Local Device Settings

Local AE Title can be provided by the user.

### 8.2 Remote Device Settings

The following parameters can be defined:

- Remote AE Title
- Remote server address
- Remote port
- Secure connection enabled/disabled

## 9 SUPPORT OF CHARACTER SETS

The Biim Ultrasound App Version 1 system supports the ISO\_IR 192 (Unicode) character set.

## 10 SECURITY

### 10.1 Secure Connection Profile

The Biim Ultrasound App Version 1 supports secure DICOM connection. In this case the association shall be opened as a TLS secured connection. The supported profile is the AES TLS Secure Transport Connection Profile. Table 7 TLS Features describes TLS features supported by Biim Ultrasound App Version 1.

**Table 7 TLS Features**

Supported TLS Feature	Mechanism
Entity Authentication	RSA based certificates
Exchange of Master Secrets	RSA
Data Integrity	SHA
Privacy	DES CBC3 SHA

The Biim Ultrasound App Version 1 doesn't verify server certificates against a certificate authority.

Table 8 Integrity Check Failure Handling describes the system's response to failures.

**Table 8 Integrity Check Failure Handling**

Service Status	Meaning	AE Behavior
A-P-ABORT	Integrity check has failed during TLS transport	Association terminated. User notified.

## 11 INFORMATION OBJECT DEFINITION

### 11.1 Patient Module of Created SOP Instances

**Table 9 Patient Module**

Attribute	Tag	Description	Presence
Patient's Name	(0010,0010)	Manually entered patient last name, first name and middle name.	ALWAYS
Patient ID	(0010,0020)	Manually entered or auto generated patient identifier.	ALWAYS
Patient's Birth Date	(0010,0030)	Manually entered date of birth.	Value may be empty
Patient's Sex	(0010,0040)	Manually entered patient gender.	Value may be empty

### 11.2 Study Module of Created SOP Instances

**Table 10 Study Module**

Attribute	Tag	Description	Presence
Study Instance UID	(0020,000D)	Auto generated	ALWAYS
Study Date	(0008,0020)	Study date	ALWAYS
Study Time	(0008,0030)	Study time	ALWAYS
Study ID	(0020,0010)	Automatically generated value starting from 1	ALWAYS
Study Description	(0008,1030)	Entered manually as an Exam Type	ALWAYS
Accession number	(0008,0050)	Manually entered value	Value may be empty
Referring Physician's Name	(0008,0090)	Manually entered clinician's name	Value may be empty

### 11.3 General Series Module of Created SOP Instances

**Table 11 General Series Module**

Attribute	Tag	Description	Presence
Modality	(0008,0060)	US	ALWAYS
Series Instance UID	(0020,000E)	Auto generated	ALWAYS
Series Number	(0020,0011)	A unique number within the Study	ALWAYS, value is 1.
Laterality	(0020,0060)	Zero length	Value is empty
Series Date	(0008,0021)	Procedure date	ALWAYS



Attribute	Tag	Description	Presence
Series Time	(0008,0031)	Procedure time	ALWAYS
Performing Physician Name	(0008,1050)	Manually entered clinician's name	Value may be empty
Protocol Name	(0018,1030)	Zero length	Value is empty
Series Description	(0008,103E)	Entered manually as an Exam Type	ALWAYS
Operator's Name	(0008,1070)	Zero length	Value is empty

## 11.4 Equipment Module of Created SOP Instances

**Table 12 Equipment Module**

Attribute	Tag	Description	Presence
Manufacturer	(0008,0070)	Biim Ultrasound	ALWAYS
Station Name	(0008,1010)	The local AE title of biim L 12-4 device. The user can configure this text manually.	Value may be empty
Manufacturer's model name	(0008,1090)	biim L 12-4	ALWAYS
Software Version	(0018,1020)	This is multi valued tag that contains SW part number, SW version and build number.	ALWAYS
Device Serial Number	(0018,1000)	Value is 0	ALWAYS

## 11.5 Image Pixel Module of Created SOP Instances

**Table 13 Image Module**

Attribute	Tag	Description	Presence
Instance Number	(0020,0013)	Auto generated	ALWAYS
Patient Orientation	(0020,0020)	Zero length	Value is empty
Content Date	(0008,0023)	Procedure date	ALWAYS
Content Time	(0008,0033)	Procedure time	ALWAYS
Lossy Image Compression	(0008,2110)	01 = Lossy Compressed	ALWAYS

## 11.6 Image Pixel Module of Created SOP Instances

**Table 14 Image Pixel Module**

Attribute	Tag	Description	Presence
Samples Per Pixel	(0028,0002)	Value is 3	ALWAYS
Photometric Interpretation	(0028,0004)	Value is YBR_FULL_422	ALWAYS
Rows	(0028,0010)	Value varies depending on tablet or smartphone screen resolution	ALWAYS
Columns	(0028,0011)	Value varies depending on tablet or smartphone screen resolution	ALWAYS
Bits Allocated	(0028,0100)	Value is 8	ALWAYS
Bits Stored	(0028,0101)	Value is 8	ALWAYS
High Bit	(0028,0102)	Value is 7	ALWAYS
Pixel Representation	(0028,0103)	Value is 0	ALWAYS
Lossy Image Compression Method	(0028,2114)	Value is ISO_10918_1	ALWAYS
Planar Configuration	(0028,0006)	Value is 0	ALWAYS
Pixel Data	(7FE0,0010)		ALWAYS