

# Gateway DICOM

## Conformance Statement

### 3.24.2.0 | User Guide



**intelerad**

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InteleShare PACS software is intended for use as a primary diagnostic and analysis tool for diagnostic images for hospitals, imaging centers, radiologists, reading practices and any user who requires and is granted access to patient image, demographic and report information.

InteleShare ProViewer, a component of InteleShare PACS, displays, modifies and manages diagnostic quality DICOM images including 3D visualization and reordering functionality.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image diagnosis or image interpretations. Mammographic images may only be viewed using cleared monitors intended for mammography display.

Not intended for diagnostic use on mobile devices.

CONTRAINDICATIONS—None.

Caution: Federal law restricts this device to sale by or on the order of a physician. Fluency in English is required as a prerequisite for operating the Ambra PACS product.

This system does not replace the education, skill, and judgment of properly trained medical practitioners. Only properly trained and qualified individuals shall have access to and use InteleShare PACS and must know of its functionality, capabilities and limitations. Typical users of this system are trained health professionals, physicians, nurses, and technologists.

Downloaded Images, Workstations and Isolated Installs: You and your users must maintain InteleShare PACS with the most current versions, including available updates and upgrades. Delaying or refusing updates or upgrades following a recall may result in a non-compliant InteleSharePACS.

SAFETY ISSUES: InteleSharePACS is a medical device, and as such, must meet medical device safety and effectiveness requirements imposed by national regulations. Any unmonitored or unconnected use of InteleSharePACS, or use of InteleSharePACS without a valid right may put the health and safety of patients at risk as you will not be advised of the availability of any software patch, bug fix, update or upgrade nor will be informed of Field Safety Notices, Medical Device Recalls or Advisory Notices related to InteleSharePACS. Client and authorized users must consult national regulatory site(s) to be informed of Field Safety Notices, Medical Device Recalls or Advisory Notices related to InteleSharePACS. Intelrad does not have access to authorized users systems to implement corrections to prevent (or correct) occurrences of patient safety issues. You are responsible to flow down recall and patient safety information to your users. The user of the medical device must report any serious incident that has occurred in relation to the medical device to the manufacturer (Intelrad) and the competent authority having jurisdiction in their locale.

Referring Physicians Use: Images for authorized referring physicians may not be of diagnosis quality and should not be used for diagnostic purposes.



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InteleShare UDI is: **+AMBRAPACS0/\$73.24.2.0D**

## DECLARATION OF CONFORMITY

Declaration of Conformity is issued under the sole responsibility of the DICOM Grid, Inc. dba Ambra Health.

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## INTRODUCTION

### Purpose

This is the DICOM 3.0 Conformance Statement for IntelShare Gateway software produced by IntelShare. The solution is in direct compliance with the DICOM Standard.

IntelShare Gateway is a Microsoft® Windows® based DICOM solution that runs automatically as a Microsoft Windows service and is easily configured to support all DICOM reports and image types, using any compression type. The system supports all DICOM Storage services to include: Store, Query Retrieve and Storage Commitment. It is ideally suited as a plug-in to any server or workstation environment, and the open architecture allows for extension through the use of a DICOM SDK.

### Symbols and Abbreviations

AE	Application Entity
DICOM	Digital Imaging and Communication in Medicine
IOD	Information Object Definition
IP	Internet Protocol
PDU	Protocol Data Unit
RQ	Request
SCU	Service Class User
SOP	Service Object Pair
TCIP/IP	Transmission Control Protocol/ Internet Protocol
UID	Unique Identifier

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## BROWSER REQUIREMENTS

InteleShare supports the following browsers:

Microsoft Internet Explorer 9 or later

Microsoft Edge

Apple Safari

Google Chrome

Firefox.

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## CONTACTING INTELERAD TECHNICAL SUPPORT

Your PACS administrator can assist you with any issues you may encounter. If you require additional assistance, you can contact IntelShare Technical Support, 24 hours a day, seven days a week.

To contact us:	Use:
On the Internet	<a href="https://serviceportal.intelerad.com/csm">https://serviceportal.intelerad.com/csm</a>
By telephone	Toll-free: 888-315-0790

These coordinates and a wealth of other information are also available on the Intelrad Service Portal.

<https://serviceportal.intelerad.com/csm>

You should regularly check the Intelrad knowledge base for the latest version of the documentation.

IntelShare PACS is a cloud-based product. Customers are informed of upcoming releases via multiple channels to ensure they stay up-to-date with the latest developments and enhancements. All customers receive timely and comprehensive e-mails from our marketing team, which not only highlight the release dates but also describe in detail the new features and functionalities that will be available in the upcoming release. When a new version of the software becomes available it will automatically upgrade on the appointed release date of that version. Please contact support with for any questions regarding upgrades.

When you contact IntelShare Technical Support to report a problem, please have at hand the following information, as applicable:

- client code and location of your IntelShare PACS installation
- full error message and the steps required to reproduce the problem
- AE Titles of the affected devices
- operating systems of any affected machines
- description of the problem and when it first occurred

If the problem affects a particular study, please also provide the following:

- patient ID or patient number (M.R.N.)
- accession number/requisition number
- modality type and name

For security information, please open a ticket with Intelrad Technical Support.

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## OBTAINING PRINTED DOCUMENTATION

Intelerad offers printed and bound versions of product documentation free of charge. To request printed copies of Intelerad documentation, contact your Client Success manager. The printed documents will be provided within 7 days or less.

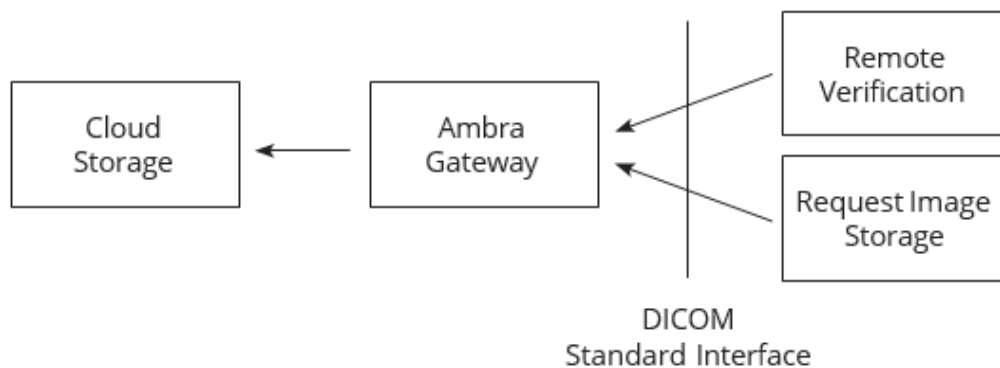


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## IMPLEMENTATION MODEL

### Application Data Flow Diagram

The specific application models for this Application Entity (AE) are shown below:



IntelShare Gateway is a Microsoft Windows® (Windows 2000,® Windows XP®, Windows 2003® and Windows 2008®) application for the transfer of DICOM images to IntelShare's cloud archive. It is executed on OS startup as a "Service" for all Microsoft Windows operating systems.

### Functional Definitions of AE's

IntelShare Gateway waits for other Application Entities (AE's) to initiate DICOM storage requests, according to the presentation contexts stated below, and then persists the transferred images to the local hard drive as a DICOM Part 10 file for a brief amount of time while it processes the backlog transport queue. Once the DICOM files have been

transferred to the IntelShare cloud, the Gateway then deletes the file from the disk. IntelShare Gateway can be configured so that delete happens after a successful store commitment communication for that IOD.

## **Sequencing of Real-World Activities**

Not applicable.

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## AE SPECIFICATIONS

### IntelShare Gateway AE Specifications

IntelShare Gateway provides Standard Conformance to the following DICOM SOP classes as an SCP.

SOP Class Name	SOP Class UID
Verification	1.2.840.10008.1.1
Computed Radiography Image Storage	1.2.840.10008.5.1.4.1.1.1
Digital X-Ray Image Storage Presentation	1.2.840.10008.5.1.4.1.1.1.1
Digital X-Ray Image Storage Processing	1.2.840.10008.5.1.4.1.1.1.1.1
Digital Mammography X-Ray Image Storage Presentation	1.2.840.10008.5.1.4.1.1.1.2
Digital Mammography X-Ray Image Storage Processing	1.2.840.10008.5.1.4.1.1.1.2.1
Digital Intra-Oral X-Ray Image Storage Presentation	1.2.840.10008.5.1.4.1.1.1.3
Digital Intra-Oral X-Ray Image Storage Processing	1.2.840.10008.5.1.4.1.1.1.3.1
CT Image Storage	1.2.840.10008.5.1.4.1.1.2
Enhanced CT Image Storage	1.2.840.10008.5.1.4.1.1.2.1
Ultrasound Multi-frame Image Storage (Retired)	1.2.840.10008.5.1.4.1.1.3
Ultrasound Multi-frame Image Storage	1.2.840.10008.5.1.4.1.1.3.1

MR Image Storage	1.2.840.10008.5.1.4.1.1.4
Enhanced MR Image Storage	1.2.840.10008.5.1.4.1.1.4.1
MR Spectroscopy Storage	1.2.840.10008.5.1.4.1.1.4.2
Nuclear Medicine Image Storage (Retired)	1.2.840.10008.5.1.4.1.1.5
Ultrasound Image Storage (Retired)	1.2.840.10008.5.1.4.1.1.6
Ultrasound Image Storage	1.2.840.10008.5.1.4.1.1.6.1
Secondary Capture Image Storage	1.2.840.10008.5.1.4.1.1.7
Multi-frame Single Bit Secondary Capture Image Storage	1.2.840.10008.5.1.4.1.1.7.1
Multi-frame Grayscale Byte Secondary Capture Image Storage	1.2.840.10008.5.1.4.1.1.7.2
Multi-frame Grayscale Word Secondary Capture Image Storage	1.2.840.10008.5.1.4.1.1.7.3
Multi-frame True Color Secondary Capture Image Storage	1.2.840.10008.5.1.4.1.1.7.4
Standalone Overlay Storage	1.2.840.10008.5.1.4.1.1.8
Standalone Curve Storage	1.2.840.10008.5.1.4.1.1.9
ECG 12 Lead Waveform Storage	1.2.840.10008.5.1.4.1.1.9.1.1
General ECG Waveform Storage	1.2.840.10008.5.1.4.1.1.9.1.2
Ambulatory ECG Waveform Storage	1.2.840.10008.5.1.4.1.1.9.1.3
Hemodynamic Waveform Storage	1.2.840.10008.5.1.4.1.1.9.2.1
Cardiac Electrophysiology Waveform Storage	1.2.840.10008.5.1.4.1.1.9.3.1
Basic Voice Audio Waveform Storage	1.2.840.10008.5.1.4.1.1.9.4.1
Standalone Modality LUT Storage	1.2.840.10008.5.1.4.1.1.10
Standalone VOI LUT Storage	1.2.840.10008.5.1.4.1.1.11
Grayscale Softcopy Presentation State Storage	1.2.840.10008.5.1.4.1.1.11.1
X-Ray Angiographic Image Storage	1.2.840.10008.5.1.4.1.1.12.1
X-Ray Radiofluoroscopic Image Storage	1.2.840.10008.5.1.4.1.1.12.2
X-Ray Angiographic BiPlane Image Storage Retired	1.2.840.10008.5.1.4.1.1.12.3
Nuclear Medicine Image Storage	1.2.840.10008.5.1.4.1.1.20
Raw Data Storage	1.2.840.10008.5.1.4.1.1.66

Spatial Registration Storage	1.2.840.10008.5.1.4.1.1.66.1
Spatial Fiducials Storage	1.2.840.10008.5.1.4.1.1.66.2
VL Image Storage Retired	1.2.840.10008.5.1.4.1.1.77.1
VL Multi-frame Image Storage Retired	1.2.840.10008.5.1.4.1.1.77.2
VL Endoscopic Image Storage	1.2.840.10008.5.1.4.1.1.77.1.1
Video Endoscopic Image Storage	1.2.840.10008.5.1.4.1.1.77.1.1.1
VL Microscopic Image Storage	1.2.840.10008.5.1.4.1.1.77.1.2
Video Microscopic Image Storage	1.2.840.10008.5.1.4.1.1.77.1.2.1
VL Slide Coordinates Microscopic Image Storage	1.2.840.10008.5.1.4.1.1.77.1.3
VL Photographic Image Storage	1.2.840.10008.5.1.4.1.1.77.1.4
Video Photographic Image Storage	1.2.840.10008.5.1.4.1.1.77.1.4.1
Ophthalmic Photography 8 Bit Image Storage	1.2.840.10008.5.1.4.1.1.77.1.5.1
Ophthalmic Photography 16 Bit Image Storage	1.2.840.10008.5.1.4.1.1.77.1.5.2
Stereometric Relationship Storage	1.2.840.10008.5.1.4.1.1.77.1.5.3
Basic Text Structured Report	1.2.840.10008.5.1.4.1.1.88.11
Enhanced Structured Report	1.2.840.10008.5.1.4.1.1.88.22
Comprehensive Structured Report	1.2.840.10008.5.1.4.1.1.88.33
Procedure Log	1.2.840.10008.5.1.4.1.1.88.40
Mammography CAD Structured Report	1.2.840.10008.5.1.4.1.1.88.50
Key Object Selection Document	1.2.840.10008.5.1.4.1.1.88.59
Chest CAD Structured Report	1.2.840.10008.5.1.4.1.1.88.65
Positron Emission Tomography Image Storage	1.2.840.10008.5.1.4.1.1.128
Standalone PET Curve Storage	1.2.840.10008.5.1.4.1.1.129
RT Image Storage	1.2.840.10008.5.1.4.1.1.481.1
RT Dose Storage	1.2.840.10008.5.1.4.1.1.481.2
RT Structure Set Storage	1.2.840.10008.5.1.4.1.1.481.3
RT Beams Treatment Record Storage	1.2.840.10008.5.1.4.1.1.481.4
RT Plan Storage	1.2.840.10008.5.1.4.1.1.481.5
RT Brachy Treatment Record Storage	1.2.840.10008.5.1.4.1.1.481.6
RT Treatment Summary Record Storage	1.2.840.10008.5.1.4.1.1.481.7
Hardcopy Color Image Storage	1.2.840.10008.5.1.1.30

Hardcopy Grayscale Image Storage	1.2.840.10008.5.1.1.29
Stored Print Storage	1.2.840.10008.5.1.1.27

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## ASSOCIATION ESTABLISHMENT POLICIES

### General

IntelShare Gateway when installed will use the configurable AE Title as its default AE Title, with a maximum PDU size of 256/Kbytes and “listen” for new clients on the configurable port (104 is the default DICOM port). IntelShare Gateway also supports arbitrary AE Title connections, which may be linked in the cloud to routing rules that run after the files have been uploaded. This is further defined in the application documentation.

### Number of Simultaneous Associations

The number of simultaneous associations is configurable with a default of 20.

### Asynchronous Nature

IntelShare Gateway, can handle any number of asynchronous operations that can be achieved through a network TCP/IP stack.

### Implementation Identifying Information

The implementation UID uniquely identifies IntelShare Gateway, and the current set of functionality. This value will only change when major functionality warrants. The version name shall reflect minor changes to IntelShare Gateway.

Implementation UID	Implementation Version Name
1.2.840.10008.114368.1.1	“IntelShare Gateway X.X”
1.2.840.10008.5.1.4.1.2.1.1	Patient Root Query/Retrieve Information Model – FIND

1.2.840.10008.5.1.4.1.2.1.2	Patient Root Query/Retrieve Information Model – MOVE
1.2.840.10008.5.1.4.1.2.1.3	Patient Root Query/Retrieve Information Model – GET
1.2.840.10008.5.1.4.1.2.2.1	Study Root Query/Retrieve Information Model – FIND
1.2.840.10008.5.1.4.1.2.2.2	Study Root Query/Retrieve Information Model – MOVE
1.2.840.10008.5.1.4.1.2.2.3	Study Root Query/Retrieve Information Model – GET
1.2.840.10008.5.1.4.1.2.3.1	Patient/Study Only Query/Retrieve Information Model - FIND
1.2.840.10008.5.1.4.1.2.3.2	Patient/Study Only Query/Retrieve Information Model – MOVE
1.2.840.10008.5.1.4.1.2.3.3	Patient/Study Only Query/Retrieve Information Model – GET



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## ASSOCIATION INITIATION BY REAL- WORLD ACTIVITY

IntelShare Gateway also makes associations for the following real-world activities.

### Real-World Activity

On the IntelShare website, the user “DICOM Sends” a DICOM Study to a pre-configured DICOM device on the network.

### Associated Real-World Activity

The associated real-world activity associated with the C-Store operation is the storage of the DICOM image to the “Inbox” on local disk. IntelShare Gateway will issue a failure status if it is unable to store the image to disk.

### Proposed Presentation Contexts

#### Proposed Presentation Context Tables

IntelShare Gateway supports all known DICOM Storage Types using the following Transfer Syntax.

Name	UID
Implicit Vr Little Endian	1.2.840.10008.1.2
Explicit Vr Little Endian	1.2.840.10008.1.2.1
Explicit Vr Big Endian	1.2.840.10008.1.2.2
RLE Lossless	1.2.840.10008.1.2.5

JPEG Baseline (Process 1)	1.2.840.10008.1.2.4.50
JPEG Extended (Process 2 & 4)	1.2.840.10008.1.2.4.51
JPEG Lossless, Non-Hierarchical (Process 14)	1.2.840.10008.1.2.4.57
JPEG Lossless, Non-Hierarchical, First-Order Prediction (Process 14 [Selection Value 1])	1.2.840.10008.1.2.4.70
JPEG-LS Lossless Image Compression	1.2.840.10008.1.2.4.80
JPEG-LS Lossy (Near-Lossless) Image Compression	1.2.840.10008.1.2.4.81
JPEG 2000 Image Compression (Lossless Only)	1.2.840.10008.1.2.4.90
JPEG 2000 Image Compression	1.2.840.10008.1.2.4.91
MPEG2 Main Profile @ Main Level	1.2.840.10008.1.2.4.100
JPEG Extended (Process 3 & 5) RETIRED	1.2.840.10008.1.2.4.52
JPEG Spectral Selection, Non-Hierarchical (Process 6 & 8) RETIRED	1.2.840.10008.1.2.4.53
JPEG Spectral Selection, Non-Hierarchical (Process 7 & 9) RETIRED	1.2.840.10008.1.2.4.54
JPEG Full Progression, Non-Hierarchical (Process 10 & 12) RETIRED	1.2.840.10008.1.2.4.55
JPEG Full Progression, Non-Hierarchical (Process 11 & 13) RETIRED	1.2.840.10008.1.2.4.56
JPEG Lossless, Non-Hierarchical (Process 15) RETIRED	1.2.840.10008.1.2.4.58
JPEG Extended, Hierarchical (Process 16 & 18) RETIRED	1.2.840.10008.1.2.4.59
JPEG Extended, Hierarchical (Process 17 & 19) RETIRED	1.2.840.10008.1.2.4.60
JPEG Spectral Selection, Hierarchical (Process 20 & 22) RETIRED	1.2.840.10008.1.2.4.61
JPEG Spectral Selection, Hierarchical (Process 21 & 23) RETIRED	1.2.840.10008.1.2.4.62
JPEG Full Progression, Hierarchical (Process 24 & 26) RETIRED	1.2.840.10008.1.2.4.63
JPEG Full Progression, Hierarchical (Process 25 & 27) RETIRED	1.2.840.10008.1.2.4.64
JPEG Lossless, Hierarchical (Process 28) RETIRED	1.2.840.10008.1.2.4.65
JPEG Lossless, Hierarchical (Process 29) RETIRED	1.2.840.10008.1.2.4.66

## **SOP Specific Conformance for Verification (C-ECHO)**

IntelShare Gateway provides standard conformance to the DICOM Verification Service class.

## **SOP Specific Conformance for Storage (C-STORE)**

IntelShare Gateway conforms to the SOP's of the Storage Service Class as s Level 2 (Full) SCP. In the event of a successful C-Store operation, the image has been successfully stored to disk as a DICOM part 10 file to the installed/configured "inbox". Once the image has been stored, the image can be accessed as any other file system file. If IntelShare Gateway returns A700 (out of resources) or C000 (processing failure) then the C-STORE operations were not successful.

## **Presentation Context Acceptance Criteria**

IntelShare Gateway will always accept any of the presentation context items stated above and when given the choice, by multiple transfer syntaxes proposed in a single presentation context item, will use the first Transfer Syntax proposed. It is therefore recommended that requestors propose all of their preferred ASN/TSN as separate presentation context items up to the maximum that DICOM allows. With this policy it is also recommended that the use of retired Transfer Syntaxes should be discouraged.

## **Association Acceptance Policy**

When IntelShare Gateway accepts an association it will receive any DICOM image transmitted on that association and store the image to the default upload queue directory. The Gateway will then try to upload the file to the IntelShare cloud, and after a successful and verified upload, will delete the file from the disk. This may happen in seconds or minutes, correlated by Gateway's load and bandwidth allowance.

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## COMMUNICATION PROFILES

### **TCP/IP Stack**

IntelShare Gateway inherits its TCP/IP stack from the Microsoft Windows operating system on which it resides.

### **Configuration**

All configuration items for IntelShare Gateway can be configured through the cloud configuration page. See IntelShare Gateway and Cloud Users Guide for more details.

### **Configurable Association Acceptance Criteria**

Calling AE Title Enforcement which will require the caller to know the called AE Title of IntelShare Gateway.

Calling AE Title Filter which can be used to include/exclude based on the Calling Title of the AE of the association requestor.

IP Address Filter which can be used to include/exclude certain IP addresses.

Implementation UID Filter which can be used to include/exclude based on the Implementation UID of the association requestor.

### **Support of Extended Character Sets**

IntelShare Gateway is indifferent to Extended Character Sets and will therefore accept all DICOM C-STORE requests using any character set, without modification to the text being sent.

## **Extensions/Specializations/Privatizations**

None at this time.

## **Codes and Controlled Terminology**

None at this time.