

IntelPACS

4.11.1 and later | IHE Integration Statement



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PERFORMANCE CHARACTERISTICS

- Customizable reading and reporting workflow for each user
- Built in redundancy and backup to support continuity of clinical operations
- Image resolution
- Integration with Electronic Health Records (EHR)
- Reliability and ease of use
- Image and data integrity
- Remote access
- High performance image management
- Optimizes workflow efficiency by reducing turnaround times
- Reduce film and storage costs

CLINICAL BENEFITS

- Improved diagnostic accuracy
- Increased speed and quality of reporting

INTENDED USE/INDICATIONS FOR USE

IntelPACS is a software application that receives digital images and data from various sources (such as CT scanners, MR scanners, ultrasound systems, R/F units, computer and direct radiographic devices, secondary capture devices, scanners, imaging gateways, or other imaging sources). Images and data can be communicated, processed, manipulated, enhanced, stored, and displayed within the system and/or across computer networks at distributed locations. Post-processing of the images can be performed using Multi Planar Reconstruction (MPR).

Only preprocessed DICOM for presentation images can be interpreted for primary image diagnosis in mammography. Mammographic images with lossy compression and digitized film screen images must not be reviewed for primary image interpretations.

Mammographic images may only be interpreted using an FDA cleared display that meets technical specifications reviewed and accepted by regulatory authorities.

For Canada, United States, Europe, Australia, New Zealand, and South Africa only: When used with a mobile device, IntelPACS is suitable for diagnostic image review

only on tested devices as specified in Intelrad product documentation. IntelPACS is not intended for primary diagnostic image review on mobile devices. Mobile usage for Mammography is for reference and referral only.

For all other countries: IntelPACS is not intended for diagnostic image review on mobile devices. Mobile usage for Mammography is for reference and referral only.

IntelPACS displays measurements in cm, square cm, and cubic cm units of measure when the appropriate DICOM attributes in the image are available, or you have applied a manual calibration. Otherwise, the units of measure are pixels, square pixels, and cubic pixels.

EXPECTED LIFE

IntelPACS is software. The lifetime of the product is approximately 3 to 4 years.

Software is fully supported during its defined lifetime. Intelrad may require that clients' systems be upgraded to the latest configuration available past the end of life of software.

CONTRAINDICATIONS—None.

WARNINGS — None

CAUTIONS — see Residual Risk section

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 IntelPACS and must know of its functionality, capabilities and limitations.

INTENDED USERS - 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 IntelPACS 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 IntelPACS.

NOTICE —

IntelPACS 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 IntelPACS, or use of IntelPACS 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 IntelPACS. Client and authorized users will be informed of Field Safety Notices, Medical Device Recalls or Advisory notices if they are impacted. Clients may also consult national regulatory site (s) to be informed of Field Safety Notices, Medical Device Recalls, or Advisory Notices related to IntelPACS that do not impact the client. Intelrad does not have access to authorized users' systems to implement corrections to prevent (or correct) occurrences of patient safety issues. When a correction is available Clients will be informed and must authorize Intelrad to upgrade their systems. 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.

USA: Report adverse events to the manufacturer and FDA at www.fda.gov/medwatch.

European Union: Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

PATIENT DATA DELETION REQUESTS: To fully delete patient data upon data subject request, please reach out to our Support department through the Service Portal.



IntelPACS



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

A paper copy of the IFU is available upon request at no additional cost.

Title: IntelePACS IHE Integration Statement
4.11.1 and later (Multiple Patient Multiple Use)
Date: 2026-05-26
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DOCUMENT REVISION

Revision	Date	Author	Comments
1	October 26, 2004	Kent Tse	Initial Revision
2	May 23, 2006	Susan Daoud	Standardized document formatting.
3	July 4, 2006	Susan Daoud	Updated for PACS 3.2.1. Corrected initial revision author. Modified formatting as per IHE Technical Framework, vol. I, Appendix D.
4	July 14, 2010	Marc Paquette	Updated for IntelPACS 4.1.1.
5	October 25, 2010	Susan Daoud	Merged IntelViewer Integration Profiles into this document (from obsolete IntelViewer Workstation Integration Statement, revision 1) and validated information for IntelPACS 4.2.1.
6	July 8, 2015	Irene Plokar	Updated for IntelPACS 4.11.1.
7	April 11, 2017	Irene Plokar	Updated the cover page and headers with Intelrad's recent corporate logo, and added a Copyright page.
8	June 15, 2022	Krishnali Kondekar	• Added copyright page. • Added the topics "Contacting Intelrad Technical Support" and "Obtaining Printed Documentation".

9	January 27, 2023	Krishnali Kondekar	Copyright changes.
10	October 30, 2023	Abhiruchi Gaikwad	• Added the UKCA Mark. • Removed the CE Mark. • Imported the project in Flare.
11	May 16, 2024	Abhiruchi Gaikwad	Updated the document per rebranding guidelines.
12	2025-03-24	Abhiruchi Gaikwad	Updated year to 2025 on Copyright page
13	2025-09-12	Abhiruchi Gaikwad	Reimplemented CE Mark

DOCUMENT CONVENTIONS

Several conventions are used throughout this document. A list of these and examples of their use are provided below.

Typographic Convention

Convention	Example
Text that you enter in a field, or on a command line are in <code>courier font</code> .	In the Date field, enter 2003/04/04.
Keyboard commands are in SMALL CAPS AND BOLD .	Press CTRL+C to copy text.
New terminology or concepts are <i>italicized</i> .	The process of automatically distributing the images is referred to as <i>autorouting</i> .
Interface elements, such as menus, buttons, options, and preferences are bold .	From the Font list, choose the desired font.
Menu selections are separated by vertical lines.	Choose File Print to print this page.
Information that is important for a user to know when performing a task, such as prerequisite information or restrictions, is represented with a note icon .	 To view reports, you must have the Report privilege enabled in your user account.
Information that is helpful to a user, such as when describing an alternate or simpler way to perform a task, is represented with a tip icon .	 You can also use the CTRL+T keyboard shortcut to show or hide thumbnail images.

ISO 15223-1 Reference

Symbol	Symbol Name
	Medical device (MD)
	Manufacturer
	Date of Manufacture
	EU Authorized representative
	UK Authorized representative
	CE mark
	Catalogue number (REF)
	Serial number (SN)
	Unique Device Identifier (UDI)
	Consult instructions for use
	Caution
	Model Number

RESIDUAL RISKS

Residual risks are communicated within this document as limitations, contraindications, precautions, cautions, or warnings.

Contraindications

None.

Cautions

The following cautions identify potential risks you should be aware of when using this device. Each caution is marked with the caution symbol ⚠.

- ⚠ Partial image loss due to software failures in DICOM load balancing leading to intermittent image spraying.
- ⚠ Failure to report image counts to central index leading to radiologist reading a study with missing images.
- ⚠ Displayed measurements of length, area, volume, and Standard Uptake Value are incorrect.
- ⚠ Federal law restricts this device to sale by or on the order of a physician.

Warnings

None.

Referring Physicians Use:

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

InteleConnect:

Images in InteleConnect are intended for review only and are not appropriate for diagnostic purposes. Please use InteleViewer for diagnostic viewing.

CD Burning and Nuage Patient Portal:

Intelerad Clients remain responsible for collecting patient consents and accesses. Images on CD and on Nuage Patient Portal are intended for review only and are not appropriate for diagnostic purposes. Please use InteleViewer for diagnostic viewing.

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INTEGRATION STATEMENT

IHE Integration Statement		Date	March 24, 2017
Vendor	Product Name	Version	
Intelerad	IntelePACS	4.11.1	
This product implements all transactions required in the IHE Technical Framework to support the IHE Integration Profiles, Actors, and Options listed below:			
Integration Profiles Implemented	Actors Implemented	Options Implemented	
Mammography Image	Image Display	None	
Scheduled Workflow	Image Manager/Image Archive	None	
	Performed Procedure Step Manager	None	
	Image Display	None	
Patient Information Reconciliation	Image Manager/Image Archive	None	
	Performed Procedure Step Manager	None	
Consistent Presentation of Images	Image Manager/Image Archive	None	
Consistent Time	Time Client	None	

Presentation of Grouped Procedures	Image Manager/Image Archive	None
	Performed Procedure Step Manager	None
Access to Radiology Information	Image Manager/Image Archive	None
	Image Display	Multiple Sources
Key Image Note	Image Manager/Image Archive	None
Evidence Documents	Image Manager/Image Archive	None
	Image Display	None
Reporting Workflow	Image Manager/Image Archive	None
	Performed Procedure Step Manager	None
NM Image	Image Manager/Image Archive	None

Integration Profiles Implemented	Actors Implemented	Options Implemented
Basic Security	Time Server	None
Portable Data for Imaging	Image Display	None
	Print Composer	None
	Portable Media Creator	None
	Portable Media Importer	None

For information on INTELEPACS, see <http://www.intelerad.com>.

Links to Standards Conformance Statements for the Implementation

HL7	https://support.intelerad.com/modules/wfsection/viewarticles.php?category=16
DICOM	https://support.intelerad.com/modules/wfsection/viewarticles.php?category=16

ory=16		
Links to General Information on IHE		
In North America: www.ihe.net	In Europe: www.ihe-europe.net	In Japan: www.jira-net.or.jp/ihe-j

OBTAINING PRINTED DOCUMENTATION

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

CONTACTING INTELERAD TECHNICAL SUPPORT

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

To contact us:	Use:
On the Internet	https://serviceportal.intelerad.com/csm
By telephone	Toll-free North America, UK, and Ireland: 1-866-951-6222 United Kingdom: 0113-360-2615 Sans frais Amérique du Nord (français): 1 844-467-7227 Toll-free Australia: 1-800-286-418 Toll-free New Zealand: 0800-467-723 Other: +1-514-931-7127

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, as well as other product-specific resources such as TechNotes, downloads, and videos.

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

- client code and location of your IntelPACS 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

SYSTEM REQUIREMENTS

For more information on system requirements, you can contact Intelrad Technical Support or access the *Intelrad Workstation and Accessories Recommendations Guide* by using the Intelrad Service Portal:

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

 A medical device such as IntelPACS must be supported and maintained to be used under applicable authority regulations. If your IntelPACS is not accessible to Intelrad's Technical Support, Intelrad will not provide maintenance (including remote monitoring, remote diagnostics, and maintenance). IntelPACS is a medical device, and as such, must meet medical device safety and effectiveness requirements imposed by national regulations. The Client is advised that using IntelPACS without access from Intelrad's Technical Support may put the health and safety of patients at risk, as the Client may not be advised of the availability of software patch, bug fix, update or upgrade, nor will be informed of Field Safety Notices, Medical Device Recalls, or Advisory Notices related to IntelPACS. Furthermore, Intelrad will not be in a position to have access to the Client's systems to implement corrections to prevent occurrences of patient safety issues. Any use of the Licensed Software beyond Intelrad's standard support practice is client's own responsibility.