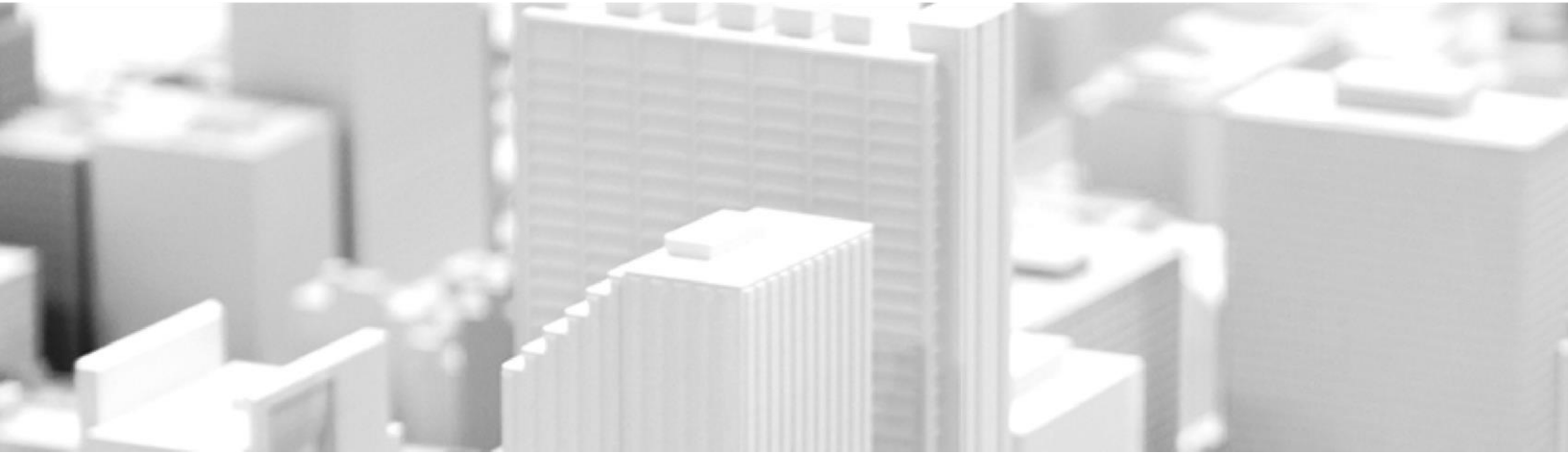# Integrating the Healthcare Enterprise (IHE) IntelePACS Integration Statement

Version 1.1
(Document Revision 8)

June 15, 2022

for IntelePACS Version 4.11.1

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TRADEMARKS

THIRD-PARTY TRADEMARKS

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PERFORMANCE CHARACTERISTICS

The main benefits of IntelePACS are the improved image accessibility and associated time savings. There is also some indication that IntelePACS can help data integrity and help reduce operating costs in radiology. There is no significant indication that it affects or improves diagnosis accuracy and image quality. There have been some reports of adverse events associated with IntelePACS and some recalls linked to possible patient safety issues, but no strong case of adverse effects of using IntelePACS technology. IntelePACS technology is a lowrisk medical device that has been used successfully and undergone continual refinements.

INDICATIONS FOR USE

IntelePACS 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. Postprocessing 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 a display that is cleared, and that meets technical specifications reviewed and accepted, by your regulatory authorities.
IntelePACS on mobile devices (applicable for IntelePACS 5.1.1 or later only):
For Canada, United States, Europe, Australia, New Zealand, and South Africa only: When used with a mobile device, IntelePACS is suitable for diagnostic image review only on tested devices as specified in your Intelerad product's documentation. IntelePACS 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: IntelePACS is not intended for diagnostic image review on mobile devices. Mobile usage for Mammography is for reference and referral only.
CONTRAINDICATIONS—None.

Caution: Federal law restricts this device to sale by or on the order of a physician.

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 IntelePACS 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 IntelePACS 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 IntelePACS

SAFETY ISSUES: IntelePACS 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 IntelePACS, or use of IntelePACS 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 IntelePACS. 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 IntelePACS. Intelerad 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 (Intelerad) 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.

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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UDI   IntelePACS UDI is: **B228INTELEPACS0**

DECLARATION OF CONFORMITY

We hereby certify that IntelePACS, a Class IIa Medical Device, is in compliance with Council Directive 93/42/EEC and marked with

CE 2797

EC	REP

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Title: IntelePACS Integration Statement

Software version: 4.11.1 and later (Multiple Patient Multiple Use)

Date: 2022-06-15

Part number: IPEN4.11.1IS-O Issue 008

Document Revision History

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 IntelePACS 4.1.1.
5	October 25, 2010	Susan Daoud	Merged InteleViewer Integration Profiles into this document (from obsolete InteleViewer Workstation Integration Statement, revision 1) and validated information for IntelePACS 4.2.1.
6	July 8, 2015	Irene Plokar	Updated for IntelePACS 4.11.1.
7	April 11, 2017	Irene Plokar	Updated the cover page and headers with Intelerad's recent corporate logo, and added a Copyright page.
8	June 15, 2022	Krishnali Kondekar	• Added copyright page. • Added the topics "Contacting Intelerad Technical Support" and "Obtaining Printed Documentation".

Contacting Intelerad Technical Support

Your PACS administrator can assist you with any issues you may encounter. If you require additional assistance, you can contact Intelerad 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: 1-866-951-6222 Sans frais Amérique du Nord (français): 1 844-467-7227 Toll-free Australia: 1-800-286-418 Toll-free New Zealand: 0800-467-723 United Kingdom: 0113-360-2615 Other: +1-514-931-7127

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

https://serviceportal.intelerad.com/csm

You should regularly check the Intelerad 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 Intelerad Technical Support to report a problem, please have at hand the following information, as applicable:

- client code and location of your 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

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.

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	
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