

Almost Always Up

3.24.2.0 | User Guide



intelerad

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INTENDED USE

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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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	https://serviceportal.intelerad.com/csm
By telephone	Toll-free: 888-315-0790

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.

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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ALMOST ALWAYS UP

IntelShare commits to 99.9% uptime as part of its SLA. Separately, IntelShare has a planned release every fourth Wednesday at 9:00 pm MST in which the system is offline for up to twenty minutes. In addition, IntelShare has scheduled maintenance the third Sunday of each month from 12:01 am MST to 4:00 am MST. In order to support always up use cases, IntelShare has developed an almost always up offering.

How it works

- IntelShare configures a mirror instance of the customer's IntelShare account in AWS.
- When there is a planned outage (release or maintenance), IntelShare flips customer over to the mirror instance. If a new study is harvested during the time that customer is on the mirror instance, it will be available for viewing and distribution via IntelShare Gateway. No other studies will show on the mirror instance.
- When there is an unplanned outage, IntelShare will immediately flip customers who leverage this service over to its mirror instance. If a new study is harvested during the time that customer is on the mirror instance, it will be available for viewing and distribution via IntelShare Gateway. No other studies will show on the mirror instance.
- Once the outage is over, IntelShare will revert customer from its mirror to regular IntelShare, and IntelShare will move any studies that came in during the mirror period to customer's regular IntelShare.

Other details

- IntelShare has signed a BAA with AWS.
- AWS's HIPAA details are available here:
<https://aws.amazon.com/compliance/hipaa-compliance/>