AMBRA™

Ambra

Almost Always Up Guide

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TRADEMARKS

THIRD-PARTY TRADEMARKS

INDICATIONS FOR USE

Ambra 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.

Ambra ProViewer, a component of Ambra 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.

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 Ambra 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 Ambra 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 AmbraPACS.

SAFETY ISSUES: AmbraPACS 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 AmbraPACS, or use of AmbraPACS 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 AmbraPACS. 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 AmbraPACS. 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.

DICOM Grid, Inc. dba Ambra Health
228 Park Avenue S.
PMB 16306
New York, New York 10003-1502.

DECLARATION OF CONFORMITY

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

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Ambra commits to 99.9% uptime as part of its SLA. Separately, Ambra 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, Ambra 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, Ambra has developed an almost always up offering.

How it works

- Ambra configures a mirror instance of the customer's Ambra account in AWS.
- When there is a planned outage (release or maintenance), Ambra 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 Ambra Gateway. No other studies will show on the mirror instance.
- When there is an unplanned outage, Ambra 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 Ambra Gateway. No other studies will show on the mirror instance.
- Once the outage is over, Ambra will revert customer from its mirror to regular Ambra, and Ambra will move any studies that came in during the mirror period to customer's regular Ambra.

Other details

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

Browser Requirements

Microsoft Internet Explorer 9 or later, Microsoft Edge, Apple Safari, Google Chrome, Firefox.