

Ambra PIN Authorization Guide

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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. 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.



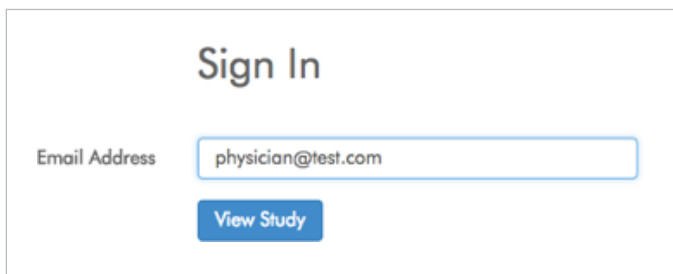
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DECLARATION OF CONFORMITY

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

Title: PIN Authorization Guide
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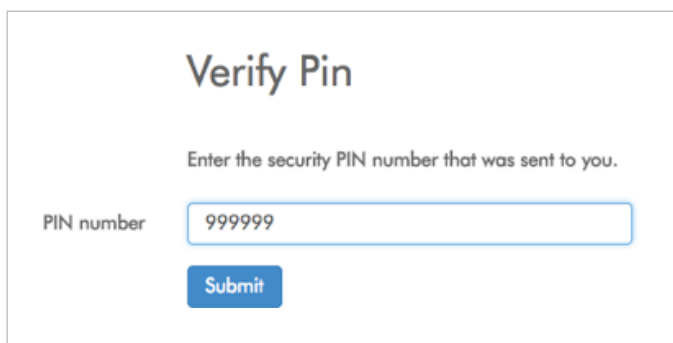
Click the link in your EMR to access your study images.
A 'Sign In' window will open.
Enter your email address and click 'View Study'.



The image shows a 'Sign In' form with the following elements:

- Title: Sign In
- Label: Email Address
- Input field: physician@test.com
- Button: View Study

A PIN number will be sent to your email address.
Enter the PIN number and click 'Submit'.
Your study images will appear.



The image shows a 'Verify Pin' form with the following elements:

- Title: Verify Pin
- Instruction: Enter the security PIN number that was sent to you.
- Label: PIN number
- Input field: 999999
- Button: Submit

Note

Your email address must be registered with the organization. If it is not, you will be alerted to contact your administrator.

PINs expire after 10 minutes.

A PIN entered incorrectly three times is invalidated.

Browser Requirements

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