Intended Use

About NilRead

NilRead is a web-based, no installation, diagnostic viewer. NilRead provides physicians with secure, interactive processing, viewing, and sharing of 2D, MPR, 3D, Fusion and other imaging exams. The product is designed for use by qualified medical practitioners to review and interpret imaging studies and reports. NilRead provides interactive image visualization tools and rule-based hanging protocols for exam viewing according to physician preference and multi-monitor display configuration. NilRead can be easily integrated with any DICOM or HL7 network, connected with a VNA, and can be invoked from a RIS or workflow/reporting solution. NilRead can also query-retrieve remote DICOM nodes, XDS repositories and other medical archives.

Physicians can easily customize how a patient study is presented using a number of configurable layouts, then further arrange images by dragging and dropping series into viewports. This allows each physician to review images based on their personal preferences.

Access NilRead using your mobile device or desktop computer. NilRead runs on all major browsers and supports multi-touch gestures on mobile devices (for details, see **Device specifics**). For hardware requirements and supported browsers, see **Hardware requirements**. Please also review the **Warnings and precautions**.

NilRead uses industry standard security mechanisms (HTTPS, SSL) and does not transfer any patient data to the client device running the viewer. This allows radiology departments and other health care organizations to provide secure access to referring physicians and radiologists on the go without having to setup and maintain an IT infrastructure on devices outside the organization. NilRead supports many modalities (see **Supported modalities**).

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

 View additional regulatory information including warnings and precautions.

Version number

The NilRead version number can be viewed by hovering over the NilRead logo.

Warnings and precautions

Before attempting to use NilRead, you must read this manual thoroughly, paying particular attention to all Warnings and Cautions incorporated in it.

WARNING		Directions, which if not followed, could cause fatal or serious injury to an operator, patient or any other person, or could lead to a misdiagnosis or mistreatment.
CAUTION		Directions, which if not followed, could cause damage to the equipment described in this Instructions for Use and/or any other equipment or goods, and/or cause environmental pollution.

General usage

 NilRead is intended for use by physicians trained in reviewing and interpreting medical images.

 Users are to ensure that the appropriate study is loaded based on the identification on the timeline and in the viewport.

 It is recommended that NilRead be installed on the minimum hardware requirements (see **Hardware requirements**). Users are to ensure guidelines and warnings (including maintenance provisions) provided by the hardware manufacturer are adhered to, and that hardware is used under safe operating conditions. Users shall not install any additional third party software on the NilRead server to prevent compromising the software performance.

 A user's access to the NilRead software is dependent upon the connectivity of their computer or mobile device to the NilRead server. A NilRead site should maintain the network integrity since the network is a critical part of the distributed image viewing system.

 NilRead uses compressed images during interactive manipulation. The diagnostic quality image is presented at the end of the manipulation, as part of a progressive refinement display. Lossless images are marked with an HD label.

 NilRead has been qualified on a variety of operating system and browsers (see **Device specifics**). However, operating system and browser version updates may affect the NilRead software. We recommend verifying the NilRead functionality after a modification to the operating system or browser.

 NilRead could be used as a temporary data cache and local changes might be out of synch with the master database. If NilRead is configured as a temporary cache, it is recommended that either the data correction functions are disabled or that an appropriate data lifecycle policy is setup to propagate changes to the master database.

 Patient data may be incorrectly removed by improperly configuring a data lifecycle policy. The system administrator shall make sure that when NilRead is used as primary data storage, data lifecycle is setup to include hierarchical storage endpoints, including a long term archive. This will prevent purging policies from automatically deleting studies when the local cache is full.

 The system administrator shall ensure that when NilRead is used as primary data storage, that the site implements an appropriate backup and recovery procedure of the NilRead database.

 The system administrator shall ensure that Data QC privileges are assigned to users familiar with the hospital's workflow.

 The stitched image is created to allow accurate measuring of distances and angles by qualified medical practitioners. Any incidental clinic findings that are seen on the source of stitched images should be verified or further evaluated by additional diagnostic methods.

 A misconfigured Auto Reconciliation can have a direct impact on patient safety, including incorrect diagnosis due to the patient information/image mismatch and/or delay in diagnosis due to images not being available in the patient record. The system administrators shall ensure that sufficient parameters (such as First name, last name, DOB, Gender) are configured.

 The data upload may result in illegal or inappropriate images being ingested into the system that can potentially introduce cybersecurity risks. The hospitals are responsible to implement the cybersecurity best practices.

 The uploading/Patient portal can only be activated under the consensus of hospital and/or the healthcare provider, and distributed under this consensus.

Use on mobile devices

 Users are to ensure guidelines and warnings provided by the mobile device manufacturers are adhered to regarding care and operation of the mobile devices.

Measurements

 On MPR and 3D views, interpolation may be done depending on the spacing between the original slices (as the spacing increases, the amount of interpolated data increases). For any image, when displaying images on the monitor at a scale other than 100%, data is interpolated. Measurement results are affected when interpolation is done. Interpolation always implies a certain inaccuracy.

 Do not perform pixel value measurement on compressed images. Compressed images are marked as “Compressed” on the screen.

 NilRead allows 3D measurements to be performed. 3D measurements can change significantly with small changes in a line’s location or with changes in opacity.

 The accuracy of any measurement also depends on the user’s ability to select appropriate measurement points on the display device.

 The accuracy of calibrated measurements should be visually verified with the size of an anatomical object.

Intended use within the USA

The NilRead software application provides desktop and portable access to multi-modality softcopy medical images, reports and other patient related information for conducting diagnostic review, planning, and reporting through the interactive display and manipulation of medical data, including mammography and breast tomosynthesis. NilRead also allows users to collaborate by sharing application sessions.

Lossy compressed mammographic images are not intended for diagnostic review. Mammographic images should only be viewed with a monitor approved by FDA for viewing mammographic images. For primary diagnosis, post process DICOM “for presentation” images must be used.

On mobile platforms, this device is not intended for diagnostic use.

Supported modalities

NilRead provides imaging data to physicians in many different specialties. Modalities such as MR, CT, Xray, fluoroscopy, ultrasound, mammography, and many more are supported by NilRead.

For a full list of supported modalities, see the NilRead **DICOM Conformance Statement**.

Hardware requirements

The computer or device used for NilRead must meet the following hardware requirements.

Desktop computers

The minimum hardware requirements for desktop computers running NilRead are:

- CPU: 1GHz Intel processor
- Available Memory: 500MB

The minimum network connection speed for a desktop computer is 1Mbps download, 256Kbps upload.

NilRead functions on any browser that supports JavaScript but has only been formally verified on the following browsers:

- Microsoft® Internet Explorer® (8.0 and higher)
- Mozilla® Firefox® (3.0 and higher)
- Google Chrome™ (3.0 and higher)
- Apple® Safari® (4.0 and higher)

Mobile devices

NilRead is verified to work on the following mobile devices:

- Apple® iPhone® (iOS 3.0 and higher)
- Apple® iPad®
- Android™ devices (2.3 and higher)
- Microsoft® Surface™
- Windows® Phone (8.0 and higher)

NilRead requires mobile devices to have a minimum network connection of 3G or WiFi.

Device specifics

NilRead is available for desktop computers with a diagnostic monitor and for mobile devices. For details, see **Hardware requirements**.

On mobile devices, images are displayed for informational purposes only — NilRead is not for diagnostic use on mobile devices.

It is the user's responsibility to ensure NilRead is used on appropriate hardware and that image quality, including display monitors, image resolution and environment lighting, are suitable for the clinical application. It is recommended that users comply with the applicable regulatory guidelines for the anatomy and pathology being studied. For reference:

- **American College of Radiology Practice Guidelines**
- **Canadian Association of Radiologists Practice Guidelines**

Using NilRead is slightly different on desktop computers and mobile devices.

Desktop computer with a diagnostic monitor

All NilRead features are available.

Mobile devices

Multi-touch gestures are supported (tap, double-tap, drag, swipe, pinch, flingable toolbar). Collaboration is not supported on smartphones.

Touch gestures

You can use touch gestures in the image viewer. The default actions for each gesture are shown below. For details on customizing touch gestures, see **Change mouse, keyboard and touch preferences**.

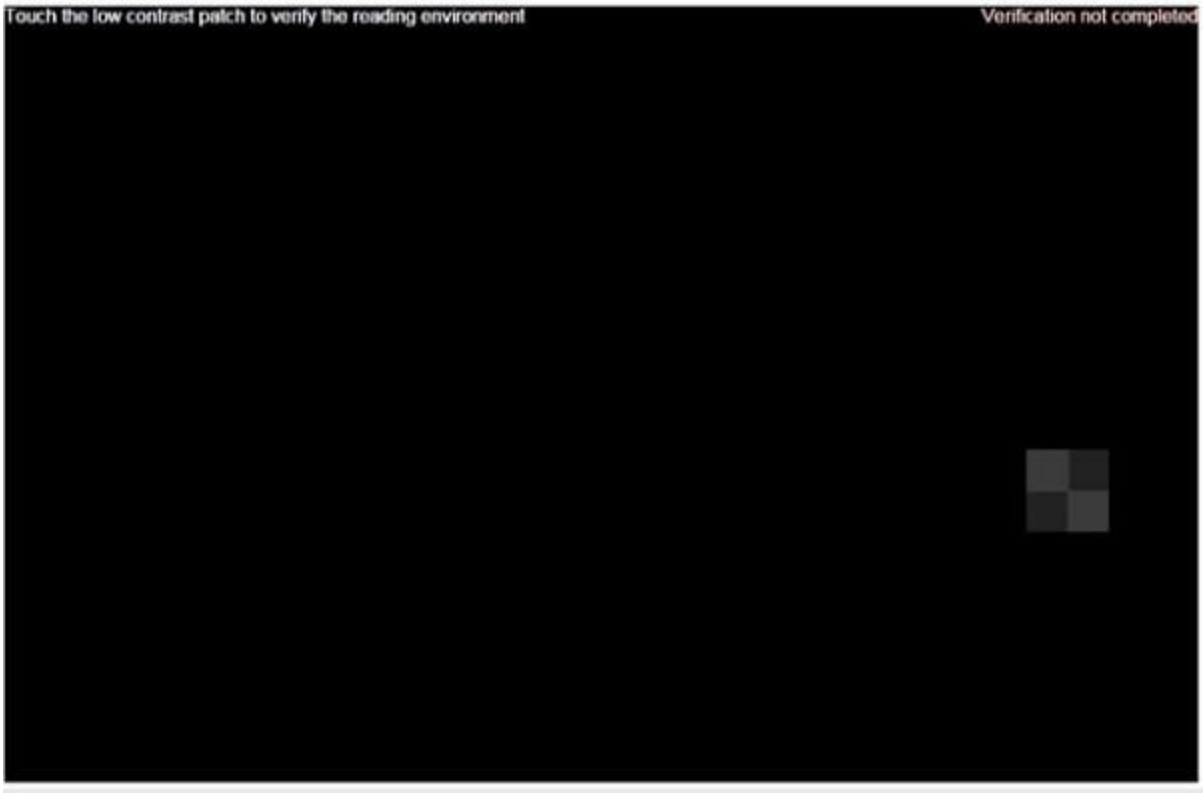
- **Pan and Zoom** Pinch-to-zoom.
- **Scroll** Touch and drag.
- **Window Level** Three finger drag.
- **Reset** Shake the device.
- **Maximize a viewport** Double-tap.

Reading environment verification

NilRead provides a reading environment verification tool to assist the user in adjusting device settings (such as brightness) on mobile platforms. It is recommended that users keep mobile screens clear of thumbprints and dirt and that they disable the auto brightness adjustment.

Follow these steps to perform a reading environment verification.

1. Select **Settings**. Under **Preferences**, select **Reading environment verification**.
2. A low contrast pattern is shown in the viewport. Note that in the following example, the contrast has been highlighted for demonstration purposes.



3. Touch the low contrast pattern to indicate its location.

   If you do not select the correct location, the lighting conditions may be too bright or the device's screen may not be at maximum brightness. It is recommended that the auto-brightness adjustment is disabled and the presence of thumbprints in critical parts of the screen is checked frequently. A bright and clean display is the best starting point for viewing images on a mobile device. Also note that LCD displays have angular dependence characteristics. During the assessment, it is recommended that the images are viewed from the front within 10-20 degrees of the viewing angle.

Studies

Open a study