User Manual

Versions 5.0.0 – 5.2.0

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IMPORTANT

READ THIS MANUAL BEFORE USING THE SYSTEM

For continued safe use of this equipment, read, understand, and carefully follow the instructions contained in this manual before using the product, and refer to it as necessary.

The user of this product is solely responsible for any malfunction that results from improper use, unauthorized alteration or faulty service by any party not authorized by Riverain Technologies™ Inc. ("Riverain").

KEEP YOUR DOCUMENTATION CURRENT

Retain this manual for future reference.

Riverain Technologies reserves the right to periodically change or enhance its products and related documentation. If you update your product, make sure to update your documentation accordingly.

OBTAIN AUTHORIZATION PRIOR TO SHARING ANY CONTENT OF THIS MANUAL

Riverain's ClearRead products are licensed technology. The content of this manual is the property of Riverain and may not be reproduced, shared, or used without prior written permission from Riverain.

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

CONTENT

[1] About This Manual

[1.1] Audience and Scope

Congratulations on becoming a ClearRead™ user!

Traditional chest x-ray is by far the most common type of radiological exam. The ubiquitous use of the chest exam is due to the enormous amount of information it provides about the health of a patient. However, interpreting a chest radiograph is a very challenging task owing to the strong degree of superimposed anatomical structures.

Given the clinical importance of chest radiographs, and to address the related challenges, ClearRead Xray is designed to improve the visibility of lung parenchyma, external lines and tubes, and provide assistance in the identification and tracking of lung nodules.

This manual contains the information necessary for safe and effective use and operation of ClearRead Xray. It provides physicians with indications for when and how to use the system, specification of the expected system input, and description of system output.

[1.2] Contact Information

For any questions, clarifications or concerns not addressed in this manual, or to seek a replacement copy of this manual visit www.riveraintech.com or contact us directly at:

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For technical support call the Riverain Technologies Customer Success Hotline at +1.800.914.1446 or +1.937.425.6950. You may also reach us by fax at +1.937.425.6493 or by email at support@riveraintech.com.

If this product was obtained via an OEM provider as part of another product (such as a PACS or an Artificial Intelligence (AI) platform), first contact the OEM provider's Customer Support.

[1.3] Typography

The following symbols and typeface styles are used throughout this manual:

WARNING: Indicates a precaution to avoid adverse effect, including damage to equipment, negative impact to quality of treatment, personal injury, or death.

NOTE: Indicates important information or special attention is required to avoid errors or mistakes.

Bold text – Used for titles and to highlight specific terms when used for the first time.

`Fixed Font` – Used for folder names, file names, code examples, or system commands.

□ Bulleted narrow text – Used for stepwise execution directions.

[1.4] Glossary

AP	Anterior-Posterior (chest radiograph)
CAD	Computer-Aided Detection
CT	Computed Tomography
DICOM	Digital Imaging and Communications in Medicine
Finding	A region of interest detected by ClearRead Xray
OEM	Original Equipment Manufacturer
PA	Posterior-Anterior (chest radiograph)
PACS	Picture Archiving and Communications System
PTX	Pneumothorax
ROI	Region of Interest
SC	Secondary Capture
SR	Structured Report
802.3	IEEE Standard for Wired Ethernet

[1.5] Additional Reading

Additional content is available outside the scope of this manual which may be of interest:

[R1] ClearRead Xray Administrator Manual[1], available from Riverain, contains the information necessary to configure, administer, and monitor ClearRead Xray devices.

[R2] ClearRead Xray DICOM Conformance Statements, available from Riverain, contain details of the DICOM objects generated by ClearRead Xray products.

[R3] ClearRead Xray DICOM Requirements, available from Riverain, contain details of the default DICOM constraints and filtering rules applied by ClearRead Xray products.

[R4] Products and support information, including scientific evidence, is available at www.riveraintech.com.

[1] When using ClearRead Xray versions prior to 5.0, refer instead to ClearRead Xray Installation and Service Manual.

[2] SAFE USE

For continued safe use of this equipment, read, understand, and carefully follow the instructions contained in this manual before using the product, and refer to it as necessary.

In particular, heed the following (which apply to all ClearRead Xray features, unless otherwise noted):

WARNING: Only the original chest images are to be used for diagnostic interpretation by physicians. ClearRead Xray Pneumothorax output is designed to only aid triage, before primary image interpretation. Other ClearRead Xray output is designed only as an aid to the interpretation process after the initial reading of the primary image.

WARNING: Degraded quality of input images from factors such as under- or over-exposure and/or manmade objects (e.g., jewelry) in the field of view during image acquisition, may diminish the effectiveness of the device.

WARNING: Incorrect DICOM headers or other factors can cause ClearRead Xray to reject an input image, in which case no result will be returned. Do not delay your reading of the primary image to view the ClearRead Xray output.

WARNING: Users should never be dissuaded from working up a finding even if it is not seen on the device output. The device may not identify all areas that represent solitary pulmonary nodules or pneumothoraces.

WARNING: Various factors can cause the ClearRead Xray Compare to fail to find an acceptable prior image. In such a scenario, the Compare component of the system is not invoked, and no result is returned. Do not delay your reading of the primary image to view the ClearRead Xray Compare output.

Note: The user and/or patient should report any serious incident related to the use of this device should report this to the manufacturer as well as the competent authority where the incident occurred.

Administrators of ClearRead Xray should also heed the following (refer to the *ClearRead Xray Administrator Manual* [R1]):

WARNING: ClearRead Xray is a medical device. It should be used only as described in the accompanying manuals. Other activities, such as web browsing, email, or installation of third-party software without specific authorization from Riverain Technologies, are prohibited. Software authorized by Riverain Technologies should be scanned with anti-virus software before use.

WARNING: On servers provided by Riverain, ClearRead Xray should be installed, serviced, and configured only by trained personnel.

WARNING: Do not make changes to the system or to the system configuration, other than as explicitly described in this manual, as this may lead to unpredictable system behavior.

WARNING: It is unlawful to use this software other than for its indicated use, or without a legitimate license.

WARNING: If your site uses a PACS that can receive and display overlays, and your ClearRead Xray Detect has been configured to send overlays, you must establish controls to prevent or record user editing of the CAD results.

WARNING: Use caution when creating patch rules. Incorrect use may create nonconforming DICOM messages.

[3] SYSTEM OVERVIEW

[3.1] System Description

ClearRead Xray includes several components designed to assist in the review of chest radiographs. The system receives chest PA/PA chest X-ray image as input, in DICOM® format, and generates output in DICOM (or other) format.

ClearRead Xray supports the following features:

ClearRead Xray Bone Suppress provides improved visibility to the lung parenchyma by suppressing normal bone structures (ribs and clavicles).

ClearRead Xray Enhance[2] provides improved visibility of tubes, PICC lines and catheters.

ClearRead Xray Confirm combines the benefits of **Enhance** and **Bone Suppress** in a single output image.

ClearRead Xray Detect identifies and marks regions of interest (ROIs) that include suspected solitary pulmonary nodules.

ClearRead Xray Compare highlights differences between a current and a prior chest radiograph, improving the visibility of suspected lung nodules.

ClearRead Xray Pneumothorax (PTX) identifies images with features suggestive of a pneumothorax, for prioritization/triage.

While this manual covers all features, it is possible that only some are licensed and enabled at your site. If a feature is missing, contact your site IT staff or Riverain's Customer Success.

[3.2] Indication for use

ClearRead Xray Bone Suppress is indicated to generate an enhanced, secondary digital radiographic image of the chest. The enhanced AP or PA image of the chest provides improved visibility of the lung parenchyma through bone suppression and tissue equalization, and may facilitate discerning the presence or absence of nodules. The Bone Suppress image provides adjunctive information and is not a substitute for the original PA/AP image. This device is intended to be used by trained professionals, such as physicians, radiologists, and technicians, on patients at risk of having lung nodules and is not intended to be used on pediatric patients.

ClearRead Xray Enhance/Confirm is intended to generate an enhanced, secondary digital radiographic image of the chest to facilitate detection of line/tubes. The enhanced AP or PA image of the chest provides improved visibility of lines and tubes. The Enhance/Confirm image provides adjunctive information and is not a substitute for the original PA/AP image. This device is intended to be used by trained professionals, such as physicians, radiologists,

[2] Also formerly known as ClearRead Xray Enhanced.

and technicians, on patients with lines and tubes and is not intended to be used on pediatric patients.

ClearRead Xray Detect is a computer-aided detection (CAD) system intended to identify and mark regions of interest (ROIs) on digital or digitized frontal chest radiographs. It identifies features associated with solitary pulmonary nodules from 9 to 30 mm in size, which could represent early-stage lung cancer. The device is intended for use as an aid only after the physician has performed an initial interpretation of the radiograph.

ClearRead Xray Compare is intended to generate a secondary residual image based on a current and prior chest x-ray image of the same patient, resulting in improved visibility of lung nodules. The Compare image provides adjunctive information and is not a substitute for the original PA/AP image. This device is intended to be used by trained professionals, such as physicians, radiologists, and technicians on patients with risk of having lung nodules and is not intended to be used on pediatric patients.

ClearRead Xray Pneumothorax is a notification-only triage workflow tool for use by trained professionals to help prioritize chest X-rays. The device operates in parallel to and independent of standard of care image interpretation workflow. Specifically, the device uses an artificial intelligence algorithm to analyze images for features suggestive of a pneumothorax 5mm or larger; it makes case-level output available to a PACS/workstation for worklist prioritization or triage. Identification of suspected cases of a pneumothorax is not for diagnostic use beyond notification. ClearRead Xray Pneumothorax is limited to analysis of imaging data as a guide to possible urgency of adult chest X-ray image review and should not be used in lieu of full patient evaluation or relied upon to make or confirm diagnoses. The device does not replace review and diagnosis of the X-rays by trained professionals. The device is not intended to be used with plain film X-ray.

[3.3] Contraindications

Not applicable.

[3.4] Adverse Effects

There are no known direct risks to the health or safety of the patient from the physical use of ClearRead Xray. This is a post-processing application and does not require added radiation dose to the patient.

Possible indirect risks are:

- A physician may be dissuaded from working up an earlier finding if the device does not mark that site, thus missing a possible nodule.
- A physician may be misled into working up a benign finding that would not otherwise have been acted upon.

[3.5] Limitations

Valid Input	ClearRead Xray has been designed to accept PA/AP chest X-ray images as input, which meets certain specifications (see [4.1] Input Data Requirements). Invalid input may lead to no output being generated by ClearRead Xray or to degraded device performance.
Quality Input	ClearRead Xray **Detect** has been optimized to process images to assist the detection of nodules (see [4.2] Input Data Considerations). Results may not be optimal for scans that do not meet these considerations.
Field of View	Input image is expected to contain both lungs. ClearRead Xray automatically segments the lung region and considers it for bone suppression, detection (including PTX), or comparison. ClearRead Xray **Detect** may or may not search the entire extent of lung tissue obscured by the diaphragm muscle, depending on factors such as patient positioning and inspiration. ClearRead Xray **Detect** does search the retrocardiac, hilar, and mediastinum regions for nodules.
False Positives and False Negatives	ClearRead Xray **Detect** and **Pneumothorax** are designed to maximize true-positive detections while minimizing the number of false positives. The following are the predominant sources of false positives: • Imaging artifacts, such as patient motion. • Benign pathologies, such as scars, or calcified tissue. • Other pathologies, such as aspergillosis or pneumonia. • Normal anatomy, such as end-on vasculature, rib overlap and organ/skin superposition. Using ClearRead Xray **Bone Suppress**, may increase the patient recall rate due to false positives, especially in the hilar region, which could lead to unnecessary CT and/or biopsy workups. ClearRead Xray **Bone suppress** and **Confirm** output may sometimes contain residual bones. This primarily happens when broken or abnormally thick ribs are present or due to suboptimal patient orientation. ClearRead Xray **Bone Suppress** and **Confirm** output may sometimes suppress tubes or lines, especially when aligning with bone structure. ClearRead Xray **Compare** normalizes and registers images to correctly calculate changes. Density differences may sometimes represent anatomic mis-registration.
Patient Age	ClearRead Xray has been validated for adult patients and should only be used on patients 18 years old or older.

[4] SYSTEM INPUT

[4.1] Input Data Requirements

ClearRead Xray has been designed to process chest radiographs, in DICOM format. Each image in an input study is considered **valid input** if it meets the following specifications:

- PA/AP chest view, showing both lungs.
- The patient is not laterally tilted by more than 15 degrees.
- Vertically oriented images should appear with patient shoulders at the top of the image.
- Horizontally oriented images should be oriented as a vertically oriented image that has been rotated 90 degrees clockwise or counterclockwise.
- Image DICOM headers properly populated according to the DICOM standard that accurately reflect the acquisition and anatomical properties of the image.

ClearRead Xray uses a rules engine that can filter input based on DICOM header fields (e.g., non-chest, pediatric). DICOM constraints and default filters are specified in *ClearRead Xray DICOM Requirements* [R3]. Refer to the *ClearRead Xray Administrator Manual* [R1] for details on how to configure input filters.

Images that do meet input constraints are marked as errors and are not processed.

WARNING: Invalid input can cause ClearRead Xray to reject an input study for processing, in which case no result will be returned for viewing. Do not delay your reading of the primary image to view the ClearRead Xray output.

[4.2] Input Data Considerations

ClearRead Xray operates over a wide range of chest images. Like a radiologist, ClearRead Xray prefers scans configured to assist the reader, such as the following:

- Inspiration over expiration
- Minimum over- or under-exposure
- Minimum artifacts (e.g., due to patient motion or device deficiency)
- Minimum external radio-opaque objects (e.g., jewelry or clothing)

Images that do not follow these recommendations are still processed, however, the results may not be as optimal as for images that do.

[5] SYSTEM OUTPUT

[5.1] Output Objects

ClearRead Xray can generate a wide array of **Output Objects** (also known as **Derived Objects**). These are made available to clinicians to be used per device indications.

The actual output objects generated are configured per device, per local preferences and available software license. Other configurations allow filtering invalid input, setting criteria for priors, selecting presentation preferences, and more. See *ClearRead Xray Administrator Manual* [R1] for details on how to configure output objects.

> **NOTE**: If ClearRead Xray is unable to process an image, you will see the text "Image processing unsuccessful" displayed on a blank image.

> **NOTE**: By default, ClearRead Xray output objects are added as images to the original series. Output images could also be generated as separate DICOM series with a single secondary capture image each; Contact Riverain Customer Success for assistance.

Each output object generated does not alter any DICOM input (primary or prior). The following sections describe each output object in detail.

[5.1.1] Bone Suppress

The **Bone Suppress** output object is a DICOM secondary capture image derived from the original image. This image has reduced noise, equalized tissue, and suppressed bones (ribs and clavicles) – providing improved visibility of the lung parenchyma, and significantly reducing the need for window/level manipulation, thereby reducing reading time.

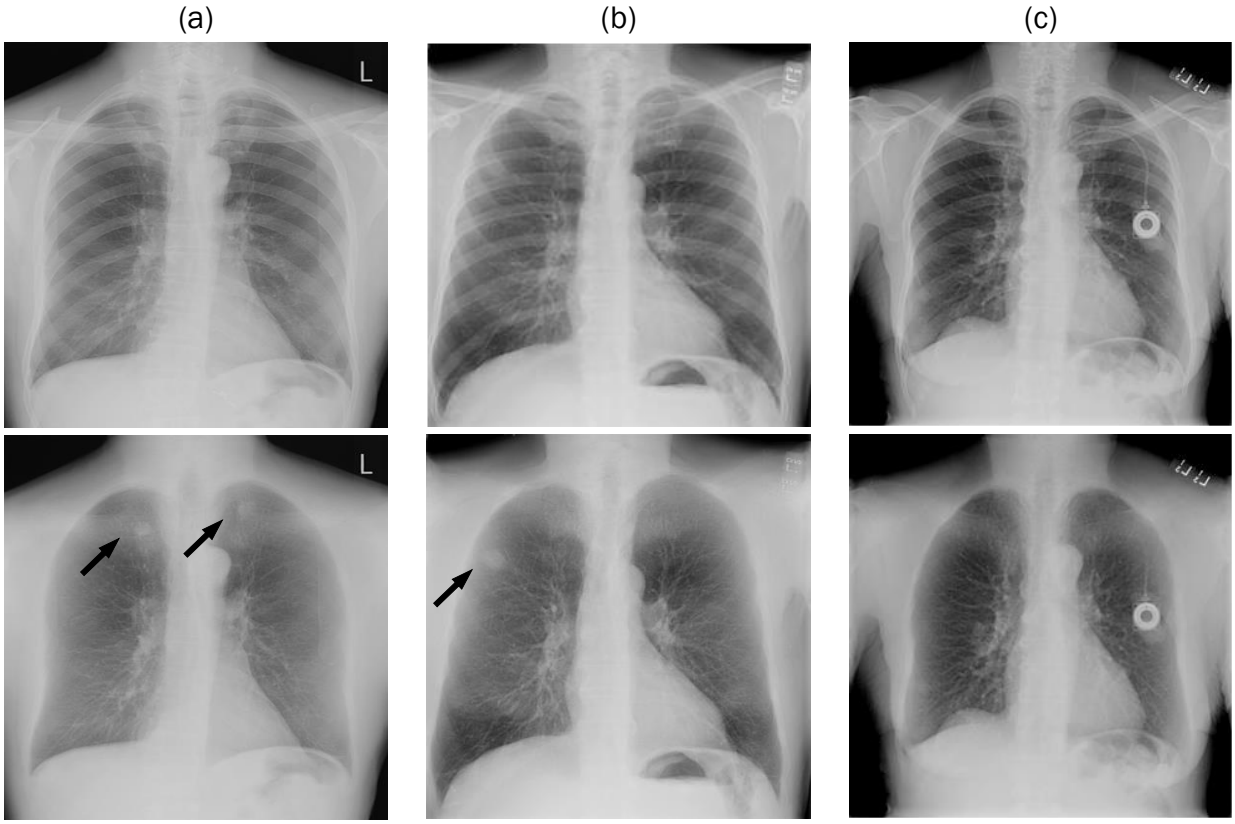
A variant of this output object is the **Bone** image. This is a secondary capture DICOM image showing *only* the bone structure, as extracted from the original image.

Table 1: Bone Suppress output objects

Code	Output Series Name[3]	Format	Prior Required	License Required
C0001	CR Bone Suppress	DICOM SC image	No	Bone Suppress
C0007	CR Bone	DICOM SC image	No	Bone Suppress

[3] When generated as separate series. Output series names can be configured. Contact Riverain Customer Success for assistance.

Figure 1: Sample Bone Suppress output objects shown below the corresponding input image, where two apical nodules are present (a), a peripheral nodule is present in the right lung (b), and a man-made object is in view (c).



[5.1.2] Enhance and Confirm

The **Enhance Image** output object is a DICOM secondary capture image derived from the original image. This image provides improved visibility of internal and external quasi-linear structures, including lines and tubes. It also significantly reduces the need for window/level manipulation, thereby reducing reading time.

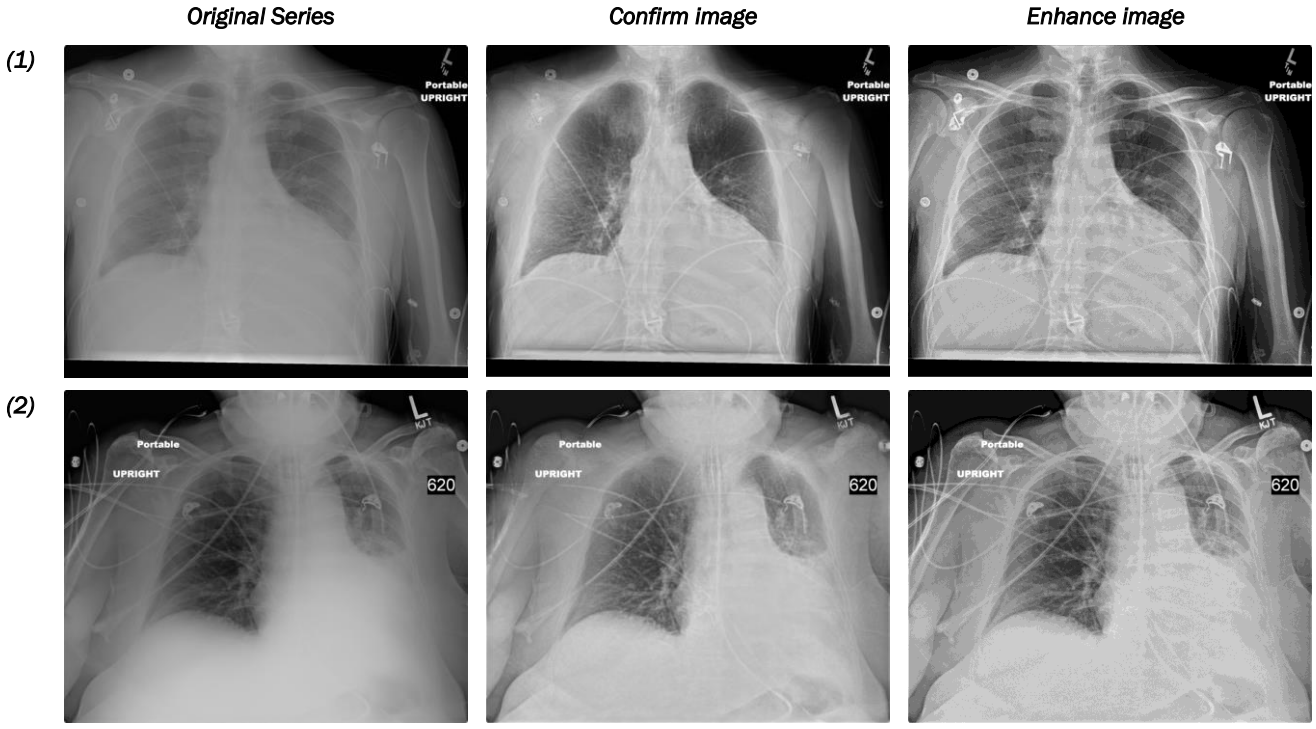
The **Confirm Image** output object is similar to the Enhance Image, however, the output image also suppresses normal bone structures (ribs and clavicles) improving overall visibility of the lung parenchyma.

Figure 2 shows a comparison of **Confirm** and **Enhance** images.

Table 2: Confirm/Enhance output objects

Code	Output Series Name	Format	Prior Required	License Required
C0010	CR Confirm	DICOM SC image	No	Confirm
C0011	CR Enhance	DICOM SC image	No	Confirm

Figure 2: Comparison of Confirm and Enhance output objects. Note improved visibility of lines in both output objects (case 1) and tube's conspicuity in the patient's mediastinum (case 2), reducing the need for window/level manipulation. Ribs and clavicles are only suppressed in the Confirm images.



[5.1.3] Detect

The **Bone Suppress with Detect** output object is similar to the Bone Suppress output object (see [5.1.1]), however, where suspected actionable nodules are identified, the output image also contains a circle indicating the finding and a label with the total number of findings. Larger circle means larger finding. In the **Detect on Original Image** output object, suspected nodules are shown on the original image (with bone structures).

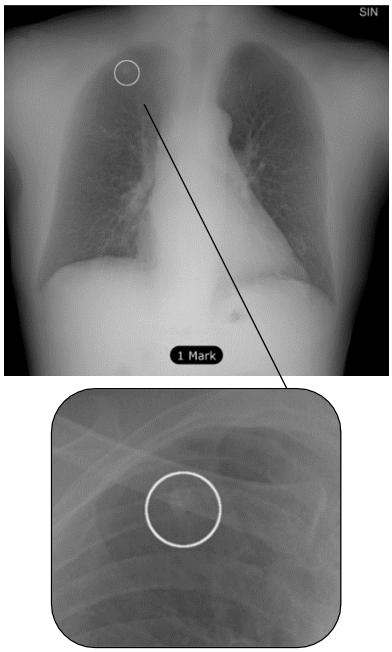
Both output objects are generated as DICOM Secondary Capture (SC) images. Findings may be burnt-in onto the image or added as an overlay to it (see Table 3).

Table 3: Detect output objects

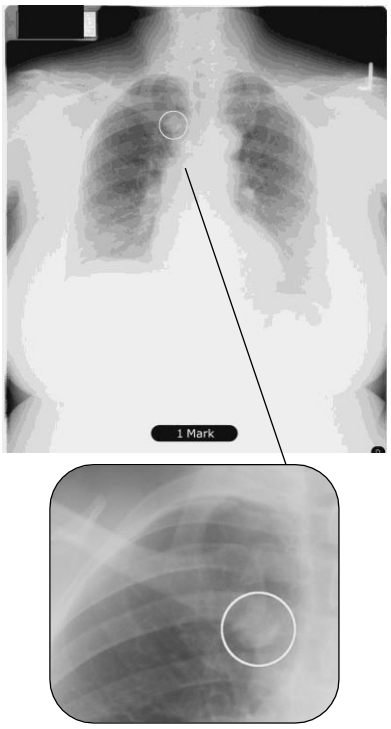
Code	Output Series Name	Format	Prior Required	License Required
C0002	CR Bone Suppress Detect Burn-in	DICOM SC image	No	Detect
C0003	CR Bone Suppress Detect Overlay	DICOM SC with overlay	No	Detect
C0008	CR Detect	DICOM SC image	No	Detect
C0009	CR Detect Overlay	DICOM SC with overlay	No	Detect

Figure 3: Examples of Detect output

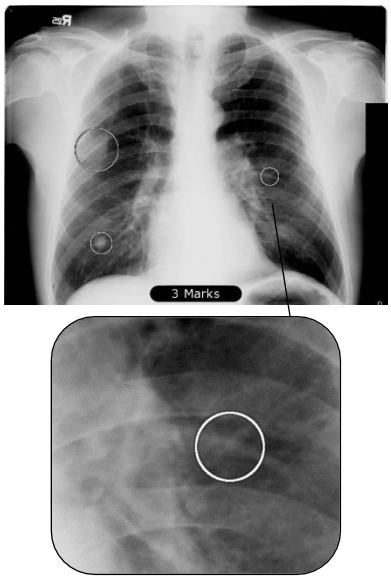
A right upper lung nodule on bone-suppressed image and on the original image (magnified)



A nodule in the right apex near the sternal extremity of the clavicle, shown on original image



A lower right lung nodule shown with 2 false positives, caused by the scapula bone (right lung) and by the crossing of two vessels (left lung, magnified).



[5.1.4] Compare

The **Compare Image** output object is a DICOM secondary capture image derived from two original images. This secondary image shows differences between the original images as grayscale values ranging from dark (higher density in new image) to light (lower density in new image). Greater changes are darker/brighter (respectively).

> **NOTE**: The order of subtraction is configurable. To represent increase in density in lighter gray/white refer to the ClearRead Xray Administrator Manual [R1].

ClearRead Xray Compare automatically normalizes and registers images to correctly calculate changes. The **Registered Prior Image** output object is a DICOM secondary capture image that is derived from the prior image. This image is the deformed version of the prior image, calculated by ClearRead Xray to match (register with) the current image.

Figure 4 shows examples of Compare images. Figure 5 shows the registered images generated from the prior image of Case (2).

Table 4: Compare output objects

Code	Output Series Name	Format	Prior Required	License Required
C0013	CR Confirm	DICOM SC image	Yes	Compare
C0014	CR Registered Prior Bone Suppress	DICOM SC image	Yes	Compare
C0015	CR Registered Prior	DICOM SC image	Yes	Compare

Figure 4: Sample Compare output objects. Case (1) has no changes between the current exam and the prior exam (1 year apart); note the hila vanish in the Compare image when there is no change; the bright crescent seen in the lower right lung is due to a slight misalignment in the breast shadow. Case (2) has dark areas indicating new densities (9 months apart): a new nodule in the lower right lung and a new mass near the left hilar region.

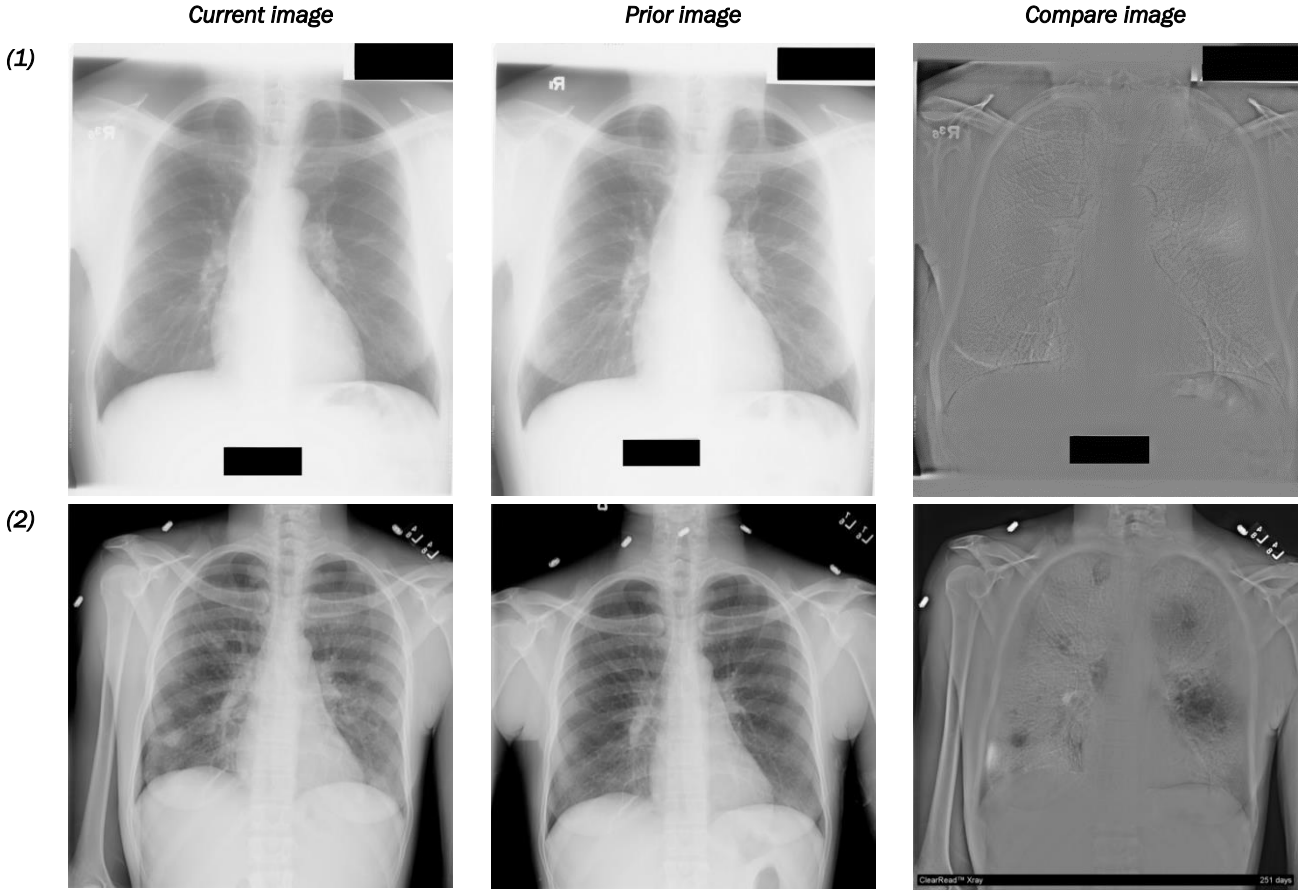


Figure 5: Optional Compare output objects: Registered prior image (middle) and with bone suppress (right) shown next to the original prior image (left). Registered prior images are calculated by ClearRead Xray to match the current image.

[5.1.5] Detect/Pneumothorax Summary Report[4]

The **Summary Report** captures information about findings (detected ROIs). The Detect Summary Report Summary Report output objects may be generated as DICOM secondary capture, or as a DICOM structured report (see Table 5).

Table 5: Summary Report output objects

Code	Output Series Name	Format	Prior Required	License Required
C1255	(Varies)	DICOM secondary capture	No	Pneumothorax
C0021	CR Structured Report	DICOM structured report	No	Detect

ClearRead Xray **Pneumothorax Summary Report** is generated as a DICOM Secondary Capture and indicates whether a suspected Pneumothorax was found or not, or if an error had occurred. The Series Description DICOM tag for the summary report indicates the result:

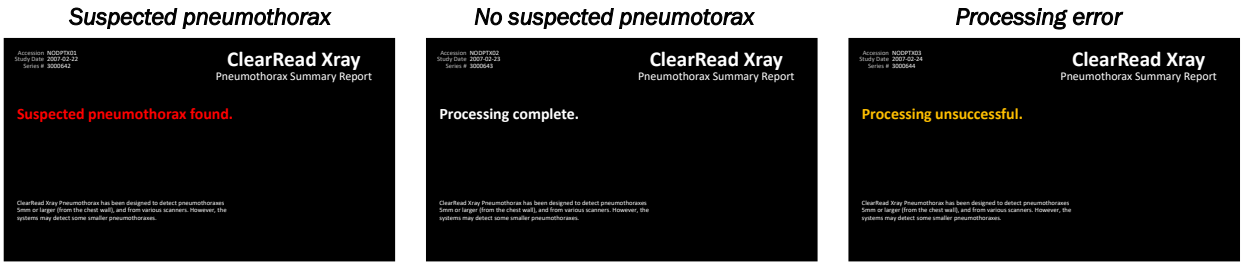
- **CR PTX Suspected** if there is at least one suspected pneumothorax. By default, this is color-coded red.
- **CR Complete** if processing completed and no suspected pneumothorax was identified. By default, this is not color coded.
- **CR Error** if processing failed when analyzing the input. By default, this is color-coded orange.

Site administrators can set up a worklist that uses the information in the DICOM header for prioritizing studies. Figure 6 shows a typical output, with findings (a), complete (b), and with an error (c). By default, output is not sent if no suspected Pneumothorax was identified.

ClearRead Xray **Detect Summary Report** is generated as a DICOM Structured Report (SR) and contains the information about nodule findings and their attributes in DICOM SR format. Refer to the ClearRead Xray DICOM Conformance Statement [R2].

[4] Available in version 5.2.0 or higher.

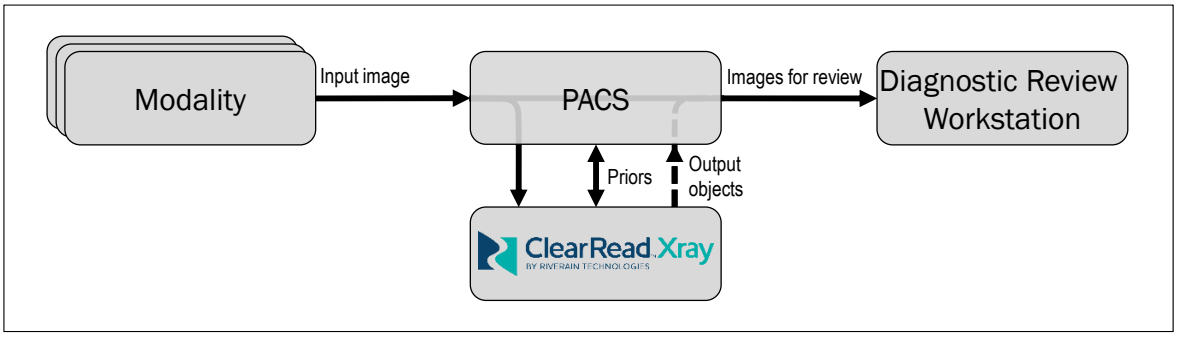
Figure 6: Typical Pneumothorax Summary Report.



[5.2] How to use system output

ClearRead Xray is designed to integrate with your native viewing environment. In a typical deployment ClearRead Xray output objects are sent to the PACS and viewed using a diagnostic review station (see Figure 7).

Figure 7: Typical viewing workflow with ClearRead Xray



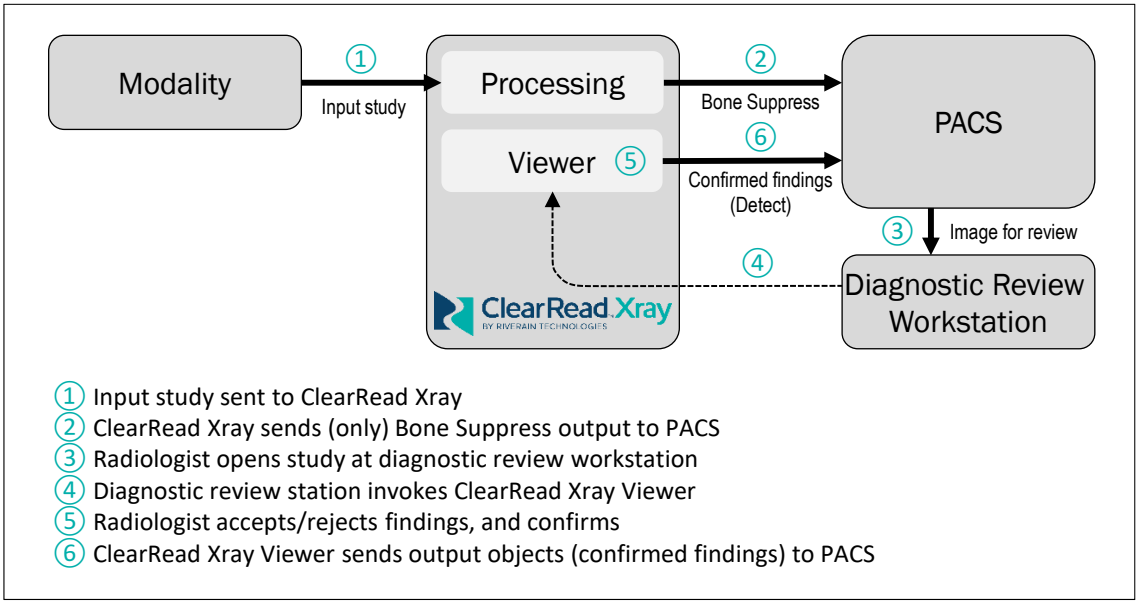
When interpreting a study, the radiologist first reviews the chest Xray image per regular clinical practices. Then:

- For ClearRead Xray **Bone Suppress**, the radiologist reviews the bone suppressed image, identifying any additional regions of interest (whether marked by ClearRead Xray Detect or not).
- For ClearRead **Enhance** or **Confirm**, the radiologist consults with the enhanced image for areas where lines or tubes may be obscured.
- For ClearRead Xray **Detect** or **Compare**, the radiologist consults with the Detect/Compare images, identifying any additional regions of interest that may represent lung nodules and determining actions required.
- For ClearRead Xray **Pneumothorax**, the radiologist uses the output to select whether to review the indicated case before or after other cases in the worklist/queue. Rules may be created by qualified physicians to take the suspected presence of a pneumothorax into account when prioritizing a patient worklist for reading.

In some instances, radiologists may require an opportunity to review ClearRead Xray's findings (Detect) prior to generating output objects or committing them to a PACS.

This can be accomplished by using **ClearRead Xray's Viewer** (see section [6.2]). When configured, the review workstation uses this viewer to display the findings, allowing users to review them before sending output objects to the PACS (see Figure 8).

Figure 8: Viewing workflow with ClearRead Xray's Viewer integration



NOTE: Using the viewer in the workflow is typically configured as part of the device installation. It requires integration with the reviewing workstation used at your site, and may not be available at all sites. See ClearRead Xray Administrator Manual [R1] for details on viewer integration.

[5.3] False Negatives and False Positives

There are two types of errors in cancer detection:

- In an **oversight error**, the radiologist fails to see a nodule.
- In an **interpretation error**, the radiologist sees a nodule but decides it is not actionable.

ClearRead Xray **Detect** and **Pneumothorax** help decrease oversight errors by pointing to suspected actionable findings, however, the radiologist makes the final determination:

- When the radiologist agrees with a finding (True Positive), patient workflow should be the same as if the radiologist noticed the finding without the use of the ClearRead Xray.
- When the radiologist does not accept or does not understand a finding indicated by ClearRead Xray they should dismiss the finding (False Positive).
- When the radiologist identifies an actionable finding (nodule or pneumothorax), the clinical action should be based on that finding, even if not marked by ClearRead Xray (False Negative).

NOTE: ClearRead Xray Detect does not mark all nodules. It identifies actionable nodules that are 9mm-30mm in diameter. .

NOTE: ClearRead Xray Pneumothorax has been designed to detect pneumothoraces 5mm or larger (from the chest wall), and from various scanners. However, the system may detect smaller pneumothoraces.

[6] TOOLS AND INTEGRATIONS

[6.1] General

ClearRead Xray offers a powerful set of configurations for input selection, output delivery, prior retrieval and more. These are designed to allow users the flexibility to integrate ClearRead Xray into their workflow in the most effective and seamless way possible.

Most configurations can be set up at device installation. See *ClearRead Xray Administrator Manual* [R1] for details on available settings.

[6.2] ClearRead Xray Viewer

The ClearRead Xray Viewer (or Viewer) is used to review findings prior to sending output objects (Detect) to a PACS.

> **NOTE**: The viewer is only intended for quick review of ClearRead Xray output and is not intended for diagnostic usage.

The viewer area is divided into the following functional components (refer to Figure 9):

① **Image Area**	Shows the current slice and the contours of any findings.
② **Viewer Controls**	Provide image viewing options/controls. Zoom in Zoom out Restore image to its original (100%) size. Fit image to viewer window Rotate 90 degrees counter-clockwise. Rotate 90 degrees clockwise. Send the image and findings to (only) the selected designated destination PACS.
③ **Message Area**	Displays informational and error messages.

Figure 9: ClearRead Xray Viewer's user interface (left) and functional areas (right)

[7] REGULATORY

[7.1] Device Manufacturer and Specifications Designer

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