ClearRead CT™
BY RIVERAIN TECHNOLOGIES

User Manual

Versions 3.6.0 – 5.5.0

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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!

Low dose CT is the preferred method for annual lung cancer screening for at-risk patients. The American Cancer Society statistics show that the 5-year survival rates more than triples if lung cancer is found early enough. However, interpreting a chest CT is a challenging task, owing to the large number of images commonly present in a chest CT series and interfering structures that compete with the detection of lung nodules.

Given the clinical importance of early detection of lung cancer, and to address the related challenges, ClearRead CT is designed to aid in the detection, characterization and tracking of nodules which may represent cancer.

This manual contains the information necessary for safe and effective use and operation of ClearRead CT. 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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Miamisburg, Ohio 45342

+1-937-425-6811 or info@riveraintech.com

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

Actionable Nodule	Image locations in the CT series with suspicious nodular features, i.e., characteristics, for which radiologist(s) recommends further examination, typically through analysis of a prior exam and/or additional imaging such as follow-up CT, diagnostic CT, etc.
CAD	Computer-Aided Detection
CT	Computed Tomography
DICOM	Digital Imaging and Communications in Medicine
Finding	A region of interest detected by ClearRead CT
GSPS	Grayscale Softcopy Presentation State
OEM	Original Equipment Manufacturer
PACS	Picture Archiving and Communications System
ROI	Region of Interest
SR	Structured Report

[1.5] Additional Reading

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

[R1] ClearRead CT Administrator Manual, available from Riverain, contains the information necessary to configure, administer, and monitor ClearRead CT devices.
[R2] ClearRead CT DICOM Conformance Statement, available from Riverain, contains details of the DICOM objects generated by ClearRead CT.
[R3] ClearRead CT DICOM Requirements, available from Riverain, contain details of the default DICOM constraints and filtering rules applied by ClearRead CT.
[R4] Additional products and support information is available at www.riveraintech.com.

Select clinical studies and references with product performance results:

K. Martini, M., C. Blüthgen, M., M. Eberhard, M., A.L.N. Schönenberger, M., I. De Martini, M., F.A. Huber, M., . . . T. Frauenfelder, M. (2020). Impact of Vessel Suppressed-CT on Diagnostic Accuracy in Detection of Pulmonary Metastasis and Reading Time. *Academic Radiology*. doi:https://doi.org/10.1016/j.acra.2020.01.014

Lo, S. B., Freedman, M. T., Gillis, L. B., White, C. S., & Mun, S. K. (2018). Computer-Aided Detection of Lung Nodules on CT With a Computerized Pulmonary Vessel Suppressed Function. *American Journal of Roentgenology, 210*, 480–488. doi:10.2214/AJR.17.18718

Milanese, G., Eberhard, M., Martini, K., De Martini, I., & Frauenfelder, T. (2018, February 15). Vessel suppressed chest Computed Tomography for semi-automated volumetric

measurements of solid pulmonary nodules. *European Journal of Radiology, 101*, 97–102. doi:https://doi.org/10.1016/j.ejrad.2018.02.020

Singh, R., & et al. (2018). Effect of Artificial Intelligence Based Vessel Suppression and Automatic Detection of Part Solid and Ground-Glass Nodules on Low-Dose Chest CT. Chicago, USA: RSNA. Retrieved from http://archive.rsna.org/2018/18014631.html

[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:

WARNING: Only the original chest CT series is to be used for diagnostic interpretation by physicians. ClearRead CT output is designed only as an aid to the interpretation process.

WARNING: Degraded image quality of input series from factors such as patient motion and/or manmade devices (e.g., pacemaker) in the field of view during the image acquisition, may lead to reconstruction artifacts and diminish the effectiveness of the device.

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

WARNING: Ensure all input sent to ClearRead CT meet device specifications. Invalid input may lead to no output being generated or to degraded device performance.

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

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

WARNING: Various factors can cause ClearRead CT to fail to find an acceptable prior CT series. In such a scenario, the Compare component of the system is not invoked, and the volumetric changes of the ROIs are not computed. Do not delay your reading of the primary or secondary CT series in order to view the ROI volumetric changes.

NOTE: If the ClearRead CT Vessel Suppress micro-nodule filter is enabled, some nodules with measured diameter of less than or equal to 5mm may still be retained.

NOTE: Use of the device on any image projection other than the axial CT chest views is not supported.

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.

NOTE: A standard CT series is expected to contain both lungs. CT series not containing both lungs might fail to be processed.

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

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

[3] SYSTEM OVERVIEW

[3.1] System Description

ClearRead CT is a computer-aided detection (CAD) system intended to identify and measure regions of interest (ROIs) in the lung, specifically solid, part-solid, and ground-glass nodules.

The system receives chest Computed Tomography (CT) studies as input, in DICOM® format, and generates output in DICOM (or other) format.

ClearRead CT supports the following features:

ClearRead CT Vessel Suppress aids radiologists in locating abnormal lung structures (nodules) by suppressing normal structures in the input chest CT series.

ClearRead CT Detect aids radiologists in the detection of findings within a primary CT series.

ClearRead CT Compare aids radiologists in tracking finding changes over time.

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 CT is comprised of computer assisted reading tools designed to aid the radiologist in the detection of pulmonary nodules during review of CT examinations of the chest on an asymptomatic population. The ClearRead CT requires both lungs be in the field of view. ClearRead CT provides adjunctive information and is not intended to be used without the original CT series.

[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 the ClearRead CT system. 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 CT has been designed to accept contrast or non-contrast axial chest CT scans as input, in DICOM format, that meets certain specifications (see [4.1] Input Data Requirements). Invalid input may lead to no output being generated by ClearRead CT or to degraded device performance.
Quality Input	ClearRead CT has been optimized to process scans configured to assist the detection and characterization 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 scan is expected to contain both lungs, and the field of view, whether square or circular, should not clip the lungs. The entire intrathoracic cavity should be included even if the patient has had prior lung surgery (e.g., lobectomy). ClearRead may fail to process scans with cropped lungs, the Compare feature might not perform optimally, and the estimated volumetric changes of nodules may not be reliable.
False Positives and False Negatives	ClearRead CT is 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 beam-hardening artifacts due to metallic structures or the contrast agent; image noise due to low-dose acquisition; and partial volume errors. • Benign pathologies, such as scars, mucous plugs, and pleural plaques. • Other Pathologies, such as tuberculosis (TB), pneumonia, and presence of other lung diseases including emphysema or pulmonary embolism. • Normal anatomy, such as residual vessels, bronchial structures, and protrusions on the pleural surface.
Patient Age	ClearRead CT 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 CT has been designed to process contrast or non-contrast axial CT studies, in DICOM format. Each series in an input study is considered **valid input** if it meets the following specifications:

- Axial orientation with no more than +/- 1 degree of rotation.
- Maximum slice thickness of 5mm for Vessel Suppress and 3mm for Detect and Compare with jitter of no more than 0.1mm.
- Maximum slice spacing of 5mm for Vessel Suppress and 3mm for Detect and Compare with jitter of no more than 0.1mm.
- Minimum contiguous volume of 80 mm.
- Maximum contiguous volume of 1067 mm.
- Consistent table height and patient position throughout the series.

NOTE: ClearRead CT relies on Patient Position and Patient Orientation information from the DICOM header. If the header is incorrect, the system might fail to process the series.

ClearRead CT 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 CT DICOM Requirements [R3]. Refer to the *ClearRead CT Administrator Manual* [R1] for details on how to configure input filters.

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

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

[4.2] Input Data Considerations

ClearRead CT operates over a wide range of CT lung scans. Like a radiologist, ClearRead CT prefers scans configured to assist detection and characterization of nodules, such as the following:

- Soft reconstruction kernels over sharp ones
- Inspiration over expiration
- Non-contrast over contrast
- Thin-slice over thick-slice
- Minimum image artifacts
- Minimum obstructions (chest tubes, excessive fluid, or other gross abnormalities)

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

[5] SYSTEM OUTPUT

[5.1] Output Objects

ClearRead CT 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 CT Administrator Manual* [R1] for details on how to configure output objects.

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

Output objects may contain measurement information, including:

Location	The lobe location of a nodule, one of right-upper-lung (RUL), right-middle-lung (RML), right-lower-lung (RLL), left-upper-lung (LUL) or left-lower-lung (LLL).
Type	The classification of a nodule, one of solid, part-solid or ground-glass.
Maximum Diameter	The largest diameter of a nodule, in millimeters (mm), measured in any axial plane.
Minimum Diameter	The diameter of a finding perpendicular to the one yielding the maximum diameter, in mm.
Average Diameter	The average of the minimum and maximum diameters, in mm.
Z-Diameter	The craniocaudal (head-to-foot) diameter of a nodule, in mm.
Volume	The estimated volume of a nodule, in cubic millimeters (mm^3).
Lung Volume	The estimated volume of a lung, in liters.
Number of Findings	The number of detected nodules, up to 5 by default. An asterisk (*) indicates additional nodules exist.
Doubling Time (Compare only)	The estimated time, in days, it would take for a nodule to double in volume, based on past growth.
Volume Change (Compare only)	The change in volume, in percent, from a prior scan to current one. For part-solid nodules, the volume change for the solid part is reported separately.

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] Vessel Suppress

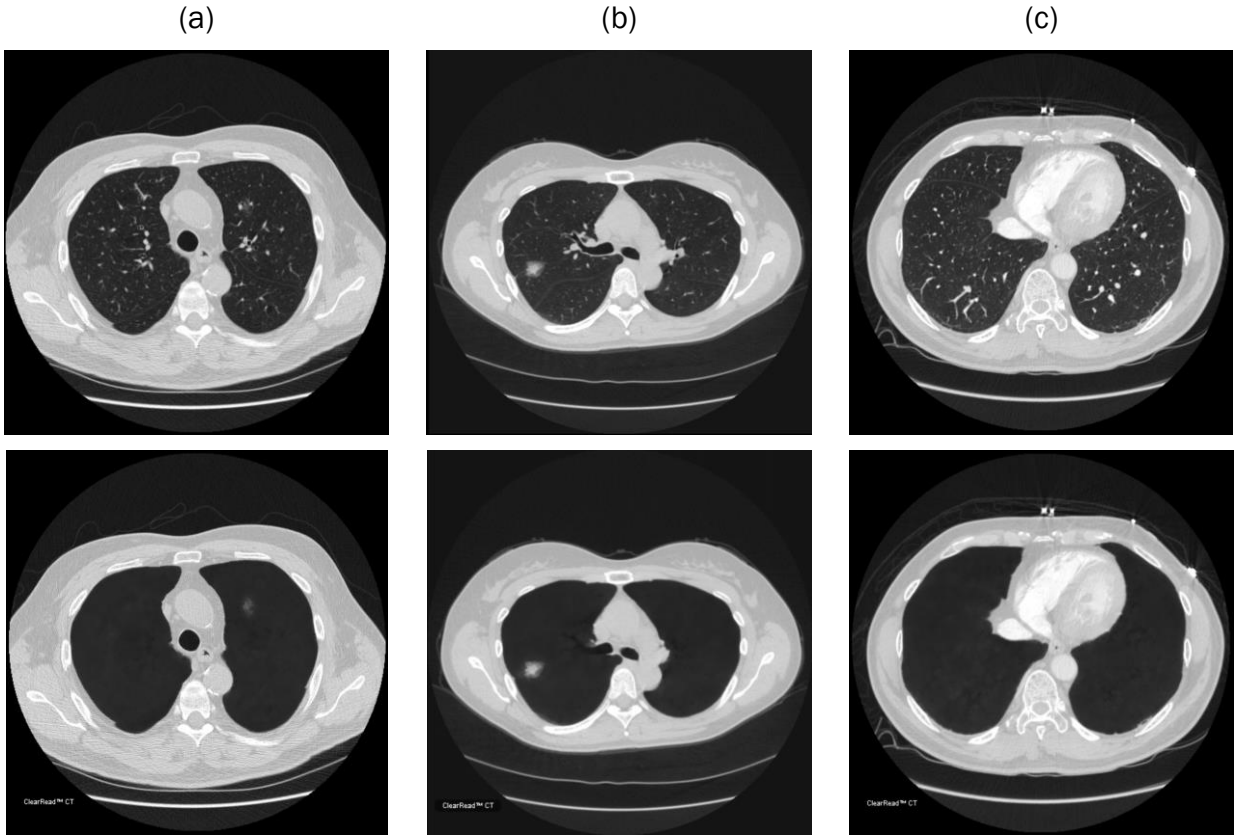
The **Vessel Suppress** output object is a native DICOM series, where each input slice is replaced with the corresponding Vessel Suppressed slice. Non-nodular structures (particularly vascular) are suppressed to improve the conspicuity and associated

detectability of nodules. The vessel suppress series has the same sampling characteristics (both in-plane and out-of-plane) as the original series.

Table 1: Variants of the Vessel Suppress output object

Code	Output Series Name[1]	Format	# Of Slices	Prior Required	License Required
C2001	CR Vessel Suppress	Native DICOM Series	Same as primary input series	No	Vessel Suppress

Figure 1: Sample Vessel Suppress output objects shown below the corresponding input image, where ground glass nodule is present (a), semi-solid nodule is present (b), and normal structures only are present (c).



[5.1.2] Vessel Suppress with Detect/Compare

The **Vessel Suppress with Detect** output object is similar to the Vessel Suppress output object (see [5.1.1]), however, where suspected actionable nodules are identified, output slices also contain a contour indicating the finding, a numeric identifier shown near the segmented nodule, and relevant measurements related to the finding (location, diameter,

[1] Output series names can be configured. For details see *ClearRead CT Administrator Manual* [R1].

classification). The **Vessel Suppress with Compare** output object includes additional information for any corresponding prior finding (diameter, growth, slice location).

This output object may be generated as DICOM overlay, GSPS object, and/or an **Index** object (see Table 2). The latter only contains the first slice, the last slice, and the center slice of each detected finding. Synchronizing the Index with the input series makes it easy to navigate between detected findings.

Table 2: Variants of the Vessel Suppress with Detect output object

Code	Output Series Name	Format	# Of Slices	Prior Required	License Required
C2003	CR VS Detect	DICOM series with overlay	Same as primary input series	No	Detect
C2004	CR VS Detect	DICOM GSPS series	Modified Vessel Suppress series	No	Detect
C2008	CR VS Detect Index	DICOM series with overlay	First, last, finding centers	No	Detect
C2023	CR VS Compare	DICOM series with overlay	Same as primary input series	Yes	Compare
C2024	CR VS Compare	DICOM GSPS series	Modified Vessel Suppress series	Yes	Compare
C2028	CR VS Compare Index	DICOM series with overlay	First, last, finding centers	Yes	Compare

[5.1.3] Primary Volume with Detect/Compare

The **Primary Volume with Detect** output object contains copies of the input (primary) images, however, where suspected actionable nodules are identified, output slices also contain a contour indicating the finding, a numeric identifier shown near the segmented nodule, and relevant measurements related to the finding (diameter, location, and classification). In the **Primary Volume with Compare** output object, additional information is included for any corresponding prior finding (diameter, growth, and slice location).

Starting version 5.2, the **Detect Mask** object is also available. Images in this object correspond to the original images and are intended to be fused with them (like a PET image would be fused with CT). The Detect Mask includes all pixels that are part of a detected nodule; other pixels are blank.

Figure 6 shows a sample **Primary Volume with Detect**.

Figure 7 shows a sample **Detect Mask** object fused with the primary volume.

This output object may be generated as DICOM overlay, GSPS object, and/or an **Index** object (see Table 3). The latter only contains the first image, the last image, and the center image of every detected finding. Synchronizing the ***Index*** with the input series makes it easy to navigate between detected findings.

Table 3: Variants of the Primary Volume with Detect output object

Code	Output Series Name	Format	# Of Slices	Prior Required	License Required
C2013	CR Detect	DICOM series with overlay	Same as primary input series	No	Detect
C2014	CR Detect	DICOM GSPS series	Modified primary input series	No	Detect
C2018	CR Detect Index	DICOM series with overlay	First, last, finding centers	No	Detect
C2033	CR Compare	DICOM series with overlay	Same as primary input series	Yes	Compare
C2034	CR Compare	DICOM GSPS series	Modified primary input series	Yes	Compare
C2038	CR Compare Index	DICOM series with overlay	First, last, finding centers	Yes	Compare
C3034	CR Detect Mask	DICOM image series	Same as primary input series	No	Detect

[5.1.4] Detect/Compare Summary Report

The **Summary Report** captures information of all findings (detected ROIs), and (when applicable) their respective matches in a prior series. Summary Report output objects may be generated as DICOM secondary capture, as a DICOM structured report, or as a DICOM encapsulated PDF report (see Table 4).

When created as a secondary capture, the first page of the summary report[2] shows the anatomical location of the findings on a lung diagram, as well as study information, case-level categorization (Lung-RADS V1.1[3] or Fleischner[4]), and thumbnail image and measurements of each finding. In **Compare** reports, similar information is shown for the corresponding prior findings (if any).

Subsequent pages contain details of each finding, one finding per page, including a thumbnail image, lobe location, slice location, contours, classification (solid, part solid or ground-glass), categorization, and measurements (volume, X/Y/Z diameters). For part-solid nodules, volume and diameter information is also available for the solid component. In **Compare** reports, details are also shown for the corresponding prior finding (if any), as well as a volume change and estimated doubling time. See examples in Figure 2 and Figure 3.

NOTE: ClearRead CT marks findings on the lung diagram based on their relative position within the series. For cropped input series, where only part of the lung is

[2] To customize the content and appearance of Summary Reports, contact Customer Success.
[3] https://www.acr.org/Clinical-Resources/Reporting-and-Data-Systems/Lung-Rads
[4] https://radiopaedia.org/articles/fleischner-society-pulmonary-nodule-recommendations-1

visible, marks may inaccurately reflect the location of the findings.

When generated as a DICOM Structured Report (SR), the report contains the information about the findings and their attributes in DICOM SR format. See an example in Figure 4. For details, refer to the *ClearRead CT DICOM Conformance Statement* [R2].

When generated as a DICOM encapsulated PDF, the report contains basic patient information and a tabulated summary of the findings in PDF format. See an example in Figure 5.

Table 4: Variants of the Summary Report output object

Code	Output Series Name	Format	# Of Slices	Prior Required	License Required
C2016	CR Summary Report	DICOM secondary capture	Summary page + page per finding	No	Detect
C2019	CR Structured Report	DICOM structured report	N/A	No	Detect
C2015	CR PDF Report	DICOM encapsulated PDF	Summary page	No	Detect
C2036	CR Summary Report	DICOM secondary capture	Summary page + page per finding	Yes	Compare
C2039	CR Structured Report	DICOM structured report	N/A	Yes	Compare

Figure 2: Sample Detect Summary Report: the first page (left) shows 5 findings, the second page (right) shows details of the first finding.

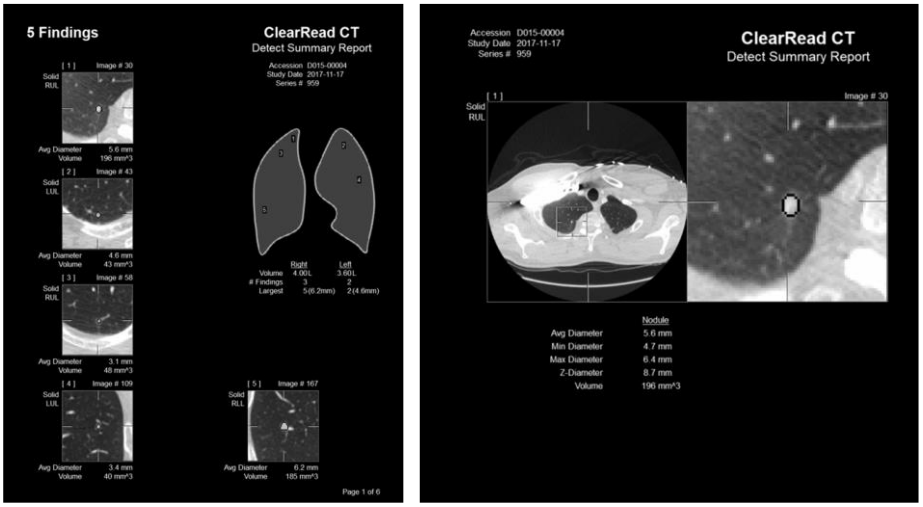


Figure 3: Sample Compare Summary Report: the first page (left) showing 2 findings, one larger and growing, one smaller and retreating; the second page (right) shows details of the first finding.

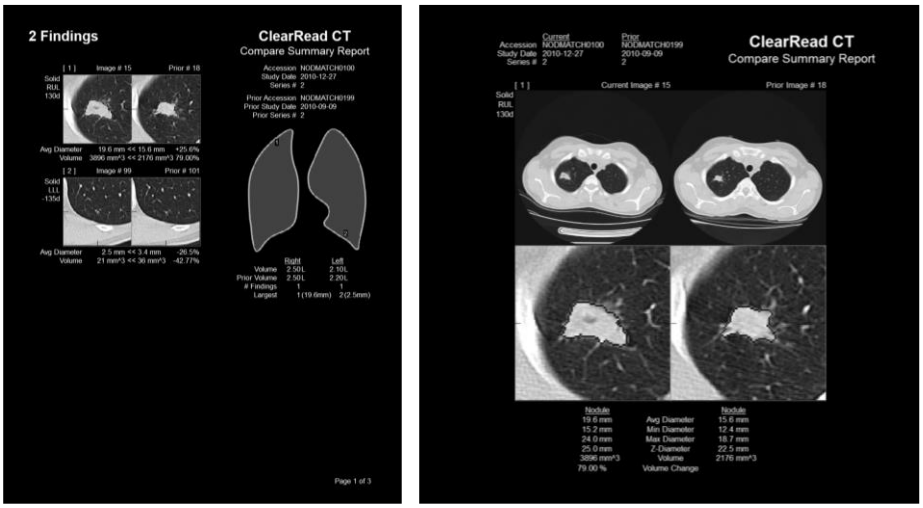


Figure 4: Sample Detect Structured Report showing one part-solid finding:

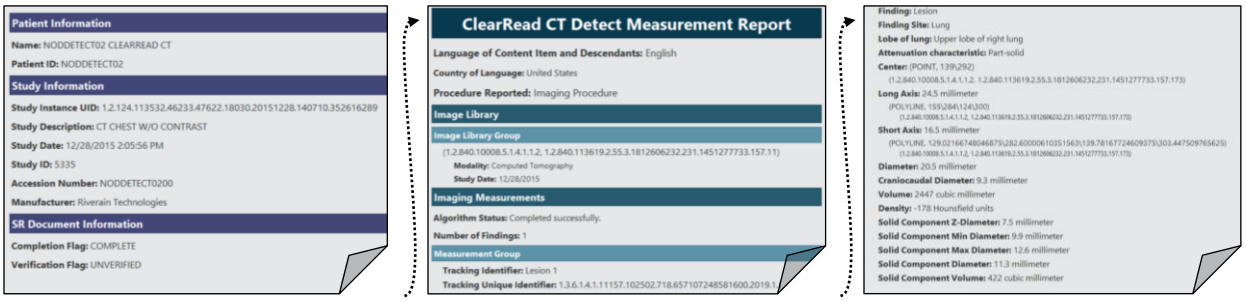


Figure 5: Sample PDF report showing 5 solid nodules detected

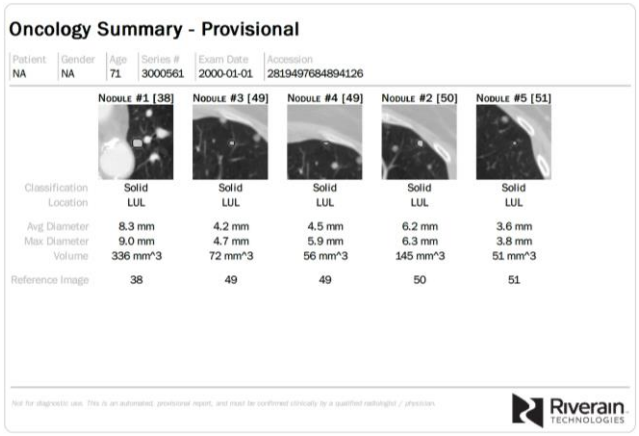


Figure 6: Comparison of output objects for (1) a ground glass nodule finding, and (2) a part-solid nodule finding.

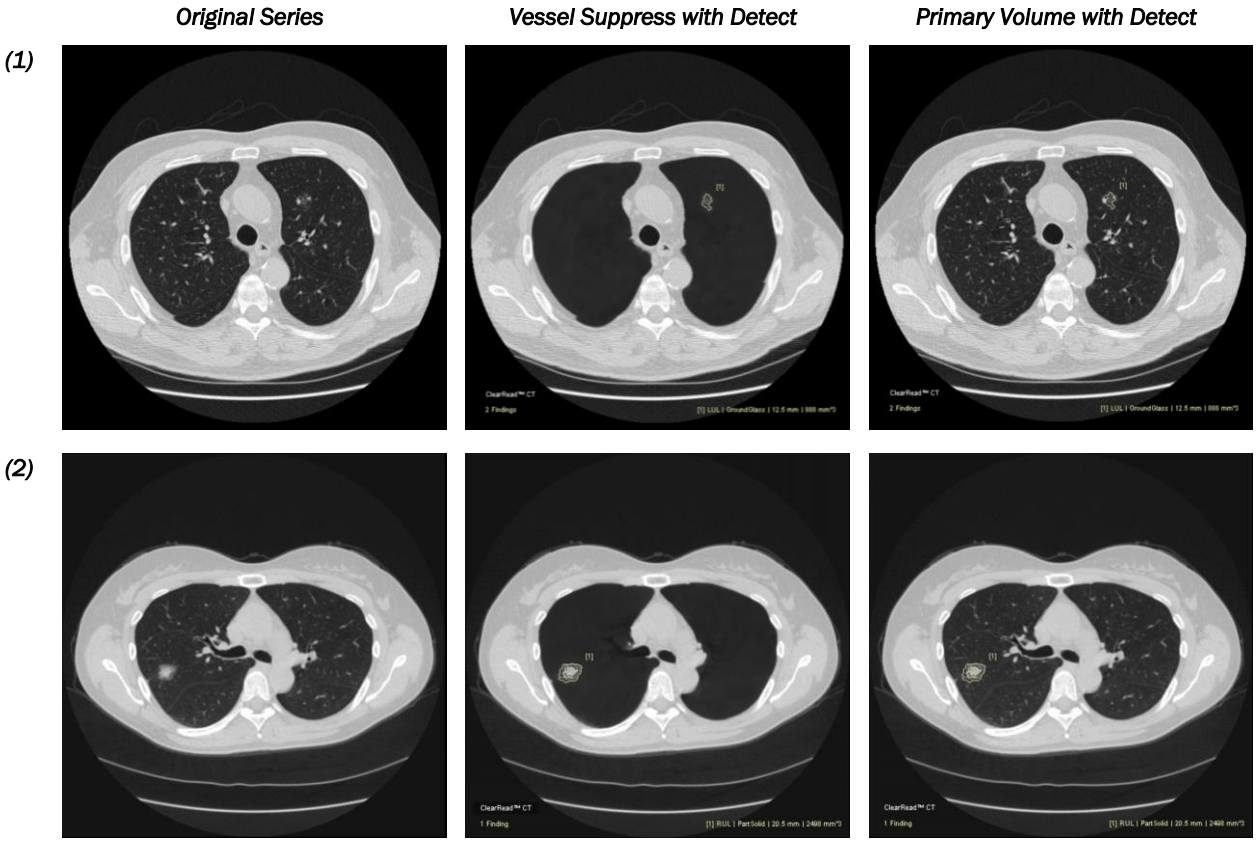
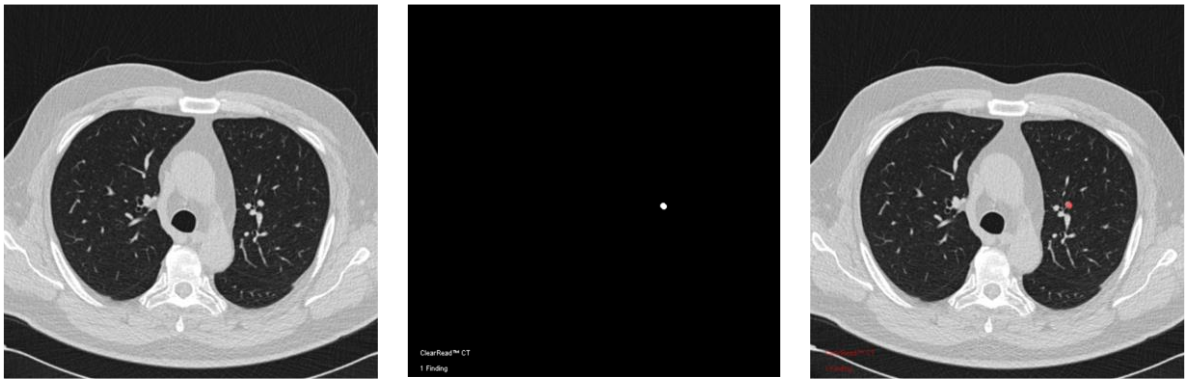


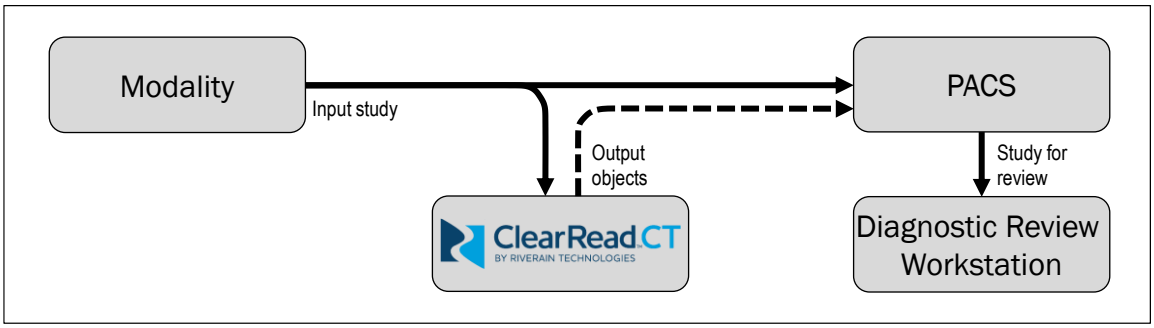
Figure 7: Example of a Detect Mask series fused with an input series.



[5.2] How to use system output

ClearRead CT is designed to integrate with your native viewing environment. In a typical deployment ClearRead CT output objects are sent to the PACS and viewed using a diagnostic review station (see Figure 8).

Figure 8: Typical viewing workflow with ClearRead CT



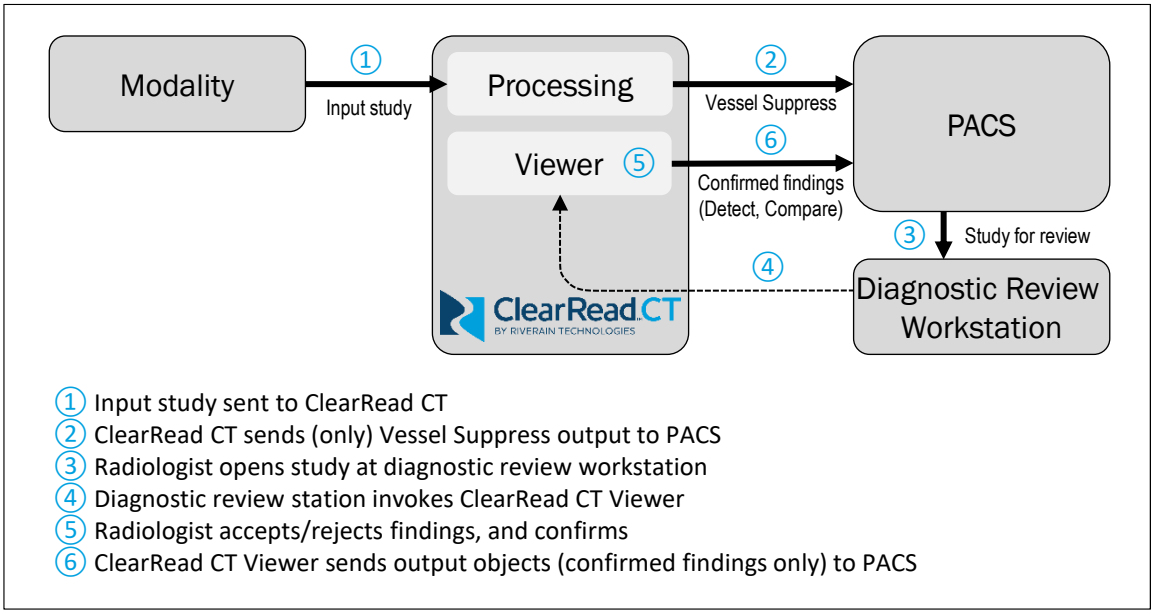
For ClearRead CT Vessel Suppress, the radiologist typically reviews a chest CT concurrently with the vessel suppressed volume, identifying regions of interest. Vessel suppression improves the conspicuity and detectability of nodules whether marked by ClearRead CT Detect or not.

For ClearRead CT Detect or Compare, the radiologist typically reviews a chest CT concurrently with the marked regions and determines whether any action is required. Nodule details (location, type, diameter, growth, etc.) may be automatically populated into Nuance® PS360 for editing (see section [6.3]).

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

This can be accomplished by using **ClearRead CT's Viewer** (see section [6.2]). When configured, the review workstation uses this viewer to display the findings, allowing users to accept or reject them, and to send output objects to PACS once their choices are made (see Figure 9).

Figure 9: Viewing workflow with ClearRead CT'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 CT 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 CT helps decrease oversight errors by pointing to suspected actionable nodules, 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 CT.
- When the radiologist does not accept or does not understand a finding marked by ClearRead CT they should dismiss the finding (False Positive).
- When the radiologist identifies an actionable nodule, the clinical action should be based on that finding, even if not marked by ClearRead CT (False Negative).

NOTE: ClearRead CT Detect does not mark all nodules. It identifies actionable nodules that are 5mm-30mm in diameter and limits the number of findings to five. Smaller nodules may still be visible in Vessel Suppress. To filter micro nodules from Vessel Suppress, see *ClearRead CT Administrator Manual* [R1].

[6] TOOLS AND INTEGRATIONS

[6.1] General

ClearRead CT 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 CT into their workflow in the most effective and seamless way possible.

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

[6.2] ClearRead CT Viewer

The ClearRead CT Viewer (or viewer) is used to review findings prior to generating output objects (Detect and Compare) and sending them to a PACS.

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

The viewer displays findings contours and details, allows easy navigation between findings and comparison with priors. After all findings are accepted or rejected, the viewer generates the output objects and sends them to the designated destination(s).

When Compare is enabled, the viewer is divided into two areas. The left side shows the primary (current) series, and the right side shows the prior series. If only Detect output is available, the right side of the viewer is hidden.

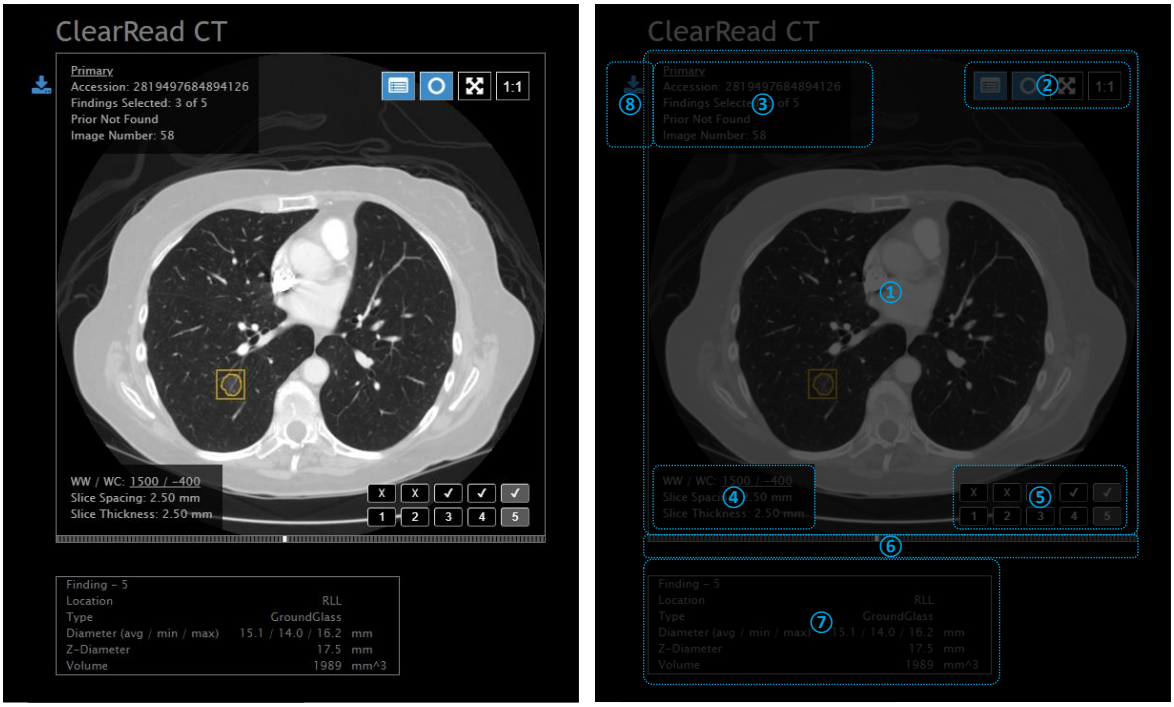
The viewer area is divided into the following functional components (refer to Figure 10):

① **Image Area**	Shows the current slice and the contours of any findings. Upon launch, the viewer shows the first finding's center slice (or the first slice if no findings).
Left mouse button	Hold and move mouse to adjust Window Width / Window Center.
Middle mouse button	Hold and move mouse to pan the image.
Right mouse button	Hold and move mouse to zoom the image (up = zoom in).
Mouse wheel	Click the Image Area then use the wheel to scroll through the series.
② **Viewer Controls**	Provide image viewing options/controls.
	Show/Hide finding info (default: hide). *[M]*[5]
	Show/Hide findings contours (default: show). *[R]*
	Contours are shown in yellow/blue for accepted/rejected findings. A bounding box is added around the current finding to distinguish it from other findings.

[5] Keyboard shortcuts for operations are shown in *[brackets]*.

	Fit image to viewer window, *[F]* Restore image to its original (100%) size. *[O]*
③ **Study Info**	Displays the number of accepted findings and details identifying the study. Click on Primary (underlined) to toggle between native and vessel suppressed view.
④ **View Info**	Shows the display window values (window width / window center), slice spacing and slice thickness. Clicking on the underlined values (or *[W]*) restores the default values.
⑤ **Findings Pane**	Allows navigation and acceptance / rejection of findings. Navigates to the numbered finding and select it as current. *[1]-[5]* Accept / Reject (default) a finding. Previous / Next page of findings (if more than 5). *[PgUp] [PgDn]*
⑥ **Slices Bar**	Shows the displayed slice (white) and loaded slices available for display (grey). By default, only the center frame of each finding is loaded for display.
⑦ **Finding Info**	Shows details of the selected finding on the primary volume and (if applicable) on the prior volume.
⑧ **Other Controls**	**Sync**: Synchronize primary and prior slice scrolling (default: on). **Save and Send**: Save (only) the selected findings and send output objects to the designated destination(s). Rejected (un-checked) findings are not saved and cannot be further retrieved.

Figure 10: ClearRead CT Viewer's user interface (left) and functional areas (right)



[6.3] Nuance PowerScribe 360 Integration

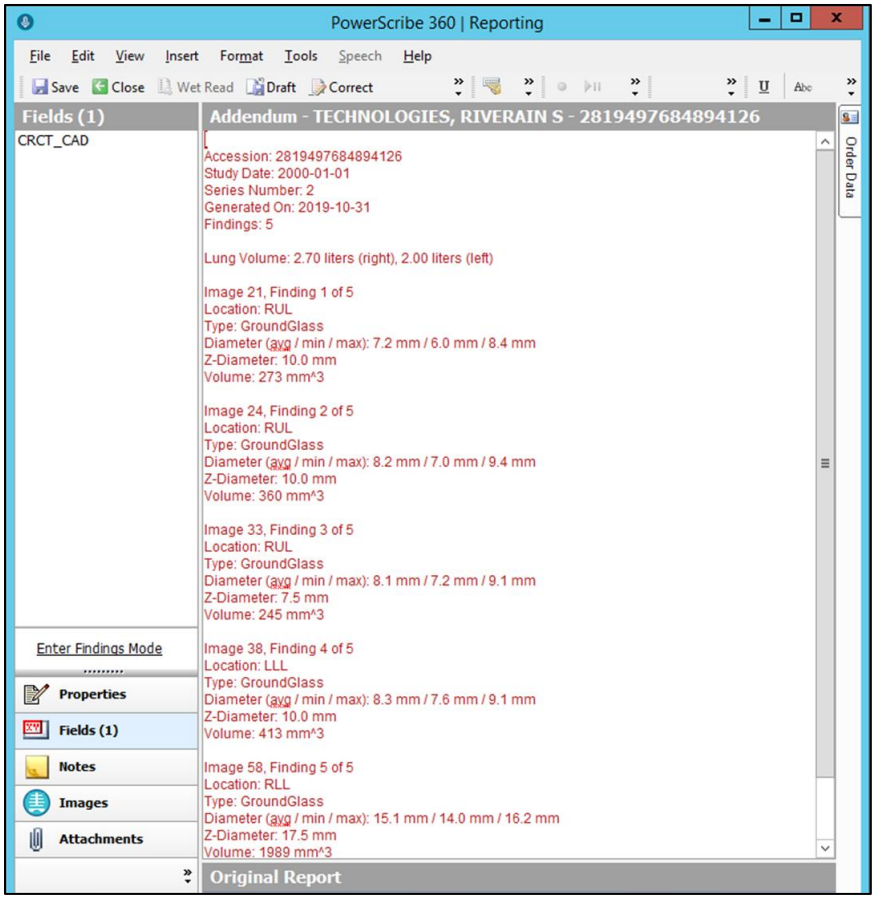
To facilitate review workflow, ClearRead CT can integrate with the Nuance PowerScribe 360 reporting software.

In a typical configuration, ClearRead CT automatically updates the order associated with the Accession Number of the processed series and populates an Auto-Text field (e.g., CRCT_CAD) with findings information. The Auto-Text field can be added to a report template or added manually to a specific report.

> **NOTE**: Nuance PS360 integration is typically configured as part of the device installation, where many aspects of the report generation can be controlled. See *ClearRead CT Administrator Manual* [R1] for details.

Figure 11 shows an example of the ClearRead CT findings populated into in a PowerScribe 360 template. The report shows the total number of findings and relevant measurements related to each finding (location, classification, diameters, volume). If the Compare feature is used, additional information is included for any corresponding prior finding (diameter, growth, slice location).

Figure 11: Nuance PS360 showing ClearRead CT output.



[7] DEVICE PERFORMANCE

Detection Accuracy	ClearRead CT has been designed to detect nodules between 5mm and 30mm in size. However, it may detect some nodules smaller than 5mm in diameter. In a blind, third-party study ClearRead CT detected 82.0% of known actionable nodules (all types), with an average false positive rate of 0.7469 false positives per CT series. On a benchmark dataset of corresponding current and prior chest exams, the ClearRead CT Compare exceeded 90% match rate on the associated true positive current-prior nodule pairs. In a third-party, peer-reviewed study, Radiologists detected 80.0% of cancers assisted by ClearRead CT versus 64.45% of cancers unaided (Lo, Freedman, Gillis, White, & Mun, 2018).
Measurement and Segmentation Accuracy	Simulated nodules of all types, ranging from 5mm to 30mm in diameter, were used to facilitate precise and automated assessment of segmentation quality. Nodules were electronically placed in approximately equal proportions as solitary (non-attached), juxta-vascular (vessel attached) and juxta-pleura (attached to the lung wall). Failures were defined as a difference exceeding 25% between measurements and actual (a 1.25mm tolerance for every 5mm of nodule diameter. In-house testing identified no failures, while generally noting highly accurate measurements. A third-party, peer-reviewed study found near-perfect agreement between ClearRead CT and reader measurements. Nodules ranged in sizes and locations and included nodules adjacent to vessels (Milanese, Eberhard, Martini, De Martini, & Frauenfelder, 2018).
Processing Time	Processing and response times may vary widely and depend on hardware used, site infrastructure, network traffic, usage patterns, and other factors. When using minimum hardware, ClearRead CT may take a few minutes to process each scan, either a primary or a prior one. In internal benchmarks, using entry-level hardware and a heterogeneous set of 40 scans, average processing time was 5 minutes and median was under 4 minutes per scan.
Reading time	In a third-party, peer-reviewed study, Radiologist interpretation time decreased from 132.3 seconds unaided to 98.0 seconds per case when assisted by ClearRead CT ($p < 0.01$), a 26% improvement (Lo, Freedman, Gillis, White, & Mun, 2018). Similar results were reported by others (K. Martini, et al., 2020).

Inter-Reader Agreement	In a third-party, peer-reviewed study, comparing inter-reader agreement among radiologists of different experience levels, using ClearRead Vessel Suppression significantly improved inter-reader agreement from fair (k=0.209) to moderate (k=0.491) (K. Martini, et al., 2020).

[8] REGULATORY

[8.1] Device Manufacturer and Specifications Designer

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