

# See Clearly. Decide Confidently.

Al imaging solutions for lung nodule detection

FDA Cleared | CE Marked | Clinically Proven | Enterprise Wide



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# Lung Nodule Detection

Pulmonary (lung) nodules are detected by chest X-ray or CT scan.

The vessels in the lung can complicate the quick, efficient identification of nodules.

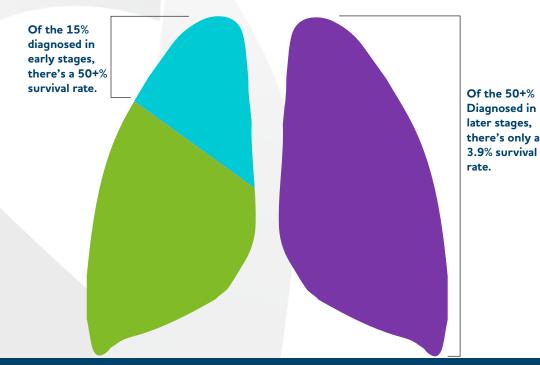
Almost 19 million chest CT scans are performed every year, and radiologists review every scan for pulmonary nodules.

CT scans allow visualization of nodules below 5 mm. If nodules are smaller than 8-10 mm, they are unlikely to be visible on a chest X-ray.

# Lung Cancer

#1 cause of cancer deaths in the world. There are close to 160,000 deaths every year in the United States.

Source: American Lung Association

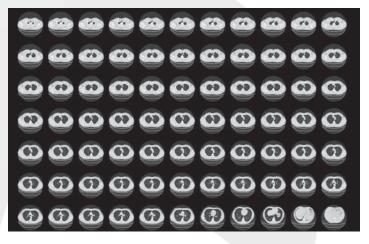


# **Empowering Radiologists with Accuracy and Time**

# Work Volume

Radiologists are under extreme pressure to read faster without compromising detection accuracy - leading to burnout, patient, and malpractice risks:

- Due to the increasing use of thin-section data (a typical chest CT exam now includes 300-500 slices to review for every patient), and a larger patient workload, radiologists have less time to read each study.
- Cancer can occupy a small fraction of the total patient volume (~1/1,000 of a percent of total volume). And it can be camouflaged by normal structures and noise.
- This trend is not sustainable radiologists need better tools. ClearRead Suite is a tool designed to improve the accuracy and efficiency of radiologists.



RIVERAIN riverain

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|--|---|--|--|---|
|  | ies™ designs advanced<br>arnational healthcare o  |  | First FDA-cleared system         for concurrent reading  |   |
|  |   |  | First FDA-cleared system to<br>demonstrate improved reader<br>accuracy and reading time            |   |
| The ClearRead <sup>™</sup> suite significantly improves a clinician's ability to accurately and efficiently detect disease – suppressing vessels in thoracic CT and bone structures in chest X-ray images – for earlier, more efficient detection of lung abnormalities. Powered by the most advanced machine learning and modeling methods available to the medical imaging market, the patented, FDA-cleared, CE marked software tools are deployable in the clinic or the Cloud. ClearRead Users: |   |  | First FDA-cleared system<br>for all nodule types<br>Supports non-contrast and<br>contrast chest CT |   |
| Academic Medical<br>Centers<br>Duke University<br>Einstein Medical Center<br>Mayo Clinic<br>University of Chicago<br>University of Michigan<br>UW Health   | International<br>Evangelical Luengen<br>Klinik, Berlin<br>University of Zurich<br>Yuanrung Medical Care<br>System<br>Radiology Groups<br>Advanced Radiology<br>Consultants<br>Atlantic Medical Imaging<br>LucidHealth Radiology<br>Group<br>Naugatuck Valley<br>Radiology | <ul> <li>Veterans Affairs</li> <li>Bay Pines VA Healthcare<br/>System</li> <li>Boston VA Healthcare<br/>System</li> <li>Durham VA Health Care<br/>System</li> <li>Hunter Holmes McGuire<br/>VA Medical Center</li> <li>Orlando VA Healthcare<br/>System</li> </ul> |  |   |







29 Fewer Missed Nodules<sup>1</sup>



1 Lo, S. B., Freedman, M. T., Gillis, L. B., White, C. S., & Mun, S. K. (2018). JOURNAL CLUB: Computer-Aided Detection of Lung Nodules on CT With a Computerized Pulmonary Vessel Suppressed Function. American Journal of Roentgenology, 210(3), 480–488. doi: 10.2214/ajr.17.18718. Enterprise-wide capability, processing scans from all CT manufacturers and acquisition protocols.

High throughput, scalable computation using off-the-shelf hardware with virtual machine deployments.

Supports standard, low-dose, non-contrast and contrast CT scans.

Automatically detects nodules at or above 5mm and supports visualization of nodules smaller than 5mm.

Detects all nodule types: solid, part-solid, and ground-glass.

Provides differential measurements.



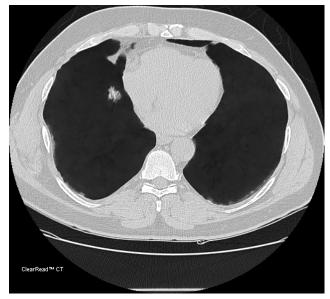
ClearRead CT is the first FDA-cleared device to support concurrent reading, allowing for faster reading with proven, superior, automatic nodule detection performance for all nodule types, including solid, sub-solid and ground-glass nodules.



# **Vessel Suppress**

ClearRead CT Vessel Suppress produces a secondary series, suppressing vessels and other normal structures within the lungs to improve nodule conspicuity as shown in the image to the right. The Vessel Suppress series gives users access to a truly unique and patented technology that aids in improving reading accuracy and efficiency. The processed series can be easily linked with the original CT series for synchronized scrolling.

Vessel Suppress not only enables improved nodule detection by eliminating obscuring normal structures, it also allows improved nodule characterizations for all nodule types.<sup>1</sup> Improved characterization derives in part from the ability for precise segmentation of nodule boundaries. Aside from volumetrics, the Vessel Suppress series enables a unique view of nodules.

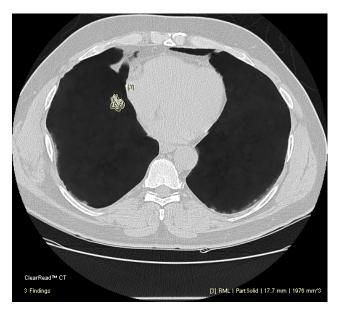


## Detect

ClearRead CT Detect leverages the vessel-suppression series to locate and characterize suspected nodules, enabling transparent, precise automatic measurements. The image to the right shows the detection and characterization of a ground-glass nodule.

Detect provides measurements for each detected region of interest including location, type, volume, maximum, minimum, and average axial plane diameters, and nodule depth.

1 Singh, Ramandeep, et. al. Effect of Artificial Intelligence Based Vessel Suppression and Automatic Detection of Part-Solid and Ground-Glass Nodules on Low-Dose Chest CT. RSNA 2018.





# Compare

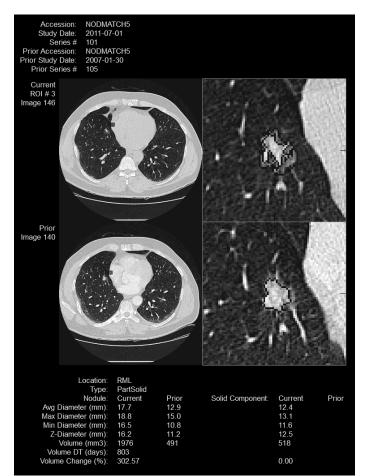
ClearRead CT Compare extends Detect by automatically matching nodules found in a current exam to the same nodule in a prior exam, enabling efficient visual and volumetric comparisons. The image to the right includes the current exam on the left and the prior exam on the right. The image chips at the bottom provide a close-up view of the individual finding, along with extracted measurements.



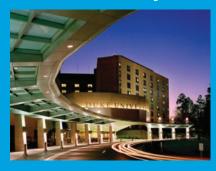
## "Vessel-suppressed CTs had 21% greater nodule detection rates, much higher inter-reader agreement rates, and significantly shorter average read times."<sup>1</sup>

Professor Thomas Frauenfelder, MD Professor of Radiology University Hospital of Zurich, participating study clinician

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



# At the Forefront of Lung Cancer Detection: Duke University Medical Center



As one of the country's first facilities to institute a Lung Cancer Screening program, Duke University Medical Center is a thought leader and reference site for

institutions initiating similar programs. As an American College of Radiology (ACR) designated center for Lung Cancer Screening, the Duke Lung Cancer Screening program is recognized for providing safe, effective care for at-risk lung cancer patients, while maintaining the highest possible standards.

The shift toward implementing lung cancer screening programs began in 2011 with the release of the National Lung Cancer Screening Trial (NLST) results. The study concluded that annual screening with low-dose computed tomography (CT) could detect lung cancer in its earliest stages, reducing lung cancer deaths by 20 percent. According to Jared Christensen, MD, Division Chief of Cardiothoracic Imaging and Director of The Duke Lung Cancer Screening program, one of their biggest challenges in thoracic imaging is searching for lung nodules.

For every chest CT exam, radiologists are obligated to search for lung nodules. Due to the lack of early-stage lung cancer symptoms, detecting incidental pulmonary nodules is critically important for early lung cancer detection. To help their radiologists detect more efficiently, Duke University Medical Center has deployed Riverain ClearRead CT software throughout their entire health network across all chest CTs, whether taken for screening or some other purpose.

"Riverain ClearRead CT was deployed as a part of our routine Chest CT exams, including patients in our Lung Cancer Screening program," said Dr. Christensen. "The ClearRead CT technology has helped us detect lung nodules that may have otherwise been missed. The workflow is faster and more accurate than other technologies."

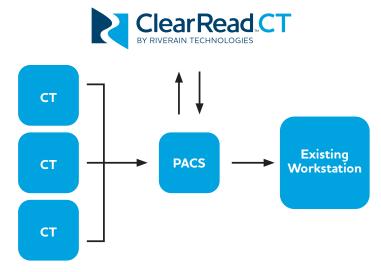
Duke University Medical Center has deployed Riverain ClearRead CT software throughout its entire healthcare network, providing a standard of care to its total patient population. The ClearRead technology seamlessly processes CT scans from all 15 CT scanners, regardless of manufacturer or acquisition protocols.



## Installation and Workflow

Acquisition normalization technology, along with programmable routing and exam filtering tools, allows rapid installation and site-specific configurations. ClearRead applications produce adjunctive content that seamlessly interfaces with the existing facility PACS. The result is a costeffective, efficient viewing experience for the radiologist.

## **Enterprise PACS Push Workflow**



# Host Machine Specifications

#### Minimum server specifications:

- Intel Xeon E3-1230 v5
- 16 GB RAM
- 100 GB disk (dedicated storage)
- Disk I/O at 300 IOPS with 4k block size
- 1 Gbit/sec Ethernet controller

#### Minimum virtual specifications:

- 4 vCPU with 14 GHz CPU reservation
- 16 GB RAM reservation
- 100 GB disk
- Disk I/O at 300 IOPS with 4k block size
  1 Gbit/sec Ethernet controller

# Operating System:

- Windows 10 Professional/Enterprise 64-bit
- Windows 2012 R2 Server 64-bit
- Windows 2016 Server 64-bit
- Windows 2019 Server 64-bit

#### Web Browser:

Microsoft Internet Explorer 11 or better, with cookies and Javascript enabled.

## Supported Virtualization Environments:

VMWare<sup>®</sup> 5 or later

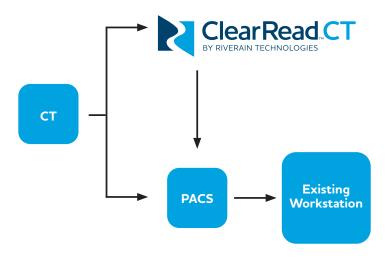
## Software Protection Key:

The HASP-HL key requires:

- One USB Type A port available
- Power consumption 50mA operating / <0.5mA standby</li>

## Third-Party Software:

Riverain strongly recommends against installing ClearRead CT on a multi-use instance of a VM or having multiple roles for a physical server by adding additional third-party software.



**Modality Dual Push Workflow** 







Enterprise-wide capability powered by acquisition normalization technology that allows "plug in" ability across all manufacturers and diverse imaging protocols.

High throughput, scalable computation on off-the-shelf hardware and virtual machine deployments.

No additional radiation dose or changes to existing imaging protocols are required.

Reduces the burden of visual search and assessment.

Automatically inserts the images into the patient's file for instant access.





1 Freedman, M. T., Lo, S.-C. B., Seibel, J. C., & Bromley, C. M. (2011). Lung Nodules: Improved Detection with Software That Suppresses the Rib and Clavicle on Chest Radiographs. Radiology, 260(1), 265–273. doi: 10.1148/radiol.11100153

2 Riverain Technologies ClearRead +Confirm FDA 510(k) Reader Study Results, 2012.



The Riverain Technologies ClearRead Xray platform is comprised of four FDA-cleared applications designed to improve reading efficiency and accuracy across the hospital enterprise without requiring additional hardware. The solutions optimize the diagnostic value of all portable and upright images.

## **Bone Suppress**

ClearRead Xray Bone Suppress increases the visibility of soft tissue in standard chest X-rays by suppressing the bone on the digital image without the need for two exposures. The bone-suppressed image helps radiologists to detect 1 out of 6 previously missed nodules.<sup>1</sup>





## Detect

ClearRead Xray Detect identifies regions of interest that warrant further examination. The software can detect 1 in 2 previously missed nodules<sup>2</sup> allowing identification of lung cancer up to 18 months sooner.<sup>3</sup>







"Certainly in our practice we absolutely have had proven cancers where, when we were reading the study, we did not see them until we looked at the bone-suppressed image."

Peter Sachs, MD University of Colorado Hospital

- 1 Freedman, M. T., Lo, S.-C. B., Seibel, J. C., & Bromley, C. M. (2011). Lung Nodules: Improved Detection with Software That Suppresses the Rib and Clavicle on Chest Radiographs. *Radiology*, 260(1), 265–273. doi: 10.1148/ radiol.11100153
- 2 Chen, J. and White, C. (2008). Use of CAD to Evaluate Lung Cancer on Chest Radiography. *Journal of Thoracic Imaging*. 23:93–96.

3 Gilkeson, Robert C. and Frolkis, Calen. Performance of a Next Generation Computer-Aided Detection Algorithm for the detection of overlooked lung cancers on Chest Radiographs. RSNA, 2013.



## Confirm

Original

ClearRead Xray Confirm optimizes and standardizes portable chest X-rays and improves the conspicuity of lines and tubes without compromising diagnostic image quality. The application minimizes or eliminates the need for image adjustments, reducing reading time by 19%.<sup>1</sup>





ClearRead Xray Enhance



**ClearRead Xray Confirm** 

1 Riverain Technologies ClearRead +Confirm FDA 510(k) Reader Study Results, 2012.

# Enterprise Deployment of ClearRead Bone Suppression and Confirm: University of Colorado



UCHealth expanded their use of Riverain Technologies ClearRead Xray Bone Suppress and ClearRead Xray Confirm software to all five of their

flagship hospitals in October 2016, after five years of clinical use at the main campus hospital, Anschutz Medical Campus in Aurora.

UCHealth is a nationally recognized system of five hospitals and more than 100 clinics, including University of Colorado Hospital, Poudre Valley Hospital, Medical Center of the Rockies, Memorial Hospital Central, and Memorial Hospital North. ClearRead Xray Bone Suppress forms a soft tissue image by subtracting the ribs and clavicles from the standard chest x-ray, allowing radiologists to more effectively detect focal densities. Powered by cutting-edge machine learning, it is the only software product to perform robust, pixel-level bone suppression throughout the entire body.

ClearRead Xray Confirm optimizes the visual quality of chest X-rays, including improving the conspicuity of lines and tubes on portable images, allowing radiologists to read up to 19% faster.<sup>2</sup>

The software immediately enhances any adult chest X-ray image after capture from upright or portable imaging machines, without the need for additional imaging equipment. It seamlessly integrates into any digital radiology department, offering universal connectivity with existing PACS, and can be used to improve the visibility and detection rates of focal densities, including nodules.

ClearRead Bone Suppress is a software solution, so it can easily be applied to every X-ray device in the facility for one fixed cost.

2 Lo, S. B., Freedman, M. T., Gillis, L. B., White, C. S., & Mun, S. K. (2018). JOURNAL CLUB: Computer-Aided Detection of Lung Nodules on CT With a Computerized Pulmonary Vessel Suppressed Function. American Journal of Roentgenology, 210(3), 480–488. doi: 10.2214/ajr.17.18718.

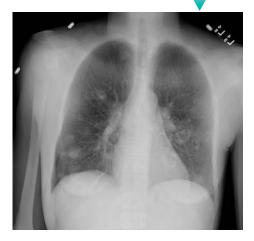


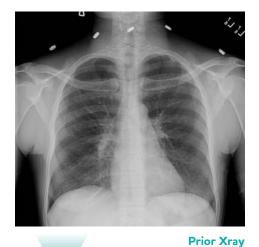
## Compare

ClearRead Xray Compare aids in the detection of soft tissue interval changes across current and prior chest X-rays by registering the bone-suppressed images and creating a difference image. The software allows detection of 1 in 10 previously missed emerging nodules.<sup>1</sup>



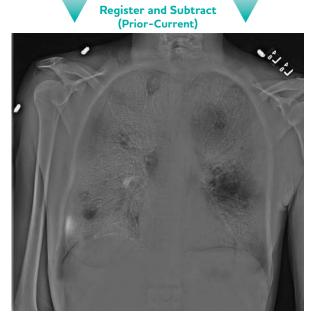
Current Xray







ClearRead Xray Bone Suppress (Current) ClearRead Xray Bone Suppress (Warped Prior)



1 Riverain Medical DeltaView FDA 510(K) Reader Study Results 2011.

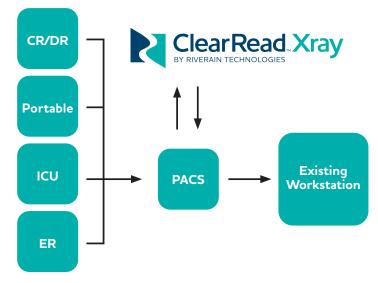
**ClearRead Xray Compare** 



## Installation and Workflow

Acquisition normalization technology, along with programmable routing and exam filtering tools, allows rapid installation and site-specific configuration. ClearRead applications produce adjunctive DICOM images and content that seamlessly interface with the existing facility PACS. The result is a cost-effective, efficient viewing experience for the radiologist.

## **Enterprise PACS Push Workflow**



## **Host Machine Specifications**

#### Minimum server specifications:

- Intel Xeon E3-1230 v5
- 8 GB RAM
- 100 GB disk (dedicated storage)
- 1 Gbit/sec Ethernet controller

#### Minimum virtual specifications:

- 4 vCPU with 14 GHz CPU reservation
- 8 GB RAM reservation
- 100 GB disk
- 1 Gbit/sec Ethernet controller

#### **Operating System:**

- Windows 10 Professional/Enterprise 64-bit
- Windows 2012 R2 Server 64-bit
- Windows 2016 Server 64-bit
- Windows 2019 Server 64-bit

#### Web Browser:

Microsoft Internet Explorer 11 or better, with cookies and Javascript enabled.

#### Software Protection Key:

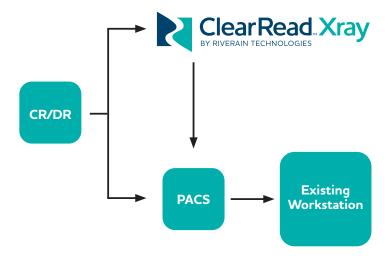
The HASP-HL key requires:

- One USB Type A port available
- Power consumption 50mA operating/ <0.5mA standby

## Third-Party Software:

Riverain recommends against installing ClearRead Xray on a multi-use instance of a VM or having multiple roles for a physical server by adding additional third-party software.

# Modality Dual Push Workflow



## "It's easy to install. It's easy to train to. And frankly, it provides immediate clinical value."

- Ella Kazerooni, MD University of Michigan Health System





# Unique Technology for Computer-Assisted Reading

Powered by machine learning and advanced modeling, Riverain Technologies suppression technology uses a local geometry model to remove structures that are not nodules. The technology has substantial advantages when compared to traditional approaches. Suppression technology opens the black box by allowing a radiologist to have an unprecedented access into the machine decision process. Normalization technology

Suppression technology

Deep learning technology

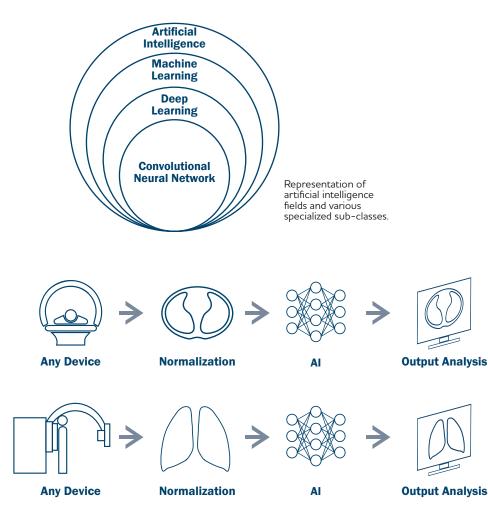
#### Teaching AI with simulation

Improve reading time and accuracy



## Reliable Deep Computation Using Machine Learning

ClearRead is a modern approach utilizing the latest advances in machine learning, such as deep learning. ClearRead has surpassed the state-of-the-art by a significant margin based on a combination of frameworks, modeling, and computational ingenuity.



## Acquisition Independence

ClearRead handles a broad range of acquisition protocols, a difficult problem for automatic analysis algorithms. Riverain Technologies developed adaptive algorithms, so each scan is normalized for factors such as:

- Noise
- Reconstruction kernels
- Slice sampling effects

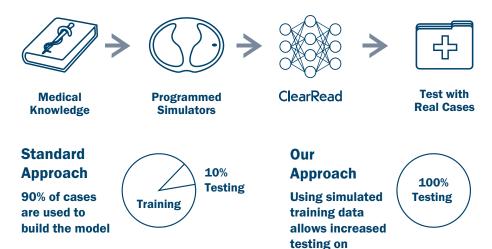
Conventional approaches collect data from different sensors to adjust component algorithms. This leaves them vulnerable to changes in hardware, protocols, and reconstruction methods.

Our adaptive process allows our software to be vendor neutral. ClearRead provides enterprise imaging without compromise, while also enabling fast and simple installation.



The standard approach to building large, complex models requires large measured training sets. These high-quality medical data sets are both time consuming and expensive, to collect. Many cases look similar, and do not include rare cases.

Riverain developed the capability to create synthetic nodules automatically and place them into relevant anatomical contexts – such as next to the pleura wall or attached to a vessel. ClearRead was built on thousands of simulated, diverse nodules. By doing this, our software has been trained on more complete cases (including more rare cases), and tested on full training sets.



measured cases



## Quantification and Unique Access to Clinically Important Quantities

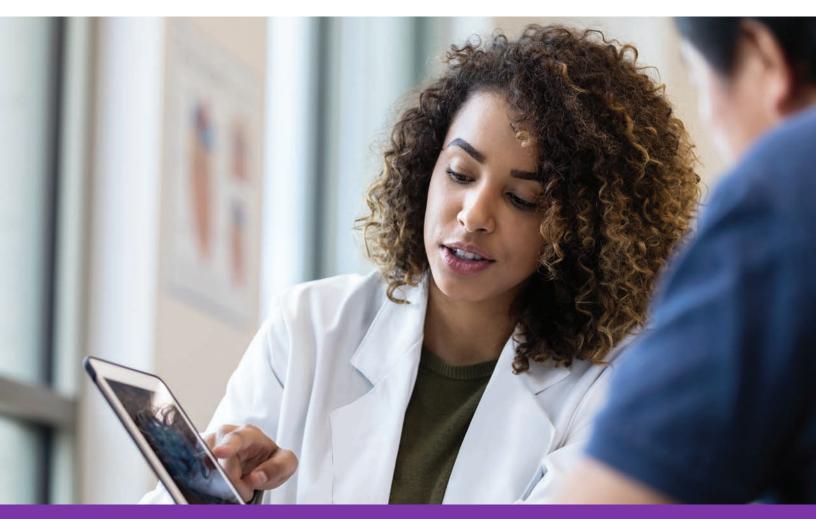
Vessel suppression enables improved nodule detection, but its benefit continues throughout the processing chain. Suppressing vessels and surrounding structures allow for a highly precise segmentation of nodules, providing an accurate assessment of size, volume, and other general nodule characteristics.

|                   | 1          |
|-------------------|------------|
| Location          | RML        |
| Туре              | Part Solid |
| Avg Diameter (mm) | 18.1       |

Example of ClearRead CT Detect measurements

#### Improving Accuracy and Efficiency for Clinicians

ClearRead aims to aid the more arduous medical interpretation tasks, including a systematic, thorough investigation of each voxel so that radiologists can focus on actual clinical decision making and improving their patients' lives.





# Dedicated to the early detection of lung disease.

Riverain Technologies believes the opportunities for machine learning and software solutions in healthcare are at an unprecedented level.

We believe software tools that incorporate increasing degrees of intelligence will facilitate decision making, leading to greater efficiency and effectiveness in healthcare.

We are excited to be part of the advances in machine learning and scalability of technology that will bring efficiency and accuracy to physicians, and ultimately, better the lives of patients.

## Partners

For a full list, please visit our website, riveraintech.com.

"Using ClearRead CT couldn't be easier. Image processing is completed in the background so that our normal workflow isn't interrupted."

- Charles White, MD Professor of Radiology & Medicine University of Maryland

#### **Mission**

To save lives through the early detection, diagnosis, and management of lung disease.

#### Vision

To be recognized as a transformative leader in the thoracic sciences.

