VolumeRAD Tomosynthesis

Superior detectability of lung nodules compared to a chest X-ray
Elevating a proven technology

VolumeRAD protocols are available for all adult and pediatric standard radiographic exams and views.

VolumeRAD* Tomosynthesis is an established, broad-indication technology utilized by radiologists for years.

The acquisition involves a single rapid sweep of the X-ray tube, and produces multiple tomographic images of the patient. This technology removes overlying structures and enables better anatomy visualization from front to back.

The key benefit of VolumeRAD Tomosynthesis is the tomographic removal of superimposed structures for a better view of detail in the area of interest. This makes it possible to see abnormalities that may not be seen with a standard X-ray examination.

During the sweep, up to 60 ultra-low dose exposures are obtained. Similar to CT exams, the acquired data is then reconstructed into a set of tomographic images (parallel to the detector plane). These images, in DICOM™ format, can be reviewed sequentially on the acquisition console or on any standard PACS review workstation.

Acquisition sweeps can be performed either at the wall stand or at the table. There are four sweeps available, including:

1. Table Horizontal Sweep: Horizontal sweep of the tube for supine imaging
2. Wallstand Vertical Sweep: Vertical sweep of the tube for upright imaging
3. Wallstand Horizontal Sweep: Horizontal sweep of the tube for supine imaging at the wall stand (requires extended arm and mobile table)
4. Wallstand Cross-table Sweep: Cross-table sweep of the tube for cross-table imaging at the wall stand

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**Trademark of the National Electrical Manufacturers Association (NEMA)
Expanded indication for use – the detection of lung nodules

A recent international multicenter clinical trial has demonstrated that VolumeRAD imaging of the chest offers improved detection and management of patients with lung nodules compared to conventional radiography.

VolumeRAD is intended for diagnostic imaging of the chest and is indicated for the detection of lung nodules for patients undergoing thoracic imaging. As the first radiographic tomosynthesis product with a specific indication, this advanced application improves the detection of lung nodules and the subsequent management of patients.

VolumeRAD generates diagnostic images of the chest that enable the radiologist to detect small lung nodules with superior sensitivity versus posterior–anterior (PA) and left lateral views of the chest at a minimal relative radiation level (<0.1 mSv). VolumeRAD aids the radiologist in being more accurate in identifying patients who require follow-up† compared to conventional two-view chest X-ray (CXR).

“We would love to have fewer indeterminate false positives that require additional follow-up.”

Voice of the Customer

“I can make a more accurate, more confident diagnosis without referring everyone to CT. We need to minimize the radiation exposure to healthy patients, and limit costs for patients and their HCPs.”

Voice of the Customer

†Defined as recommendations for further advanced imaging, based upon the Fleischner Society guidelines for pulmonary nodule management.
Embrace the benefits of VolumeRAD Tomosynthesis...

For patients

- Patients benefit from improved sensitivity without decreased specificity:
  - Those presenting with a lung nodule are more likely to receive an accurate recommendation for appropriate follow-up
  - The increased sensitivity is not achieved at the expense of additional false positive findings
- Small lung nodules are more likely to be detected with VolumeRAD compared to conventional chest radiography
- Patients benefit from the low dose of VolumeRAD:
  - With a VolumeRAD Tomosynthesis exam, including a standard PA image, patients receive only 1.6 times more radiation than they do with a two-view (PA and LAT) chest X-ray exam.

<table>
<thead>
<tr>
<th>EFFECTIVE DOSE (mSv)</th>
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<tr>
<td>2-View CXR (PA and LAT)</td>
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<tr>
<td>Thoracic VolumeRAD Sweep</td>
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<tr>
<td>Average Annual Dose from Natural Background radiation in US²</td>
</tr>
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<td>Thoracic CT²</td>
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</tbody>
</table>

“...I need to have higher sensitivity to lung nodules earlier in the patient’s care cycle.”

Voice of the Customer

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Embrace the benefits of VolumeRAD Tomosynthesis...

For radiologists

- Superior lung nodule detection sensitivity compared to conventional CXR
- Improved identification of cases that require follow-up† (1.5 times more sensitive than two-view CXR without decreased specificity)
- Improved conformity with guidelines for patient follow-up and care
- Improved sensitivity of detection of small lung nodules in the range of 3–20 mm in diameter; 3.6 times more sensitive than conventional two-view CXR, without decreased specificity††
- A minimal-dose, volumetric imaging technique with the simplicity and efficient workflow of conventional chest X-ray; superior to CXR for lung nodule detection

Sensitivity for Pulmonary Nodule Detection Relative to CXR Sensitivity for 3–20 mm Nodules

I think they’re intuitive to read, so even people who haven’t trained on them before can read them easily. The whole appearance of the image is intuitive. It doesn’t take much longer than a radiograph to interpret.

Voice of the Customer

†Defined as recommendations for further advanced imaging, based upon the Fleischner Society guidelines for pulmonary nodule management.

††See the clinical study highlights on the next page for sensitivity values at specific nodule size ranges.
Clinical study highlights

**Primary endpoint**
Determine whether the use of VolumeRAD increases physician accuracy in the detection of lung nodules between 3 and 20 mm in diameter when compared to conventional two-view chest radiography.

**Secondary endpoint**
Determine whether the use of VolumeRAD increases physician accuracy in the identification of cases recommended for follow-up and further imaging, per the Fleischner Society Guidelines.1

**Study design**
**Patient sample:** 158 patients undergoing thoracic imaging as part of routine care. 115 patients had at least one CT-confirmed pulmonary nodule and 43 did not. 516 total nodules between 3 and 20 mm. No clinical evidence has been established supporting the following claims in patients with active lung or pleural disease that could obscure pulmonary nodules, including fibrosis, emphysema, compressed lung, scarring, severe lung disease, and in patients with objects in or around the lungs that could obscure pulmonary nodules. The effectiveness of the device may vary depending on nodule prevalence and type.

**Reader study:** Five general radiologists read all cases with both conventional X-ray and VolumeRAD.

**Reference standard:** CT, determined independently by a panel of three board-certified expert thoracic radiologists.

**Statistical analysis:** Multi-reader, multi case, free-response ROC analysis of individual nodule localizations (JAFROC4)
ROC analysis of actionability decisions for each case.

**Primary endpoint results – Nodule detection (VolumeRAD relative to conventional CXR)**

<table>
<thead>
<tr>
<th>NODULE SIZE RANGE</th>
<th>INCREASE IN SENSITIVITY</th>
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<tbody>
<tr>
<td>3–4 mm</td>
<td>2.8 fold (or 2.8x)</td>
</tr>
<tr>
<td>4–6 mm</td>
<td>7.5 fold (or 7.5x)</td>
</tr>
<tr>
<td>6–8 mm</td>
<td>2.9 fold (or 2.9x)</td>
</tr>
<tr>
<td>8–20 mm</td>
<td>2.1 fold (or 2.1x)</td>
</tr>
<tr>
<td>3–20 mm</td>
<td>3.6 fold (or 3.6x)</td>
</tr>
</tbody>
</table>

**Nodule specificity:** No difference between VolumeRAD and two-view chest radiography

**JAFROC Figure of Merit:** 8.1% increase (for nodules 3–20 mm)

**Secondary endpoint results – ROC analysis of case actionability**

**Sensitivity:** 1.5 times improvement in identifying cases that require follow-up with further imaging

**Specificity:** No difference between VolumeRAD and two-view chest radiography

**Area under ROC curve:** 13.5% increase

All results significant at p <0.05, for all readers and all cases.

**Further information**


Accuracy and confidence

The [VolumeRAD] workflow is quite easy. It doesn’t take much longer than a radiograph to interpret, making it very straightforward. And the images are simple to read with a familiar look to them, further supporting workflow.

Voice of the Customer
About GE Healthcare

GE Healthcare provides transformational medical technologies and services that are shaping a new age of patient care. Our broad expertise in medical imaging and information technologies, medical diagnostics, patient monitoring systems, drug discovery, biopharmaceutical manufacturing technologies, performance improvement and performance solutions services help our customers to deliver better care to more people around the world at a lower cost. In addition, we partner with healthcare leaders, striving to leverage the global policy change necessary to implement a successful shift to sustainable healthcare systems.

Our “healthymagination” vision for the future invites the world to join us on our journey as we continuously develop innovations focused on reducing costs, increasing access and improving quality around the world. Headquartered in the United Kingdom, GE Healthcare is a unit of General Electric Company (NYSE: GE). Worldwide, GE Healthcare employees are committed to serving healthcare professionals and their patients in more than 100 countries. For more information about GE Healthcare, visit our website at www.gehealthcare.com.

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Data subject to change.
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