
ONGUARD PRODUCT FAQ's

1. What is OnGuard?
 - a. OnGuard is a computer aided detection product for detection of solitary pulmonary nodules from 9 to 30mm.
2. How does OnGuard work?
 - a. The OnGuard **software** works by analyzing a chest x-ray for regions that resemble solitary pulmonary nodules. To accomplish this, OnGuard detects and segments objects it considers to be candidate nodules. It then analyzes these regions by computing features to describe each of the candidate regions in detail. Regions with descriptions that are recognized to resemble a solitary pulmonary nodule are marked as regions of interest by the software.
 - b. The OnGuard **server** works by accepting standard PA/AP chest x-ray images either directly from the modality or PACS, processing the image to identify regions of interest, and then sending the CAD image to the PACS to be joined with the original study.
3. What do you mean when you say "Pattern Recognition"?
 - a. Pattern recognition is a foundational discipline of the information sciences. It combines theoretical results from engineering, mathematics, statistics and computer science in order to analyze data for patterns. Patterns constitute regularities – predictable behavior – within the data. In the context of OnGuard, we seek to detect patterns indicative of suspicious nodules within chest x-ray images.
4. What is the clinical benefit?
 - a. A multi-reader, multi-case study was conducted by researchers at Georgetown University as part of the FDA-PMA approval process. The independent set of images used for the study contained normal cases and those with truth confirmed cancer. The study demonstrated that a reader aided with OnGuard was statistically superior to the unaided reader based on the area under the localized receiver operating characteristic curve.
 - i. OnGuard 5.1 Reader Study for FDA PMA Approval 2009

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- b. The clinical benefit is an increase in nodule detection from a reduction in oversight errors. Studies have shown the use of OnGuard can result in as much as 30% and almost 50% improvement of missed cancers being detected.
 - i. Li F, Engelmann R, Metz CE et al: Lung Cancers Missed on Chest Radiographs: Results Obtained with a Commercial Computer-aided Detection Program. *Radiology*: Volume 246: Number 1, January 2008.
 - ii. White CS, Flukinger T, Jeudy J, and Chen JJ. Use of a Computer-aided Detection System to Detect Missed Lung Cancer at Chest Radiography *Radiology* 252, 2009.
 5. Does the image become part of the permanent record?
 - a. Yes.
 6. Is OnGuard on a dedicated review station?
 - a. No, the OnGuard image is stored as part of the original patient study and is available for review on the existing PACS review station with the original study.
 7. Will it work with my PACS? Will it work with all PACS?
 - a. OnGuard is fully DICOM compliant and will work on all PACS systems.
 8. How many false positives does OG have?
 - a. On average, less than 1.5 false positives. The newest version demonstrates a 73% reduction in false positives and a 50% relative improvement in sensitivity.
 9. How much storage does it take?
 - a. Depending on implementation, the additional storage per study can be as small as a few bytes for overlays to as large as 10MB for an image with burned in annotations.
 10. Who sees the image?
 - a. Generally, anyone with access to the studies would also have access to the OnGuard image as it is stored on the PACS with the original study. However, in some installations controls on the PACS have been exercised to exclude access to specific readers, e.g., referring physicians.

11. Is there reimbursement?

- a. There is no reimbursement by Medicare, but there is some third party reimbursement at this time.

12. Are there any clinical publications available or in development on OnGuard?

- a. Li F, Engelmann R, Metz CE et al: Lung Cancers Missed on Chest Radiographs: Results Obtained with a Commercial Computer-aided Detection Program. *Radiology*: Volume 246: Number 1, January 2008.
- b. White CS, Flukinger T, Jeudy J, and Chen JJ. Use of a Computer-aided Detection System to Detect Missed Lung Cancer at Chest Radiography *Radiology* 252, 2009.

13. Are there any claims to be made on improved nodule detection rate?

- a. See above publications.

14. How does OnGuard effect workflow?

- a. Individual results vary, and workflow accelerates as one becomes accustomed to reading with OnGuard. Generally, we would anticipate the CAD requires only a few additional seconds.

15. How long does it take to process an image?

- a. The average processing time per image is less than 1.5 minutes.

16. Where is OnGuard available for sale?

- a. OnGuard 5.1 is available in U.S. Canada and EU.