

The information in this supplement provides details on the performance evaluation of Genius AI® Detection software version 2.0 in comparison to the previously released Genius AI Detection software. Details are also provided on the accuracy of CC-MLO Correlation software.

1. Genius AI Detection Software v2.0

Following the release of the first version of Genius AI Detection software, Hologic® continued to improve the cancer detection algorithm for 3D breast tomosynthesis images. The improved algorithm is referred to as Genius AI Detection software 2.0. The study results of the updated version of Genius AI Detection software shows improved specificity of the originally released Genius AI Detection software by reducing the number of false positive marks.

In addition to improved specificity, the marks generated by Genius AI Detection software 2.0 also offer additional information regarding correlation of marks between the standard screening orthogonal views (CC and MLO). Such information is generated by an independent algorithm that operates on regions of interest indicated by Genius AI Detection software 2.0 marks. Review workstations can utilize the CC-MLO correlation information to display this lesion pair in some manner that can be useful to the user and indicate marks that correspond to same regions of interest.

2. Study Design

2.1 Genius AI Detection Software

The study evaluated the performance of Genius AI Detection software 2.0 in comparison to the previously released Genius AI Detection software. The performance comparison was done using fROC analysis and key metrics at each product's operating point. A single sequestered dataset of Hologic's 3D™ breast tomosynthesis exams was used to compare the detection performance between the already released Genius AI Detection software and Genius AI Detection software 2.0. Primary standalone performance comparison between Genius AI Detection software 2.0 and Genius AI Detection software was done using fROC curves and key performance metrics on Hologic's current high resolution image acquisition mode (Hologic Clarity HD® imaging technology). In addition, a supplemental analysis was also done to compare the performance stratified by two acquisition modes (high and standard resolution), lesion types (calcifications versus masses), and breast density (dense and fatty breasts).

2.2 CC-MLO Correlation Software

The study evaluated performance of CC-MLO Correlation software by comparing suggested CC-MLO correlated pairs of Genius AI Detection software marks against the ground truth pairs of biopsied malignant lesions that were identified by an expert radiologist. In addition, an expert radiologist also reviewed and evaluated the predicted pairs of CC-MLO correlated marks on screening negative cases to assess the accuracy of the pairing predicted by the CC-MLO Correlation feature.

3. Conclusions

3.1 Genius AI Detection Software 2.0

The results of the standalone performance evaluation between Genius AI Detection software 2.0 and the previously released Genius AI Detection software illustrated in this analysis confirms that performance of Genius AI Detection software 2.0 meets or exceeds the performance of the previously released Genius AI Detection software on every aspect of this standalone evaluation in either high resolution or standard resolution acquisition modes.

1. Genius AI Detection software 2.0 maintains the same high sensitivity of 94% as the previously released Genius AI Detection software.
2. The overall false positive mark rate at the Genius AI Detection software 2.0 operating point illustrates a significant reduction by close to 0.3 false marks (from 0.53 to 0.23) per view, which is equivalent to a reduction of 1.2 marks per case when compared to the previously released Genius AI Detection software. This amounts to over 50% reduction in false positive marks.
3. The specificity as defined by the percentage of the number of cases with no marks on the set of non-cancer cases (including or excluding biopsy benign cases) increased significantly by about 12% in Genius AI Detection software 2.0 compared to that of the previously released Genius AI Detection software.
4. The observed specificity of Genius AI Detection software 2.0 on non-cancer cases excluding biopsy benign cases was 59%. Thus, overall, more than half of the screening negative cases had no marks.
5. The overall improvements observed in fROC performance for Genius AI Detection software 2.0 against the previously released Genius AI Detection software hold when fatty and dense breasts were analyzed separately.

3.2 CC-MLO Correlation Software

The CC-MLO Correlation algorithm is highly accurate in biopsied malignant cases where Genius AI Detection software 2.0 marked the same lesion in the two orthogonal views. For screening negative cases, a large majority of identified correlations are accurate based on an expert radiologist's opinion.

Thus, based on an analysis of 106 biopsy-proven cancer cases and 658 negative cases:

- The CC-MLO Correlation algorithm accurately correlated the Genius AI Detection software 2.0 marks on 97% of the biopsy-proven malignant lesions when the lesions were accurately marked by the Genius AI Detection software 2.0 algorithm in both views. When all the malignant lesions including those not marked by Genius AI Detection software 2.0 algorithm in both views were considered, the accuracy of correlation was 64%.
- 82% of the pairs of the Genius AI Detection software 2.0 marks on negative cases (including screening negative and biopsied benign cases) that were correlated by the CC-MLO Correlation algorithm were considered by an expert radiologist as correctly correlated for being in the same region of interest in the breast.
- The CC-MLO Correlation algorithm gave an incorrect correlation on less than 5% of marks on biopsy-proven malignant ROIs and less than 18% of marks on negative and benign ROIs.