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FDA nod for Siemens Mammography Platform

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The Food and Drug Administration (FDA) has approved the MAMMOMAT Inspiration with Tomosynthesis Option - the breast tomosynthesis add-on option for Siemens Healthcare's MAMMOMAT Inspiration digital mammography platform.

Siemens' breast tomosynthesis algorithm reconstructs multiple 2D images of the breast into an approximation of a 3D image to enable detection of tumors that are hidden by overlapping breast tissue, enabling more accurate diagnosis than standard 2D digital mammography and reducing the number of false-positive findings. In a recent study involving 22 readers with a broad range of reading experience, Siemens demonstrated that all readers improved their accuracy in detecting and diagnosing cancers when reading digital breast tomosynthesis as an adjunct to full-field digital mammography.

In tomosynthesis mode, the X-ray tube of the MAMMOMAT Inspiration digital mammography system rotates in a circular motion around the breast to acquire an image every two degrees while moving through an angular range of 50 degrees. The resulting 25 projections are reconstructed as three-dimensional (3D) digital breast tomosynthesis (DBT) images.

Conventional analog mammography and full-field digital mammography display only the 3D structure of the breast on a 2D level, hampering physicians' efforts to identify certain types of tumors since anatomical structures in the breast can overlap and obscure lesions. Tomosynthesis acquires several breast projections from different angles and uses raw data to generate a 3D volume set. Using this data set, clinicians can better analyze the type and size of breast lesions as well as microcalcifications compared to other forms of mammography. Breast tomosynthesis increases mammography's sensitivity and specificity, in addition to improving efforts to differentiate and classify breast tumors.

"Our clinical data has demonstrated that the addition of Siemens' digital breast tomosynthesis to a patient's traditional 2D digital mammogram increases detection of breast tumors. We know that in clinical practice, this increased diagnostic accuracy also means fewer diagnostic biopsy procedures and fewer anxiety-inducing recalls, which typically contributes to both improved patient outcomes and reduced cost," said Mr Gregory Sorensen,president and CEO of Siemens Healthcare North America. "With the FDA approval of the MAMMOMAT Inspiration with Tomosynthesis Option, Siemens Healthcare reaffirms its longstanding commitment to cutting-edge innovation in women's health."