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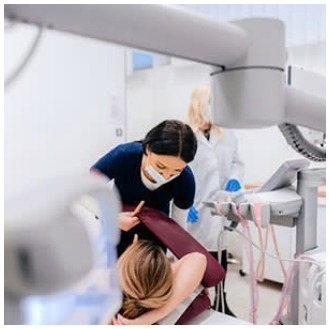
FDA Approves Delphinus 3D Whole Breast Ultrasound System



The U.S. FDA recently granted PMA approval to Delphinus Medical Technologies' SoftVue™ 3D Whole Breast Ultrasound Tomography System. This system is intended to supplement digital mammography for cancer screening women with dense breasts. About 40% of U.S. women have dense breast tissue, a risk factor for breast cancer. This risk is three-to-six times higher in dense than fatty breast tissue. Unfortunately, mammography is less sensitive in dense breast tissue, which means alternate screening methods are necessary.

The company compared the diagnostic efficacy of combining mammography with the SoftVue 3D ultrasound to mammography alone in a multisite clinical trial (NCT0325839). About 32 radiologists across ten U.S. clinical sites read images from over 8500 patients. SoftVue increased sensitivity by 20% and specificity by 8% over mammography screening alone. Thus, SoftVue enhanced dense breast screening by better identifying and distinguishing between normal and abnormal lesions leading to greater accuracy and potentially fewer biopsies. After their SoftVue exam, about 95% of surveyed women said that they would recommend SoftVue to others.

Unlike traditional ultrasound, which utilises only reflection, SoftVue 3D uses a proprietary technology [TriAD (Triple Acoustic Detection)] to characterise tissue by recording sound wave reflection, speed, and direction moving through breast tissue. During the exam, the patient lies in prone position with her breast submerged in a warm water bath. A disposable gel pad stabilises and centres the breast. Imaging is performed with a 360-degree ring transducer, capturing new images every two millimetres. The system scans each breast from chest wall to nipple in an about three minutes. Captured signals are then algorithmically analysed to provide cross-sectional slices of the breast tissue.

Mark J. Forchette, president and chief executive officer at Delphinus, said: 'Our SoftVue System delivers a breakthrough in tissue characterization and improves the ability to find cancers in dense breast patients. It will be a game changer that will transform clinical practice with a fundamentally new, and highly impactful approach… The SoftVue PMA approval opens the door to a technological advance in dense breast screening that will help physicians save lives.'

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