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FDA's New Policy to Increase Use of 3-D Digital Breast Screening Tools Will Be Market Driver for Breast CT

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There is mounting evidence from many sources about mammography being an inferior method for identifying or helping in the diagnosis of suspicious breast lesions that may be cancer. [See article links at the end of this press release].

Some informed sources say mammography is completely unnecessary, and others go as far to say that mammography causes more harm than good. Regardless, mammography is the current gold standard for breast screening, which is evidenced by the over 20,000 mammography units in use daily in the USA, and by the approximately forty (40) million women in the US who will have a mammogram in 2019.

Most women believe breast cancer screening is reliable, identifies cancers at an early stage, and reduces the mortality of breast cancer by allowing it to be treated earlier – and this is true. Although concerns with the reliability of mammography appear widespread, early diagnosis is nevertheless a critical factor in reducing mortality. There is a distinct lack of alternatives for breast cancer screening for women presently, and many ask why, that in our technologically advanced world, an affordable and accurate technology has not emerged. Such a technology needs to be superior to mammography in reducing false positives and increasing the cancer detection rate and eliminating breast compression would be a bonus – since more than 10% of women avoid mammography because of the discomfort of breast compression.

Mammography is the current gold standard, but we believe that along with tomosynthesis, ultrasound and MRI, mammography will soon face stiff competition from dedicated breast CT imaging.

In March of this year, the FDA published a news release entitled “FDA advances landmark policy changes to modernize mammography services and improve their quality” in which an FDA Commissioner explains that the organization is *“proposing new policies to modernize (the FDA’s) oversight of mammography services, by capitalizing on a number of important advances in mammography, like the increased use of 3-D digital screening tools and the need for more uniform breast density reporting... to ensure patients continue to benefit from advances in new tools and robust oversight of this field.”* [emphasis added]

The time for measurable advancements in breast imaging technology is nearing as the company continues its product development, its U.S. patent prosecutions and plans to commercialize. Breast CT is a breast imaging technology that utilizes true 3D computed tomography technology, that eliminates the need for breast compression and overcomes the problem of breast density. Our goal is to see breast CT adopted by the breast imaging community and replace 2D mammography and pseudo-3D tomosynthesis.



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Izotropic believes that this is achievable and is committed to delivering a new imaging technology that dramatically improves diagnostic accuracy, reduces negative biopsy rates, does so in a cost-effective manner and which also eliminates breast compression.

The company is encouraged to see this FDA policy supporting 3D technology and expects its Breast CT technology to be welcomed by hospitals and care providers and beneficial to patients in future.

Article Links

FDA Press Release

<https://www.fda.gov/news-events/press-announcements/fda-advances-landmark-policy-changes-modernize-mammography-services-and-improve-their-quality>

Forbes.com

<https://www.forbes.com/sites/nextavenue/2015/11/02/the-breast-cancers-mammograms-are-likely-to-miss/#3b474aca7d29>

National Cancer Institute

<https://www.cancer.gov/types/breast/mammograms-fact-sheet>

New England Journal of Medicine

<https://www.nejm.org/doi/pdf/10.1056/NEJMp1401875?articleTools=true>

NaturalNews.com

https://www.naturalnews.com/055806_breast_cancer_mammography_harming_women.html

About Izotropic Corp.

The company is engaged in the development and commercialization of 3-D breast CT imaging technology for early diagnosis of breast cancer, that improves patient comfort, provides true high-resolution images and delivers high diagnostic accuracy. The company has also established Izotropic Imaging Corp, a wholly owned Nevada based subsidiary that will manage operations in the U.S.A.

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