

Densitas Gets Approval for Canada, EU

Weeks after announcing a \$250,000 equity investment, Halifax-based [Densitas](#) has received regulatory clearance in the European Union and Canada to sell its first product, DM-Density.

When the company revealed its \$250,000 funding from [Innovacorp](#) in October, it said it would use the money to finance the launch of DM-Density, which enhances breast screening by assessing the density of the breast being examined. Breast density is a key determinant in a patient's risk of contracting breast cancer, so Densitas helps doctors understand a patient's risk profile.

"It's exciting to have DM-Density entering markets with such great potential for sales," said CEO Mohamed Abdolell in a statement Tuesday. "Our products will address the real clinical challenges in the mammography enterprise, focusing on key value pathways that lead to improved care for women."

[Innovacorp Invests \\$250K in Densitas](#)

While attending the annual Radiological Society of North America conference in Chicago, Abdolell said the product had received the CE Mark from the European Commission and a medical device license from Health Canada. Plans are also underway to secure regulatory clearance for DM-Density in the United States.

Radiologists use DM-Density when reviewing a woman's mammogram to assess breast density. Accurately assessing breast density is an important part of the mammography process, as dense breasts have a higher risk of developing breast cancer, and the dense breast tissue makes it challenging to differentiate it from cancer on the X-ray image.

DM-Density is the first of a series of mammography imaging products that are currently in various stages of development by Densitas.

The company's website details a few of the coming iterations – DM-Dose, a radiation dose-reporting solution for mammography; DM-Analytics, which processes the vast amount of data generated by mammography; DM-Workflow, which is a mammography workflow solution; and DM-Research, which helps to process digital mammograms used in research.

In May, Densitas received certification from the International Standards Organization, or ISO, which means customers in international markets are assured that Densitas products meet national standards throughout their lifespan.

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