

## Company announcement

# PME receives FDA clearance for Breast Density Algorithm

2 February 2021

### HIGHLIGHTS

- **First Artificial Intelligence (AI) algorithm developed by PME**
- **Developed using PME's unique end to end AI Accelerator solution**
- **FDA clearance is in addition to previously received CE (Europe) and TGA (Australia) approvals**
- **Paves the way for commercialisation in North America, Europe and Australia**
- **Opens up further research collaboration opportunities**

Leading health imaging company Pro Medicus Limited [ASX: PME] today announced that it has received FDA clearance for its Breast Density AI Algorithm. This is in addition previously receiving CE clearance (Europe) and TGA clearance (Australia) paving the way for the company to market the algorithm across all three jurisdictions.

The Breast Density algorithm is intended for use with compatible full field digital and digital breast tomosynthesis systems. It assesses breast density from a mammography study and provides an ACR BI-RADS Atlas 5th Edition breast density category to aid radiologists in the assessment of breast tissue composition.

“We developed this algorithm using our own AI Accelerator platform which enabled us to significantly speed up every stage of the process from concept to FDA approval” said Dr Sam Hupert, Pro Medicus CEO. This not only provides us with a fast-track mechanism to develop our own algorithms in future, it paves the way for further collaborations with the growing number of our research oriented clients”.

Authorised by the Board of Pro Medicus Limited.

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**About Pro Medicus Limited:**

Pro Medicus Limited [ASX: PME] is a leading medical imaging IT provider. Founded in 1983, the company provides a full range of radiology IT software and services to hospitals, imaging centres and health care groups worldwide. In late January 2009, the company announced the purchase of Visage Imaging, which has become a global provider of leading edge enterprise imaging solutions, pioneering the best-of-breed, or Deconstructed PACS® enterprise imaging strategy. Visage 7 technology delivers amazingly fast, multi-dimensional images streamed via an intelligent thin-client viewer. The company offers a leading suite of RIS, PACS and e-health solutions constituting one of the most comprehensive end-to-end offerings in radiology. Pro Medicus has global offices in Melbourne, Berlin and San Diego. [www.promed.com.au](http://www.promed.com.au)