

VolparaEnterprise Software will Help Breast Imaging Providers Comply with FDA's New Enhancing Quality Using the Inspection Program (EQUIP)

Volpara Solutions Launches Support Program to Help Accredited Breast Imaging Centers Become "EQUIP-ready"

WELLINGTON, NZ, November 7, 2016 – Volpara Solutions today announced the launch of the “EQUIP-ready” support program to help the more than 8,700 accredited breast imaging centers in the United States prepare for compliance to the EQUIP initiative, “Enhancing Quality Using the Inspection Program” recently launched by the U.S. Food and Drug Administration (FDA). The “EQUIP-ready” program, which includes draft processes, procedures, and forms designed to help users accelerate their compliance efforts, is included with the company’s Volpara®Enterprise™ cloud-based quality assurance solution.

The EQUIP initiative, launched on October 27, 2016 to coincide with the 25th anniversary of the passage of the Mammography Quality Standards Act (MQSA), emphasizes “the need for ongoing facility review of clinical image quality.” Beginning in 2017, accredited breast screening providers will have to address three new questions to ensure compliance with regulations relating to quality assurance in the FDA’s annual facility inspections. Every facility will need to demonstrate that it has: a corrective action system that can address when clinical images are of poor quality; a means of establishing that clinical images continue to comply with the standards of its accreditation body including quality attributes such as positioning, and include regular reviews of sample images from each technologist and each interpreting physician; and, a procedure for oversight of QA/QC records and corrective actions.

“VolparaEnterprise software is the only solution currently available that provides a comprehensive assessment of image quality on every screening mammogram, including such factors as positioning and compression, which can significantly impact the quality of the image. In fact, the FDA attributes poor positioning to be the cause of most clinical image deficiencies and most failures of accreditation,” said Ralph Highnam, PhD, Volpara Chief Scientist and CEO. “The wide array of quality control features and performance data we provide enhance quality and productivity, and help facilities more easily comply with the new EQUIP requirements.”

VolparaEnterprise software, which delivers key performance indicators (KPIs) for hundreds of performance and quality metrics, including positioning, compression and equipment utilization, is designed to help sites prepare for the EQUIP inspection questions:

- VolparaEnterprise monitors every screening mammogram for image quality issues related to positioning and compression.
- VolparaEnterprise data’s easy sorting by technologist helps isolate cases for EQUIP review.

- VolparaEnterprise can help rapidly locate poor quality images for review during Image Review Quality Meetings (as well as good-quality images for review in preparation for machine accreditation).

Designed to support large or small enterprises, VolparaEnterprise software enables breast imaging providers to provide objective evidence to demonstrate compliance and quality of care. Users can perform rapid quality control checks to optimize the productivity and efficiency of imaging resources, to help reduce costs through the reduction of retakes, and to increase staff effectiveness. The Microsoft Azure-based solution provides real-time quality assurance and performance monitoring through dynamic, interactive dashboards.

Further information from the FDA regarding the EQUIP initiative can be found here: [EQUIP: Enhancing Quality Using the Inspection Program](#)

About Volpara Solutions

Founded with the goal of helping radiologists give women the most accurate information possible regarding their breast health, Volpara Solutions is the wholly owned sales and marketing arm of Volpara Health Technologies Limited of New Zealand (formerly Matakina Technology). Available in most markets where breast cancer screening is commonplace, VolparaDensity provides an objective volumetric measure of breast density from both digital mammography and tomosynthesis data. VolparaDensity is part of a suite of quantitative breast imaging tools built on the Volpara Solutions algorithm that allows for personalized measurements of density, patient-specific x-ray dose, breast compression, breast positioning and other factors designed to provide critical insight for breast imaging workflow. For more information, visit www.volparasolutions.com.

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Media Contacts:

Chris K. Joseph
Volpara Solutions
+1.510/435-4031
chris.joseph@volparasolutions.com