HEALTHCARE

Densitas AI platform automates breast density, image quality, and breast cancer risk assessment

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densitas

Mammography providers require automated, reliable, and reproducible tools to deliver breast density, image quality, and breast cancer risk results in a manner that optimizes radiology workflows. The Densitas AI platform delivers standardized, on-demand results that integrate seamlessly into existing processes to address time-consuming, subjective, and fatiguing tasks. Resulting efficiency gains enable care teams to focus on more critical aspects of their role. FDA-cleared Densitas models are being integrated into PowerScribe via the Nuance AI Marketplace and PowerShare Network, connecting 8,000+ healthcare facilities in the U.S.

In a value-based healthcare environment, mammography providers and facilities require automated tools that support efficient workflows and deliver needed clinical insights, while providing the qualitative and quantitative data necessary to meet standard reporting requirements. Densitas® has developed AI solutions for digital mammography designed for value-based care delivery that enable mammography practices and health systems to cost-effectively provide high-quality care and improve clinical outcomes for their patients.

Mo Abdolell, **CEO of Densitas**, shares his perspectives about the Densitas journey and the impact of their pioneering AI solutions for the breast imaging industry.

Jonathon Dreyer: Tell us about your business—when and how you started and your development journey.

MA: The company was founded to address radiologists' need for fully automated, reliable, and reproducible tools that processed mammograms in

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a way consistent with how radiologists see breast tissue on mammograms. The only available solutions were based on physics models that did not address this need. It was immediately obvious that it was time to take an innovative approach by applying modern AI techniques to tackle these challenges. This led to the development of **densitas®** intelli**Mammo™**, a comprehensive AI platform that delivers breast density, clinical image quality, and short-term breast cancer risk results that are reliably reproducible and aligned with how radiologists see mammograms.

As part of this journey, I have been fortunate to work with extraordinary individuals and teams at the intersection of artificial intelligence, medicine, and engineering with a focus on developing solutions that help clinical care teams deliver better patient outcomes.

JD: What AI solutions do you have and what do they do?

MA: The **densitas®** intelli**Mammo™** software platform provides a set of AI models that assess breast density, clinical image quality, and breast cancer risk in a comprehensive, advanced analytics and workflow solution for mammography facilities.

densitas® intelli**Mammo™** comprises **densitas®** density**ai™**, quality**ai™**, and risk**ai™** models that provide the foundation for an advanced embedded analytics platform that enables benchmarking, monitoring, trend detection, and corrective actions uniquely using data from current and prior standard DICOM mammograms that are routinely archived on PACS. Additionally, **densitas®** intelli**Mammo™** digitalizes reporting, quality assurance, and workflows with automated worklist generation, electronically documented corrective actions, and simple on-demand generation of comprehensive audit reports.

densitas density**ai** is FDA 510(k) cleared as a Class II medical device; **densitas** quality**ai** and **densitas** risk**ai** are both registered with the FDA as Class I medical devices and are also cleared for sale.

— **densitas** density**ai** provides qualitative breast density assessments that align with the ACR BI-RADS Atlas 5th edition breast density scale as well as quantitative percent mammographic density; each of these density scales has its own dedicated deep learning model.

— **densitas** quality**ai** provides mammography clinical image quality, focusing on positioning errors at the

point of care to enable more effective and efficient management of mammogram image quality before the patient leaves the exam room.

— **densitas** risk**ai** provides rapid, short-term breast cancer risk assessments without the extensive patient clinical histories that traditional models require. It enables worklist prioritization using image-derived risk factors to provide personalized risk scores that identify priority risk patients at the point of care.

JD: What's the big "Aha" moment when you first show users what your AI application(s) can do for them?

MA: When users see the AI automation of workflows for their mammography practice, they immediately react with a response of, "Every mammography facility needs to be using this software."

Radiologists appreciate the on-demand access to AI results at the time of their reporting on mammography exams and the significantly increased efficiencies gained in reporting workflows in their role as interpreting physicians under the FDA MQSA EQUIP framework. Radiological technologists value the availability of AI results at the point of care that provide real-time second-reader assessments on clinical image quality. QC technologists and diagnostic imaging managers value having access to a continuous quality assurance platform that enables mammography facility quality oversight and benchmarking performance.

JD: What challenges or needs did you see that drove you to focus on this?

MA: There was a need for a unified solution that provides AI automation and digitalization to clinical care teams and facility managers, with on-demand access to advanced analytics supporting value-based care decision making. The challenges covered several areas.

— Mammography facility certification hinges on a facility's ability to demonstrate effective implementation of the FDA Mammography Quality Standards Act (MQSA) Enhancing Quality Using the Inspection Program (EQUIP) criteria. For example, the lead interpreting physician must ensure proper maintenance and updates of records concerning quality control and patient positioning, and corrective actions in the event of inadequate clinical image quality. The MQSA EQUIP also requires establishment of a QA program and maintenance of associated records and sets stan-

dards. Subjective visual assessment of clinical image quality makes continual on-demand quality assurance and benchmarking impossible. Administration of a quality system that is the responsibility of the LIP and lead QC technologist is time-consuming and not reimbursable.

— The move to improve appropriateness of care drives the adoption of risk-based stratification of breast screening-eligible women to help determine appropriate adjunct imaging, such as breast MRI and breast ultrasound following a mammogram. But generating rapid and reliably reproducible breast cancer risk assessments for every woman is not typically feasible using classical breast cancer risk models. This is because such models require data inputs that are usually not universally available, are time-consuming and resource-intensive to collect, and are based on subjective assessments and unreliable patient self-reports of risk factors.

Densitas has developed AI solutions for mammography focused on cost-effective delivery of high-quality breast health care and patient experience while reducing the workload on clinical care teams and mitigating risk of radiologist burnout.

JD: What's the number one benefit you offer?

MA: Our AI models integrate seamlessly into existing workflows to support clinical care teams in mammography facilities. Our automated solutions provide standardized and on-demand results that address routine, time-consuming, subjective, and fatiguing tasks. The resulting efficiency gains enable clinical care teams to focus on more critical aspects of their role.

JD: Are there any stories you can share about how your AI solutions drove measurable patient care outcomes?

MA: A Headroom analysis by the Institute of Health Economics shows that the use of **densitas®** intelli**Mammo™** to help avert 50% of all technical recalls (assuming 2.5% technical recall rate in standard care) may potentially yield an average health benefit of nearly one extra day lived in perfect health per woman participating in a breast cancer screening program. This translates into nearly 273 extra years collectively for all women in a health system with 100,000 women participating in

a breast cancer screening program.

Additionally, **densitas®** intelli**Mammo™** to help radiological technologists achieve 100% good quality images may potentially yield an average health benefit of 9.5 extra days lived in perfect health per 50-year-old female participating in a breast cancer screening program.

JD: What benefits does Nuance, and its AI Marketplace for Diagnostic Imaging bring to your users? What problems does the marketplace and integration into Nuance's workflow solve?

MA: Mammography is a high-volume reading setting in which exam results must be comprehensively and efficiently recorded in structured reports. Visually evaluating and manually recording standardized and reproducible breast density, clinical image quality, and breast cancer risk results are time-consuming steps that can distract from the radiologist's primary task of cancer detection. The integration of the **densitas®** intelli**Mammo™** AI models with Nuance PowerScribe 360 and PowerScribe One reporting workflows provides on-demand, automated solutions that address these key challenges. Radiologists will appreciate the zero-click process that delivers standardized and reliably reproducible results and efficient reporting workflows in compliance with state and federal laws mandating breast density and quality.

JD: What has your experience been working with the Nuance team?

MA: In designing the integration of our AI solutions for mammography, the Nuance team quickly understood the unique reporting workflows that mammographers must manage. The Nuance team is composed of members with broad experience in the medical image reporting domain, enabling them to seamlessly assimilate our AI models into the AI Marketplace infrastructure and PowerScribe reporting workflow. The team's extensive experience has streamlined our integration efforts and allowed us to identify opportunities for even deeper technical collaboration.

JD: What is your vision for how your solution(s) will evolve over the next five years?

MA: Densitas will continue to expand our **densitas®** intelli**Mammo™** platform and AI models, focusing on

advanced analytics, reporting, and workflow optimization. Our goal is to develop an increasingly intelligent platform that will further improve reporting workflows and process management for better patient and health system outcomes.

JD: In one sentence, tell us what you think the future of medicine will look like.

MA: The ever-increasing volumes of medical data being generated at greater velocity will continue to overwhelm physicians who are already experiencing data overload and high burnout rates; those who use AI to augment their practice will replace those who do not.

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To learn more about Nuance AI Marketplace for Diagnostic Imaging, please visit: https://www.nuance.com/healthcare/diagnostics-solutions/ai-marketplace.html