



OUR PURPOSE  
OUR PASSION  
OUR PROMISE

ConDENSED  
Solutions for  
MQSA Guidelines

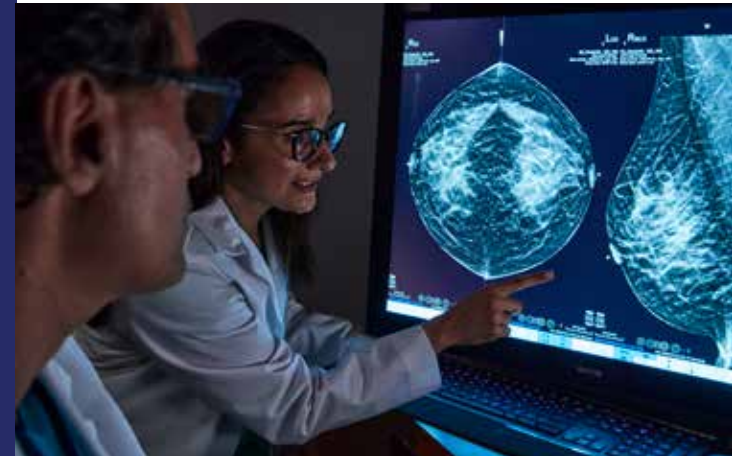
## Transforming Women's Health



\*compared to 2D alone

**References:** 1. F. R. (2023, March 10). Mammography Quality Standards Act Vol. 88, No. 47. Federal Register- The Daily Journal of the United States Government. Retrieved March 30, 2023, from <https://www.govinfo.gov/content/pkg/FR-2023-03-10/pdf/2023-04550.pdf>. 2. FDA submissions P080003, P080003/S001, P080003/S004, P080003/S005, P080003/S006. 3. Friedewald SM, Rafferty EA, Rose SL, et al. Breast cancer screening using tomosynthesis in combination with digital mammography. JAMA. 2014 Jun 25;311(24):2499-507. 4. Data on file and from public sources, 2017 5. Zuckerman SP, Conant EF, Keller BM, et al. Implementation of Synthesized Two-dimensional Mammography in a Population-based Digital Breast Tomosynthesis Screening Program. Radiology. 2016 Dec;281(3):730-736. 6. Skaane P, Bandos A, Eben EB, et al. Two-view digital breast tomosynthesis screening with synthetically reconstructed projection images; comparison with digital breast tomosynthesis with full-field digital mammographic images. Radiology. 2014 Jun;271(3):655-63. 7. Bernardi D, Macaskill P, Pellegrini M, et al. Breast cancer screening with tomosynthesis (3D mammography) with acquired or synthetic 2D mammography compared with 2D mammography alone (STORM-2): a population-based prospective study. Lancet Oncol. 2016 Aug;17(8):1105-13. 8. McDonald ES, Oustimov A, Weinstein SP, et al. Effectiveness of Digital Breast Tomosynthesis Compared With Digital Mammography: Outcomes Analysis From 3 Years of Breast Cancer Screening. JAMA Oncol. 2016 Jun 1;2(6):737-43. 9. Rafferty EA, Durand MA, Conant EF, et al. Breast Cancer Screening Using Tomosynthesis and Digital Mammography in Dense and Nondense Breasts. JAMA. 2016 Apr 26;315(16):1784-6. 10. DHM-05051-002

MISC-08988 Rev.001 (4/23) Hologic Inc. ©2023 All rights reserved. Hologic, C-View, Genius, Intelligent 2D, Quantra, The Science of Sure and associated logos are trademarks and/or registered trademarks of Hologic, Inc., and/or its subsidiaries in the United States and/or other countries. This information is intended for medical professionals in the U.S. and other markets and is not intended as a product solicitation or promotion where such activities are prohibited. Because Hologic materials are distributed through websites, eBroadcasts and tradeshows, it is not always possible to control where such materials appear. For specific information on what products are available for sale in a particular country, please contact your local Hologic representative.



With MQSA's focus on providing breast density information to patients and healthcare providers, Hologic highlights key solutions that can help find invasive cancers, increase clinical confidence, and allow for greater operational efficiencies.<sup>2,3,5-9</sup>

### Report to include classification to healthcare provider:

- (A) The breasts are almost entirely fatty.
- (B) There are scattered areas of fibroglandular density.
- (C) The breasts are heterogeneously dense, which may obscure small masses.
- (D) The breasts are extremely dense, which lowers the sensitivity of mammography.<sup>1</sup>

Provide breast density assessment to patients and HCPs; categorizing breasts as “dense” or “not dense” and include a written lay summary.<sup>1</sup>

“Poor quality images or inaccurate interpretations can lead to a false positive diagnosis when normal tissue is misinterpreted as abnormal. This could lead to needless anxiety for the patient, costly additional testing, and unnecessary biopsies.”<sup>1</sup>

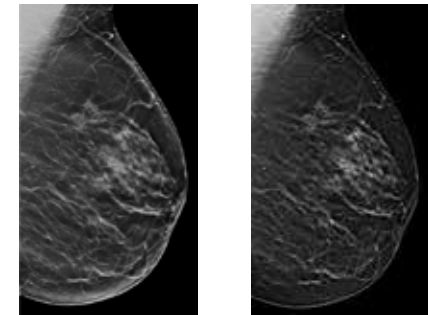
**Quantra® 2.2 Breast Density Assessment Software** removes subjectivity and automates breast density assessment (based on BI-RADS 5th edition).



**The Genius® 3D Mammography™ exam** is the only mammogram that’s FDA approved as superior for women with dense breasts.\*<sup>2,3</sup>



**Hologic Clarity® HD** has the fastest<sup>10</sup> and highest-resolution 3D™ images in the industry.\*<sup>4</sup> 2x the resolution of the standard 3D™ images.



C-View™  
standard resolution

Intelligent 2D®  
high resolution

“...for some patients there may be some degree of variability in the determination of breast density due to interobserver and intra-observer variability”...“there have been advancements in technology (e.g., density classification software devices) that may help mitigate such variability in assessment.”<sup>1</sup>

“Breast tissue density is an important factor in mammography, both because of the **masking effect** of dense tissue, which limits the sensitivity of mammography”...“and because density is an **independent risk factor for the development of breast cancer.**”<sup>1</sup>

“Mammogram is among the most difficult radiographic images to interpret”...“The mammogram must be of high quality for accurate image interpretation (Government Accountability Office (GAO))”<sup>1</sup>