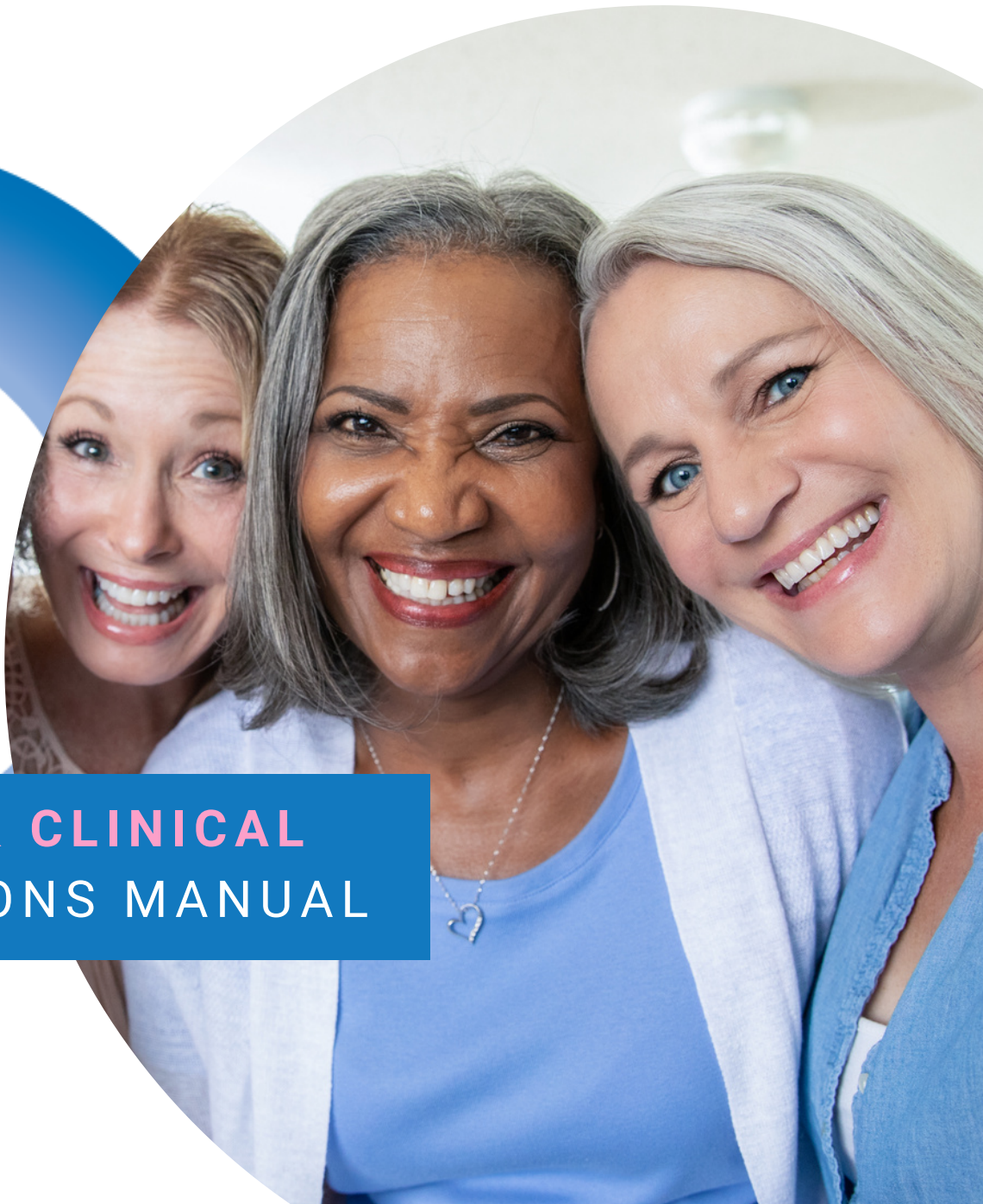


Veria by Koning

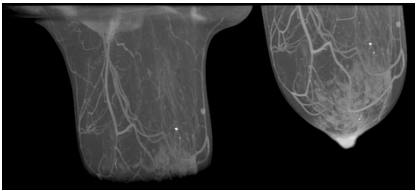
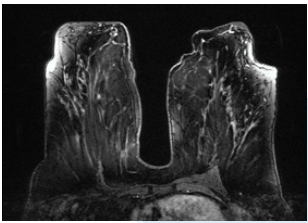
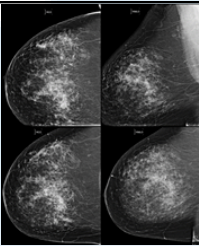
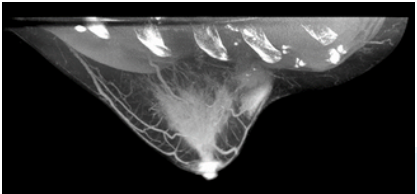
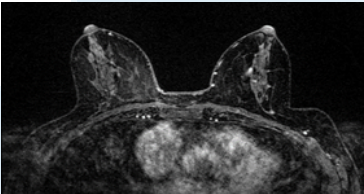
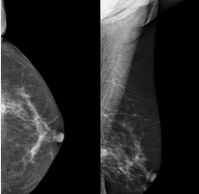
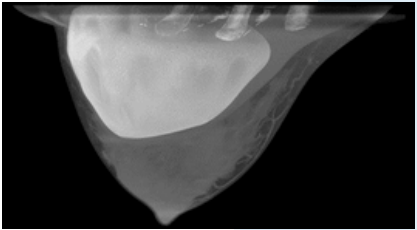
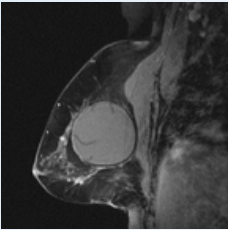
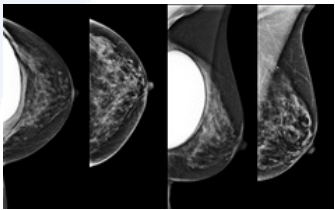
A BETTER WAY OF BREAST IMAGING

No Compression | Low Dose | Real 3D Imaging



TECHNICAL & CLINICAL
SPECIFICATIONS MANUAL

TECHNICAL SPECIFICATION COMPARISON

Items	Koning Breast CT	Breast MRI	Digital Mammography	Digital Breast Tomosynthesis
2D/3D	3D Isotropic	3D Non-isotropic [1][2]	2D Projection	Limited 3D (2D with depth info)
Spatial Resolution (mm)	Standard Mode: 0.2 x 0.2 x 0.2 High Res Mode: 0.1 x 0.1 x 0.1 <i>voxel resolution up to x1000 higher than MRI</i>	1.5 T: 0.85 × 0.85 × 1.6 [1] 3.0 T: 0.50 × 0.50 × 1.3 [1] 0.80 × 0.80 × 1.6 [1]	~0.1 mm [3]	~0.1mm [4]
Acquisition Time	One 7-second Scan	~30 Minutes	Four 5-second exposure; More time for extra views	up to 25 seconds depending on angular range [4]
Breast Compression	No	No	Yes Average ~120 Newtons (26 lbs), up to 200 Newtons (45 lbs) per image [5]	Yes Similar to Digital Mammography
Patient Position	Prone (open)	Prone (enclosed in small bore)	Standing	Standing
Machine Noise	Low	High (up to 130 dB, close to a construction jackhammer) [6]	Low	Low
Patient Comfort	Good (Short exam, Open scanning, No compression, Low noise)	Poor (Long exam, Distressed in noisy and confined space)	Painful (Compression and Manipulation)	Painful (Compression and Manipulation)
Radiation Dose Mean Glandular Dose (MGD)	For Standard Breast: 5.8mGy/Scan(Exam)* <i>Below MQSA reqmt for screening mammo</i>	No Ionizing Radiation	Diagnostic Mammography 8.67mGy/exam*	Average 38% higher dose than Digital Mammography [7]
average # of scans per exam	Standard: 1 scan per breast Contrast: 2 scans per breast <i>60 scans/day vs 10 MRI scans/day</i>	5-7 scans per breast	4 images per breast plus extra views	2 scans per breast
Breast Coverage (with images)				
Large Breasts	Largest field of view in the industry: up to 34 cm longitudinal coverage. Covers chest wall.	Coil limitation ~20 cm [8]. Anterior interference on long breast	Maximum 24 x 30 cm. Tiling and multiple exposure needed for large breast	Only the largest portion of the tile is imaged with DBT. The remainder is imaged with tiled DM [9]
				
Small Breasts	No special technique. Covers chest wall	No special technique. Covers chest wall	Difficult, with positioning and posterior coverage issues	Difficult, with positioning and posterior coverage issues
				
Implant Breasts	Complete evaluation	No Limitation	Multiple Views w. displacement; Difficult for Small Breasts	Only implant displaced views are performed using DBT [9]
				
Implant Evaluation	Yes, in 3D	Yes, in 3D	No	No
Contraindications	None	Claustrophobia; Metal Implantable devices; Patient weight restrictions	Intolerant to pain from compression; Implant ruptured	Intolerant to pain from compression; Implant ruptured
Contrast Imaging	Without or With	Required	Contrast Enhanced Mammogrpahy option for purchase	NA
Conrast Media	Non-Ionic CT Contrast	Gadolinium	Iodinated (for Contrast Enhanced Mammography)	NA
Biopsy Capability	Yes, in 3D	Yes, in 3D	Yes, 2D Stereotactic	Yes, Tomo stereotactic
Average Biopsy Time	~15 min	~ 1 hour	29 Minutes	~ 15 min [10]
Radiation Dose for Biopsy Mean Glandular Dose (MGD)	~30 mGy for medium size breast [11] (50% Less than Stereotactic Biopsy)	NA	62.5 mGy for medium size breast [11] (twice as much as KBCT biopsy)	50% Less than Stereotactic Biopsy [12] [13]

Note: The information in this chart is accrued directly or indirectly from clinical trials, reported studies, manufacture specifications and industry consensus. The reported numbers in this chart are subject to change with future studies.

CLINICAL SPECIFICATION COMPARISON

Items	Koning Breast CT	Breast MRI	Digital Mammography	Digital Breast Tomosynthesis
Sensitivity (non-contrast)	85.6%-89.2% From Clinical Trials* and Literature [14]	NA	76.1% - 84.5% From Clinical Trials* and Literature [14]	77.2% - 88% [15][16]
Specificity (non-contrast)	79.5% - 84% From Clinical Trials* and Literature [14]	NA	73.1% - 81.3% From Clinical Trials and Literature [14]	71% - 84.8% [15][16]
Cancer Detection Rate (non-contrast)	Estimated CDR†: 5.55 - 5.79 per 1000 exams	NA	Reported CDR [17]: 4.6 - 4.8 per 1000 exams	Reported CDR [17]: 5.0 - 5.7 per 1000 exams
Sensitivity (contrast)	92.7% - 98.7% From Clinical Trials* and Literature [14]	90% - 98% From Literature [18, 19]	For CEM [20, 21]: 61.1% - 90.5%	NA
Specificity (contrast)	79.5% - 85.0% From Clinical Trials* and Literature [14]	65% - 72% From Literature [18, 19]	For CEM [20, 21]: 76.1% - 87.8%	NA
Cancer Detection Rate (contrast)	Estimated CDR†: 27.2 - 28.9 per 1000 exams	Reported CDR [22, 23]: 14 - 26 per 1000 exams	For CEM, Reported CDR [24]: ~15.5 per 1000 exams	NA
Calcification Detection	~0.2-0.3 mm (Single) > 3mm (grouped)*	No	~0.2-0.3 mm (Single) > 3mm (grouped)*	~0.2-0.3 mm (Single) > 3mm (grouped)*

Note: The information in this chart is accrued directly or indirectly from clinical trials, reported studies, manufacture specifications and industry consensus. The reported numbers in this chart are subject to change with future studies.

* Koning Breast CT Regulatory Clinical Trials and Technical Documents
† Estimated with KBCT sensitivity and population from reported studies

- Rahbar, H., et al., Clinical and technical considerations for high quality breast MRI at 3 Tesla. J Magn Reson Imaging, 2013. 37(4): p. 778-90.
- Newell, M., et al., ACR practice parameter for the performance of contrast enhanced magnetic resonance imaging (MRI) of the breast. American College of Radiology, Reston, VA, 2018.
- Huda, W. and R.B. Abrahams, X-ray-based medical imaging and resolution. AJR Am J Roentgenol, 2015. 204(4): p. W393-7.
- Vedantham, S., et al., Digital Breast Tomosynthesis: State of the Art. Radiology, 2015. 277(3): p. 663-84.
- Poulos, A., et al., Breast compression in mammography: how much is enough? Australas Radiol, 2003. 47(2): p. 121-6.
- Noise To Expect During An MRI. Available from: <https://www.enrvm.com/noises-to-expect-during-an-mri/>.
- Gennaro, G., D. Bernardi, and N. Houssami, Radiation dose with digital breast tomosynthesis compared to digital mammography: per-view analysis. Eur Radiol, 2018. 28(2): p. 573-581.
- Breast 18 Coil. [cited 2023 05/30]; Available from: <https://www.siemens-healthineers.com/en-us/magnetic-resonance-imaging/options-and-upgrades/coils/breast-18-coil>.
- American College of R., ACR PRACTICE PARAMETER FOR THE PERFORMANCE OF DIGITAL BREAST TOMOSYNTHESIS (DBT). 2018.
- Waldherr, C., et al., Tomosynthesis-guided vacuum-assisted breast biopsy: A feasibility study. Eur Radiol, 2016. 26(6): p. 1582-9.
- Seifert, P.J., et al., Initial Experience with a Cone-beam Breast Computed Tomography-guided Biopsy System. J Clin Imaging Sci, 2017. 7: p. 1.
- Nguyen, D.L., et al., Comparison of Diagnostic Mammography-Guided Biopsy and Digital Breast Tomosynthesis-Guided Biopsy of Suspicious Breast Calcifications: Results in 1354 Biopsies. AJR Am J Roentgenol, 2023. 220(2): p. 212-223.
- Clinical Benefits of Tomosynthesis Guided Breast Biopsy. Available from: <https://www.hologic.com/sites/default/files/Clinical-Benefits-of-Tomosynthesis-Guided-Breast-Biopsy.pdf>.
- He, N., et al., The utility of breast cone-beam computed tomography, ultrasound, and digital mammography for detecting malignant breast tumors: A prospective study with 212 patients. Eur J Radiol, 2016. 85(2): p. 392-403.
- Gilbert, F.J., et al., Accuracy of Digital Breast Tomosynthesis for Detecting Breast Cancer Subgroups in a UK Retrospective Reading Study (TOMMY Trial). Radiology, 2015. 277(3): p. 697-706.
- Georgian-Smith, D., N. A. Obuchowski, J. Y. Lo, et al. (2019). "Can Digital Breast Tomosynthesis Replace Full-Field Digital Mammography? A Multireader, Multicase Study of Wide-Angle Tomosynthesis." Am J Roentgenol 212(6): 1393-1399
- Sprague BL, Coley RY, Kerlikowske K, et al. Assessment of Radiologist Performance in Breast Cancer Screening Using Digital Breast Tomosynthesis vs Digital Mammography. JAMA Netw Open. 2020;3(3):e201759.
- Peters, N.H., et al., Meta-analysis of MR imaging in the diagnosis of breast lesions. Radiology, 2008. 246(1): p. 116-24.
- Wienbeck, S., et al., Contrast-enhanced cone-beam breast-CT (CBBCT): clinical performance compared to mammography and MRI. Eur Radiol, 2018. 28(9): p. 3731-3741.
- Sorin, V., et al., Contrast-Enhanced Spectral Mammography in Women With Intermediate Breast Cancer Risk and Dense Breasts. AJR Am J Roentgenol, 2018. 211(5): p. W267-W274.
- Lawson, M. B., S. C. Partridge, D. S. Hippe, et al. (2023). "Comparative Performance of Contrast-enhanced Mammography, Abbreviated Breast MRI, and Standard Breast MRI for Breast Cancer Screening." Radiology 308(2): e230576.
- Bakker, M. F., S. V. de Lange, R. M. Pijnappel, et al. (2019). "Supplemental MRI Screening for Women with Extremely Dense Breast Tissue." N Engl J Med 381(22): 2091-2102.
- Riedl, C. C., N. Luft, C. Bernhart, et al. (2015). "Triple-modality screening trial for familial breast cancer underlines the importance of magnetic resonance imaging and questions the role of mammography and ultrasound regardless of patient mutation status, age, and breast density." J Clin Oncol 33(10): 1128-1135.
- Sung, J. S., L. Lebron, D. Keating, et al. (2019). "Performance of Dual-Energy Contrast-enhanced Digital Mammography for Screening Women at Increased Risk of Breast Cancer." Radiology 293(1): 81-88.

GET IN CONTACT

General Inquiries

info@koningcorporation.com
888-558-5228

Sales

dgeorges@koninghealth.com
888-558-5228 ext. 800

Marketing

naomi.cosman@koninghealth.com
888-558-5228 ext. 802

BE AT THE FOREFRONT OF THE BREAST IMAGING INDUSTRY