Vera by Koning

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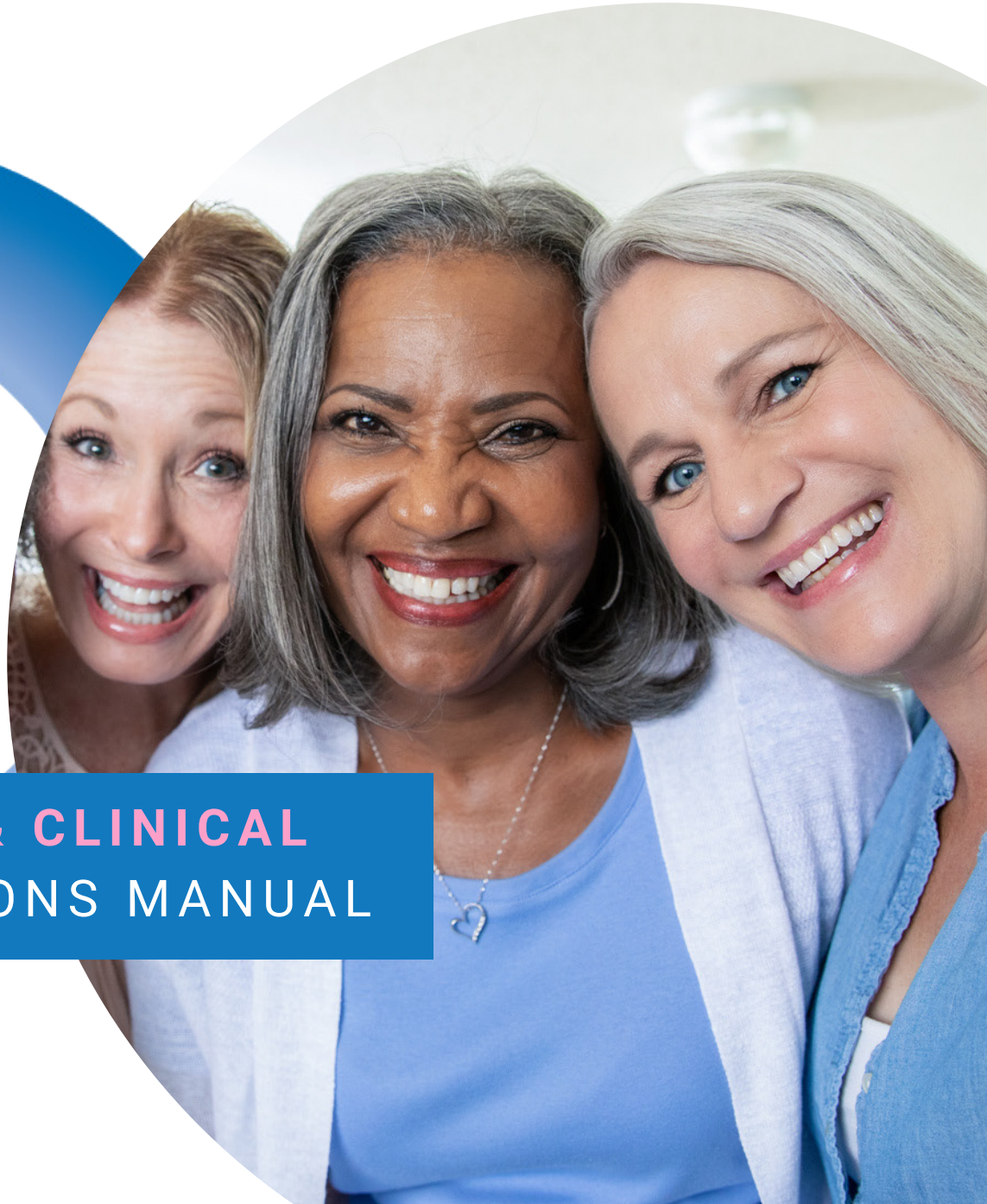
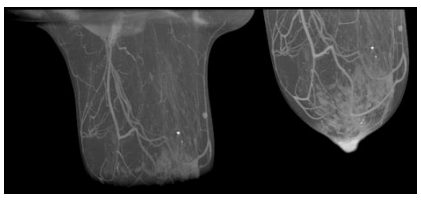
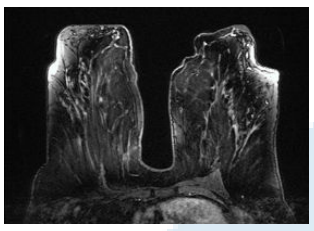
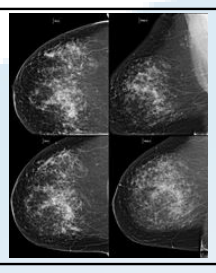
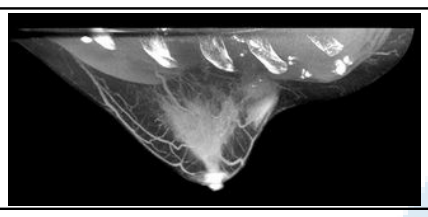
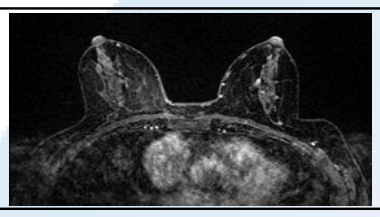
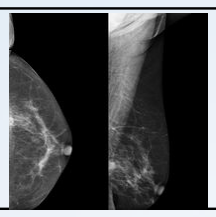
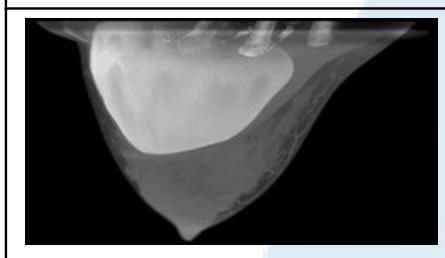
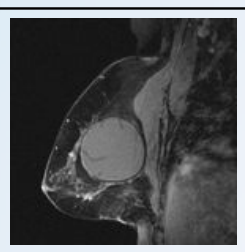
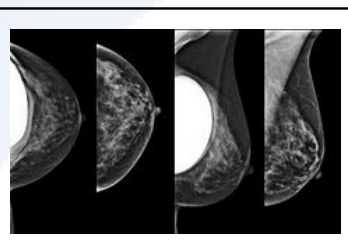
A BETTER WAY OF BREAST IMAGING

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	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)	Fair (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)*	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	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]	88% [15]
Specificity (non-contrast)	79.5% - 84% From Clinical Trials* and Literature [14]	NA	73.1% - 81.3% From Clinical Trials and Literature [14]	72% [15]
Cancer Detection Rate (non-contrast)	Estimated CDR†: 4.75-4.9 per 1000 exams	NA	Reported CDR [16]: 4.6-4.8 per 1000 exams	Reported CDR [16]: 5.0-5.7 per 1000 exams
Sensitivity (contrast)	92.7% - 98.7% From Clinical Trials* and Literature [14]	90% - 98% From Literature [17, 18]	For CEM [19]: ~90.5%	NA
Specificity (contrast)	79.5% - 85.0% From Clinical Trials* and Literature [14]	65% - 72% From Literature [17, 18]	For CEM [19]: ~76.1%	NA
Cancer Detection Rate (contrast)	Estimated CDR†: 17 - 27 per 1000 exams	Reported CDR [20, 21]: 14 - 26 per 1000 exams	For CEM, Reported CDR [22]: 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

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