Standard of Care Today[1,2]

How QT Scan Fits In

Patient **under the age of 40** undergoes risk assessment

Patient age and risk assessment determines the screening pathway

Patient **over the age of 40** undergoes routine mammographic screening

Patient is above-average risk

Patient is high-risk

Patient is average or intermediate risk

Breast MRI recommended by guidelines

Patient and Physician decide on the imaging modality

Standard mammography/ DBT screening

Patient undergoes breast MRI

Patient undergoes QT Scan as an alternative

MRI findings evaluated

QT Scan findings evaluated

Potential change to current clinical paradigm

Results feed into diagnostic workup and follow-up plan

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(1) J Am Coll Radiol. 2023 Sep;20(9):902-914.
(2) J Am Coll Radiol. 2024 Jun;21(6S):S126-S143

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Current Standard of Care in Breast Imaging

Risk Category	Lifetime Risk	Breast Density	Recommended Imaging Modalities	Guideline Recommendations
Average Risk	≤12–15%	Fatty Breasts	**Screening Mammography** (2D or 3D) annually starting at age 40	**NCCN**[4]: Annual mammography for women aged 40 and older. **ACR/SBI**[1,2]: Annual mammography starting at age 40. **EUSOBI**[3]: Biennial mammography for women aged 50–69; consider starting at 40.
Average Risk	≤12–15%	**Dense Breasts**	**Screening Mammography** (2D or 3D) annually starting at age 40 **Supplemental Imaging**: Consider **Ultrasound** or **MRI**	**NCCN**: Consider supplemental imaging for women with heterogeneously or extremely dense breasts. **ACR/SBI**: Recommend supplemental MRI for women with dense breasts and additional risk factors. **EUSOBI**: Recommend MRI screening every 2–4 years for women aged 50–70 with extremely dense breasts.
Above Average Risk	15–19%	Any Density	**Screening Mammography** (2D or 3D) annually starting at age 40 **Supplemental Imaging**: Consider **MRI** or **Ultrasound**	**NCCN**: Annual mammography; consider MRI for women with a 20–25% lifetime risk. **ACR/SBI**: Recommend MRI for women with a 20–25% lifetime risk. **EUSOBI**: MRI screening for women with a 15–20% lifetime risk.
High Risk	≥20–25%	Any Density	**Screening Mammography** (2D or 3D) annually starting at age 30 **Supplemental Imaging**: **Annual MRI** starting at age 25–30	**NCCN**: Annual MRI and mammography for women with ≥20% lifetime risk. **ACR/SBI**: Recommend annual MRI and mammography for women with ≥20% lifetime risk. **EUSOBI**: Recommend annual MRI for women with BRCA mutations or equivalent risk.

(1) J Am Coll Radiol. 2023 Sep;20(9):902-914.
(2) J Am Coll Radiol. 2024 Jun;21(6S):S126-S143
(3) Eur Radiol. 2024 Oct;34(10):6348-6357
(4) J Natl Compr Canc Netw. 2023 Sep;21(9):900-909

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QTI's Current Indications For Use

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K220933

Device Name
QT Scanner 2000 Model A

Indications for Use *(Describe)*

The QT Scanner 2000 Model A is for use as an ultrasonic imaging system to provide reflection-mode and transmission-mode images of a patient's breast. The QT Scanner 2000 Model A software also calculates the breast fibroglandular tissue volume (FGV) value and the ratio of FGV to total breast volume (TBV) value as determined from reflection-mode and transmission-mode ultrasound images of a patient's breast. The device is not intended to be used as a replacement for screening mammography.

The QT Scanner 2000 Model A is indicated for use by trained healthcare professionals in environments where healthcare is provided to enable breast imaging in adult patients.

Broad intended use to allow breast imaging of any subject of age 18 or older

First FDA clearance for an ultrasound-based device to be able to quantify breast tissue volume

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QT Scanner 2000 Model A 510(k) Summary (link)

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How QTI Potentially Fits Into the Current Paradigm

Risk Category	Potential Role of QTI Device
Average Risk (≤12–15%)	QTI offers a non-ionizing, high-resolution alternative for supplemental imaging, **especially useful in patients with dense breasts where mammography is limited**. Ideal for **frequent monitoring without radiation exposure**.
Above-Average Risk (15–19%)	QTI provides a **safer alternative to MRI for moderate-risk individuals**, including those with family history or dense tissue. It avoids gadolinium-based contrast risks, offering **functional imaging with fewer contraindications**.
High Risk (≥20–25%)	QTI **may supplement or replace MRI in high-risk individuals, especially where MRI is contraindicated or poorly tolerated**. **Supports early, radiation-free surveillance with improved soft-tissue contrast, aligning with early screening needs**.

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