

Informed Consent for QTScan

The QT Ultrasound Breast Scanner is an FDA-cleared, non-invasive, ultrasonic imaging system providing images (the “QTscan”) of a patient’s breast. The QTScan combines transmission ultrasound and reflection ultrasound to create 3D images of a patient’s breast without radiation or compression. This can provide the Doctor with information on breast findings to inform decisions about breast health. Couri Center is not owned by QT Imaging, Inc. but is a separate business.

Description of Exam/Procedure

Following informed consent, you will be asked to remove your clothing from the waist up and will be given a robe to wear. You will be asked to lie on your stomach and put one breast at a time into the QT Ultrasound Breast Scanner. If your breast(s) does not fit into the scanner, the QTScan will not be performed. The staff member will attach a piece of tape with a small magnet onto the lowest hanging part of your breast. This will require that the staff member touch your breast to attach the tape. Once the tape is placed, the table will be lowered so that your breast is in the water bath. The small magnet attached to your breast will then attach to the rod in the water bath. Your breast may feel a slight tug at this time. The ultrasound arrays (curved probes inside the water bath) move around your breast. This allows the scanner to get information about your breast. It may take up to 20 minutes to scan one breast. On average, it takes approximately 20 – 35 minutes for the QTScan to complete the imaging of both breasts.

What are contraindications of a QTscan?

Contraindications would include if you are currently pregnant or breastfeeding, if you exceed 400 pounds, or if your breast size exceeds DDD.

What to avoid before the day of the exam?

Unlike a mammogram, wearing deodorant on the day of your scan is okay. However, we ask that you do not apply lotion to your breasts before the exam, as this may cause the adhesive to not stick properly.

What are the limitations of the technology?

The QTscan uses a different technology for imaging the breast than is used in mammography and other commonly used procedures. It may not identify all findings that can be or have been detected by mammography or other breast imaging methods. Only breast tissue is evaluated in a QTscan, this does not include the axilla.

What are the risks of the exam?

1. You may feel body soreness or ribcage redness from lying on the scanner. This goes away after the scan is complete.
2. Your skin may react to the chlorine in the water or to the tape. If you are allergic or sensitive to chlorine or certain adhesives/tape, please inform the staff prior to commencing the scan.

The primary objective of a breast imaging procedure utilizing Quantitative Transmission (QT) Imaging is to detect breast abnormalities – including cancer – early, when the likelihood for curative treatment is greater. The majority of findings detected by the QTscan are benign. However, some questionable findings may require follow-up evaluation. Like all medical imaging tests, QT scans of the breast are limited in their ability to detect certain abnormalities and should not be performed for the evaluation of clinical symptoms. We recommend that our patients bring QT Imaging reports to the attention of their personal physician so they can be part of the permanent medical record.

Electronic Consent

All QT images, files, and reports are stored electronically in a secure location at the Couri Center. Couri Center works with QTImaging, Inc. to improve image quality and may provide your ANONYMIZED Dicom electronic files to QTImaging, Inc. for product improvement. Your image data will have no identifiable information regarding you or your scan and is allowed under US privacy laws and Human Research Regulations.

By signing below, I certify that (a) I have read this document, (b) I understand the risks and hazards outlined for the procedure and Telehealth and agree to the above advisements (c) I have been given an opportunity to ask questions about the procedure and the information contained in this document and any such questions have been answered to my satisfaction, and (d) I believe I have sufficient information to give this informed consent. I voluntarily consent and authorize Facility Staff to perform the QTscan.

Patient Signature:

Name: _____

Date: _____

Staff Signature:

Name: _____

Date: _____