Medical Tactile, Inc.

- Medical Tactile, Inc. (MTI) is a Los Angeles based medical device company that manufactures and sells digital clinical breast examination products to physicians and medical facilities around the globe
- Our mission is to provide physicians better tools for the early detection and assessment of breast cancer
- MTI is a privately held Delaware corporation founded in October 2001
- MTI’s Core Technology Platform is the SureTouch™ system
FDA cleared medical device for “performing and documenting the Clinical Breast Exam (CBE)”

Self-contained tactile sensors measure the reactive pressures generated by harder cancerous tissue

Documents the shape, location, hardness and size of lesions

Accurate, affordable and comfortable in all women of all ages

Objective, quantifiable, repeatable

Compact, portable and easy to set up in a physician’s office
Tactile Sensing Platform

**Capacitance**

\[ C \propto \frac{\text{Area}}{d} \]

- 15 mm dia. under 15 mm
- 12 mm dia. under 15 mm
- 8 mm dia. under 15 mm
- 5 mm dia. under 15 mm

**Tactile Sensors**

- Proprietary compressible dielectric matrix,
- Pressure

- Human Palpable Region
- SureTouch Palpable Region
Overall Goals of the SureTouch System

• Improve the overall performance of Clinical Breast Examination (CBE)
• Reduce the inter and intra operator variability associated with the CBE
• Provide simple and quick test that can be utilized in out patient setting as part of normal patient work-up
• Establish a common set of lexicons to describe the CBE results
Clinical Breast Examination (CBE)

• Most universal examination utilized for the detection and assessment for the detection and assessment of breast health
  o Every three years for women under 40
  o Every year for women over 40
  o More often for high risk women

• Overall sensitivity and specificity ranges from 50 to 60% and 94% respectively
  o Barton et al 54% & 94%
  o US national screening report 59% & 93%

• High variability between users report (~30%)
Clinical Breast Examination (CBE)

• SABC 2008
  • Study by California Pacific Medical Center Research Institute (1522 women) suggests that properly documenting the CBE nearly doubled the rate of breast mass detection.
  • Study by Duke University (147 women) suggested that BSE & CBE were as effective in detection of cancer in risk women as conventional imaging such as mammography and MRI.

• Since 70% of all cancers are presently found through palpation, a method that mimic CBE but with enhanced sensitivity and specificity could improve screening yield in the general population as well as high risk women
Breast Tissue Elasticity


SureTouch Clinical Information

- Position of lesion in breast
- Size of lesion
- Shape of lesion
- Hardness of lesion
- Mobility of lesion within the breast tissue
SureTouch Exam Screen

Double-click to add notes or delete

Breast Map

Location: Left Breast, 1 o'clock, Region B
Size: 13 mm x 15 mm, 164 mm²
Hardness: 5.0
Shape: One Peak

Size calculation level: 60%
Exam Force: 0.6 kg
Clinical Lesion Images
Shape and Hardness

SINGLE NODULE

FIRM

MULTINODULAR TUMOR

SOFT
Clinical Comparison

Tumor measurement size in comparison to mammography & breast ultrasound
Clinical Studies

  23 women undergoing surgical excision of breast masses following pre-operative CBE, ultrasound and ST examination. ST measurements were repeatable and estimates of lesion size showed good correlation with the post-resected lesion measurements.

  31 women with breast masses. ST sensitivity and specificity for detection of masses were 80% and 75% and for cancer detection, 92% and 72% respectively. A majority of patients reported that ST screening was at least as comfortable as CBE.

- **Kearney (2004)** “Tactile breast imaging to increase the sensitivity of breast examination, J Clin Oncol, 22:1037”
  Study of six breast specialists and seven unskilled lay persons to determine their ability to detect masses in breast phantoms by manual palpation and ST scan. ST imaging by lay persons had higher sensitivity than manual breast palpation in identifying masses. In addition, lay persons then received four training sessions in the use of ST. This training increased the detection of masses to the level achieved by the specialists.

- **Ables (2007)** “Development of a device for documenting the clinical breast exam using a capacitive tactile array sensor.”
  Study of 7 operators examining six breast phantoms. ST use demonstrated consistent measurements of lesion size and hardness as well as reproducibility on repeated measurements.
Clinical Studies


  110 patients presenting with a complaint of breast mass. ST identified the mass in 94% of cases versus 86% by CBE. Positive predictive value for breast cancer was 94% by ST and 78% by CBE. The inclusion of an ST record in the consultation note implied competence, experience and skill by the breast surgeon.


  137 patients at a UK NHS breast clinic, 66 of whom had palpable breast masses. 77 of these were chosen at random to have an ST examination in addition to CBE. Use of ST reduced the percentage of missed lesions by senior and junior surgical trainees. The reproducible reports allowed efficient review by examiners with various levels of experience.


  179 patients with breast masses identified by mammography, ultrasound and/or CBE. All patients had an ST examination plus a biopsy. ST was able to differentiate 174 benign and 32 malignant lesions with a sensitivity and specificity of 91% and 80% respectively. Authors conclude that ST has the potential to be used as a cost-effective device for cancer diagnostics, reduce the benign biopsy rate, serve as an adjunct to mammography and be utilized as a screening device for breast cancer detection.
SureTouch

- Produces more objective and reliable data than CBE
- Less likely to miss breast masses than CBE, especially particularly with less experienced clinicians.
- In some women with dense breasts (especially those under age 40), ST technology could better detect lesions than mammography or CBE
- Has fewer risks and is much less expensive to perform than mammography. It is suitable for women who are not in the recommended groups for mammography (e.g., women less than 50 years of age) or are in an interval between regularly scheduled mammography
- Has the potential to improve the overall referral process between primary care providers and breast surgery consultants
SureTouch

- The digital record standardizes the CBE for better communication of results among clinicians.
- Role in differentiating benign and malignant lesions.
- Potential as a cost-effective device for breast cancer detection. This may be especially true in countries where mammography equipment is not available nor supportable.
- Its use after standard screening procedures (mammography alone or combination of mammography and conventional ultrasound) has the potential to reduce the benign biopsy rate.
- Modelling studies suggest that by adding ST to mammography, a 23% reduction of the benign biopsy rate is possible without any missed cancer cases and a 50% reduction of the benign biopsy with 4.6% missed cancer cases.
Breast Cancer Detection

The Problem: Breast Cancer

- 1.2 million women are diagnosed annually
- 10,000,000 living the disease
- 500,000 women die each year

The Solution: SureTouch Enhanced CBEs

- Early detection is the only means to improve survival rate
- SureTouch enhances a standard of care
- Suitable for every woman

Business Opportunity: The Need is Everywhere

- Breast cancer is growing 10X global average - up to 5% per year
- While 80% of the mammogram devices are in NA & WE, 70% of deaths occur in other areas.
- Mammography is cost prohibitive for most developing countries, and requires great expertise to perform and interpret results.
- Less than 10% of 125 million mammograms/year occur in these regions and CBE remains the only viable screening method.
Limited Screening Alternatives

1.4B women (ages 30-70) in the world (2005)

- ~ 80% live in developing nations
- ~ 70% of breast cancer deaths in developing regions
- < 10% of 125 million mammograms in developing countries

Percent of Total

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SureTouch is being sold primarily through distributors around the globe.

The distributors target primary care physicians and women health practices performing CBE for breast cancer screening, as well as prestigious medical institutions with significantly larger women’s health practices.

Medical Tactile currently has 18 international distributors in North America, Europe, Africa, Asia and Australia.
# Comparison of Imaging Methods

<table>
<thead>
<tr>
<th>CBE</th>
<th>Sensitivity/Specificity</th>
<th>Procedural Cost</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>CBE</td>
<td>.56/.94</td>
<td>$       36</td>
<td>Highly variable, poor PPV</td>
</tr>
<tr>
<td>Mammography</td>
<td>.74/.94</td>
<td>$       110</td>
<td>Ionizing radiation, limited effectiveness in younger women</td>
</tr>
<tr>
<td>Ultrasound</td>
<td>limited data</td>
<td>$       70</td>
<td>Highly variable, require significant training, time consuming</td>
</tr>
<tr>
<td>MRI</td>
<td>.88/.93</td>
<td>$     1,037</td>
<td>Expensive, require contrast agent, time consuming</td>
</tr>
<tr>
<td>Infrared</td>
<td>.65-.90/.75-.9</td>
<td>$       67</td>
<td>Early marker for breast cancer, no positional or volumetric information, recommended only as adjunct to other technologies</td>
</tr>
<tr>
<td>Biopsy</td>
<td>.96 (.99)/1</td>
<td>$     2,061</td>
<td>Invasive, not suitable for screening</td>
</tr>
<tr>
<td><strong>SureTouch</strong></td>
<td><strong>.92/.88</strong></td>
<td><strong>low</strong></td>
<td>Portable, inexpensive, requires less training</td>
</tr>
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## Competition

<table>
<thead>
<tr>
<th>SureTouch</th>
<th>Other Breast Imaging Technologies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Makes the Clinical Breast Examination more quantitative, repeatable and reduces inter-operator variability. Enhances the current Clinical Breast Examination that is a standard of care for all primary physicians.</td>
<td>Highly operator dependent often resulting in variations between the expert and the non expert in interpretation of results.</td>
</tr>
<tr>
<td>Replicates the sense of touch and is easy to understand and learn to operate.</td>
<td>Requires extensive education and certification in imaging technologies to properly use often resulting in the need for specialized staff</td>
</tr>
<tr>
<td>Does not use ionizing radiation, magnetic fields or high frequency sound hazards.</td>
<td>Often require a large area and extensive shielding. Due to potential toxicity, these exams are often limited in frequency of their use.</td>
</tr>
<tr>
<td>Small and portable with the ability to serve multiple users and clinics</td>
<td>Fixed or semi -fixed units require space that makes portability problematic</td>
</tr>
<tr>
<td>SureTouch studies generate relatively small digital data packets that can be easily stored and handled by mobile networks</td>
<td>X-ray, ultrasound and MRI examinations generate many gigabytes of data per study making the networking and storage of large quantities of studies more challenging.</td>
</tr>
<tr>
<td>Inexpensive ($15 to 20K) with a low per use cost $1 - $10 depending on labor cost</td>
<td>Ultrasound suitable for Breast - $50 to 150K, Mammography - $100 - 400K, MRI - $1M +</td>
</tr>
</tbody>
</table>
Regulatory Approvals

- USA - FDA 510K
- Europe - CE mark
- China - SFDA
- Canada - CSA
- Australia/NZ - TGA
- South Korea - KFDA
Thank you