Early Breast Cancer Detection using The MarTouch (tactile) tBra

Assignment #1

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Course: TTMG 5101
Integrated Product Development

Carleton University
August 11 2008
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1.0 Product Opportunity

1.1 The job the customer needs done

When it comes to addressing cancer, the medical establishment has come to the realization that early diagnosis is as crucial as treatment. Physicians rely on diagnostic results when assessing various treatment options such as chemotherapy, radiation therapy, surgery and photodynamic therapy. In the case of breast cancer, it can be detected using a range of diagnostic methods from low tech/low cost methods such as breast self-exams or clinical breast examinations to high tech/high cost approaches such as mammograms, ultrasound or Computerized Tomography (CT), Magnetic Resonance Imaging (MRI) or Positron Emission Tomography (PET) scans. Traditionally, cancer researchers have recommended that women assess their breasts for cancer themselves on a regular (monthly) basis through Breast Self-Exams (BSE) to identify changes (lumps) in their breasts with their fingers. BSE, then, is the first line of defense in the fight against breast cancer. BSE is especially important in developing countries where high tech clinical screening facilities are not readily available.

Since BSE is a voluntary at-home medical examination, medical regulatory bodies such as FDA or Health Canada can not establish performance standards or enforce adoption. However, the Canadian and American Cancer Societies have established breast cancer screening guidelines which recommend the number and type of clinical breast assessments women should undergo based on a number of predisposition factors such as age and family histories.

Standardized Breast Self-Exam procedures (consisting of a 34 step process) are widely available to women described in brochures available from health practitioners or in electronic format on the web. However, based on a questionnaire conducted of 150 randomly selected women from the Ottawa area, women state that it is difficult to translate the written procedures into actual practice. Many women also state that they often do not conduct their breast self-exams regularly due to their busy schedules. When they do exam their breasts, they are unsure whether they are performing the procedures properly. Given the month long interval between exams and the subjective nature of the procedure it is not surprising that BSE often fails to detect early onset cancer. It is also provides poor discrimination of cancerous tissue versus benign lumps resulting in many unnecessary biopsies.

There is evidence that, as currently implemented, BSE is ineffective as a screening tool.

Regardless of the age and health status of women in the Ottawa area, they strongly feel the need for a device capable of assisting them to perform their breast self exam to enable early detection of breast abnormalities. Women believe early breast cancer detection leads to early cancer treatment resulting in saving or extending the life of breast cancer patients.
Imagine that you are a 45 years old woman with no family history of breast cancer. Today, a health professional has conducted a clinical breast examination (mammogram) and revealed that the test results are negative. This is good news for you and your family. However, in accordance with Health Canada guidelines, your next appointment is scheduled for July 2010 two years from now. If a breast cancer were forming unless caught by a BSE, the cancer would have up to 24 months to develop and spread. Women must be pro-active in assessing or monitoring their own breasts between clinical assessments.

1.2 The gap in current offerings by competitors

Currently, the only direct competitor to the tBra is the manual Breast Self-Exam.

Today’s manual BSE is inconsistent and inaccurate. The reason is that women may apply different level of pressure at different surface area of breast tissue during BSE. Also, the BSE results are not repeatable and reproducible. At the same time, women need to remember all 34 steps described in the BSE guidelines. Once women conduct the BSE, it is challenging for them to interpret the results.

MarTouch’s tBra is a digital breast self examination device. It is capable of providing consistent and accurate exams. Since the tBra is digital, the results are reproducible and repeatable. The results can be integrated with the woman’s electronic medical records. Most importantly, the tBra is very user-friendly. Women just simply wear the tBra to conduct breast self exam. To minimize false alarms and resultant stress for our clients, when anomalies are detected, the results of the tBra scan will be verified by MarTouch’s breast care consultants before the woman is advised to have it checked by the health system. However, existing biomedical companies could enter the early breast cancer detection market utilizing pressure sensors similar to those used by podiatrists to detect foot pressure distribution. These foot pressure sensor devices are currently positioned in high-technology but low-style grid in the market positioning map. They are capable to capturing the part of the foot where maximum pressure occurs when standing, walking or running. These devices are used to design foot support to be installed in the patients’ shoes to correct for misalignment of joints etc. These devices would require significant re-engineering to apply them to breast exams, not only because they are not user friendly or ergonomic (bulky) but they are also low-style, an important factor in this market. Regardless of usage, these foot pressure sensor devices have demonstrated that pressure sensor technology can be applied to a human body.

The tBra can be positioned in the high-technology and high-style grid of the market positioning map.
The tBra’s advanced pressure and thermal sensors place it in the high-technology half of the market positioning map. The pressure and thermal data are processed using intelligent algorithms designed to determine whether abnormalities detected by the system may require further clinical assessment.

The tBra is positioned in high-style half of the positioning map, because the pressure and thermal sensors are embedded in a bra. The tBra is very user friendly. Women only need to simply wear the tBra for about 5 minutes before sleep to allow the tBra assess her breast tissue and provide an accurate, error free indication of any abnormalities that could be an indication of developing cancerous tissue.

The tBra is designed to accommodate various breast shapes and sizes. The cup size will range from AA to DD, while the tBra chest size will range from 30 to 42 covering the 95th percentile of women. The proper cup and chest size will ensure an entire breast area is covered properly during breast tissue assessment.

In terms of detection, the tBra will provide earlier breast cancer detection than breast self-exam. Since it is used whenever a woman wants as opposed to Health Canada’s biannual schedule it can provide earlier detection than clinical tools like mammograms. In term of technology, the tBra utilize much higher technology than breast self-exam. While tBra technology is not as sophisticated as the mammogram it will be much lower cost to deploy.

The tBra does cost more than breast self-exam, but the benefits of better early detection, convenience and ease of use more than offset that cost.

1.3 A scenario of using the product

The product is intended to perform as a substitute for the conventional (34 step) manual Breast Self-Examination (BSE) performed by women on a monthly basis. As such it must be not only more reliable in terms of cancer detection, it must also be an easier and less stressful experience for women to use. A more positive experience will ensure that adoption rates improve from the typical 20-30% of women who perform BSE on a regular (monthly) basis. More regular screening together with the improved test fidelity provided by the tBra will enable earlier diagnosis of cancers resulting in earlier intervention, improved outcomes and reduced cost to the health system.

A typical use scenario for the product then would be:

1. Monthly, the subscriber will receive a reminder email, SMS message or automated phone call to remind her to perform a scan sometime that day. If a scan is missed, a follow-up reminder will be sent the following day.
2. Typically in the evening, prior to sleep, the woman will simply put-on the tBra, lie down and activate the scan.

3. A scan will take significantly less than the 5 minutes typical for BSE and since data are automatically recorded and stored there will be no need for her to record results in a journal as required with manual BSE.

4. After the scan is complete the data will be analyzed and compared with previous history files to verify that there are no new abnormalities that may require further investigation. This will take no more than a few seconds.

5. If an anomaly is found, the system may perform a second scan to confirm the finding.

6. The tBra then notified her that she may remove the tBra and go to bed.

7. Data indicating a possible positive indication of cancer will be reviewed by company clinicians within 24 hours to verify the conclusions of the detection algorithm.

8. Where the clinician concurs with the positive finding the subscriber will be contacted with a recommendation to schedule an appointment with her health professional for follow-up as soon as possible. She will be offered counseling and cancer treatment information personalized for her circumstances.

9. All scan data and subscriber medical histories are backed-up on the company’s servers to ensure historical records are not lost in case of an equipment fault in the home unit and to enable the company to continually improve our detection algorithms. Of course during transmission and storage these data will be encrypted and protected to guarantee the subscribers’ privacy.

2.0 Value Opportunity

2.1 Stakeholders

1. Initially we expect that the purchasers of the tBra will be the women who are the end-users of the product and their loved-ones. Once the efficacy of the tBra has been proven through a large scale randomized trial it may be possible to market the product to government health agencies (third world) or insurance companies/Health Maintenance Organizations (first world) in the hope that they may purchase it for their constituents to save overall costs of delivery of cancer diagnosis/treatments.
2. Other major stakeholders include:

   a. Government and private (US) health care providers interested in ensuring improved early diagnosis and intervention and a reduction in the false positives characteristic of BSE. Together, these will result in improved outcomes and reduced costs/load on the health system.

   b. Cancer society funded Breast cancer researchers interested in early diagnosis tools will be interested in the opportunities offered by these data to further optimize early detection methods.

   c. Investors will be needed to fund commercialization, initial manufacturing and trials before the product can become self-financing

   d. Sales and marketing channel partners will be needed to seed the early market. Initially we plan to leverage contacts at the cancer society to access potential participants in trials and lead users.

   e. Infrastructure partners will be needed for manufacturing (Contract Manufacturers) and IT services and supports (internet cloud providers).

   f. Other cancer researchers interested in whether the tBra diagnostic technologies can be transferrable to other cancer regimes.

2.2 What do they buy?

The tBra system, the early breast cancer detection system will consist of three main components:

1. tBra wearable thermal-pressure sensor/actuator
2. Optional wireless basestation/processing unit
3. Subscription service

The tBra is a wearable device in the form of a bra which can sense abnormalities in breast tissue that could be an indication of early onset breast cancer. The tBra implements revolutionary tactile sensing technology and an advanced surface pressure actuator to sense the lumps typically associated with breast cancer self-exams. The tBra also incorporates thermal sensors which allow the system to construct a detailed thermal map of abnormalities which have been recently shown by cancer researchers to provide significantly improved cancer diagnostic results. The tBra incorporates a low power Bluetooth wireless link to a local PC or tBra basestation where data processing is performed.

The scan data are analyzed and compared with scan history either via a local PC or an optional wireless basestation. Scan data are encrypted and forwarded to
MarTouch servers via the internet for backup and to augment the scan database to allow researchers to continue to optimize the detection algorithms.

As part of the complete solution MarTouch will provide a low cost subscription service where customers can access experts experienced in assessing the outputs of the tBra system who can confirm the results of the digital analysis. Subscription will include counseling and personalized breast cancer information services as well.

For users without internet access, a low cost wireless internet portal will be offered bundled with the basestation and subscription service.

2.2 Why should they buy from you?

MarTouch provides a dedicated team of experienced engineers focused on building a high quality experience to help our subscribers manage this highly sensitive part of their lives:

- The tBra offers a comprehensive feature set designed to provide women with the confidence that their risk of breast cancer is being closely monitored at a reasonable price
- The tBra provides a complete integrated solution
- Intellectual Property protection will prevent competitors from capturing the market for home based tactile/thermal co-analyses of breast tissue
- By being first to market and by capturing the scan data of our customers we will be able to construct database of breast scan data that can be used with cancer incidence data/false positive diagnoses to improve the detection algorithms on an on-going basis.
- By focusing on core competencies in product development and advanced cancer detection, sensor-actuators and wireless communication technologies we can leverage outside expertise and economies of scale in complementary assets such as manufacturing, IT management, channel sales etc to keep costs low and to allow the firm to scale with demand.
- The MarTouch executive team has strong network and access to leading edge cancer researchers.
- MarTouch will sponsor a series of randomized clinical evaluations to assess efficacy of the tBra versus BSE prior to wide scale deployment in the market. This will allow us to not only assess the product’s performance but will also permit further optimization of the detection
algorithms and early evaluation of usability or ergonomics for a large population of women.

3.0 Conclusion

MarTouch identified a product opportunity (customer need) to improve early breast cancer detection. MarTouch realized a value opportunity by developing the tBra. The customer involvement is crucial to MarTouch and that goal is achieved by consulting with potential end-users, Canadian Cancer Society and the Ottawa Hospitals. MarTouch is ready to form an open innovation with potential suppliers and other stakeholders.
4.0 References


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