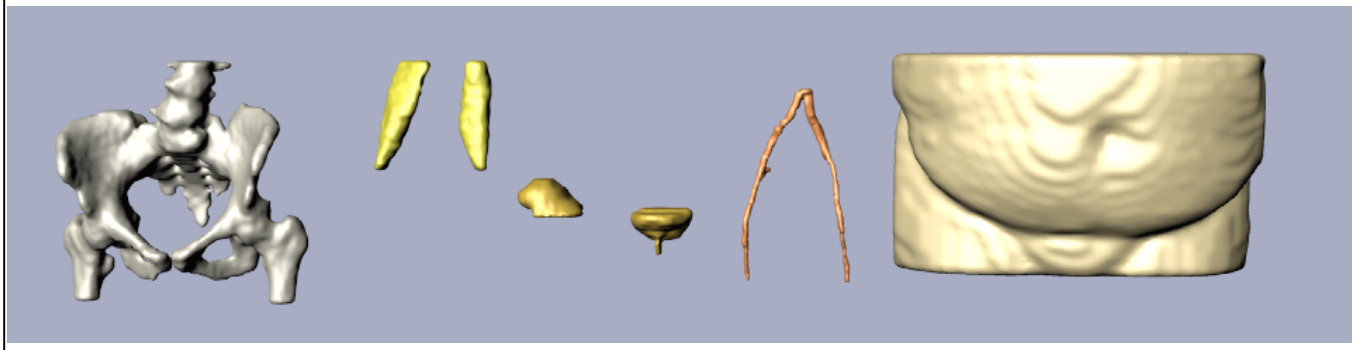
School of Biomedical Engineering, Science & Health Systems

Virtual Endovaginal Ultrasound Simulator (VEUSim)



Executive Summary

All the information contained in this business plan is in accordance with the best knowledge, judgment, and consideration of Drexel University. However, neither Drexel University nor any of its employees shall be responsible for the accuracy of the information or for any incorrect information that may be unintentionally included in this business plan.

1. Background

Ultrasound examination via natural orifices, such as transesophageal ultrasound for echo cardiography and endovaginal ultrasound for diagnosing gynecologic disorders, are gaining increasing popularity. However, training physicians and medical students to perform these procedures is difficult and expensive due to the complex anatomy of the orifices, shortage of volunteer subjects, and very limited capabilities of available but expensive human mannequin-based systems. To fill this gap in the medical education market Drexel's clinicians and engineers have developed VEUSim, a virtual reality training system with haptic interface to provide real-life experience of ultrasound examination via a natural orifice. VEUSim has unlimited capabilities for modeling various anatomical structures and creating and modifying associated pathologies, and a unique trainee/instructor interface for recording and quantitative evaluation of trainees' performance and progress. VEUSim has been developed as a Virtual Endovaginal Ultrasound Simulator (hence the name, VEUSim) as described below, and can be easily adapted to simulate ultrasound examination via any other natural orifice such as esophagus, colon etc. In future this same technology can potentially be utilized for training other Ultrasound, surgery and tracheotomy techniques.

The VEUSIM Technology is available for licensing from Drexel University now. See Paragraph 8 for contact information.

2. Product

What unmet medical need does the product address?

Endovaginal ultrasound is a valuable tool for early screening, detection, and diagnosis of life-threatening diseases such as ovarian cysts/cancer and ectopic pregnancy. Endovaginal ultrasound equipment is relatively inexpensive even for the small clinics or emergency room. The procedure can be easily performed by an adequately trained doctor or technician who inserts the ultrasound probe into the patient's vagina and manipulates the probe while viewing an image on the screen. However, training for this procedure is difficult and expensive because volunteers are rare, and mannequin-based training systems are expensive (>$100K) and rely on a limited number of pre-recorded 'case studies'. The shortage of trained users has slowed widespread adoption of endovaginal and endoscopic ultrasound for screening or diagnosis.

What Technology is the Product based on?

To facilitate training in using these ultrasound modalities Drexel's clinicians and engineers have developed 3-D, portable virtual reality (VR) training system, VEUSim, originally designed to train users in the endovaginal ultrasound examination. A true 3-D visual display (NVidia, 9800GT with GForce 3D Vision) and touch sensitive haptic interface (Phantom Omni, Sensable, Inc.) provide an immersive VR experience with realistic probe "feel". 3-D pelvic anatomy MRI scans are used to generate realistic, real-time simulated ultrasound imaging on-the-fly. Because the system is primarily software-based (using newly available off-the-shelf components) the simulator is *portable* and much less expensive than existing mannequin systems that cost over $100,000 per unit.

VEUSim has been programmed in C++ and Python using a combination of open-source technologies: (1) VTK/ITK, (2) Qt, and (3) OpenHaptics toolkits. Although the VEUSim software is open-source, VEUSim authors have also developed (and are continuing to develop) training sessions using proprietary a much more instructor friendly Virtual Parametric Pathology system. Moreover the instructor can easily add pathologies of various kind and size to the intact anatomy. Training sessions are designed for high clinical relevance and provide a means for trainees to learn the basic procedure as well as diagnosing 'difficult' cases.

Simulated ultrasound is generated computationally in real-time, creating experience of using actual endovaginal or endoscopic ultrasound machine. A 'cutting plane' is passed through the 3-D MRI data at angles corresponding to the probe orientation. As the user moves the haptic probe, the cutting plane is continuously updated. The resulting image is then converted using a sequence of image processing procedures based upon the physics of ultrasound imaging, including fan-beam projection, echo, and shadowing effects. VEUSim uses relatively simple filters (simulated noise, contrast enhancement, etc.) and masking techniques to generate ultrasound images that appear realistic, without the need for high-powered computing resources. The end

result is a realistic ultrasound experience running on any inexpensive PC equipped with standard (NVidia) graphics capability.

Who Owns the Intellectual Property Rights on the Technology?

VEUSim is described in Drexel's invention disclosure 06-0664D, "A virtual endovaginal ultrasound simulator for physician training (VEUSim)". VEUSim is a complex, fully operational software system protected by copyright. Additional protection is rendered via the know-how of the VEUSim inventors and implemented in the design and contents of encrypted training modules and procedures for generating training problems and the assessment of the trainees' performance. The copyright and the know-how are owned by Drexel University.

3. Market Size and Potential

Who are the Customers and what is the Potential for this device?

VEUSim can have an indirect, but significant impact on patient care. Ovarian cancer is extremely hard to detect in its earlier, treatable stages because it has no symptoms. Alone, it is responsible for at least 84,000 deaths each year in the United States. The ultimate goal of this project is to enable use of ultrasound examination as an *early screening tool*.

VEUSim can facilitate widespread use of ultrasound examination. Impact on healthcare in general could be significant, since the VEUSim platform can be easily applied to simulate a wide variety of other ultrasound modalities such as endoscopic and transesophageal. Adoption of transesophageal echocardiography by cardiologists opens a particularly attractive market for VEUSim as an initial training tool for this modality.

In addition to its impact on patient care, VEUSim can be viewed as a highly valuable marketing tool. The VEUSim GUI is customizable to match the look of any brand-name ultrasound system (GE, Siemens, Phillips, Sonosite, etc.). A large volume of potential customers is available. The main groups of performers of endovaginal ultrasound are GYN and emergency physicians and ultrasound technologists. VEUSim can provide basic training for new trainees and advanced training for experienced practitioners. There are presently approximately 39,000 OB GYN physicians and approximately 27,000 emergency physicians in the US. There are also about 125,000 Internists in the US.

VEUSim could have a significant impact on medically related education at all levels, including K-12 and undergraduate education. The VEUSim simulator would be an exciting and affordable addition to any medical course material, and we hope it will generate broad enthusiasm in K-12 through graduate education.

4. Competitive Landscape and Advantage

Traditional medical training utilizes the ***"See One, Do One"*** teach philosophy. However, this 100 year-old Halstedian apprenticeship model is running into a myriad of problems associated with the lack of training opportunities in today's healthcare education community. The lack of opportunities are related to numerous factors: new resident work hour limitations, expense, lack of live human volunteers, ethical issues surrounding the utilization of animal labs, malpractice costs, and overall patient dissatisfaction in being live training tools. These factors coupled with the continued advances in medical technology have made it extremely difficult to produce well-trained health care providers. The lack of opportunities has driven the education industry to explore new methods for training and assessing competency of their students and establish the need for this future mantra: ***"See One, Simulate Many, Achieve a Level of Competence, and Then, and Only Then, Perform Procedures on Patients".*** *As a result,* a paradigm shift is taking place. Training curriculum for medical students and other health care providers is moving from the apprentice model to endorsing and using simulation technology and techniques to build competence.

Beyond live volunteers there are physical simulators which require a fixed installation and a price tag in excess of $100,000. This type of simulation is done on a mannequin-like base and not in a virtual 3-D environment. Its bulky design, dated technology (10 years old), and high cost places it out of reach for even large hospitals.

Furthermore, such simulators offer very small variety of pathologies to practice on, which limits their training efficiency, and acquiring additional pathology components makes them ever more bulky and expensive.

What are the advantages of this technology?

There are three key advantages of the VEUSim training system over existing technologies:

- **Unlimited, variable pathologies.** The software-based design of the system allows the instructor to generate any number of parametric virtual pathologies or 'virtual case studies' depending on the needs of the training course or a particular trainee, etc. VEUSim is NOT limited to a few pre-recorded sessions. This allows the instructor to develop new training modules to meet specific training needs and goals.
- **Quantitative performance and progress monitoring.** The second main advantage is that the user's performance can be *quantitatively monitored* and assessed. The Phantom Omni haptic interface records both the user's kinematic motion during the training session and the forces generated in *real-time*. Thus, the software (or the instructor) can determine if the trainee is having difficulties positioning the wand, has found the correct orientations, has difficulties with hand-eye control, or any other related factor. Individual trainee's performance is recorded, and the progress can be monitored from session to session. No other training system can provide this quantitative, verifiable trainee performance data.
- **Unlimited anatomies.** The third crucial advantage of the VEUSim platform is that it is not limited to a particular orifice anatomy. Because anatomy of the orifice is generated by the computer, not a physical mannequin as in currently available systems, training on anatomical variations for the same orifice or entirely different orifices can be accomplished using the same hardware. Changing to a different anatomy can be as easy as selecting a new item from a drop-down menu.

Compared to most other mannequin-based training technologies, VEUSim has very low development costs, a streamlined path to market, protected IP (training modules and virtual parametric pathology), and high volume of potential customers, beginning with introduction to current users of endovaginal ultrasound systems, and ultimately for medical student and physician training programs.

5. Regulatory

As a medical education software training tool the system does not require FDA approval.

6. Development status

To date, the training system GUI development is complete, including the difficult tasks of computational ultrasound simulation and 3-D haptic interaction with live recording and playback capabilities. Simple, introductory training modules have been developed. The trainee 'results' and evaluation GUI has been developed. Work on the Instructor GUI is ongoing and additional training modules are under development. We are now actively demonstrating the system to and obtaining feedback from ultrasound experts at Drexel's College of Medicine and Temple University Medical School.

7. The Team

Todd Doehring, Ph.D. is an assistant professor in the Drexel School of Biomedical Engineering Science and Health Systems, bringing expertise in biomechanics of soft tissues, computational modeling, and a proven track record of advanced GUI development from concept to practical application. His novel open-source SuperSlicer 3-D reconstruction software (www.SuperSlicer.net) is being used by several institutions: notably Prof. Guon Li at MIT, Dr. P. Cavanagh of the Cleveland Clinic, and Dr. L. Blankevoort of the University of Amsterdam.

Dr. Neal Handly, M.D. is an established clinical professor of emergency medicine at the Drexel School of Medicine with a strong research background in training, use and performance of ultrasound by OB-GYN and emergency physicians. He has 26 hours of direct patient contact each week and additional time is spent in doing QA and teaching ultrasound techniques to residents and general topics of Emergency medicine to residents and students. He has been a Drexel University College of medicine faculty for 6.5 years performing ultrasound in the ED for an additional three years.

Pablo Burstein, Ph.D. is a Research Assistant faculty Drexel School of Biomedical Engineering Science and Health Systems. He has an established record of accomplishments ranging from industrial computer science (IBM, Inc.) to academic computational projects while completing his Ph.D. and post-doctoral research at the University of Pennsylvania.

8. Further information and licensing inquiries

Drexel University's School of Biomedical Engineering, Science and Health Systems is an integral part and a driver of the regional economy. The focus of the School of Biomedical Engineering on translational research resulted in several ground breaking biomedical innovations. It is the goal of Drexel University to license those technologies either to established corporations or start-up companies to move those innovations from bench to bedside.

For licensing information please contact:

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