

**Developing a Novel Ultrasound Probe-Body Interface**

**The Social Construction of the Handheld Ultrasound Probe**

A Thesis Prospectus

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By

**Thomas Dugan**

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Technical Team Members:

Paul Deaton

On my honor as a University student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

ADVISORS

Dr. Masahiro Morikawa, Department of Family Medicine

Joshua Earle, Department of Engineering and Society

## **Introduction**

Medical imaging is a powerful tool in doctors' battle against disease; it allows them to see directly into the body. Medical imaging helps doctors identify disease states that they otherwise would not be able to, which is the first step when treating a patient. Once such medical imaging technology is medical ultrasound. Medical ultrasound transducers emit high-frequency sound waves that travel through the body and return, where they are measured by the ultrasound probe and integrated into a two-dimensional image.

Ultrasound technology is a common imaging tool, but the ability for generalist physicians to quickly and efficiently use it is recent. Handheld, battery-operated ultrasound machines only begin to be available in the late 1990s (Tse et al.). These point-of-care ultrasound (POCUS) machines make it possible for the internal medicine doctor to examine the internals of their patients, diagnose what is wrong, and take appropriate action. Where delaying could be deadly, POCUS saves lives. In addition, POCUS is significantly less expensive than cart-based ultrasound machines, where handheld machines start at \$3000 and cart-based machines typically cost over \$100,000 (Falkowski et al.). This transformative technology is a major advance: having quick, easy scanning ability is a great benefit to both doctors and patients.

A technology that evolved alongside ultrasound scanning technology is ultrasound gel.

Ultrasound gel is a watery polymer substance in several different formulations, such as the Turkuaz Konix® Sterile Gel, and the Parker Labs Aquasonic® 100 Ultrasound Gel. For ultrasound technology to work properly, there must be a material in between the ultrasound probe and the body so that the waves do not travel through air, and gel serves this function.

**Technical project: Development of a novel ultrasound interface material**

Medical ultrasound imaging technology is a powerful tool to help doctors visualize the structures inside the human body; however, one major barrier to its efficient use is the necessity for the use of ultrasound gel. Materials like PDMS silicone have been proposed as an interface material<sup>1</sup>; yet, no product or material has been designed for the criteria and constraints that is needed to replace ultrasound gel. We first intend to find non-toxic interface materials that can pass FDA sensitization and irritation tests. These materials must have a similar acoustic impedance value to soft tissue to allow for the capture of clear images. Silicone elastomer formulations such as Sylgard 184 and Sylgard 170 are among the materials to be tested. They were chosen for their inert chemical structure, their tunable physical properties, and for their specific acoustic impedance values reported in the literature. Second, we intend to test the materials for the clarity of image they produce and to select and develop a prototype. The control in this experiment will be Parker Labs Aquasonic® 100 Ultrasound Gel, as it is the common ultrasound gel formulation used by Dr. Morikawa in his daily practice, as well as a well-established ultrasound gel product.

### **STS project: the Social Construction of the Handheld Ultrasound Probe**

This part of the project will focus on an analysis of the development of the handheld ultrasound probe. Initially, this will be done using actor-network theory, in order to identify the relevant groups affecting handheld ultrasound. However, after the groups have been identified, a social construction of technology (SCOT) approach will be used to analyze how POCUS came about (Bijker et al.). This approach recognizes that technology exists in the context of the society that creates it, and that technology is the result of different groups acting on and advocating for their needs.

Given the context for the development of POCUS technology occurring after the Gulf war, the military had a sizeable impact on pushing for its development (“Point-of-Care Ultrasound Diagnostic Tool Use on the Rise”). Following the pattern of many technologies, POCUS was adapted for civilian use after military development, and it has been gaining prominence ever since. Other actors in the rise of POCUS are doctors who see the power of the technology, and attempt to integrate it into their practice. However, there are doctors who champion the stethoscope over POCUS, saying that they have more confidence in using a stethoscope, and that a stethoscope is quicker and more efficient. The necessity for gel is a large part of this inefficiency, but more than that, these actors represent technological inertia. People do not want to adapt to a new technology because they are used to the old one. Another group of actors is the ultrasound machine companies, who have an incentive to see ultrasound grow as a clinical practice.

An important group of users of ultrasound technology is pregnant women, who use ultrasound imaging for a variety of reasons (Roberts, F. E. Griffiths, et al.). Ultrasound imaging plays a role in the social construction of family, and fathers who view ultrasound images of their unborn children are also affected (Draper). Ultrasound technicians also form a group of users.

Ultrasound technology is inseparable from pregnancy, and sometimes associated with pregnancy is abortion. The relationship between ultrasound and abortion is a complicated one, but it will be discussed.

## **Research Question and Methods**

The research question being explored in this paper is: how was point-of-care ultrasound developed as a technology, and what factors have contributed to its acceptance or lack thereof?

This paper will explore the topic with an in-depth literature review of the history of POCUS

technology. The acceptance of POCUS technology will also be studied using case studies of POCUS machines being integrated into hospitals and the reactions of doctors, patients, and other relevant actors. Getting the opinions of doctors who use POCUS will be critical, as this will tell us where some of the major difficulties associated with the technology lie, and where technological or societal development should occur for the technology to come to greater acceptance.

### **Key Texts**

“The Social Construction of Technological Systems,” by Bijker, et al. expounds the thesis that technological progression does not occur linearly, but is a result of social forces that guide and shape how the technology develops (Bijker et al.). This will be a key text for my paper because I will be using the social construction of technology (SCOT) framework to study how the handheld ultrasound probe was developed and what social obstacles exist to its increased use.

“Point-of-care ultrasound (POCUS): Unnecessary gadgetry or evidence-based medicine?,” by Smallwood and Dachsel explores the medical evidence surrounding the effectiveness of point-of-care ultrasound technology (POCUS) (Smallwood and Dachsel). This source is important to my paper because it is necessary to consider the clinical outcomes that come from using POCUS because this will factor in to decisions made regarding whether POCUS is widely taken up and adopted.

“Seeing the Baby, Doing Family: Commercial Ultrasound as Family Practice?,” by Roberts, et al. is a sociological research article in which interviews were conducted with pregnant women who underwent commercial ultrasound imaging for the purpose of seeing their unborn baby

(Roberts, F. Griffiths, et al.). Pregnant mothers as a group are people who often take advantage of portable ultrasound imaging and their opinions on it will be important for my project.

“Hand-Held Portable Versus Conventional Cart-Based Ultrasound in Musculoskeletal Imaging,” by Falkowski et al., is a research experiment where the effectiveness of portable and cart-based ultrasound equipment were compared (Falkowski et al.). The study found that there was little to virtually no difference between the decisions made as a result of the change in imaging technology. With their added portability, the effectiveness of handheld ultrasound devices is technically greater than cart-based systems.

“Handheld ultrasound in training – The future is getting smaller!”, by Wilkinson and Saxhaug, is a research article that discusses the progression of ultrasound machines from large cart-based systems to smaller handheld models (Wilkinson and Saxhaug). This source is important because it describes the enormous potential ultrasound has for increasing the clinician’s ability to make accurate diagnoses.

“Constructing the meaning of ultrasound viewing in abortion care,” by Kimport and Weitz, is a sociological research article concerned with how the viewing of the fetal ultrasound impacted the process of abortion care (Kimport and Weitz). Interviews were conducted with ultrasound workers in abortion care as to their impressions on how ultrasound viewing impacted their practices. This source is important for the dimension of how pregnant mothers are impacted by ultrasound technology.

“Why do women seek ultrasound scans from commercial providers during pregnancy?”, by Roberts et al. is a sociological research study seeking to understand the reasons for why, without a clinical or medical purpose, pregnant women choose to undergo ultrasound imaging (Roberts,

F. E. Griffiths, et al.). Interviews were conducted with pregnant women undergoing commercial ultrasound, and these reasons were grouped into five categories: finding out the sex of the fetus, reassurance, seeing the baby, acquiring keepsakes, and facilitating bonding. This source deals with the relationship between pregnant women and ultrasound technology.

“A much valued tool that also brings ethical dilemmas,” by Åhman et al, is a sociological research paper that interviewed midwives and sought to understand midwives’ experiences and views on the role of ultrasound in clinical management of pregnancy (Åhman et al.). The midwives expressed that prenatal diagnoses, including those following ultrasound, “might create a society where only ‘perfect’ children are valued” (Åhman et al.). This source is important to my project because the ethical concerns surrounding a technology must be considered when it occupies such an important position in society.

“The ultrasound scan, fathers and the power of visual knowledge,” by Draper, is a sociological paper discussing men’s experiences with the ultrasound scan as they transition to fatherhood (Draper). An ethnographic study is used to illustrate the function of seeing the baby in making the reality of the pregnancy salient. I will use this source to demonstrate ultrasound’s powerful social role in the construction of family.

“The Use of Handheld Ultrasound Devices in Emergency Medicine,” by Malik et al., is a scientific review article that observes the increase in use of portable ultrasound machines in emergency medicine contexts (Malik et al.). This source goes into the emergency medicine angle of handheld ultrasound, where the portability and ease of use multiply the technology’s efficacy.

## **Conclusion**

For portable ultrasound scanning technology to reach its highest potential, the interface problem must be solved. Doctors will have greater ability to diagnose and treat patients. For the STS project, an understanding of how the handheld ultrasound probe came into existence will allow greater insight into the problems that hold it back from greater acceptance in the patient care setting. This paper will explore these in an effort to better understand this revolutionary technology.



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