



Pantas and Ting

# Sutardja Center

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## Low-Power, Wireless, Ultrasonic Imager Study of Potential Applications

### Abstract

We introduce a portable, battery-powered, wireless ultrasonic imager that uses a custom silicon chip to transmit and capture 2-D sonographs. Here, we explore a number of potential industries to identify a set of promising applications for our ultrasound technology. We evaluate and score each space based on the market size, the need for a cheap, portable ultrasound system, compatibility of our device to meet the technical requirements, and barriers to entry. We found that while medical space faced high barriers to entry due to regulatory environment and the food industry lacked the need for a portable solution, the field of quality assurance, in particular non-destructive testing of materials, met all our criteria and seemed most promising.

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## Introduction

Ultrasound is a powerful tool for non-invasive body monitoring and sonography has a decades-long track record in medical imaging. Various features such as blood flow, stiffness, and anatomy of tissue can be quickly computed based on the time-of-flight of ultrasonic echoes. Unfortunately, current ultrasonic systems are expensive, bulky, highly complex, and power hungry. There are several reasons for the complexity, such as immense computational power required to store and process image data on-the-fly for real-time visualization and hardware to drive many elements in the transducer arrays (often more than 100+ elements). There have been a number of efforts to miniaturize both transducer arrays and the receiver electronics by employing fabrication techniques used in micro- and nano-fabrication and innovations in integrated circuits designs. However, inefficiencies of the transmitter circuits and the need for external, bulky high-voltage power supplies limit the overall energy efficiency of commercially available ultrasonic imagers. Significant improvement in the energy efficiencies of these transmit driver circuits can enable high-voltage power supplies to be generated on-chip, which can enable orders of magnitude reductions in both size and power consumption of these imagers.

## Section I: Competitive Landscape

Today's ultrasound imager market can be broadly categorized based on price and accuracy. A snapshot of the competitive landscape is shown in **Figure 1**. On one end of the spectrum, there are medical-grade, high-performance ultrasound imagers. Medical ultrasound must meet strict guidelines set by the regulatory agencies, such as the Food and Drug Administration (FDA) and National Electrical Manufacturers Association (NEMA), and operate under the As Low As Reasonably Achievable (ALARA) principles (FDA 2014). As a result, although robust and versatile, these imagers tend to be bulky, hard-to-use, and expensive, costing more than \$100k and requiring constant maintenance. In general, these machines are not readily accessible.

With a growing consumer interest in economical and easy-to-use solutions for monitoring personal health and fitness, several ultrasonic imager manufacturers have introduced portable, hand-held imagers, such as GE VSCAN, Philip VISIQ, Siemens ACUSON, and Samsung UGEO. While compatible with medical ultrasound transducer arrays and orders of magnitude lighter than traditional imagers, these devices are still typically priced around \$10k, and exhibit less than 2 hours of battery life, which make them still inaccessible to large parts of the world. On the other end of the spectrum, there are extremely affordable (less than 1k) and portable imagers, such as Bodymetrix, that have been used to measure body-fat thicknesses. However, these systems are inaccurate and not user-friendly.

In contrast, we believe that our system proposed in this report is situated on the untapped corner of the spectrum, where an ultrasonic imager is both accurate and affordable.

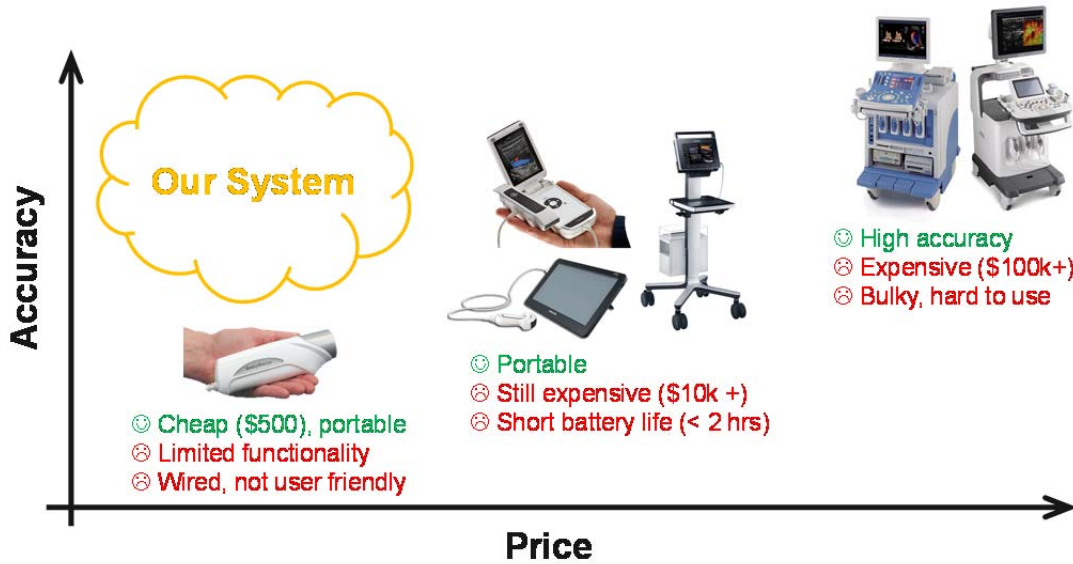


Figure 1. Current ultrasound imager market and our system in the competitive landscape

## Section II: Technology

Driven by a growing interest in an economical, portable, and complete point-of-care diagnostic tool, we have developed the first prototype of a miniature ultrasonic imager that fits onto the palm of our hand (Figure 2). Our technology introduces a novel, energy-efficient high-voltage transmitter architecture and circuit techniques to enable integration of high-voltage generation on-chip with a single 1.8 V battery. By extremely miniaturizing an ultrasonic imager, we believe that we have technology that can have huge implications for several applications.

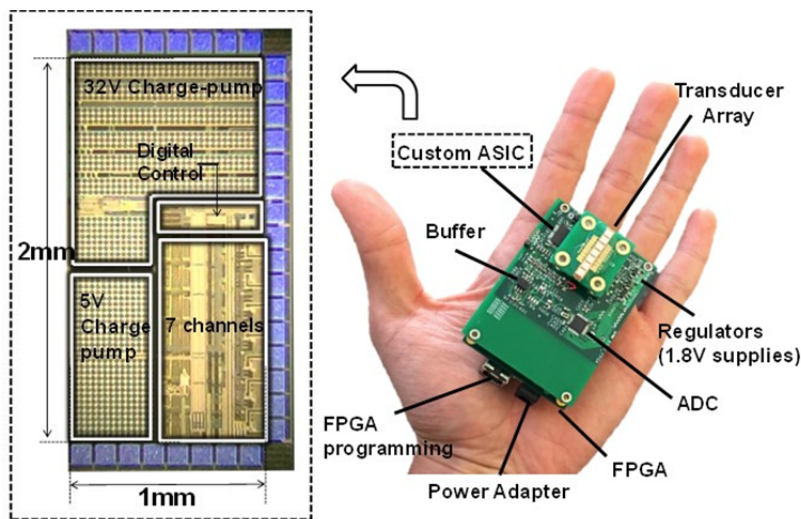


Figure 2. System and die photo of the custom silicon chip

## II.1. Technical Details

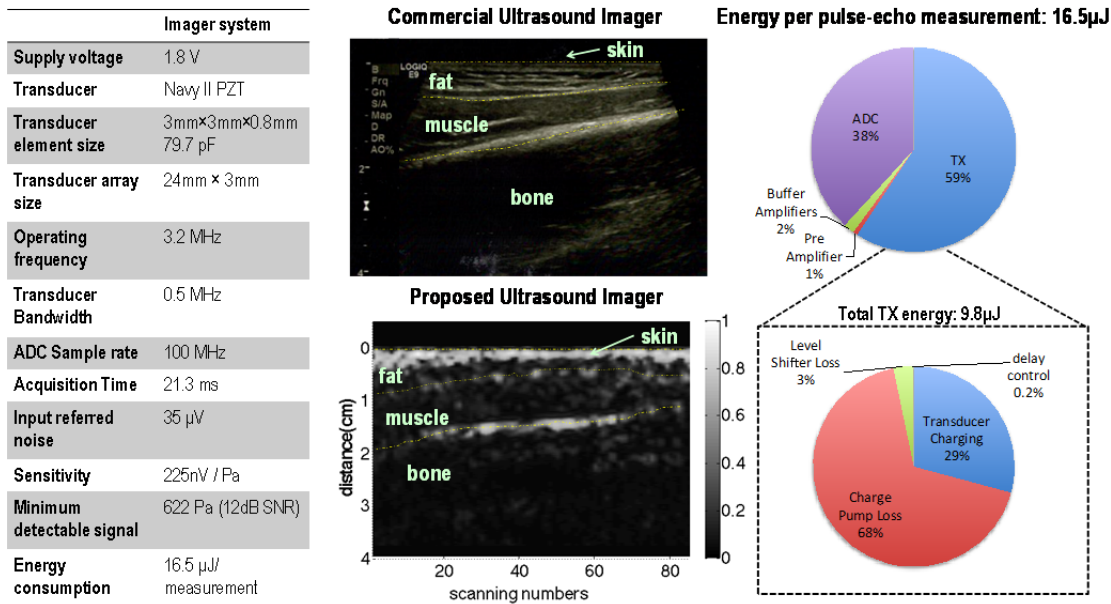
Briefly, the core innovations of our system are:

1. **Energy-efficient transmitter architecture:** Ultrasonic transmitters are fast-switching circuits that are used to drive transducer arrays and typically consume the largest portion of the imager's energy consumption. Unfortunately, the energy-efficiency of current designs are limited by the conduction current (crow-bar current) from the high voltage supply to ground during switching cycles and most techniques used to alleviate this issue result in the speed degradation. Our system is based on novel circuit architecture and techniques that can suppress crow-bar current while maintaining high speed.
2. **Battery operation:** Interfacing with transducers often necessitates high-voltage supplies (10's to 100's of volts) in order to generate sufficient acoustic pressure waves. As an example, a commercially available ultrasonic transmitter module requires external power supplies, in addition to the wall socket. Our efficient transmitter architecture allows our system to operate with a single 1.8 V battery. Also, our system consists of circuitry to generate all these necessary voltage levels with miniature and easily integrated capacitors.

## II.2. Performance summary

A 2-D scan of a human arm was first obtained using a commercial medical ultrasound machine (LOGIQ E9) as shown in **Figure 3**. We obtained a similar 2-D sonograph using our imager, shown in **Figure 3**, by placing the transducer array on the same spot and manually sliding the imager. The fat, muscle, and bone layers were clearly visible in both scans, resulting in ~9 mm and ~11 mm of fat and muscle thicknesses, respectively. Although the image obtained from a commercial ultrasound imager had better resolution, it consumed orders of magnitude more energy per pixel compared to our imager.

The entire image took ~2.2 s to obtain. The overall system performance and the power breakdown are summarized in **Figure 3**. An energy consumption of 16.5  $\mu\text{J}$  per each pulse-echo measurement can truly enable battery powered operation. To illustrate, assuming a 5.45 Wh battery found in iPhone 5, we calculate approximately 1.2 billion pulse-echo measurements. Given that each image takes approximately 100 pulse-echo measurements, this results in 12 million images before having to recharge the battery.



**Figure 3.** Imager performance summary and the power breakdown chart. Comparison of measurement from a commercial ultrasound imager and our imager shows similar features.

## Section III: Potential Market Space

Our goal for this class was to explore a number of potential markets and start to hone in on the most promising ones for our ultrasound technology. We began with a few general industries of interest and received excellent feedback from many mentors at the start of the class to do research on each of these areas and analyze their market size, potential for growth, compatibility with our technology's specifications, competitive landscape, and regulatory environment. Here we present our findings and explain why we believe certain areas are not a good match for our technology while others are the most promising ones to target.

### III.1. Medical diagnostics

#### III.1.A. Overview of Medical Benefits and Drawbacks of Ultrasound

As the safest of the medical imaging modalities, ultrasound has incredible promise for use in healthcare settings. X-ray, CT, PET, and other common imaging methods involve ionizing radiation. Exposing patients to ionizing radiation is a chief concern in medical imaging, and high levels of ionizing radiation have been linked to increased risk of cancer, skin erythema and cataracts. MRI is another common technique but there are many reported cases of injuries and deaths due to the magnetic fields that are produced – when objects containing ferrous metal such as oxygen tanks, knives, and scissors are brought too close to an MRI machine, they become projectiles. Even ferrous metal inside patients' bodies (surgical clips, aneurysm clips, shunts, metal shard in the eyes from welding, etc.) have caused death and injury. Furthermore, patient claustrophobia is a concern in MRI.

(ISU Radiographic Science, 2012) Ultrasound does not use ionizing radiation and does not produce dangerous magnetic fields. It is also superior in patient comfort and is a relatively inexpensive diagnostic imaging system.

However, ultrasound does not come without some drawbacks. It has limited penetration ability, so bone deep within soft tissue may not be well visualized. It is more operator dependent than other modalities, yet there are currently few specialists in this area, particularly in the field of orthopedics. (ISU Radiographic Science, 2012). Importantly, the FDA has also issued guidelines that facilities that utilize ultrasound follow the ALARA (As Low As Reasonably Achievable) Principles (FDA 2014).

### *III.1.B. Potential Medical Applications*

The field of medical devices, diagnostics, and health is huge, so here we focus on a few key areas where ultrasound has been shown to be useful: fetal monitoring, ultrasound-guided needle placement, fracture diagnosis in the emergency department, and triage.

#### Fetal Monitoring

Since ultrasound is based on non-ionizing radiation, it does not incur the same risks as X-rays and many other imaging systems, prompting an excellent safety record. However, ultrasound does have the potential to produce biological effects on the body. For example, it can slightly heat tissue in the area of interest and in some cases produce small pockets of gas in body fluids or tissues. For these reasons, the FDA discourages use of ultrasound for non-medical purposes such as obtaining fetal ‘keepsake’ videos. Similarly, there are over-the-counter fetal heartbeat monitoring systems (doptones), but they should only be used trained healthcare professionals when medically necessary. Especially when the fetus is in its first trimester, use of these devices by untrained personnel could expose the fetus to unsafe energy levels. (FDA 2014). While fetal monitoring is a huge market, pregnant women are expected to get regular check-ups with their obstetrician for medical purposes, and should not be taking ultrasound images on their own for non-medical reasons.

#### Ultrasound-Guided Needle Placement

Common ultrasound imaging procedures include ultrasound-guided needle placement in blood vessels and ultrasound-guided biopsies to collect tissue samples. While ultrasound is non-invasive, free of radiation, relatively inexpensive, and quite accurate in bone registration, there are many difficulties inherent in the use of ultrasound guidance in surgery. Since ultrasound waves have limited penetration in a patient’s tissues, patients with excessive fat (obese) or excessive muscle tone (hypersthenic) may not be able to benefit from these methods. (ISU Radiographic Science 2012). Ultimately, these procedures are performed in a hospital setting and are unlikely to be replaced by equipment that is cheaper if the resolution is not as good. We feel that this would be a difficult sell to both hospitals and insurance companies.

#### Fracture Diagnosis in the Emergency Department

Fracture diagnosis is one of the most common procedures done in the emergency department, as 20% of emergency department visits by children are fractures (Keen 2010). Pediatric patients would be a good target population for ultrasound diagnosis because they are at greatest risk when exposed to

ionizing radiation. (ISU Radiographic Science 2012). Ultrasound has been shown to have a relatively high sensitivity and specificity to detect fractures, particularly when they occur along long bones. In fact, ultrasound is superior to X-rays and CT in detecting rib fractures because the transducer can be oriented along both the long and short axis of the rib, whereas non-displaced fractures of other thoracic structures may not appear in an X-ray. (Hoffman 2015). An intriguing niche market in this area derives from the fact that emergency departments can get overcrowded and the wait times for radiographs can exceed several hours in a facilities with high patient flow. A portable ultrasound solution would allow for a quick and noninvasive alternative to identify bone fractures in the emergency department setting. (Sinha 2011) However, this market is difficult to define, since overcrowded emergency departments would be the main target rather than all emergency departments. Furthermore, there would likely be competition from other companies in the ultrasound industry as depicted in Figure 1, since emergency departments may choose to use a slightly more expensive alternative with better resolution.

#### Triage – Natural Disasters, Developing Countries, Military

While fractures are a fairly common reason for emergency department visits, treatment is often insufficient because according to an estimate by the World Health Organization, close to 70% of the world's population has no access to diagnostic imaging services (Keen, 2010). This pushed us to think about a very different sector of healthcare – triage in areas all around the world that require rapid response to a large number of casualties.

For example, an average of 388 natural disasters occur per year, affecting 216 million people and killing hundreds of thousands of them (Guha-Sapir 2014). In developing countries, the use of trauma ultrasound has already been shown to decrease the time to operation by 64%, as well as decrease complication rates and hospital lengths of stay as compared to standard clinical evaluation. In fact, the increased affordability, portability, and durability of ultrasound machines is allowing for an increase in ultrasound services even by nonradiologists in resource-limited settings. (Sippel 2011) Another interesting application space is for the military. For military personnel that may be injured and have a fracture, sometimes the nearest facility with X-ray capability could be reachable only by air medical evacuation (ISU Radiographic Science 2012). In this situation, our technology could be used by the physical therapist or physician and images could be sent to a radiologist for confirmation of diagnosis. Overall, we believe our cheap, portable ultrasound system can be the solution for disasters and mass casualty scenarios for rapid triage that can guide operative care. While the market is large and our device is compatible with the need, more work needs to be done to clarify any barriers to entry, as working with government agencies will potentially require a different approach than what is taken by traditional companies in this space.

#### *III.1.C. Fitness Tracking*

With the growing popularity of fitness trackers, we thought that this may be an industry with engaged consumers interested in monitoring their own health. Fitness trackers were a \$2 billion industry in 2014 and are set to almost triple by 2019 (Parks Associates 2015). Market adoption has also risen, as connected health devices jumped from 24% adoption in 2013 in the United States alone up to 30% by the end of 2014. (Lamkin 2015). While we believe our technology is compatible with the user desires

to measure body fat composition, for example to calculate how much fat is overlaying their abdominal muscles, ultrasound does not seem like something that should go into consumer products due to the ALARA principle.

## III.2. Quality Assurance

### III.2.A. Industry Overview

From manufacturing plants and construction sites to nuclear power plants, oil refineries and shipyards, nondestructive testing (NDT) is used for numerous applications across a wide range of industries. NDT services are used to detect flaws, cracks, variations and minute changes in structures and surface finish without damaging the products being tested. Rapidly changing technology and the increasing complexity of products and processes that need testing have boosted demand for industry services. Also, strict government regulation relating to health, safety and the protection of the environment continues to drive industry revenue growth. Overall, the industry is expected to grow an annualized 6.8% in the five years to 2015 to \$2.6 billion (IBIS 2015).

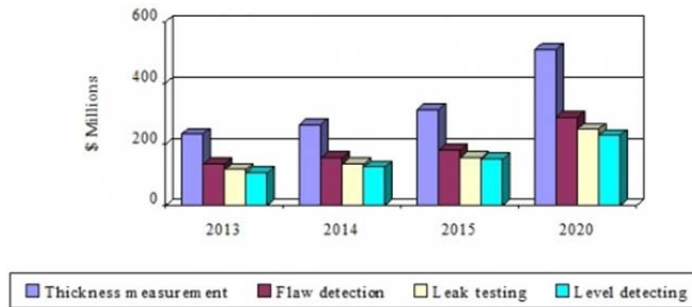
The industry's rapid expansion will continue in the five years to 2020, with revenue estimated to grow an annualized 4.3% to \$3.2 billion over the five-year period (IBIS 2015). Frost & Sullivan research estimated the ultrasonic NDT equipment market at \$434.6 million in 2011 growing at a compounded annual growth rate of 7.2 percent, and is expected to reach \$615.5 million by 2017. From an end-user industry perspective oil and gas and power generation are the biggest markets for ultrasonic NDT equipment contributing 29 and 24.4 percent respectively in 2012. Aerospace, military and defense is the next biggest segment accounting for 15.8 percent of the market. (Sandler 2014; Frost 2013). Continuing technological innovation will make NDT services more cost effective and efficient for end users, thus boosting demand for industry services.

The ultrasonic testing equipment market can be broadly classified into the following (BCC 2014):

1. Ultrasonic thickness gauges: A measuring probe connected by cable to a small amplifier and numeric display screen. Most of the instrumentation is digital and portable. Thickness gauges can be further subdivided into precision gauges and corrosion gauges. Corrosion gauges are used to measure the remaining wall thickness in metal pipes, tanks, structural parts and pressure vessels that are affected by internal corrosion. Precision gauges are used in industries that require greater accuracy in measurement, as they have the ability to measure thin metals.
2. Ultrasonic flaw/corrosion detectors: These are the most commonly used ultrasonic NDT equipment. This relatively less expensive equipment can be used for a wide variety of applications of varying sensitivity levels and ease of operation.
3. Ultrasonic leak testing/detection equipment.
4. Ultrasonic level detecting equipment.

The breakdown of the global market for ultrasonic testing equipment is depicted in the following figure.





### III.2.B. Existing technologies

Thickness Measurement (Off the shelf, hand held devices, price ranges from 120\$ to 2000\$):

1. The **PosiTector UTG** measures the wall thickness of materials such as steel, plastic and more using ultrasonic technology. Ideal for measuring the effects of corrosion or erosion on tanks, pipes or any structure where access is limited to one side. Multiple echo (*UTG M*) Thru-Paint models measure the metal thickness of a painted structure without having to remove the coating.
2. **GM100** Ultrasonic Wall Thickness Gauge Meter Tester
3. **DMS Go+ Series A-Scan Thickness Gauge** from GE

Corrosion/Flaw detection (More sophisticated equipments costing a few thousands to a few ten thousand dollars)

1. **HydroFORM, RexoFORM, Dual Linear Array Corrosion Probe** : Phased Array Corrosion Mapping Solutions from Olympus
2. **Veo Series**, Sonatest
3. **Phasor Series Ultrasonic Flaw Detectors** from GE
4. **USM Vision Weld Inspection System** from GE

### III.2.C. Suitability of our device

1. The current device design is suitable for thickness measurement.
2. For flaw detection, the device is particularly good due to the design of multiple transducer elements which permits more sophisticated scanning using phased pulsing of the elements.
3. While the device can be used for level detection, the market is flooded with off the shelf sensors that provide the same function with substantially lesser cost (less than \$10).

## III.3. Food industry

Ultrasound has been finding increased use in the food industry for analysis, modification, and quality assurance of food products. Studies have shown that a wide range of ultrasonic frequencies from kHz to MHz and power levels from  $\mu$ W to Watts can be used to change physical and chemical properties of

materials through cavitation related mechanisms, such as high shear, pressure, and temperature (Dickens 1991; Dolatowski 1998; Got 1999; Jayasooriya 2004). As a result, ultrasound fits applications ranging from emulsifying and testing homogeneity to inducing membrane cell disruption that could increase meat tenderness. Furthermore, using veterinary ultrasound technologies, ultrasound has been used to predict fat and muscle content in live cattle as early as 1950s (Wild 1950). Today, ultrasound technology is routinely used by the meat beef industry to evaluate and its quality. Compared to other markets in the report, the global beef market is estimated at \$2 trillion in 2015 with an average annual growth of 1.2% (Global Meat 2015).

Given that our system is currently designed to interface with the human tissue, it can be easily adapted to work with animal tissue (in the case of cattle imaging) and food products which consist mostly of water. Additionally, low frequency operation, low power level, and low accuracy tolerance relax performance requirements of the imager. Furthermore, there are lack of existing and competing products (Global Meat 2015).

Despite these upsides, food industry may not be a great market for our system for the following reasons:

1. For food processing, ultrasonic machines are typically built as part of the factory. As a result, reliability and robustness of the equipment are essentially, while the benefits of portability and low-power operation may not be so evident.
2. For meat quality assurance, there is a need for inexpensive and easy-to-use solution to assess aspects of the animal's food potential. However, interpretation of ultrasonic images requires education to train the users, which could present as a high barrier.

## Summary

Ultimately we were able to take a detailed look at a number of sub-fields within our initial list of broad industries, and our findings are summarized in **Figure 4**. We focused our research on first determining the market size in a given field and the associated need for a cheap, portable ultrasound system. We also looked at compatibility of our device to meet the technical requirements of an ultrasound system within that application space. Lastly, we examined barriers to entry, which included competition from other companies as well as regulatory hurdles. In general, applications in the medical space faced high barriers to entry due to the regulatory environment, while the food industry is already set up to deal with large, high-power equipment and thus has less of a need for a portable solution. The field of quality assurance and particularly in non-destructive testing was the most promising, and the only one to meet all 3 of our criteria. We plan on continuing to do research on this potential market to best understand how our technology can fit into this materials testing space.

	Market Size	Compatibility	Barriers to Entry
<b>Fetal Monitoring</b>	✓	✗	✗
<b>Guided Needle Placement</b>	✗	✓	✗
<b>ED Fracture Diagnosis</b>	?	✓	✗
<b>Triage</b>	✓	✓	?
<b>Fitness Tracking</b>	✓	✗	✗
<b>NDT Flaw Detection</b>	✓	✓	✓
<b>NDT Thickness Monitoring</b>	✓	✓	✓
<b>NDT Level Detection</b>	✓	✓	✗
<b>Food Processing</b>	✓	✗	✗
<b>Meat Quality</b>	✓	✓	✗

**Figure 4.** Summary table presenting the results of our research in various industries. A checkmark indicates a positive result while an 'x' mark indicates a negative one; a question mark indicates complex or unclear analysis.

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