

Ergonomic Interventional Design of an Articulated Arm for Echocardiography

Application

Thesis

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By

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Abstract

Several publications reported high prevalence of musculoskeletal issues among medical sonographers. Only a few intervention efforts have focused on solving the problem from an engineering control point of view. Echocardiography is a specialty field of ultrasound of the cardiovascular system, and is currently a growing field due to the trends of longer life expectancy and rising obesity levels. Further investigations of cardiac sonographers identified recurring issues such as prolonged probe pinching, forceful exertion, awkward posture and maintaining static posture. This study aims to design an engineering intervention that can potentially reduce these exposure risks. The design process includes observation, interview, literature review, product conceptualization, evaluation and focus group sessions. Cardiac sonographers, engineers, ergonomists, a radiologic sciences professional, and manufacturing technicians were involved in various stages of the design development process. A design of an articulating arm that uses a simple locking mechanism was envisioned to reduce prolonged probe pinching, force exertion, awkward postures, and static postures. A functional prototype was assembled, and pilot tested among cardiac sonographers in a clinic setting. The session revealed the concept's potential in addressing previously identified issues. However, several design iterations and more comprehensive evaluations will be needed before the device will be ready for implementation in echocardiography settings.

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Chapter 1: Introduction

High prevalence of Work-related Musculoskeletal Disorders (WMSDs) among health care workers has been reported in several publications (d'Errico et al. 2007, Li et al. 2004, Evanoff et al. 1999). WMSDs are defined as “soft tissue disorders of nontraumatic origin that are caused or exacerbated by interaction with the work environment” (Silverstein & Evanoff, 2006). The injury rates in the health care industry, which include musculoskeletal disorders, “are equal to or exceed the rates in traditionally high risk occupations” such as construction and manufacturing (Li et al. 1997, Evanoff et al. 1999). According to data from the Bureau of Labor Statistics (2009), the non-fatal injuries and illness that required medical treatment or days off work for hospital workers in 2009 were 7.3 cases per 100 workers. Those in nursing and residential facilities have a higher rate of 8.4 cases per 100 workers. In comparison, there were only 4.3 cases per 100 workers in both construction and manufacturing industries.

This trend has resulted in design and policy changes in many hospitals and nursing homes. Utilization of mechanical assistive devices as well as other engineering solutions have been shown to result in reductions of injuries (Chhokar et al. 2005, Collins et al. 2004, Owen et al. 2002, Garg & Owen 1994). Chhokar et al. (2005), for example, conducted a longitudinal case study to evaluate the effect of a ceiling lift among nurses

and nursing aides. The analysis across three years pre-intervention and three years post-intervention found significant improvements in annual workers' compensation cost, lost day injury rates, and other direct costs associated with patient handling injuries.

However, less attention has been paid to developing interventions for other types of health care professionals who also experience high rates of WMSD injuries, such as ultrasound technologists. Over the last two decades, a number of studies have documented that over 80% of the sonographers experienced work-related musculoskeletal issues at some point in their career (Vanderpool et al., 1993, Magnavita et al., 1999, Pike et al., 1997, Wihlidal & Kumar, 1997). Vanderpool et al. (1993) in a self report study documented that 17% of the sonographers missed work because of work-related symptoms. In addition, 31% of sonographers reported receiving treatment for work-related injuries. Wihlidal & Kumar (1997) in another self report study documented that due to work-related musculoskeletal symptoms, 21.2% of sonographers utilized their sick leave, 9.4% reduced their working hours, 14.6% reported decreased ability to perform regular job duties, and 11% received workers' compensation benefits. Brown and Baker (2004) in a more recent publication estimated that 20% of the sonographers are either leaving the profession or opt for early retirement due to work-related musculoskeletal issues.

Ultrasound technology is essentially a high frequency sound wave that is emitted, reflected, and read to capture real-time visual images inside the human body. According to Hangiandreou (2003), ultrasound "poses no known risk to the patient" in its current application as a medical diagnostic tool. Parhar (2006) added that ultrasound technology

is both time and cost effective compared to other imaging technologies such as the computed tomography (CT) and magnetic resonance imaging (MRI). One of the many applications of the ultrasound technology is to diagnose heart pathologies, and this specific field is called echocardiography. Today, echocardiography is reported as “the most commonly used imaging procedure for the diagnosis of heart disease” (Ehler et al., 2001).

Echocardiography technicians’ or cardiac sonographers’ main responsibility is to map the structure of the patient’s heart, including the valves and heart walls. This procedure will then give physicians information on how the valves are working, blood pumping capabilities, and efficiency of blood flow. It also identifies potentially problematic heart muscles and detects possible blood clots or fluid buildup in the heart region (echocardiography.net, 2010).

Similar to the general population of ultrasound technologists, the sub-population of echocardiography technologists are also exposed to high rates of work-related injuries. Several risk factors for WMSDs are commonly seen among cardiac sonographers’ work activities (Horkey et al., 2004, Smith et al., 1997). Manipulating the transducer rapidly without support may lead to repetitive and awkward upper extremity postures. Forceful exertion from pushing the transducer against the patient’s chest, especially when gripping the transducer in a pinching posture is also a risk factor for developing WMSDs. In addition, maintaining the exertion for a period of time to get stable images requires static postures. Over time, these activities may cause cumulative strain leading to damage of

the muscles, tendons, and/or nerves which can lead to chronic disorders such as Carpal Tunnel Syndrome (CTS), tendonitis, bursitis, tenosynovitis, or epicondylitis.

Previous publications such as Vanderpool et al. (1993) and Horkey et al. (2004) documented relationships between cardiac sonographers' activities and the high prevalence of musculoskeletal discomfort. Various recommendations have been proposed in the literature to address this issue, focusing mainly on administrative and behavioral changes in the workplace. However, it was seen in the literature that engineering intervention efforts which aim to solve problems by tackling the root causes are limited in number. An engineering control is designed to eliminate or reduce exposure to some specific risk factors, to which workers are exposed. Lighter weight cables that connect the ultrasound probe to the ultrasound machine are an example of an engineering control. The development of WMSDs among cardiac sonographers is expected to be reduced if exposure to risk factors such as repetitive motions, pinching grip, forceful exertion, awkward postures, and static postures can be effectively reduced.

The current study seeks to address the research void of using engineering intervention as a method to reduce the work-related risk exposures to cardiac sonographers. The issues were identified, specific scanning activities were targeted, and an intervening solution classified as an engineering control was developed. An active intervening effort focusing on early stages of the design process was undertaken to develop a user-centered device that can be used in the echocardiography settings. Established design tools and methodologies were used in various design stages including user needs identification, idea generation, concept screening, concept evaluation,

prototype building and finally design prototype testing and evaluation. Feedback and expertise from experienced cardiac sonographers, engineering graduates, certified professional ergonomists, a radiologic sciences professional, and manufacturing technicians were sought at various stages in the iterative design process. A refined design prototype was then pilot tested by the end users to determine if the design would work as it was envisioned and whether or not recommendations could be made to go further with the development of the design.

Chapter 2: Literature Review

2.1. Musculoskeletal injuries and disorders among sonographers

According to the recent Occupational Outlook Handbook published by the Bureau of Labor Statistics (2009), there were 49,500 workers employed in 2008 as “Cardiovascular technologist and technicians”. In the future, the employment for this particular occupation is expected to increase faster than the average for all occupations, as fast as a 24% increase in 10 years (BLS, 2009). The increasing demand for cardiac technologist is expected due to the increasing trend of obesity, as well as longer life expectancy in the modern world.

Evans et al. (2009) in a large scale survey of 5200 registered diagnostic sonographers and vascular technologist revealed that “90% of the respondents were scanning in pain”. Vanderpool (1993) in a survey study of cardiac sonographers found that 86% of the respondents in the United States reported one or more symptoms of musculoskeletal disorders. Case report studies on larger number of sonographers in the United States by Smith et al. (1997) and McCulloch et al. (2002) also found similar associations between sonographers’ occupational activities and the prevalence of musculoskeletal symptoms.

The high prevalence of musculoskeletal disorders among sonographers is not exclusive to the United States. There have been publications from other countries that reported similar findings. These publications from Canada, Israel, Australia, New Zealand, United Kingdom and Brazil concluded that there is a significant relationship between sonographers' activities and development of musculoskeletal disorders. These studies consisted of mostly clinical self report surveys, and some cross-sectional studies from general populations of sonographers. A list of epidemiology studies is summarized in Table 2.1.

| Source (Years) | Country | Prevalence of musculoskeletal issue (%) |
|--|----------------|---|
| Vanderpool (1993) | United States | 86 |
| Necas (1996) | United States | 66 |
| Smith et al. (1997) | United States | 80 |
| Pike et al. (1997) | United States | 81 |
| McCulloch (2002) | United States | 82 |
| David (2005) | United States | 81 |
| Evans et al. (2009) | United States | 90 |
| Wihlidal et al. (1997) | Canada | 88.5 |
| British Columbia Ultrasound Sonographers Society (1999) | Canada | 80 |
| Russo (2002) | Canada | 91 |
| Gregory (1998) | Australia | 77.8 |
| Gregory (1999) | Australia | 95.4 |
| Muirhead (2001) | New Zealand | 69 |
| Magnavita et al. (1999) *(study performed on physician sonographers) | Italy | 80 |
| Schoenfeld et al. (1999) | Israel | 65 |
| Ransom (2002) | United Kingdom | 96.4 |
| Feather (2001) | United Kingdom | 98.7 |
| Chapman-Jones (2001) | United Kingdom | 80 |
| Miles (2005) | United Kingdom | 85 |

Table 2.1: Previous studies of the prevalence of musculoskeletal issues among sonographers, adapted from Brown et al. (2004) and Morton & Delf (2008).

The prevalence of musculoskeletal issues from these publications ranged from 65% to 98%, with most studies reporting prevalence at around 80%. The epidemiological evidence shows that there is a strong association between ultrasound sonographer activities and the prevalence of musculoskeletal issues. Schoenfeld et al. (1999) concluded that, based on available evidence, the prevalence of upper limb musculoskeletal disorders among ultrasound sonographers “are etiologically related to occupational factors”. Baker & Murphey (2006) reported that there is an increasing rate of frequency and severity of musculoskeletal issues among ultrasound sonographers. The authors claimed that 84% of sonographers experience occupational pain and 20% of this population suffers career ending injuries.

These studies report a wide range of ergonomics issues that may be associated with the prevalence of musculoskeletal disorders. Probe pinching, awkward postures, duration of scanning for each patient, cumulative duration of scanning throughout one's career, duration of rest, repetitive motion, static muscle activation, amount of training received, scanning styles, furniture design, and equipment design were among the potential factors identified. However, the two main physical factors that were discussed in most of the publications reviewed are: 1) pinching and pushing the probe and 2) awkward and static postures. These risk factors will be discussed in the next section.

2.2. Risk factors and exposures

2.2.1. Forceful pinching

Cardiac ultrasound probes are generally smaller in size compared to ultrasound probes used in other medical applications. The small size of the cardiac ultrasound probes facilitates the pinch grip posture, which is essential for fine manipulation of the probe. Since cardiac sonographers have to perform scans with the probe in several different orientations, it is important that they be able to precisely maneuver the probe in order to locate the scanning area of interest on the patient's chest. Baker (n.d) in testimony to OSHA stated that the transducer must be gripped tightly while the sonographer pushes the probe forcefully against the patient's chest to obtain high quality images. Even though pinch grips allow for fine precision control, prolonged forceful pinching is disadvantageous as it put pressure on muscle tendons of the fingers as well as the median nerve, which may ultimately lead to discomfort or even injury.

A self report survey by Vanderpool et al. (1993) of 225 cardiac sonographers identified hand grip pressure as one of the major risk factors of WMSDs. The study found a significant statistical association between high grip pressures and CTS symptoms. In a study of a larger population of medical diagnostic sonographers, Pike et al. (1997) reported that the specific activity of "manipulating the transducer while sustaining applied force" was one of the key activities that led to pain and discomfort.

In a paper published in 1997, Wihlidal and Kumar found that surveyed sonographers believed that gripping the transducer somehow contributed to their injury.

In addition, applying sustained pressure with the transducer was also an activity that they thought contributed to injury. Evans et al. (2010) in a cross-sectional study reported that 65% of the sonographers experiencing wrist-hand-finger discomfort found that applying the pressure during the scan aggravated discomfort. Interestingly, the authors also found that cardiac sonographers reported higher wrist-hand-finger discomfort aggravation due to holding the transducer compared to those in Vascular and other multi-credentialed sonographers.

Another self report study by Schoenfeld et al. (1999) found that high grip pressure of the transducer was positively linked with CTS symptoms in the respondents. The paper also reported that prolonged handling of the probe contributed to occupational injury among sonographers. The authors concluded that “continuous high grip pressure by the sonographer on the transducer may eventually lead to the development of musculoskeletal dysfunction”.

Armstrong & Chaffin (1979) in a biomechanical study reported that pinch grip causes higher resultant reaction force on tendons compared to grasping grip. Keyserling et al. (1991) wrote that pinch grip “produce localized pressure on the underlying tendons in the fingers”, increasing the risk of tissue damage especially at the pressure point. The internal pressure from point of pinch contact will be transmitted along through tendons and other tissues, and will result in the “increase of contact stress on the median nerve”, leading to a higher risk of developing musculoskeletal injuries and disorders (Keir & Wells, 1999).

Sonographers, especially cardiac sonographers often work with obese patients (M. Orsinelli, personal communication, July 29, 2010). Obesity is widely known to be a major risk factor for heart disease (Eckel, 1997). Aside from causing potential problems for the patient, the adipose tissue may also pose problems for the sonographer as fatty tissue provides a physical barrier between the ultrasound probe and the heart, which may interfere with ultrasound signals. Parhar (2006) reported that ultrasound imaging quality tends to be limited in obese patients “due to acoustic noise that occurs when the ultrasound beam echoes from the surrounding fatty tissue”. As a result, the sonographer has to push the probe deeper into the skin, exerting higher forces for better readings. The frequency of forceful pinching of the probe seems to be increasing due to the current increasing trend of obesity among the general population (M. Orsinelli, personal communication, July 29, 2010).

Ultrasound gels also play a role in exacerbating the pinching force required by sonographers. The water-based conductive gel is usually applied to the patient’s skin before the scanning procedure to facilitate sound wave transmission (Medor, 2007), which usually translates to better quality of the image. However, there is a trade off in that the gel reduces the friction between the probe and the gloved hand of the sonographer, effectively reducing the efficiency of the force exertion. The slippery surface between the probe and the sonographer’s hand may result in higher level of muscle exertion to grip the probe more firmly as the gel reduces the coefficient of friction between the sonographer’s hand and the transducer. The model in Figure 2.1 presents a simple force diagram of the probe handling. This is in agreement with an earlier finding

by Habes and Barron (1999) who reported that forces needed to grip and manipulate the probe are higher when the gel migrates to the gripping surfaces of the probe.

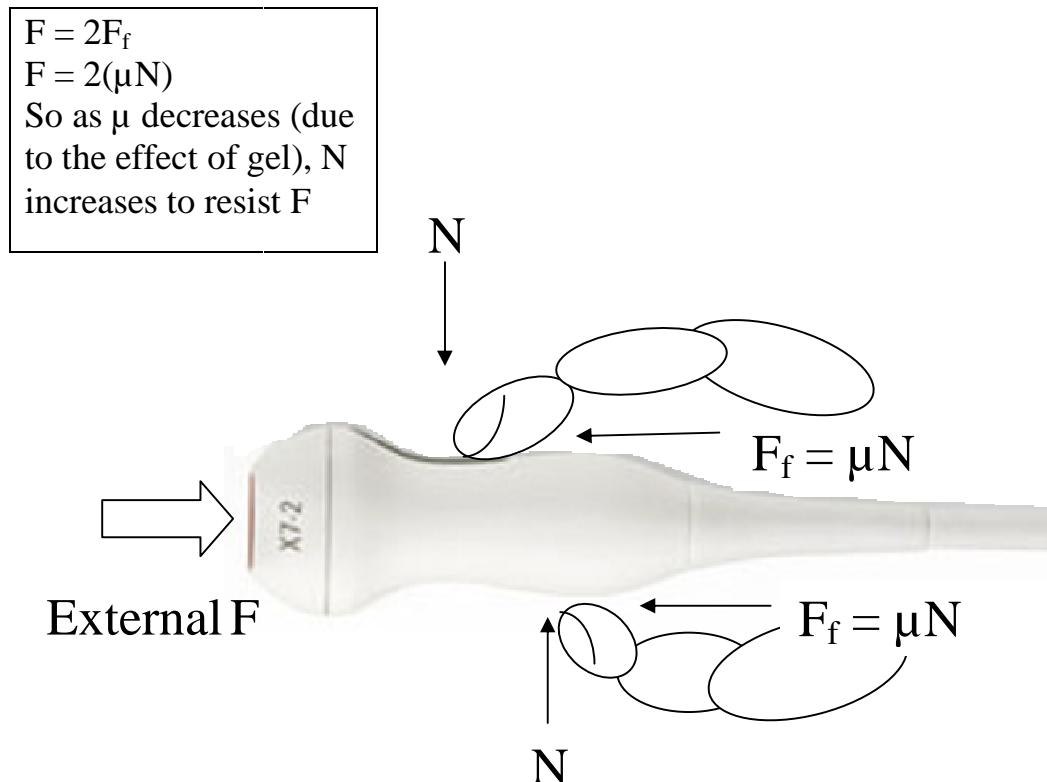


Figure 2.1: A simple biomechanical model of force and friction. N is the force exerted by the finger while F is the resisting force from pushing the probe onto the patient. F_f is the force of kinetic friction where μ is coefficient of kinetic friction. As μ decreases (through introduction of ultrasound gel), the sonographer has to exert more N to maintain the grip against F .

2.2.2. Repetitive and sustained awkward postures

In addition to forceful pinching, the sonographers are also exposed to musculoskeletal injury risk due to awkward postures. During the scan procedure, the probe must be oriented in various angles, and this may result in deviated upper extremity postures. With eyes focusing on the display screen, the sonographers have to repetitively move and hold the probe in various directions, sometimes without realizing that they are assuming awkward upper extremity postures.

There are a number of variables that come into play in positioning the probe during an echocardiography procedure. These include the amount and location of adipose tissue, orientation of the heart, anthropometry of the patient and the sonographer, condition of the heart, the sonographer's training, scanning habit, scanning technique, probe design and bed or exam table design. Since the patient's scanning window¹ is a small area on the chest, all of these factors and their combinations may affect how the sonographer positions the probe. The rapid repetitive manipulation of the probe and reaching activities performed during the scan increase the possibility of the sonographer assuming awkward postures. In addition, the sonographers's upper extremities can be abducted, twisted and unsupported during the scanning procedure for a majority of the time (Horkey & King, 2004). Figure 2.2 illustrates these awkward, abducted and unsupported upper extremity postures that are prevalent during an echocardiography scanning.

¹ Scanning window is a small area on the chest where the ultrasound images can be obtained. These windows include parasternal, apical, subcostal, and suprasternal.

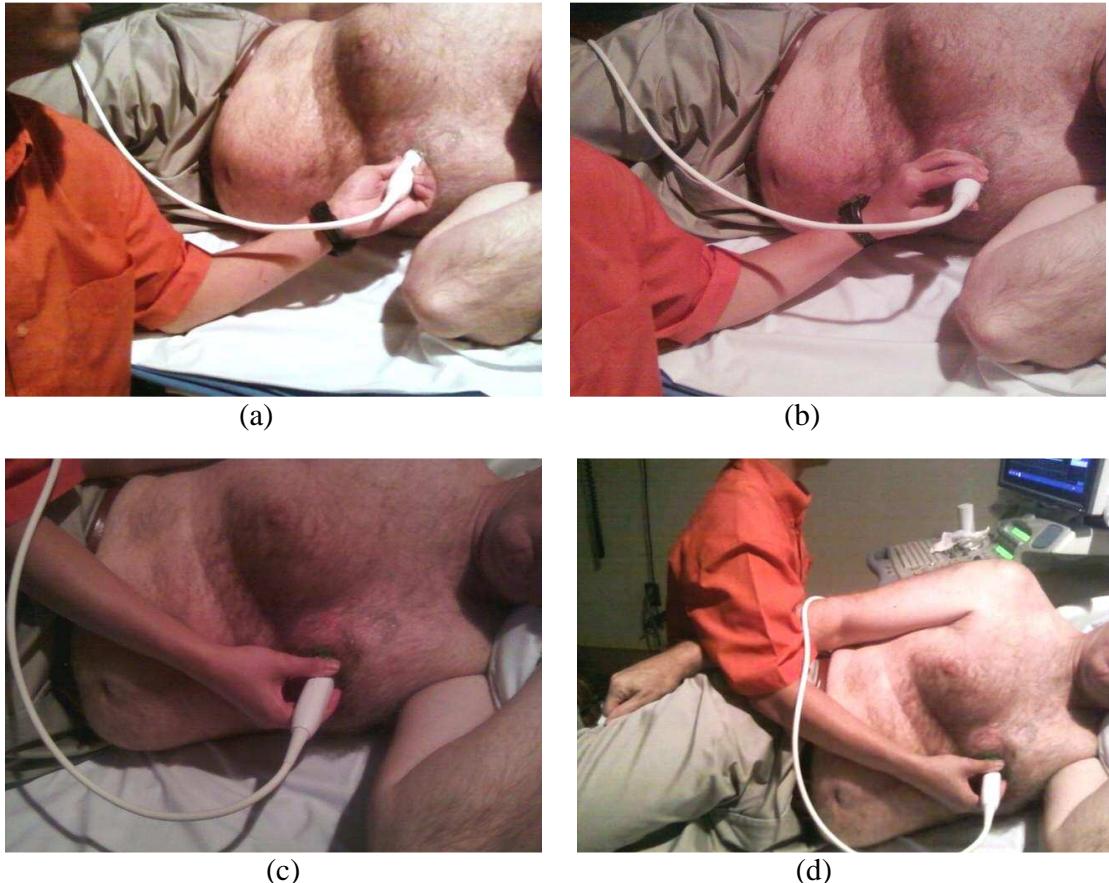


Figure 2.2: Example of different postures and pinch grip styles during echocardiography scanning procedure for left hand scanning (a-b), and right hand scanning (c-d). Figure (a) and (b) shows awkward wrist posture and abducted shoulder. Figure (c) and (d) show unsupported prolonged upper arm posture.

Another issue that may contribute to repetitive awkward postures is the loss of the scanning window. This occurs because patients move due to discomfort, coughing, or sneezing during the scanning process. This then causes the sonographer to lose the scanning window, which then means more probe manipulation to relocate the scanning window. On the other hand, lapse of attention or regular activities such as the need to get extra ultrasound gel or management of the transducer's cord may also put the sonographer out of position. The issue with the probe going out of the patient's window

is that the sonographer has to find the spot again, which involves additional repetitive motions especially at the wrist. Reducing the need to reposition and find the same window again may help reduce fatigue due to repetitive motion.

Reports in the literature suggest that there is a relationship between awkward upper extremity postures and musculoskeletal issues. Vanderpool (1993) in a survey study of cardiac sonographers reported the twisting motion of the wrist correlated positively with the prevalence of CTS symptoms. Schoenfeld et al. (1999) also concluded that awkward postures, such as twisting and pushing motions of the wrist correlated with an increased incidence of CTS. The authors also reported that sonographers' upper body postures were found to be influencing the level of musculoskeletal complaints. Magnavita et al. (1999) reported that repetitive and dynamic motions of the joints of the upper extremity, from shoulder to fingers, are essential to manipulate and adjust the transducer to attain the correct transducer position. Similarly, Smith (1997) concluded that cardiac sonographers have a high prevalence of musculoskeletal issues due to "frequent use of repetitive motion or isometric muscle tension".

According to Gilad (1995) repetitive motion is strenuous because the recovery period of the musculoskeletal system is limited. As a result, the muscles cannot fully recuperate, and this wear and tear process will usually lead to muscular soreness and inflammation of muscles. A biomechanical study by Armstrong & Chaffin (1979) on the causes of CTS concluded that forceful exertion, especially combined with awkward wrist extension or flexion, leads to compression of the median nerve. As a result, forceful

exertion in certain awkward wrist positions may “aggravate, precipitate or cause occupational carpal tunnel syndrome”.

In addition to awkward and repetitive postures, sometimes sonographers have to maintain their upper body posture for extended periods of time during a scanning procedure. According to Horkey & King (2004), sustaining the contraction of muscles in certain body parts, including shoulder and upper extremity is necessary to obtain certain required scan images. Similarly, Magnavita et al. (1999) reported that sustaining static postures is necessary to maintain the transducer in the appropriate position for the scans. Static postures require that muscles sustain their exertions for a prolonged period of time (Sjoogard, 2006). Previous studies have demonstrated that sustained static postures can increase the rate of muscle fatigue. The explanation behind it was that sustained contractions lead to high intramuscular pressure, which causes disruption in muscle blood flow (Sjoogard, 2006). This may ultimately affect microcirculation and foster the formation of highly toxic free radicals. In addition, disruption of blood flow impedes the supply of oxygen to the muscle tissue, which results in the interruption of the energy conversion process. As a result, continuously recruited muscle fibres will be metabolically exhausted, and this will ultimately lead to localized muscle fatigue.

Other reports also connect relationships between static postures and musculoskeletal issues. A survey study by Wihlidal and Kumar (1997) found that the respondent sonographers believed that sustained shoulder and trunk abduction in their work activities strongly contributed to injury. Pike et al. (1997) reported that body parts that are susceptible to pain during scanning were neck, shoulder, wrist, hand, fingers and

back. The authors clarified that shoulder abduction, sustained twisting of the wrist, and maintaining constant pressure from the probe were among the factors associated with pain and discomfort. In a later publication, Russo et al. (2002) reiterated that unsupported abduction of the arm and static contraction to maintain arm position were some of the factors leading to musculoskeletal symptoms. The paper summarized the finding by reporting that there is “significant association between activities involving awkward postures, static postures and forceful actions, and degree of musculoskeletal symptoms”.

Publications reviewed identified several risk factors that connect sonographers activities with the development of WMSDs. These epidemiological and biomechanical studies demonstrate that there are musculoskeletal issues in the specific occupation of imaging sonographers. Thus, a next step consisting of intervening effort will be required to address these issues. The next section will discuss the classification of interventions and prior intervening studies performed in the general population of sonographers.

2.3. Classification of interventions

Intervention efforts to reduce the prevalence of WMSDs among sonographers have been documented by several studies. Three major categories of ergonomic interventions are engineering, administrative, and behavioral interventions (Goldenhar et al., 1996). Even though the primary goals of the interventions are the same, there is a hierarchical prioritization among the three categories of interventions. According to Castillo et al. (2006), the most effective way of performing intervention control is focusing on engineering factors. These are interventions that eliminate or reduce hazards through new or retrofitted design of devices (tools, equipment, etc) into work systems to provide protection. Zwerling et al. (1996) defined engineering interventions as those that target the “physical work environment”.

Specific to ultrasound imaging, Murphy & Russo (2000) recommended reducing the exposure to musculoskeletal injury risks by engineering controls through design of equipment and workstation. Administrative controls such as organization of work and work practices, as well as behavioral controls such as job risk awareness, training, and education were also proposed to mitigate the prevalence of WMSDs issues among sonographers.

Various interventional measures, mostly administrative and behavioral controls, to address the ongoing musculoskeletal issues faced by sonographers have been recommended in the literature. Examples of these recommendations include stretching exercises, frequent rest breaks, alternating between sitting and standing during scans, training on scanning techniques, scheduled stretching exercises, providing adjustable

furniture, rotating between types of scans and providing educational programs on postures (Murphy & Russo, 2000, Christenssen, 2001, Horkey & King, 2004). Some of these recommendations have been tried. For example, Christenssen (2001) in a 12-week study reported that the sonographers found the stretch exercise to beneficial. However, a decrease in the number of “reported levels of sign and symptoms of musculoskeletal injury” could not be established.

Vanderpool (1993) recommended that research should also examine equipment design for a more effective intervention. Equipment manufacturers can play a role by modifying their equipment to allow for better posture and probe handling experience. Horkey & King (2004) concluded that equipment design is one of areas that needed more attention for interventional study. The authors claimed that “the frequency and severity of musculoskeletal disorders will not be reduced” if there is no ergonomic intervention effort.

2.3.1. Poor equipment design in sonographer’s occupational settings.

Ransom (2002) reported that half of the 55 sonographers interviewed in their study believed that musculoskeletal disorders were caused by poor equipment design. Similarly Paschoarelli et al. (2008) concluded that ultrasound sonographers are currently facing musculoskeletal problems due to the use of poorly designed equipment, such as the ultrasound transducer. The authors implied that the traditional transducer designs are generally uncomfortable, and require sonographers to assume extreme wrist postures. Magnavita et al. (1999) reported that the design of the transducer can affect

musculoskeletal complaints of the hands and wrists. Similarly, Horkey & King (2004) claimed that “transducer design was found to be the best predictor of hand-wrist complaints”. Robson & Wolstenhulme (2010) proposed a method of assessment to self-evaluate the design of ultrasound equipment such as transducer, monitor, keyboards, scan bed, and operator chair. This method is intended as a guide for sonographers to audit their scanning room, aiming to increase awareness of design problems in their workplace.

It should be noted that there have been some efforts made to improve the design of the modern ultrasound equipment. The modern ultrasound machines, especially the portable ones, are generally smaller in weight and size as illustrated in Figure 2.3. Similarly, many newer ultrasound transducers and their cords are lightweight and balanced for easy control. In addition, the machine’s height, especially the full size machines can often be adjusted to accommodate both taller and shorter sonographers. Extra features such as larger wheels and handles were introduced to allow for easier transportation of the equipment. An adjustable articulating arm supporting the display allows wide range of motions to minimize awkward neck posture. Ultrasound equipment manufacturers market their merchandise as ergonomically designed equipment (Siemens Medical, 2010 & GE Healthcare, 2005). However, fundamental issues of sonographers having to use forceful pinch grips as well as awkward and static postures have yet to be addressed through equipment design.

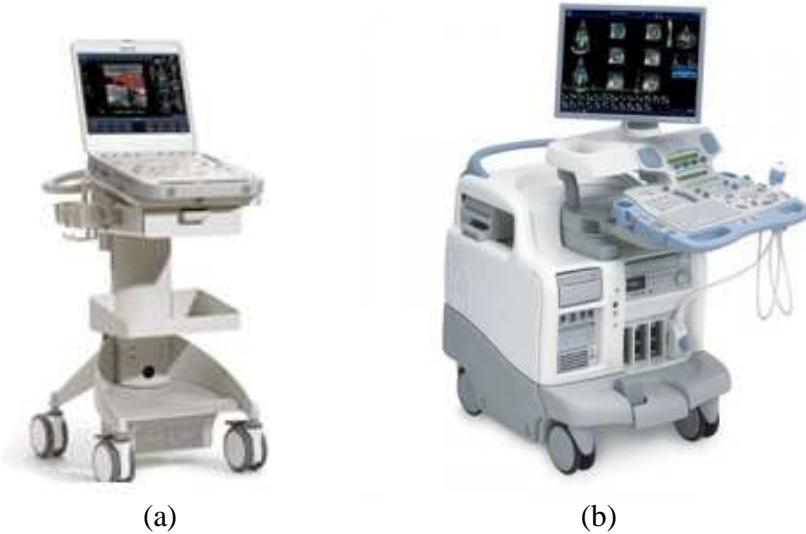


Figure 2.3. The differences in size/weight between the portable ultrasound machine (usedultrasound.com, 2010) (a) and the traditional full size ultrasound machine (medcorpllc.com, 2010) (b)

Currently, the responsibility for equipment design lies in the hands of equipment manufacturers (Wihlidal et al., 1997). However, the design of equipment, especially in an endeavor to address more fundamental ergonomics issues, should also involve the end user in the product's design process. This is because the end user is the one who interacts with the product on a daily basis, and is an expert on usability and real application of the product. Thus, sonographers can point out design issues that they face based on their experience; this should foster designs that are compatible with work settings. In the literature, the participation of sonographers in the product design stage has been recommended to address the issues associated with poor product design (Morton et al., 2008, Wihlidal et al., 1997). This principle of involving the end user in the product design process has long been known to be a key element of the participatory ergonomics

process. Collaboration between designers, ergonomists and the end users has the potential to bridge the gap between designers and users, which may ultimately lead to better ergonomic product design.

2.3.2. Previous engineering intervention studies for sonographers

Despite the evidence of problematic equipment design in the field of ultrasound imaging, there has been limited research done to improve the current situation. Review of previous literature revealed several studies focusing on the application of engineering interventions in the general field of ultrasound sonography. These studies are summarized in Table 2.2. However, none of these studies were specifically focused on intervention efforts for cardiac sonographers.

2.3.2.1. Design strategies in previous research

Previous studies and publications that have tried to address musculoskeletal issues of sonographers using the pathway of engineering intervention are listed in Table 2.2. These publications were reviewed, and the three main categories of strategy were identified: 1) redesign the physical shape of the probe, 2) design a physical attachment interface to the probe, and 3) provide an external arm to assist with pushing and maintaining force.

| Author | Year | Strategy | Type of publication | Status |
|---------------------|------|--|---|--|
| Lyon et al. | 1999 | Case handle grip surfaces | Patent | Not known |
| Kreofsky et al. | 2004 | Two handed probe, strap design, mechanical arm, memory foam transducer | Student project | Ideation, concepts |
| Lu et al. | 2004 | Handle redesign (physical interface attachment), transducer shape redesign, mechanical arm | Student project | Mock-up model |
| Joines et al. | 2007 | Transducer sleeve & Probe ring | NCSU File 07-054 - Intellectual Property Committee: North Carolina State University | Prototypes were created, some end user testing was conducted |
| Meador | 2007 | Transducer cover, transducer harness, wide grip transducer (transducer shape redesign) | Graduate thesis | Controlled experiment was performed |
| Paschoarelli et al. | 2008 | Transducer shape redesign | Journal article | Controlled experiment was performed |
| Corbeille et al. | 2009 | Ultrasound probe holder | Student project, submitted for journal article | Controlled experiment was performed |

Table 2.2: Recent publications related to engineering interventions for sonographers.

Redesigning the shape of the body of the probe

Several publications focused on redesigning the shape of the probe. Manipulation of the shape may directly change the hand posture of the sonographer, allowing for a more neutral posture. Examples include mock-up probes as discussed by Paschoarelli et al. (2008) and Meador (2007) as shown in Figure 2.4. Paschoarelli et al. found that redesigning the probe shape resulted in improvement in terms of lower average amplitude of wrist movements, as well as longer working time spent closer to neutral postures. Meador reported that changing the shape of the probe to allow for a power grip instead of a pinch grip decreased the muscle activity of the first dorsal interosseous as much as 50%.

However, redesigning the physical shape of the probe involves acceptance from users and active participation from the probe manufacturers. In addition, an unconventional shape of the probe might also find resistance from experienced sonographers who are already familiar with a traditional probe. Moreover, precision manipulations that are needed in finding specific locations on the patient may be difficult to perform if the shape of the probe only allows for a power grip as opposed to a precision pinch grip. Thus, application of this concept in an area such as echocardiography, where fine tuning of the probe is imperative might not work well compared to some other areas of sonography where fine manipulation of the probe is not as important.

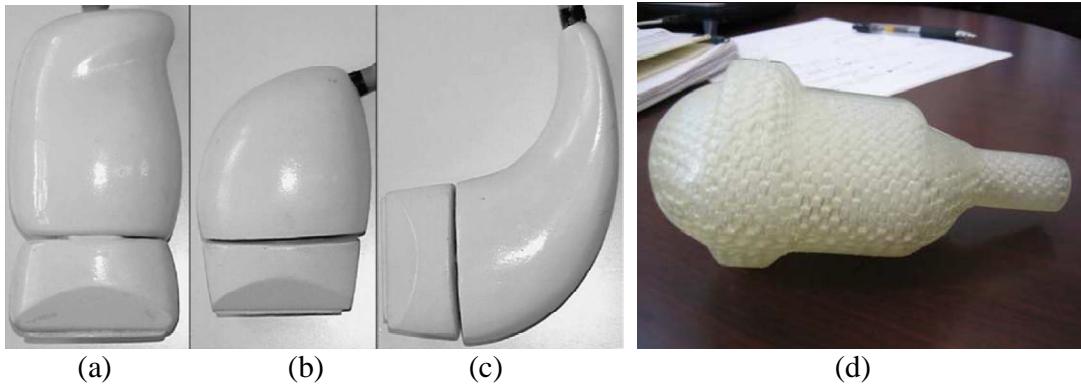


Figure 2.4: Examples of the design of new probe shapes by Paschoarelli (2008) (a - c) and Meador (2007) (d)

Designing a physical attachment interface for the probe

Another design pathway found in previous studies was an external interface attached to a traditional probe. The idea is to provide a more advantageous physical shape, thus allowing better grip especially for tasks requiring force exertion. Without changing the current design of the manufacturer's probe, an external attachment is expected to cost less and could be retrofitted to any type of existing probe. Ideas such as providing extra padding, a harness, additional surface barriers or contours, and higher friction gripping surface theoretically might improve the probe gripping experience. Extra padding acts as a damper, while a higher friction surface, additional surface barrier and a harness provide physical support to assist the probe pushing task. Examples of these concepts are shown in Figure 2.5.

Medor (2007), for example, studied the effect of a surface barrier and harness on the activity in several muscles and found that these interventions reduced the activity of the first dorsal interosseous, the flexor digitorum superficialis muscles in the forearm,

extensor digitorum muscles in the forearm, the lateral deltoid and trapezius muscles.

Lyon (1999) and Joines (2007) proposed the use of a transducer cover made out of higher friction materials. The cover would be slipped over an existing transducer and would act as a physical interface to the sonographers's hand. Joines also proposed the use of several elastic rings that could be easily positioned on traditional probes. The rings could provide physical ridges for sonographers to hold onto, providing a better grip interface.

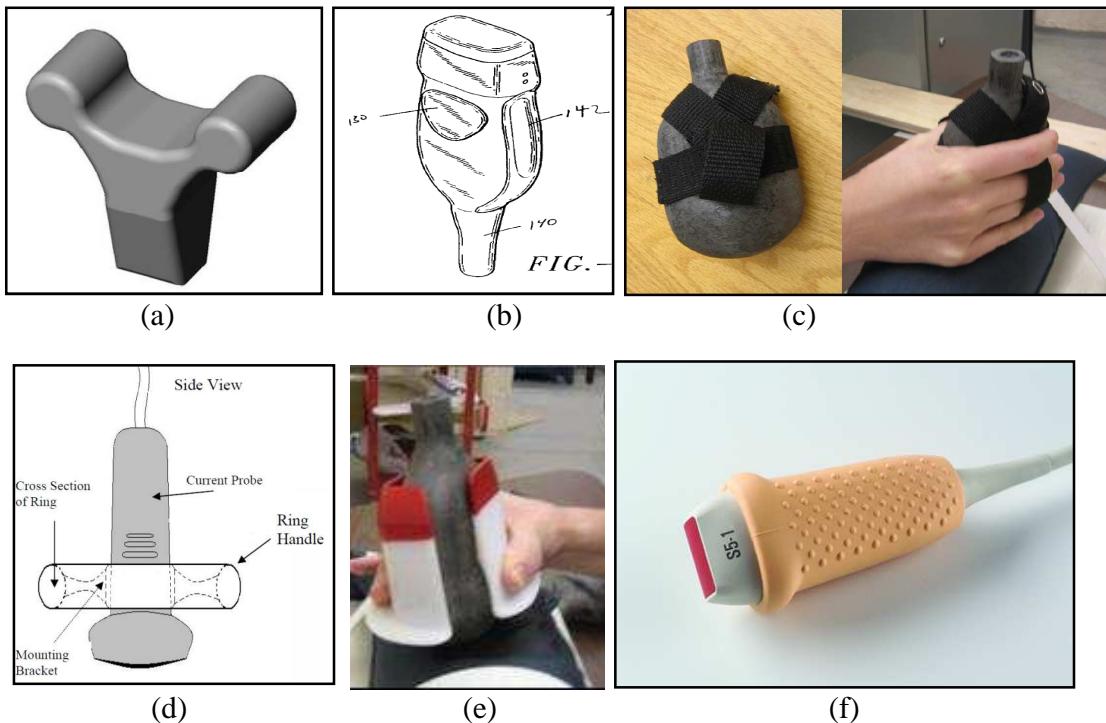


Figure 2.5: Examples of external probe attachments – a) two handed probe holder (Kreofsky et al. 2004), b) transducer sleeve (Lyon, 1999), c) probe harness (Meador, 2007), d) probe ring Kreofsky et al. (2004), e) surface barrier (Meador, 2007), f) probe grip (Civco Worldwide, 2010)

Kreofsky et al. (2004), in a student project, proposed different designs of a two-handed probe holder, intended to distribute pushing forces to both hands. Another design proposed by the authors was a visco-elastic foam encasement to provide padding which would minimize pressure on the tips of the gripping fingers. A similar product already available in the market is a probe grip manufactured by Civco Worldwide as shown in Figure 2.5f. The challenge with designing an external interface is that it must fit different sizes and shapes of probes, from different manufacturers. Thus, a one size fits all device is desirable. Other issues that might prevent wide adoption are unacceptable cleaning and set-up times.

Application of external arm to assist probe holding and force augmentation

Kreofsky et al. (2004) proposed several concepts for applying the use of a mechanical arm in the field of sonography. A mechanical arm consisting of mechanical and electrical structures may solve some problems associated with sustained upper body postures. Since the technology required to create mechanical arms is available, the application creating an arm for use in ultrasound imaging opens up a new research opportunity. A mechanical arm could be expected to assist sonographers with force exertion tasks using mechanisms such as a motor, springs or hydraulics. The sonographer could initially manipulate the arm to a desired location, and once in position, the mechanical arm could take the role of exerting and maintaining force. Lu et al. (2004) suggested the use of an arc over the patient's bed, as shown in Figure 2.6a. The arc would hold a slider, ball and socket joint, and an arm to allow for fine adjustment of

the probe. Once the arm is at the correct location, the arm would be locked in place to sustain forces. The initial non-functional prototype of this design has been made, but further work is needed to address issues related to stability and the locking mechanism.

Corbeille et al. (2009) proposed the use of an articulating arm with a gooseneck for vascular reactivity studies. This set-up of this design is illustrated in Figure 2.6b. The design also tackles the static upper body posture issue as the articulating arm would hold the probe after it was placed correctly. The flexible gooseneck provides more probe manipulation options and a simple locking mechanism would lock everything in place. The prototype was tested in a controlled study, and time study and usability testing showed that comparable time and image quality could be achieved compared to the conventional scanning method. Further research emphasizing control, adjustability, portability and usability of the external arm is needed as safety and image quality are essential to every ultrasound scan procedure.

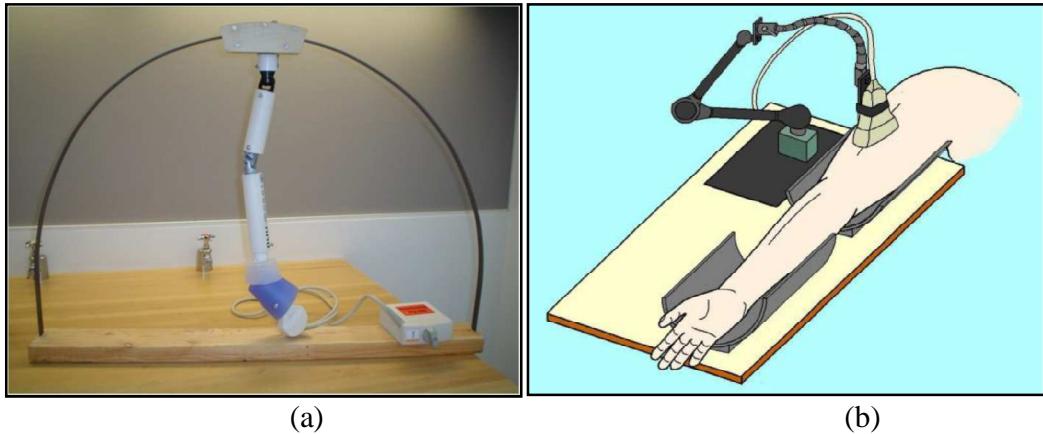


Figure 2.6: Articulating arm designs by Lu et al. (2004) (a) and Corbeille et al. (2009) (b).

2.4. Research objectives

The publications reviewed in this chapter demonstrate a need to focus on solving musculoskeletal issues among sonographers. The three intervention methods, engineering, administrative, and behavioral methods, have been studied and reported in various academic publications. However, the most effective type of intervention, the engineering intervention, was seen to be very limited in numbers of reports. In addition, those publications that proposed some design intervention were mostly in a conceptual stage, and a very limited number of these have gone to the prototyping stage. Moreover, there has been very limited experimentation performed to evaluate these designs. More research efforts on conceptual designs, prototypes, and controlled experimentation are needed before an intervention product can be implemented in a clinical setting.

The current study aims to address this void of engineering intervention application in echocardiography settings. The paucity of engineering controls that address the fundamental issues such as reduction of probe gripping, pushing force, sustained exertion, and repetitive awkward body postures reveals a significant limitation in current interventions available to sonographers. This study involves the early stages of the design process in addressing these issues. Methodologies such as observation, interview, and focus group sessions were conducted to elicit user needs. These needs were then translated into product specifications, and potential solutions were generated through creative endeavors. Involvement was sought from the end users, the experienced cardiac sonographers, as well as certified ergonomists in the design stage, consistent with suggestions by Wihlidal et al. (1997) and Horkey & King, (2004). Collective efforts

from engineers, ergonomists, a radiologic sciences professional, engineering graduate students, and manufacturing technicians lead to the development of a detailed design, and later, a functional prototype. Several cardiac sonographers were then gathered for a pilot evaluation of the new design. The evaluation focused primarily on potential usability, usefulness, and desirability of the proposed design. Results and feedback from this session gave the design team a direction to move forward with the proposed concept.

Chapter 3: Design Process

3.1. Introduction

When talking about the field of product design, both ergonomists and product design practitioners share a common value, which is to deliver beneficial products to their respective clients. However, different approaches to design are generally taken by these two parties. This is because they were trained in different ways; ergonomists usually from a scientific background, where they work based on quantitative evidence, while designers are primarily from an art-based discipline wherein they usually work with data that are more qualitative in nature (Green, 1999). Each discipline has its own strengths and weaknesses, and integration of knowledge from both areas might complement each other, potentially leading to a better design outcome. Thus, communication and collaboration between these two areas is essential as they both can contribute expertise in their respective fields to a common goal.

Stanton (1998) reported that the field of ergonomics promotes the study of interaction between the product and end users which “offers a unique perspective on design”. Ergonomists are trained to look at systems with a special focus on the end user. Compatibility of a product or a system to fit the human’s capability is important, as it may reduce the risk of injury as well as potentially improve productivity. This

complements the work of the industrial designers, who usually focus more on the functionality and aesthetic aspects of the product. Porter (1999) reported that “designers may not have an understanding of both physical and physiological characteristics of the population for whom they are designing” thus potentially causing injuries or serious safety implications.

Green (1999) reported that considering ergonomics input in the design process is seen by the manufacturers to give products a competitive advantage in the market. Porter (1999) proposed that the design process incorporate information and data from various disciplines such as industrial design, ergonomics, engineering, and manufacturing in the early design process as it might be a beneficial strategy. There is usually more than one dimension in product design, such as aesthetic, usability, technology, quality, cost, etc. These variables and their interactions play important roles in determining the success of the product, and having design involvement from various disciplines from the earliest stages of the process may contribute to the added value of the product. Stanton (1998) argued that it is easier to integrate data in early stages as “the design is relatively fluid” and is more open to changes and modification. Stoll (1999) reported that high quality decisions made in the early design stages are beneficial as these reduce cost and minimize design improvements after the product is released into the market.

This chapter will start by reviewing the product development cycle as a general starting point of the design process. The next step will involve discussion of the design models proposed by several authors. This is an important step as it lays out the general pathway of the design process utilized in this study. A short overview on the steps taken

in this study will then be presented to provide readers with a general framework of all the major milestones achieved. This chapter will then provide detailed discussions on the major phases of the product design process used in this study.

3.2. Design models

Looking at the bigger picture, the model in Figure 3.1 summarizes how the author understands the product development cycle. There are six main stages involved in a product cycle: 1) Problem Identification, 2) Intervention Research, 3) Translational Research, 4) Marketing and Commercialization, 5) Product Usage / Implementation, and 6) Product Iterations.

Incompatible interactions between products and users, whether physical or cognitive, usually lead to Problem Identification (stage 1). This can be in the form of complaints, injuries, sales returns, results from research studies, etc. Identification of problems usually leads to intervening effort, the Intervention Research stage (stage 2) which involves further corrective measures to solve the identified problems. An existing product might be redesigned, or a new design might be proposed in a newly defined context. The product development process, involving a multidisciplinary team with backgrounds in engineering, ergonomics, design, marketing, and manufacturing will then be assembled to perform this task. Refinement through iterations of design and collaboration with end users will then go through initial lab and field testing.

The next step, which involves strategic collaboration between marketing, supplier, and relevant organizations aims to disseminate information and receive constructive

feedback. This third stage is called Translational Research and one of its main objectives is to translate product from research to practice, with a special focus on studying the dynamic acceptance of the market. Output from this stage is used for further iterations before the design of the product is finalized and mass produced later. The fourth stage (Marketing and Commercialization) involves mainly those from manufacturing, sales and marketing departments, as the product is mass produced and made available in the market. Manufactured products will be packaged and shipped to local and internet retailers, and those in the service sectors such as customer service, sales representatives, and marketing officials will play a major role at this stage.

The last two stages involve interaction of the product with the end users. The fifth stage, Product Usage / Implementation, is where the new product is being used in real settings by real users. Acceptance or rejection of the new product can be evaluated through sales, effectiveness (pre-post) market evaluation, survey, merchandise return rate, and product recall rate. The last stage, Product Iteration, involves a product being used in different contexts and settings for which it was originally designed. Product misuse by the user is also considered to be in this stage. The misuse of a product, as well as its application in different contexts, might lead to different problems and the product development cycle begins again.

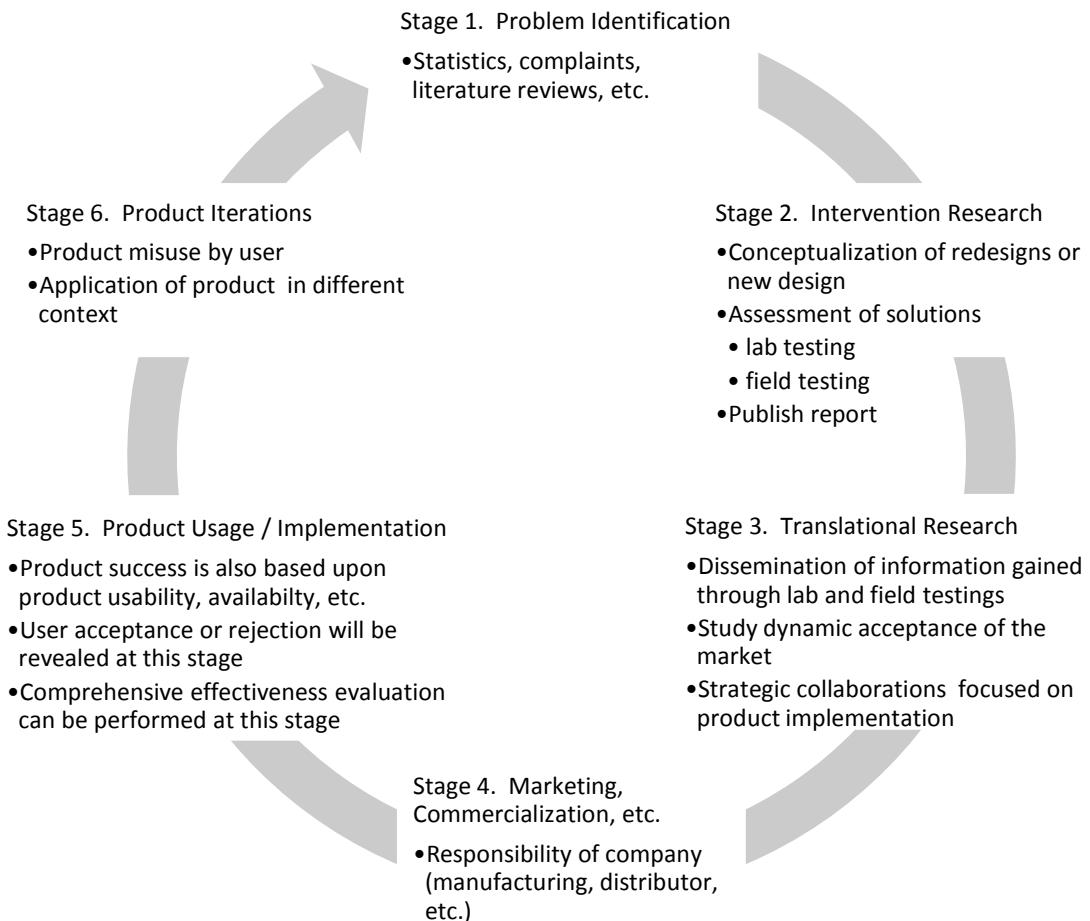


Figure 3.1. A model of the generic product development cycle.

This study will focus mainly on stage 2 of the conceptual model depicted in Figure 3.1, the Intervention Research stage, where efforts will be concentrated on corrective measures to mitigate problems identified in stage 1, the Problem Identification stage. Previous and ongoing research focusing on ergonomics issues affecting several imaging technologist populations have been conducted by a group of researchers from

The Ohio State University and North Carolina State University. That research has identified a number of ergonomics issues through a number of activities including a literature review, observations, discussions, and focus group sessions. This report aims to focus on the next phase of that research and particularly on one aspect of work performed by cardiac sonographers. In short, some of the findings from the larger study provided the foundation for this study.

Another conceptual model that is more detailed, and at the same time, relevant to the Intervention Research stage of the product development cycle model is shown in Figure 3.2. This model by Ulrich and Eppinger (2000) provides a generic pathway applicable to the product design process. The major phases described in this model were used as a framework to guide the product development process in this study.

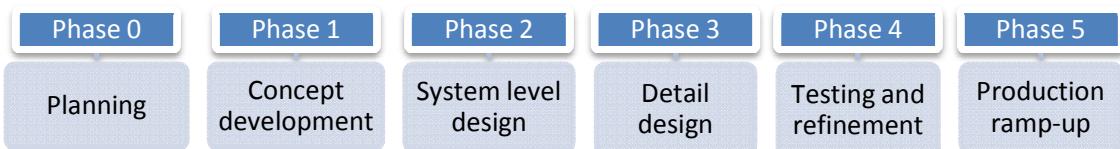


Figure 3.2. A model of the phases of the product development process (Ulrich & Eppinger, 2000)

The model starts with phase 0 which is essentially a background study and planning such as checking the feasibility, resources, market demands, and time needed to complete the project. Phase 1 which is the concept development is a major step where initial data collection takes place. Observation, interview, discussions and focus group

sessions are conducted to identify needs and define the problem statement. Based on the outcomes of this phase, initial ideations and concepts are generated. Phase 2, which is a system level design, involves a higher level effort as more relevant factors need to be considered. The integrated system consisting of interactions of the product's interface with the environment, user, culture, and work organization are all important design factors that need to be considered. The third phase, which is the detailed design phase, includes the methodology to systematically evaluate, select, and iterate design versions. In addition, technical specifications such as product geometry, material and tolerances will all be defined. Phase 4 of their model, which is testing and refining, includes building prototypes and testing them. This chapter of the report will partly discuss building prototypes and refinement of the model, but testing the functional prototype will be discussed in Chapter 4. This study in general covers the first four phases of Ulrich and Eppinger's model and would recommend the last phase for commercialization purposes.

Another relevant model proposed by Norris & Wilson (1999) showed how ergonomics practitioners can contribute to major phases of the product development process. The authors argued that incorporation of ergonomic knowledge in all major phases of product development is possible, and that it promotes a safer interaction between products and end users. Figure 3.3 shows another generic model that integrates the two fields of ergonomics and product design.

This model describes the product development process as having five major phases. In the first phase, which is defining product objectives, ergonomists can contribute by identifying problems of incompatible interactions between a product and

the users. Ergonomists are trained to identify issues such as awkward working postures, repetitive motions, and high force exertions through observation and measurement. In addition, epidemiological and occupational health data are used by ergonomists to identify health related problems including occurrence of musculoskeletal disorders, injuries, job turnover, and error rates while operating a product (piece of equipment, tool, software or other).

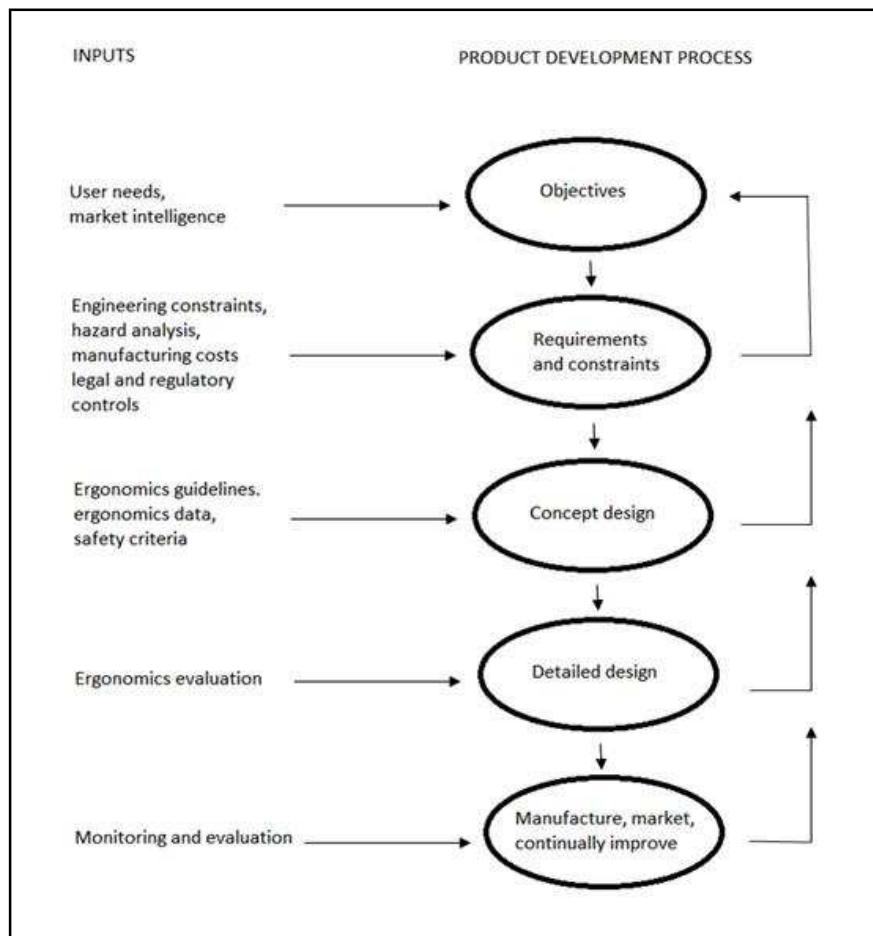


Figure 3.3. Ergonomics input to product development processes (Norris & Wilson, 1999)

The second phase in Norris & Wilson's model is a phase where in the design team is defining the product requirements and constraints. Human factors / ergonomics practitioners can be involved in the product specification stage by providing information on how the human body and mind work, as a framework for a more user-centered design. Consultation on limitations and capabilities of the end users, as well as how they might interact with the product will be a specific area within the expertise of ergonomists. The third phase, which is the concept design phase, involves developing conceptual ideas of how the product will look. In this stage, ergonomist may offer their skill in using well established ergonomics guidelines and other resources, including anthropometry databases, lift/lower/push/pull psychophysical limits, or maximum exposure limits to vibration, noise, or other relevant environmental exposures.

The detailed design phase is the fourth phase discussed in Norris & Wilson's model. Ergonomics specialists can contribute in this stage by providing quantitative biomechanical and physiological evaluations of the product. Biomechanical evaluation of the force and load handled can be estimated through biomechanical modeling and calculation, and be compared against competitors' products. A product's physiological effect on a user's body can be quantified by measuring muscles activity, heart rate, oxygen consumption, and/or energy expenditure, as appropriate. In addition, general assessment tools such as Rapid Upper Limb Assessment (RULA), Rapid Entire Body Assessment (REBA), NIOSH Lifting Equation (NLE), Ovako Working Posture Analysis System (OWAS), Strain Index, and Occupational Repetitive Assessment (OCRA) may be used to systematically compare work tasks performed with the newly designed product to

work performed with other benchmarked products. The last stage discussed in the model is when the product is out in the market. Ergonomist can be actively involved in surveillance and epidemiological study on the long term effect of the product.

The conceptual models of Ulrich & Eppinger (2000) and Norris & Wilson (1999) provide similar frameworks for the design development process. Design methodologies and tools proposed by those authors were consulted to guide the design effort in this study. Figure 3.4 below gives an overview of the major steps taken to summarize the overall design process in this specific study.

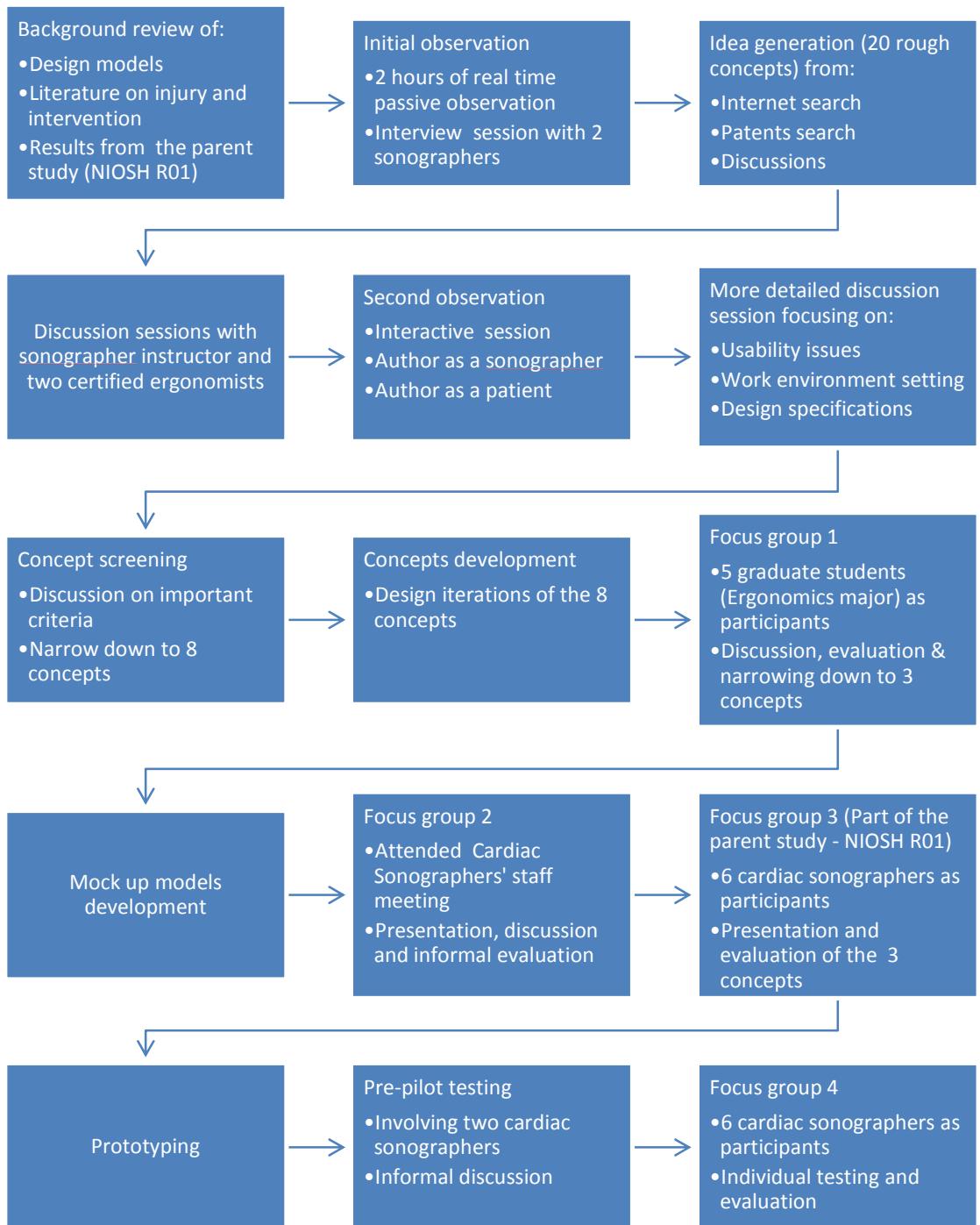


Figure 3.4. An overview of the design process adopted in the current study.

3.3. Needs assessment

Otto & Wood (2001) argued that there is a linear relationship between fulfilling customer needs and customer's satisfaction. Thus, it is important to conduct a needs assessment to identify issues that really matter to the end user. However, precautions should be taken as needs are divided into two major categories: expressed needs and latent needs. It is the responsibility of the design team to identify both types of needs as they are the foundation of why a new product development is needed.

Earlier stages of design include collection of data pertinent to actual end users, which in this case are the cardiac sonographers. Ulrich & Eppinger (2000), Popovic (1999), Stoll (1999), Stanton (1998), and Cushman & Rosenberg (1991) discussed several different methods that were used by designers to elicit and document end users' needs. The common methods that are used by designers include reference to previous relevant studies, literature review, checklists, observation (with notes & video recording), interview, questionnaires, benchmarking, and conducting focus group sessions. This section will discuss the user needs assessment extracted mainly from the first stage of the parent study. A more detailed needs assessment effort was further pursued in the later stage, and will be discussed in the next section.

This study is a part of a larger project (NIOSH R01OH009253) undertaken by an interdisciplinary research team from the Ohio State University (OSU) and North Carolina State University (NCSU). There have been reported musculoskeletal problems among imaging technologists, including cardiac sonographer in the literature. This larger study aims to work with imaging technologists to identify risk factors associated with those

problems and develop recommendations for intervening action to mitigate several of them. The first phase of the parent study primarily involves identification of ergonomics problems. The problem statement of this constituent study is derived from the parent study, but specifically focuses on addressing issues among cardiac sonographers, a sub-population of the larger population of imaging technologists.

A first stage of the parent (NIOSH R01OH009253) study included a series of interactive workshops that were held for each of five types of imaging technologist, including a workshop for cardiac sonographers. The workshops were designed to elicit information from the technologists about the key challenges they face in performing their jobs and to provide them with opportunities and means for generating solution concepts to their top priority challenges. Within the methodology employed, the solution concepts are also viewed as expressions of needs rather than explicit solution ideas.

Five full time professionals participated in the workshop for cardiac sonographers. The participants were varied in experience, ranging from 6 months to 27 years of experience. All in all, the cumulative year of experience of these 5 participants is 77.25 years. A methodology named “Make-Tools” was utilized to facilitate the exchange of thought and experience between the end user and the design team in the latter portion of the workshop. The purpose of this method is to “discover as-yet unknown, undefined, and/or unanticipated user needs” through creation of concept solutions made from a tool kit provided by the research team (Sanders, 1999).

The five cardiac sonographers were given a workbook where they documented issues that they were having at work. In addition, disposable cameras were given so that

they could take pictures to complement what they wrote about in the workbook. The information provided in the workbook, including a 2-day procedures diary and the workplace photos were then reviewed by the NIOSH R01OH009253 research team to identify the common themes from the various sections of the workbooks.

The contents of the workbook confirmed the initial premise that the cardiac sonographers were exposed to some degree of musculoskeletal risks due to the current configuration of their work. Among the issues that were listed in the workbook include awkward postures when positioning the probes, having to grip the transducer firmly, and having to apply forces on the probe to get better images. Figure 3.5 shows an example of a picture that was taken by one of the participants to complement her point on the issue of uncomfortable gripping of the transducer.



Figure 3.5. Example of a picture taken by a cardiac sonographer to point out the issue of uncomfortable pinching posture.

Discussion during the workshop revolved around the issues that were previously reported in the workbook. The participants were asked to elaborate and share their experience on those issues. Among the issues that were discussed include awkward working postures, requirement to exert high forces, assuming prolonged pinching postures, and maintaining static postures while scanning. These issues were summarized and sorted accordingly as shown in Figure 3.6. The recurring issues of prolonged pinching, forceful exertion, repetitive motions, sustained exertion, and unsupported postures were then translated as problem statements, and their needs for interventions that will minimize the magnitude of these issues.

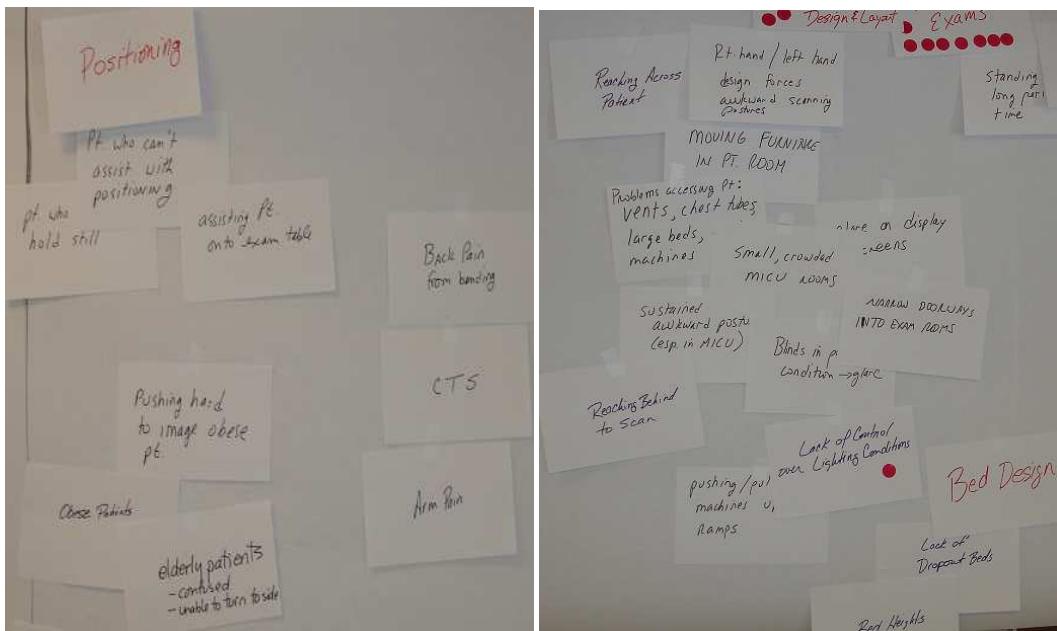


Figure 3.6. Some of the issues identified by the cardiac sonographers during the workshop

3.4. Design formulation

3.4.1. Initial data collection

Using information gained from the first stage of the parent study, a more focused area for in-depth study was identified. Thus, a more focused needs assessment analysis was needed to comprehensively understand the previously identified issues. In addition to the information obtained from the workbook and workshop, a more involved effort was conducted for further needs analysis. Several established methodologies used by designers including literature review, observation, interview, and focus group sessions were employed to elicit the needs from the cardiac sonographers.

Literature review was done as a first step to justify the need of this study. Previous studies relevant to the topic were searched and analyzed to get an overall background of the problem. In addition, reviewing published materials informs the researcher about what has been done in the past, and potential opportunities that have not been tried by others. A review of the relevant literature was summarized in Chapter 2 of this report. The common recurring themes found throughout the literature review process were probe pinching, repetitive motions, awkward upper extremity postures, and static postures. The data and information collected from these published papers may be used to justify the need to do this research, complementing the needs expressed by the end users in the parent study.

Another method of identifying users' need is by observing them performing actual work themselves in real work settings. The researcher may appreciate and be

made aware of the issues in more effective ways by real time observation. This is supported by Ulrich & Eppinger (2000) where they claimed that ideally, observation should be done in an actual environment. The authors also claimed that direct observation of how a user performs a task “can reveal important details about customer needs”. Popovic (1999) reported that observation can help a design team to understand the dynamics of the interaction between users and the product that they are using. Thus, observation on how cardiac sonographers perform their work was seen to be essential as it gave the opportunity to the author to having a firsthand understanding of the job.

Observations of two cardiac sonographers were conducted in the Ohio State University’s Ross Heart Hospital, while they performed scanning procedures on three patients. In addition, information noted included duration of each scanning activity, postures adopted by the sonographers, and environmental constraints that affected the sonographers’ movements. The Table 3.1 summarizes the general scanning procedure observed.

It was observed that the patients are always asked to lie on their left side while the examination is performed. Both sonographers were scanning with their left hand and performed the task while seated on a wheeled chair. The patients’ examination bed, sonographer’s chair, and the ultrasound machine were all height adjustable. After adjusting the height of the furniture and machine, the sonographer attached the electrodes on to the patient, looked at the physician’s notes, keyed in the patient’s information, chose the appropriate probe, applied ultrasound gel, and begin scanning.

| Time | Task |
|-------------|--|
| 5 -10 min | 1. Set-up patient 2. Set-up machine |
| 5 min | 3. Positioning transducer |
| 15 - 20 min | 4. Maintain posture 5. Push + pinch 6. Repeat within the “window” 7. Enter data in the computer |
| 5 min | 8. Change probe 9. Position transducer |
| 10 min | 10. Maintain posture 11. Push + pinch 12. Repeat within the “window” 13. Enter data in the computer |
| 5 min | 14. Wrap up – clean up |

Table 3.1. Cardiac sonographer's activities observed during a standard examination.

Starting with two hands, the sonographer located the scanning location of interest with several rapid, repetitive movements of the hand and wrist. It was observed that awkward wrist and shoulder postures were prevalent. Once the location of the scanning window of interest was found, the repetitive movement stopped. However, the probe was then firmly pushed against the patient while the sonographer was in an awkward posture. The forceful pushing is necessary because losing contact will result on loss of the scanning window. The next 15 to 20 minutes were spent pinching and pushing the probe using one hand, while the other hand operated the control panel of the ultrasound machine. The sonographer's left shoulder and elbow were seen to be supported by the patient's bed. It was also seen that the intermittently, the hand that was operating the machine was used to support the other hand to help relieve the pressure. It was also

observed that during the scanning procedure, the sonographers took one long duration rest, but was still holding the transducer in place so as to not lose the scanning window. After about 20 minutes of using the first probe, the sonographer changed the probe to a larger, heavier 3D probe, and repeated the procedure for about 10 minutes.

Among the main points that caught the author's attention were pinching, exerting and maintaining force, and awkward upper extremity postures. These activities were also reported in the workbooks from the parent study, as well as in the literature.

Interviewing is an important form of information gathering that was employed in this study. McClelland (1995) reported that interviewing is a common method used in the design process. According to the author, interview can be a very productive way of collecting information, if approached in the right way. Otto & Wood (2001) discussed the technique of conducting interviewing sessions with customers. Like and dislike questions were recommended as the user demonstrates how they usually perform the task at the actual site of usage. Like and dislike questions ensure comprehension on what is expected and bothers the user. In addition, the authors also recommended the interviewer follow up with "why" questions as these can uncover latent customer needs that were not verbally expressed before. Popovic (1999) reported that interviewing can provide insights and "gives better knowledge about user's acceptability of design concepts. In addition, it also clarifies user needs". Similar to observation, Ulrich & Eppinger (2000) recommended that interviews be conducted in the end user's environment, because that environment may trigger expressions from the user about relevant experiences and emotions during the interview session.

An informal interview session with two cardiac sonographers was conducted to better understand the nature of their work. The questions included how they would usually hold and operate the transducer, as well as things that they liked and disliked with the current method of scanning. In addition, worst case scenarios were also asked about to provide an overview of what is expected during extreme conditions. As part of defining problem, questions relevant to pain, location of pain, and causes of pain were asked. A perception of pain ratings was also used to help the sonographers convey their perception of the pain that they were experiencing while scanning. According to Borg (2005), this type of subjective assessment method can be used to quantify subjective experience of both physical and mental work.

The two sonographers who participated in the informal interviews had 10 and 3 years of experience, respectively. One of them reported that he had an intermittent throbbing pain in his upper extremity for the first few years of working. Specifically, the locations of pain included the left side of the palm, wrist, upper arm and shoulder. The severity of pain was so great that he reported feeling the pain throughout some nights. He claimed to have developed a higher tolerance for pain after a few years. The other sonographer interviewed was bigger physically, and although he did not encounter serious pain, he did mention discomfort felt while scanning the patient.

When asked about their biggest issue that they disliked with current work conditions, they replied that having to push the transducer into the patient, and maintaining the upper extremity posture to obtain a clear image were the most challenging parts of scanning. A cardiac sonographer in that hospital typically handled

seven to eight patients on a busy day, with each patient requiring about 50 minutes of scanning. Thus, the majority of the working time was spent on scanning, and localized muscle fatigue built up rapidly if they were working with overweight patients. With verbal anchor of 10 as excruciating pain, 3 being moderate pain, and 0 as no pain at all, a perception of pain rating of 6 was estimated for an average size patient. Another point made was that the majority of the sonographers are female, so it would be logical to deduce that they may generally feel more pain when scanning a patient. The sonographers interviewed never tried any kind of device or mechanism that provided them physical supports, but they were open to try one if available.

Another method of collecting data to guide the design effort is the focus group. Langford & McDonagh (2003) defined a focus group as a “carefully planned discussion, designed to obtain the perceptions of the group members on a defined area of interest”. Popovic (1999) reported that focus groups help to “identify issues that are important for the user but not taken into consideration by designers”. The discussion lead by facilitators allows participants to demonstrate and share their firsthand experiences and voice opinions on things that they think are both significant or not. A well conducted focus group can facilitate the making of a framework for a design team to work on, as well as guide the team to focus more on things that matter to end users instead of relying on their own experiences, which could be biased. Expressed and latent needs and issues can also be discovered through a series of follow up discussions. However, the focus group session has also disadvantages as discussed by Popovic (1999) and Langford & McDonagh (2003). Among the drawbacks of a focus group session are the tendencies of

discussion straying out from the topic, the bias effect of dominant members, the quality of the discussion, and the difficulty of managing the group dynamics.

Focus groups can be performed at various stages of the product development process, from understanding potential end users' identifying problems, to generating new concepts, evaluation of concepts, and usability testing (Langford & McDonagh, 2003). As discussed in the previous section, focus group sessions (workshops) to identify problems had been conducted as part of the parent study. However, it should be noted that several focus group sessions have been conducted in several different phases of this study. Those sessions will be discussed later in this chapter.

3.4.2. Data decomposition

Information collected from observation, interview, literature review, and focus group sessions can be huge in number and disorganized. The qualities of information collected were usually mixed in terms of their usefulness, and systematic categorization of these data is important to filter out irrelevant data. In addition, an orderly categorization of data is important for effective information retrieval in the later design stages. In this study, the data collected from literature review, observation, interview, and information from the earlier focus group session were sorted, filtered, and categorized through a series of steps.

3.4.2.1. Discussion and Validation

The information collected through all of the methodologies above was filtered through several discussion sessions. The weekly discussion sessions participants were two associate professors from the Ohio State University's College of Engineering and College of Medicine. The associate professor from the College of Engineering is also a certified professional ergonomist (CPE) while the associate professor from college of medicine is the Chair of the Department of Radiologic Sciences. From time to time, another faculty member who is also a certified professional ergonomist from the College of Engineering was also consulted. These three are leading experts in their respective fields, and are all members of the parent study's research team. Ulrich and Eppinger (2000) recommended consultation sessions with leading experts as part of the design process. The reasoning behind this was that the experts may contribute by approving or “redirecting the design process to a more fruitful area”.

The discussion sessions during this stage were mainly focused on trying to narrow down the focus of this constituent study. Issues reported by observation, interview and literature review were identified, elaborated, discussed, and prioritized. In addition to verbal discussion, the information gained was also validated through an interactive session with an experienced cardiac sonographer in the hospital clinic where she is currently working. A certified professional ergonomist, a radiologic sciences professional and the author participated in this session. The purpose of this session was to confirm what was previously seen in the earlier passive observation of the two sonographers. However, this session was a bit different in that it was an active

observation, where informal question and answer was exchanged while the author was being guided in performing an actual echocardiography scan. In addition, the issues that were earlier identified based on the literature review and workshop from the parent study were reiterated to gauge the accuracy of what was found, from this sonographer's point of view. Very specific information and experience were gained in this session regarding how the sonographer holds and pushes the transducer. Under the guidance of the sonographer, the design team switched roles of being the observer, the sonographer, and the patient. Switching roles allowed the designers to look at the problems from different perspectives.

Otto & Wood (2003) recommended that the design team act as the end user in an actual location where the product will be used. By doing this, the designers will have a better appreciation of the issues that they are trying to solve. Simulating the actual task with the goal of taking good quality images gave the designers a different perspective from the previous passive observation activity. The magnitude of force exertion was experienced first-hand, and the fatigue that accumulates while sustaining the awkward and static postures gave the designers information that is nearly impossible to be gained by passive observation and could otherwise only be gained through objective measurement using electromyographic techniques. In addition, trying out the different gripping techniques used by the real sonographers gave a better understanding of the dynamic nature of the scanning procedure. By simulating the sonographers' work procedure, the designers gained a better appreciation of the need for having a free range of movement for the hand and probe. This is an important customer need that was not

realized before this session. By acting as the patient, the designer may see other issues from the perspective of the patient. In this session, the designer acting as a patient was able to experience how much force was against a patient's body during this type of examination. The designer as a patient can also get a better picture of what the sonographer is focusing on when performing the scan procedure.

3.4.2.2. Categorization of data through a Morphological Matrix

The information collected was also classified according to the major scanning activities for better data management. The systematic classification will provide a foundation for the management of alternative solutions (Otto & Wood, 2001). Stoll (1999) claims that design problems can usually be divided into several sub-problems, and he proposes the use of simple matrices to organize the data collected for easy information retrieval. A Morphological Matrix is one of the methods that is used to systematically categorize possible alternatives in a structured way. Table 3.2 shows the Morphological Matrix that was developed for this study.

Decomposing the scanning procedure into the main activities performed is a first step when building the matrix. The sonographers' major scanning activities were listed under the first column in Table 3.2, while the second column describes the current approach adopted by the sonographers. The third column contains a list of possible alternative solutions. These potential solutions were generated from various methods including brainstorming, discussion, interview, and the designers' imagination. However, such a list at this stage is explored only at the surface, a mere few words about

each idea without going into the details of how the concepts operate or look. The purpose of this activity is just to provide a groundwork for the next step, which is design conceptualization.

| Function | Current Method | Possible Solutions | | |
|--------------------------------|--|--------------------|----------------------------|--|
| Push | Manual push | Solution 1 | Solution 2 | Solution 3 |
| | | Lever system | Two hands | Hydraulic |
| | | Solution 4 | Solution 5 | Solution 6 |
| | | Gear/ crank based | Fulcrum/pivot /wedge based | Spring/ elastic mechanism based |
| | | Solution 7 | Solution 8 | Solution 9 |
| | | Magnet | Additional weight | Handle/posture redesign |
| Grip | Pinch grip | Solution 1 | Solution 2 | Solution 3 |
| | | Palmar grip | Power grip | External grip (no grip from user) |
| Arm/ shoulder Support | Some sonographers, especially the shorter ones use the patient's bed for elbow support | Solution 1 | Solution 2 | Solution 3 |
| | | Line hanging | Foam support | Support attached to bed rail |
| | | Solution 4 | Solution 5 | Solution 6 |
| | | Roller ball | Exoskeleton structure | Support attached to ultrasound machine |
| 360 degrees handling + control | Manual free handling | Solution 1 | Solution 2 | Solution 3 |
| | | Socket with lock | Lever | Robotic control |
| | | Solution 4 | Solution 5 | Solution 6 |
| | | Redesign handle | Line hanging | Ball head |

Table 3.2. The Morphological Matrix developed to decompose data and provide a framework for concept generation in this constituent study.

3.4.3. Design specifications

Stoll (1999) stated that “design specification is the foundation of the product development program”. According to Cushman & Rosenberg (1991), this is because the specifications provide the design team with a “vision of what to build”. These specifications usually provide both qualitative functional characteristics and quantitative performance of the product. In a way, the design requirements provide a framework for the design development team to develop a more focused technical design and features. Information gained from previous activities was filtered down to more refined issues intended to be tackled. It was concluded from the literature review, observation, interview, and discussion sessions that this study would focus on the interventional design that could mitigate the issues of:

1. Prolonged pinch grip of the transducer
2. Prolonged push force exertion
3. Awkward upper extremity postures
4. Maintaining static posture

These four issues were the recurring themes that we identified throughout the previous inquiry activities. A design that can address the four issues above is expected to reduce the cardiac sonographers’ risk exposure to developing work-related musculoskeletal disorders. Thus, it was concluded that the design specifications will be:

1. Reduce the duration of pinch grip of the transducer
2. Reduce the duration of force exertion from pushing task

3. Reduce the duration of awkward upper extremity postures
4. Minimize the need to maintain static posture

3.5. Design

3.5.1. Conceptualization of designs and theoretical basis

The concept generation stage as discussed by Otto & Wood (2001) is intended to explore as many conceptual alternatives as possible. This is the stage where knowledge from various fields needs to be brought together to generate potential solutions to the identified problems. Those authors claimed that the concept generating process starts with understanding user needs, decomposing data collected, searching for solutions, and lastly combining solutions into concept variant. Ulrich & Eppinger (2000) defined concept generation as a “process that begins with a set of customer needs and target specifications and results in a set of product concepts from which the team will make a final selection”. The authors also proposed a five-step concept generation method which is 1) Clarify the problem, 2) Search externally, 3) Search internally, 4) Explore systematically, and 5) Reflect on the solutions and the process.

Based on the information that was previously gathered and filtered from user needs analysis, alternative solutions are actively explored by creative endeavors. This process starts right after the initial observation and interview sessions, after the design team had some understanding of how the scanning procedures are performed.

Conceptual ideas were searched for externally using internet search engines, patents available online, considering products that are already in the market, discussion with peers, benchmarking against the current methodology, and literature reviews. Internal searches included brainstorming with simple sketches and words, imagination, and mind mapping of thoughts. Using the morphological matrix as a summary table, the conceptual solutions were explored systematically according to the alternatives generated from earlier brainstorming. Those potential solutions that were previously only written down in simple words were further explored by conceptualizing how they might look, how they might interact with the user, and generally how they would work in cardiac sonography settings.

Twenty different concepts were generated at this stage. The sketches were at this point very rough, with each sketch only representing the main mechanism of how it potentially would work. The concepts were generated from several perspectives: how it could change the grip posture, how it could affect the upper extremity posture, how it could augment force, and how it could provide support. These perspectives were based on the design specifications discussed earlier. However, the design team does not consider only the concepts that meet all four specifications at once at this stage, because that will limit the creative exploration of ideas. Instead, the concepts that were generated focused on addressing one or two specifications at a time. By doing this, a rough main mechanism can be assigned to each concept, and the design team can always combine the different ideas generated in the later stages. Various mechanisms that were explored included exoskeleton structural systems, a spring mechanism, an articulating arm, a gear

system, a cam shaft lever system, a fulcrum-based mechanism, a two handed system, and an elastic material system. Figure 3.7 shows sketches of some of the concepts that were explored.

Discussions with two certified professional ergonomists and the radiologic sciences professional on the how these concepts were envisioned to work resulted in further development on some of the design concepts. Some concepts were combined to be a single concept, while some were eliminated all together. Constraints were continuously added to make the design more practical and feasible with every design iteration. After several conceptual iterations through discussion sessions, these concepts went through the next stage, which is the concept evaluation and selection stage.

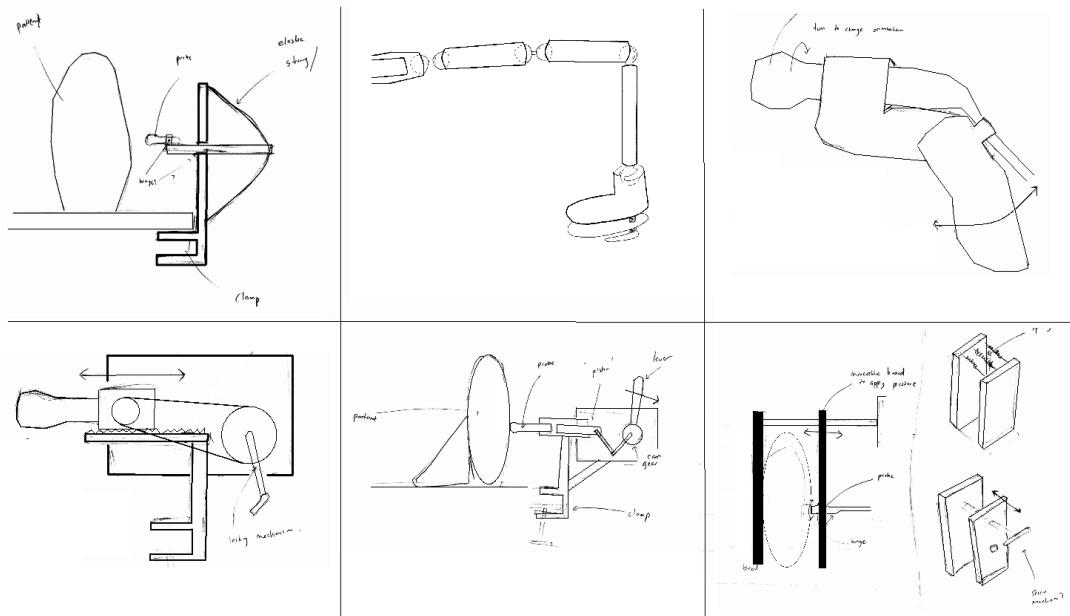


Figure 3.7. Example of concepts generated during the concept generation stage. From upper left clockwise: elastic mechanism system, external articulating arm, pistol grip probe attachment, spring/screw mechanism system, cam shaft lever system, and gear mechanism system.

3.5.2. Concept Screening

A lot of ideas are generated in the conceptualization stage. However, these ideas have to be examined, evaluated, filtered and finally chosen to be pursued further. There are many screening and evaluation approaches discussed in the literature. Stoll (1999) reported that these approaches “range from using pro-con lists, following intuitive feel, decision made by concept champion, using customer surveys, to structured rating schemes”. The author argued that the structured rating scheme is the best approach as it strikes a balance between evaluation through comprehensive engineering analysis and intuitive feel. Popovic (1999) also discusses several concept evaluation techniques such as focus group, mock-up evaluations, and prototype testing. Mock-up evaluation helps by providing a physical structure for designers to evaluate. Simulation of the mock-ups in the contextual environment may reveal advantages and disadvantages of one concept versus another. In a later stage, when the concepts have been narrowed down to one or two designs, working prototypes may be built and evaluated to verify the design outcome under the real conditions. This may be more involved than mock-up evaluation, and is considered to be the “most effective method of assessing the usability of an artifact or system” (Popovic, 1999).

The 20 concepts discussed above were screened down using a screening matrix developed by Stuart Pugh in the early 1990s. Pugh’s screening method has been recommended by Ulrich & Eppinger (2000) to narrow down the number of concepts, allowing the designers to focus on a smaller number of concepts for further improvement. Stoll (1999) claimed that this screening method “is effective and easy to use, especially

when a large number of alternatives are to be considered”. The screening matrix consists of two main columns, the first one lists the selection criteria based on the customer needs, while the second one indexes the twenty concepts into independent columns. Stoll (1999) summarized the screening matrix as follows:

- “
 - 1. *All evaluation criteria are assumed to be of equal importance.*
 - 2. *The alternatives (concepts) are scored using the reference based scoring method.*
 - 3. *Instead of a point scale, concepts are scored relative to the reference using a “better than” (+), “same as” (0), or “worse than” (-) system.*
 - 4. *The overall score is determined by simply counting the plusses, minuses, and “sames” for each alternative.* ”

The modified screening matrix for this project is shown in Table 3.3. The only change that was introduced was in the scoring system. Instead of a 3 level scoring system (+, 0 and -), the modified scoring system used a 5 level scoring system (++, +, 0, -, and --). The reasoning behind this modification was that it provides a more detailed and thorough evaluation. For example, an exoskeleton system is expected to perform much better in augmenting force compared to an articulating arm that can lock into place. However, the articulating arm is expected to perform better than the current method, which is manual exertion. Thus, the five level scoring system recognizes that there are gradations of difference between the concepts for certain criteria.

| Selection criteria | Concept | | | | | | | | | |
|---|-------------|--------------------|--------------------------|------------------|-------------------------------|------------------------------|-------------------------|--------------------------------------|---------------------------------------|-------------------------------------|
| | Arch glider | Exoskeleton system | Cranking screw mechanism | Articulating arm | Articulating rest with spring | Articulating arm with spring | Weight augmented system | Customizable length articulating arm | Handle attachment (pronation posture) | Handle attachment (neutral posture) |
| Augment force | + | ++ | ++ | + | ++ | ++ | ++ | + | 0 | 0 |
| Avoid prolonged pinching posture | + | + | + | + | + | + | ++ | + | + | + |
| Avoid prolonged awkward upper extremity posture | + | - | + | + | + | + | + | + | + | + |
| Provide support | + | + | 0 | 0 | ++ | 0 | -- | 0 | -- | + |
| Providing rest | + | + | + | + | + | + | -- | + | -- | -- |
| Ease of handling (& fine motor adjustment) | + | - | + | ++ | - | ++ | 0 | ++ | -- | -- |
| Set up time | - | -- | - | 0 | - | 0 | - | 0 | + | + |
| Procedure time | - | - | - | 0 | - | 0 | - | - | -- | -- |
| Development time (+ complexity + expertise) | - | -- | + | - | - | - | - | + | ++ | ++ |
| Cost | - | -- | - | - | - | - | - | - | ++ | ++ |
| Portability | - | + | + | + | + | + | -- | ++ | ++ | ++ |
| Maintenance | - | -- | - | - | - | - | - | 0 | - | - |
| Total score | 0 | -5 | 2 | 4 | 2 | 5 | -6 | 7 | 0 | 3 |
| Proceed to the next level? | yes | no | yes | yes | yes | yes | no | yes | yes | yes |

| Selection criteria | Concept | | | | | | | | | |
|---|------------------------|---------------------------|------------------------|-------------------------------|-------------------------|-----------------------------|-------------------------------------|------------------------------|-------------------|------------------|
| | Bicycle gear mechanism | Cam shaft lever mechanism | Fulcrum / pivot system | D-shape grip handle interface | Movable board mechanism | Elastic string / bow system | Modification of keyboard's arm rest | Augmentation on elbow system | Foot pedal system | Two hands system |
| Augment force | ++ | ++ | + | 0 | + | ++ | + | + | ++ | 0 |
| Avoid prolonged pinching posture | + | + | + | + | + | + | - | - | 0 | + |
| Avoid prolonged awkward upper extremity posture | + | + | + | -- | + | + | - | - | 0 | -- |
| Provide support | 0 | - | 0 | -- | 0 | 0 | + | + | - | -- |
| Providing rest | 0 | - | + | -- | 0 | + | -- | -- | - | -- |
| Ease of handling (& fine motor adjustment) | - | - | -- | -- | -- | -- | -- | -- | -- | -- |
| Set up time | -- | - | - | + | -- | -- | + | - | - | + |
| Procedure time | - | - | -- | -- | -- | -- | 0 | -- | - | -- |
| Development time (+ complexity + expertise) | - | - | - | ++ | - | - | + | - | - | ++ |
| Cost | - | - | - | + | + | + | - | - | - | + |
| Portability | -- | - | + | ++ | + | + | + | + | -- | ++ |
| Maintenance | - | - | - | - | - | - | - | -- | - | ++ |
| Total score | -5 | -5 | -3 | -4 | -2 | -1 | -3 | -10 | -9 | -1 |
| Proceed to the next level? | no | no | no | no | no | no | no | no | no | no |

Table 3.3. Screening matrix used to evaluate the initial 20 concepts.

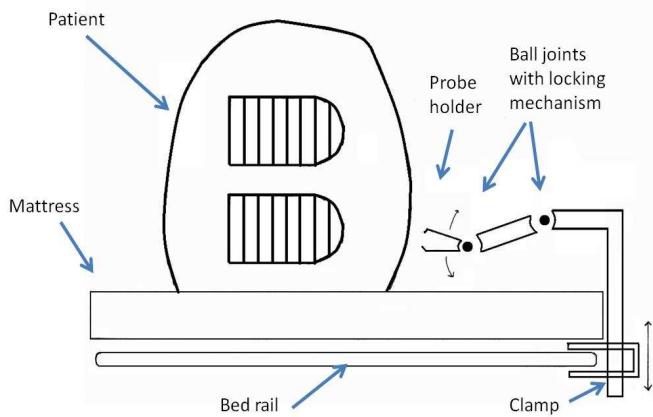
The eight best concepts were selected for further refinement based on positive scores from this activity. These eight concepts were the arch glider, screw based system, articulating arm, spring system, arm rest system, customizable joint system, handle attachment system, and another iteration of a handle attachment system. The screening activity performed does not consider every single detail. It was meant as a rough evaluation method to narrow down the alternatives to a smaller number. However, focusing the detail design effort on eight different concepts is not a simple undertaking. These concepts will have to go into a second level of screening, which should be more involved compared to the screening matrix method used in the first level.

The next method that was utilized to screen down further the existing concepts was conducting focus group sessions. Nelson (2007) reported that designer usually is too “immersed in the problem and is unable to see many of the possible issues” with the current concepts in hand. Thus having a discussion with peers might help to give a new insight on how to move these eight concepts chosen for further refinement. Five engineering graduate students majoring in physical ergonomics were gathered in a room for a concept discussion and evaluation session. The engineering students came from different engineering backgrounds, including biomechanical, mechanical, cognitive, and industrial engineering. All participants have at least taken an ergonomic design course at the Ohio State University.

A short demonstration highlighting musculoskeletal problems was presented to the group of graduate students. The eight screened concepts were then presented, and a discussion focusing on usability, usefulness, and feasibility of each concept was

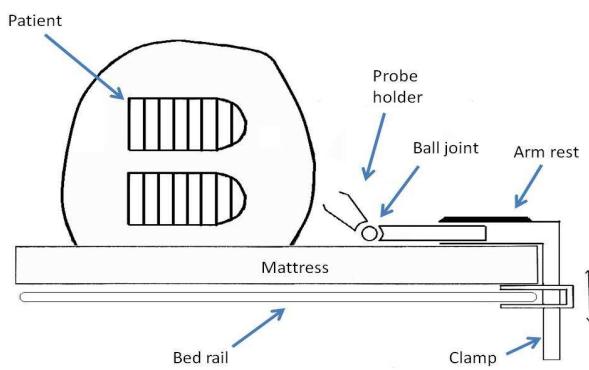
conducted. Comments and design improvements were offered and debated among the students. The students provided some useful comments regarding some of concepts that required two hands to scan, suggesting that they might involve resistance among sonographers due to significant changes in how they perform the scanning procedure. Another example is that while some students argued that even though the articulating arm idea was interesting, precaution on how it might interfere with the end user's line of sight, as well as requiring extra space in an already limited space. Feedback from this exercise was important as it highlights the need to focus on usability issues from a fresh perspective.

Before the session ended, quick votes on the designs were conducted. Each of the participants was asked to vote on the three concepts that they liked the most. This “multivote technique” was proposed by Ulrich & Eppinger (2000) to evaluate the concepts as a team. It is an evaluation method where each team member “simultaneously votes for three to five concepts by applying ‘dots’ to the sheet describing their preferred concepts”. The three concepts that had the most votes were 1) articulating arm 2) articulating arm rest 3) U-ring glider. These three holder concepts and three push assist mechanism concepts that can be incorporated in any of the three holder designs are shown in Figure 3.8 and Figure 3.9, respectively.



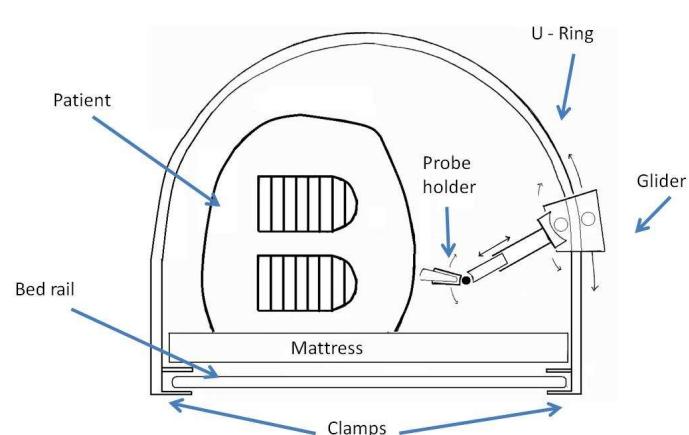
A flexible articulating arm consisted of several ball joints that could be locked into place was envisioned to reduce the duration of pinch grip, force exertion, awkward posture, and static posture.

(a) Concept 1- Articulating arm



An articulating arm rest was envisioned to provide arm support. When it is locked in place, the device was expected to reduce the duration of pinch grip, force exertion, awkward posture, and static posture.

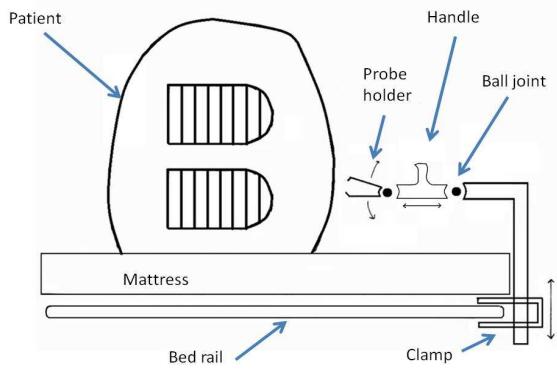
(b) Concept 2- Articulating arm rest



(c) Concept 3- Arch-glider.

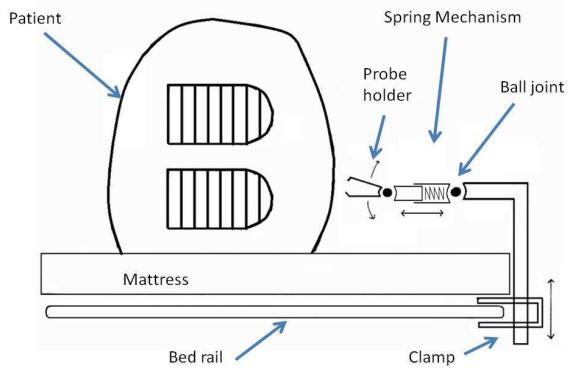
An arch clamped on both side of the patient's bed was envisioned to provide a structure to support a gliding articulating arm. This articulating arm could be locked into place, and was expected to reduce the duration of pinch grip, force exertion, awkward posture, and static posture.

Figure 3.8. The three holder designs with highest number of votes from focus group participants.



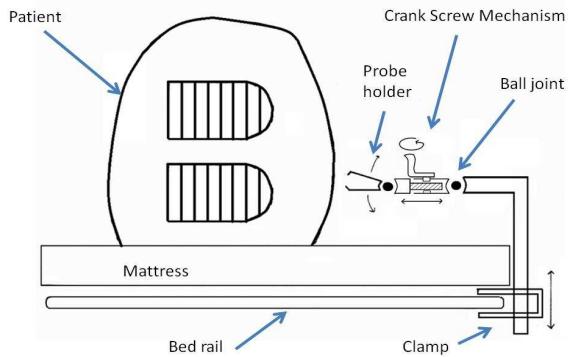
(a) Articulating arm with external handle

A handle connected to the articulating arm was envisioned to provide a physical interface for manual force exertion task.



(b) Articulating arm with spring mechanism

A compression spring inside the articulating arm was envisioned to provide force augmentation. The magnitude of exertion can be controlled using a control knob.



(c) Articulating arm with crank-screw mechanism

A handle connected to a crank screw mechanism was envisioned to provide fine adjustment control of the force exertion.

Figure 3.9. Example of alternative push assist mechanisms integrated into Concept 1 (articulating arm). Any of these mechanisms can also be integrated into Concept 2 and Concept 3.

3.5.3. Mock-up models

A large number of concepts were generated during the concept generation stage, and the only methods of communicating those ideas were sketches and verbal descriptions. In the later stage, after the number of concepts was screened down to the best eight concepts, the method of communication evolved from sketches to more detailed drawings. However, the next stage involved a discussion session with graduate students who had no background in echocardiography. The detailed drawings will not make sense to the novices if the issues are not clearly defined. Thus, a simulation of the scanning procedure was chosen as a method of communication. The ultrasound transducer was seen as an important component of the simulation. Since ultrasound transducers are very expensive, the use of a real one in a discussion session might not be a good idea. Thus, we decided to use a mock-up transducer to replicate the scanning procedures. At the end of the discussion session with the students, the concepts were narrowed down further to three concepts. The next stages involved direct interactions with the end users, so a more effective method of communication to raise the fidelity of their interaction with the concepts was required. Physical mock-ups of the concepts were created to assist us in communicating the concept ideas more effectively to the sonographers.

Ulrich & Eppinger (2000) claimed that a physical model is a better communication tool compared to verbal description, sketches and detailed drawings. This is because the three dimensional representation of the product allows the end user to physically interact with the concepts in addition to their mental understanding of how the

concepts work. Thus, information gained through interacting with a physical model has a higher level of data “richness” compared to visual interaction gained through sketches and detailed drawings.

Mock-up models using PVC pipe, foam, and clay were used in this study. The mock-up of the transducers such as those shown in Figure 3.10 were especially helpful in focus group and discussion sessions, where interaction between the concepts and the transducer can be demonstrated physically. In addition, the mock-ups of the transducer also helped at the later stage when we were designing the probe holder attachment for the functional prototype. The communication and exchange of ideas with the people from the machine shop were made easier by having the physical models of the transducer, as the mock-up transducer models were used to test the fabricated probe holder prototype model.



Figure 3.10. Mock-up models of the cardiac transducer made from molding clay (a) and foam (b).

The mock-up model of the three concepts presented to the cardiac sonographers in the departmental meeting and a focus group evaluation session were built using PVC pipe, foam, tape, cardboard, and clamps. These mock-ups as shown in Figure 3.11 were made to approximate the envisioned dimensions, and were intended to give a general idea of how the interventions might look. Detailed features such as a functional locking mechanism were omitted in the mock-up models, as feedback from the sessions with the sonographers would help to determine if it would be worthwhile to pursue any of the concepts in more detail at later stages.

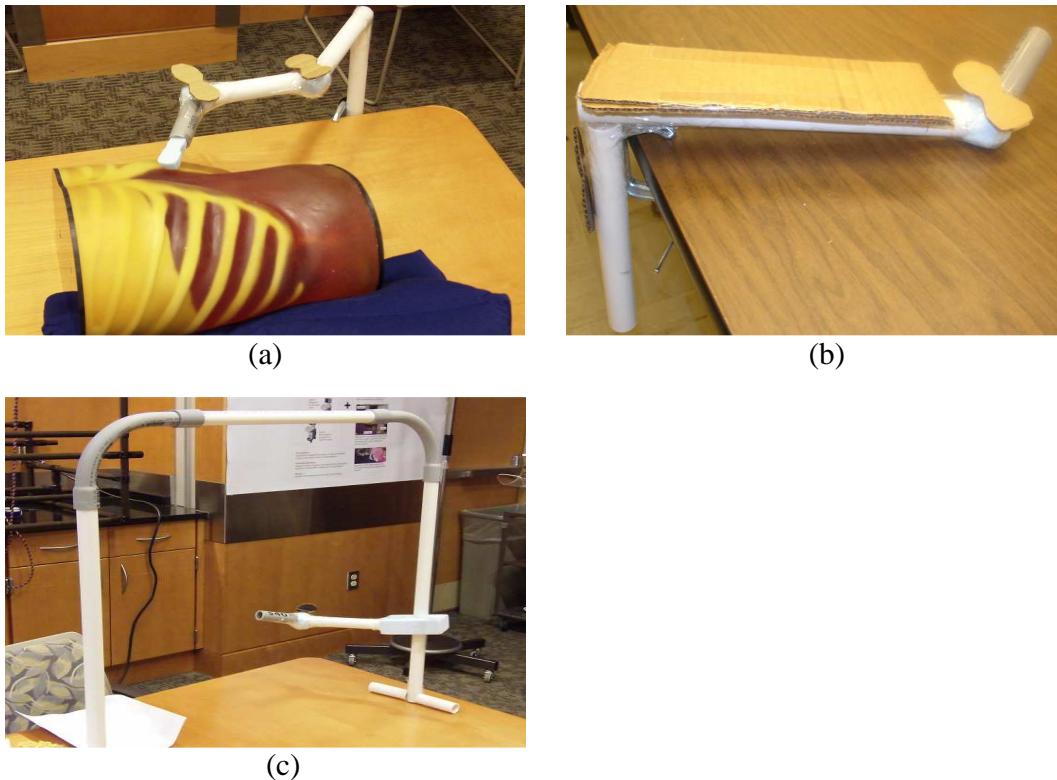


Figure 3.11. Mock-up models of the articulating arm (a), articulating arm rest (b), and arch-glider (c).

3.5.4. Concept Evaluation

After narrowing down the concepts to the top three designs, the next step was to discuss the short list of concepts with potential end users. Feedback from them would pave the way to gauge the acceptance of any of these concepts. The three main ideas were presented to a group of about ten cardiac sonographers at the start of their biweekly departmental meeting. In addition, the three alternative push assist mechanisms that can be incorporated into any of the main concepts were also presented. Drawings of the designs were shown, with the help of mock-up PVC prototypes. This semi-informal session allowed the sonographers to ask questions as well as permitted some discussion. The session was well received, with new ideas and modifications suggested by them. Informal evaluation of the concepts was performed by a show of hands. Information gained from the session included:

- Proposal of a combination hybrid of Concept 1 and Concept 2.
- Rejection of the Concept 3, due to issues such as portability and set-up time.
- Spilt vote between Concept 1 and Concept 2, where Concept 2 had a slightly more votes.
- Concern about time it would take to “crank” the force augmentation mechanism.
- Concern that the spring mechanism would take away their control of how much pressure to exert on a patient.
- Concern that the handle might be in the way when rotating the transducer around, resulting an awkward posture when using it.
- Foldable physical barrier to replace the external handle.

- Most of the sonographers perform this task left handed.
- Portability is a big issue since half of the scanning procedures were performed in the patient's room in this facility.
- Majority of the sonographers do not like force augmentation for the fear of losing control.

Further design constraints were then added after the session, such as focusing only on the left handed scanning technique since the majority of the cardiac sonographers are scanning with their left hand. In addition, it was also perceived that having full control of the pushing magnitude is an important issue to them.

The next step was conducting another focus group, a concept review session which provided a formal evaluation of the three concepts. The session was held as a part of the parent project, and the probe holder concepts were one of several interventional concept categories that were reviewed by the participants in that session. The session consisted of six cardiac sonographers from two different medical facilities around Columbus, Ohio. The three probe holder concepts, and the alternative push assist mechanisms that can be integrated into any of the three concepts were again presented with demonstration of the mock-up prototypes on a phantom patient as illustrated in Figure 3.12. In addition, a 3 by 4 foot poster shown in Figure 3.13 was also used as a visual aid during the presentation.

After the presentation, the presenter gave the focus group participants a chance to ask questions before giving them an evaluation survey to complete. The evaluation survey consisted of three main sections: 1) usability, 2) usefulness, and 3) desirability. Sanders (1999) argued that product success depends on these three criteria, and they "had

to be satisfied simultaneously". Additionally, the cardiac sonographers were asked to review a list of barriers to adoption for the reviewed concepts. They were then asked to mark all relevant barriers that they thought might hold back the implementation of the reviewed concepts.



Figure 3.12. Demonstration of how Concept 1 is envisioned to work during the cardiographers concept-review focus group session.

From the formal evaluation, we heard, again, that the sonographers were concerned about losing full control when pushing the probe against the patient's chest. Another issue that was raised is related to the locking mechanism. They did not like the current design of any of the several locking mechanisms² shown to them because they thought that the design would slow them down too much. The echocardiography relies

² The locking mechanisms lock the arm position through a clamping system. Each arm is connected by a ball head on its end. Turning the locking knob would clamp the ball heads, resulting a firm hold and positioning of the connecting arms.

on different pressures at any given time, so having to lock and unlock the different joints would be time consuming. Similar to the session during the departmental meeting, all six participants rejected concept 3 due to portability and usability issues. At the end of the session, one participant said that the concepts shown to them had potential, but were all still in their infancy stage. They also raised the issue of having a hard time evaluating the concepts due to the demonstration using non-working prototypes. They gave a positive response when asked if they would like to try testing functional prototypes in the future

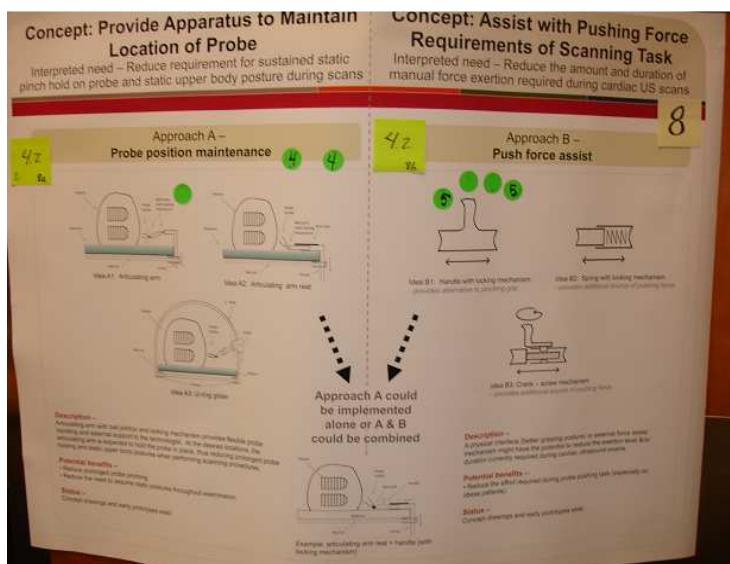


Figure 3.13. A poster as a visual aid summarizing the screened concepts to complement the demonstration and mock-up models presented during the concept-review focus group session.

In summary, we decided to further explore Concept 1 and Concept 2. Concept 3 was not pursued further due to unanimous rejection from the two sessions with the cardiac sonographers. As for the alternative push assist concepts, there were different

opinions of what might work. However, the majority of the sonographers did not like the idea of having a spring or crank-screw mechanism as it would take away their full control of applying the appropriate pressure with the probe. The idea of using a handle interface to assist the pushing task was met with a mixed reaction. Some sonographers expressed concern that the handle would be in the way if it was not positioned correctly. Since the transducer is rotated frequently, the extra handle protruding out of the arm might interfere with the way they are handling the probe.

3.5.5. Functional Prototype

Ulrich and Eppinger (2000) define a prototype as “an approximation of the product along one or more dimensions of interest”. The main purpose of having a prototype is to validate the functionality of the concept. Previous design efforts were mainly theoretical concepts, and even though they might work on paper, they might not be practical in reality. Having functional physical mock-ups of the concepts would allow both the design team and the end users to test out the potential concepts. The outcome of prototype testing would determine if it is worthwhile to invest more resources in those concepts.

The evaluation of the mock-ups from the staff meeting and focus group sessions gave us some ideas on how to move forward with a working prototype. General comments on issues related to usability, practicality, set-up, and interaction with the sonographers in previous sessions were documented. Taking into consideration the issues that were previously raised, an internet search on similar products or parts already

in the market was conducted. Several keywords such as articulating arm, mechanical arm, gooseneck, ball head, ball joints, ball clamps, circular clamps and their combinations were searched using several internet search engines. Four products that are already in the market were short-listed because they were found to be similar to the concepts we had in mind. These four products were ordered to be delivered to the design team for further investigation. The rest of this section will focus on the development our functional prototype based on ideas and information gained through the exploration of the four short-listed products.

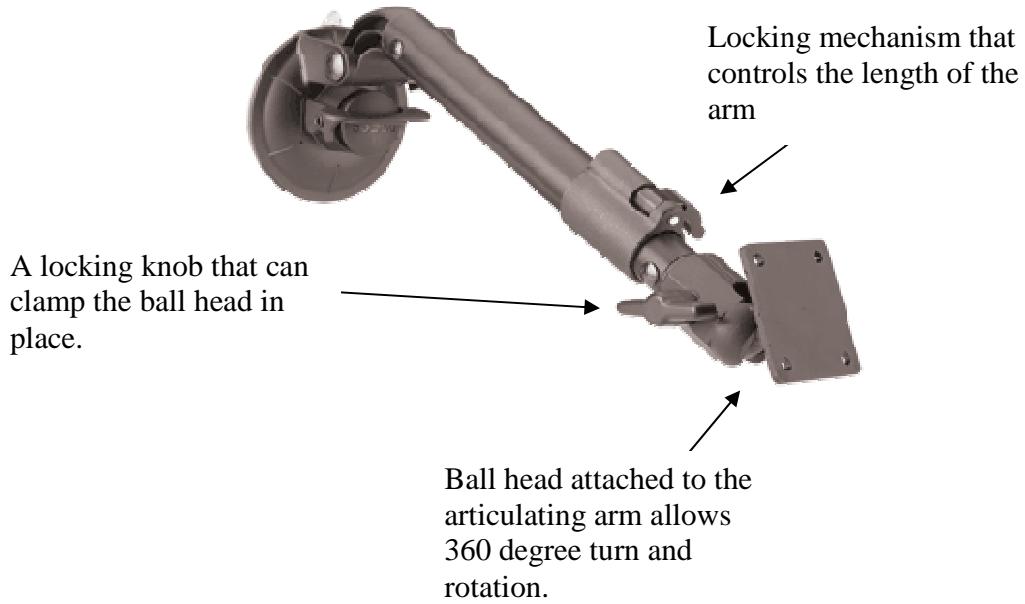
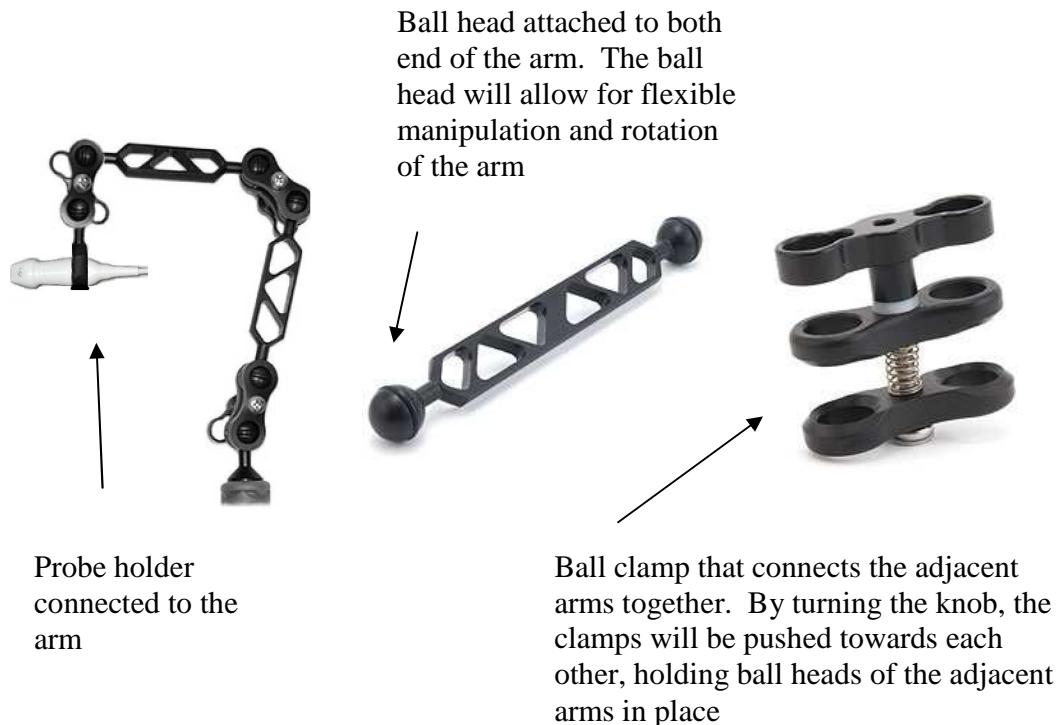


Figure 3.14. WindowGrip Deluxe Telescoping Mount (Panavise.com)

An articulating arm manufactured by Panavise (WindowGrip Deluxe Telescoping Mount Model 709B, Nevada) was first explored for the working prototype. The product is shown in Figure 3.14. The telescoping arm length is adjustable from 13.25" to 18" with a simple locking mechanism which is indexed to prevent arm rotation. In addition, the arm has a ball head that has a 360 degree turn and rotation for flexible positioning purposes. A locking knob that connected the arm and the ball joint functioned as a locking mechanism, tightening the ball clamp to hold the ball arm in place. The arm itself was of aircraft grade aluminum, which would be capable of supporting high loading forces.

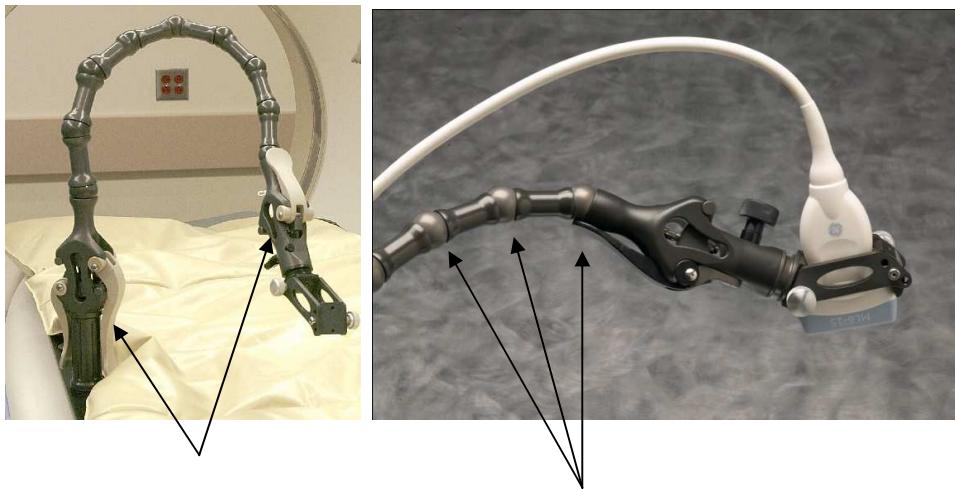


Figures 3.15. Articulating arm system from Ultralight (Backscatter.com)

The next product that was explored is the articulating arm system by the manufacturer Ultralight (model number UL-AC-CSF and UL-AC- USL, USA). The system consisted of two main components: an arm and a clamp. A ball head is usually attached to the end of the arm, while the ball clamp has dual functions as a locking mechanism as well as the connector joining one arm to another. In its unlocked configuration, the instrument is flexible and can be manipulated into various positions. By turning the clamp's knob in a clockwise direction, the two planes of the clamp will mechanically be pushed towards each other, resulting in a firm hold of the ball heads connected to the arms. This system is specially designed to hold a flashlight for underwater photography activities. The device is made out of aircraft grade aluminum, stainless steel and nylon. The system is lightweight and can be customized to any length that a user wants. The locking mechanism of ball joint and clamps allows for great range of motion. However, each joint must be locked individually to hold the arm in place.

The third product that we explored was a positioning system manufactured by Civco Medical Solutions (Model number 810-200, Iowa). This device is specifically marketed to hold an ultrasound transducer in a minimally invasive surgical procedure. Civco's main positioning arm, as shown in Figure 3.16, consists of several ball joints connected to one another through a mechanical system. The main positioning arm can be connected to external attachments at both ends: one end is designed for mounting purposes and the other end is designed for holding an ultrasound transducer. The positioning arm itself is flexible and can be easily manipulated to assume various positions. In addition, the instrument has two locking mechanisms that "allow the arms

to go from a completely flexible to a semirigid and finally a completely rigid configuration” (Davol et al, 2006). By pulling the locking levers, the mechanical system tightens the ball joints together, holding the articulating arm in a fixed position. In its locked configuration, the arm is designed to withstand up to 12 lbs of force “without yielding more than 0.25 inches of movement” (Civco Worldwide, 2010).



Locking levers to lock the arm in place

The articulating arm consists of several ball joints for flexibility

Figures 3.16. Positioning arm system by Civco (Civco.com)

Wellan Medical’s Ultrastand (Model number B1P1R1F1H1, New Hampshire) is also an interesting product that was explored in our effort to build a functional prototype. Similar to the positioning arm system by Civco, this device is specifically designed to hold an ultrasound transducer in place. This instrument is basically an articulating arm

attached to a gooseneck for flexible positioning of the ultrasound probe. The gooseneck is flexible and can be positioned in various configurations. Even though the arm does not have any locking mechanism, it is quite stiff and able to stably hold the ultrasound transducer in place to a certain degree. The instrument can either be mounted to a compatible ultrasound machine or a stand for support as pictured in Figure 3.17b and 3.17a, respectively. The probe holder is made from plastic with a ball hinge at the end connected to the gooseneck. A Velcro strap can be wrapped around the plastic mounts to hold the transducer in place.



(a)
The system can be mounted on a wheeled stand for portability

(b)
Velcro straps for better management of the transducer's cord
The system can also be mounted on compatible ultrasound machine

Figures 3.17. Ultrastand probe holder by Wellan Medical (Wellanmedical.com)

These four products that were shortlisted from internet searches were in some degrees disassembled for better understanding of the main mechanisms behind their functional features. Understanding the mechanical system of these devices is imperative in order to make our own prototype that can be compatible with echocardiography procedures.

Interestingly, the Ultralight articulating arm system already in the market is very similar to Concept 1 presented earlier to the cardiac sonographers. On the other hand, the Panavise arm which is basically an adjustable length articulating arm with a ball joint for flexible positioning is very similar to Concept 2. However, there are issues related to usability for Concept 1 and Concept 2 which were legitimate and needed to be addressed. The Ultrastand positioning system by Wellan Medical was then thought to be the solution as the website claims the arm “can be quickly positioned in a wide variety of configurations and yet allows sensitive fine-adjustment” (wellanmedical.com, 2010). However, upon receiving the product, we decided that the Ultrastand would not work well in cardiac sonography setting due to the stiffness of the gooseneck. The ease of fine tuning the probe is an integral component of echocardiography scanning, and the stiffness of the gooseneck will restrict the quick motions needed by the cardiac sonographers. The Ultrastand nevertheless provided us with ideas on how to move forward with our own probe holder attachment. A plastic holder with a foam cushion only adds a small profile to the probe and a Velcro strap that holds the probe securely to the probe holder were good ideas that may be incorporated someway in our own prototype.

The Civco's positioning arm was seen as the best option as it addressed several usability problems with the other products. The flexible arm that can be manipulated by the sonographers is expected to provide a wide range of motion freedom, enabling them to control the position of the transducer. The way we envision this instrument to work is as an external assisting device that can help hold and maintain the location of the transducer. This will in turn reduce the time spent on forceful pinching, pushing, and maintaining awkward and static postures required during a cardiac ultrasound examination. In addition, locking the arm to a semirigid or rigid setting allows the transducer to be locked within the scanning window. Thus, the sonographer can take an intermittent rest without losing the location of the scanning window.

However, the current set-up of the Civco positioning system is not a perfect solution for our intended application, as it was not designed to be used for scanning echocardiography activities. The probe end attachment was a bit too long, and the current probe holder attachments provided by the manufacturer do not accommodate the echocardiography transducers. Thus, an external probe holder compatible with Civco's positioning arm had to be designed and fabricated in order to hold the echocardiography transducers.

There were several probe holder concepts generated in order to try to solve this problem. The concepts were generated mainly from internet searches and consultation with the machine shop supervisor from the Integrated Systems Engineering Department and a student worker majoring in Mechanical Engineering, both at the Ohio State University. After several discussion sessions, the concept chosen was a single mount

machined from either an aluminum or plastic block. The contour of the probe holder is based on General Electric's and Acuson's probes currently in use at the OSU's Medical Center. A Velcro strap would be wrapped around the mount to secure the transducer. The design team went to the cardiac echo department of the OSU's Ross Heart Hospital to identify the most commonly used transducer brand in the facility. Molding clay was used to trace the dimensions of the probe, as shown in Figure 3.18a. The probe dimensions were transferred to Solidworks, a 3-D Computer Aided Design (CAD) software. A probe holder design was then modeled in the software before being fabricating using a computer numerical control (CNC) machine. A pre-prototype made from wax was fabricated as illustrated in Figure 3.18b, and design adjustments were made to address some issues related to tolerance of the pre-prototype. The finalized design of the probe holder was made from both plastic and aluminum as shown in Figure 3.18c.

In addition to the need for a compatible probe holder attachment, there is another issue that needed to be addressed before the device could be tested in cardiac sonography settings. The current articulating arm was designed to be mounted on a surgical bed or computed tomography scan (CT) table. There is no stand that is made for the arm by the manufacturer. Because the echocardiography procedure is usually performed in a sitting position, the articulating arm should be mounted low to the ground for better access and manipulation of the arm. An external mounting stand that holds the instrument in front of the sonographer was envisioned to address this issue. Ideally, the stand should be sturdy and heavy enough to support the forces that will be acting against the arm when in use. It

is important that the stand does not raise the articulating arm too high, such that it interferes with sonographer's movements. In addition, it should also be easily transportable. A prototype stand made from Creform pipes and connectors, designed, and fabricated in house, was an initial design attempt to address these needs. The mounting stand prototype is shown if Figure 3.18d.

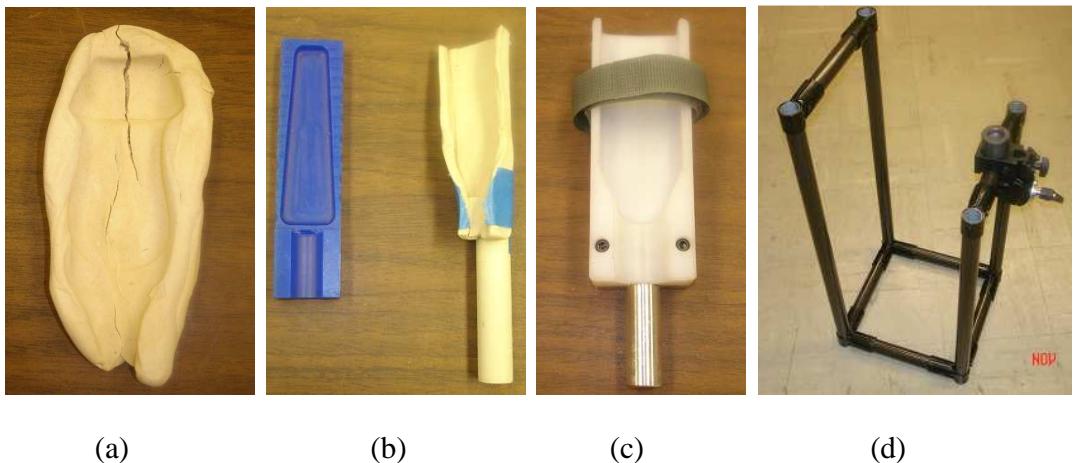


Figure 3.18. a) Molding clay used to trace the dimension of the cardiac ultrasound transducer. b) A first probe holder prototype fabricated using wax and the iteration of design using clay and PVC pipe. c) The final probe holder design fabricated using plastic and aluminum. d) A mounting stand assembled using Creform pipes and connectors.

3.6. Final design of the first functional prototype

The final design of the first pass of the functional prototype is an iteration of both Concept 1 and Concept 2, and is essentially an articulating arm with ball joints. The final design is based on Civco's positioning arm combined with a new probe holder attachment and an external support stand. The design consists of four different parts: probe holder attachment, articulating arm, clamp attachment, and a mounting stand as shown in Figure 3.19.



Figure 3.19. The functional prototype consisting of a probe holder, articulating arm, and a mounting stand.

The functional prototype appeared to meet the product specifications that were set forth before the start of the design process, which were:

1. Minimize the duration of pinch grip: Probe holder holds the transducer thus minimizing the need to grip the transducer at all times.
2. Minimize the duration of force exertion (probe pushing): The need to maintain the pushing force at all time is minimized, reducing the overall duration of force exertion.
3. Minimize awkward upper extremity postures: By utilizing the locking mechanism, the sonographers can reposition themselves into a more neutral posture from an awkward posture that may have been required to initially position the transducer for the particular scan. The sonographer may resume performing the task with a more comfortable posture when needed.
4. Minimize the need to maintain static postures: The sonographer does not have to maintain a static posture once the quality images are found. The locking mechanism that locks the probe into position will hold the probe in place, minimizing the need to maintain forceful exertions during the scanning procedure.

An additional advantage with being able to lock the arm into position includes allowing the sonographer to have intermittent rest without losing the scanning window. In addition, activities such as assisting the patient or applying ultrasound gel to the

transducer can also be conducted without the need to find the scanning window all over again. The device assumes the weight of the transducer and the cord, both of which cumulatively contribute to muscle fatigue. Lastly, the device is expected to provide a more stable positioning of the transducer over the course of a shift, possibly contributing to better image quality.

Chapter 4: Pilot Testing and Results

4.1. Introduction

Based on feedback from the end users, the design team developed a full scale functional prototype of the articulating arm concept. Ulrich and Eppinger (2000) reported that a functional prototype is very useful as it provides the opportunity to quickly test the main idea of the selected concept. The functional prototype is a major milestone in the product development process as the previous theoretical concepts can now be physically tested and verified. The authors also discussed the advantages of testing the functional prototype in the end users' context and environment. One of the major purposes of testing the prototype is that the design team can use it as a learning tool, to understand if the concept works and how well it addresses user needs. In addition, the testing session can also help the design team detect unanticipated issues that cannot be discovered by considering the theoretical concept. This chapter will focus on the topic of prototype testing with the cardiac sonographers, the intended end users for the designed device. In addition, the results gained from the pilot testing will also be presented in this chapter.

4.2. Pre-Pilot testing

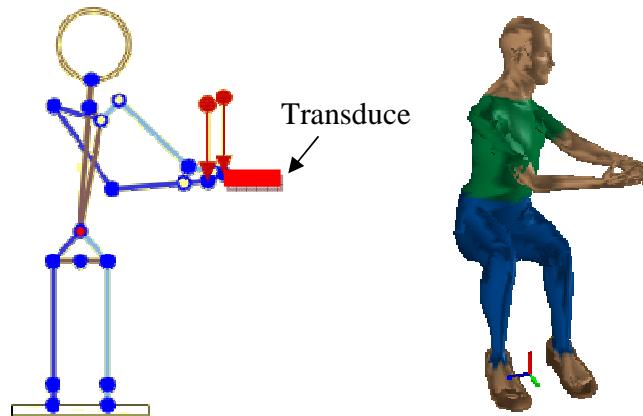
The design team fully understood that the prototype was not (and is not yet) a complete solution. We recognized some issues in the design and set-up, but we were not sure if we had identified them all. In one of the design team's discussions, it was decided that consistent with a good practice, we wanted to take another step to make sure that the prototype would be ready to present to a group of cardiac sonographers for testing. Ulrich & Eppinger (2000) reported that the principal issue with a prototype is that the "respondents will equate the prototype with the finished product". Thus, presenting the prototype that is not reasonably ready might backfire, as an incomplete prototype might give such a poor impression to the participants that recovery might not be possible. As part of the preparation for the pilot session, a pre-pilot session in an actual scanning room was conducted in order to identify problems that might arise later during the pilot session.

The pre-pilot session with two professional cardiac sonographers was conducted at The Ohio State University's Ross Heart Hospital. This pre-pilot session was intended to be a quick simulation to see how the prototype would fit in the scanning room. Previous activities and testing of the prototype were limited to a laboratory setting, so a simulation in an actual work setting allowed the design team to identify important usability issues and make modifications if possible. In addition, the session would allow us to get initial feedback from the lead technologist, which would be beneficial as it could aid the design team in planning the pilot session and preparing ways to address limitations of the prototype in a way that would still allow for a successful pilot session.

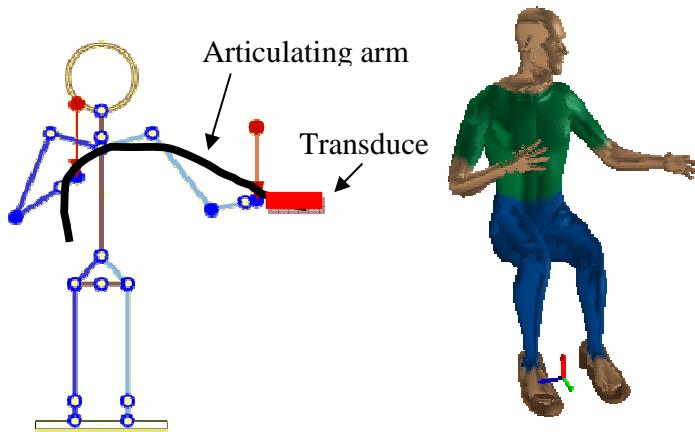
In the pre-pilot session, a short demonstration of how the device is envisioned to work was conducted prior to the actual scanning. A male member of the design team was scanned, and the sonographers were asked to perform several scans, focusing on the image quality. In addition, the sonographers were also asked to make comments about the device as they were performing the scans.

The prototype was well received based on overall comments from these two sonographers. They liked the flexibility of the arm and the simple locking mechanism. In addition, they reported that they could see the benefit of not having to continuously hold and push the transducer into the patient's chest. They thought that the articulating arm was, overall, intuitive and easy to use.

During the probe positioning, it was seen that both sonographers were manipulating the probe with both hands. When using the articulating arm, the left hand held the probe while the right hand was used to grasp and maneuver the articulating arm which was located directly in front of them. This allowed them to manipulate the articulating arm in a more upright upper extremity posture compared to the traditional scanning method. Manipulating the probe with two hands during probe positioning in the traditional scanning method requires the technologist to reach across her body to enable her to grasp the end of the probe with her right hand, while her left hand holds the distal end of the probe. This forces the sonographer to assume a more twisted posture. Figure 4.1 shows the difference of the upper extremity and torso postures with the introduction of the articulating arm during the probe positioning task.



(a) The traditional positioning task using two hands to manipulate the probe. The right hand reaches far across the midline of the body, resulting in a deviated, twisting posture.



(b) The articulating arm provides a physical attachment to the probe. The sonographer can manipulate the articulating arm because it makes a connection to the probe, essentially creating a long “tail” that the sonographer can grasp with the right hand.

Figure 4.1. Upper extremity postures when positioning the transducer without (a) and with (b) the device.

Despite the general approval of the prototype, the cardiac sonographers also shared several concerns with the set-up. The stand where the arm was mounted was rigid, and they believed that the stand should allow for some adjustability, permitting the whole arm to be moved up, down, and sideways. The articulating arm was thought to lose its flexibility at certain extreme angles; the extreme angles of the main articulating arm would be encountered less frequently by increasing the adjustability of the stand, thus ensuring the flexibility of the articulating arm.

They also had concerns about the design of the end of the arm that connects to the probe holder. The cardiac sonographers thought that the end was too long and too rigid, thus limiting the flexibility of the end of the articulating arm where it connects to the probe. As a result, this can restrict the fine tuning of the probe. Figure 4.2 shows that reducing the length of the probe end of the arm could provide better flexibility of the probe holder. This issue was recognized and anticipated earlier by the research team. However, before speaking to the sonographers, we did not know how much this might affect the scanning procedure. The comments from the pre-pilot session revealed the magnitude of this issue, making it one of the important priorities for change in the next prototype iteration.

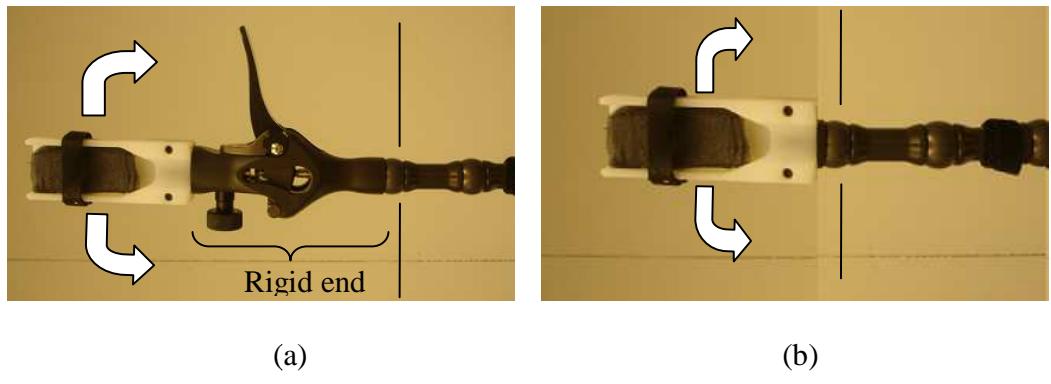


Figure 4.2. Current prototype has a non-functional rigid end connecting the ball joint of the articulating arm with the probe holder. This long rigid end limits the fine manipulation of the probe holder (a). Having the ball head closer to the probe holder (probably with a separate locking mechanism) as well as eliminating the lever might improve probe handling experience when using the device (b).

Another comment made was that the scanning was conducted on a volunteer that did not represent the patient population that the cardiac sonographers typically have to scan, which includes many overweight patients. The overweight patients are a problem because their adipose tissue adds a physical barrier between the probe and the heart, requiring the sonographer to exert greater force against the patient's chest. Since the test was conducted on a skinny "patient", it was difficult for the sonographers to evaluate how much the locking mechanism would help them in reducing the magnitude of force exertions with typical patients.

When asked if the arm would be in the way, one of them said it might be in the way while the other one said that it was not. It should be noted the sonographer that said the arm might be in the way is a shorter sonographer. In addition, she usually scans with her right hand. Thus, these two factors may have affected her views on this issue. However, the other sonographer who is taller and usually scans with her left hand felt that

the articulating arm was not in her line of sight nor did it pose other problems due to its presence in her working space.

The pre-pilot session gave the design team ideas for a framework for the pilot testing. In addition to the sonographers' comments, observations made by the team were also helpful in identifying potential issues, and how to troubleshoot those issues. For example, it was observed that it was a bit challenging for the first sonographer to operate the device, compared to the second sonographer. There were moments when the arm would bind, and two different approaches were taken by the two sonographers when that occurred. The first sonographer kept fighting to push the device to try to obtain the scan, while the second sonographer reset the arm by straightening it before restarting the scan. It was also observed that because the first sonographer was quite short compared to the second sonographer, the arm interfered with her direct access to the keyboard of the ultrasound machine. Making use of adjustments in the height of the sonographer's chair and/or the patient's bed might be a solution to address this issue.

As for the probe end of the articulating arm being too long and too rigid, a possible step that could be taken to address this issue would be to ask the patient to roll back slightly. It was observed during the pre-pilot session that the first sonographer was struggling to manipulate the probe end of the arm to achieve the desired scanning window location. Since the probe end of the current prototype is too long and rigidly connected to the probe and probe holder, the fine manipulation of the front end of the articulating arm was a bit difficult (Figure 4.3a). The second sonographer took a completely different approach when dealing with this issue. Instead of fighting to

manipulate the inflexible probe end of the articulating arm, she asked the “patient” to roll over slightly to reveal the desired scanning window (Figure 4.3b).

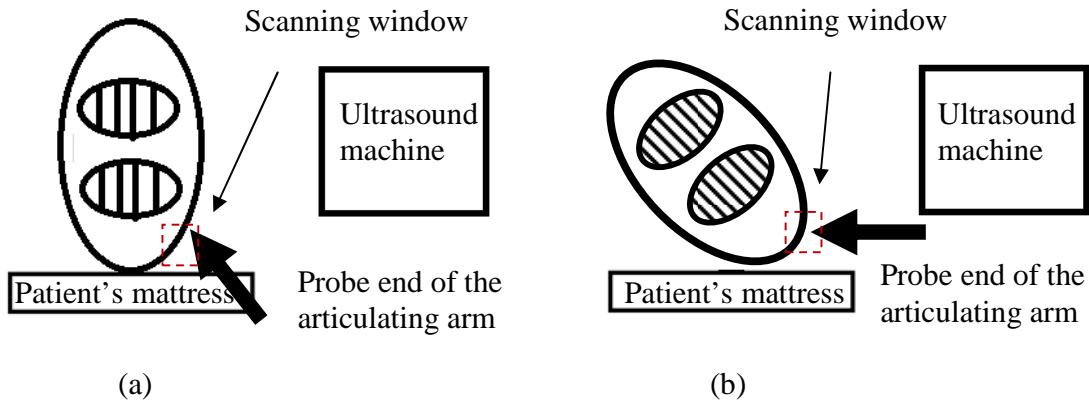


Figure 4.3. When using the device, accessing the apical window is difficult with the patient in the normal position for obtaining this view. The long rigid probe end of the device causes the probe and device to be pushed into the mattress as the sonographre tries to access the apical window (a). Asking the patient to roll over slightly gives the sonographer better access to the Apical window (b).

In conclusion, the pre-pilot session revealed several important issues to be addressed during the pilot session. First, the pilot session participants should be informed that the prototype is not a complete version. They would be asked to focus on the bigger picture of having an external arm as part of their equipment rather than focusing on secondary components such as the mounting stand. Second, the participants should be allowed to use the device so they can become familiar with how it works. Third, it would be more beneficial to have a larger “patient” for the cardiac sonographers to test the device as the larger person would better represent the general population of the patients

they scan everyday. Fourth, troubleshooting techniques should be addressed during the introduction of the device to educate the participants on what to do if they have issues with the device when using it. Fifth, specific questions would need to be asked in a real pilot session to facilitate the direction of further iterations of the prototype. These five identified issues from the pre-pilot session were considered when the design team was designing the next focus group session, which was a pilot study involving a larger sample of cardiac sonographers.

4.3. Pilot Testing

The previous concept review session with a larger sample of cardiac sonographers and numerous intervention concepts involved only drawings and non-functional mock-up models. The technologists commented that it was difficult to assess something as novel as the probe holder and the articulating arm without having the chance to try it. Image quality of the scan is something that cannot be compromised, so the concept is a no go if it cannot produce quality images. Even though the articulating arm concept might work on paper, the only way to see if it can produce comparable image quality and in a comparable amount of time was to try it out. A working prototype was fabricated so that the cardiac sonographers could have physical interaction with the device in order to determine if the team should continue to pursue this intervention concept.

The purpose of the pilot session was to gain feedback from cardiac sonographers, gauging their interest and at the same time determining whether or not to pursue this concept. The session was intended to verify whether the user needs were adequately addressed by the current design. In addition, this pilot session was designed to gather information that would guide the design team to further refine the design in the near future. The direct information gathered in this session will help the design team to move forward with the design, as it was driven by the end users feedback instead of pure decisions by the design team.

Six professional cardiac sonographers who all scanned left handed were recruited for this pilot session. They all worked in the echocardiography department of the Ohio

State University's Ross Heart Hospital and were recruited through personal contact. The demographic information of the participants is shown in Figure 4.4. The articulating arm device is specially designed to address the left-handed scanning process. No exclusions were made with respect to race, ethnicity, or gender.

| Subject ID | Sex | Age group (yrs) | Height (in.) | Years of experience | Work hrs/wk |
|------------|-----|-----------------|--------------|---------------------|-------------|
| 6403 | f | 30-45 | 74 | 2 | 40+ |
| 6713 | f | >45 | 62 | 23 | 40-50 |
| 6870 | f | 30-45 | 67 | 17 | 24 |
| 6500 | f | <30 | 67 | 1 | 40 |
| 6505 | m | >45 | 69 | >20 | 40 |
| 6502 | m | 30-45 | 73 | 19 | 43 |

| Subject ID | Involvement in first phase of parent study | Involvement in full concept review session (Focus group 3) | Involvement in the pilot study (Focus group 4) |
|------------|--|--|--|
| 6403 | yes | | yes |
| 6713 | | yes | yes |
| 6870 | | yes | yes |
| 6500 | | | yes |
| 6505 | | | yes |
| 6502 | | | yes |

Table 4.1. Demographics of the pilot session's participants

Two males and four females participated in this pilot study. Each volunteered to participate and all read and signed an informed consent document prior to the start of the session. None of the participants were clinically diagnosed to have musculoskeletal disorders, but most of them reported the feeling of discomfort in shoulder blade, trapezius muscle, wrist, forearm and fingers when they were scanning patients.

The pilot session consisted of two parts: a group meeting session followed by individual evaluation sessions. The sonographers were able to try the device using a Siemens Sequoia ultrasound machine system, with Acuson 4vc1 transducer. They were able to scan one of two male volunteers: the first one was 68" (172.7 cm) in height and 201 lb (91.2 kg) in weight while the second one is 69" (175.2 cm) in height and 190 lb (86.1 kg) in weight. These "patients" were considerably taller and heavier than the "patient" scanned during the pre-pilot session. The room set-up for this pilot session is shown in Figure 4.4.

The group session was intended to provide an introduction to the device. The session started with a brief introduction of how the concept was developed. A specific point that was emphasized was that the concept was developed based on prior interactions with and feedback from cardiac sonographers. It was important to acknowledge these contributions to the design in order to ensure that the pilot session's participants knew that sonographers were a significant part of design process. Another important point made was that the device is still in a prototype phase, and there were some limitations in the current set-up. To avoid bias, the participants were told to withhold their criticism because they might influence each other's perceptions. However,

the participants were told that they would be given a chance later in the individual session to express their concerns as well as provide their independent evaluation of the device.

They were encouraged to ask questions during the group session.

The session was then switched into a demonstration of how the device is envisioned to be used. The sonographers were also told how to troubleshoot the device in case they were having difficulties using the device. After the demonstration, the sonographers were invited to try the device. One sonographer tried to scan a volunteer “patient”, while the other sonographers watched the scanning process. A quick discussion and question & answer session was conducted before the group session ended.

The individual sessions expanded the basis upon which the sonographers could evaluate the device, by giving each the opportunity to scan one of the research team members. The sonographers were asked to first scan as they normally would, performing a list of specific scans which were saved for later evaluation. Right after finishing the scan, the sonographers were asked about the average level of force they exerted during the process on a scale of 0 to 10. The sonographers were given the verbal anchor of 0 being no exertion, like “you are sleeping” and 10 being exerting maximum force like “you are lifting a truck”.

The sonographers were then asked to perform the same scans in the same order using the device. With similar wordings, the sonographers were again asked the average level of force they exerted right after they finished scanning with the device. Next, the cardiac sonographers were asked to fill out a modified evaluation form consisting of questions addressing the usability, usefulness and desirability of the device. This

modified evaluation form was similar to the sheet used during the multiple concept review session, but this form addressed specific features of the device. These questions were intended to evaluate as well as to give a sense of direction for future iterations of the design.

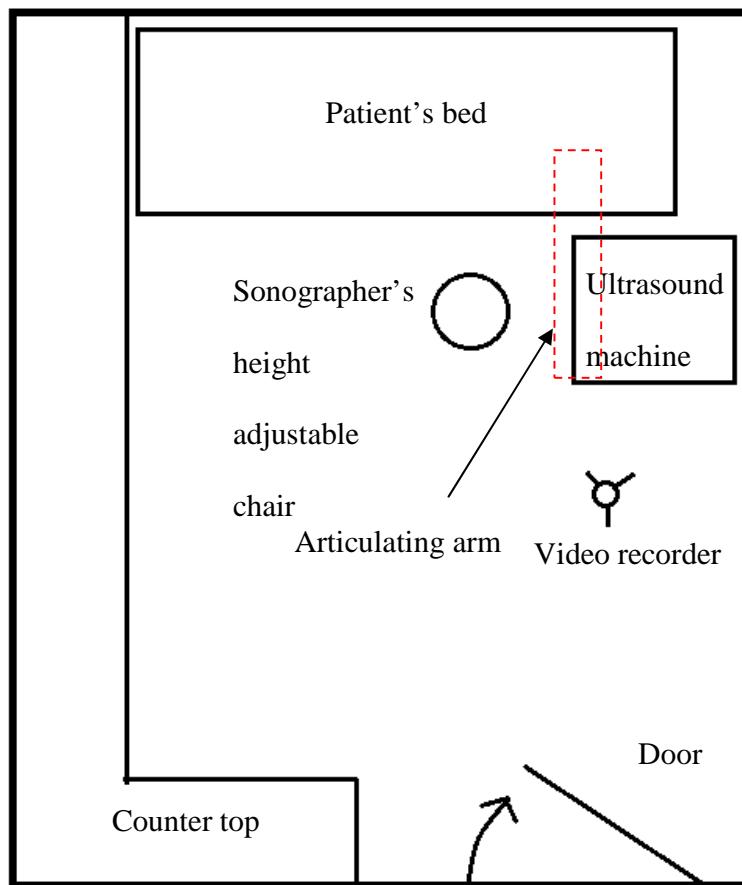


Figure 4.4. The room set-up for the pilot session

4.4. Results and discussion

During the individual pilot sessions, the design team took notes on the observable trends of interaction between the cardiac sonographers and the device. The observation offers a learning opportunity to understand how the device fits into the work system and identify unexpected issues that may not have been anticipated. The cardiac sonographers were also asked to think out loud and make verbal comments during the scanning procedure. In addition to the notes, those interactions were also documented through video and audio recordings. Analyzing the information from the notes, video, and audio recordings revealed several important issues.

In general, it was observed that the sonographers were able to perform scanning tasks within a reasonable time frame. In addition, while performing the scanning procedures, the cardiac sonographers verbally expressed that they were able to obtain comparable image quality when scanning with and without the device. The echocardiographers manipulated the articulating arm with ease and did not appear to have any difficulties moving the arm. In fact, the flexible arm and light weight of the device seemed to pleasantly surprise some of the participants. The verbal expressions that were heard included “It turns really easy” and “it’s easier to use than I thought it would be”. This is important, as limiting the range of motion would result in loss of fine tuning manipulation, which would compromise the image quality. Overall, the design of the device was intuitive, even at this initial prototype stage. The cardiac sonographers did not need a lot of time to familiarize themselves with the operation of the device.

There were two main variations in scanning techniques when the sonographers were performing the scan with the device. Some sonographers preferred to hold the probe end of the articulating arm when performing fine manipulation of the transducer while some others preferred to hold the middle portion of the arm. Holding the probe end of the articulating arm was not previously observed in the pre-pilot session, so it was an interesting discovery. However, holding the probe end of the articulating arm required the right shoulder to be flexed and internally rotated for extended reaches as demonstrated in Figure 4.5a. This technique was similar to the traditional two-handed positioning method, where the left hand holds the probe at the head of the transducer and applies the pressure. Meanwhile, the right hand holds the probe where it connects with the cord, performing the fine angling positioning of the transducer. In order to do this, the right arm has to reach well past the midline of the sonographer's body. This technique was disadvantageous for two reasons. The first one was that they were assuming a more disadvantageous posture, as the torso was twisted and their right arm was flexed, internally rotated about 45 to 60 degrees, and unsupported. The second reason was that the sonographers were essentially trying to move the arm at the end point for fine tuning movements, which is a somewhat less direct way to position the arm, and as a result makes the adjustment more difficult. By contrast, holding the articulating arm at the middle portion of it was biomechanically better because the right arm was in a more neutral position, as shown in Figure 4.5b. As a result, the sonographer has more direct control of the position of the arm, which makes it easier to manipulate and finely tune the position of the arm and the probe.

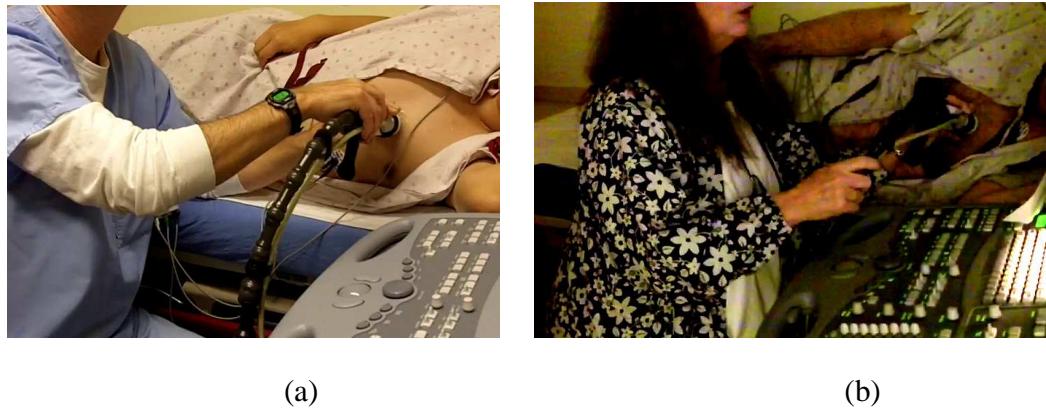


Figure 4.5. Two main variations of scanning techniques with the device. Some sonographers were holding the probe end of the articulating arm when performing the positioning task (a). In contrast, some sonographers were holding the middle portion of the articulating arm for fine manipulation of the transducer.

In general, it was observed that scanning with the device reduced the overall duration of pinch gripping and forceful exertion. The traditional method requires the cardiac sonographer to perform prolonged forceful pinching as shown in Figure 4.6a. By utilizing the locking lever, the articulating arm maintains the location of the transducer as well as the magnitude of exertion into the patient. This reduced the need for the cardiac sonographers to constantly grip and maintain the forceful exertion on the transducer. As a result, this allows an opportunity for temporary breaks from physical exertion especially on the sonographer's left hand as demonstrated in Figure 4.6b.

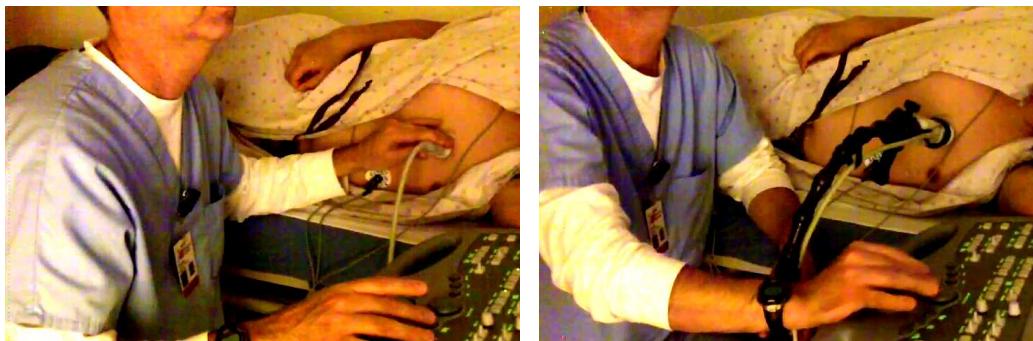


Figure 4.6. With the traditional method, the sonographer was constantly applying a pinch grip while forcefully pushing the probe (a). When using the new device, the sonographer's left hand was able to rest while the sonographer made measurements of the heart (b).

All cardiac sonographers in the individual sessions took the opportunity to take these intermittent rests when they got the chance. The sonographers verbally admitted that they were feeling high pressure at their wrist and shoulder area when they were scanning using the traditional method, and some even commented on the location of pain as they were scanning. In one case, a sonographer commented that she felt the pain in her left wrist as early as the first five minutes of scanning. Interestingly, all the cardiac sonographers reported that they felt the difference in their left upper extremity muscles when using the device, because it took the prolonged pressure off their left hand.

Another interesting point that was made by the cardiac sonographers was that the device supports the weight of the transducer and the cord. Several cardiac sonographers mentioned that supporting the weight of the transducer and the cord relieves some pressure off the hand. The weight of the long cord connecting the transducer to the ultrasound machine provides some physical resistance to the cardiac sonographers. The cumulative effect of relieving this pressure throughout the day may potentially reduce the

rate of development of localized muscle fatigue. Additionally, the Velcro strips that were strapped onto the arm prevent the cord from dangling, ensuring better cord management.

Another relevant point related to the issue of gripping was that some of the sonographers were observed to keep on holding the probe even though the articulating arm was locked into position. These sonographers successfully utilized the locking mechanism, and they were not exerting pushing force into the patient. However, they were seen to firmly grasp the probe holder while taking the heart's measurements as illustrated in Figure 4.7. When they were asked why they continued to hold the probe, they responded that they were not used to letting go of the transducer. Another reason that they gave was that they did not know what to do with their left hand now that it was free. However, with practice this tendency might abate after the sonographers become more familiar with using the device.



Figure 4.7. The sonographer continued to hold the probe with her left hand even though the articulating arm is locked in place.

In addition to reducing the duration of pinch gripping and forceful exertions, the device was also observed to improve the cardiac sonographer's overall postures. The sonographers were generally seen to be twisting and leaning a lot when scanning with the traditional method, as illustrated in Figure 4.8a. In addition, the participants were also observed to assume prolonged unsupported abducted arm posture as shown in Figure 4.8c. The twisting and leaning postures of the low back, as well as unsupported abducted arm posture may take the place of making several initial adjustments prior to the scan. The adjustments that may also reduce the magnitude of these awkward postures include making adjustments to chair height or location relative to the patient, bed height adjustments, and/or position of the patient in the bed; appropriate relative positioning of the sonographer and the patient is necessary in order to position the probe to obtain the required images. Figure 4.8b and 4.8d demonstrate how the device allows a more appropriate relative positioning between the transducer and the patient. As a result, the cardiac sonographers were able to assume a more upright back posture as well as reducing the need for prolonged abducted posture of the left arm.

Similar to the pre-pilot session, we observed that the sonographers were having difficulties interacting with both the mounting stand and the inflexible rigid probe end of the articulating arm. The cardiac sonographers need the stand to provide height adjustability for the arm as well as provide lateral movement during the scanning procedure. As discussed, the rigid unmovable stand may cause extreme bending of the articulating arm, effectively reducing its flexibility during the probe positioning. Addressing this requirement was not within the scope of this phase of the development.

Therefore, the design team simply manually moved the mounting stand according to the instruction from the sonographers. Because of this limitation, the sonographer did not have full control when the stand was being moved. Even though the sonographers were able to finally have the stand moved to the correct location, it took a bit of extra scanning time. According to the cardiac sonographers, a seamlessly movable stand would improve their scanning experience.

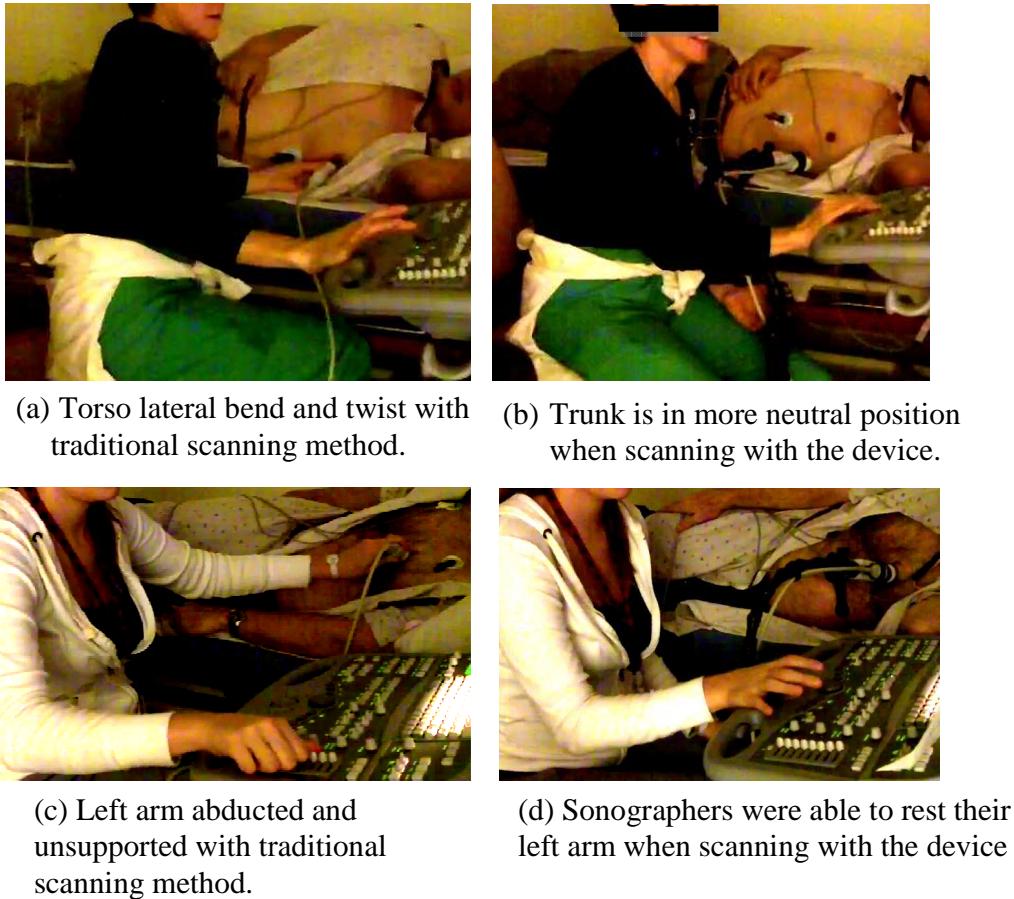


Figure 4.8. Scanning with the device may reduce awkward postures (a) vs. (b). The device may also reduce unsupported postures (c) vs. (d).

Another issue related to the current design of the stand was that the location of the sonographer's knee might interfere with the articulating arm's locking lever. Since the current stand design requires the right knee to be close to the locking lever, it was observed that from time to time, the knee will interfere with the locking process as shown in Figure 4.9. This situation mainly occurred with taller sonographers as their knee height was almost at the same height as the lever. Having a height adjustable stand in a future prototype iteration should solve this issue.



Figure 4.9. The sonographer's knee is in the way of the locking lever.

The other recurring issue observed was that the rigid end of the articulating arm is too long. Even though the sonographers were able to finally position the transducer to their desired locations, it required extra scanning time to position the probe and the arm due to the inflexible probe end of the articulating arm. Having a ball joint closer to the

probe holder might increase the flexibility at the probe end, making the articulating arm easier to maneuver, and ultimately improving the scanning experience while using the device. An interesting point previously not discovered during the pre-pilot session was that it might be beneficial to have another independent locking mechanism that can control the rotation of the probe holder. Several cardiac sonographers proposed this idea of allowing the probe to rotate 360 degree, but at the same time maintaining the transducer location through the locked articulating arm. This is proposed because scanning of Apical 4, Apical 3 and Apical 2 windows requires the probe to be in essentially the same location, but each view requires a different contact angle between transducer and heart.

In conclusion, overall feedback received from the individual sessions was generally positive. Other than the issues of the currently rigid mounting stand and the inflexible end of the articulating arm being too long, there were no additional issues raised by the sonographers in this focused concept review session. From their verbal expressions during the interaction with the device, it can be seen that the cardiac sonographers were optimistic regarding the device's potential. Positive oral comments that were shared by the cardiac sonographers as they were performing the scan with the device included "amazing", "fantastic", "love it", "it feels like not working a lot", "its pretty nice actually", "I feel like I have better control", "I don't have to push hard at all", "I'm resting!", "this device takes the weight off my hand", "the image is much better", "I'm enjoying this", and "the picture is more stable". These comments indirectly indicate their acceptance of the device.

In addition to the notes, video and audio recordings, the design team also collected the overall perception of exertion ratings and directed subjective assessments of the device from the sonographers. Scanned images of selected views with and without the device were also saved and compared for their quality. The nature of these data will be discussed in the next three sections.

4.4.1. Image quality assessment

An important issue raised by the cardiac sonographers during the concept review session was that even though the concept of the articulating arm was interesting, they would not be able to evaluate it until they tested it in a clinical setting. This is mainly because they were not sure how the proposed concept will affect the image quality, which cannot at all be compromised. The proposed concept would only gain acceptance on whether or not to be pursued further if it allows the sonographers to produce comparable image quality to the current scanning method. The concept's prototype was later fabricated and pilot tested in a clinic setting, with special focus on trying to get quality images.

In general, the sonographers said they were pleased with the overall image quality when they were scanning with the device during the pilot session. We did not hear any comment about reduced image quality during this session. Most sonographers claimed that they had better image quality when using the device, while one sonographer claimed that even though it would take a bit more time than their traditional method, comparable

image quality can be achieved using the device. In addition to these verbal comments, the written directed subjective evaluations relevant to image quality were also generally positive. Five out of six sonographers reported that scanning with the device would not adversely affect image quality. Similarly, five out of the six sonographers also reported that they were able to get quality images when they were scanning with the device.

In addition to verbal comments and written subjective evaluation of the image quality from the sonographers, the scanned images were extracted from the ultrasound machine and were independently evaluated by two experienced sonographers. A total of four different views were evaluated: Apical 2, Apical 3, Parasternal Short Axis- M-mode (PSAX- M-mode), and Apical 4- Doppler. The two sonographers independently evaluated the image quality from the two scanning methods (with and without the device).

The first evaluator had more than twenty years of experience in echocardiography, and she conveyed to the design team the importance of obtaining good image quality on apical views. She reported that some of the parasternal views can be also be indirectly obtained though the apical views. Because of that, she chose to evaluate image quality on Apical 2 and Apical 3 windows. The second evaluator had never scanned cardiac images professionally. However, he had more than twenty years of experience with Vascular and Obstetrics/Gynaecology sonography. He chose to evaluate the PSAX-M-mode view since he had experience scanning these images of fetal hearts. He also chose to evaluate the Apical 4-Doppler view due to his vascular experience obtaining Doppler images of the arterial system in the extremities.

In general, the images scanned with and without the device were comparable in quality. In most cases, the images scanned with the device have better quality compared to images scanned without the device. There were a small number of images in which the quality was better when scanned with the traditional method. However, influences such as fatigue build-up (since unassisted scanning always preceded scanning with the device in this pilot) and inexperience of operating the device might contribute to this outcome.

Images of the Apical 2 and Apical 3 views were better when scanned with the device for four out of the six sonographers. For one sonographer the Apical 3 image was better with the device, while the Apical 2 view was comparable in quality between the two scanning methods. The last sonographer had comparable image quality when he scanned both with and without the device for both Apical 2 and Apical 3 views. The Apical 4-Doppler image quality was better when using the device for five out of the six sonographers while one's image quality was better without the device. However, this trend of having better image quality when scanning with the device did not hold for the PSAX-M-mode view. For only one sonographer was the M-mode view better when scanning with the device, while two sonographers produced comparable images quality when scanning with and without the device. For the other three sonographers, the M-mode view was better without the device. The M-mode view can be affected by a patient's breathing. As such, this provides an important example of how a new device often cannot be simply inserted into an existing process or procedure, but may require a modification to current methods. In this case, similar to the request made by some of the

sonographers for the patient to roll back slightly to better expose the Apical window when using the device, it may also be necessary to determine what breathing instructions might be necessary to introduce as well, in order to obtain high quality M-mode images when using the device. The image quality assessment results are summarized in Table 4.2.

| Subject ID | Apical 2 | Apical 3 | Apical 4-Doppler | PSAX-M-mode |
|------------|---|---|---|---|
| 6870 | The image was better with the device | The image was better with the device | Comparable image quality between the two methods | The image was better without the device |
| 6403 | The image was better with the device | The image was better with the device | Comparable image quality between the two methods | The image was better without the device |
| 6713 | Comparable image quality between the two methods | The image was better with the device | Comparable image quality between the two methods | The image was better with the device |
| 6505 | The image was better with the device | The image was better with the device (*Apical 4-color was evaluated instead. This subject did not take Apical 3 views) | The image was better without the device | The image was better without the device |
| 6502 | Comparable image quality between the two methods | Comparable image quality between the two methods | Comparable image quality between the two methods | Comparable image quality between the two methods |
| 6500 | The image was better with the device | The image was better with the device | Comparable image quality between the two methods | Comparable image quality between the two methods |

Table 4.2. Summary of the image quality evaluations performed by two professional sonographers.

According to several sonographers, the device in its locked position provides a stable positioning of the transducer, and this might contribute to better image quality. This condition might be important especially later in the shift, when a sonographer may be physically tired. Fatigue may make it more difficult to maintain the same magnitude of force exertion, leading to unstable images. Another reason provided by two sonographers was that the articulating arm provides a more guided manipulation of the transducer, as the transducer was mounted on a fixed sturdy structure. This limited the degrees of freedom of movement compared to the traditional scanning method, where the transducer can easily fall away from the scanning window. Limiting the degrees of freedom of movement of the transducer provides better control of transducer manipulation, and may ultimately improve the images quality.

4.4.2. Perception of exertion ratings

The articulating arm device introduced in the echocardiography setting was aimed to mitigate the issues of prolonged pinch grip, force exertion, awkward extremity postures and static postures. These four physical activities put undue stress on upper extremity, neck, shoulder, and torso muscles which may lead to localized fatigue. Prolonged exposure to these physical activities is believed to increase the sonographers' overall perception of their workload.

Borg (2005) reported that “the human sensory system can function as an effective instrument to evaluate workload”, and this can be utilized to subjectively estimate the

physical effort required by the task. The participants in this study were asked about their perception of average exertion right after they performed both scans with and without the device. The participants were given the same verbal anchor of the ten point scale, with 0 being no exertion at all, like “sleeping”, and 10 being exerting the maximal exertion, like “lifting a truck”. The results of the subjective average exertion ratings from the participant are shown in the Table 4.3.

A general trend observed with all the participants was that their perception of average exertion was reduced when they were using the interventional device. On a closer look, every participant reported at least reduction of two points when they were scanning with the device. This indicated a subjective agreement in that the device noticeably reduced the level of overall force exertion. This result is consistent with the verbal remarks received, as the sonographers stated that they felt a noticeable difference when not having to continuously pinch, push and maintain their exertion when scanning with the device.

| Subject ID | Average exertion rating (traditional method) | Average exertion rating (with the device) |
|------------|---|--|
| 6870 | 6 | 3.5 |
| 6403 | 4 | 2 |
| 6713 | 4 | 2 |
| 6505 | 5.5 | 2 |
| 6502 | 6 | 2.5 |
| 6500 | 5 | 3 |

Table 4.3. Perceived level of exertion among the six cardiac sonographers when performing the scans with and without the device.

Since most of the cardiac sonographers' time was spent on forceful physical activities such as pinching, pushing, and maintaining exertions, having an external arm that could perform those activities during part of the procedure would reduce the overall amount of physical energy expenditure. Intermittent rests from forceful pinching and prolonged exertion would allow their muscles to recuperate, possibly leading to the perception of lesser overall average exertion. In addition to the pinching and forceful exertion, awkward and static postures might also contribute to higher perceived physical efforts. Awkward and static postures accelerate the rate of fatigue as the muscles are not working optimally (Hedge, 1998). The device reduces the duration of these postures and the effect of having more natural postures might also play a role in lowering the participants' overall level of perceived exertion.

4.4.3. Subjective evaluations of usability, usefulness, and desirability

The questions in the evaluation form were organized into four main sections: 1) Usability, 2) Usefulness, 3) Desirability, and 4) Barriers to adoption. The usability section focuses on evaluating the overall easiness of using the different parts of the device. The questions in this section were designed not only to evaluate the usability of the current prototype, but also to direct the design team to specific usability issues in the next prototype iteration. The usefulness section, on the other hand, consisted of questions to evaluate the potential benefits of the device from the perspective of both cardiac sonographer and patient. The desirability section consisted of several questions to

estimate how excited and eager the sonographers were to use this device in their daily work activities. The last section, which contained a list of barriers to adoption, listed possible barriers that might keep the cardiac sonographers from incorporating the device into their work.

| Points of comparison and development | Probe holder ratings from the first concept review session (Focus group 3) On a scale of 1 -7, where 1 = very poor and 7 = very good | Probe holder ratings from the pilot session (Focus group 4) On a scale of 1 -7, where 1 = very poor and 7 = very good |
|--------------------------------------|---|--|
| Avg. of overall usability | 4.5 | 6.2 |
| Avg. of overall usefulness | 4.2 | 6.2 |
| Avg. of overall desirability | 3.9 | 6.1 |
| Number of barriers / subject | 2.3 | 1.1 |

Table 4.4. Comparison of the evaluation results of the device between the previous concept review session and the more recent pilot session.

In general, participants who tested the prototype gave positive evaluations to the first three sections in the evaluation form. On a scale between 1 to 7, where 1 is “very poor” and 7 is “very good”, the average evaluated scores of overall usability, usefulness, and desirability of the device were 6.2, 6.2, and 6.1, respectively. These scores were considerably different to the overall scores received in the multiple concept review session, where the concepts were presented only with non-functional mock-up models and technical drawings (Table 4.4). These new scores indicated that the six participants in this pilot study were optimistic about the potential of this articulating arm concept.

Even though the concept needed some additional development work, the positive responses from these professional cardiac sonographers gave us confidence that the current design is on the right track.

4.4.3.1. Usability

The questions under the usability section were further divided into four smaller sections. These four sections are: 1) probe holder, 2) articulating arm, 3) locking mechanism, and 4) general usability. The probe holder section consisted of questions asking about the holder's shape, material/texture, size, and orientation as shown in Table 4.5. All participants felt comfortable gripping the current rectangular shape of the probe holder. Similarly, all participants felt that the probe holder would not slip out of their hand due to its material or texture. They also felt that the size of the probe holder was appropriate for a comfortable prolonged grip. However, there were mixed responses when they were asked if it is easy to determine the correct orientation of the transducer when it was mounted in the probe holder. Half of the participants felt that it was really easy for them to determine the transducer's orientation while the other half somewhat disagreed. This shows that the design team needs to put more effort into the cognitive aspect of the probe holder, so that it is intuitive for the cardiac sonographers to determine the orientation of the transducer by just gripping the probe holder.

| I. Usability | Strongly Disagree 1 | 2 | 3 | 4 | Strongly Agree 5 |
|---|------------------------|---|---|---|---------------------|
| <i>Probe Holder</i> | | | | | |
| I feel comfortable gripping the current rectangular shape of the probe holder prototype. | 0 | 0 | 0 | 3 | 3 |
| I think the probe holder would have a tendency to slip out of my hand due to its material or texture. | 5 | 1 | 0 | 0 | 0 |
| I think the current probe holder's size is too wide for a comfortable prolonged grip . | 2 | 4 | 0 | 0 | 0 |
| It is easy to determine the correct orientation of the transducer in the current probe holder prototype. | 0 | 2 | 1 | 0 | 3 |

Table 4.5. Distributions of the cardiac sonographers' responses on the usability of the probe holder.

The series of questions in the articulating arm section were related to its length, flexibility, weight, and its effect during the scanning procedure. The cardiac sonographers' responses were documented in Table 4.6. In general, the results were somewhat more mixed for the arm, in comparison to those for the probe holder. Four of the six cardiac sonographers were in agreement that the articulating arm is long enough for them to position the transducer to the desired location, and two were neutral on this issue. When asked if the articulating arm is flexible enough for fine manipulation of the transducer, four of the cardiac sonographers agreed, one disagreed, and the other one was neutral on the issue. All respondents were in agreement that the articulating arm was not too heavy for prolonged operation. The last three questions in this section were gauging whether or not the articulating arm interfered with the cardiac sonographers' work activities. Five of the six cardiac sonographers agreed that the articulating arm did not

interfere with their line of sight to the patient and to the ultrasound machine. Similarly, most of the cardiac sonographers agreed that the articulating arm would not interfere with their access to the control panel. However, one sonographer disagreed. She reported that she was used to having the control panel very close to her and that having the arm in between the panel made it feel as though it was in the way.

| I. Usability | Strongly Disagree 1 | 2 | 3 | 4 | Strongly Agree 5 |
|---|------------------------|---|---|---|---------------------|
| <i>Articulating Arm</i> | | | | | |
| I think the arm is long enough to allow me to locate the transducer where I want to position it. | 0 | 0 | 2 | 1 | 3 |
| I think the arm is flexible enough for fine manipulation of the transducer. | 0 | 1 | 1 | 4 | 0 |
| I think the arm is too heavy for prolonged scanning. | 2 | 4 | 0 | 0 | 0 |
| I think the arm interferes with my line of sight to the patient. | 2 | 3 | 1 | 0 | 0 |
| I think the arm interferes with my line of sight to the ultrasound machine. | 3 | 2 | 0 | 0 | 1 |
| I think the arm interferes with my access of the control panel. | 2 | 2 | 1 | 0 | 1 |

Table 4.6. Distributions of cardiac sonographers' responses on the usability of the articulating arm.

The next couple of questions were related to the device's locking mechanism as shown in Table 4.7. Half of the participants thought that the prototype's locking mechanism was not cumbersome to use while the other half were neutral on this. A mix

of views was also seen when the participants were asked if it was cumbersome to lock and unlock the device repeatedly throughout the scanning procedure. Half of the cardiac sonographers thought that it was not cumbersome, two of them were neutral, and one of them thought that it was cumbersome to operate the locking mechanism repeatedly.

| I. Usability | Strongly Disagree 1 | | | | Strongly Agree 5 |
|---|------------------------|---|---|---|---------------------|
| <i>Locking Mechanism</i> | | | | | |
| I think the current locking mechanism set-up is cumbersome to use. | 2 | 1 | 3 | 0 | 0 |
| I think it is cumbersome to lock and unlock the arm repeatedly. | 2 | 1 | 2 | 0 | 1 |

Table 4.7. Distributions of cardiac sonographers' responses on the usability of the locking mechanism.

The last set of questions were focused on the general usability of the overall prototype set-up (Table 4.8). A majority of the respondents felt that it would be worth their time and effort to set-up the device prior to scanning. Most of them also thought that they would not need to spend a lot of time practicing using the device before they would be ready to use it on the patients. In addition, they thought that most people would learn how to use the device very quickly, indicating that the overall mechanism of the device is easy to understand and operate.

When they were asked if the device would adversely affect their image quality, half of them strongly disagreed, two of them disagreed, and one of them somewhat

agreed. This demonstrates a somewhat strong belief that the device allows them to obtain image quality that is comparable to the traditional scanning method. Most of the respondents strongly disagreed when they were asked if the device is unnecessarily complex. However, there were mixed responses when the cardiac sonographers were asked if they feel comfortable having the device between them and the patient and the ultrasound machine. Half of the respondents reported that they felt somewhat uncomfortable while the other half reported that they did not feel uncomfortable with the location of the device.

| I. Usability | Strongly Disagree 1 | 2 | 3 | 4 | Strongly Agree 5 |
|---|------------------------|---|---|---|---------------------|
| <i>General Usability</i> | | | | | |
| I think it would be worth the effort/time to set-up this device. | 0 | 0 | 1 | 1 | 4 |
| I feel uncomfortable having this device between me and the patient. | 3 | 0 | 1 | 1 | 1 |
| I feel uncomfortable having this device between me and the ultrasound machine. | 3 | 0 | 0 | 2 | 1 |
| I think that using the device will not adversely affect image quality. | 0 | 1 | 0 | 2 | 3 |
| I find this new approach unnecessarily complex. | 4 | 2 | 0 | 0 | 0 |
| I imagine that most people would learn to use this new approach very quickly. | 0 | 0 | 0 | 3 | 3 |
| I would need to spend a lot of time practicing with this new approach before I could use it on patients. | 3 | 2 | 1 | 0 | 0 |

Table 4.8. Distributions of cardiac sonographers' responses on the general usability of the device.

4.4.3.2. Usefulness

The usefulness section consisted of sixteen questions focusing on evaluating the advantages of the device. The results are shown in Table 4.9. The first four questions asked were directly related to the needs assessment provided by the end users in the early stages of design. In general, the majority of the cardiac sonographers strongly agreed with the statements that the device would reduce the amount of time spent on 1) gripping the transducer, 2) exerting force onto the patient's chest, 3) working in awkward postures, and 4) working in static postures. Additionally, all the participants reported that they would be inclined to take intermittent rests during the scanning procedure because they believe that the locking mechanism would hold the probe in place for them. The majority of the respondents also thought that there was a significant physical benefit from having the weight of the probe and the cord supported by the device. Similarly, most of them thought the articulating arm would be able to sustain enough load when they were scanning an overweight patient. The consistent agreement on these questions demonstrates that the needs identified in earlier design stages are being addressed by the current design.

The cardiac sonographers were also positive when asked if they would be able to get quality images with the device. Four of the six disagreed when they were asked if the device would significantly lengthen their scanning time. These trends illustrate that the sonographers believed the device would not drastically affect their scanning performance compared to the current method of scanning.

However, the participants' reactions to a couple of questions related to the patient's comfort were mixed. Four of the six respondents were neutral when asked if the device would make the patient physically more uncomfortable. One respondent thought that the device would not make the patient uncomfortable while another respondent thought it would. When the respondents were asked if they thought the patients would be intimidated by the device, three disagreed, two agreed, and one held a neutral opinion.

In general, the cardiac sonographers found the device to be useful. Five of the six reported that the device would make their job physically easier. All agreed to the statement that the device would reduce their physical fatigue by the end of the day. The trends shown here demonstrate that the device is useful in that it lowers the overall physical effort of the scanning procedure. This is consistent with the results from the exertion ratings, where the cardiac sonographers gave lower ratings of average exertion for the scans performed with the device.

However, this trend of unanimous agreement does not hold when they were asked if the device would help them perform their work more efficiently. Half of the cardiac sonographers thought that the device would help them work more efficiently while the other half maintained a neutral opinion. It is encouraging that even at this stage of development, none of the sonographers reported that the device reduced their work efficiency, which is often a reason why interventions that make sense from a biomechanical design view are not adopted in practice. Overall, four of the six sonographers reported that they would rather use the device than their traditional method. One of them maintained a neutral opinion while the other sonographer would prefer using

the traditional method. This illustrates a good chance for acceptance of the device, if modifications can be designed to address the current shortcomings

| II. Usefulness | Strongly Disagree 1 | 2 | 3 | 4 | Strongly Agree 5 |
|--|------------------------|---|---|---|---------------------|
| I think using this device would reduce the total amount of time I grip (hold) the transducer during a scanning procedure | 0 | 0 | 0 | 1 | 5 |
| I think this device would reduce the total amount of time I am pushing with the probe during a scanning procedure | 0 | 0 | 0 | 2 | 4 |
| I think this device would reduce the total amount of time I work in awkward postures during a scanning procedure | 0 | 0 | 1 | 2 | 3 |
| I think this device would reduce the total amount of time I have to hold myself in a fixed posture during a scanning procedure | 0 | 0 | 1 | 1 | 4 |
| I would be inclined to take intermittent rests because I believe the locking mechanism would hold the probe location in place for me. | 0 | 0 | 0 | 3 | 3 |
| I think there is a significant benefit of having the weight of probe and the cord supported by the device . | 0 | 0 | 1 | 2 | 3 |
| I would rather use this device than our traditional approach. | 0 | 1 | 1 | 3 | 1 |
| I am able to get quality images with this device. | 0 | 0 | 1 | 2 | 3 |
| I think the arm can sustain enough load when scanning an overweight patient. | 0 | 1 | 1 | 1 | 3 |
| I think this device would lengthen the time of a scanning procedure by too much. | 2 | 2 | 2 | 0 | 0 |
| I am concerned that it would make the exam more physically uncomfortable for some patients. | 0 | 1 | 4 | 1 | 0 |
| I am concerned that many patients might be intimidated by the device. | 0 | 3 | 1 | 2 | 0 |
| I believe that using this new approach would make my work easier, physically . | 0 | 0 | 1 | 2 | 3 |
| I believe this new approach will help me perform my work tasks more efficiently . | 0 | 0 | 3 | 2 | 1 |
| I believe this new approach will reduce my physical fatigue at the end of each work day. | 0 | 0 | 0 | 2 | 4 |

Table 4.9. Distributions of cardiac sonographers' responses on the usefulness of the device.

4.4.3.3. Desirability

The series of questions under the desirability section was designed to assess how excited the sonographers were regarding the incorporation of the device into their work. This section provides some assessment of the acceptance of the device among the sonographers. Four of the six cardiac sonographers reported that they would really benefit from using the articulating arm device, and five of six thought that their co-workers would want to use the device. As anticipated, most of the sonographers did not expect to use the device to scan all of the patients, but four agreed that they needed it for a select group of their patients. All of the sonographers expressed their interest in trying a more refined version of the prototype in the future. Table 4.10 summarizes the responses from the cardiac sonographers on their desirability for using the device.

| III. Desirability | Strongly Disagree 1 | 2 | 3 | 4 | Strongly Agree 5 |
|--|------------------------|---|---|---|---------------------|
| I would really benefit from the use of this new approach. | 0 | 0 | 2 | 1 | 3 |
| I see myself using this device all the time with every patient. | 0 | 1 | 3 | 1 | 1 |
| I would be interested in using a more refined version of this device in the future. | 0 | 0 | 0 | 1 | 5 |
| I think some of my co-workers will want to use this new approach. | 0 | 1 | 0 | 2 | 3 |
| I really need this new approach for a select group of my patients. | 0 | 0 | 2 | 1 | 3 |

Table 4.10. Distributions of cardiac sonographers' responses on the desirability of the device.

4.4.3.4. Barriers to adoption

The last section consisted of a list of several potential barriers that might hinder the implementation of the device into their workplace. The list of these barriers is shown in Table 4.11. There are five potential issues that were raised by the participants. One cardiac sonographer reported that the device would slow her down too much. Another one was concerned that the device would not be acceptable to patients. The issues of difficulty to store and clean up the device were also raised by one sonographer. The last issue raised was related to portability. Three sonographers reported that they were concerned about the lack of portability with the current set-up. The external stand and the articulating arm will be additional items that they would have to carry on their portable equipments when they are scanning in the patients' ward, if they chose to use it there as well as in the clinic. The latter location is where the design team envisioned the device would be used. However, we view this as a positive sign; the sonographers were optimistic with the device as they were considering to utilize this device even in their portable examinations.

The average number of barriers per respondent was 1.1, which was an improvement from 2.3 barriers per respondent in the previous concept review session. Since the cardiac sonographers had a chance to try this concept in their actual work setting, it was believed that the barriers identified in this pilot session have more validity than the barriers identified only through theoretical discussion in the previous review session.

| | | | |
|---|--|---|---|
| | I don't think I need this | 1 | Hard to clean |
| 1 | Would slow me down too much | | Too many pieces |
| | Would take too long to learn how to use | 3 | Lack of portability |
| | Would adversely affect patient safety | | Looks as though it would be too expensive |
| | Would adversely affect exam quality | 1 | Difficult to store |
| 1 | Would not be acceptable to patients | | Inconvenient to access when needed |
| | Would not help with enough patients | | Would take up too much space in the exam or pt room |
| | Other barriers not listed above (<i>please list here</i>): | | |

Table 4.11. The list of potential barriers shown to the cardiac sonographers. The barriers identified by the sonographers were bolded.

4.5. Summary

In conclusion, the results from the pilot session showed that the device generally worked as it was envisioned. The verbal comments, image quality assessment, average exertion ratings, and directed subjective evaluations of the device were somewhat consistent, in that the cardiac sonographers could see the potential of having this device to assist them in performing some parts of the scanning procedure. There were some important issues pointed out during the testing session that affect the functionality of the device. These issues should be addressed in the future design iterations, and should then be re-evaluated by the cardiac sonographers. The next chapter contains discussion of the important findings of this study, limitations of this project, and recommendations for future work.

Chapter 5: Discussion

5.1. Important findings

A literature search revealed that several publications have identified connections between the cardiac sonography activities and the prevalence of WMSDs. However, there have been a very limited number of research studies that have gone beyond the stages of problem identification and recommendations.

Previous recommendations on interventional activities were concentrated primarily on administrative and behavioral interventions, and less on engineering controls (Horkey & King, 2004). Changes that were proposed by previous literature reports including training, work schedule rotation, additional breaks, organization of work practices, and education may help in addressing some ergonomics issues. However, they do not tackle some of the fundamental problems that occur from incompatible relationships between the human, tools, and environment. This is where the field of human factors engineering and applied ergonomics plays a role. To address fundamental challenges, the incompatible interactions must first be understood before the effort to address the issues begins. Once these interactions are understood, higher reactivity studies, which involve changing the system under study, might be conducted.

In general interventional research, particularly involving engineering controls, has been limited due to the complex interactions and interrelationships between several variables in the work place, including many that cannot be controlled by researchers. In the specific case of cardiac sonographers, a number of variables in different work dimensions play a role in determining the magnitude of risk exposure to the sonographers. These variables include the patient (weight, age, gender, orientation of the heart, condition of the heart, ability to respond to sonographer's instruction), room space (the room size, the layout of equipment, the size of equipment, the lighting), equipment (ability to adjust machine/bed/chair height, weight of machine for transportation, weight and length of transducer and the cord, the size and shape of the transducer), work organization (shift scheduling, in-patient vs. out-patient scanning, rest break, work protocol, number of patients scanned per day), the cardiac sonographers (anthropometry, amount of training, previous injuries history, scanning style, years of experience, scanning with left hand vs. right hand) and psychosocial work factors (interpersonal relationships at work, emotional support from family, sonographer's perception on work load and work pace, etc.). Combinations of any of these variables would result in a different risk exposure to each sonographer (Figure 5.1). This highly dynamic environment makes development of engineering controls difficult, in contrast to other more organized and repetitive activity cycle settings such as those in manufacturing. Complex interactions between several variables require more research effort, making the identified problems more difficult to tackle.

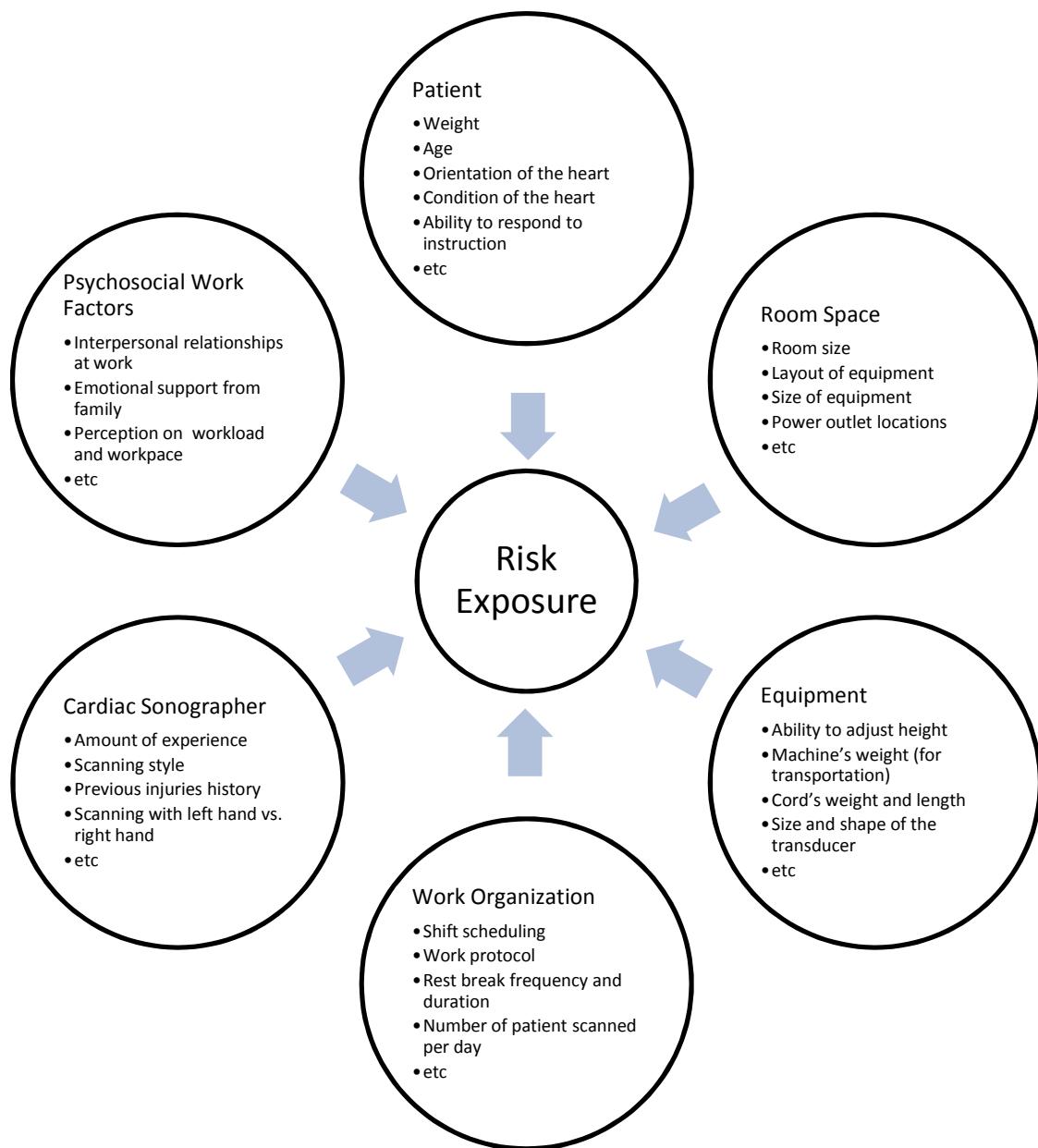


Figure 5.1. Different variables that may influence risk exposure in echocardiography.

Previous studies relevant to the topic were mostly self-reported survey and cross-sectional studies. These studies have done a good job of identifying problems and created awareness of the issues. These kinds of studies have high face validity and realistically present the system. But once the problems have been identified, it is time to move into the next mode of research, which is the active intervention effort.

Further investigation, employing observation, interview and focus group sessions revealed recurring issues with the cardiac sonographers' current work set-up. Consistent with prior studies, the cardiac sonographers in this study found it to be challenging to hold, push and to maintain the exertion on the ultrasound transducer. In addition, awkward and static postures were also recognized to be part of the problem. However, these activities provide the image quality desired by the cardiac sonographers. Since the image quality is something that cannot be compromised, the cardiac sonographers are essentially required to perform and endure these undesirable work activities. There have been numerous research reports in epidemiological and biomechanical fields connecting the activities of pinching, forceful exertion, awkward postures, and sustained postures to the development of musculoskeletal disorders in many other populations of workers as well.

Reducing the cardiac sonographers' exposure to pinching, pushing, maintaining exertion and awkward posture may eventually contribute to reducing the overall risk of them developing WMSDs. In this study, these four issues were translated into the user's needs. The goal of the device designed in this study was to address these four issues, and ultimately implement a functional prototype in the real setting. We realized that efforts

focusing on usability, usefulness, and desirability would need to be considered in order for the device to be practical and applicable to the work setting. A systematic design effort, integrating the knowledge of ergonomics and product design, and applied in the specific field of echocardiography was then conducted.

A design process that involved end users through the process was found to be useful to guide the direction of the design development. There has been a lack of studies focusing on human-centered design concepts in this specific area, though we think this approach can offer an added value to the finalized design. In this study, the cardiac sonographers as the end users were involved throughout several design development stages, and this process allowed the design team to better understand what was needed and what was not. The feedback from the end users gave us the confidence to move forward with our concepts. Their enthusiasm and eagerness to help, share their experience, and offer opinions provided a valuable input to a more user-centered design, which will facilitate the development of a user-friendly device.

Involvement of people from different backgrounds and with different expertise such as engineering, design, manufacturing, and radiologic sciences was found to be beneficial to this project. Discussions on a single issue, but coming from different perspectives provide more comprehensive understanding of the problem at hand. Getting feedback from these groups of people, even though it is time consuming, ensures the designs are well thought out and considered from a wider angle. In this study, we initially did not include those with a manufacturing background when we were designing the probe holder. Thus, when the technical drawings were given to the manufacturing

people, it was revealed that even though fabricating the prototype of the design would be possible, it would be too expensive because of the different tooling and machining needed. Another design iteration process involving individuals with manufacturing backgrounds reduced the fabrication costs, due to a more effective use of machining techniques.

A pilot session was conducted to assess the concept for effects on image quality, as well as initial usability feedback from the sonographers. Since the image quality of the cardiac scan cannot be compromised, the pilot session was held in a clinic setting, with special focus on trying to get quality images. The pilot session was treated as a learning opportunity, as well as the decision point to determine if the concept was worth pursuing further. From the pilot session, we found that the cardiac sonographers were optimistic for the potential of the device. The device was seen to address the user needs identified in the earlier design stages. There are several issues that require improvement, but overall, the participants gave positive feedback on the device. This can be seen through documented observations as well as by the cardiac sonographers' consistent responses through verbal comments, exertion ratings, and directed subjective assessments. In addition, the preliminary image assessment demonstrated that the quality of the scanned images taken with and without the device were generally comparable. The prototype was evaluated positively, with overall scores on usability, usefulness, and desirability all above 6 out of 7, where 1 equated to "very poor" and 7 equated to "very good". These high scores indicated that the cardiac sonographers were satisfied with the overall

performance of the prototype and saw potential for it to be developed into something they would like to be able to use in their practice.

5.2. Limitations

The main limitation in this study is that the design is not yet in its complete form. The concept is still in the development process, and it will take several more design iterations before the device is ready to be implemented in echocardiography settings. As discussed in a previous chapter, issues such as the rigid stand and inflexible probe end are legitimate and have to be worked out before the complete design is ready for a comprehensive evaluation. As a result, the evaluations gained from this study should not be treated as if they applied to a final design, but instead should be treated as an assessment to check whether or not the concept has potential and is worth being further pursued.

The cardiac sonographers who participated in the study were all employed at the Ohio State University's medical facilities. The feedback they provided could be biased by their specific working environment. Different medical facilities might have different equipment, work organization, work protocol, room set-up, etc. that might influence the content of cardiac sonographers' perception of the device. As a result, there is a risk that the device might not work well if implemented in a completely different environment. However, the sonographers involved in this study had many years of experience, and most of them have experience working in other facilities. The cumulative years of

experience of the six sonographers involved in the pilot study was more than 82 years. Their previous experience of working in different facilities should in some degree compensate for the limitation of recruitment only from the OSU's medical facilities.

Another limitation of this study was that it involved a small sample of professional cardiac sonographers. In total, there were twelve cardiac sonographers involved in one or more of the different design stages of this study, from the first workshop conducted under the parent R01 research to the most recent pilot testing in the clinical setting. The problem with a small sample group is that the data collected might not represent the larger general population of cardiac sonographers. However, the subject sample in this study was demographically diverse. The participants in this study consisted of a group of professional cardiac sonographers that was diverse in gender, age, anthropometrical dimensions, and years of experience.

In the individual pilot sessions, the trial order was not randomized or counter-balanced. The cardiac sonographers all were asked to first use the traditional scanning method and then to scan with the device. As a result, there might be cumulative fatigue that built up in their muscles, which may have influenced the perception of overall exertion, and ultimately affected their overall evaluations. Other carry-over influences, such as familiarity with the "patient's" heart orientation or mental fatigue were also possible. However, this pilot session was intended to investigate and gauge initial acceptance. A full scale comprehensive study would be appropriate when the design is further evolved. For the present, having them scan in the same order simplified the testing as well as the data processing time and analysis effort.

Another limitation of this study is that the data collected directly from the sonographers were mostly in the form of subjective opinions. Evaluations on force exertion and postures that were assumed were difficult to assess subjectively, leading to potential errors. These subjective errors might be due to judgment bias and coincidence. However, subjective opinions on sonographer's postural behavior were verified through postural analysis from video recordings. In addition, verbal comments on image quality were also independently verified at a later stage.

It would improve the validity of the study to have the cardiac sonographers performing complete full scans instead of a partial scan. The pilot session only required the cardiac sonographers to perform two major scans, which were the Parasternal window and Apical window, and they did not include making measurements on the images, which is an important component of the scan procedure. Performing a full scan would reveal more information, such as extra scanning time that the sonographers may have needed or the overall effect of the device on the sonographers' muscle. However, the device developed in this study is not far enough along, so it would not make a lot of difference in the outcome of the result to have the sonographers perform a complete full scan. In addition, the sonographers were still learning to use the device, so it is believed that having them perform a full scan at this initial stage would not have been appropriate.

Another issue that might affect the evaluation of this device was that the cardiac sonographers were involved in the study at different portions of their shift. Half of the participants tested the device earlier in their shift when they might have had more energy and motivation. The other half tested the device towards the end of their shift, where

they may have felt tired due to fatigue build up accumulated over the course of their workday. As a result, this might affect the overall evaluation results as the physical and mental conditions varied among these cardiac sonographers. However, we found no obvious differences between data collected in morning and data collected in the afternoon.

Another issue with the pilot session is that the “patients” tested in this study were healthy and cooperative. This does not represent the typical cardiac patient population, many of whom are overweight and/or elderly. In some cases, the patients are sedated, and unable to respond to the cardiac sonographer’s instructions. Another comment made by the sonographers was that one of the “patients” in this study, which four of the six sonographers scanned, has an easily accessible heart orientation. Thus, the cardiac sonographers did not need to do intense fine manipulation of the transducer to get good images for him. However, the other “patient” who was scanned by the two remaining sonographers was considered to have a difficult heart orientation, which is more representative of the population of patients.

In spite of these limitations, the pilot study provides the groundwork for more comprehensive studies in the future. The prototype evaluated in this pilot study is a functioning prototype even though it is in early stage of design. The cardiac sonographers’ interactions with the device provided a learning opportunity for the design team to understand the design flaws in this initial prototype. Some of these flaws would never be discovered through theoretical concept discussions. Limitations that were

identified and discussed in this section open up an opportunity for future work, which will be discussed in the next section.

5.3. Future work

As mentioned in previous chapters, this study is not at the level of a complete set-up. The prototype made in this study was a strong first attempt, constructed from a blend of commercially available and custom made equipment in order to create a functional prototype that would provide a means to test a concept that was difficult for sonographers to evaluate from verbal description and 2-D sketches. An obvious future step is to improve on the design by further refining the prototype. Ulrich & Eppinger (2000) reported that a functional prototype is given to the end users to “identify any remaining design flaws before committing to production”. The two design flaws identified in both the pre-pilot and pilot sessions were the inflexible probe end of the articulating arm and the rigid mounting stand. The idea of an extra locking mechanism to allow probe holder rotation should also be explored, as at least two sonographers suggested this same idea. Some sonographers were also concerned about the location, portability and rigidity of the mounting stand. It would be necessary to investigate alternative set-ups to make sure that the locking lever will not be in the way of the sonographer’s knee. A mounting stand that can be integrated into the ultrasound machine or under the bed, powered by a small motor to adjust the height and move sideways, or one that has lockable wheels are some of the ideas offered by the sonographers.

Another improvement that could be made would be to design a universal probe holder. Hospital facilities usually have several different ultrasound systems, made by different manufacturers. The design, shape, size, and weight of these transducers are usually different from one another. Cardiac sonographers have to use different systems according to the machine's availability, so availability of a probe holder that accommodates different sizes and shapes of the probe should improve usefulness and usability of the device. The current probe holder is only compatible with two different transducer designs. Further iteration of the probe holder design should consider a wider range of compatibility to different transducer designs.

A cue or a landmark on the probe holder to signal the orientation of the transducer should be explored in the future. At least two out the six sonographers in the pilot session reported having difficulty determining the correct orientation of the probe. Knowing the correct orientation of the probe would save sonographers some time, possibly improving the cardiac sonographer's scanning experience with the device. A more proper mechanism to secure the transducer should also be designed. In this study, the transducer was only secured using rubber bands and Velcro straps. A more refined but simple and quick to use securing mechanism, such as snapping on and off the transducer by means of a press fit or a quick release mechanism might make the device more usable.

A higher level study employing a randomized control design of the experiment and a larger subject sample from multiple clinic settings should be performed in evaluating more refined iterations of the design. In addition, a more representative

sample of patients should be involved in those evaluations. Muscles activity can be objectively studied using electromyography (EMG) system, and a systematic comparison between the scanning methods can be made. In addition, fatigue analysis can also be performed to understand the effect of using the device on the cardiac sonographers' fatigue rate. Statistical analysis quantifying the significant trends observed may also contribute to the study's validity.

While the design of the device is still being refined, if the new device is to be successfully incorporated into a clinic setting, consideration of how it will be incorporated should also be addressed. This should include an examination of current scanning protocols and determining the extent to which this device might provide an opportunity to possibly re-invent or at least modify echocardiography scanning protocols. Further, in order to take full advantage of the benefits of the device, plans should be made for educating and training sonographers about the origins of the device and how to make the best use of it in order to reduce their exposure to forceful, sustained, pinch grip pushing exertions that the device is designed to alleviate. Once the device is completed, protocols are modified, and sonographers trained, then research that examines the next step in the question of adoption of the device should be conducted to shed light on the translational stage of the device's product life cycle (referring back to the six stages Design Cycle Model presented in Fig. 3.1).

The objective of the current study was to support the 2-D probe. However, volume scanning with a 3-D probe may be the future of ultrasound, at least in clinic settings. Currently sonographers may be required to collect both 2-D and 3-D scans of a

patient. 3-D probes are quite large and heavy in comparison to the small 2-D probes currently used in echocardiography. The method for acquiring volumes scans is described as follows on GE's website³: "Once the automatic volume scan is initiated the hand must remain very still and the patient can be asked to hold breath briefly. This helps in reducing the breathing artifacts and gives better results." As described, this requirement for the sonographer to hold her hand very still during the scan fits well with the design objectives for the articulating arm device that was developed in the current study. The benefits of 3-D scanning are that the required images can be acquired more quickly than a comparable series of 2-D scans. From a biomechanical standpoint, this is a benefit to the sonographer, but the trade-off of having to handle a much heavier, bulkier probe offsets the reduce time benefit. If the articulating arm could support the weight of the larger probe and its cord, then that trade-off would be eliminated.

Another opportunity for future study is quantifying the magnitude of force exertion required in the echocardiography activities. Cumulative load supported by the articulating arm can be quantified using force sensors, and comparison of overall magnitude of exertions between the two methods can be made. In addition, quantification of forces involved in echocardiography activities might pave the way for future biomechanical study. The results can then be used as a foundation to develop biomechanical models to guide a more involved design development in the future.

Additional opportunity for future work would include doing a time study of the postures involved during the use of the device. Work-sampling based approaches for postural behavior analysis such as PATH (Posture, Activity, Tools, and Handling) or

³ http://www.gehealthcare.com/usen/ultrasound/education/products/cme_3d4d.html

OWAS (Ovako Working Posture Assessment System) may be conducted to provide additional bases for further comparison of the two scanning methods. These systematic techniques of quantifying postural behaviors might give more comprehensive data in terms of the percentage of time the sonographers were involved in awkward and static postures while scanning with and without the device.

In summary, this interventional device is not yet ready to be implemented in a clinical setting. More efforts focusing on the design iterations as well as planning of more comprehensive evaluations will be needed to address the limitations discussed in the previous section. However, this concept is believed to have potential based on initial feedback from the sonographers and overall results in this study. Thus, it can be concluded that it would be worthwhile to continue to pursue this intervention concept in the future.

Chapter 6: Conclusion

Even though there have been well documented publications connecting WMSDs with cardiac sonographers' activities, limited intervention research has been done in this area. This study primarily focused on addressing the common issues of pinching, forceful exertion, awkward postures, and static postures experienced by cardiac sonographers through engineering intervention methods. A highly flexible articulating arm system with a locking mechanism was introduced to minimize the cardiac sonographers' exposure to those activities.

Using several conceptual design models as a framework, a design effort involving individuals from several different relevant backgrounds was launched. Involvement from end users, engineers, ergonomists, radiologic sciences professionals, and manufacturing technicians in the design process was beneficial as every individual contributed to the design according to their area of expertise.

Design methodologies of collecting data and generating ideas were utilized to systematically guide the development of the product. The design iteration process included literature review, observation, interview, discussions and focus group sessions. Intervention concepts generated through these efforts were screened and narrowed down before being presented to the cardiac sonographers in a second round of focus group

sessions. Discussions and focus groups used posters, drawings, and mock-up models to facilitate the exchange of ideas. Two concepts that were well received by the cardiac sonographers were explored further. A functional prototype was developed and another focus group session was convened to evaluate it.

This focus group session enabled the sonographers to pilot test the concept in practice, rather than evaluate it in theory, as they had been limited to in the previous concept review session. The feedback from the end users would determine if it was worthwhile to continue investing effort in this particular concept. In general, it was observed that the cardiac sonographers were optimistic about the prototype. Overall evaluations on usability, usefulness, and desirability indicated overall acceptance of the design. The sonographers reported that the average force exerted when scanning with the device was reduced considerably compared to the traditional scanning method. The image quality was also found to be comparable between the two scanning methods for most participants, even at this very early point of introduction to the device.

The data collected in the pilot session provided a sense of future direction for this concept. Several legitimate usability issues were identified, and future design iterations will be needed before the design is ready to be implemented in an actual echocardiography setting. Future work opportunity includes more comprehensive evaluations involving objective data such as muscle activities, postural analysis, and force distribution analysis. These evaluations should be performed on a larger sample of cardiac sonographers from different that is diverse in the age, experience, scanning techniques, and anthropometry.

In conclusion, the cardiac sonographers are facing persistent musculoskeletal issues due to several fundamental scanning activities such as forceful pinching as well as assuming awkward and sustained postures. These fundamental issues can be addressed through engineering controls, such as the articulating arm device introduced in this study. This intervention is expected to reduce the cardiac sonographers' exposure to injury risk factors, which could lead to reducing the prevalence of WMSDs in this group of workers. However, it should be noted that relying on engineering controls alone may not be the best interventional solution. Engineering controls, accompanied by related changes in work methods, protocols, or procedures, and coupled with appropriate training in the use of the new equipment and new or revised practices is a more holistic interventional approach that provides a more complete intervention solution than any one of these approaches alone.

The ultimate goal of this project would be to see a finalized version of this device implemented in echocardiography settings, and see it bring about future benefits such as reductions in the prevalence of discomfort, lost work days, occupational turn-over rate, and compensation claims. Scanning with the device is expected to improve the cardiac sonographers' quality of work life, by reducing the physical strain to which they are currently exposed on a daily basis. Unlike some engineering controls, the device is not expected to reduce the sonographer's productivity, which should make adoption attractive not only to sonographers, but also to clinic managers.

This project provides an interventional design roadmap for other researchers to follow. The participatory ergonomics process used in this study offers an alternative to

“the more common ‘top-down’ safety programs”, as it takes advantage of workers’ expertise and knowledge of the workplace system (Evanoff et al., 1999). The steps and methodologies presented in this study offer an organized framework for future engineering control efforts. This framework is envisioned to be applicable not only to the specific echocardiography area, but also to other occupational areas.

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APPENDIX A: CONCEPT GENERATION

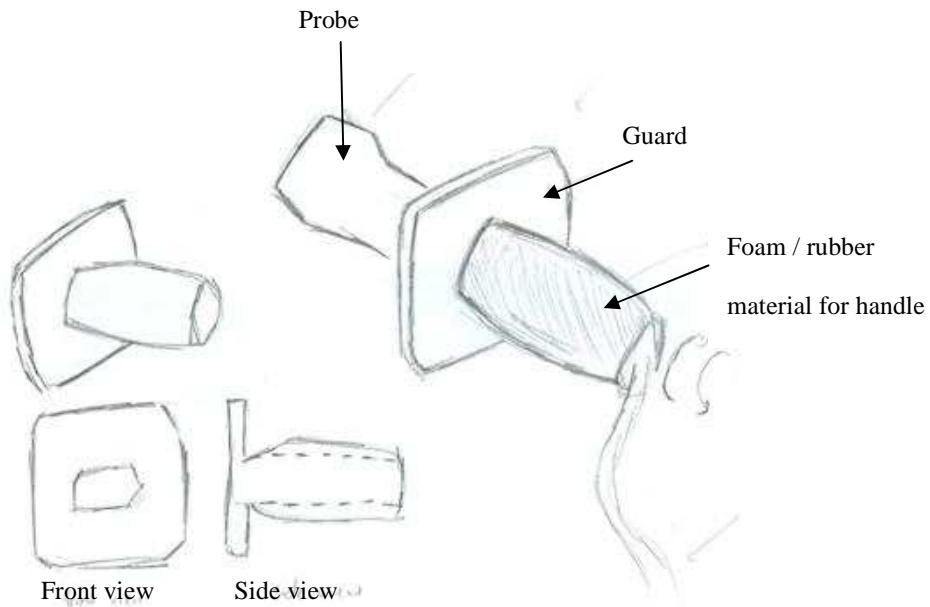


Figure A.1. This probe holder concept replaces a pinching grip with a palmar grip. A physical barrier/guard would provide an extra contact interface for the sonographer's hand when exerting the force.

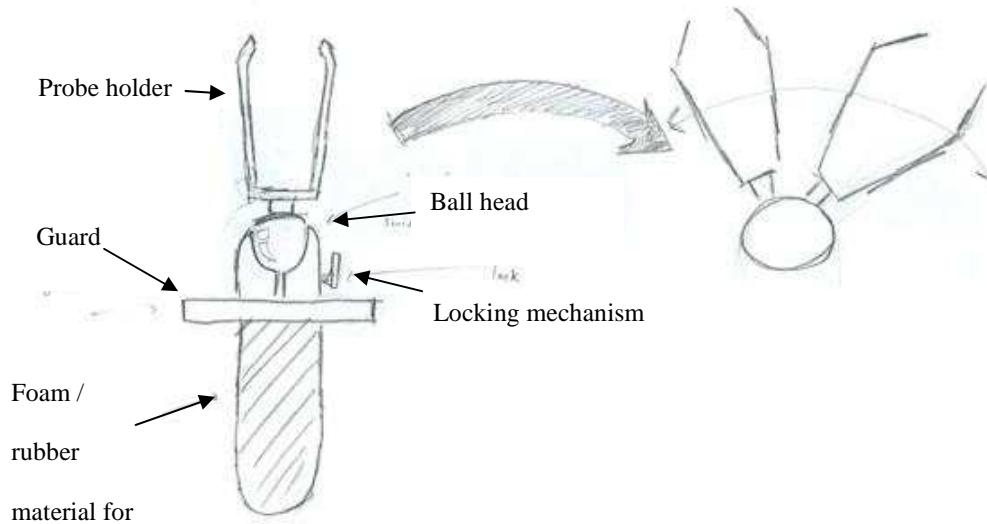


Figure A.2. This concept was an iteration of the concept shown in Figure A.1. We realized in a later session that the probe end would need to be flexible for fine manipulation of the transducer. Thus, a similar concept to concept A.1, but with an additional ball joint and locking mechanism was proposed.

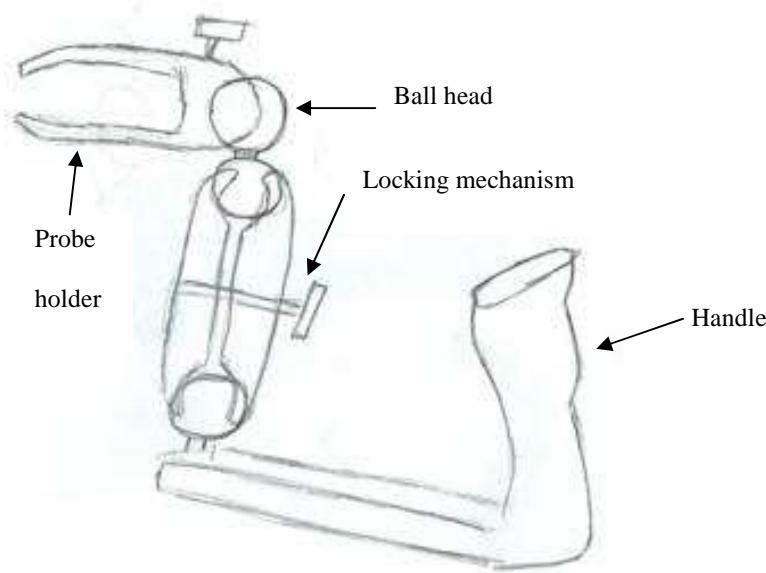


Figure A.3. This concept consists of a handle that was connected to several ball joints. The handle provides the sonographer an interface to maintain force exertion at a more neutral wrist posture.

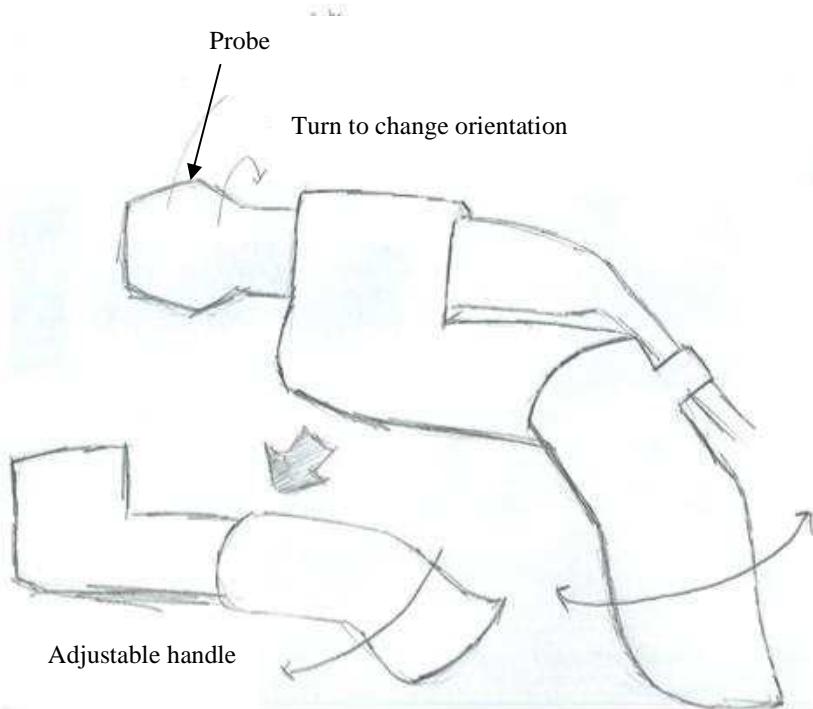


Figure A.4. This pistol grip probe holder concept replaces a pinching grip with a power grip. This was envisioned to provide a more neutral wrist posture when the sonographer is pushing the transducer against patient's chest.

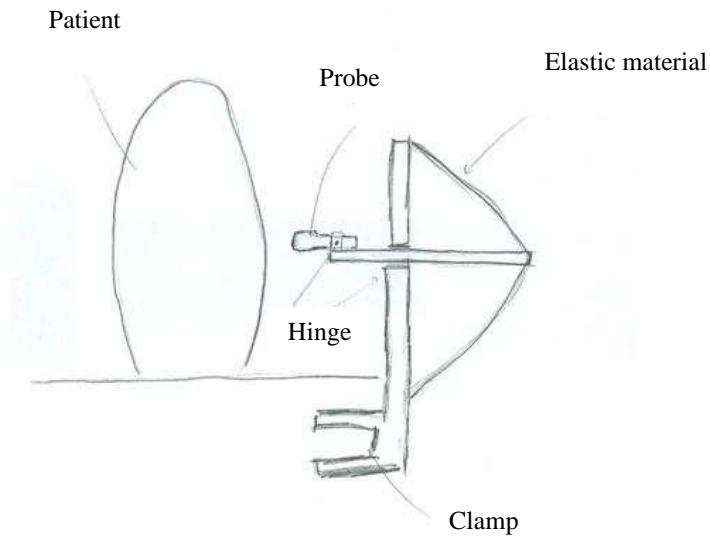


Figure A.5. This concept proposes the use of elastic materials to assist the sonographer with force exertion.

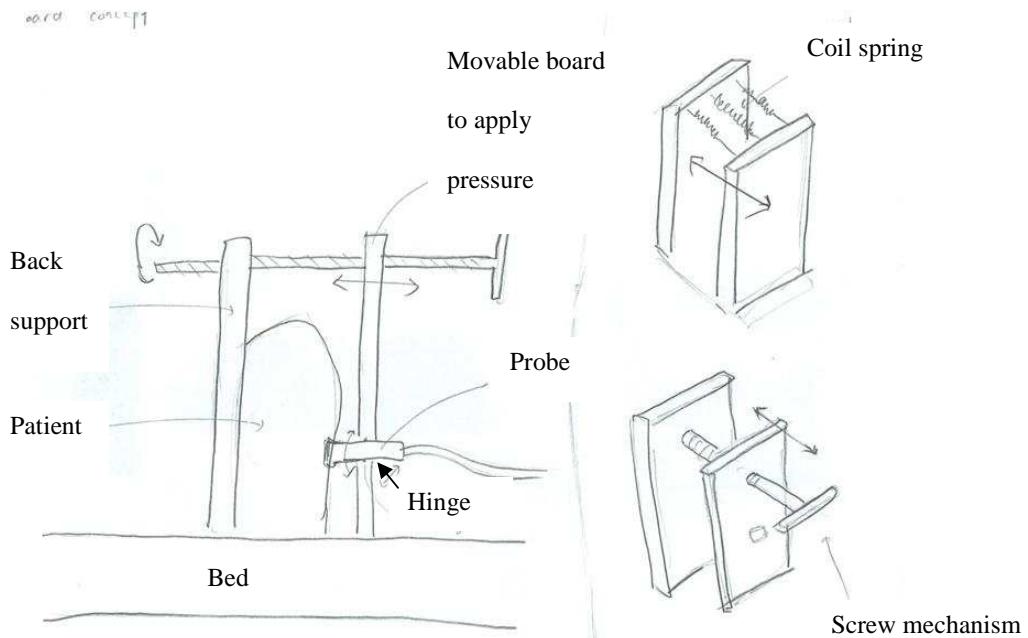


Figure A.6. This is a movable board concept, where the transducer would be mounted on a movable board. One board will move towards the other through a screw cranking mechanism or a spring system, providing an additional force augmentation.

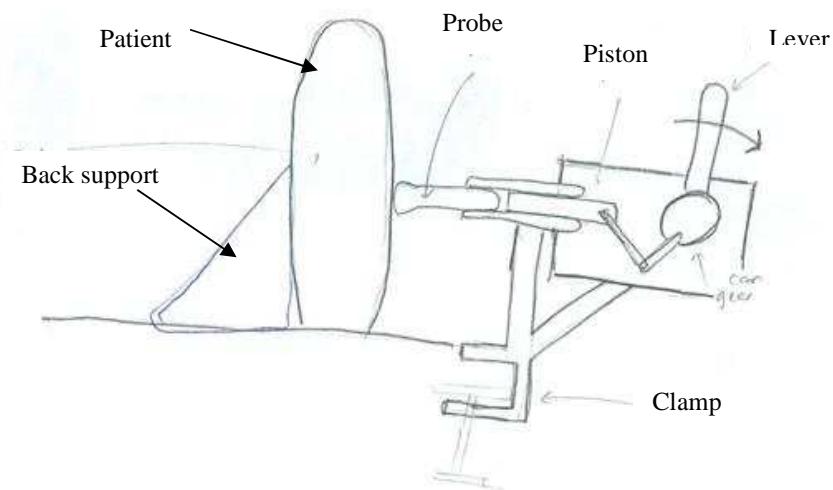


Figure A.7. A concept of a probe holder with a shaft cam mechanism was proposed to reduce prolonged pinching as well as augment force. Pulling the lever would rotate the shaft cam, and mechanically push the transducer towards the patient.

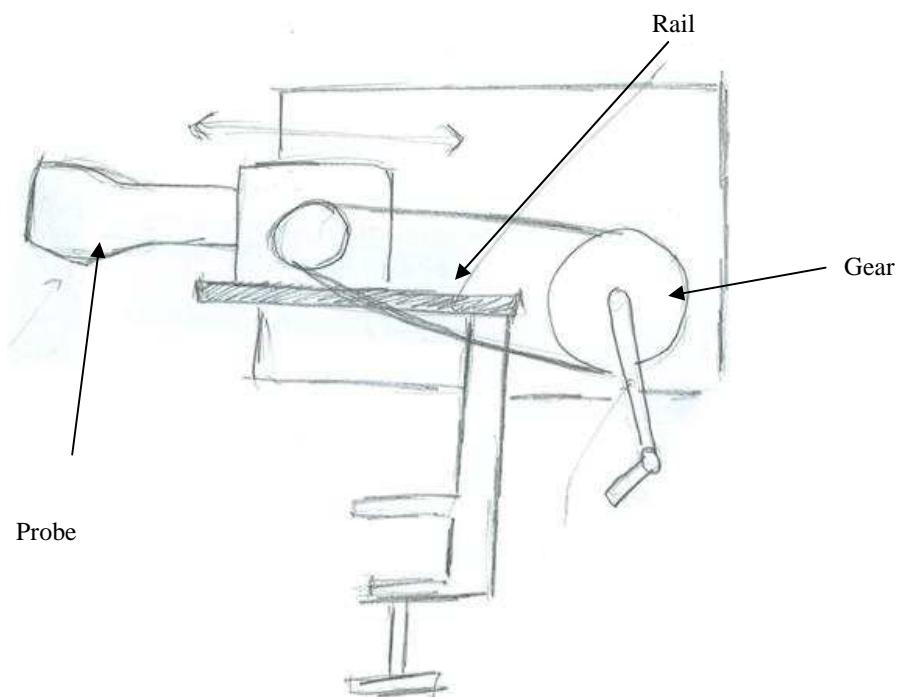


Figure A.8. This is a concept generated from a bicycle gear system. Cranking the gear would allow the sonographer to control the magnitude of force exertion.

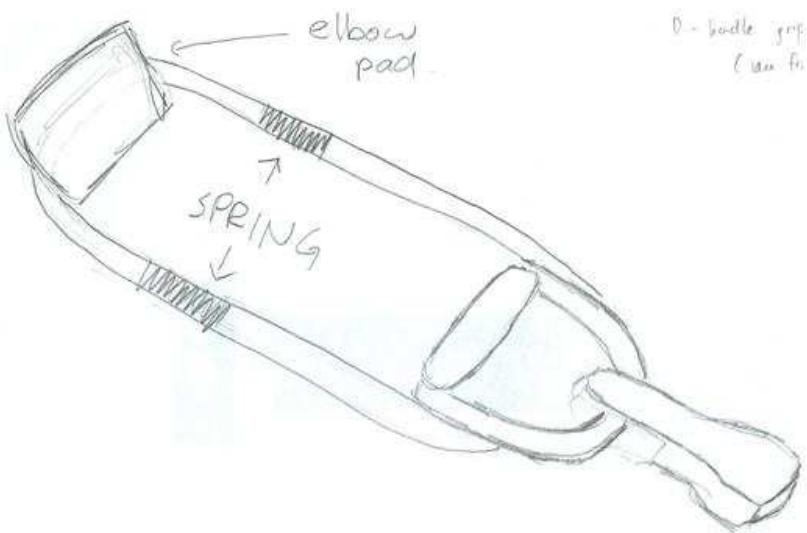


Figure A.9. This concept aimed to replace the pinch grip with a more neutral palmar grip through the D-shape handle. A spring mechanism was envisioned to assist the sonographer in augmenting force.

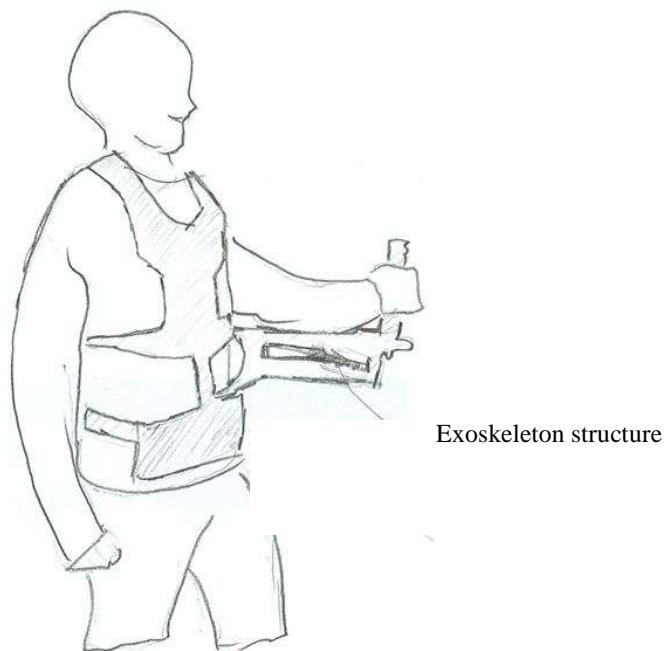


Figure A.10. An exoskeleton concept was envisioned, where the sonographer would be able to rest their hand on an articulated exoskeletal structure. The exoskeleton would provide arm support as well as augment force.

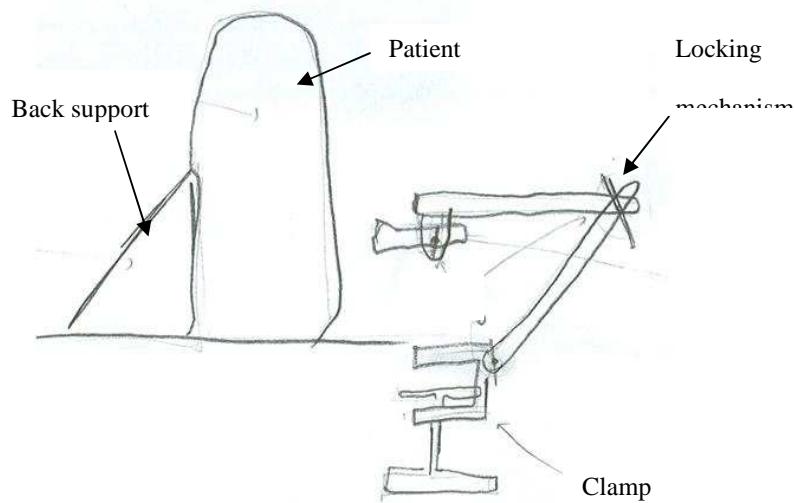


Figure A.11. This articulating arm concept was aimed to minimize the duration of pinch grip and awkward postures. Wing-nut knobs were envisioned to be used to lock the arm in place.

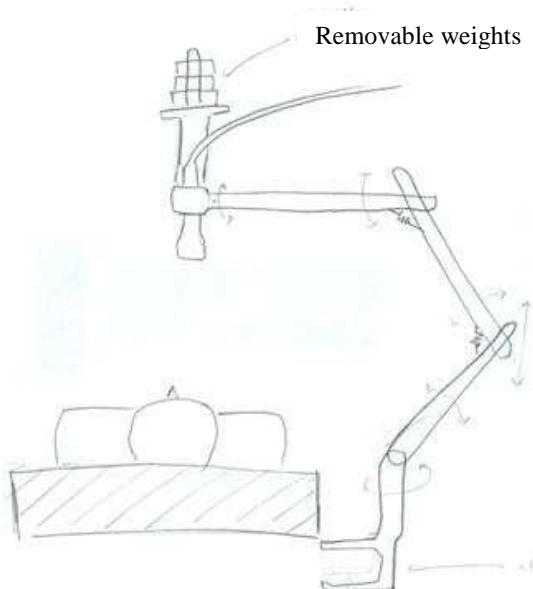


Figure A.12. This is another version of an articulating arm concept. Movable weights were envisioned to provide gravitational force augmentation.

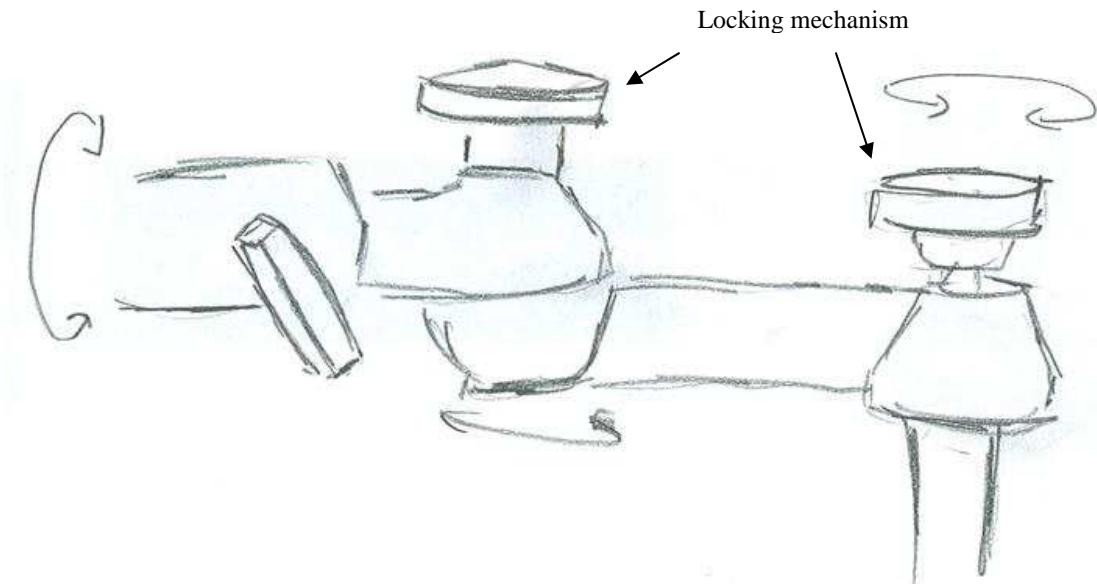


Figure A.13. This articulating arm concept has a slightly different locking mechanism than concept A.11. Instead of having wing-nut knob, this articulating arm has a larger radius turning knobs as part of it's locking system.

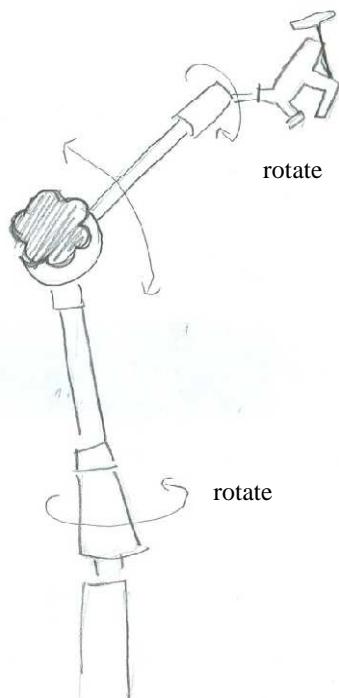


Figure A.14. This articulating arm concept was derived from a microphone stand system. This concept aims to reduce prolonged awkward and static postures.

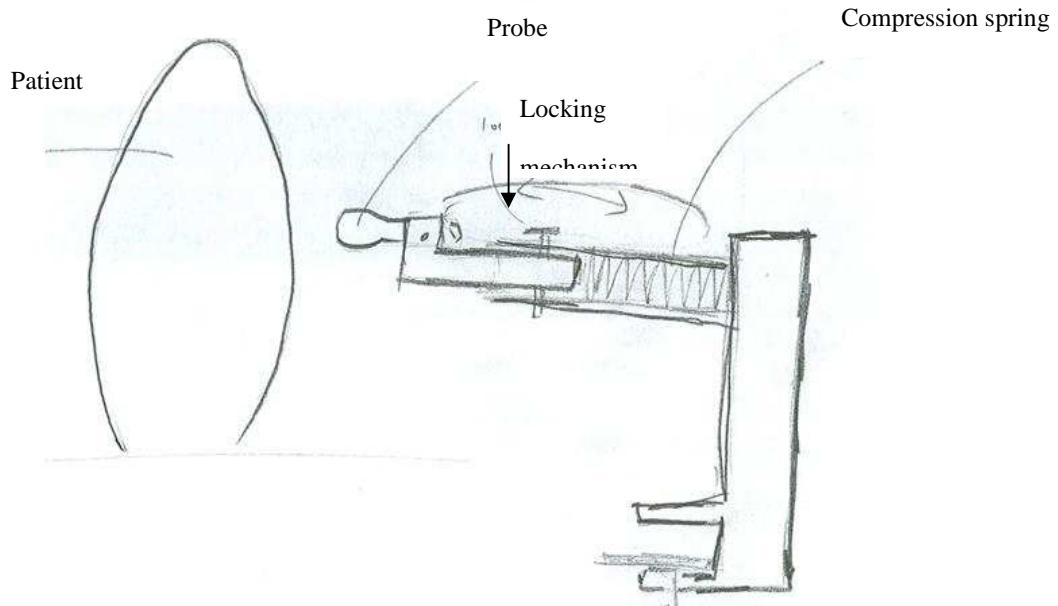


Figure A.15. This articulating arm concept has a spring mechanism to augment force exerted on the patient's chest.

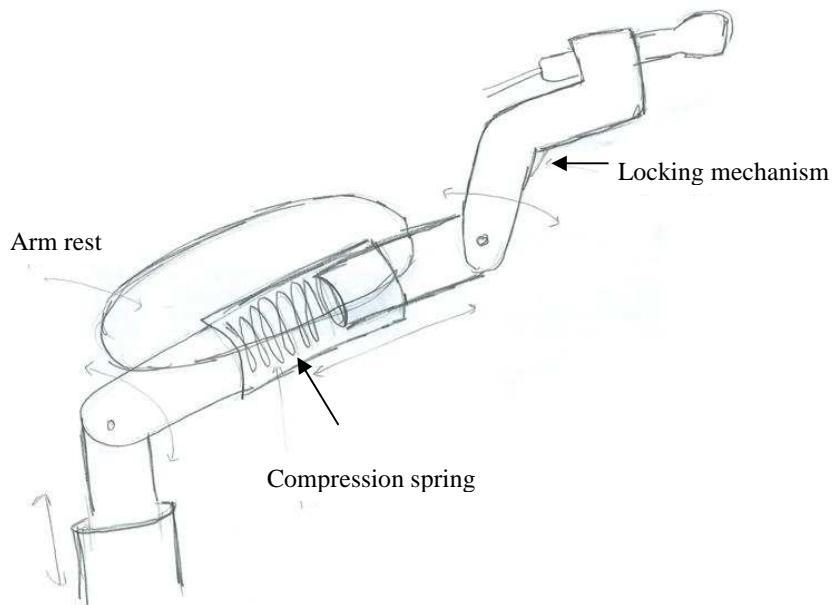


Figure A.16. This articulating arm concept is a combination of concepts A.4 and A.15. This concept promotes power grip as well as providing force augmentation through spring mechanism. In addition, there would be a padded arm rest to support sonographer's arm.

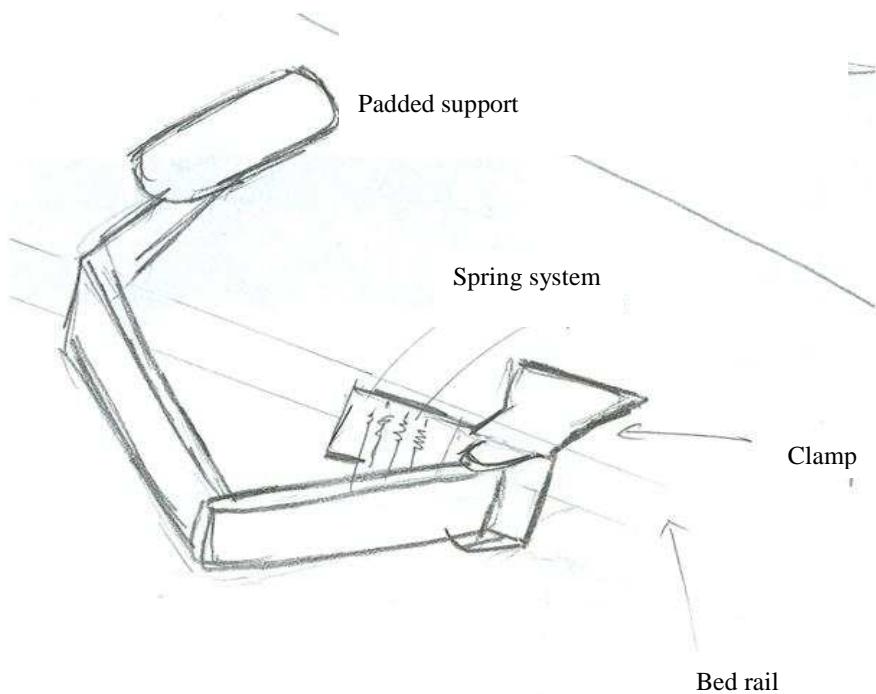


Figure A.17. This concept is a modification of keyboard's arm rest to allow an external support to the sonographer's arm. A spring mechanism was envisioned to assist the sonographer with force exertion.



Figure A.18. This is an elbow augmentation system, which pushes the sonographer's elbow towards the patient. The idea was that an external force to the back of the elbow would provide the sonographer augmentation to pushing activities.

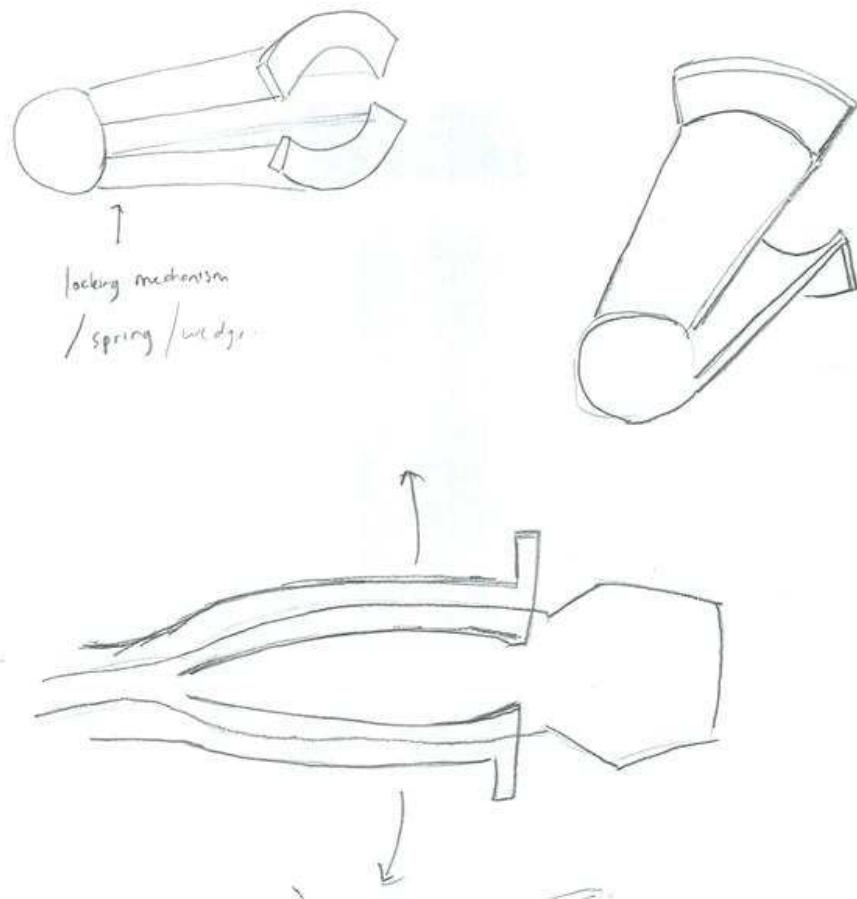


Figure A.19. This probe holder concept consisted of two panels connected at the end by a ball head. The transducer was envisioned to be secured between the two panels.

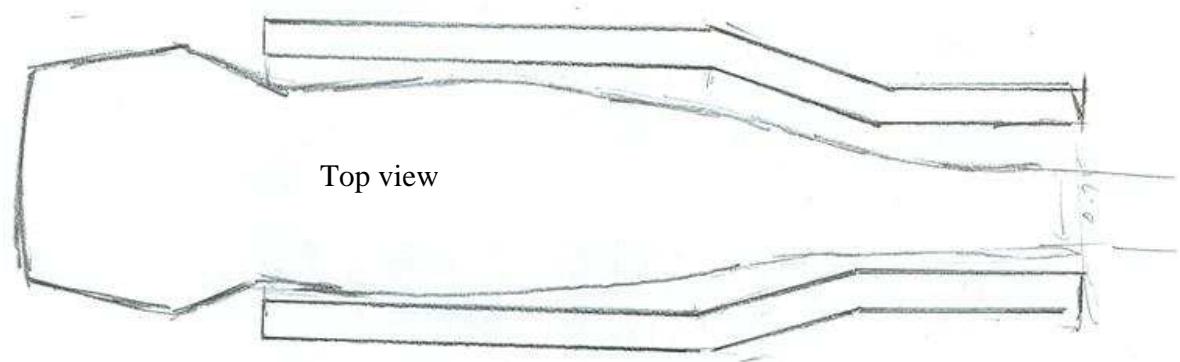


Figure A.20. This probe holder consisted of only one panel that would be machined close to the probe's shape. A rubber band or Velcro strap would secure the transducer in place.

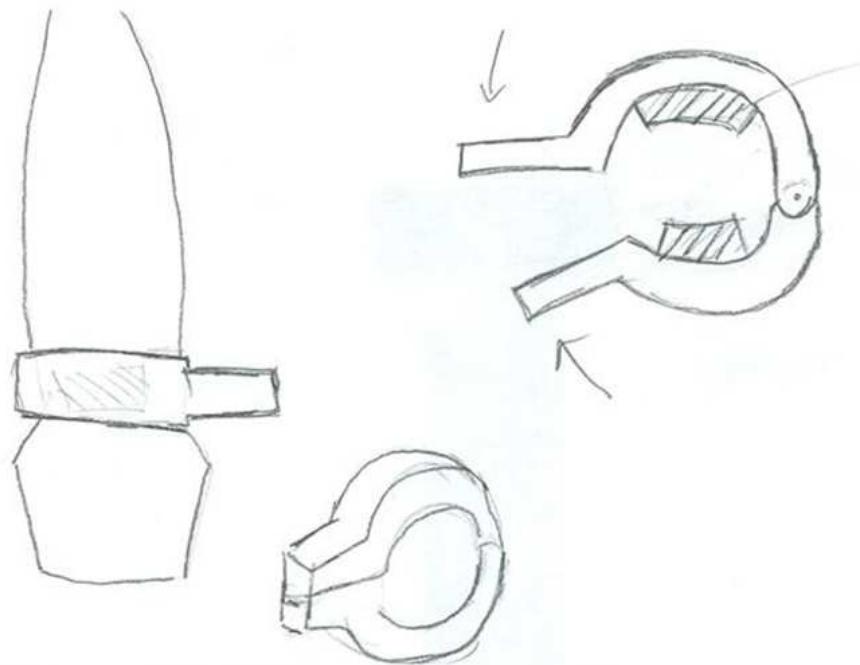


Figure A.21. A probe ring concept that would provide additional physical barrier around the transducer was expected to provide a better physical interface for force exertion task.

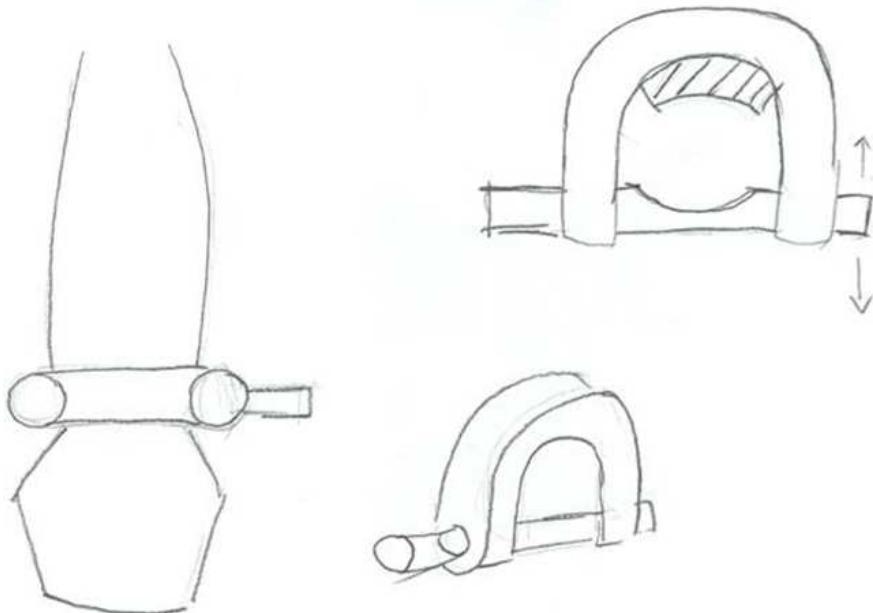


Figure A.22. This is another probe ring concept, similar to concept shown in Figure A.21. The additional physical barrier around the transducer was expected to provide a better physical interface for force exertion task.

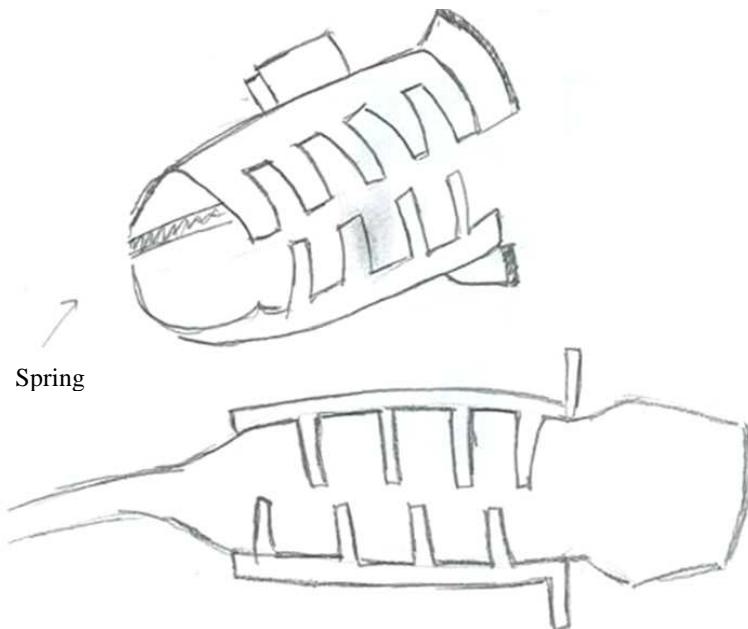


Figure A.23. This probe holder concept was derived from existing hair clamp available in the market. This concept was envisioned to hold the transducer in place via a spring coil mechanism.

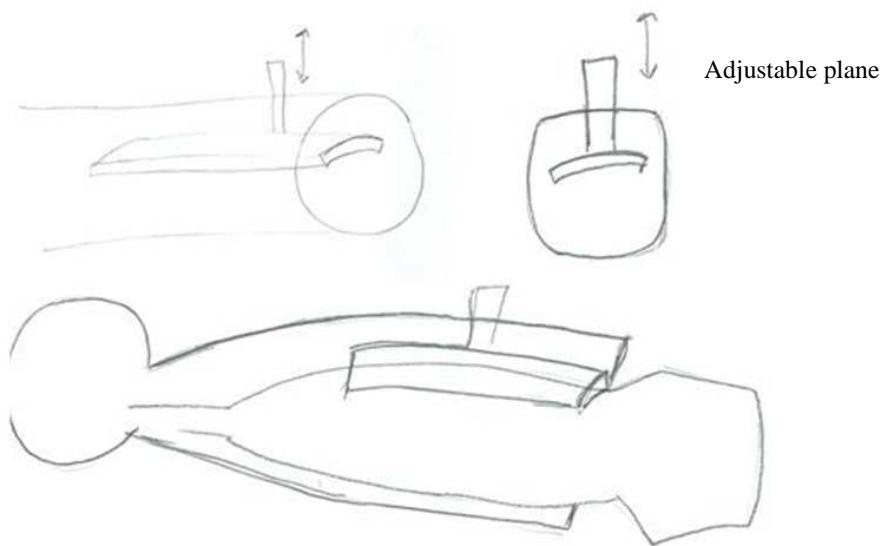


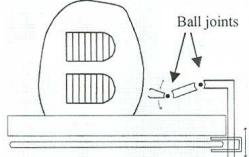
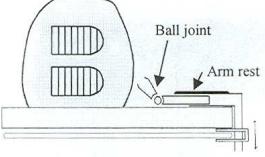
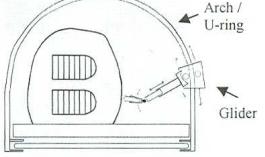
Figure A.24. This probe holder concept was envisioned to be compatible to transducers of different sizes and shape. The probe holder has an adjustable panel on the inside of the holder to clamp the transducer in place.

APPENDIX B: EVALUATION FORMS

Participant name: _____

| | |
|---|---|
| Interpreted need: Reduce the need for prolonged pinching and static awkward hand postures during exam. | Main solution concept: Articulating arm providing external support to maintain location of probe |
|---|---|

Approach A. Probe position maintenance

| Idea A1. Articulating arm | Idea A2. Articulating arm rest | Idea A3. U-ring glider |
|---|---|---|
|  |  |  |

Instructions: Circle (above) the Idea (A1, A2 or A3) you prefer for this approach and then provide your evaluation of this approach, in sections I – IV of this sheet.

| I. Usability | Strongly Disagree 1 | 2 | 3 | 4 | Strongly Agree 5 | | |
|--|------------------------|---|---|---|---------------------|---|---|
| 1. I think this new approach would be easy to use , especially with the targeted patient groups. | | | | | | | |
| 2. I find this new approach unnecessarily complex . | | | | | | | |
| 3. I think that I would need assistance to actually use this new approach. | | | | | | | |
| 4. I imagine that most people would learn to use this new approach very quickly . | | | | | | | |
| 5. I think this new approach would be very cumbersome to use. | | | | | | | |
| 6. I would need to spend a lot of time practicing with this new approach before I could use it on patients. | | | | | | | |
| 7. My overall rating of its usability potential (1 = very poor, 7 = very good): | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Comments: | | | | | | | |

| II. Usefulness | Strongly Disagree 1 | 2 | 3 | 4 | Strongly Agree 5 | | |
|--|------------------------|---|---|---|---------------------|---|---|
| 1. I would rather use this new approach than our traditional approach. | | | | | | | |
| 2. I believe that using this new approach would be more comfortable for the patient . | | | | | | | |
| 3. I believe that using this new approach would make my work easier physically . | | | | | | | |
| 4. I believe this new approach will help me perform my work tasks more efficiently . | | | | | | | |
| 5. I believe this new approach will reduce my physical fatigue at the end of each work day. | | | | | | | |
| 6. My overall rating of its potential usefulness (1 = very poor, 7 = very good): | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Comments: | | | | | | | |

Turn page over to continue evaluation of this new approach....

| III. Desirability | Strongly Disagree 1 | 2 | 3 | 4 | Strongly Agree 5 | | |
|---|------------------------|---|---|---|---------------------|---|---|
| 1. I would really benefit from the use of this new approach. | | | | | | | |
| 2. I would like to try this new approach as soon as you can get me a workable version. | | | | | | | |
| 3. I think some of my co-workers will want to use this new approach. | | | | | | | |
| 4. I really need this new approach for a select group of my patients. | | | | | | | |
| 5. My overall rating of its desirability (1 = very poor, 7 = very good): | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Comments: | | | | | | | |

IV. Barriers to Adoption. Which of the following would keep you from incorporating this new approach into your practice? *(Mark all that apply.)*

| | |
|--|---|
| I don't think I need this | Would not be worth the effort to set up |
| Would slow me down too much | Too many pieces |
| Would take too long to learn how to use | Too complex |
| Using this concept would make me uncomfortable | Hard to clean |
| | Lack of portability |
| Would adversely affect patient safety | Looks as though it would be too expensive |
| Would adversely affect exam quality | Difficult to store |
| Would not be acceptable to patients | Inconvenient to access when needed |
| Would not help with enough patients | Would take up too much space in the exam or pt room |
| Other barriers not listed above <i>(please list here):</i> | |

Please contact me; I have suggestions that I would like to contribute concerning this concept.

Combining Approaches A & B? Would you like to see one of the ideas from Approach A (probe position maintenance) combined with one of the ideas from Approach B (push force assist)?

Participant name: _____

| | |
|--|--|
| Interpreted need: Assist probe pushing task (especially on the obese patients). | Main solution concept: Push force assist mechanism. |
|--|--|

Approach B: Push Force Assist

| Idea B1. Handle with locking mechanism | Idea B2. Spring with locking mechanism | Idea B3. Crank - screw mechanism |
|--|--|----------------------------------|
| | | |

➔ Circle (above) the Idea (B1, B2 or B3) you prefer for this approach and then provide your evaluation of this approach in sections I – IV of this sheet.

| I. Usability | | Strongly Disagree 1 | 2 | 3 | 4 | Strongly Agree 5 |
|---|---|------------------------|---|---|---|---------------------|
| 1. I think this new approach would be easy to use, especially with the targeted patient groups. | | | | | | |
| 2. I find this new approach unnecessarily complex. | | | | | | |
| 3. I think that I would need assistance to actually use this new approach. | | | | | | |
| 4. I imagine that most people would learn to use this new approach very quickly. | | | | | | |
| 5. I think this new approach would be very cumbersome to use. | | | | | | |
| 6. I would need to spend a lot of time practicing with this new approach before I could use it on patients. | | | | | | |
| 7. My overall rating of its usability potential (1= very poor, 7 = very good): | 1 | 2 | 3 | 4 | 5 | 6 |
| Comments: | | | | | | |

| II. Usefulness | | Strongly Disagree 1 | 2 | 3 | 4 | Strongly Agree 5 |
|---|---|------------------------|---|---|---|---------------------|
| 1. I would rather use this new approach than our traditional approach. | | | | | | |
| 2. I believe that using this new approach would be more comfortable for the patient. | | | | | | |
| 3. I believe that using this new approach would make my work easier physically. | | | | | | |
| 4. I believe this new approach will help me perform my work tasks more efficiently. | | | | | | |
| 5. I believe this new approach will reduce my physical fatigue at the end of each work day. | | | | | | |
| 6. My overall rating of its potential usefulness (1= very poor, 7 = very good): | 1 | 2 | 3 | 4 | 5 | 6 |
| Comments: | | | | | | |

Turn page over to continue evaluation of this new approach....

| III. Desirability | Strongly Disagree 1 | 2 | 3 | 4 | Strongly Agree 5 | | |
|--|--|---|---|---|---------------------|---|---|
| | 1. I would really benefit from the use of this new approach. | | | | | | |
| 2. I would like to try this new approach as soon as you can get me a workable version. | | | | | | | |
| 3. I think some of my co-workers will want to use this new approach. | | | | | | | |
| 4. I really need this new approach for a select group of my patients. | | | | | | | |
| 5. My overall rating of its desirability (1= very poor, 7 = very good): | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Comments: | | | | | | | |

IV. Barriers to Adoption. Which of the following would keep you from incorporating this new approach into your practice? *(Mark all that apply.)*

| | |
|--|---|
| I don't think I need this | Would not be worth the effort to set up |
| Would slow me down too much | Too many pieces |
| Would take too long to learn how to use | Too complex |
| Using this concept would make me uncomfortable | Hard to clean |
| Would adversely affect patient safety | Lack of portability |
| Would adversely affect exam quality | Looks as though it would be too expensive |
| Would not be acceptable to patients | Difficult to store |
| Would not help with enough patients | Inconvenient to access when needed |
| | Would take up too much space in the exam or pt room |
| Other barriers not listed above <i>(please list here):</i> | |

Please contact me; I have suggestions that I would like to contribute concerning this concept.

Figure B.1. Evaluation form used in concept review session.

Participant name: _____

Interpreted need:

- Reduce the duration of pinch grip
- Reduce the duration of force exertion
- Reduce the duration of awkward postures
- Reduce the need to maintain static postures

Main solution concept: An articulating arm with a locking mechanism providing external support to grip and hold the transducer in place.



Instructions: Please provide your evaluation of this device, in sections I – IV of this form.

| I. Usability | Strongly Disagree 1 | 2 | 3 | 4 | Strongly Agree 5 |
|---|------------------------|---|---|---|---------------------|
| <i>Probe Holder</i> | | | | | |
| I feel comfortable gripping the current rectangular shape of the probe holder prototype. | 0 | 0 | 0 | 3 | 3 |
| I think the probe holder would have a tendency to slip out of my hand due to its material or texture. | 5 | 1 | 0 | 0 | 0 |
| I think the current probe holder's size is too wide for a comfortable prolonged grip . | 2 | 4 | 0 | 0 | 0 |
| It is easy to determine the correct orientation of the transducer in the current probe holder prototype. | 0 | 2 | 1 | 0 | 3 |
| <i>Articulating Arm</i> | | | | | |
| I think the arm is long enough to allow me to locate the transducer where I want to position it. | 0 | 0 | 2 | 1 | 3 |
| I think the arm is flexible enough for fine manipulation of the transducer. | 0 | 1 | 1 | 4 | 0 |
| I think the arm is too heavy for prolonged scanning. | 2 | 4 | 0 | 0 | 0 |
| I think the arm interferes with my line of sight to the patient . | 2 | 3 | 1 | 0 | 0 |
| I think the arm interferes with my line of sight to the ultrasound machine . | 3 | 2 | 0 | 0 | 1 |
| I think the arm interferes with my access of the control panel. | 2 | 2 | 1 | 0 | 1 |
| <i>Locking Mechanism</i> | | | | | |
| I think the current locking mechanism set up is cumbersome to use. | 2 | 1 | 3 | 0 | 0 |
| I think it is cumbersome to lock and unlock the arm repeatedly . | 2 | 1 | 2 | 0 | 1 |
| <i>General Usability</i> | | | | | |
| I think it would be worth the effort/time to set up this device. | 0 | 0 | 1 | 1 | 4 |
| I feel uncomfortable having this device between me and the patient . | 3 | 0 | 1 | 1 | 1 |
| I feel uncomfortable having this device between me and the ultrasound machine . | 3 | 0 | 0 | 2 | 1 |
| I think that using the device will not adversely affect image quality . | 0 | 1 | 0 | 2 | 3 |
| I find this new approach unnecessarily complex . | 4 | 2 | 0 | 0 | 0 |
| I imagine that most people would learn to use this new approach very quickly . | 0 | 0 | 0 | 3 | 3 |
| I would need to spend a lot of time practicing with this new approach before I could use it on patients. | 3 | 2 | 1 | 0 | 0 |
| My overall rating of its usability potential (1= very poor, 7 = very good): | 6.16 / 7 | | | | |
| Comments: | | | | | |

| II. Usefulness | Strongly Disagree 1 | 2 | 3 | 4 | Strongly Agree 5 |
|--|------------------------|---|---|---|---------------------|
| I think using this device would reduce the total amount of time I grip (hold) the transducer during a scanning procedure | 0 | 0 | 0 | 1 | 5 |
| I think this device would reduce the total amount of time I am pushing with the probe during a scanning procedure | 0 | 0 | 0 | 2 | 4 |
| I think this device would reduce the total amount of time I work in awkward postures during a scanning procedure | 0 | 0 | 1 | 2 | 3 |
| I think this device would reduce the total amount of time I have to hold myself in a fixed posture during a scanning procedure | 0 | 0 | 1 | 1 | 4 |
| I would be inclined to take intermittent rests because I believe the locking mechanism would hold the probe location in place for me. | 0 | 0 | 0 | 3 | 3 |
| I think there is a significant benefit of having the weight of probe and the cord supported by the device . | 0 | 0 | 1 | 2 | 3 |
| I would rather use this device than our traditional approach. | 0 | 1 | 1 | 3 | 1 |
| I am able to get quality images with this device. | 0 | 0 | 1 | 2 | 3 |
| I think the arm can sustain enough load when scanning an overweight patient. | 0 | 1 | 1 | 1 | 3 |
| I think this device would lengthen the time of a scanning procedure by too much. | 2 | 2 | 2 | 0 | 0 |
| I am concerned that it would make the exam more physically uncomfortable for some patients. | 0 | 1 | 4 | 1 | 0 |
| I am concerned that many patients might be intimidated by the device. | 0 | 3 | 1 | 2 | 0 |
| I believe that using this new approach would make my work easier, physically . | 0 | 0 | 1 | 2 | 3 |
| I believe this new approach will help me perform my work tasks more efficiently . | 0 | 0 | 3 | 2 | 1 |
| I believe this new approach will reduce my physical fatigue at the end of each work day. | 0 | 0 | 0 | 2 | 4 |

My **overall rating of its potential usefulness** (1 = very poor, 7 = very good): 6.16 / 7

Comments:

| III. Desirability | Strongly Disagree 1 | 2 | 3 | 4 | Strongly Agree 5 |
|--|------------------------|---|---|---|---------------------|
| I would really benefit from the use of this new approach. | 0 | 0 | 2 | 1 | 3 |
| I see my self using this device all the time with every patient. | 0 | 1 | 3 | 1 | 1 |
| I would be interested in using a more refined version of this device in the future. | 0 | 0 | 0 | 1 | 5 |
| I think some of my co-workers will want to use this new approach. | 0 | 1 | 0 | 2 | 3 |
| I really need this new approach for a select group of my patients. | 0 | 0 | 2 | 1 | 3 |

My **overall rating of its desirability** (1 = very poor, 7 = very good): 6.08 / 7

Comments:

IV. Barriers to Adoption. Which of the following would keep you from incorporating this new approach into your practice?
(Mark all that apply.)

| | |
|---|---|
| I don't think I need this | Hard to clean |
| Would slow me down too much | Too many pieces |
| Would take too long to learn how to use | Lack of portability |
| Would adversely affect patient safety | Looks as though it would be too expensive |
| Would adversely affect exam quality | Difficult to store |
| Would not be acceptable to patients | Inconvenient to access when needed |
| Would not help with enough patients | Would take up too much space in the exam or pt room |

Other barriers not listed above (please list here):

Please contact me; I have suggestions that I would like to contribute concerning this concept.

Figure B.2. Directed subjective evaluation form used in pilot session.

Figure B.3. Data collection form used in pilot session.

File name/designation:

| Scanning window | Comparable quality between the two images? (if yes, please check) | Image quality in one image is better than the other? (if yes, please provide timestamp of the better image) | Note (if applicable) |
|----------------------------------|--|--|----------------------|
| PLAX (Parasternal long axis) | | | |
| PSAX (Parasternal short axis) | | | |
| PLAX – color | | | |
| RV INFLOW : PLAX – color | | | |
| RV INFLOW : PLAX – without color | | | |
| RV INFLOW : DOPPLER | | | |
| PSAX : M- Mode | | | |
| PSAX : Sweep | | | |
| Apical 4 chamber | | | |
| Apical 2 chamber | | | |
| Apical 3 chamber | | | |
| Apical 4 : Color | | | |
| Apical 4 : Doppler | | | |

Overall comment:

Figure B.4. Evaluation form used in image quality assessment.