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Design of a Holding Device for an Ultrasound Probe in Brachial Artery Reactivity Testing

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Abstract

Advanced atherosclerosis, an inflammation of the arteries, can lead to thrombosis and heart attacks or strokes. Vascular reactivity studies examine the brachial arteries' reaction to occlusion. An ultrasonic probe must be held in the correct orientation for 5 min. Since the images are influenced by motion artifact caused by slight movements of the sonographer's hands, a probe holder that stabilizes an ultrasonic probe in the correct orientation would improve the quality of the sonogram. A prototype was constructed that enables the probe to be moved in any direction by adjusting a string of ball and socket joints. Major motion can be achieved by loosening one knob and moving an articulated arm. Any sized probe can be attached to the device using Velcro straps. The prototype also contains a comfortable arm rest that stabilizes the patient's arm. Test show that the prototype eases use and effectiveness of the probe holder.

Introduction

Arteries distribute oxygenated blood from the heart to the rest of the body. These vessels must be strong, flexible, and elastic in order to contract and pump blood. However, if increased pressure reduces the elasticity and causes the blood vessels to become hard, this is known as arteriosclerosis. One specific type of blood vessel hardening is atherosclerosis, in which the blood vessel walls become thick and stiff due to the buildup of fat in and on the walls[1]. Due to this stenosis, blood flow is usually restricted. While this is commonly referenced in the heart, the plaque buildup which leads to atherosclerosis can occur anywhere in the body[2].

Ultrasonography is a "noninvasive, safe, well-validated, reproducible technique for quantifying the burden of subclinical vascular disease and assessing CVD [cardiovascular disease] risk".[3] Therefore, many vascular physicians have begun using ultrasonography to study properties of artery walls. Since the brachial artery on the upper arm can be easily located and manipulated noninvasively, this makes it a good vessel to image when studying the effects of atherosclerosis. Increased pressure due to plaque buildup can be simulated in the brachial artery by occluding blood flow using a blood pressure cuff. Studies can use either upper or forearm cuff occlusion; however, upper arm occlusion is "technically more challenging for accurate data acquisition as the image is distorted by collapse of the brachial artery and shift in soft tissue"[4]. Once blood flow can been occluded, ultrasonography can be used to image the brachial artery walls to track its elastic movements.

One of the major concerns of using ultrasonography for vascular reactivity studies is the training and ergonomic issues faced by the sonographer[5]. To correctly image the desired artery and its reaction, a sonographer trained in

the principles and technical aspects of 2D and Doppler ultrasonography is required to perform the procedure. Because of the angles required to obtain the optimal imaging, the sonographer should "sit in a comfortable position and support the arm holding the probe… [to] minimiz[e] stress-related fatigue and injuries"[4]. Ergonomic concerns for wrist strain and injuries such as carpal tunnel syndrome have led to the requirement that only one study can be conducted per hour. While this OSHA[6] regulation protects the sonographer, it has limited the rate at which studies can be conducted and results can be obtained.

Methods

Fabrication

Figure 1 shows the device in use. The individual components of the device were constructed in the methods described below. The supplemental CAD drawings shown below serve as a visual guide for fabrication, where the numbers correspond to the components described below (Figure 2).

1. Base: The base was constructed from a 1.9 cm melamine containing hard board and dimensioned to 51.1 × 35.6 cm.
2. Magnet: The material used to hold the magnetic base of the articulating arm was made out of 0.3 cm thick sheet metal and dimensioned into a 24.1 × 15.9 cm piece. This piece was then fitted to the base leaving 2.5 cm. from the top of the board and flush with the right side of the board.
3. Arm Rests: The arm rests were fabricated by cutting a hollow 0.6 cm thick acrylic cylinder (17.8 cm radius) in half and lining it with 1.3 cm thick polyurethane foam. These rests were then mounted on wood supports measuring 9.5 × 9.5 × 6.3 cm. The wood supports were then attached to the base using wood screws. Support A was positioned 15.2 cm from the top of the base and 2.5 cm from the left side of the base. Support B was positioned 16.5 cm from the top of the base and 2.5 cm from the right side of the base.
4. Articulating Arm: The articulating arm was purchased from Noga Engineering (Model No. NF60103) and the dimensions can be found at the manufacturers website.
5. Bridge: The bridge used to connect the articulating arm to the gooseneck was constructed out of thin steel and dimensioned to 1.3 × 3.2 cm. Two 0.6 cm holes were drilled in either end (from the top and bottom respectively, the distance to the center of the hole was 1.3 cm) to provide clearance for proper anchoring.
6. Probe Holder: The probe holder was constructed out of a thin steel metal measuring 3.2 cm × 8.9 cm x 0.2 cm. A hole for the connection screw was drilled 1.3 cm from the center of the hole to the top of the probe holder. Velcro (McMaster-Carr, Model No. 6605K51) was used to secure the probe to the probe holder, however this can be altered if one so chooses.

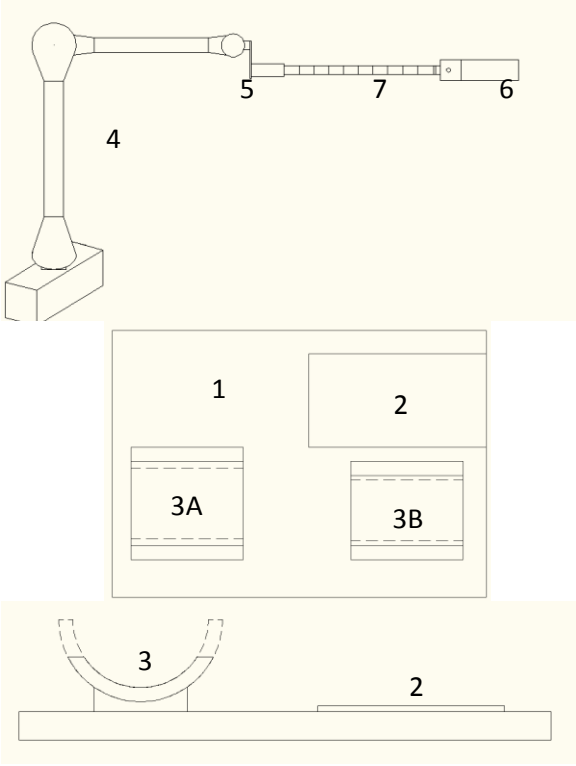

Figure 2 – CAD drawings of device with dimension keys.

7. Goose Neck: The gooseneck was purchased from Harbor Freight Tools (Cen-Tech, Model No. 93051)and the dimensions can be found on the manufacturer's website.

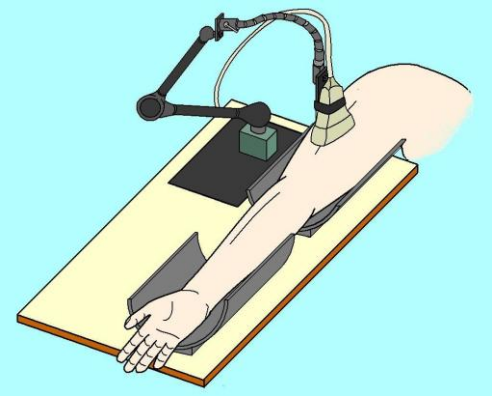

Figure 1 – Schematic of the device in use.

Structural Integrity

In order to verify that the device was able to withstand the typical loads applied by the ultrasound probe, a simple stress–strain analysis was taken. Forces (Accuracy to 0.5 N) were applied to the tip of the device in a typical configuration and the corresponding deflections were measured. Additionally, a certified ultrasound technician was asked to estimate the typical amount of force necessary to obtain an image to a force gauge. This number was doubled to account for variability when establishing the upper limit of forces necessary to be withstood by the device.

Brachial Arterial Reactivity Testing (BART) Procedure

The Institutional Review Board of our institution approved the study, and informed consent was obtained from each subject. BART procedures were conducted on a test population of healthy individuals aged 18 to 25. Subjects were selected on a volunteer basis. No physiological screening was conducted beyond filtering from known existing cardiovascular irregularities. Each subject underwent two BART studies, one with the device in use and one based on the standard technician-only protocol. The order of study was randomized to offset a learning bias in time studies. In each case, the subject was first prepped and stabilized. A certified ultrasonography technician then searched for the ideal image aspect of the brachial artery. When the ideal ultrasound image was within focus, the technician then obtained a baseline Doppler reading of blood-flow velocity. After this, a tourniquet-style blood pressure cuff already positioned around the subject's forearm was inflated. With blood flow of the brachial artery occluded, a 5 min timer was then set. At this point, if the study were conducted without the device, the technician was required to remain at the patient retaining the image of the artery. However, with the device in use, the technician was free to move about the study room, making any adjustments necessary. After 5 min, the blood pressure cuff was released, a second Doppler was taken and the patient's artery was monitored for an additional 2 min.

Validation

Throughout both forms of the study, detailed timing measurements were taken of actions taken by the sonographer. Key time elements obtained were set-up, seeking to the ideal image, and total study length. Average and deviation of the time elements were computed to identify any discrepancies between the two methods. After the studies were completed a second ultrasound sonographer, blinded to whether or not the device was in use, was asked to score the exams on quality and relevance. Feedback from the sonographers interacting with the device was also solicited to identify any discrepancies.

Results

Structural Integrity

It was found that a typical force applied to the transducer end of a probe during a study was below 3.5 N, therefore an upper-requirement of 7 N was established. The device was subject to forces of up to 20 N at 4 N increments and the resulting deflections are shown in Fig 3. Below

12 N of force, plasticity in the device was observed such that the tip of the arm would return to its original position. At 16 N the deflection after the force was removed was 0.32 cm and at 20 N and the deflection after the force removed was 0.91 cm. Despite these deflections, it should be noted that such offsets were well beyond the intended use limits.

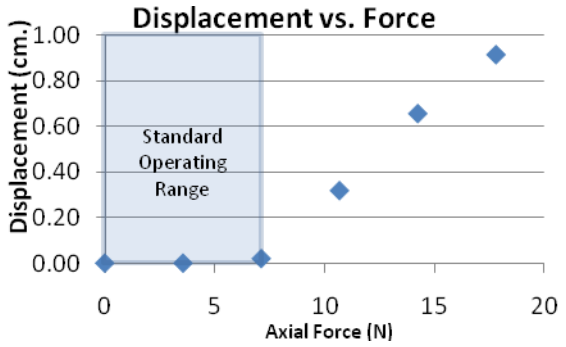

Figure 3 – Displacement vs. Force. Within the standard operating range, the displacements are negligible.

Time-Study

The results of the time study showed that the average time of a study conducted with the device was 12:56 ± 2.02 min while the average time of a study conducted without the device was 16:30 ± 6:33 min. The largest variation was in setup times where the device required an average time of 4:30 min but without the device it required an average time of 5:40 min. Fig 4 summarizes these data. Because of the limited size of this study, however, the time data cannot be provided with statistical significance.

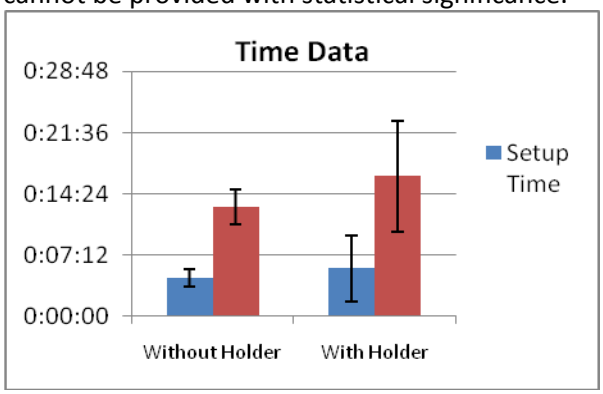

Figure 4 – Time Data in min. The probe holder did bring a minimal increase in the length of time

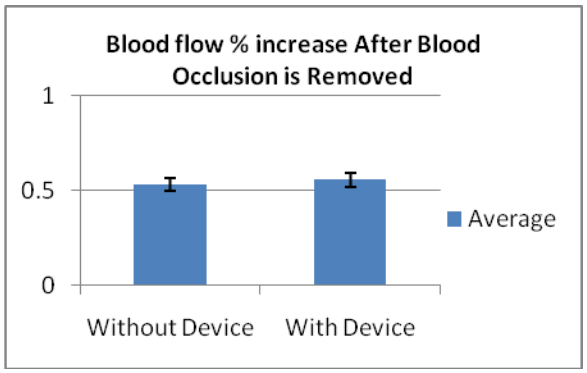

Figure 5 - Blood flow increase after release of pressure with and without the device. Almost no change was noticed with the device

Usability

Scoring of image quality was obtained along with anecdotal feedback of usability. The images obtained with the device had slightly lower quality. Nevertheless, quality was not compromised to a level that would make them invalid. All images obtained were scored as above an acceptable quality, despite a slight decrease in quality from the standard BART acquisitions without the device. User feedback was overwhelmingly optimistic however as technicians recognized the relief of occupational stress by using the device. The technicians noted they may even be able conduct studies on multiple patients at once with the device in use since they were not required to attend to the patient for the duration of the study. The relief of wrist strain from the removed requirement to hold the probe was also unanimously recognized as significant and beneficial.

Discussion

During the vascular reactivity study, the sonographer must hold their wrist in a deviated position for a long period of time. This position can pose a serious risk for development of carpal tunnel syndrome and other occupational hazards to the wrist[7]. Our device was designed to hold the probe for the sonographer throughout the study without sacrificing the

image quality. The device also contains a comfortable arm cradle that stabilizes the patient's arm throughout the procedure

Running reactivity tests both with our device and without our device yielded the result that our device was able to successfully hold the probe without a loss of image quality. It also took around 15 min for the study, which was about the same without the device. The sonographers reported that the device was easy to use, had excellent image quality, and was able to show the vessel's true diameter throughout the procedure.

Because the time of the test with the device was still about the same as without it, the sonographers will now be able to do more tests during the day. Because OSHA[6] limits the sonographers to only one test per hour, this will allow them to do up to 4 tests per hour. Also because the device is effective it will free the sonographer from positioning and allows them to administer other tests. This could potentially reduce the personnel that are required for the studies.

This device will greatly benefit the ultrasonography field as testing procedures may be improved by maintaining current quality while decreasing occupational stress which can lead to the sonographer developing carpal tunnel syndrome. Additionally, more comprehensive testing will be able to be completed since some of the OSHA[6] safety requirements will no longer limit the number of studies that can be conducted in a given time period. The knowledge of Atherosclerosis and endothelial function may be improved with the completion of studies using the prototype.

Conclusions

The ultrasound probe holder was able to be used during the vascular reactivity tests without causing any loss of image quality. This device enabled the sonographer to not have to hold the probe throughout the study and freed them to perform other tests. With this device in use, it has effectively enabled more vascular reactivity tests to be run throughout the day while significantly reducing the chance of carpal tunnel syndrome.

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To whom it may concern,

The following report includes work done by University of Wisconsin-Madison undergrads in the department of Biomedical Engineering on an Ultrasound Probe Holder in response to a project request from Dr. James H. Stein. The report is broken down into three sections as detailed below:

1. Technical Paper describing design and fabrication of the final device.
2. Journal Article submitted to the Journal of Ultrasound in Medicine.
3. IRB submission, approval, and consent.
4. Raw data collection.

Ultrasound Probe Holder

Final Design Report

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12/9/2009

Abstract

Vascular reactivity studies will greatly increase the understanding of atherosclerosis, inflammation of the arteries. Advanced atherosclerosis may result in thrombosis, which causes heart attacks and strokes. Examining the brachial artery reaction to occlusion requires continuous acquisition of ultrasonic imaging during an atherosclerosis study, which last five minutes or more. Due to the length of the studies and the deviated wrist position that the sonographer must maintain throughout a trial, brachial artery imaging poses serious risks for development of carpal tunnel syndrome. A design was drafted for a prototype that would release the sonographer from holding the probe for the entirety of the trial. The position of the probe can be established with a train of ball and socket joints and then locked into place by the control of one lever. The prototype also contains a comfortable arm cradle that stabilizes the patient's arm. Future work will include verifying that the prototype's performance is comparable to that of a professional alone and if it provides a time saving aspect to the work flow.

Contents

Problem Statement

To reduce the occupational hazards incurred while administering the study of arterial reactivity, a simple, stable, adjustable probe holder is needed. The functions provided by such a holder would reduce wrist injuries and could potentially improve productivity. The device should be able to be finely adjusted with 6 degrees of freedom and free the hands of the technician for the duration of the study.

Introduction and Motivation

The use of ultrasound for the study of vasculature health has become common practice in medicine. Ultrasound can be used for a variety of diagnostic techniques including arterial imaging and blood flow measurement. This design project focuses specifically on the use of ultrasound in vascular reactivity studies of the brachial artery. Reactivity studies are conducted on patients to monitor the epithelial response of the tissues to pressure changes in the vasculature (Coretti, *et. al.,* 2002). Abnormalities can be early indicators of atherosclerosis (Harrison, *et. al.,* 1987). Thus, improvement of the techniques for obtaining vascular ultrasounds can provide medical staff with a more effective and reliable means of diagnosis.

The reactivity study under specific focus for this project involves the use of ultrasound on the upper arm of a patient. The brachial artery is imaged for more than 5 min at one position. Typically, a sonographer will properly position the probe and then hold it in the desired position for the duration of the study. While the study is conducted and the vasculature is monitored, the blood flow through the artery is restricted with a tourniquet style blood pressure cuff downstream of the imaged area. As pressure builds up in the brachial artery, vascular response is observed, then after a certain time, the cuff is released, again eliciting a reactive response of the artery (Korcarz).

The limitations to this current method are not difficult to recognize. The reliance of a sonographer to stabilize the probe is not only inefficient, but also does not ensure that the same region of the artery is being imaged throughout the study. Furthermore, the practice of the study puts undesirable stress on the sonographer, who often must sustain unhealthy postures that may lead to musculoskeletal injuries, such as Carpal Tunnel Syndrome.

In this report, the specifications of how to stabilize and efficiently position an ultrasound probe have been investigated. Several different methods have been identified and analyzed. The application of a positioning system in to the broader specifications of the device are also addressed, including the task of holding the ultrasound probe and stabilizing the patient's arm to ensure image stability. The positioning device has been established. Preliminary evaluation of the prototype has shown to be successful. A comprehensive validation plan has been designed and is currently under institutional review for implementation.

Specifications

Below is an overview of the considerations for the design. For more detailed and quantitative specifications, see Appendix A for the Design Specifications.

Positioning Freedom

In order to correctly image the artery, the probe must have six degrees of freedom. The two lateral directions, along with the vertical direction, would be used mainly as a rough adjustment to find the artery. These movements would enable the sonographer to move the probe from its resting position to the upper arm of the subject. Once the probe is in position, the three rotational degrees of freedom would be used to obtain the best image possible since the probe must be perpendicular to the artery. The rotational movement will allow differential pressure to be applied to the arm, an important quality for image resolution. Finally, when the stimulus—the pressure applied to the lower arm—is removed, the artery may shift slightly and the probe will have to be readjusted. Finding the correct position again may require all six degrees of freedom as modeled in Figure 1 - Degrees of Freedom needed for proper positioning. Therefore, the probe's ability to move freely in all directions is a vital component of the design.

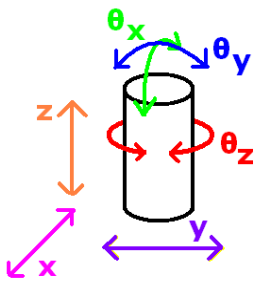

Figure 1 - Degrees of Freedom needed for proper positioning.

Adjustment abilities

The device should be easily adjustable and sensitive to fine tuned movements. When beginning a study, the sonographer will orientate of the probe with very subtle adjustments in order to obtain the proper cross sectional image of the artery. However, the location of the artery within a patient may be subject to slight shifts throughout a study due to the pressure changes on the arterial walls. The device must allow for quick, fine tuned adjustment of the probe position with as little complexity as possible. Similarly, minimizing the set up time of the exam and the required labor to position the probe is also essential. Simple but accurate adjustability is one of the main requirements of any design option.

Accommodation of Probe Varieties

The final design of the device should be able to accommodate a variety of different ultrasound probes. Although the general dimensions of different probes are within a common range, they can vary in their shape and orientation. Either a universal or modular clamping mechanism must be designed to accommodate the variety of probe shapes. Figure 2 shows three examples of common probe designs, each about 20 cm long and 8 cm wide.

Figure 2 - Variety of probes to be accomodated in design. All of similar sizes, but contours vary significantly

Ergonomics

The usability of this device is key to its success in improving ultrasound studies. The ultimate goal of the probe holder is to simplify the ultrasound procedure and improve its consistency. Therefore, considerable attention was given to the ease of use of the device, which is to allow the most freedom and control with the least amount of adjustments. The device must be able to integrate into the workflow without hampering or impairing the flexibility of the sonographer. A device which does not require much training to operate will be the most desirable.

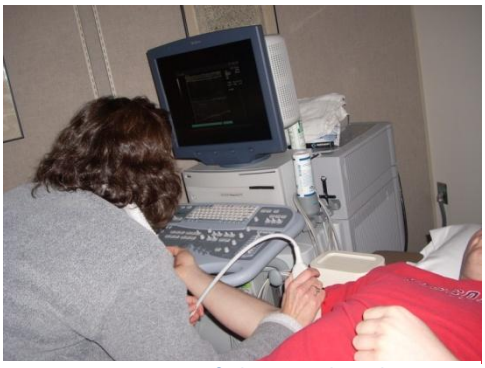

Figure 3 - Image of ultrasound workspace layout. Sonographer (left) will be required to hold the probe in the shown position for 5+min. The wrist is in a radially deviated posture.

There is a significant element of occupational ergonomics to this device as well. A well designed device will reduce or eliminate the occupational stress on the sonographer associated with poor wrist postures (Figure 3). A sonographer holding the probe in the position shown has a radial deviation of the wrist which, over time, can put unhealthy pressure on the Carpal Tunnel and lead to musculoskeletal disorders (Keir *et al.,* 1997). In the laboratory where this device is to be implemented, OSHA limits a sonographer to one study per hour due to the stress that the procedure can induce on the test administrator (OSHA). The implementation of this design could potentially relieve some of the stresses associated with conducting these studies, and allow a sonographer to complete more studies in less time.

Design Considerations

Positioning Mechanism Options

Design Rating Criteria

Six main characteristics were taken into consideration when choosing a design for this project: cost, weight, gross adjustment, fine-tune adjustment, range and reliability. These criteria and their associated importance were determined by the client's requirements.

The most important aspect of this device is that it improves the ultrasound procedure. However, it must not impede the workflow and efficacy of the sonographer. The ability to make all the necessary adjustments is paramount to the integration of this device into a healthcare setting. The device should be able to make fine tuned adjustments as well as gross adjustments with the same efficiency.

The second most important criterion for this device is angular range. The device must ensure that the probe can be placed in a 100 degree range around the arm to accommodate the majority of patients, since arterial orientations within the arm can vary.

The reliability of the device is important for the quality of the image and it frees the sonographer to do other activities during the procedure. Ideally, the final product would be rigid enough that the

sonographer can set the probe in place and then do other things while the procedure is being conducted.

The weight of the device is taken into account because it increases the usability of the device. If the device is too heavy and bulky to adjust, then the sonographer will have a hard time using it and will struggle to make any adjustments.

Lastly, the cost must be considered. A vascular ultrasonic machine may cost between $10,000 and $20,000, so a budget of a few hundred dollars or more is not unreasonable. The primary focus of this project is on quality and functionality rather than cost. Even though minimizing the cost is always a goal, it is not a main goal for this project.

Option 1 – Articulated Arm

The articulated arm functions just like a human arm (Figure 8). There are two ball and socket joint sand a hinge joint that provides 7 degrees of freedom. The entire device is controlled by one knob, which makes it easier to use and adjust. Fine tuning adjustments can be made at the end of the devices. The fine tuning will be beneficial if the artery shifts slightly as a result of the reduction in pressure. While this device is costly and bulky, it provides a wide range of motion. The device can hold its shape and the necessary pressure for long periods of time. It is easy to use, reliable and capable of supporting forces much greater than needed.

Figure 4 - Several Articulated Arm models. One knob at the corner joint tightens all three joints, allowing size degrees of freedom with one adjustment. From Noga Engineering.

Figure 5– Gooseneck that is made up of a series of ball and socket joints that can be tightened.

Option 2- Gooseneck

The gooseneck (Figure 5) is essentially many ball and socket joints linked together with a cable running through the middle. Each ball has limited rotation abilities, but the collection of all the joints allows the snake to have a wide range of motion. The cable can be tightened to act as a locking mechanism. It pulls all the links together so the friction between them does not allow them to move freely. With this design, the probe can be repositioned and adjusted easily. This design is very easy to use, cheap and relatively easy to replace in the event of a malfunction. A single knob makes the device easy to operate. The limitation to this concept is that the range of motion is restricted. A larger range of motion can be attained by increasing the length of the arm, but doing so reduces the maximum load capacity of the device.

Option 3 – Hybrid

The hybrid combines the gooseneck and articulated arm into one device. This provides the user with a wider range of motion with the probe and enables the sonographer to make small adjustments. The gooseneck is attached to the end of the articulated arm with the clamping mechanism at the other end. The articulated arm provides rigidity and gross adjustments while the

gooseneck enables easier fine-tuned adjustments and a wider range of use. This device is the most complicated and expensive and it is the heaviest of the three options

Design Matrix

The three design options were analyzed using the following criteria: cost, weight, gross adjustment, fine-tune adjustment, range, rigidity. Based on the client's requirements, each category was given the following weights: cost – 5%, weight – 10%, gross adjustment – 25%, fine-tune adjustment – 30%, range – 20%, and rigidity – 10%. Based on the design matrix show below the hybrid design was chosen as the final design.

Table 1 - Design Matrix

	Score	Arm	Gooseneck	Hybrid
Cost	5	5	5	5
Weight	10	6	7	5
Gross Adjustment	25	22	17	20
Fine-tune Adjustment	30	15	28	28
Range	20	20	4	20
Rigidity	10	10	8	8
Total	**100**	**78**	**69**	**86**

Probe Clamping

3 Pronged Clamp

A 3 pronged clamp was implemented last semester (Figure 6). The prongs on the clamp fit around each size of probe and they can be tightened with screws to ensure that the probe does not move during the procedure. The prongs have a rubber casing around each tip to ensure that the probe is not damaged. The clamp's rod attaches to the positioning device. However, initial testing by the client indicated that the usability of the 3 pronged clamp may slow the ultrasound procedure. Primarily, use of the device required more than one hand. The complexity of

Figure 6 -A 3 pronged clamp that could be used to hold the probes in position. The two screws are used to tighten the clamp when it is in the correct position.

attachment to the positioning arm added unnecessary complexity to the design. Therefore, more intuitive and user-friendly clamping was sought.

Plate System-"sandwich"

A plate system composed of two parallel HDPE plates that could be tightened to fit different sized probes was initially constructed this semester (Figure 7). The inner surfaces were lined with neoprene rubber to cushion the probe while several adjustable screws connected the two plates and could be tightened to secure the probes. Initial testing of this clamping system by the client revealed that the design was not able to maintain the needed torque applied once the positioning device was locked in place, due to a lack of rigidity in the HDPE. To add rigidity, one of the HDPE plates was replaced with an aluminum one. For both designs, however, it was difficult to switch probes and the system was bulky.

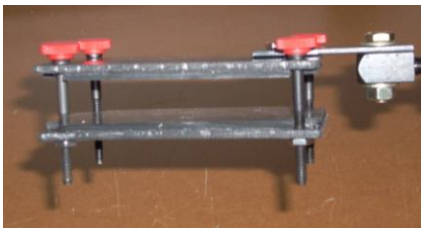

Figure 7 - Sandwich clamping concept

Velcro Straps

To reduce bulkiness and maintain rigidity, the final design consists of a small metal bar which attaches to the positioning device and the transducer is secured to the bar with Velcro (Figure 8). This design accommodates many sizes and allows for quick interchanging of probes. The Velcro straps provide enough rigidity so that the probe does not move under normal amounts of torque required to obtain a proper ultrasonic image.

Figure 9 - Velcro attachment concept

Arm Cradle

Arm cradles are needed to provide support for the arm so that it does not move during the procedure.

Dimensioning: Anthropometric Design Accommodations

The dimensioning of the arm cradle required considerable care to ensure the device would comfortably fit to a large range of patient sizes. Since two segments were used, the dimensions considered were the diameter of the cradle, and the lengths and spacing of each cradle. Approximations for limits were calculated based on anthropometric data from the US Army Survey completed in 1988. Using the normalized data from this survey, estimates for accommodation were made.

The dimensioning of the diameter of the cradle was specified to the bicep circumference, and therefore a calculation for the maximum size accommodated was taken for a male in the 95^{th} percentile. This afforded a minimum inner diameter of 12.42 cm. Then, with the addition of a 0.63 cm of foam padding on the cylinder, the minimum inner diameter of 13.69 cm was determined. Based on available supplies a tube of inner diameter 14 cm was selected.

The length of the support segments were then calculated to accommodate the shortest arm lengths anticipated. From the same set of anthropometric data the total arm length, upper arm and forearm

lengths of a 5th percentile female were calculated. The key data determined was the total arm length of 48.90 cm. In order to allow room for both the tourniquet style blood pressure cuff and the patient's elbow, a spacing of 15.25 cm was determined optimal between cradles. The forearm and upper arm lengths of the smallest individual are 20.9 cm and 30.12 cm, respectively. The length of each cradle was selected to be 15.25 cm to accommodate for each arm segment.

The design of these dimensions were intended to allow for supportive positioning while avoiding any major pressure points that may disturb the results of the study. The cradle should be positioned such that the elbow is centered over the gap between supports. This avoids placing any significant pressure at the elbow, wrist or axilla. Complete calculations for the above dimensioning are shown in Appendix A.

Previous Design

From the anthropometric data above, a hollow acrylic cylinder was cut in half, lined with polyurethane foam, and mounted with wood supports (Figure 9). The acrylic tubes have an inner diameter is 14 cm, a length of 15.2 cm and the two segments are separated by 15.2 cm. The cradle was lined with closed cell polyurethane foam to cushion the patient's arm and to avoid pressure points on the arm. Wood supports attach the semi-circular cradle to the board. However, some concerns after preliminary testing indicated that the closed cell foam still appeared to be absorbing the gel used the ultrasound procedure and that the height of the arm cradle on the patient's upper arm may cause some pressure points discomfort for larger patients.

Figure 10 - Basic concept of cradle for stabilizing the forearm

New Design

The upper arm cradle's height was reduced by 2.5 cm so that no pressure points would occur for patients with larger arms. Both arm cradles were then covered with black vinyl to improve the overall aesthetics while making it impervious to gels, washable, and more comfortable for patients.

Construction Budget

Below are the costs associated with the construction of the device including raw materials and prefabricated components. Some items do not have costs associated since they were obtained through scrap or surplus supplies. Costs do not include shipping and handling fees for materials. All construction was completed in the Student Shop in the College of Engineering at the University of Wisconsin – Madison.

Table 2 - Cost of materials used in construction of first generation prototype.

Item	Supplier	Cost
Sheet Metal (1'x1')	Home Depot	5.84
Emory Paper	Home Depot	5.47
23 3/4 x 48 Melamine	Home Depot	11.98
1x4x2 Poplar	Home Depot	2.63
Positioning Arm w/ magnetic base	MSC-Direct	229.02
Acrylic Pipe	McMaster-Carr	27.17
3 Pronged Clamp	Fisher Scientific	39.83
Silicon Foam Rubber	McMaster-Carr	24.29
1/8" Low Carbon Steel	COE Machine Shop Scrap	0.00
1/2" Wood Screws	COE Machine Shop Scrap	0.00
HDPE Black 1/8 In T	Grainger	16.75
Rubber Neoprene 1/8 In	Grainger	16.75
Stops Rust White Primer	Menards	3 .97
Stops Rust Gloss Black	Menards	3 .97
J-B Mini Adhesive	Menards	2 .98
1/4-20x1 Hex Cap C	Menards	0 .29
1/4 SAE Flat Washer	Menards	0 .29
1/4-20 Hex Nut Coarse	Menards	0 .29
Dial Indicator and Holder	Harbor Freight	31.70
Nuts and bolts	Dorn Hardware	09.56
Vinyl Upholstry and Adhesive	Hancock Fabrics	14.20
Velcro Straps	McMaster-Carr	14.20
Total		**449.39**

Final Design

Based on the above analysis, a design for a modified prototype was drafted. The final design consists of the hybrid positioning device along with the Velcro strap clamping mechanism (Figure 10). The hybrid design provided the most range of motion while still being able to provide fluid adjustments and motion. The probe clamping mechanism proved to be the simplest design that was easy to use and the most reliable. Preliminary testing has verified its proof of concept while keeping costs at a minimum. When further testing has been completed, it will validate the design's ability to improve productivity and prevent occupational injury.

Figure 10 – Final design combining the hybrid positioning mechanism and the Velcro strap clamping mechanism.

Design Verification and Validation

The functional prototype presented above was used in several preliminary test environments to ensure its functionality and efficacy. However, a more thorough and quantitative test has been designed to verify the functionality of the device and validate how well it integrates into the study. Preparations for conducting these tests require approval from the Institutional Review Board (IRB) of the University of Wisconsin – Madison since the device will be used in a clinical setting with human subjects involved. The complete submission for institutional review is contained in Appendix C. This includes cover documents, the research protocol, consent forms for subject recruitment and conflict of interest disclosure. Below the protocol is broadly described. These tests are broken into two main categories: usability and efficacy.

Device Usability

The device should integrate into clinical work flows as seamlessly as possible. To score the procedural impact, several tests will be conducted with and without the device in use. Three certified ultrasound technicians are available to participate in the study. The technicians will individually conduct a series of typical brachial reactivity studies by traditional procedures without the device and aspects of set-up and execution will be timed and documented. Human subjects to be used will be recruited on a voluntary basis. The requirements for participation include that the subjects are of healthy adult age without vascular abnormalities. As a preliminary study, a sonographer will conduct studies on five patients without the device, and then five different patients with the device. The set-up and complete procedural times will be measured for each study.

The current resources to this study limit the number of available participants. Therefore, it is desirable to identify the statistical confidence of the data and determine if more participants will be needed in an expanded study to properly validate the impact on work design and study lengths. Once data for the five subjects in each study is taken, the mean and standard deviation will be used to calculate the confidence level of the obtained range. A confidence level of 95% will be sought to identify a confidence interval of expected average times of each study. If the results do not yield this level, the study will require expansion and recruitment of more subjects.

The ultimate goal is to identify if or by how much the use of the device may alter procedural times. It is expected that the initial set-up time with the device will be larger than without because more parameters of setup must be made before the study can begin. However, during study administration, the device may be capable of reducing the time necessary by eliminating time lost to readjustment. Also, with the sonographer freed from having to hold the probe to the patient, they may be able to complete other aspects of the study with more efficiency.

To supplement the timed data for setup times, anecdotal data will also be sought from each of the three technicians after they have used the device for an extended period. Feedback of ease of use of the device will be used for continual evaluation for potential modifications and improvements. The technicians are poised to directly benefit from an effective and improved device, so their feedback will be taken with significant weight.

Procedural Efficacy

As stated in above sections, one of the primary goals in the development of this device is the relief of occupational health hazards. Any increase in length of study may also be overcome by the ability to conduct more studies within a given time frame since less rest time will be required for sonographers between studies. It is important to verify that the device does not degrade quality of data obtained during a study. Because of the added stabilization, a more consistent image throughout a study may be obtained with the device and actually improve the quality of data.

To rate the impact of the device on data gathered, data from studies conducted with and without the device will be used. A sonographer will be presented with the data obtained by a different technician. Without being told whether or not the device was used, the sonographer will be asked to evaluate the

quality of data. The sonographers will rate image quality, ability to identify structures, and confidence in comparing morphological elements throughout a study, each on a scale of 1 to 10. A consistent image and ability to identify features in each image is crucial. The numerical ratings will be used to identify if one study provided more ability and confidence over another.

Once again, direct feedback will be asked from sonographers after completing each use with a series of question to rate the ability of completing the procedure with the device. Areas of questioning will include, but are not limited to, the ability to keep image consistent, the ability to regain a desired image if necessary and the ability to complete other tasks while the device is in use (i.e. use a second Doppler probe, engage a tourniquet to occlude blood flow, administer a treatment to the patient).

Potential Impacts of Results

Once results of ease of use and timing impacts of the device are known, it may be possible to reformulate workflows in atherosclerosis clinics. If the device is effective in freeing the sonographer from positioning and allows them to administer other tests, personnel required for some studies may be reduced. Once device effectiveness and efficacy is verified, large scale workflow analyses could be conducted to evaluate the impact the device may have in the workplace. While currently no comparable devices exist on the market, workflow optimization could benefit clinics and research laboratories around the country. If a market demand can be identified, intellectual property protection may be pursued.

Professional and Ethical Considerations

The testing protocol must be approved by the IRB since it will involve human patients. With certified ultrasound technicians, the risk is minimal to patients as the procedure will follow standard approved ultrasonic protocols. The only deviation between the study and normal procedures is that the transducer will be held by the prototype instead of being manually held by the sonographer. Once the use of the prototype has been approved by the IRB, testing can be done to determine the efficacy and ease of use of the prototype. The results will greatly benefit the ultrasonography field as testing procedures may be improved by maintaining current quality while decreasing occupational stress which can lead to the sonographer developing Carpal Tunnel Syndrome. Additionally, more comprehensive testing will be able to be completed since some of the OSHA safety requirements will no longer limit the number of studies that can be conducted in a given time period. The knowledge of Atherosclerosis and endothelial function may be improved with the completion of studies using the prototype.

Conclusions

The second generation probe positioning device has been constructed and verified to be functional on a preliminary basis. With a functional prototype fully constructed, future work will focus on carrying out the validation plan outlined above. That said, other potential improvements or added features to the device will be continually considered. Preliminary testing has shown the device is effective in meeting the main goals of the project: positioning freedom and prolonged stabilization of the probe to sustain an

image over an extended study. In achieving these goals, the device may relieve occupational health hazards and provide a potential for improved efficiency in the clinic and streamlined workflows.

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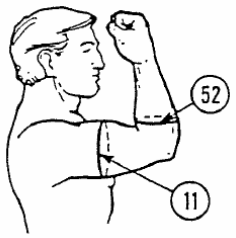
Appendix A – Anthropometric Calculations

Cradle Diameter:

a.



- Bicep Circumference, Fixed (Measurement 11 Figure A1.a at Right):

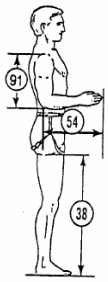
  Male Mean = 33.76 cm, SD = 2.72 cm

  33.76+ 1.96 (2.72) = 39.07 cm

  Minimum Inner diameter = 12.42 cm

  Selected Cylinder with inner diameter of 14 cm. to allow room for foam padding (0.64 cm thick).

b.



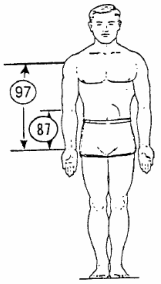
Cradle Lengths:

- The maximum length of the cradles were determined from lengths of 5th percentile Females
- Upper Arm from Shoulder-Elbow length (Measurement 91 Figure A1.b at Right):

  Female Mean = 33.58 cm, SD = 1.73 cm

  33.58 – 1.96 (1.73) = 30.18 cm.

c.



- Forearm from Radiale-Stylion Length (Measurement 87 Figure A1.c at Right):

  Female Mean = 24.33 cm, SD = 1.55 cm

  24.33 - 1.96 (1.55) = 20.9 cm.

- Total Arm Length from Sleeve Outseam Length (Measurement 97 Figure A1.c at Right):

  Female Mean = 54.81 cm, SD = 3.02 cm

  54.81 – 1.96 (3.02) = 48.9 cm

Figure A1 - Illustrations of dimensions used in anthropometric calculations.

a. Measurement 11 provided sizing for Bicep Circumference.

b. Measurement 91 was used for the Shoulder Elbow Length.

c. Measurement 87 was used for Forearm length, and Measurement 97 was used for total arm length

For simplicity of construction, the length of each cradle was selected to be 15.25 cm to stay within the limits calculated. A 15.25 cm gap was added to give a total length of the cradle to be 45.72 cm, below the calculated minimum arm length

Appendix B

Project Design Specification—Ultrasound Probe Holder (Group 42)

Leon Corbeille, Neal Haas, Peter Kleinschmidt, Lein Ma

December 9, 2009

Function:

A simple, stable, adjustable ultrasound probe holder to aid in the ultrasonography of arterial reactivity. The holder would stabilize the ultrasound probe to improve image quality and reduce motion artifact for better diagnostic effectiveness. The device should reduce strain on the sonographer by decreasing the amount of time the probe is handled.

Client Requirements:

- Provides 6 degrees of positioning freedom
- Stable, no movement after being positioned
- Adjustable for small changes during study
- Cost efficient
- Ergonomic
- Cradle to stabilize patient arm
- Accommodate a variety of probe sizes

Design Requirements:

1) Physical and Operational Characteristics
    a) *Performance requirements* – Easily adjustable without interfering with the ultrasound procedure, able to make small adjustments quickly, securely holds the probe, stabilizes the patient's arm while in use, must hold the probe stable for 5 to 10 min periods. It should function with 6 degrees of freedom. The device should move the probe to any position between 20° to 120° from horizontal.
    b) *Safety* –The materials should not be hazardous, and should not interfere with the ultrasound procedure.
    c) *Accuracy and Reliability* – The device should be able to make small changes quickly and hold its position throughout the procedure. Once the positioning device is set, the probe should have a 30° range of heel/toe movement.
    d) *Life in Service* – The device should last at least 5 years.
    e) *Shelf Life* – The device should be able to be stored indefinitely without compromising its integrity.
    f) *Operating Environment* – The probe holder will be used in typical laboratory and clinical settings.

g) *Ergonomics* – The device should be able to accommodate a large range of users (95th percentile male) without interfering with the ultrasound procedure.
h) *Size* – The platform of the device should be less than 3 feet long and 2 feet wide. The probe clamp should be small enough (12.7 by 10.2 cm) to fit into the sonographers hand once the probe has been secured.
i) *Weight* – The probe should be as lightweight as possible while proving a stable support. The device should be less than 30 kilograms
j) *Materials* – The materials should be cost efficient and should not interfere with the ultrasound procedure.
k) *Aesthetics* – The device should be aesthetically pleasing and blend in with the examination room.

2) Production Characteristics
   a) *Quantity* – Only one product is currently needed, but it should be designed with the intention of mass production.
   b) *Target Product Cost* – The device should cost less than $1000.
3) Miscellaneous
   a) *Standards and Specifications* – Because this device is only for research purposes, there are currently no standards.
   b) *Customer* – The device will be used by medical personnel in a laboratory or clinical setting.
   c) *Patient related concerns* – The device should not harm the patient.
   d) *Competition* – There are currently some ultrasound probe holders in use, but none are available commercially.

Appendix C – IRB submission Forms

Document 1 – Student Letter

We are Biomedical Engineering design students working on our capstone design project in the UW College of Engineering. Part of the curriculum is to verify that the prototype accomplishes the goals set up by our client, Dr. James Stein. Since this is part of an academic project, we are limited by the timeline of this semester and need to complete testing before December. We would appreciate it if you would expedite our application process.

The device will be used to hold an ultrasonic probe for atherosclerosis studies in a clinical research setting. Ongoing studies that might use such a holder already have been approved by regulatory boards, but their progress could be improved by use of an ultrasound probe holder. Dr. Stein's lab approached us to create a device that will allow them to reduce occupational risks, increase the number of patients they can scan in a day, and potentially improve image reproducibility over time. Currently, the sonographer holds an ultrasonic probe with his/her wrist in a deviated position, over the brachial artery for about five minutes. Our clients wish to eliminate this strain by having a device which will hold the probe for them once it has been placed.

The basic functions of the device will be to comfortably stabilize the patient's arm and to retain the probe's position once it has been locked into place. The probe will be grasped by an articulated arm which can accommodate any orientation of the probe along the patient's upper arm. The joints in the articulated arm have the ability to be loosened, repositioned, and then locked to place easily so the sonographer will be able to handle all operation independently (figure 1).

The device does not directly interact with the patient and poses no danger. The aim of this protocol is to test the effectiveness of the device when compared to current procedures without the device. The protocol requires ten subjects and the testing could be completed within two weeks. We will appreciate a timely review of this protocol so that we may have adequate time to conduct our investigation.

Document 2 – Consent Form

University of Wisconsin-Madison

Research Subject Information and Consent Form

Title of Study: "Prototype evaluation for ultrasonic probe holder to perform brachial artery imaging"
Study Investigator: James H Stein, MD
Version and Date of Consent Form: Version 3, March 8, 2010

INVITATION AND SUMMARY
You are invited to take part in a research study that is testing a prototype (preliminary) ultrasound probe holder that was developed by biomedical engineering undergraduate students. Your participation is voluntary. Approximately 10 subjects will participate in this study. This study involves 1 visit. The main study procedure will evaluate if the prototype can act as a reliable substitute for a trained human holding an ultrasound probe while using ultrasound to bounce sound beams off of your upper arm artery. If you decide not to participate, any relationship you have with the University of Wisconsin-Madison (UW-Madison) or the University of Wisconsin Hospitals and Clinics (UWHC) will not be affected in any way.

PURPOSE OF THE STUDY
The purpose of this study is to test the effectiveness and ease of use of the prototype probe holder.

WHAT WILL MY PARTICIPATION INVOLVE?
If you decide to participate in this research study, you will be asked to lie supine on a hospital bed during the procedure with your right arm extended 90 degrees from your chest for about 30 minutes. While on the bed, two ultrasound studies will be conducted on your brachial artery, each lasting approximately 10 minutes. During the 10 minutes, the ultrasound probe will be carefully positioned, a tourniquet-style blood pressure cuff will be applied below the elbow and pressure will be applied for approximately 5 minutes. Pressure will then be released and your brachial artery diameter will be observed for 3-5 minutes.

You should not experience any pain or discomfort in the study, although your arm will be in the same plane as the bed and resting on the devices' arm cradle forming a 90 degree angle. A silicon based contact gel will be used as part of the ultrasound procedure and the probe will apply some pressure to your upper arm. One procedure will be done using the device and the other will be done without the device. Your whole participation will last about 40 minutes.

ARE THERE ANY RISKS?
The main risk of taking part in this study is that your study information could become known to someone who is not involved in performing or monitoring this study. However,

this risk is extremely minimal as we will not collect any identifying information from you and the data collected will be saved under a randomly assigned subject identification number. No personal information will be recorded. The ultrasound system used fits within FDA approved guidelines.

ARE THERE ANY BENEFITS?

You are not expected to benefit directly from participating in this study. Your participation in this research study may improve the way this procedure is conducted in the future. The probe holder may assist the technician by minimizing fatigue and work related injuries secondary to repetitive use. It may also improve the quality of data obtained in a research setting. The probe holder does not present an immediate clinical application.

ARE THERE ANY COSTS?

There are no financial costs.

WILL I BE PAID FOR MY PARTICIPATING IN THE STUDY?

You will not be paid to take part in this study.

IF I DECIDE TO START THE STUDY, CAN I CHANGE MY MIND OR CAN I BE WITHDRAWN FROM THE STUDY WITHOUT MY PERMISSION?

Your decision to take part in this study is voluntary. You do not have to sign this form and you may refuse to do so. You may completely withdraw from the study at any time.

WILL MY CONFIDENTIALITY BE PROTECTED?

Researchers might use information learned from this study in scientific journal articles or in presentations. No identifiers nor personal information will be collected from you and therefore will not be published or presented.

WHAT IF I HAVE QUESTIONS OR CONCERNS?

If you have problems, concerns, questions, or complaints about the research, or about research- related injuries, you can contact the study investigator, the UWHC Patient Relations Representative, or University of Wisconsin Medical Foundation Patient Relations Representative. If you have any questions about your rights as a research subject, you can contact the UWHC Patient Relations Representative or University of Wisconsin Medical Foundation Patient Relations Representative.

The study investigator, James H Stein, can be contacted at 608-263-9648.
The UWHC Patient Relations Representative can be contacted at 608-263-8009.
The University of Wisconsin Medical Foundation Patient Relations Representative can be contacted at (800) 552-4255 or (608) 821-4819.

<u>Authorization to participate in the research study:</u>

I have read the information in this consent form, reviewed any questions, and I voluntarily agree to participate in this study. I have received a copy of this consent form.

Signature of Subject	**Date**
Signature of Investigator or Person Obtaining Consent	**Date**

Document 3 – Conflict of Interest Form

University of Wisconsin-Madison Health Sciences IRBs Potential Financial Conflict of Interest (COI) Assessment Form for Applications for Initial Review of Research Involving Human Subjects Version Date: July 3, 2008			DO NOT WRITE IN THIS AREA
This form must be submitted with all *Applications for Initial Review of Research Involving Human Subjects*.			
Protocol Title: "Prototype evaluation for ultrasound probe holder to perform brachial artery imaging"			
PI Name: James H Stein, MD			
	Please note that research participation is restricted when individuals have a significant financial interest in the entity or entities. Does ANY of the study team involved in the design or conduct of the research study, or their immediate family*, have interests related to the research that meet or exceed one of the thresholds below: Compensation of $20,000 or more in a calendar year from a business entity An ownership interest in a publicly traded business entity valued at $20,000 or more or a 5% or greater equity interest An ownership interest in a privately held business entity A leadership position in a business entity (Leadership positions are positions with fiduciary responsibility, including senior managers (e.g. presidents, vice presidents, etc.) and members of boards of directors. Scientific advisory board membership is not a leadership position.) A proprietary interest in the research, such as royalties, patents, trademarks, copyright, or licensing agreement, including any agent, device, or software being evaluated as part of the research study [Do not include those managed by the Wisconsin Alumni Research Foundation (WARF)]	☐ Yes	☒ No

	If yes, identify the personnel who have this interest and include copies of any management plans or documentation of exceptions granted from the campus Conflict of Interest Committee to allow the personnel to participate in this study:		
	Does ANY of the study team involved in the design or conduct of the research study, or their immediate family*, have a financial interest that requires disclosure to the sponsor or funding source? If yes, identify the personnel who have this interest:	☐ Yes	☒ No
	Does any of the study team receive incentives for recruiting human subjects or for any other purpose directly related to the study? If yes, describe the nature of the incentives:	☐ Yes	☒ No
	As PI for this protocol, I take full responsibility for the accuracy of the information provided in this form. PI Signature and Date		

* “Immediate family” includes spouse and dependent children

Document 4 – Application for Initial Review

University of Wisconsin-Madison

Do not write in space below – IRB Office use only

Protocol #

Application for Initial Review of Research

Projects Involving Human Subjects

Health Sciences IRB ▪ Health Sciences Minimal Risk IRB

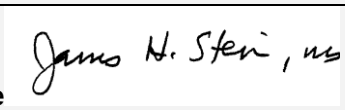
Before submitting an application, please review the instructions on the IRB website at www.medicine.wisc.edu/irb to ensure the correct documents and numbers of copies are provided. The number of copies required, when paper copies should be submitted, and the number of paper copies needed depend on whether the study is required to undergo institutional scientific review prior to IRB review. All questions must be answered. "Not applicable" is only an option where indicated.

I. STUDY IDENTIFICATION

1.	Study Title: **"Prototype evaluation for ultrasound probe holder to perform brachial artery imaging"**	
2.	Sponsor Protocol Number and Version Date:	☒ Not applicable
3.	Is this study being transferred to the University of Wisconsin-Madison from another institution? • If yes, attach documentation of IRB approval from the prior review of this study.	☐ Yes ☒ No

II. PRINCIPAL INVESTIGATOR (PI) & POINT OF CONTACT INFORMATION

A. PI INFORMATION AND RESPONSIBILITY STATEMENT

1.	Name: **James H Stein**
2.	Office Address: (street, city, state, zip code): **Cardiovascular Medicine Division** **G7/341 CSC, MC 3248** **600 Highland Avenue** **Madison, WI 53792**
3.	Academic/professional degree(s) (e.g., PhD, MD): **MD**
4.	Department: **SMPH, Department of Medicine, Cardiovascular Medicine Division, University of Wisconsin Atherosclerosis Imaging Research Program (UW AIRP).**
5.	Telephone: **(608) 263-9648**
6.	Fax: **(608) 263-1534**
7.	Pager: **(262-2122) 9525**
8.	As PI for this protocol, I take full responsibility for the accuracy of the information provided in this application and for the conduct of this research study, which includes ensuring all study team members have undergone adequate training to perform their responsibilities and have completed required human subjects protection training.
	PI Signature and Date  **11-09-2009**

B. POINT OF CONTACT INFORMATION – the point of contact is the person to whom IRB correspondence should be sent

1.	☐ This section is NOT completed because the PI is the point of contact for this project.
2.	Name: Claudia E. Korcarz, DVM
3.	Office Address: (street, city, state, zip code): 600 Highland Ave, MC 3248
4.	Department: Medicine (Cardiovascular Medicine)
5.	Telephone: (608) 265-9947
6.	Fax: (608) 263-1534

III. SPONSOR, FUNDING, AND FINANCIAL DISCLOSURE INFORMATION

☒	A *University of Wisconsin-Madison Health Sciences IRBs Submission Cover Sheet for Initial Review and Ongoing Studies* is attached to this submission. NOTE: If this document is not attached, the submission cannot be processed. This document is available under the *Forms* link on the Health Sciences IRBs website at www.medicine.wisc.edu/irb.
☒	A *University of Wisconsin-Madison Health Sciences IRBs Potential Financial Conflict of Interest Assessment Form* is attached to this submission. NOTE: If this document is not attached, the submission cannot be processed. This document is available under the *Forms* link on the Health Sciences IRBs website at www.medicine.wisc.edu/irb.

IV. STUDY TEAM IDENTIFICATION

1.	Will this study involve any faculty, staff, or other personnel as part of your study team that do not hold an appointment at or are not employed by the UW-Madison, University Hospital and Clinics, or Madison VA?	☐ Yes ☒ No
2.	Will this protocol involve any students as part of your study team person who are NOT employed by or enrolled at UW-Madison?	☐ Yes ☒ No
3.	Identify the study team members below, their credentials, departmental affiliation, and role. List all local study personnel and other personnel who fall under UW-Madison purview but who may not have a UW, VA, or UWHC appointment (e.g., UW-Madison serves as the IRB of record for a non-UW site) engaged in human subjects research. NOTE: The principal investigator of this protocol is responsible for verifying that any study team members engaged in human subjects research have completed the human subjects protection training that meets University of Wisconsin–Madison policy. In addition, the principal investigator is responsible for ensuring that individuals using protected health information (PHI) have completed HIPAA Privacy Rule training.	

Name	**Credentials**	**Department** **(if outside the UW, VA, or UWHC - identify institutional affiliation here)**	**Description of role related to this study (e.g., recruits subjects, analyzes data)**
Leon Corbeille	**UW Madison** **Undergraduate Student**	**Dept. of Biomedical Engineering**	**Student Researcher- recruits subjects, collects and analyzes data**
Neal Haas	**UW Madison** **Undergraduate Student**	**Dept. of Biomedical Engineering**	**Student Researcher- recruits subjects, collects and analyzes data**
Peter Kleinschmidt	**UW Madison** **Undergraduate Student**	**Dept. of Biomedical Engineering**	**Student Researcher- recruits subjects, collects and analyzes data**
Lein Ma	**UW Madison** **Undergraduate Student**	**Dept. of Biomedical Engineering**	**Student Researcher- recruits subjects, collects and analyzes data**
Claudia E Korcarz	**RDCS**	**UWSMPH, Dept. of Medicine,**	**Research Sonographer**

		Cardiology	
Elizabeth Lauer Brodell	**RDCS, RVT**	**UWSMPH, Dept. of Medicine, Cardiology**	**Research Sonographer**
Susan Aeschlimann	**RVT, RDMS**	**UWSMPH, Dept. of Medicine, Cardiology**	**Research Sonographer**

V. ANCILLARY APPROVALS

Final approval from the Health Sciences IRBs may require review and/or approval by another committee representing the University, its affiliates, a department, or a section. Please submit a notice of review and/or approval by any of the following entities. If review is pending, please indicate the date on which it will occur.

Committee	Phone	Review Required?	Review or Approval Date
University of Wisconsin Comprehensive Cancer Center Protocol Review and Monitoring Committee *Reviews all cancer-related research protocols.*	263-0169	☐ Yes ☒ No	
Institute of Clinical & Translational Research Scientific Review Committees *Reviews (1) all research protocols using Clinical and Translational Research Core (CTRC; formerly GCRC) resources; (2) research studies that present more than minimal risk to subjects and have not otherwise had their scientific design evaluated (e.g., non-federally funded studies); (3) research studies limited to sample, specimen, data, or image analysis when they have not otherwise had their scientific design evaluated (e.g., non-federally funded studies) and do not represent a research service.*	262-3005	☐ Yes ☒ No	
Institutional Biosafety Committee / Office of Biological Safety *Reviews the research use of recombinant DNA and its derivatives.*	263-9026	☐ Yes ☒ No	
Radioactive Drug Research Committee *Reviews research involving radiopharmaceuticals that do not deliver an intended clinical benefit or that are not FDA approved.*	263-4856	☐ Yes ☒ No	
William S. Middleton Memorial Veterans Hospital (VA) Research and Development Committee *Reviews all research protocols involving: 1) UW health sciences researchers with paid appointments at the VA; 2) enrollment of subjects (including use of residual tissue and access to medical records) associated with the VA; or 3) use of VA facilities, e.g. space*.	256-1901, ext 7863 or 280-7007	☐ Yes ☒ No	
Research Safety Committee *Reviews protocols possessing health hazards, such as gene transfer studies, and protocols intentionally exposing subjects to infectious agents.*	263-8902	☐ Yes ☒ No	
Meriter Hospital Institutional Review Board	267-6411	☐ Yes ☒ No	
Stem Cell Research Oversight Committee *Reviews research at UW or involving UW faculty or staff that involves either: (1) the use of human embryonic stem cells or their derivatives; or (2) the introduction of human pluripotent stem cells, or their derivatives, obtained from a non-embryonic source, into non-human animals at any embryonic, fetal, or postnatal stage, if*	265-2011	☐ Yes ☒ No	

an expected effect is that human cells will be integrated into the central nervous system, testes, or ovaries of the animal.			

VI. STUDY LOCATION

1.	Is this a multi-site study?	☐ Yes ☒ No
	• If yes, will the UW-Madison, UWHC, or Madison VA serve as the lead or coordinating center? ○ **NOTE: If the UW-Madison, UWHC, or Madison VA serve as the lead or coordinating center ensure the following are addressed in a <u>formal protocol</u> developed for this study:** **(a) Provide a plan for review of each site's IRB approval documents and each site's IRB approved consent forms (if applicable)** **(b) Include a list of all sites that will be involved in the study.** **(c) Provide a plan for ensuring each participating site has on file an FWA with OHRP in the case of federally funded research.** **(d) Describe the method that will be used to assure all sites have the most current version of the protocol will be communicated to all centers.** **(e) Describe the method that will be used to assure all sites receive and have IRB approval for amendments to the protocol.** **(f) Provide a plan for collection and management of data from all centers.** **(g) Describe a process for reporting and evaluating protocol unanticipated problems, adverse events and deviations from all centers.**	☐ Yes ☐ No
2.	Indicate below all sites at which research procedures will be conducted by UW, VA, or UWHC personnel or personnel under UW-Madison IRB purview. For multi-site studies, list performance sites only for the UW-Madison, UWHC, or VA principal investigator. ☐ University of Wisconsin Hospital and Clinics ☐ WisPIC ☐ Clinical and Translational Research Core ☐ Madison VA ☐ Meriter Hospital ☐ St. Mary's Hospital ☐ UW Health, 1 S Park ☐ Pharmacy Clinical Research Center ☐ UW Health, 20 S Park ☐ Sports Medicine Fitness Center ☐ Other UWMF Clinic(s), specify: ☐ UW Family Medicine Clinic(s), specify: ☒ Other sites at the UW-Madison, specify: **UW SMPH, Cardiovascular Medicine Division, Atherosclerosis Imaging Research Program** ☐ Wisconsin Oncology Network (WON) sites, specify:	

	☐ Other site(s) not at the UW-Madison, but within the US • Specify the site(s): • Identify the research activities occurring at each site: • Attach documentation of IRB approval from each site involved (if federally funded) or, if applicable, attach a request for the UW-Madison to serve as IRB of record for the site(s). • Attach letters of support for the research study from the appropriate institutional official(s) at each site, if the study is not federally funded and no IRB exists for that site. ☐ Other site(s) outside the US • Specify the site(s): • Identify the research activities occurring at each site: • Attach documentation of IRB or International Ethics Committee (IEC) approval from each site involved or provide justification as to why IRB or IEC approval is not needed or possible. • Attach letters of support for the research study from the appropriate institutional official(s) at each site. • Attach letters of support or approval from relevant health or governmental authorities for each site.

VII. STUDY DESCRIPTION

Describe your study in the format outlined below. For multicenter clinical trials, it is critical that you provide information about how the protocol will be implemented locally, such as how local subjects are identified and recruited, the local standard of care and how the study procedures differ or do not differ from these procedures, and any adjuvant or prophylactic treatments that would be standard and used to reduce the risk of side effects to subjects that are not described in the protocol. Please do **NOT** refer to sections of your protocol or to "see attached" in your study description. Make sure that all questions are answered and that the format below is followed.

A. BRIEF SUMMARY

☐	The rest of this section (Section VII.A) was not completed because either (a) the UW's role is limited to that of a reading center, statistical data analysis center, or analysis center (e.g., of specimens, such as blood or saliva); or (b) the purpose of this submission is solely to obtain approval of a

	training grant, core grant, or umbrella grant.
1.	In lay terms and avoiding abbreviations, briefly describe your research question. **Determine the efficacy of a device to assist in the acquisition of data during a brachial ultrasound study. The device serves as a stereotactic probe holder.**
2.	Briefly describe the subject population for this study. **Healthy individuals between the ages of 18-50 years.**
3.	Explain why this study is being done (i.e., the **rationale** for your study in the context of currently available data and relevant knowledge). **A device to position and hold an ultrasound probe during a procedure has been developed. This study aims to determine the effectiveness of the device to serve as a replacement for a manual positioning by a sonographer. The device should improve imaging quality while reducing occupational health stresses on the sonographer.**
4.	Describe why the research design chosen will likely allow the study's objectives to be met. **By conducting paired tests with and without the device, we will identify performance differences.** **The study is designed to evaluate the effectiveness of the device by comparing images acquired using the device (probe holder) versus the traditional method of a sonographer manipulating the probe. We also will subjectively evaluate its ease of use. The images acquired will follow the brachial artery reactivity testing protocol. This protocol includes the acquisition of timed B-mode and Doppler images obtained before and after the inflation of a small blood pressure cuff placed on the forearm.** **Assessment of device performance will be done by (i) the scanning sonographer, who will grade the image quality and describe the ease of use of the device, and (ii) by a second sonographer who will review paired image sets. This sonographer will have no knowledge of whether or not the device was used during image acquisition.**
5.	Estimate how long this project will take. • Expected start date: **November 2009 (or as soon as UW IRB approval is obtained)** • Expected end date: **June 2010**

B. STUDY DESIGN AND PROCEDURES

1.	Indicate whether the UW's role is solely limited to any of the following: ☐ Serving as a Statistical Data Analysis Center for a multi-site research study ☐ Serving as a Reading Center for a multi-site research study (e.g., ultrasounds, fundus photographs, other images) ☐ Serving as an analysis center for samples/specimens/data collected at other sites for this research study If any of the above applies, address the following. a) Briefly describe the purpose of the overarching study. b) Briefly describe the study population of the overarching study, especially noting if any vulnerable populations will be or have been enrolled. c) Clarify whether the overarching study is ongoing or has reached completion. d) Briefly describe the UW's role in relation to overarching study. e) Describe what data, images, and/or specimens the UW or VA will receive, including the information associated with them, how they will be transmitted, and whether they are coded or directly identifiable. If coded, indicate whether the UW or Madison VA study team will have access to the code. f) Attach documentation of (i) IRB approval from the coordinating center/lead site for this protocol, (ii) a copy of the model consent form; and (iii) a copy of the study-wide protocol or protocol from the main site. **NOTE: IF THIS STUDY FALLS UNDER ONE OR MORE OF THE CATEGORIES**	☒ Not applicable

	INDICATED ABOVE, THIS APPLICATION IS COMPLETE. NO FURTHER SECTIONS NEED TO BE ADDRESSED.	
2.	Indicate whether the purpose of this submission is solely limited to any of the following: ☐ Request of IRB approval of a Training Grant ☐ Request of IRB approval of a Core Grant ☐ Request of IRB approval of an Umbrella Grant If any of the above applies, address the following: a) Briefly describe the purpose of the grant (ensure a copy of the grant is attached). b) Address how it will be ensure that any activities involving human subjects will be submitted as individual IRB submission (either new Initial Review Applications or Applications for Exemption). **NOTE: IF THIS STUDY FALLS UNDER ONE OR MORE OF THE CATEGORIES INDICATED ABOVE, THIS APPLICATION IS COMPLETE. NO FURTHER SECTIONS NEED TO BE ADDRESSED.**	☒ Not applicable
3.	Describe the primary procedures and interventions that will be performed for this study and all study arms involved. **Ultrasound images of the brachial artery will be obtained on healthy volunteers. The only variance is that for some image acquisitions the device will hold the ultrasound probe in lieu of a sonographer.** **Ultrasound images of the brachial artery will be obtained twice for each subject, once by a sonographer holding the ultrasound probe, and a once using the probe holder. The order of acquisition will be random, Random labels for each scan will be assigned in order to maintain the reviewer blinded from the acquisition modality used. The subjects will lay supine during the scans for a total of 30 minutes. While on the bed, an ultrasound of your brachial artery will be taken for 10 minutes. During the 10 minutes, a tourniquet will be applied to your lower arm and pressure will be applied for the whole 10 minutes. No personal identifiers will be used.**	
4.	Describe the procedures subjects will undergo as part of screening to determine	☒ Not

	eligibility.	applicable
5.	Identify any study procedures that will be conducted before written informed consent is obtained from subjects. NOTE: If a waiver of informed consent is being requested for all components of this study, indicate "Not applicable" in response to this question. **No procedures will be conducted before informed consent is obtained.**	☒ Not applicable
6.	Briefly describe the number of study visits involved and how long individual subject participation will last (distinguishing between treatment phases and follow-up). For example, "Subjects will complete 5 study visits (including 1 screening visit, 3 clinic visits, and one close out visit), and will be followed for one year after completion of study procedures." **Each subject will be required to attend one 30 minute visit only. No follow-ups will be necessary**	☐ Not applicable
7.	If this study involves randomization, indicate the ratio at which subjects will be randomized to each arm. **Each subject will undergo both techniques for paired comparisons. We will randomize what technique will be performed first. There are no different arms in this study.**	☐ Not applicable
8.	If this study involves performing any biopsies (e.g., kidney, skin) or bone marrow aspirations solely for research purposes, provide specific justification for these procedures.	☒ Not applicable
9.	If this study will involve surveys, questionnaires, or cognitive or psychological assessments (e.g. EEGs, SCID, Beck Depression Inventory) for research purposes, identify the assessments that will be used and ensure copies of applicable documents are attached to this application.	☒ Not applicable
10.	If this study involves the use of deception, provide a justification for this and a	☒ Not

	debriefing plan.	applicable
11.	If this protocol involves physical interventions (e.g., blood draws, exercise testing, allergy testing) that will not be conducted in a clinical setting (i.e., hospital or medical clinic): (a) Identify the physical interventions performed outside the clinical setting (b) Describe the credentials and/or training of the staff who will perform these procedures. (c) Identify where the interventions will occur. (d) Describe the plan for handling medical emergencies. **NOTE: If the research involves more than minimal risk to subjects, the IRB may require the procedures to be conducted in a clinical setting or the presence during study procedures of someone with appropriate medical expertise.**	☒ Not applicable
12.	Describe the current alternatives to participation in this research study, including treatments subjects could undergo outside of the research study. If there is no accepted treatment or no effective treatment, state this. If this does not apply to your type of research study (e.g., collection of samples, creation of tissue bank protocols), indicate this.	☒ Not applicable
13.	Identify the procedures that will be performed solely for research purposes (e.g., those that are not performed as part of local standard of care or what subjects would undergo outside the research study). **This study will be performed solely for research purposes using clinically approved equipment operated by qualified personnel. The only experimental device is the clamp holding the ultrasound probe in place.**	

14.	Describe what would occur if the subjects were not participating in this research study (e.g., what procedures or treatments are in addition to what would be received outside of the study or what procedures or treatments will not be received because of participation in this study).	☒ Not applicable

15.	For studies that involve testing a device, address the following.	☐ Not applicable
	a) Has an Investigational Device Exemption (IDE) number been assigned by the FDA or will you apply to the FDA for an IDE? • If yes, address the following: i) Provide the IDE #(s): _____. NOTE: Attach a copy of the FDA letter granting an IDE for the proposed use. ii) If an IDE has been applied for but not yet assigned, indicate date of submission of request to FDA: _____ **Note: A copy of the FDA letter granting an IDE for the proposed use will need to be provided to the IRB before approval for enrollment can be issued.** iii) Indicate who holds or will hold the IDE: _____. *NOTE: If you hold the IDE*, please provide 3 copies of the application submitted to the FDA. • If no, indicate which of the following situations apply: ☒ This study does not involve a device that is defined as a *medical device* under federal regulations. ☐ This study only involves devices used within their FDA-approved indications. ☐ A letter from the sponsor is attached stating that the study is a non-significant risk device study. ☐ The device is an exempt diagnostic device because the sponsor has complied with all requirements in 21 CFR 809.10(c) relating to labeling for in vitro diagnostic procedures and the testing: • Is noninvasive; • Does not require an invasive sampling procedure that presents significant risk; • Does not by design or intention introduce energy into a subject; and • Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure. ☐ A letter is attached explaining why the investigation is otherwise exempt from the IDE requirements under 21 CFR 812.2(c).	☐ Yes ☒ No
	b) Will the investigational device be used in a clinical setting?	☐ Yes ☒

	• If yes, attach a copy of the device control policies and procedures that will be followed or describe your device control policies and procedures that will be used to assure compliance with FDA regulations. **This device will not be used in a clinical setting. The BART test is not a clinical test. The test and the clamp have no clinical applications.**	No

16.	For studies that involve the testing of drugs, address the following.	☒ Not applicable
	a) Drug dose, as well as frequency and mode of drug administration per each study arm.	
	b) If the drugs are not produced according to Good Manufacturing Practice standards, describe in detail where the drugs will be produced and provide a plan for ensuring uniform quality of the drugs.	
	c) Has an IND been issued for the drug or combination of drugs used in this study? • If yes, address the following: i) Provide the IND #(s): _____ ii) If an IND has been applied for but not yet assigned, indicate date of submission of request to FDA: _____ **Note: A copy of the FDA letter granting an IDE for the proposed use will need to be provided to the IRB before approval for enrollment can be issued.** iii) Indicate who holds or will hold the IND: _____ *NOTE: If you hold the IND*, please provide 3 copies of the application submitted to the FDA. iv) Attach documentation from the sponsor or FDA verifying the IND number for this research. Indicate any that are attached: ☐ FDA letter ☐ Sponsor letter ☐ IND number is in protocol or other sponsor-generated document ☐ Other (specify): _____ • If no, indicate which of the following situations apply: ☐ This study only uses FDA approved drugs (or combinations of drugs) within their FDA-approved indications. ☐ This study involves the use of drugs approved by the FDA but that will be used outside of their FDA-approved indications and **ALL** of the following are true: ▪ there is no intention for the study to support FDA approval of a new indication or a significant change in the product labeling; ▪ the study is NOT intended to support a significant change in the advertising for the product; and ▪ the investigation DOES NOT involve a route of administration or dosage level or use in a patient population or other factor that *significantly increases the risks* (or decreases the acceptability of the risks) associated with the use of the drug product.	☐ Yes ☐ No

	d) Will the drug control be managed through the Pharmaceutical Research Center? • If no, attach a description of your drug control policies and procedures that will be used to assure compliance with FDA regulations.	☐ Yes ☐ No
17.	For studies that involve the administration of radioactive drugs, address the following: ☐ Radioactive Drug Research Committee review is not needed because an IND has been obtained from the FDA, as noted above. ☐ Radioactive Drug Research Committee approval will be/has been obtained for this study instead of an IND because one of the following applies: • The study is intended to obtain basic information regarding the metabolism (including kinetics, distribution, and localization) of a drug. • The study is intended to obtain basic information regarding human physiology, pathophysiology, or biochemistry.	☒ Not applicable
18.	For studies that involve the administration to subjects of recombinant DNA materials (e.g., gene transfer studies), indicate which of the following apply: ☐ The NIH Recombinant Advisory Committee has reviewed and approved this protocol. A copy of the outcome of its review is attached. ☐ The NIH Recombinant Advisory Committee is not required for this protocol, because: _____ ☐ The consent form(s) submitted for this study follow NIH Guidance on Informed Consent For Gene Transfer Research. • NOTE: Consultation with the staff of the Biological Safety Office at 263-9026 and the UWHC Research Safety Committee are recommended to determine whether their review is needed.	☒ Not applicable

19.	For studies involving the administration of nutritional supplements to subjects, address the following. a) Provide the source of the supplement(s): b) Indicate the dose, as well as frequency and mode of administration per each study arm:	☒ Not applicable
20.	If participation in this study requires a washout period or result in the withholding or postponement of standard treatment (including the use of placebo), address the following. a) Describe what treatment will be withheld, postponed, or the nature of the washout. b) Provide justification for the washout or withholding treatment. c) Indicate how subjects will be monitored for safety during this period. d) If placebo will be used, indicate the source of the placebo.	☒ Not applicable
21.	Indicate which, if any, of the following procedures this study involves: ☐ Administration, implantation, or transplantation of **non-embryonic stem cells** into human subjects ☐ Administration, implantation, or transplantation of **embryonic stem cells** to human subjects ☐ Administration, implantation, or transplantation of **embryonic or fetal tissue** into human subjects ☐ Implantation or transplantation of **nonhuman animal tissue** into humans (xenotransplantation) ☐ Collection of embryos or fetuses or embryonic or fetal tissue	☒ Not applicable

22.	If this study involves the collection of tissue/specimens and they will NOT be banked for future research (i.e., research beyond the scope of the current study), address the following. **NOTE: If the study involves collection of samples that will not be banked in addition to samples that will be banked for future use, answer this question and question 23.** a) Describe the type(s) of tissue/specimens collected. b) Describe the information that will be associated with the samples, including how they will be labeled and indicate whether the samples will be **coded** (i.e., direct identifiers like names and medical record numbers removed, but able to be linked to individually identifiable information) or **de-identified** (i.e., no one can link the samples back to the individuals from whom they were obtained). c) Describe the source(s) and circumstances of the tissue/specimen collection, especially noting whether samples will be obtained directly from subjects or from a secondary source (e.g., residual specimens). **NOTE: Any samples obtained during surgery that will not be first processed by pathology will require special permission from pathology.** d) Describe the purpose of collecting the samples. e) Indicate who will have access to the samples. f) Describe where the samples will be kept and the security provisions in place.	☒ Not applicable

	g) Describe where the information associated with the samples will be kept and the security provisions in place. h) Indicate how long the samples will be kept. i) Describe the process for destruction or de-identification of identified/coded samples.	

23.	If this study involves the banking of tissue/specimens for future research address the following. **NOTE: If the study involves collection of samples that will not be banked in addition to samples that will be banked for future use, answer this question and question 22.** a) Describe the type(s) of tissue/specimens collected and stored. b) Describe the information that will be associated with the tissue/specimens, including how they will be labeled and indicate whether the tissue/specimens will be **coded** (i.e., direct identifiers like names and medical record numbers removed, but able to be linked to individually identifiable information) or **de-identified** (i.e., no one can link the tissue/specimens back to the individuals from whom they were obtained). c) Indicate whether tissue banking is optional. d) Describe the source(s) and circumstances of the tissue/specimen collection, especially noting whether samples will be obtained directly from subjects or from a secondary source (e.g., residual specimens). **NOTE: Any samples obtained during surgery that will not be first processed by pathology will require special permission from pathology.** e) Describe the purpose of collecting and storing the tissue/specimens. f) Explain whether there will be limits on the intended future use of the tissue/specimens (e.g., for cancer research only).	☒ Not applicable

	g) Specify the procedures by which participants can withdraw their specimens from storage for future research or note whether de-identification makes withdrawal impossible. h) Indicate whether the tissue/specimens will be released to other investigators. i) Indicate who will have access to samples. j) Describe where the samples will be stored and the security provisions in place. j) Describe where the information associated with the samples will be kept and the security provisions in place. k) Indicate how long the tissue/samples will be stored. l) Describe the process for destruction or de-identification of identified/coded specimens at the end of the retention period (as applicable) or if the PI leaves UW-Madison or the Madison VA.	
24.	If this study involves the creation of a research database or registry address the following: **NOTE: Separate IRB approval is required for any subsequent studies using databases or registries created for research purposes.** a) Describe the data elements that will be collected and stored.	☒ Not applicable

b) Describe the source(s) and circumstances of the data collection and explain whether data will be obtained directly from subjects or from a secondary source.

c) Describe the purpose of registry or database.

d) Explain whether there will be limits on the intended future use of the data (e.g., for cancer research only).

e) Specify the procedures by which participants can withdraw their information from the database or registry.

f) Indicate whether the data will be released to other investigators.

g) Indicate who will have access to data.

h) Describe where the data will be stored and the security provisions in place.

i) Indicate how long the data will be stored.

j) Describe the process for destruction or de-identification of data at the end of the retention period (as applicable) or if the PI leaves UW-Madison or the Madison VA.

25.	If this study involves testing diseases or conditions for research purposes (and are not performed as part of the patients' clinical care) that require reporting under Wisconsin Law (e.g., HIV, hepatitis), address the following: a) Identify the tests that will be conducted: b) Describe how subjects will be informed of the potential need for disclosure (e.g., in the consent documents): c) Indicate who will be responsible for reporting to the local health authorities or state epidemiologist: **For a list of diseases and conditions that require reporting under Wisconsin Law, how to report them, and the timing of the report, see:** http://www.dhfs.state.wi.us/Communicable/diseasereporting/	☒ Not applicable
26.	If this study involves the potential for incidental or adventitious findings (e.g., in studies that include MRIs performed for research purposes other than subject safety monitoring) address the following: a) Who assesses whether the findings should be reported to subjects and the qualifications of those making such assessments b) Which findings would be released to subjects c) The timeframe for reporting findings to subjects d) How findings will be reported to subjects, and if applicable, their physicians	☒ Not applicable
27.	If the release of information from biomarker or genetic testing to subjects is planned, address the following.	☒ Not applicable

	a) Which findings would be released to subjects b) Who assesses whether the information should be reported to subjects and the qualifications of those making such assessments c) The timeframe for reporting the results to subjects, and if applicable, their physicians d) How results will be reported to subjects e) Whether any additional resources are in place, such as genetic counseling, to assist subjects in understanding the information being provided to them.	

C. SUBJECT POPULATION AND RECRUITMENT

1.	Describe the primary inclusion/exclusion criteria. NOTE: This should not be a cut and paste from a sponsor protocol, but highlight the major inclusion/exclusion criteria. **Inclusion: subjects 18-50 years of age, either sex and any race** **Exclusion: subjects that cannot rest comfortably supine for 30 minutes, with their right arm abducted**
2.	Indicate the age range of subjects you will enroll. **18-50 years**
3.	Indicate how many participants the entire study will enroll. For multi-site research, provide the number of subjects that will be enrolled study-wide.

	10	
4.	Indicate the approximate number of participants that will be enrolled locally (i.e., at sites under UW IRB purview). **10**	
5.	Indicate how potential subjects will be identified. **Volunteer subjects will be enrolled. The subjects will be identified from classmates of the student researchers. Because of the nature of the study, this does not induce a bias. The results of the study are not dependent on comparisons between subjects. Results will be based on paired evaluations with and without the device for each person independently. Furthermore, a subject does not have control over the results of the study. There is not any way that a subject could skew results by their personal actions since all measurements will either be dependent on internal anatomy of the subject or on the use of the device, which will not be influenced by subjects.** **The study aim is to assess the usability and effectiveness of the device. Ultrasound phantoms do not exist for testing this device and are not feasible to create.**	
6.	Indicate who will identify potential subjects. **Student investigators will identify classmates through personal contact.**	
7.	Describe how subjects will be recruited. **As part of an academic project, subjects will primarily be classmates of the student investigators that volunteer to be part of it when asked.**	
8.	Indicate who (and their role) will recruit potential subjects. NOTE: If the potential subjects are patients, the IRB generally requires that first contact is made by someone involved in the care of the patients. **Student investigators will recruit subjects.**	
9.	If medical records are being used to identify potential subjects, address the following: a) Who will review these records and how they have valid clinical access to them. b) What records will be used.	☒ Not applicable

10.	If subjects will be paid or offered other material inducements to participate in the study, address the following: a) Whether the payment is limited to covering travel expenses and other costs incurred by subjects as a result of study participation. b) How much subjects will be paid. c) If the payment is an inducement, indicate when subjects will be paid and, if subjects withdraw early, whether their payment will be prorated. d) Describe other inducements that may be used.	☒ Not applicable
11.	If any advertising materials will be used to recruit subjects, including flyers, posters, website information, press releases, radio or television advertisements, emails, letters, describe the methods used, where materials will be posted, and provide a copy of the materials or commercial scripts.	☒ Not applicable
12.	If a recruitment database will be used to disseminate recruitment materials or to contact subjects, address the following: a) Identify the IRB protocol number of the recruitment database. b) Attach a letter of support for the use of the database for this research study from the holder of the database. c) Indicate what will be disseminated to individuals who agreed to be included the recruitment database.	☒ Not applicable
13.	Indicate any of the following populations will be enrolled in this study: ☐ Minors (people less than 18 years of age) ☐ Minors (people less than 18 years of age) who are Wards of the State	☒ Not applicable

	☐ Minors (people less than 18 years of age) who have given birth ☐ Prisoners ☐ Pregnant women ☐ Individuals who may have a status relationship with the PI (e.g., students or employees) ☐ Psychiatric inpatients ☐ People who are institutionalized (e.g., in a mental health facility, nursing home, or halfway house) ☐ Adults who have impaired decision-making capacity (e.g., coma, dementia, confusion, or mental disorders) ☐ Madison VA patients (this includes the use of their tissue or medical records) Provide justification for the inclusion of the populations indicated above.	
14.	If any racial/ethnic group will be targeted for or excluded from this study, identify the group that will be targeted or excluded and provide justification for this.	☒ Not applicable
15.	If men or women will be targeted for or excluded from this study, identify which sex will be targeted or excluded and provide justification for this.	☒ Not applicable

D. DATA SAFETY AND MONITORING

1.	Describe the provisions in place to identify and address unanticipated problems or complications. **The test described does not pose any risk to the subjects. The procedure does not deviate from normal ultrasound procedures. The treatment of any problems that may arise would follow standard clinical safety procedures.**	
2.	If the study is more than minimal risk, describe the data and safety monitoring plan for this study. NOTE: If a formal Data Safety Monitoring Board or Data Monitoring Committee exists, provide a general description of the committee or board's	☒ Not applicable

	membership e.g. number of members, expertise, and whether the members are independent of the sponsors/researchers) and the expected frequency of their meetings.	

E. STUDY DESIGN JUSTIFICATION

1.	If this protocol presents minimal risk to subjects, provide a rationale for the number of subjects proposed. **This is a pilot evaluation of a device performance as part of a student project. At the completion of this preliminary data collection the student will be able to access the benefits and/or deficiencies of their prototype model compared with the traditional hand held protocol.**	☒ Not applicable
2.	If this protocol presents more than minimal risk to subjects, provide a formal justification for the sample size and analysis of results.	☒ Not applicable

F. PRIVACY AND CONFIDENTIALITY PROTECTIONS

1.	Describe the precautions that will be used to ensure subject *privacy* is protected (e.g., research intervention is conducted in a private room; collection of sensitive information about subjects is limited to the amount necessary to achieve the aims of the research). **NOTE**: Privacy is a subject's ability to control how other people see, touch, or obtain information about the subject. Violations of privacy can involve circumstances such as being photographed or videotaped without consent, being asked personal questions in a public setting, being seen without clothing, being observed while conducting personal behavior, or disclosing information about abortions, HIV status, illegal drug use, etc. **All data will be collected at the UW Atherosclerosis Imaging research Program. This area is restricted solely to research personnel. No identifiable data will be recorded from the subjects. Images saved do not contain personal data or individually identifiable information.**	
2.	Describe the protections in place to protect the *confidentiality* of the data, including how and where data will be stored. Specify the measures that will be implemented by your research team to safeguard the identifiable subject information from unauthorized use or disclosure for both paper and electronic forms of information. **NOTE**: Confidentiality is an extension of the concept of privacy; it refers to the subject's understanding of, and agreement to, the ways identifiable information will be stored and shared. Identifiable information can be printed information, electronic information, or visual information such as photographs. **The images will be stored on a password protected computer, backed up to the DOM network.**	
3.	Describe your plan for destroying the identifiers at or before the conclusion of the study or provide a justification for long term or permanent retention of the identifiers. Specify which identifiers and information will be destroyed. **Personal information will not be recorded.**	
4.	If this research study will be conducted by a PI under a Madison VA, UWHC, or UW Medical Foundation appointment or an appointment that is within the Health Care Component (HCC) of the UW-Madison address the following: **NOTE: The HCC of the UW-Madison currently includes - School of Medicine and Public Health clinical departments; School of Pharmacy (clinical units only); School of Nursing; University Health Service; State Laboratory of Hygiene; Athletic Department (athletic trainers and health information systems only); Waisman Center (clinical units only); and L&S Psychology Clinic.** a) Describe what PHI will be used for this study and the identifiers associated with it.	☒ Not applicable

	b) How it will be ensured that access to PHI is restricted to individuals with valid clinical access to it or have been allowed permission to access PHI via written authorization from participants.	
5.	If subject data, specimens, or images be shared outside the UW-Madison, the Madison VA, or UWHC (including UWMF clinics), address the following. a) List the individuals or groups to whom the data, specimens, or images will be shared. b) Describe what information will be associated with the data, specimens, or images that will be shared. c) Describe how the data, specimens, or images will be transmitted and how confidentiality will be protected, including who maintains the code or whether the samples are anonymized. d) Address whether the data, specimens, or images will be returned to UW-Madison, the Madison VA, or the UWHC and if not, why not (e.g., samples will be exhausted). e) Describe the potential uses of or analyses that will be performed on data, specimens, or images sent to other sites. f) Indicate whether the data, specimens, or images sent to other sites will be banked for future research uses (i.e., research uses beyond the current study).	☒ Not applicable
6.	If this study involves the collection of audio recordings, video recordings, or photographs that may be used for purposes other than the current research study,	☒ Not applicable

	address the following: a) How the recordings will be used. b) How long the recordings or photographs will be kept. c) Who will have access to the recordings or photographs. d) Where the recordings or photographs might be used or displayed. NOTE: This potential for other uses should be described in any consent documents.	

G. POTENTIAL RISKS

1.	a) Describe the most common or frequent physical risks expected related to study participation. Bruising from a falling component of the device due to misuse or improper handling b) Describe how these risks will be minimized. **Parts will be secured and checked before each use. The operator of the device will be trained for proper operating procedures.**	☐ Not applicable
2.	a) Describe any risks that are rare, but serious, or irreversible. b) Describe how these risks will be minimized.	☒ Not applicable
3.	a) Describe any late effects that are possible (e.g., secondary cancers). b) Describe how these risks will be minimized.	☒ Not applicable
4.	a) Describe any potential psychosocial risks to subjects, such as psychological stress, confidentiality risks (including risk to reputation, economic risks, and legal risks). b) Describe how these risks will be minimized.	☒ Not applicable
5.	a) Describe any risks for discovery of illicit behavior or behavior that raises concern about subject self-harm or harm to others (e.g., child abuse, elder abuse, suicidal or homicidal ideation). b) Describe how these risks will be minimized, including addressing whether a Certificate of Confidentiality will be obtained. c) Describe any plans for potential referral to other resources.	☒ Not applicable

6.	a) Identify any risks to a developing embryo or fetus, gametes, or a nursing child or other reproductive risks. b) Describe how these risks will be minimized.	☒ Not applicable

H. POTENTIAL BENEFITS, ANALYSIS OF RISK/BENEFIT RATIO

1.	Identify any potential direct benefit to subjects. If no direct benefits to subjects are expected, please state so. **No direct benefits to the subjects are foreseen.**
2.	Assess the risk/benefit ratio of the study, especially addressing whether the potential benefits of the research to individual subjects or society are greater than the potential risks to individual subjects. **There are not any risks posed to the subjects. The potential benefits are the improvement in logistics and quality of brachial artery reactivity testing for the non-invasive assessment of endothelial function.**

I. INFORMED CONSENT

1.	a) Describe the **consent process** and explain when and where it will occur and especially how it will be ensured that potential subjects are given sufficient time to consider participation. **Written consent of involvement in the study will be obtained from volunteer subjects prior to conducting the procedure. They will be given the forms by the student researchers a minimum of 3 days before their procedure and will be able to have their questions answered anytime before the procedure takes place**	☐ Not applicable
	b) If you plan to enroll subjects **who do not speak English** or **have limited English-speaking skills**, describe your plan for obtaining informed consent from these individuals in a language understandable to them and address how the consent form and/or process will be rendered into the subjects' native language. In addition, clarify who will perform the consent process and whether an interpreter will be involved and their qualifications and/or level of experience serving as interpreters.	☒ Not applicable
	c) If you plan to enroll subjects **who are illiterate or have limited reading skills**, describe the consent process for these individuals. Please note that in these cases the consent form can be read to the subject, but a neutral third party must be present to witness this process and sign the consent form attesting that what was read to the subject is the IRB-approved consent document.	☒ Not applicable
	d) If this study will enroll adults **who have impaired decision-making capacity** (e.g., coma, dementia, confusion, or mental disorders), address the following, describe the consent process to be used with this population. Include a description of how capacity to consent will be assessed, who will access this capacity, the extent to which (if any) the subject will be included in the consent process, from whom surrogate consent will be obtained, and plans (if any) to obtain consent from the subject should they regain the ability to provide informed consent on their own behalf.	☒ Not applicable

	e) If this study will enroll children, describe the **assent process**, taking into account the ages and maturity of the minors.	☒ Not applicable
2.	If you are requesting a **waiver of informed consent** for some or all components of the study or a waiver or alteration of some elements of informed consent, address the following. a) Indicate whether a waiver or alteration is being requested for the entire study or identify the components of the study for which the waiver is being requested (e.g., for a chart review). b) Indicate how the following criteria for waiver or alteration of informed consent for some or all components of this study will be met: i) The study research involves no more than minimal risk to the subjects; ii) The waiver will not adversely affect the rights and welfare of the subjects; iii) The research could not practicably be carried out without the waiver. NOTE: If you are requesting a waiver of informed consent for some or all components of this study and the research team is part of the UW-Madison Health Care Component or an Affiliated Covered Entity, an *Application for a Waiver of Authorization under the HIPAA Privacy Rule* or an *Application for a Partial Waiver of Authorization under the HIPAA Privacy Rule* is likely needed and should be attached to this application.	☒ Not applicable

3.	If you requesting a **waiver of written consent** for some or all components of the study, address the following. a) Indicate whether a waiver of written consent is being requested for the entire study or identify the components of the study for which the waiver is being requested. b) Provide justification for the waiver of written informed consent for some or all components of this study. c) Indicate whether you plan to conduct an oral consent process or provide an	☒ Not applicable

	information sheet to subjects. NOTE: If you are requesting a waiver of written informed consent for this study and the research team is part of the UW-Madison Health Care Component or an Affiliated Covered Entity, an *Application for am Altered of Authorization under the HIPAA Privacy Rule* is likely needed and should be attached to this application.	
4.	List the investigators and key personnel who will conduct the informed consent process and training they will undergo regarding obtaining informed consent. **Claudia Korcarz, Susan Aeschlimann and Elizabeth Lauer-Brodell are research sonographers at the UW AIRP lab. They have all completed the online CITI Human Subjects Protection Training, are listed under the study personnel, and have been adequately trained in the consent process.**	
5.	List the documents used in the consent process, including telephone screening scripts, assent forms, information sheets and attach copies of them.	☒ Not applicable

Document 5 – IRB Approval

THE UNIVERSITY of WISCONSIN MADISON

Minimal Risk IRB
NOTICE OF ACTION
Approval
Date of Correspondence: 4/9/2010

Principal Investigator:	James H Stein, M.D. Mail Code #3248-Cardiovascular Medicine-Rm.G7/341 CSC 600 Highland Ave., Madison, WI 53792
Point of Contact:	Claudia E Korcarz Cardiovascular Medicine, 116/377 CSC, Mail Code 3248 600 Highland Ave., Madison, WI 53792
Protocol:	**M-2009-1381** "Prototype Evaluation for Ultrasound Probe-holder To Perform Brachial-artery Imaging"
Review Period:	12 months
Approval Expires:	2/21/2011
IRB Staff Contact:	Carla M Phillips, 608-261-1156, cmp@medicine.wisc.edu

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Your Initial Review Application, including the supporting materials you submitted with your application, was reviewed by the full Minimal Risk IRB at its 2/22/2010 meeting and modifications or clarifications were requested. Your response letter dated 3/10/2010 and email dated 3/22/10 have addressed the IRB's concerns. You may now begin your above-referenced research and enroll subjects, using the consent documents noted in the enclosure section below. The review period and expiration date of your approval are indicated above.

Note: The full MR-IRB reviewed the previous determination regarding your device and made a new determination that the device does not meet the definition of a medical device and is therefore not subject to FDA regulations.

Please be sure to do the following:

- Use your Minimal Risk IRB protocol number (listed above) on any documents or correspondence with us concerning your protocol.
- Keep a copy of this approval letter with your files.
- Use only copies of the enclosed consent forms or information sheets, which have the IRB approval and expiration date-stamp, to obtain informed consent; give all subjects a copy of the consent document.
- If applicable, use only copies of the approved authorization form or altered authorization form to obtain subjects' permission to access, use, or disclose their protected health information.
- Comply with all requirements described in the **Investigator Responsibilities Related to the Protection of Human Subjects** attachment.

If you have any questions, please contact the staff person listed above.

UW-Madison Health Sciences Institutional Review Boards Mail Code #9425
800 University Bay Dr.(UBOB), Ste. 105
Madison, WI 53705
Phone 608-263-2362 FAX 608-265-5811

University of Wisc... al Review Boards
...500 Overlook Terrace Madison, Wisconsin 53705
www.medicine.wisc.edu/irb/

Sincerely,

Carla Phillips, MA. (alternate for G. Anding)

Gretchen Anding, MA
Manager
Minimal Risk IRB

Enclosure(s):
Investigator Responsibilities Related to the Protection of Human Subjects
Approved Consent Form(s): Version 3.0, 3/8/10