UNIVERSITY OF WISCONSIN –MADISON, DEPT. OF BIOMEDICAL ENGINEERING

Ultrasound Probe Holder

Final Design Report

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Abstract

Vascular reactivity studies will greatly increase the understanding of Atherosclerosis, an inflammation of the arteries. A possible complication of advanced Atherosclerosis is thrombosis, which in turn may lead to heart attacks or strokes. When examining how the brachial arteries react to occlusion, an ultrasonic probe must be held in the correct orientation for prolonged periods of time. Ultrasonic images are influenced by motion artifact caused by the sonographer's movements. The development of a probe holder that would stabilize and consistently position the ultrasound probe would improve the quality of the sonogram. A design was drafted for a probe holder that would stabilize and consistently position the ultrasound probe would improve the quality of the sonogram. The prototype constructed enables the probe to be moved in 6 degrees of motion. The positioning of the probe can be adjusted by the control of one knob. Fine tuning adjustment is also available. The table also contains a comfortable arm

rest that stabilizes the patient's arm. Future work will include testing the prototype to determine if it meets the sonographer's requirements.

Problem Statement

To aid the use of ultrasound for study of arterial reactivity, a simple, stable, adjustable probe holder is needed. The stabilization provided by such a holder could potentially improve probe imaging quality and diagnostic effectiveness. 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 and future work will be directed to integrating all components of the device into a functional and usable prototype.

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.

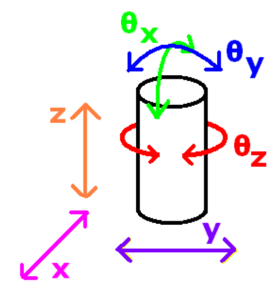


Figure 1 - Degrees of Freedom needed for proper positioning.

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

Five main characteristics were taken into consideration when choosing a design for this project: ease of use, reliability, durability, complexity, and cost. These criteria and their associated importance were determined by the client's requirements.

The most important aspect of this device is that improves the ultrasound procedure. However, it must not impede the workflow and efficacy of the sonographer. Ease of use is paramount to the integration of this device into a healthcare setting. The device should be quickly adjustable and require minimal training to use. Additionally, shorter setup times will allow for greater productivity.

The second most important criterion for this device is reliability. The device must ensure that the probe only moves as desired. Ideally, the final product would be reliable enough that the sonographer can set the probe in place and then do other things while the procedure is being conducted.

There is a need for the device to last for many years. A durable device is much more valuable, and less expensive, than having many devices with unknown life spans.

The complexity of construction was the fourth category which we considered for this project. A device with a few modular sections is much easier to fix than a product that needs to be wholly replaced if one part breaks. It is advantageous to design something which requires less machined parts or unique tools to assemble. This would reduce the time to fix the device in the event of a malfunction.

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 – Snake

The main component of this design was the snake like positioning arm (Figure 4). The arm itself is essentially many ball and socket joints linked together with a spring 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 spring acts as a locking mechanism. It pulls all the links together so the friction between them doesn't 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. It has no buttons or knobs so it requires minimal training to operate. However, the springs within the snakes tend to lose their rigidity over time and the snake becomes unreliable. If a stronger spring were to be used to offset the spring degradation, it would require much more force to overcome that spring when the probe had to be repositioned. It may be hard to make fine adjustments once the probe is set in place.

Figure 4 - Illustration of snake positioning concept. From McMaster-Carr.

Option 2 – Post Holder

This design has a vertical bar with a horizontal bar that has a knob which will allow it to slide up and down the pole (Figure 5). Additionally, the horizontal bar can swing laterally 360 degrees on the pole, increasing its range of motion. Other knobs will enable the user to change the angle of the horizontal bar. While the device is very secure and able to hold its position accurately for long periods of time, it is difficult to change the position quickly and has a limited range of motion.

Figure 5 - Post Holder Design. The horizontal bar is free to move up, down and rotationally along the vertical post. From Noga Engineering.

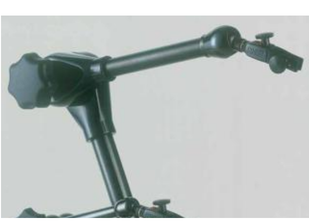


Figure 6 - Several Articulated Arm models. One knob at the corner joint tightens all three joints, allowing size degrees of freedom with one adjustment. From Noga Engineering.

Option 3 – Articulated Arm

The articulated arm functions just like a human arm (Figure 6). There are two ball and socket joint sand a hinge joint that provide 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 most costly, it provides the greatest 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.

Design Matrix

The three design options were analyzed using the following criteria: ease of use, reliability, durability, cost, and complexity. Based on the client's requirements, each category was given the following weights: ease of use – 40%, reliability – 30%, durability – 15%, cost – 5%, and complexity – 10%. Based on the design matrix show below the articulated arm design was chosen as the final design.

	Snake Design	Post Holder	Arm Design
Ease of Use (40%)	9	5	7
Reliability (30%)	5	10	10
Durability (15%)	4	9	9
Cost (5%)	10	7	6
Complexity (10%)	10	7	6
Total (Out of 10)	7.2	7.4	8.05

Figure 7 - Design matrix of positioning options. Based on weighted rankings of each option, the final score of the Arm design was selected as the best choice.

Probe Clamping Options

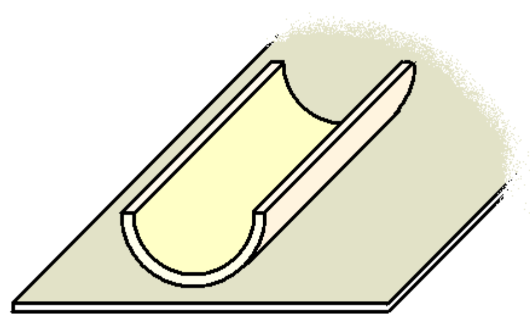
Option 1 - 3 Pronged Clamp

A 3 pronged clamp may be used to hold the probe (Figure 8). The prongs on the clamp are able to fit around each size of probe and they can be tightened to ensure that the probe is not moved during the procedure. The prongs have a rubber casing around each tip to ensure that they do not damage the probe and are able to firmly hold different sizes. The prongs are adjusted by the screws. The rod can easily be attached to the mechanical arm.

Figure 8. 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.

Option 2 - Plate System

The plate system is composed of two parallel plates that sandwich the probe that can be tightened to fit around each different sized probes. The inner surface will have foam or rubber that will cushion the probe when it is locked into place by the plates. Several adjustable screws will connect the two plates at different points and be able to be tightened to fit each probe.



A.

Arm Cradle

In order to ensure that the probe position on the arm remains constant, a cradle should be designed to hold the patient's arm in position. An arm cradle will provide the support for the arm so that the patient does not tire and move around. A possible design is to cut a hollow cylinder in half and pad it (Figure 9). Additionally, if a handle was placed at one end, the subject would be able to hold it in their hand and further minimize movement. Eventually the arm cradle should be attached to the subject's bed.

Figure 9 - Basic concept of cradle for stabilizing the forearm

Final Design

Based on the above analysis, a design for a preliminary prototype was drafted. The goal behind this design was to keep costs minimal while providing a proof of concept. Long term testing of this device will provide a better insight to the necessity of potentially costly improvements. The sections below include considerations for dimensioning of the device, a detailed description of all components of the design, and an overview of the costs associated with construction of the prototype.

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. With the design concept of using two segments of semi-cylindrical cradles, the dimensions of consideration 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 95th 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.

Design Components

The final design consists of an arm cradle and a probe positioning device that are attached to a melamine board which is lightweight, sturdy, and easy to clean.

Arm cradle

The cradle used to hold the subject's arm was constructed from a hollow acrylic tube, polyurethane foam, and wood supports. From the anthropometric data above, the acrylic tube's inner diameter is 14 cm. Each cradle is 15.2 cm long and separated by 15.2 cm. The acrylic tube is lined with polyurethane foam to cushion the patient's arm and to avoid pressure points on the arm. Because the foam was made from closed cell polymer, its weather resistant properties will allow the foam to be easily cleaned. Wood supports attach the semi-circular cradle to the board.

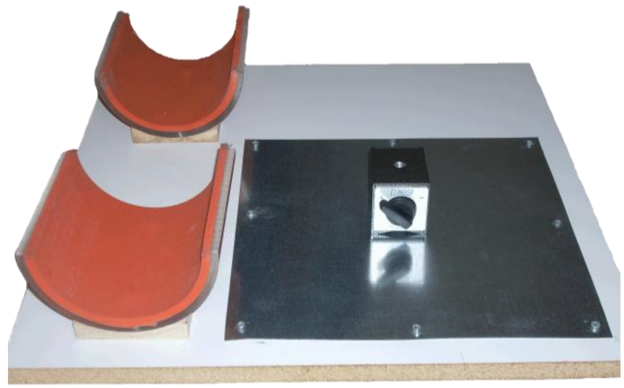


Figure 10 - Completed arm cradle and magnetic mounting surface.

Probe positioning device

An articulated arm, magnetic base, steel sheet and a 3 pronged clamp were used to securely hold and position the ultrasonic probe. The articulated arm consists of 2 ball and socket joints and 1 hinge joint. This models a human arm and is able to provide a large range of motion since each ball and socket joint provides 3 degrees of freedom while the hinge point provides 1. The fine tuning adjustments at the end of the articulated arm provide up to 3 additional degrees of freedom. A knob controls the movement of the all the joints while another knob for fine tuning allows for smaller adjustments. The articulated arm is attached to a magnetic base, which in turn is locked onto a steel sheet attached to the melamine board. The magnetic base can be turned on and off as needed to move the entire articulated arm and provide gross adjustments. Finally, a 3 pronged clamp is attached to the fine-turning device at the end of the articulated arm to accommodate a variety of probes (See Figure 8).

Figure 11 – Articulated positioning arm ing armBall joints at the end and a hing joint in the middle are all tightened by a nob at the middle.

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 1 - Cost of materials used in construction of first generation prototype.

Item	Product Number	Supplier	Cost
Sheet Metal (1'x1')	43374560329	Home Depot	5.84
Emory Paper	76607478559	Home Depot	5.47
23 3/4 x 48 Melamine	40933106189	Home Depot	11.98
1x4x2 Poplar	10286399428	Home Depot	2.63
Positioning Arm w/ magnetic base	MA61003	MSC-Direct	229.02
Acrylic Pipe	8486K393	McMaster-Carr	27.17
3 Pronged Clamp	057697Q	Fisher Scientific	39.83
Silicon Foam Rubber	8785K181	McMaster-Carr	24.29
1/8" Low Carbon Steel	-	COE Machine Shop Scrap	
1/2" Wood Screws	-	COE Machine Shop Scrap	
Total			**346.23**

Future Work

The next step is to deliver the prototype to the client for testing and usability evaluation. Feedback from the client will help determine which elements of the design need improvement or replacement. In addition to this there are some known areas of improvement. Further machining and modifications are required for improved attachment of the clamp to the articulated arm. The current attachment method is unstable; several ideas have been discussed to remedy this issue.

One option is to remove the fine tuning device of the articulated arm and replace it with a fabricated piece which will allow the clamp to be attached more effectively. Threading on the end of the arm allows for easy changing. The custom piece would have a hole for the rod to pass through and a tightening screw.

A second option would be to use a “sandwich” clamp rather than the 3 pronged clamp. It would consist of two PVC plates with rubber padding on one side. These plates would be applied to opposite sides of a probe, securely accommodating all probe shapes. The sandwich would then attach to the arm in a fashion similar to the 3 pronged clamp. Further development of this idea depends on the feedback from the client. This design will also change the general orientation of the arm which may be more convenient for operation.

Another area for improvement is to switch the magnetic base attachment with a set of linearly adjustable platforms. The magnetic base has no fine tuning adjustability. The arm would attach to a planar platform so that it could be moved in 2 directions and a third linear slide could be added for movement in the vertical direction. This alternative would significantly increase the overall cost and would only be implemented if the client expressed the need for additional operational ability.

Lastly, a method for positioning the table next to the patient's bed has not been developed. Discussions have been conducted for two possible structures. The first would be to have a separate table for the device which could be wheeled from room to room. The other method proposed would attach the melamine board to the bed. The client can determine if either of these improvements is necessary.

Conclusions

A design was drafted for a probe holder that would stabilize and consistently position the ultrasound probe would improve the quality of the sonogram. The prototype constructed enables the probe to be moved in six degrees of motion. The positioning of the probe can be adjusted by the control of one knob. Fine tuning adjustment is also available. The table also contains a comfortable arm rest that stabilizes the patient's arm. Future work will include testing the prototype to determine if it meets the sonographer's requirements.

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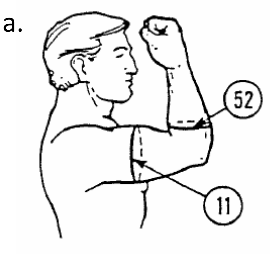
Appendix A – Anthropometric Calculations

Cradle Diameter:

a.



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

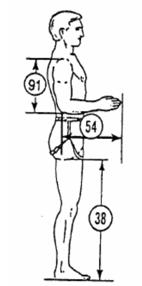
  Male Mean = 33.76 cm, SD = 2.72 cm

  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.



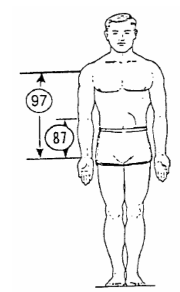
Cradle Lengths:

- 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

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

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

Appendix B

Project Design Specification—Ultrasound Probe Holder (Group 44)

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May 3, 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.

Client Requirements:

- Provides 6 degrees of positioning freedom
- Stable, won't fall over or move probe
- Adjustable for small changes
- 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, able to make small adjustments quickly, securely holds the probe, stabilizes the patient's arm while in use, must be able to be stable for 5 to 10 min periods
    b) *Safety* – The materials should not be hazardous and should not interfere with the ultrasound
    c) *Accuracy and Reliability* – The device should be able to make small changes quickly and hold its position without changing. It should have 6 degrees of motion
    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 without interfering with the ultrasound procedure

h) *Size* – The device should be small and compact, should be able to fit for different sized probes
i) *Weight* – The probe should be as lightweight as possible while proving a stable support
j) *Materials* – The materials should be cost efficient and should not interfere with the ultrasound procedure
k) *Aesthetics* – The device should be aesthetically pleasing

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* – The device should follow all required standards in regards to ultrasonography
   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, but none are available commercially.