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(54) **ULTRASOUND PROBE HAND SHIELD**

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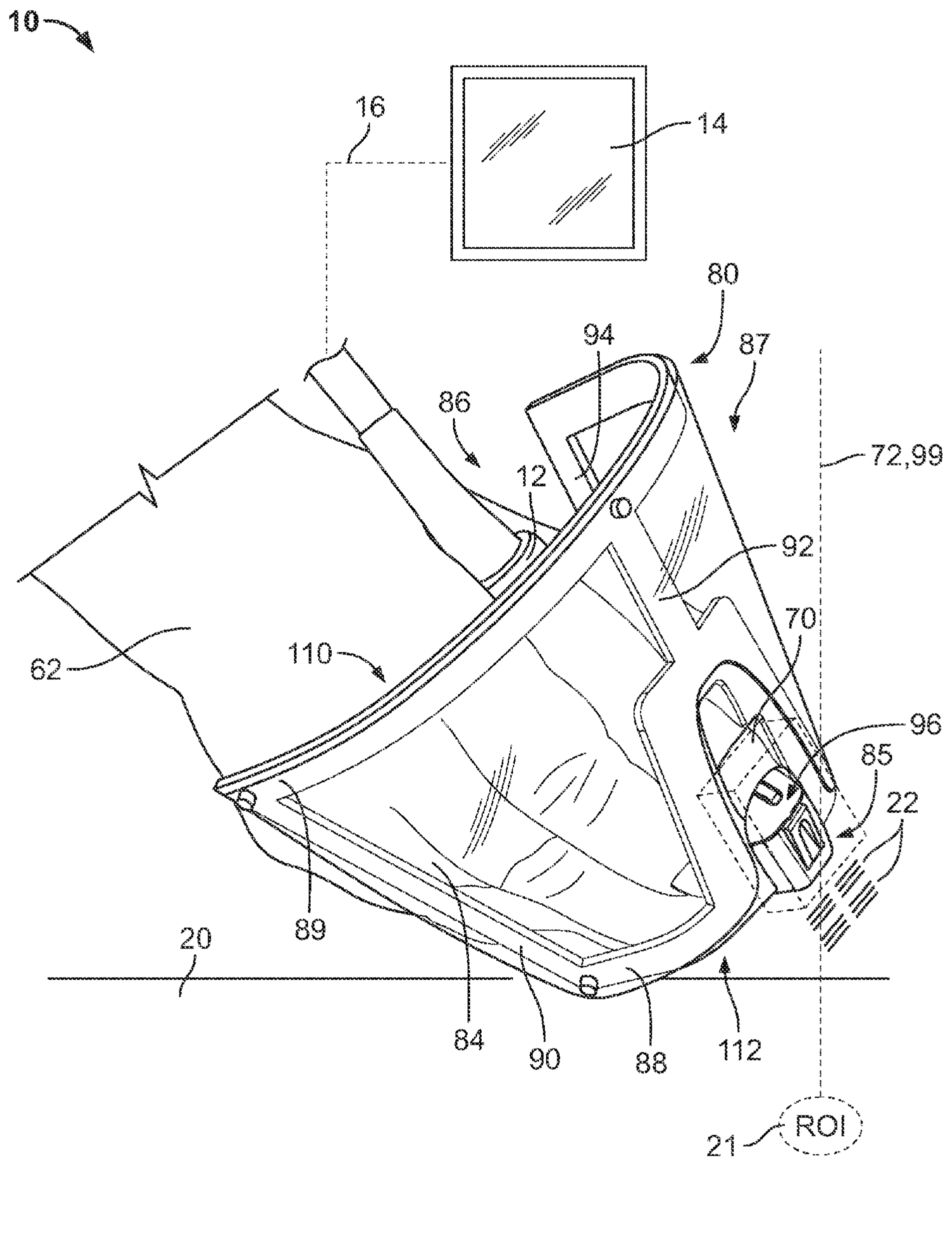
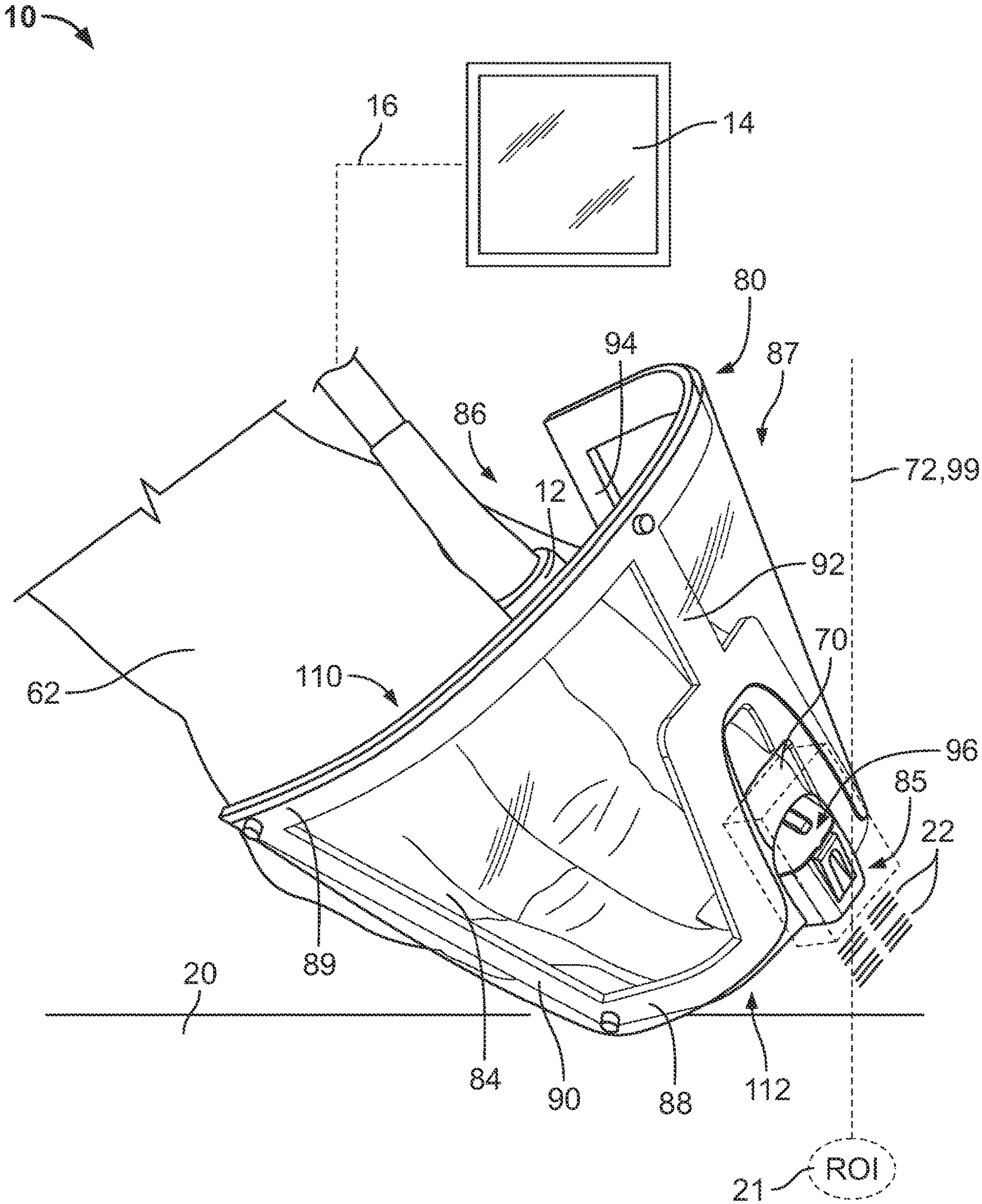
(57) **ABSTRACT**

A hand shield may be installed onto an ultrasound probe to protect the operator from needle sticks. The transparent shield may be a disposable, sterilized film attachable to a frame which, when securely attached to the frame, blocks the needle from accidentally contacting and sticking the operator's hand during needle insertion. The shape and size of the frame avoids interference with the operator's hand and maintains normal operation of the ultrasound probe, thus recognizing the need for the angle of insonation (i.e., angle of the ultrasound beam relative to the tissue or organ of interest) to be adjusted and the ultrasound probe to be pressed into the tissue.

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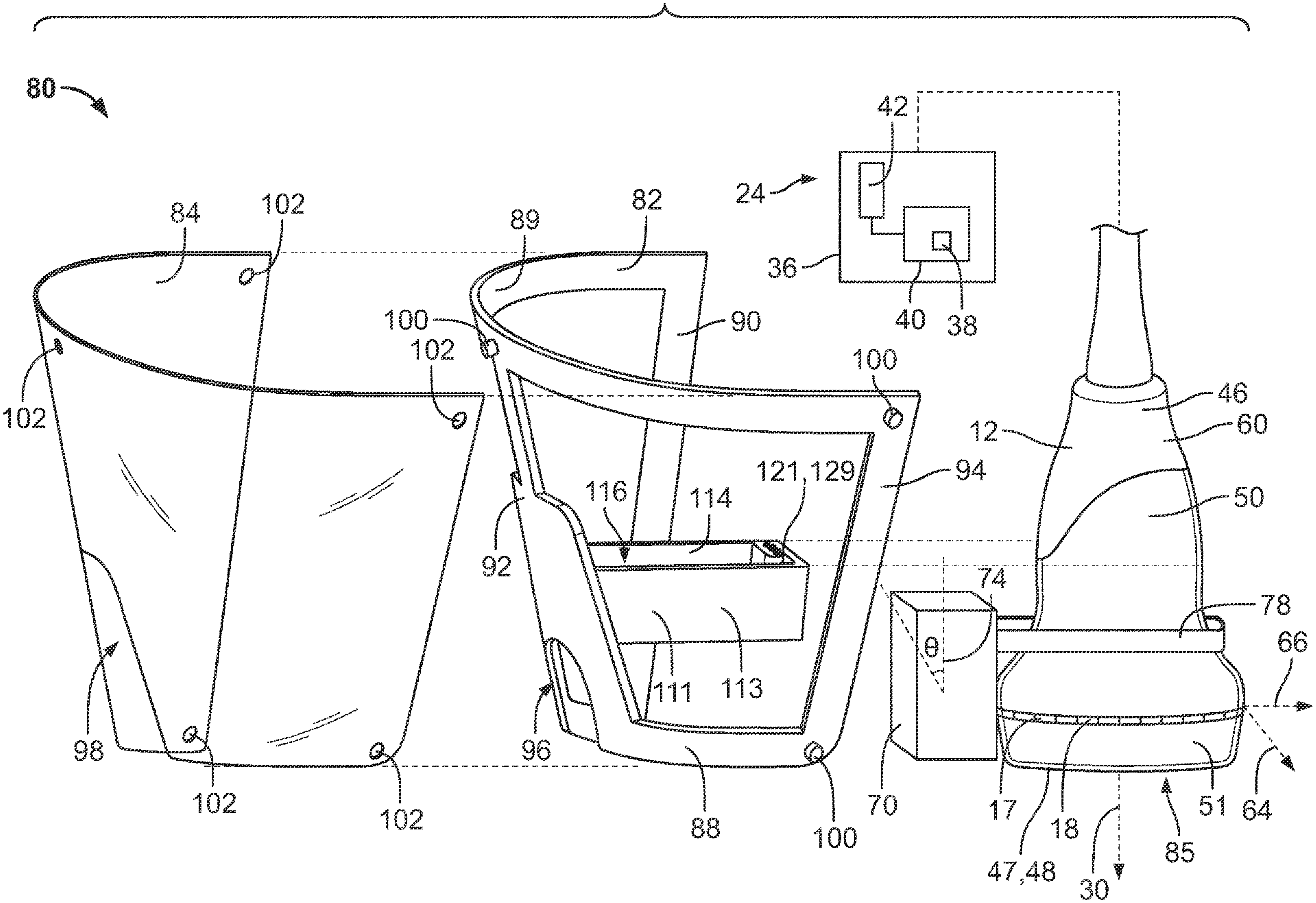
ROI

FIG. 1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111
113
24
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47,48
85
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FIG. 2

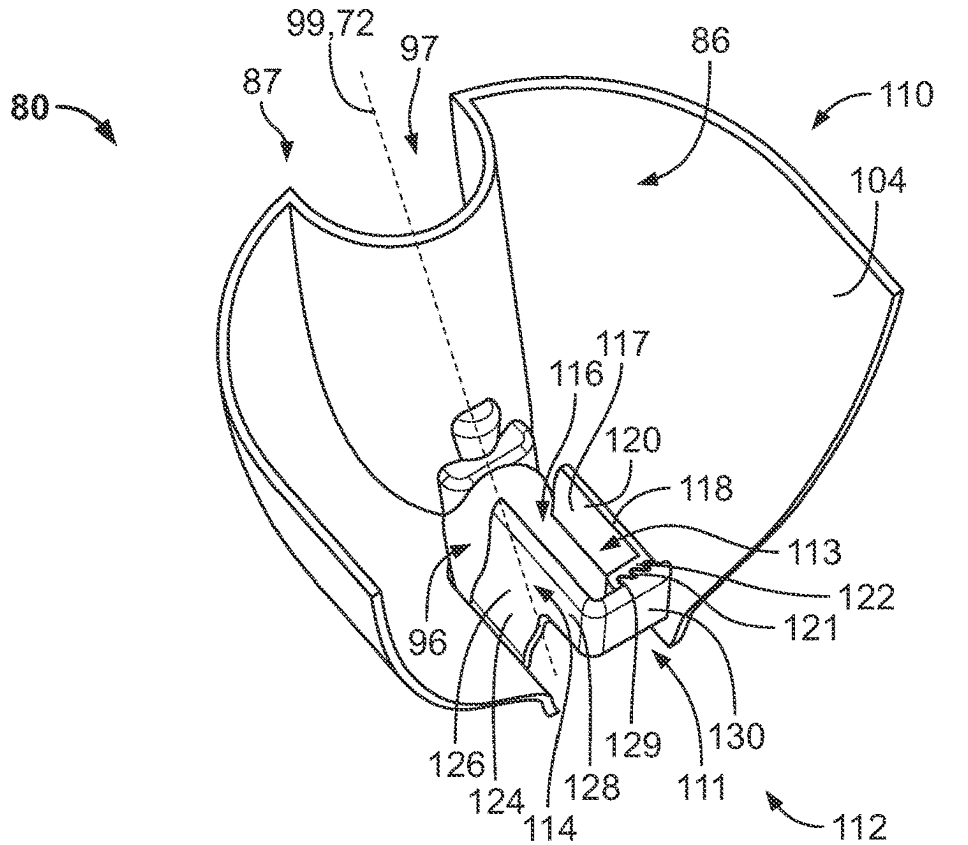
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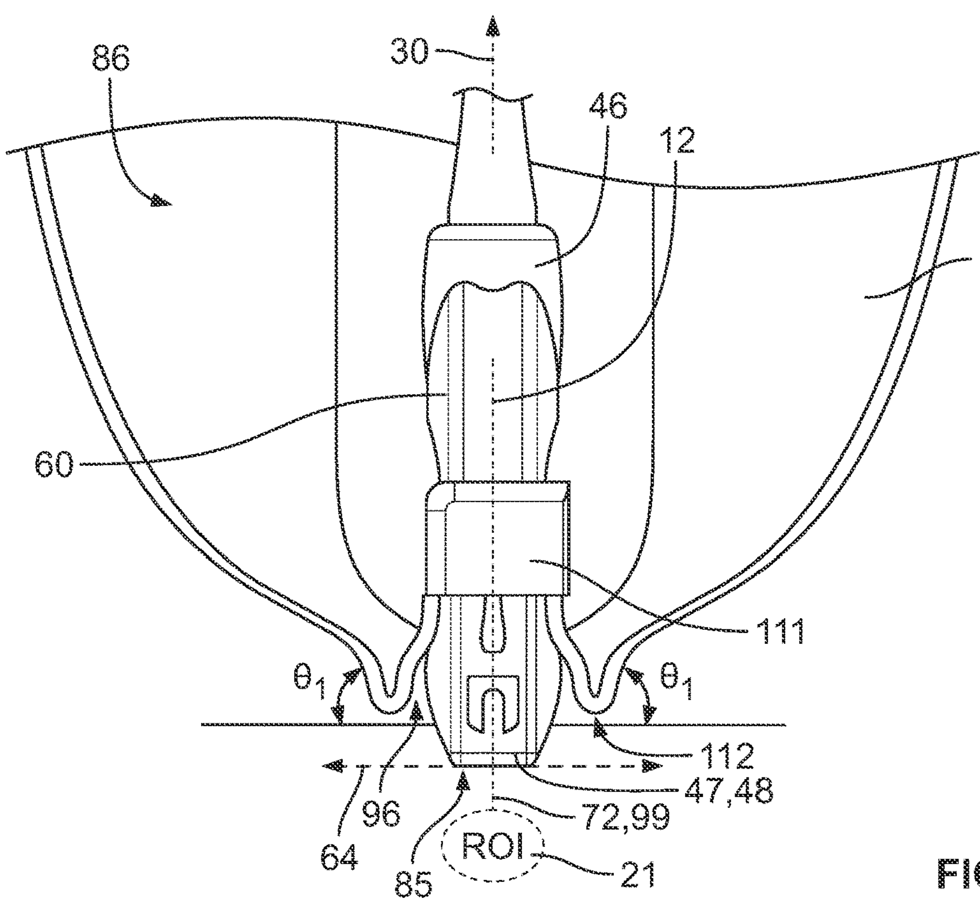
FIG. 3


30
86
46
12
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111
θ_1
θ_1
112
47,48
96
72,99
64
ROI
85
21

FIG. 4

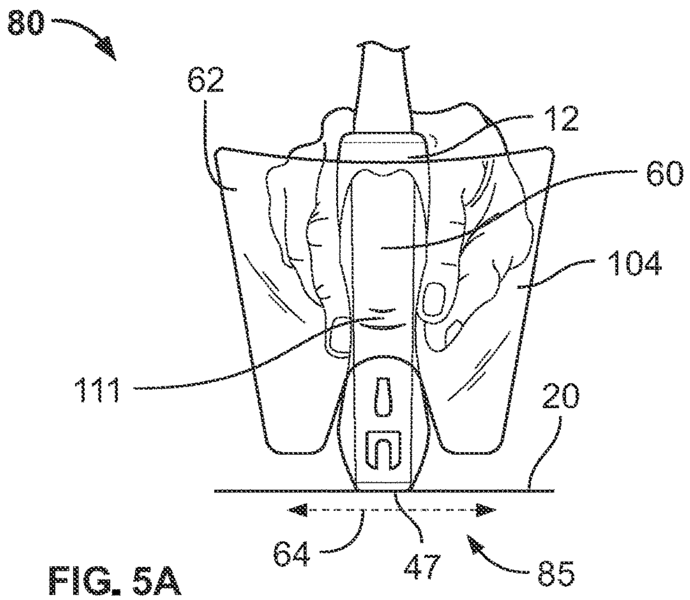

FIG. 5A

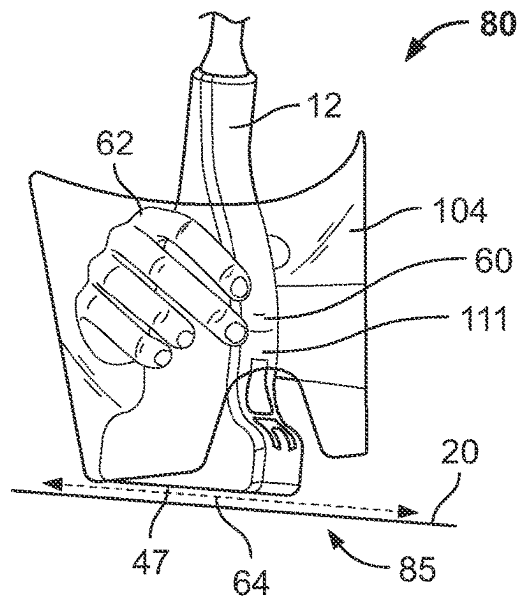

FIG. 5B

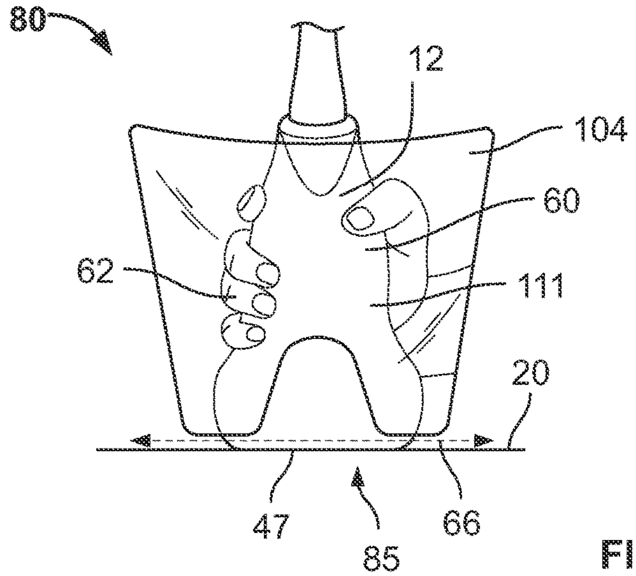

FIG. 5C

ULTRASOUND PROBE HAND SHIELD

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0001] —

CROSS REFERENCE TO RELATED APPLICATION

[0002] —

Background of the Invention

[0003] The present invention relates to personal protective equipment to protect the wearer from injury during medical procedures and in particular to a protective hand shield worn during ultrasound probe operation to protect the wearer's hand during simultaneous needle insertion.

[0004] An ultrasound transducer or ultrasound probe is a medical device allowing a healthcare professional to create an image or sonogram of organs, tissues, and other structures beneath the tissue and inside the body. A simple ultrasound transducer provides for a wand-like instrument that is passed over the surface of the body, or sometimes inserted into an orifice of the body, that emits sound waves and picks up the echoes that bounce off the organs, tissues, and structures of interest to create the image or sonogram.

[0005] The ultrasound transducer typically includes a transducer bar that holds an arrangement of piezoelectric crystals located near the skin-contacting face of the transducer that generates the ultrasound waves in response to an electric current applied to the piezoelectric crystals. The piezoelectric crystals also receive the echoes and sends them back to a computer as an electric current to produce the sonogram. The transducer bar is supported by an acoustically insulated housing to prevent other external echoes from affecting the sonogram. The housing of the transducer provides an operator handgrip so that the operator can effectively grip the transducer during movement of the transducer bar over the surface of the skin and over the target organ or tissue of interest.

[0006] There are three common types or shapes of ultrasound transducers used for imaging: linear, convex/curvilinear, and sector (phased) array. A linear ultrasound transducer has a linear piezoelectric crystal arrangement and produces a rectangular beam shape. A convex/curvilinear ultrasound transducer has a curvilinear piezoelectric crystal arrangement and produces a convex shaped beam. A sector (phased) array transducer has a linear or curvilinear piezoelectric crystal arrangement and produces a beam with a narrow point that expands to a triangular shape. The type of transducer chosen depends on the desired depth of the target organ or tissue of interest and application (e.g., visualization of tissue and organs such as the thyroid, breast, tendon, abdomen, heart, brain, nerve, musculoskeletal system; vascular examination; venipuncture; intraoperative laparoscopy; photoacoustic flow velocity imaging; body fat measurement; locomotive syndrome check; etc.).

[0007] Examples of these ultrasound transducers are manufactured by GE Healthcare and are found at <https://www.gehealthcare.com/products/ultrasound/ultrasound-transducers>, hereby incorporated by reference.

[0008] Ultrasound transducer operators (e.g., sonographers or physicians) are trained to use proper hand mechanics when operating the transducer to prevent fatigue, strain, and overuse injuries. For example, the operator must use the proper hand grip and the grip cannot be too tight. The transducer is often held at the base of the transducer to facilitate control and the operator may maintain contact with the patient's skin while scanning to maintain stability and prevent the transducer from moving or rotating out of the desired image location. For example, in one gripping orientation, the operator may contact the patient with the pinky and ring fingers and ulnar aspect of the hand while gripping the transducer with the thumb, index, and middle fingers providing stability and optimizing control.

[0009] During the ultrasound, the computer will provide a real time image which helps guide that operator to producing the optimal image. In some cases, the ultrasound is used during an interventional procedure (e.g., injection or aspiration of joints, tendons, or tendon shrouds; aspiration of cysts, fluid collections, and abscesses; peripheral nerve blocks/perineural injections; lavage and aspiration of tendon calcifications; fine-needle aspiration and biopsy; and foreign body retrieval) to diagnose, ensure therapeutic efficacy or procedural success, and to reduce procedural risk. The ultrasound requires looking back and forth at the ultrasound screen showing the real time image and the patient/ultrasound probe. These back and forth head movements add complexity to the procedure. The recorded sonogram may be later interpreted by an imaging specialist (e.g., radiologist or physician) who will report on the results of the image and provide a diagnosis.

SUMMARY OF THE INVENTION

[0010] Ultrasound is useful for guiding interventional procedures such as aspirations, ablations, and biopsies, by providing real-time imaging to clearly visualize the pathway for a needle. Ultrasound guided interventional procedures are desirable because they can use a small and portable ultrasound machine, has lower medical costs, and poses no radiation hazard compared to other image guidance techniques. However, the technique has a steep learning curve and involves training the operator in proper ultrasound mechanics and guidance.

[0011] The present inventors have recognized that ultrasound guided interventional procedures increase the risk of accidental needle sticks, for example, during medical training when the medical trainee is performing a needle insertion during ultrasound scanning by the same medical trainee or a separate ultrasound operator. Moreover, the stabilization of the ultrasound probe often requires the operator's hand (i.e., ulnar aspect) to be placed on the surface of the patient's skin, close to the needle insertion site, increasing the risk of needle sticks.

[0012] Ultrasound guided interventional procedures may involve one or more operators holding the ultrasound transducer scanning and holding the needle for insertion, respectively. Whether one, two or more operators are involved in the procedure, coordination of the ultrasound probe simultaneously with the needle insertion runs the risk of accidental needle sticks. The ultrasound screen is often positioned outside the line of sight of the ultrasound probe or needle insertion site, therefore increasing the risk of needle sticks during back and forth head movements of the operator.

[0013] Multiple needle reinsertions and redirections during the ultrasound guided interventional procedure increases the risk of needlestick injuries and increases the risk of exposure to the operator of bloodborne pathogen transmission and must be reported and managed immediately to prevent serious injury and consequences.

[0014] In one embodiment, the invention may provide a shroud comprising a frame and replaceable transparent shield that may be installed onto an ultrasound probe to protect the operator from needle sticks. The transparent shield may be a disposable, sterilized film attachable to the frame which, when securely attached to the frame, blocks the needle from accidentally contacting and sticking the operator's hand during needle insertion. The shape and size of the frame avoids interference with the operator's hand and maintains normal operation of the ultrasound probe, thus recognizing the need for the angle of insonation (i.e., angle of the ultrasound beam relative to the tissue or organ of interest) to be adjusted and the ultrasound probe to be pressed into the patient's skin to provide optimal imaging.

[0015] In different embodiments, the hand shield assembly may allow for an ultrasound needle guide, attached to the ultrasound probe, to be accommodated and used with the probe.

[0016] In different embodiments, the hand shield assembly permit the operator to grip the ultrasound probe and will accommodate operator grip preferences. Further, the frame and transparent shield may permit the operator's hand to contact the patient's skin to stabilize the ultrasound probe during scanning as would be done during normal operation of the probe.

[0017] In different embodiments, the hand shield assembly may accommodate different shapes and sizes of ultrasound transducers and different shapes and sizes of needle guides.

[0018] Specifically, then, in one embodiment, the invention provides an ultrasound transducer hand shield for protecting a hand of a healthcare professional gripping a transducer in a scanning position with a front end of the transducer adjacent to tissue of a patient supporting an array of piezoelectric elements, and a rear end of the transducer supporting a hand grip extending along an axis of the transducer perpendicular to the array of piezoelectric elements. The hand shield comprises a shroud removably supported by the transducer to extend along the axis of the transducer and configured to extend at least partially around the transducer to create a physical barrier between the hand grip and a needle insertable into the tissue of the patient below the transducer; and a connector supporting a connection of the shroud at a front end of the transducer wherein the shroud extends around but does not contact the rear end of the transducer.

[0019] It is thus a feature of at least one embodiment of the invention to provide the protective benefits of personal protective equipment during ultrasound probe use while preserving the operator's ability to grip the ultrasound probe at different hand angles and stabilization of the hand on the patient's tissue. The interior of the shroud permits the operator's hand to take different grips and to accommodate different hand and probe sizes.

[0020] The shroud may be sized to fit around the hand grip to receive the hand of the healthcare professional therein.

[0021] It is thus a feature of at least one embodiment of the invention to optimize the trade-off between needle stick protection during simultaneous needle insertion and natural gripping of the ultrasound probe without interference.

[0022] The shroud may extend at least 100 mm from the probe axis at all angles about the probe axis.

[0023] It is thus a feature of at least one embodiment of the invention to permit the operator to adjust their grip, for example, to achieve different probe angles with respect to the patient's tissue thus permitting natural twisting and turning of the operator's hand grip.

[0024] The top end of the shroud may have a width of at least 150 mm. The bottom end of the shroud may have a width that is less than 50 mm.

[0025] It is thus a feature of the invention to provide an interior volume of the shroud resembling the natural tapering of the human operator's hand when gripping the probe. The shield may provide enough clearance to accommodate various and sometimes unconventional probe grips of the operator's hand.

[0026] The shroud may extend at least 180 degrees around the transducer.

[0027] It is thus a feature of at least one embodiment of the invention to provide protection at the front and sides of the ultrasound probe to protect the operator's hand during freehand insertion of the needle (without a needle guide) and insertion of the needle into the needle guide which may occur when the ultrasound probe is also being rotated for scanning.

[0028] The transducer may have four sides and the shroud may extend around at least three sides of the transducer.

[0029] It is thus a feature of at least one embodiment of the invention to ensure proper shielding with rectangular shaped ultrasound probes having four sides.

[0030] The connector may be a clamp configured to extend around a front end of the transducer housing.

[0031] It is thus a feature of at least one embodiment of the invention to minimize the interference of the connector with the operator's hand on a top end of the handgrip and permitting extension of the probe below the connector at a bottom end of the transducer without causing discomfort to the patient.

[0032] The shroud may have a bottom opening permitting extension of the front end of the transducer from a bottom of the shroud.

[0033] It is thus a feature of at least one embodiment of the invention to minimize the risk to needle stick but still allowing the bottom of the probe to be pressed into the patient's tissue during scanning.

[0034] The shroud may provide a cutout supporting extension of a corner of a front end of the transducer.

[0035] It is thus a feature of at least one embodiment of the invention to allow the shield to be used with ultrasound probes with built in or are attached to needle guides.

[0036] The shroud may provide a transparent window.

[0037] It is thus a feature of at least one embodiment of the invention to promote a line of sight of the needle with respect to the operator's hand, and the front end of the transducer with respect to the patient's tissue, which would normally be expected during training and ultrasound use without the shield.

[0038] The shroud may provide a frame supporting a replaceable film attachable to the frame. The replaceable film may be transparent allowing viewing therethrough. The replaceable film may be attachable to the frame by tabs receivable into corresponding holes.

[0039] It is thus a feature of at least one embodiment of the invention to permit a protective covering of the frame to be replaceable to prevent cross-contamination of the frame with the patient using a disposable film layer whereby the frame can be sterilized and reused. In an alternative embodiment of the present invention, the frame and film are manufactured as a unitary device that is disposable or sterilized and reused.

[0040] The shroud may be a curved cone with a wall curved around the transducer. The bottom end of the shroud may have curved corners.

[0041] It is thus a feature of at least one embodiment of the invention to provide an intuitive shroud resembling the shape of the operator's grip around the probe and minimizing discomfort to the patient when the probe is pressed into the tissue.

[0042] The invention may in addition or alternatively provide an ultrasound transducer having a housing supporting a hand grip extending along the axis and perpendicular to an array of piezoelectric elements of the transducer.

[0043] It is thus a feature of at least one embodiment of the invention to provide a hand shield that could be attached to and used with various commercial ultrasound transducers.

[0044] The invention may in addition or alternatively provide a needle guide attached to and extending outwardly from the transducer housing and providing a guide channel permitting a needle to extend into to the tissue of the patient below the transducer.

[0045] It is thus a feature of at least one embodiment of the invention to provide a hand shield that could be attached to and used with various commercial needle guides.

[0046] One embodiment of the present invention provides an ultrasound transducer comprising a housing supporting a hand grip extending along an axis perpendicular to an array of piezoelectric elements of the transducer; a needle guide attached to and extending outwardly from the transducer housing and providing a guide channel permitting a needle to extend into to the tissue of the patient below the transducer; and a hand shield providing a shroud supported by the transducer extending along the axis of the transducer and at least partially around the transducer to create a physical barrier between the hand grip and a needle insertable into the tissue of the patient below the transducer; and a connector supporting a connection of the shroud at a front end of the transducer and a space around the rear end of the transducer without contacting the transducer.

[0047] One embodiment of the present invention provides a disposable hand shield for an ultrasound transducer of a type having a shroud supported by the transducer and extending along the axis of the transducer to extend at least partially around the transducer to create a physical barrier between the hand grip and a needle insertable into the tissue of the patient below the transducer; and a connector supporting a connection of the shroud at a front end of the transducer and a space around the rear end of the transducer without contacting the transducer.

[0048] These particular objects and advantages may apply to only some embodiments falling within the claims and thus do not define the scope of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0049] FIG. **1** is a perspective view of an ultrasound hand shield constructed according to the present invention and held by an operator's hand, the hand shield attached to an ultrasound probe with a needle holder and providing a frame attached to a front end of the ultrasound probe and supporting a transparent film blocking the operator's hand from a needle inserted through the needle holder into the patient's skin at an angle;

[0050] FIG. **2** is an exploded, perspective view of the ultrasound shield of FIG. **1** showing the replaceable film removed from the frame and an opening of the film and frame permitting the needle guide to extend to an outside of the ultrasound shield;

[0051] FIG. **3** is a perspective interior view of an alternative embodiment of the present invention, the ultrasound hand shield formed as a unitary shroud and a clamp of the ultrasound shield permitting the ultrasound shield to be attached to a front of the ultrasound probe;

[0052] FIG. **4** is a rear cross sectional view of the ultrasound hand shield of FIG. **3** showing a front of the ultrasound transducer extending below the shield to allow for various angles of insonation to be achieved; and

[0053] FIGS. **5**A-**5**C are simplified, perspective views of various operator grips of an operator holding the ultrasound probe while the ultrasound shield is attached to the probe.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0054] Referring now to FIG. **1**, an ultrasound system **10** of the present invention may include an ultrasound transducer **12** for acquiring ultrasound echo data and communicating that ultrasound data with a display unit **14** for the display of information related to acquired ultrasound data. As shown, the transducer **12** and display unit **14** are separate so as to aid in the viewing of the display unit **14** during scanning of the transducer **12**; however, it is contemplated that these two elements can be integrated into a single device. When separate, the transducer **12** may communicate with the display unit **14**, for example, wirelessly by radio, ultrasound, or optical signals **16** or by means of a flexible electrical conductor. A keyboard may receive commands from an operator to provide information derived from ultrasonic measurements to be described.

[0055] During a typical medical procedure, the patient will lay down on an operating table, e.g., prone, supine, or on their side, and the operator will be standing or seated on the side of the operating table and patient to pass the transducer **12** over the patient tissue **20** and over a region of interest **21**. It may be desired to position the display unit **14** in a position which minimizes the amount of operator head movement, for example, positioning the display unit **14** in a line of sight that minimizes side-to-side head movement of the operator but understandably may require some up-and-down head movement of the operator to view the display unit **14** and then the transducer **12** and patient tissue **20** below them during ultrasound scanning.

[0056] Referring also to FIG. **2**, the ultrasound transducer **12** provides an array **17** of regularly spaced transducer elements **18** that each may convert a received electrical signal into an acoustic signal (or ultrasonic beams **22**) delivered to the patient tissue **20**, for example, through an aqueous gel or the like (not shown). The acoustic signals (or ultrasonic beams **22**) are generally compression (longitudinal) ultrasonic signals that are in the same direction as the particle motion. The transducer elements **18** are also operated as sensors to receive ultrasonic acoustic energy to produce an electrical signal that may be measured, as further described below.

[0057] The ultrasound transducer **12** may provide for transducer elements **18** arrayed along a single dimension or a two-dimensional array. The transducer elements **18** are each capable of emitting ultrasonic acoustic waves into patient tissue **20** in contact with the underside of the array **17** and of receiving and detecting echo signals from those emitted ultrasonic acoustic waves for the generation of ultrasonic data. A signal processing system **24** generally controls the transducer elements **18** to provide separate diverging ultrasonic beams **22** that may be controlled in amplitude and phase for beamforming and other known techniques and are spaced along a longitudinal axis **66** of the transducer face **47**. The signals necessary to produce the ultrasonic beams **22** and to measure the echo signals are generated by the signal processing system **24** using a programmed electronic processor **36** executing a stored program **38** contained in a computer memory **40**. The resulting data from measurement of the propagation of the ultrasonic beams **22** may be stored as image or other data files **42**.

[0058] The ultrasound transducer **12** may include a housing **46** supporting at a front end **85** of the transducer **12** an acoustic lens **48** forming a tissue contacting face **47** of the transducer **12** which may be a hard rubber that focuses the ultrasound waves into the contacting the patient tissue **20**. Examples of hard rubber materials which may be used for the acoustic lens **48** include butadiene rubber, polybutadiene rubber, acrylic rubber and polyurethane, and the like.

[0059] Behind the acoustic lens **48** are several layers including a matching layer **51**, the transducer elements **18**, and a backing layer **50**. The matching layer **51** and backing layer **50** sandwich the transducer elements **18** on a front side and a back side of the transducer elements **18**, respectively.

[0060] The matching layer **51** help to transfer the ultrasound energy to the patient tissue **20** and reduces the impedance between the transducer elements **18** and the patient tissue **20**. Examples of materials which may be used for the matching layer **51** include epoxy, polyurethane, polystyrene, parylene, composite materials, and the like.

[0061] The backing layer **50** suppresses vibrations of the transducer elements **18** and prevents them from ringing back into the transducer elements **18**. Examples of materials which may be used for the backing layer **50** include graphite, porous graphite filled with resin, aluminum, and the like.

[0062] The housing **46** is acoustically insulated to prevent external soundwaves from interfering with the transducer **12**. In some embodiments the housing **46** has a plastic outer shell with a metal shielding layer and acoustic insulator layer.

[0063] The housing **46** has a handle portion **60** receivable by a grip of the operator's hand **62** to extend generally along a central axis **30** behind and covering the backing layer **50**. When held by the operator with the acoustic lens **48** extending downwardly to contact the patient tissue **20**, the handle **60** may extend upwardly away from the array **17** of regularly spaced transducer elements **18** generally perpendicular to the array **17**.

[0064] The handle **60** is manipulated with a light grip by the operator's hand **62** in a manner that, for example, orients the operator's hand **62** in a "pencil grip" configuration on the handle **60** whereby the operator's thumb and index finger squeeze the neck of the handle **60** across a narrower dimension of the handle **60** (the narrower dimension extending along a transverse axis **64** of the transducer face **47** perpendicular to the longitudinal axis **66** of the transducer face), and the underside of the handle **60** is supported by the operator's middle finger. The operator's pinky and ring finger may rest lightly on the patient tissue **20**.

[0065] Ultrasound transducers of the type used with the present invention may be as described in U.S. Pat. Nos. 5,497,662 and 4,257,278, and as sold by GE Healthcare under "Probe-9L-D" found at <https://services.gehealthcare.com/gehcstorefront/p/5499510>, which define the scope of the prior art and are hereby incorporated by reference.

[0066] In some embodiments, a detachable needle guide **70** is attached at the front end **85** of the transducer **12** to improve needle **72** placement and visibility to the operator. The needle **72** may be aligned with the longitudinal axis **66** (not shown), or the transverse axis **64** of the transducer face of the transducer **12** (FIGS. **1** and **2**). Therefore, a housing of the needle guide **70** may be attached to either the shorter or longer side of the transducer face **47** depending on the desired needle direction. In an exemplary embodiment, as seen in FIGS. **1** and **2**, the needle guide **70** is a rectangular housing attached to and extending from the shorter side of the transducer **12** in order to align the needle **72** with the longitudinal axis **66** of the transducer face.

[0067] The needle guide **70** is commonly used in procedures, for example, for needle insertion in small body parts, tissue biopsies, fluid aspirations, kidney/liver biopsies and vascular access, to direct a needle **72** through a guide channel or sleeve **74** of the needle guide **70** along a predetermined direction and angle to a desired depth within the patient's tissue **20**. The needle **72** is inserted through the guide sleeve **74** and then releasably clamped within the guide sleeve **74** of the needle guide **70** to be held in a fixed position within the guide sleeve **74** during the procedure at a predetermined angle with respect to the transducer **12**. It is understood that the guide sleeve **74** may accommodate needles **72** with a range of different gauges (e.g., 14 to 20 gauge) and may alternatively support a catheter or guidewire desirably inserted into the patient tissue **20**.

[0068] A long sterile plastic or latex shroud may be used to cover the transducer housing **46** before attaching the needle guide **70** to the transducer **12** to prevent contamination. The needle guide **70** may include a connector that permits secure attachment of the needle guide **70** to the transducer housing **46**. In one embodiment as shown, the connector is a clamp ring **78** that extends around the transducer housing **46** and may be screw tightened or finger tightened to secure the clamp ring **78** around the transducer housing **46**. In an alternative embodiment, the connector includes mating connector parts, e.g., male and female connector, of the needle guide and the transducer housing **46**, respectively. In still another alternative embodiment, the needle guide **70** is permanently fixed to the transducer housing **46** for example being a part of the housing **46** or molded onto the housing **46**.

[0069] A path **99** of the needle **72** with respect to the needle guide **70** may be visualized electronically on the display unit **14**, as guidance lines seen on the ultrasound image, prior to needle insertion. The needle guide **70** and/or guide sleeve **74** may be adjusted to provide a predetermined, desired angle of insertion with respect to the transducer **12**. For example, the guide sleeve **74** may be adjusted so that the tip or bevel of the needle **72** is angled (**0**), e.g., between 20 and 60 degrees, with respect to the acoustic lens **48** or tissue contacting face **47** of the transducer **12**.

[0070] An insertion depth of the needle **72** can also be estimated or measured on the display unit **14**, and thus the needle **72** length chosen or needle **72** position adjusted by sliding the needle **72** along the guide sleeve **74**, to provide a desired depth of insertion into the tissue **20**.

[0071] Needle guides of the type used with the present invention may be as described in U.S. Pat. Nos. 8,073,529, 8,449,531, and may be as sold by Civco under the trade name "Ultra-Pro II In-Plane Ultrasound Needle Guides-Multi-Angle" found at <https://www.civco.com/catalog/ultrasound-needle-guides/ultra-pro-2-ultrasound-needle-guides-multi-angle/>, which define the scope of the prior art and are hereby incorporated by reference.

[0072] The needle **72**, either freehandedly inserted or with the assistance of the needle guide as described above, may be inserted parallel to the transverse axis (across the ultrasound beam) or parallel to the longitudinal axis **66** (along the ultrasound beam). The needle **72** direction will depend on the applied anatomy, desired direction of needle insertion, ease of visualization of structures with ultrasound, and operator skill and experience. In one embodiment of the present invention, as shown in FIG. **1**, the needle **72** is inserted along the transducer array elements **18**, parallel to the longitudinal axis **66**, such that the needle **72** is parallel to the ultrasonic beam **22**. In another embodiment of the present invention, as shown in FIG. **5**C, the needle **72** is inserted perpendicular to the transducer array elements **18**, parallel to the transverse axis **64**, such that the needle **72** intersects the ultrasonic beam **22** at a certain depth.

[0073] Referring to FIGS. **1** and **2**, the present invention provides a hand shield assembly **80** which in some embodiments provide a frame **82** supporting a transparent film **84** that may be removably attached to the frame **82**. A connector may be used to attach the frame **82** to the transducer **12** at the front end **85** of the transducer **12** near the acoustic lens **48** of the transducer **12** to allow for normal handling of the handle **60** by the operator without obstruction.

[0074] The frame **82** of the hand shield assembly **80** may take a curved conical shape curved around the transducer housing **46** which in turn supports the flexible, transparent film **84** curved around the frame **82** and forms a shield or curved wall positioned between (a) the handle **60** and the operator's hand **62** on an interior **86** of the curved transparent film **84** (i.e., concave side) and (b) the needle **72** and the path **99** of the needle **72** as it is being inserted into the patient's tissue **20** on an exterior **87** of the curved transparent film **84** (i.e., convex side). In this respect, the hand shield assembly **80** provides a protective barrier between the operator's hand **62** and the needle **72** minimizing the risk to needle sticks.

[0075] The frame **82** may include an upper curved band **89** attached to a lower curved band **88** by transverse column members **90**, **92**, **94** supporting connection of the upper curved band **89** and the lower curved band **88**. The outer left and right column members **90** and **94** define the outer left and right edges of the frame **82**, respectively, and the central column member **92** supports a center of the frame **82**. The upper curved band **89** and the lower curved band **88** are semi-circular, semi-oval, or semi-elliptical bands that curve at least 180 degrees to shield at least three sides (front facing side and lateral sides) of the rectangular transducer housing **46**. The upper curved band **89** has a radius of curvature that is greater than the lower curved band **88** to support a wider portion of the operator's hand **62** when gripping the transducer **12** which narrows or tapers toward the front end **85** of the transducer **12**.

[0076] A center of the lower curved band **88** located between the outer left and right column members **90** and **94** may include a cutout **96** framed by the lower curved band **88** curving upward into an arch shape which permits the transducer **12** and the attached needle guide **70** to protrude outwardly from the interior of the frame **82**. The cutout **96** may be a rounded arch permitting a side or a bottom corner of the transducer housing **46** to extend out thought the cutout **96**. The height and width of the cutout **96** may be between 30 and 50 mm in height and between 30 and 50 mm wide to accommodate the size and shape of the transducer housing **46** (and part of the needle guide **70**). In this respect, a portion of the transducer housing **46**, and the needle guide **70**, if attached, may extend to the exterior **87** of the frame **82** and the hand shield assembly **80** may be used in the presence of a needle guide **70**. It is understood that the cutout **96** may take different shapes or sizes such as a rectangular or circular shape which resemble and accommodate the shape or the size of the extending transducer housing **46** and/or needle guide **70**.

[0077] Referring still to FIGS. **1** and **2**, but best seen in FIG. **2**, the transparent film **84** may be a clear film of, e.g., polyester film, polycarbonate, polyethylene terephthalate, and the like, which provides high transparency, is bendable/flexible around the frame **82**, is easy to clean, and can be die cut to be easily manufactured and attached to the frame **82**. The transparent film **84** may be curved to bend around the outside of the frame **82** and attached to the frame **82** to provide a physical barrier.

[0078] The transparent film **84** generally conforms to the shape of the frame **82**, aligning to the shape of a perimeter of the frame **82** and providing the same indentations and cutouts. The transparent film **84** may take a curved conical shape resembling the frame **82**. The transparent film **84** provides a corresponding cutout **98** which aligns with the cutout **96** of the frame **82** and permitting the transducer housing **46** and the needle guide **70** to extend outwardly to the exterior **87** of the frame **82** past the transparent film **84**.

[0079] The transparent film **84** may be attached to the frame **82** by various connection methods which allow the transparent film **84** to be easily removed and replaced. In one embodiment, the outer surface of the frame **82** may include outwardly extending notches **100** which may be inserted into corresponding holes **102** of the transparent film **84** allowing the transparent film **84** to be attached to frame **82** by punching or pushing the notches **100** through the perforated holes **102**. The notches **100** of the frame **82** may be positioned at the corners of the frame **82** and at the center of the frame **82** to ensure that the transparent film **84** is securely attached along the outer perimeter of the frame **82** and inside the concave channel **97**.

[0080] In an alternative embodiment, the outer surface of the frame **82** may receive an adhesive, such as a glue, tape or Velcro, which may allow the transparent film **84** to stick to the outside frame **82**. It is understood that other transparent film **84** attachment methods may be used and are contemplated as being within the scope of the present invention.

[0081] The transparent film **84** may be removable from the frame **82** and disposable. The frame **82** may then be sterilized to be reused with a new transparent film **84**.

[0082] Referring now to FIGS. **3** and **4**, it is understood that in an alternative embodiment, the frame **82** and the transparent film **84** may be integrally formed as a unitary piece such that the entire hand shield assembly **80** is disposable or sterilized to be reused. In this respect, the hand shield assembly **80** may be manufactured of a molded shroud **104** providing full transparency or at least some partial transparency or transparent windows within the shroud **104** of the hand shield assembly **80**.

[0083] The shroud **104** may take an outer shape that is similar to the perimeter of the frame **82** as described above but may be a solid material that provides a shield or curved wall between the handle **60** and the operator's hand **62** on an interior **86** of the shroud **104** (i.e., concave side) and the needle **72** and the path **99** of the needle **72** as it is being inserted into the patient's tissue on an exterior **87** of the shroud **104** (i.e., convex side). The wall of the shroud **104** generally conforms to the shape of the frame **82** and/or transparent film **84** to provide a curved conical shape around the transducer **12**.

[0084] The shroud **104** provides a similar cutout **96** as described above with respect to the frame **82** which allow the transducer housing **46** and needle guide **70** to extend outwardly from the interior **86** of the shroud **104** and exposing the needle guide **70**.

[0085] Further, in some embodiments, a concave channel **97** may also be formed within a front surface of the shroud **104**, the concave channel **97** extending from the top to the bottom of the shroud **104** and centered between the left and right edges of the shroud **104**. The concave channel **97** may be formed by a semi-cylindrical, inward indentation formed directly within the front surface of the shroud material. In this respect, the needle **72** may extend on an exterior **87** of the shroud **104** and along the pathway **99** through the concave channel **97** and into the needle guide **70** without interference from the frame **82**. Other similar indentations may be formed within the shroud material in order to accommodate the transducer **12**, needle **72**, or needle guide on the exterior **87** of the shroud **104**.

[0086] It is understood that if the concave channel **97** was applied to the frame **82** and transparent film **84** as shown in FIGS. **1** and **2**, the concave channel **97** may be formed by an inward bend within the center upper curved band **89** and the lower curved band **88**. The central column member **92** at the center of the frame **82** therefore may also be positioned inwardly to permit the clear pathway **99** of the needle **72** into the needle guide **70**. The transparent film **84** may then also bend inwardly into the concave channel **97** of the frame **82** to align with the inward bend of the frame **82** and permitting the needle **72** to be guided through the concave channel **97** and into the needle guide **70** on the exterior of the transparent film **84**.

[0087] Referring now to FIGS. **1** through **4**, the curved corners of the frame **82**, formed at the outer edges of the upper curved band **89** and the lower curved band **88** or by the corners of the shroud **104** are rounded to eliminate any sharp corners from contacting the patient tissue **20** or the operator's hand **62** during ultrasound scanning and causing discomfort.

[0088] The hand shield assembly **80**, formed either by the frame **82** and transparent film **84** as seen in FIGS. **1** and **2**, or the unitary shroud **104** as seen in FIGS. **3** and **4**, may have a shape providing an upper end **110** that is wider than the lower end **112** and thus tapering downward to the front end **85** of the transducer **12**.

[0089] The upper end **110** of the frame **82** (and transparent film **84**) or shroud **104** has an upper width, e.g., extending between the outer edges of the upper curved band **89**, that is between 100 mm and 200 mm wide and between 150 mm and 200 mm wide and between 150 mm and 180 mm wide and approximately 165 mm wide. The lower end **112** of the frame **82** (and transparent film **84**) or shroud **104** has a lower width, e.g., extending between the outer edges of the lower curved band **88**, that is between 40 mm and 100 mm wide and between 40 mm and 80 mm wide and between 40 mm and 60 mm wide and approximately 50 mm wide. The lower end **112** of the frame **82** (and transparent film **84**) or shroud **104** is narrower than the upper end **110** of the frame **82** (and transparent film **84**) or shroud **104** to allow for better tilt of the transducer **12** and, in particular, to provide a desired angle of insonation (**01**) of the acoustic lens **48** with respect to the patient tissue **20** for proper imaging.

[0090] A depth of the frame **82** (and transparent film **84**) or shroud **104**, e.g., correlating with the radius of curvature of the upper curved band **89** and the lower curved band **88**, is between 50 mm and 150 mm and between 80 mm and 130 mm and 90 mm and 120 mm and approximately 115 mm.

[0091] A height of the frame **82** (and transparent film **84**) or shroud **104**, e.g., extending between the upper curved band **89** and the lower curved band **88** is between 50 mm and 150 mm and between 90 mm and 140 mm and 100 mm and 130 mm and approximately 100 mm. The height of the frame **82** or shroud **104** may allow for the entire hand of the operator or most of the operator's hand **62** to be shielded.

[0092] The width, depth, and height of the hand shield assembly **80** may approximate average proportions of the operator's hand **62** when gripping the handle **60** of the transducer **12** but providing additional space to accommodate for variations in hand size and grip. For example, the width, depth, and height of the hand shield assembly **80** may approximate the average width, depth, and height of the operator's hand **62** when gripping the handle **60** of the transducer **12**. In one embodiment and depending on the size of the transducer housing **46** and the operator's grip, an average width and height of the operator's hand **62** when gripping the handle is approximately 100 mm to 150 mm in width, 70 mm to 100 mm in depth, and 60 mm to 90 mm in height. Therefore, the width, depth, and height of the hand shield assembly **80** may be at least as large as the dimensions of the average width and height of the operator's hand **62** when gripping the handle **60**. Each of the dimensions may be at least 5% and at least 10% and at least 15% and at least 20% larger than the dimensions of the average width and height of the operator's hand **62** when gripping the handle **60**.

[0093] The hand shield assembly **80** may extend from the central axis **30** of the transducer **12** at least 100 mm and at least 110 mm and at least 120 mm and at least 130 mm and at least 140 mm and at least 150 mm.

[0094] The volume formed within the interior **86** of the hand shield assembly **80** may be at least 5% and at least 10% and at least 15% and at least 20% larger than the volume of the operator's hand **62** when gripping the handle **60** to allow the interior **86** to comfortably accommodate the operator's hand. Therefore, it is contemplated that the interior **86** of the hand shield assembly **80** provides a volume sufficient to allow the operator's hand **62** to be supported therein and the volume is at least as large as the volume of the operator's hand **62** when gripping the handle **60**.

[0095] Referring specifically to FIG. **3**, the hand shield assembly **80** is attached at the front end **85** of the transducer

12 by a connector which may be a clamp **111** receiving the front end **85** of the transducer **12**. The clamp **111** is attached at the bottom of the frame **82**, for example, to the lower curved band **88**, or the lower edge of the shroud **104**. The clamp **111** provides a pair of inwardly extending arms **113**, **114** biased inwardly toward a center of the interior **86** of the frame **82**.

[0096] In one embodiment, the clamp **111** provides a first clip arm **113** and an opposed, mating second clip arm **114**. The first clip arm **113** is attached at a left side of the frame **82** or shroud **104**, and the second clip arm **114** attached at a right side of the frame **82** or shroud **104** and which when placed together form a rectangular shaped grip opening **116**.

[0097] The first clip arm **113** may provide a vertically extending member **117** further connected to a horizontally extending L-shaped member **118**. The horizontally extending L-shaped member **118** has a first member **120** and a second member **122** forming the L-shape, the first arm connected to the vertically extending member **117** at a top end and extending in a rearward direction to the perpendicular second member **122** which provides interlocking teeth **121** on an outer surface of a second member **122**. In some embodiments, for example as shown in FIG. **1**, the vertically extending member **117** is eliminated.

[0098] The second clip arm **114** may provide a vertically extending member **124** connected to a horizontally extending L-shaped member **126**. The horizontally extending L-shaped member **126** has a first member **128** and a second member **130** forming the L-shape, the first member **128** connected to the vertically extending member **124** at a top end and extending in a rearward direction to the perpendicular second member **130** which provides interlocking teeth **129** on an inner surface of the second member **130**. In some embodiments, for example as shown in FIG. **1**, the vertically extending member **124** is eliminated.

[0099] The L-shaped member **118** of the first clip arm **113** and the L-shaped member **126** of the second clip arm **114** form a three sided rectangle surrounding the rectangular shaped grip opening **116**, with the first members **120** and **128** of the first clip arm **113** and the second clip arm **114**, respectively, forming opposed sides of the rectangle and the second members **122** and **130** of the first clip arm **113** and the second clip arm **114**, respectively, forming a third side of the rectangle.

[0100] The second members **122** and **130** of the first clip arm **113** and the second clip arm **114**, respectively, overlap, with the second member **130** of the second clip arm **114** on the outside and the second member **122** of the first clip arm **113** on the inside, thus permitting the outer interlocking teeth **121** of the second member **122** to engage with the inner interlocking teeth **129** of the second member **130** to interlock. The interlocking of the teeth **121** and **129** enclose the rectangular shaped grip opening **116** and secure the clamp **111** around the transducer **12**.

[0101] The enclosed rectangular shaped grip opening **116** is sized to receive the front end **85** of the transducer **12** so that the clamp **111** can securely grip the transducer housing **46**. The multiple teeth along the transverse axis **64** of the interlocking teeth **121**, **129** permit a width of the rectangular shaped grip opening **116** extending along the transverse axis **64** to be varied in order to accommodate various dimensions of the transducer face **47**. For example, an engaging of interlocking teeth **121**, **129** at more distal ends of the second members **122** and **130** will accommodate a wider transducer face **47** and likewise, an engaging of interlocking teeth **121**, **129** at more proximal ends of the second members **122** and **130** will support a narrower transducer face **47**.

[0102] It is understood that the first clip arm **113** and the second clip arm **114** are tensioned outwardly by the transducer housing **46** positioned therein to keep the interlocking teeth **121**, **129** engaged, but may be "unhooked" by applying an inward and then outward force to release the interlocking teeth **121**, **129** from engagement. The interlocking teeth **121**, **129** may take an interlocking wave-shaped profile as shown but understandably may take other profile shapes allowing for similar variable width, interlocking engagement.

[0103] Referring specifically to FIG. **4**, in operation, the first clip arm **113** and the second clip arm **114** may extend around the transducer housing **46** slightly rearwardly from the acoustic lens **48** so that the acoustic lens **48** extends below the lower end **112** of the hand shield assembly **80** thus permitting the acoustic lens **48** and the front end **85** of the transducer **12** to be pressed, tilted, or rocked in the patient tissue **20** without interference from the hand shield assembly **80**. The acoustic lens **48** may extend at least 5 mm and at least 10 mm and at least 15 mm below the lower end **112** of the hand shield assembly **80**.

[0104] It is understood that other types of connectors may be used to attach the front end **85** of the transducer **12** to the hand shield assembly **80**. For example, different types of clamps, clips, mating connectors, and the like may be used. The connector desirably provides an unobstructed space or gap around the entire handle **60** of the transducer **12** which the operator can grip freely without obstruction from the connector. The connector does not contact the transducer **12** at the rear end opposite the front end **85** to avoid any interference. The connector further allows the front end **85** of the transducer **12** to extend downwardly below the connector and past the lower end **112** of the hand shield assembly **80**. The connector further accommodates various sizes and widths of the transducer **12** by providing a flexible grip opening **116** to grip the transducer **12**.

[0105] Referring now to FIGS. **5**A to **5**C, the various hand grips of the operator's hand **62** on the transducer **12** may be accommodated by the shape and size of the hand shield assembly **80**. Exemplary operator hand grips are shown in FIGS. **5**A to **5**C.

[0106] Referring to FIG. **5**A, as shown, the "palmar grip" positions the ultrasound transducer **12** between the operator's index and middle finger. The operator's fingers pinch or grip the transducer **12** across the transverse axis **64** of the transducer **12**.

[0107] Referring to FIG. **5**B, as shown, the "longitudinal grip" positions the ultrasound transducer **12** between the operator's index finger and thumb. The operator's fingers pinch or grip the transducer **12** across the transverse axis **64** of the transducer **12**. The operator's ulnar aspect of the hand may rest upon the patient tissue **20**.

[0108] Referring to FIG. **5**C, as shown, the "transversal grip" positions the ultrasound transducer **12** between the operator's index finger (and optionally, the middle finger) and the operator's thumb. While similar to the longitudinal grip of FIG. **5**B, this transversal grip positions the pinching or squeezing fingers across the longitudinal axis **66** of the transducer face **47** rather than the transverse axis **64**. The operator's ulnar aspect of the hand may rest upon the patient's tissue **20**.

[0109] When the transducer **12** is handled using the transversal grip, the hand shield assembly **80** may also be attached to curve around the longer dimension of the face of the transducer **12**. In this respect, it is understood that the dimensions of the shroud **104** may correspond with and accommodate the dimensions of the longer face of the transducer **12**, and optionally, the extension of the needle guide **70** from the longer side of the transducer **12** by providing the cutout **96** as described above.

[0110] In operation, the transducer **12** is held by the hand shield assembly **80** by locking the front end **85** of the transducer **12** into the clamp **111** of the hand shield assembly **80**. The side or bottom corner of the front end **85** of the transducer housing **46** extends through the cutout **96** of the hand shield assembly **80**, from the interior **86** to the exterior **87** of the hand shield assembly and permit the attached needle guide **70** of the transducer **12** (not shown in FIGS. **5**A-**5**C) to extend on the exterior **87** of the hand shield assembly **80**.

[0111] The operator will grip the handle **60** of the transducer **12**, e.g., as shown in FIGS. **5**A to **5**C, on the interior **86** of the hand shield assembly **80** without interference from the clamp **111** or the frame **82** (and transparent film **84**) or shroud **104**. The operator will slide the transducer **12** over the patient tissue **20**, for example, pressing, tilting and rocking the transducer **12** and transducer face **47** into the patient tissue **20**. When the region of interest **21** inside the patient and beneath the transducer **12** is located on the display unit **14**, the operator may insert the needle **72** through the needle guide **70** attached to the transducer **12** at a desired angle of insonation and depth into the patient tissue **20**. The path **99** of the needle **72** may pass through the concave channel **97** of the hand shield assembly **80**. Therefore, the hand shield assembly **80** will create a blocking wall or barrier between the operator's hand **62** and the needle **72** minimizing the risk of needle sticks.

[0112] It is understood that the present invention contemplates use of the hand shield assembly **80** with various commercially available ultrasound transducers **12** and needle guides **70**. Therefore, the hand shield assembly may be a "one size fits all" for many or most ultrasound transducer **12** and/or needle guides **70**.

[0113] The hand shield assembly **80** may be sold with the ultrasound transducer **12** and/or the needle guides **70** as part of a kit which may be sized to a particular size and shape of the ultrasound transducer **12** and/or needle guide **70**.

[0114] Certain terminology is used herein for purposes of reference only, and thus is not intended to be limiting. For example, terms such as "upper", "lower", "above", and "below" refer to directions in the drawings to which reference is made. Terms such as "front", "back", "rear", "bottom" and "side", describe the orientation of portions of the component within a consistent but arbitrary frame of reference which is made clear by reference to the text and the associated drawings describing the component under discussion. Such terminology may include the words specifically mentioned above, derivatives thereof, and words of similar import. Similarly, the terms "first", "second" and other such numerical terms referring to structures do not imply a sequence or order unless clearly indicated by the context.

[0115] When introducing elements or features of the present disclosure and the exemplary embodiments, the articles "a", "an", "the" and "said" are intended to mean that there are one or more of such elements or features. The terms "comprising", "including" and "having" are intended to be inclusive and mean that there may be additional elements or features other than those specifically noted. It is further to be understood that the method steps, processes, and operations described herein are not to be construed as necessarily requiring their performance in the particular order discussed or illustrated, unless specifically identified as an order of performance. It is also to be understood that additional or alternative steps may be employed.

[0116] References to "a controller" and "a processor" can be understood to include one or more microprocessors that can communicate in a stand-alone and/or a distributed environment(s), and can thus be configured to communicate via wired or wireless communications with other processors, where such one or more processor can be configured to operate on one or more processor-controlled devices that can be similar or different devices. Furthermore, references to memory, unless otherwise specified, can include one or more processor-readable and accessible memory elements and/or components that can be internal to the processor-controlled device, external to the processor-controlled device, and can be accessed via a wired or wireless network.

[0117] It is specifically intended that the present invention not be limited to the embodiments and illustrations contained herein and the claims should be understood to include modified forms of those embodiments including portions of the embodiments and combinations of elements of different embodiments as come within the scope of the following claims. All of the publications described herein, including patents and non-patent publications are hereby incorporated herein by reference in their entireties.

[0118] To aid the Patent Office and any readers of any patent issued on this application in interpreting the claims appended hereto, applicants wish to note that they do not intend any of the appended claims or claim elements to invoke 35 U.S.C. 112(f) unless the words "means for" or "step for" are explicitly used in the particular claim.

What we claim is:

1. An ultrasound transducer hand shield for protecting a hand of a healthcare professional gripping a transducer in a scanning position with a front end of the transducer adjacent to tissue of a patient supporting an array of piezoelectric elements, and a rear end of the transducer supporting a hand grip extending along an axis of the transducer perpendicular to the array of piezoelectric elements, the hand shield comprising:

a shroud removably supported by the transducer to extend along the axis of the transducer and at least partially around the transducer to create a physical barrier between the hand grip and a needle insertable into the tissue of the patient below the transducer; and

a connector supporting a connection of the shroud at a front end of the transducer

wherein the shroud extends around but does not contact the rear end of the transducer.

2. The hand shield of claim **1** wherein the shroud is sized to fit around the hand grip to receive the hand of the healthcare professional therein.

3. The hand shield of claim **1** wherein the shroud extends at least 100 mm from the axis at all angles about the axis.

4. The hand shield of claim **1** wherein a top end of the shroud has a width of at least 150 mm.

5. The hand shield of claim **1** wherein a bottom end of the shroud has a width that is less than 50 mm.

6. The hand shield of claim **1** wherein the shroud extends at least 180 degrees around the transducer.

7. The hand shield of claim **1** wherein the transducer has four sides and the shroud extends around at least three sides of the transducer.

8. The hand shield of claim **1** wherein the connector is a clamp configured to extend around a front end of the transducer housing.

9. The hand shield of claim **1** wherein the shroud has a bottom opening permitting extension of the front end of the transducer from a bottom of the shroud.

10. The hand shield of claim **1** wherein the shroud provides a cutout supporting extension of a corner of a front end of the transducer

11. The hand shield of claim **1** wherein the shroud provides a transparent window.

12. The hand shield of claim **1** wherein the shroud provides a frame supporting a replaceable film attachable to the frame.

13. The hand shield of claim **12** wherein the replaceable film is transparent allowing viewing therethrough.

14. The hand shield of claim **12** wherein the replaceable film is attachable to the frame by tabs receivable into corresponding holes.

15. The hand shield of claim **1** wherein the shroud is a curved cone with a wall curved around the transducer.

16. The hand shield of claim **15** wherein a bottom end of the shroud has curved corners.

17. The hand shield of claim **1** further comprising an ultrasound transducer having a housing supporting a hand grip extending along the axis and perpendicular to an array of piezoelectric elements of the transducer.

18. The hand shield of claim **17** further comprising a needle guide attached to and extending outwardly from the transducer housing, and providing a guide channel permitting a needle to extend into to the tissue of the patient below the transducer.

19. An ultrasound transducer for use on tissue of a patient comprising:

- a housing supporting a hand grip extending along an axis perpendicular to an array of piezoelectric elements of the transducer;
- a needle guide attached to and extending outwardly from the transducer housing and providing a guide channel permitting a needle to extend into to the tissue of the patient below the transducer; and
- a hand shield providing
  - a shroud supported by the transducer extending along the axis of the transducer and perpendicular to the axis of the transducer configured to extend around the transducer and to create a physical barrier between the hand grip and a needle insertable into the tissue of the patient below the transducer; and
  - a connector supporting a connection of the shroud at a front end of the transducer and a space around a rear end of the transducer without contacting the transducer.

20. A disposable hand shield for an ultrasound transducer used on tissue of a patient of a type comprising:

- a shroud supported by the transducer extending along a central axis of the transducer and to extend at least partially around the transducer to create a physical barrier between the hand grip and a needle insertable into the tissue of the patient below the transducer; and
- a connector supporting a connection of the shroud at a front end of the transducer and a space around a rear end of the transducer without contacting the transducer.

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