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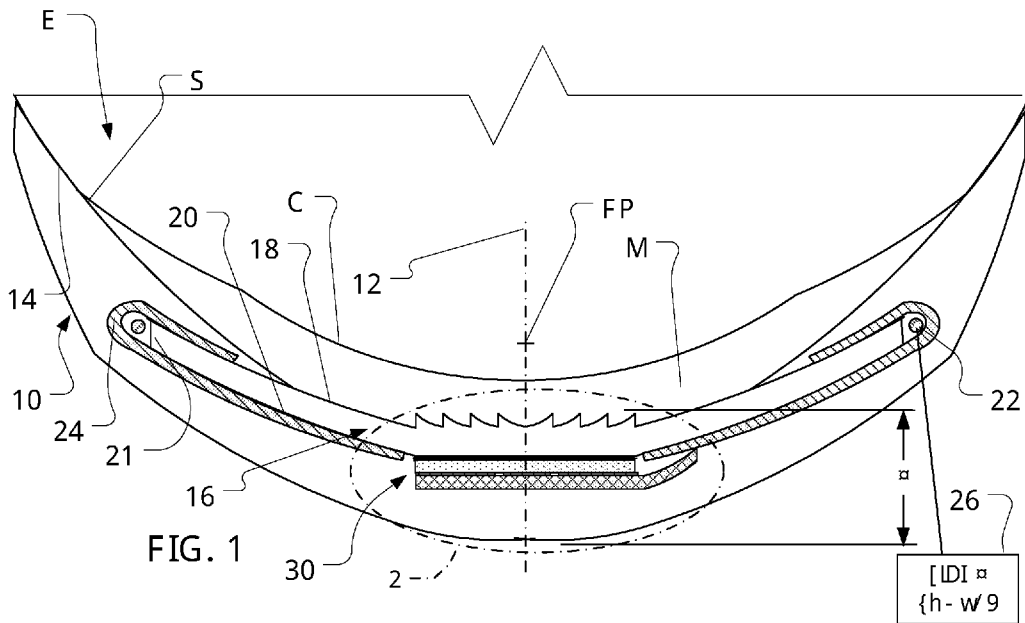
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(57) Abstract: A lens (16) has one or more refractive surfaces arranged to focus ultrasound passing through the lens into a focal region (FP). The lens may be a Fresnel lens, in which a refractive surface includes a plurality of discrete surface portions (32, 34a, 34b and 34c). An ultrasonic transducer includes a first part aligned with a first one (32) of the refractive portions and a second part aligned with additional ones (34a, 34b, 34c) of the refractive portions. In a first state, an electrical circuit (50) actuates the first part of the transducer to send and receive ultrasound through the first refractive surface portion; the ultrasound used in this state may be a broadband signal such as a brief pulse. In a second state, the circuit actuates the second part of the transducer and may also actuate the second part of the transducer, so that ultrasound is transmitted through multiple refractive surface portions in a phase-coherent manner. Desirably, the ultrasound transmitted in the second state has a narrow frequency distribution. This arrangement can be used, for example, in apparatus



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ULTRASONIC LENS AND TRANSDUCER SYSTEM

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims benefit of United States Provisional Patent Application 62/851,901 filed May 23,2019, the disclosure of which is incorporated by reference herein.

BACKGROUND

[0002] The present invention relates to ultrasonics, and more particularly relates to a system incorporating an ultrasonic lens and transducer and to devices and methods incorporating and utilizing the same.

[0003] Ultrasonic systems are widely used in a variety of applications. In one common application, a pulse of ultrasound is directed from a transducer to an object and an echo pulse from the object returns back to the transducer. Characteristics of the return signal can be used to determine characteristics of the target object. For example, the interval from the time the pulse is sent from the transducer to the time the echo pulse returns to the transducer varies directly with the distance between the object and the transducer. Ultrasonic techniques can be used to monitor the response of the cornea of the eye during corneal crosslinking. In corneal crosslinking, light such as ultraviolet light, is applied to the cornea in the presence of a crosslinking catalyst. The light causes crosslinking of collagen within the cornea, which stiffens the cornea. Precisely targeted and titrated stiffening can be used to treat diseases such as keratoconus. This technique can also gradually reshape the cornea to correct refractive errors, such as myopia and hyperopia. As disclosed in United States Patent 9,907,698, the disclosure of which is incorporated by reference herein, the ultraviolet light may be applied using a device in the form of a contact lens having optical elements, such as a fiber for directing light into an optically scattering element so that light scattered by the scattering element impinges on the cornea. As disclosed in United States Patents 9,833,970 and in United States Patent Application Publication 20170246471, the disclosures of which are incorporated by reference herein, an ultrasonic transducer such as piezoelectric transducer may be mounted within the contact lens structure so that ultrasound from the transducer passes through the scattering element to the eye.

[0004] In certain techniques disclosed in the aforementioned documents, it is desirable to apply a strong “push pulse” of ultrasound, so that a mechanical force is exerted on the cornea as the cornea reflects part of the ultrasound of the push pulse and absorbs the

remaining part of the ultrasound of the push pulse. This type of force is called acoustic radiation force, or ARF. Lower level, shorter duration monitoring pulses of ultrasound can be applied to detect the position of the cornea before and immediately after application of the push pulse so as to determine the deflection of the cornea induced by the push pulse. Because the deflection varies inversely with the stiffness of the cornea, this can be used as one measure of the stiffness of the cornea and as a measure of the degree of crosslinking achieved.

[0005] Still further improvement in ultrasonic systems and structures usable in this application and in other applications would be desirable.

SUMMARY

[0006] One aspect of the invention provides an ultrasonic system which includes an ultrasonic Fresnel lens having oppositely facing front and rear surfaces, the front surface of the lens including a plurality of discrete refractive portions. A system according to this aspect of the invention desirably includes an ultrasonic transducer acoustically coupled to one of the front and rear surfaces of the lens, the ultrasonic transducer including a first part aligned with a first one of the refractive portions and a second part aligned with one or more additional ones of the refractive portion. A system according to this aspect of the invention desirably also includes an electrical circuit cooperating with the first part of the transducer but not with the second part of the transducer when the circuit is in a first state and cooperating with the second part of the transducer when the circuit is in a second state. In certain embodiments, the electrical circuit cooperates with both the first part of the transducer and the second part of the transducer when the electrical circuit is in the second state. Desirably, the electrical circuit is operative in the first state to apply and detect pulsatile signals having a first bandwidth and is operative in the second state to apply a drive signal having a second bandwidth narrower than the first bandwidth.

[0007] In the system according to this aspect of the invention, the lens may include a central element defining one of the refractive surfaces and one or more peripheral elements at least partially surrounding the center element, each of the peripheral elements defining another one of the refractive surfaces. For example, the central element may be disposed on a central axis and each of the peripheral elements may be annular and concentric with the central axis. Each of the refractive surfaces may be a surface of revolution around the central axis. In this arrangement, the central element may define the first refractive surface and the

first part of the transducer may be aligned with the central axis, and the lens may be constructed and arranged to focus ultrasound onto a location in front of the lens on the central axis.

[0008] Systems according to the foregoing aspect of the invention may be used, for example, in apparatus for measuring a physical property of the cornea of the eye of a living subject. Such apparatus may include a structure adapted to rest on an anterior surface of the eye, the lens being mounted to the structure so that the lens overlies the cornea when the structure rests on the eye. The lens may be optically scattering and ultrasonically transmissive, and the apparatus may further include an optical element in optical communication with the lens, the optical element being operative to direct light into the lens so that light scattered by the lens will pass into the eye.

[0009] Yet another aspect of the invention provides an ultrasonic lens. The ultrasonic lens according to this aspect of the invention desirably is formed from an ultrasonically transmissive, optically scattering material, the lens having oppositely-facing front and rear surfaces, the lens being constructed and arranged to focus ultrasound passing through the lens into a focal region forward of the front surface and to scatter light passing through the lens. The lens optionally may be a Fresnel lens in which one or both of the front and rear surfaces includes a plurality of discrete refractive surface portions.

[0010] Yet another aspect of the invention provides apparatus for corneal crosslinking. Apparatus according to this aspect of the invention desirably includes a lens as discussed in the immediately preceding aspect of the invention, together with means for holding the lens in alignment with the eye of a living subject so that the front surface of the lens faces toward the eye and so that the focal region of the lens is disposed within the cornea of the eye. The apparatus according to this aspect of the invention desirably further includes an optical element in optical communication with the lens, the optical element being operative to direct light into the lens so that light scattered by the lens will pass through the front surface of the lens into the cornea. Most desirably, the apparatus according to this aspect of the invention also includes an ultrasonic transducer mounted to the structure rearwardly of the lens and in sonic communication with the lens, the ultrasonic transducer being arranged to emit ultrasound through the lens, the lens being arranged to focus ultrasound emitted by the lens into a focal region within the cornea. The means for holding

the lens may include a structure having a base surface adapted to rest on an anterior surface of the eye. Desirably, the lens and the ultrasonic transducer are mounted to the structure.

[0011] Yet another aspect of the invention provides methods of corneal crosslinking. A method according to this aspect of the invention desirably includes the step of directing light into a cornea of an eye of a living subject through an optically scattering, ultrasonically transmissive ultrasonic lens so as to cause crosslinking within the cornea. The method according to this aspect of the invention desirably further includes passing ultrasound through the lens so that the lens focuses the ultrasound into a focal region within the cornea.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] Fig. 1 is a fragmentary, diagrammatic sectional view depicting apparatus according to one embodiment of the invention in conjunction with a portion of an eye.

[0013] Fig. 2 is a fragmentary sectional view on an enlarged scale depicting the area indicating in Fig. 1.

[0014] Fig. 3 is a fragmentary view taken along line 3-3 in Fig. 2.

[0015] Fig. 4 is a fragmentary view taken along line 4-4 in Fig. 2.

[0016] Fig. 5 is a functional block diagram of a circuit used in the embodiment of Figs. 1-4.

[0017] Fig. 6 is a partially diagrammatic, partially sectional view depicting apparatus according to a further embodiment of the invention.

DETAILED DESCRIPTION

[0018] Apparatus for corneal crosslinking according to one embodiment of the invention is schematically depicted in sectional view in Fig. 1 in conjunction with an eye E. The apparatus includes a structure in the form of a scleral contact lens shell 10 having a central axis 12, the shell being generally in the form of a body of revolution about the axis. The shell has a base or eye-contacting surface 14 which is arranged to contact the anterior surface of the sclera S of the eye so as to maintain the central axis 12 in alignment with the axis of the eye, *i.e.*, the central axis of the cornea C of the eye. An optically scattering element 16 is mounted to structure 10. Because this same element also serves as a lens to refract ultrasonic waves as discussed below, it is referred to herein as the "lens." Lens 16 has a front surface 18 facing generally in an inward direction (towards the top of the drawing as seen in Fig. 1), and a rear surface 20 facing in the opposite, outward direction. The structure 10 is configured to hold the front surface of the lens spaced from the eye when the structure

rests on the eye. In use, a preselected liquid medium M fills the space and contacts the front surface 18 of the lens.

[0019] One or more optical components such as an optical fiber 22 extending around the periphery of lens 16 are arranged to introduce light into lens 16 through its circumferential surface 21. An optical reflector 24 extends around the periphery 21 of the lens and over the rear surface 20 of the lens. For example, fiber 22 may be optically coupled to a light source 26 such as a laser. Lens 16 is formed from a material which will transmit ultrasound and which will transmit ultrasound at the frequencies to be used in operation, typically above 1 MHz, and most typically above 10 MHz. The material also is operative to transmit ultraviolet light while scattering the ultraviolet light. For example, the lens can be formed from a cyclic olefin copolymer which is transparent to ultraviolet light, the polymer having minute particles of barium sulfate dispersed therein. The degree of optical scattering increases with the amount of particles dispersed in the mixture. The particles may cause some degree of scattering of ultrasound transmitted through the lens, but desirably such scattering is minimal. Moreover, as further explained below, the ultrasound passes through a relatively short path through the lens, in the thickness direction parallel to axis 12. This minimizes the amount of scattering of any ultrasound transmitted through the lens.

[0020] As further discussed below, an ultrasonic transducer 30 overlies the rear surface 20 of lens 16 in the area surrounding axis 12. The transducer is arranged to emit ultrasound in the forward direction, through the lens. Lens 16 is configured as an ultrasonic lens operative to focus ultrasound emitted by the transducer into a focal point FP on axis 12. As shown in detail in Fig. 2, which is an enlarged fragmentary view of the area indicated in Fig. 1, the lens is in the form of a Fresnel lens. Lens 16 includes a first refractive surface portion 32 on axis 12 and additional refractive surface portions 34a, 34 b, and 34c. As best seen in Fig. 3, the first refractive surface portion 32 is circular and concentric with the central axis 12 whereas each of the additional surface portions 34a-34c is a ring concentric with the central portion 32 and with the central axis 12. Stated another way, the additional surface portions 34 surround the central refractive surface portion 32. The refractive surface portions are separated from one another by step-like discontinuities 35. In this instance, each of the refractive surface portions 32 and 34a-34c is concave, and is a section of a spherical surface so that the refractive surface portions would form a continuous spherical surface if the discontinuities 35 were not present. The focal point of the first or central refractive surface

portion 32 desirably lies at the anterior surface of the cornea C or within the cornea as, for example 1 mm to 3 mm posterior to the anterior surface of the cornea.

[0021] The radial positions and depths of discontinuities 35 are selected so that lens 16 is “phase-continuous” when used with the preselected liquid medium M in contact with the refractive surface portions of the lens. In this embodiment, the preselected liquid medium desirably is a liquid which is pharmaceutically acceptable for contact with the eye, and which is transmissive to ultrasound and ultraviolet. Desirably, the liquid also has substantial oxygen solubility. Examples of such liquids include aqueous liquids and perfluorocarbons. In the particular embodiment depicted, the preselected medium is a perfluorocarbon.

[0022] A lens is exactly phase-continuous at a particular ultrasound frequency referred to herein as a “continuity frequency” f_C when used with a particular medium M if the step distance D (Fig. 2) at each discontinuity between refractive surfaces is selected so that at each discontinuity, :

$$D/(\lambda_M) - D/(\lambda_L) = N \quad (\text{Formula 1})$$

where:

λ_M is the wavelength of ultrasound at continuity frequency f_C in the medium;

λ_L is the wavelength of ultrasound at the continuity frequency f_C in the material of the lens;

and

N is a positive or negative integer.

For a given lens and medium, there will be plural continuity frequencies, corresponding to different values of N. Desirably, all of the discontinuities in the lens have the same step distance D, corresponding to the same value of N.

[0023] The wavelength of ultrasound depends on the frequency and on the velocity of ultrasound in the medium:

$$\lambda_M = v_M / f_C \quad (\text{Formula 2})$$

where v_M is the velocity of ultrasound in the medium.

[0024] Likewise,

$$\lambda_L = v_L / f_C \quad (\text{Formula 3})$$

where

v_L is the velocity of ultrasound in the material of the lens. Thus, a particular lens is adapted

for use with a preselected medium, and a continuity frequency established by the lens and medium is referred to herein as a continuity frequency of the lens.

[0025] The cyclic olefin copolymer material used in this embodiment provides an ultrasound velocity of approximately 2200 meters per second, whereas the perfluorocarbon liquid mentioned above has an ultrasound velocity of approximately 550 meters per second. In one embodiment the lens has a continuity frequency f_c of 35 MHz and D is about 63 microns.

[0026] Transducer 30 includes a layer 40 of piezoelectric material having a front face facing forwardly toward the lens and a rear face facing rearwardly away from the lens. In this embodiment, layer 40 is a unitary solid layer of a ceramic piezoelectric material. Layer 40 extends outwardly from the central axis 12, slightly beyond periphery of the outermost refractive portion 34c of lens 16. A first electrode 42 is provided on the front surface of the piezo-electric layer, and abuts the rear surface of the lens. The first electrode 42 is a continuous thin metal layer covering the entire front surface of layer 40. Desirably, first electrode 42 is reflective to ultraviolet. Although this electrode is depicted as a separate element from reflector 24, the first electrode and reflector 24 may be formed integrally with one another. In this embodiment, the first electrode serves as a common electrical ground electrode. A central or first part electrode 44 overlies the rear surface of layer 40. Electrode 44 is in the form of a small disc coaxial with the central axis 12 of the lens. Central electrode 44 thus is aligned with the central refractive surface 32 of the lens. A peripheral or second part electrode 46, separate from the central electrode 44, is in the form of an annulus surrounding the central electrode but spaced apart from the central part and overlies the remainder of the rear surface of the piezoelectric layer 40. The parts of the electrodes may be formed, for example, as conductive materials plated on the layer of piezoelectric material. A flexible printed circuit 48 overlies the electrodes 44 and 46 on the rear surface of the electrodes. The structure optionally may include additional layers such as a layer of an acoustic coupling material (not shown) disposed between the electrode 42 and the lens. Also, a backing layer (not shown) may overlie electrodes 42 and 44. The backing layer may include a first portion overlying the central electrode 44, the first portion being formed from a material such as an epoxy which will absorb acoustic energy directed outwardly, through the rear surface of the piezoelectric layer and through the center electrode 44. The backing layer may include a second portion formed from a material such as air-filled microspheres which

will cause reflection of outwardly-directed ultrasound at the rear surface of the piezoelectric layer. One or both of these materials may be electrically conductive, so that one or both portions of the backing layer may serve as parts of the electrical connections to electrodes 42 and 44. Where both portions are electrically conductive, the layer may include an electrically insulating material separating the portions from one another. The term “acoustic stack” is used herein as referring to transducer 30 taken together with the coupling layer and backing layer.

[0027] An electrical circuit 50 (Figs. 4 and 5) is connected to the transducer 30. As best seen in Fig. 5, circuit 50 includes a pulse circuit 51 and a drive circuit 53. Drive circuit 53 includes one or more signal generators 61, amplifiers 62, matching networks 63 and other electronic components commonly used to provide a narrow band electrical signal such as a continuous wave sinusoidal signal for driving an ultrasonic transducer at reasonably high power. Drive circuit 53 is connected to peripheral electrode 46, and is further connected to the central electrode 44 through a high-speed switch 60. Pulse circuit 51 includes electronic elements commonly used in transmission and reception of broadband pulses in ultrasound systems. These elements typically include a high voltage broadband electrical pulser 55, a receive amplifier 58, one or more matching networks 56 or transformers 65 to match the electrical impedance of the ultrasound transducer to the pulser 55 as well as a receive amplifier 58, a protection circuit or transmit/receive switch 59 to limit exposure of the receive amplifier to high voltage, and a digitizer 57 to convert an analog signal to a digital signal. Pulse circuit 51 is connected to the center electrode 44. Both the pulse circuit 51 and the drive circuit 53 are connected to the common ground electrode 42 (Fig. 2) on the front surface of the transducer. Electrical circuit 50 further includes a controller 64 such as a programmable digital controller which is connected to pulse circuit 51 to drive circuit 53, and to switch 60. Controller 64 is operative to command the pulse and drive circuits to perform the operations discussed below.

[0028] The controller 64 actuates the other elements of circuit 50 to operate in two distinct states. In a first state, also referred to herein as a monitoring state, switch 60 is open, pulse circuit 51 is active and drive circuit 53 is inactive. In this state, electrical signals applied by pulse circuit 51 will be applied only across a first or central part of layer 40, disposed between the central electrode 44 and the front surface electrode 42, and only voltages generated by this central part of layer 40 in response to ultrasonic signals will be

communicated to drive circuit 51. Stated another way, in this first state the electrical circuit 50 as a whole cooperates with the first or central part of transducer 30 which is aligned with the first or central refractive surface 32 but does not cooperate with a second or peripheral part of the transducer, aligned with the additional refractive surfaces 34. In a second state, also referred to as a drive state, switch 60 is closed, pulse circuit 51 is inactive and drive circuit 53 is active. The signals applied by drive circuit 53 will be applied through central electrode 44 and peripheral electrode 46, so that these signals will be applied to the entire layer 40. Thus, in the second state the electrical circuit 50 cooperates with both the first or central part of transducer 30 and with the peripheral part of the transducer.

[0029] In a method of corneal crosslinking, the cornea is pretreated with a catalyst such as riboflavin, and the structure 10 is positioned on the eye, base surface 14 resting on the sclera S of the eye, so that central axis 12 is substantially coincident with the optical axis of the eye and extends through the cornea C. The medium M is introduced into the space between the lens 16 and the cornea, and light source 28 is operated to direct light such as ultraviolet light into lens 16, via fiber 22 and reflector 24, so that the light passes into the lens in directions generally transverse to central axis 12. The light is scattered within lens 16, and some of the scattered light passes through the front surface 18 of the lens, including the surface portions 32 and 34, and passes into the cornea C. The particulates in the lens sufficiently scatter the light, making any refraction of light which occurs at surface portions 32 and 34 irrelevant to the overall distribution of light passing into the cornea. The light passing into the cornea causes crosslinking of collagen within the cornea and making the cornea stiffer.

[0030] To monitor the progress of the crosslinking treatment, circuit 50 is operated to apply high power, relatively long-duration push pulses of ultrasound so as to deform the cornea, as well as low-power, short-duration monitoring pulses, and to detect the ultrasonic echoes reflected back from the cornea after the monitoring pulses so as to monitor the position of the cornea. In one arrangement, a monitoring pulse is applied while the cornea is in an undeformed state, referred to as the rest position. The echo from this monitoring pulse is detected. The time elapsed between the monitoring pulse and return of its echo represents the distance between the ultrasonic transducer and the cornea with the cornea in the rest position. A push pulse is applied so as to deform the cornea. Another monitoring pulse is applied after the push pulse has deformed the cornea. The time between this monitoring pulse and return

of its echo represents distance between the cornea and the transducer in a deformed state. The difference between the distance measured in the rest state before application of the push pulse and the distance measured in the deformed condition after application of the push pulse represents the deflection of the cornea caused by the push pulse. The measurement cycle of monitoring pulse, push pulse and monitoring pulse is repeated. As the degree of crosslinking and the stiffness of the cornea increase, the deflection for a given amount of force applied to the cornea decreases. Stated another way, the deflection or the difference in travel time before and after each push pulse serves as a proxy for the degree of crosslinking. Such a proxy can be used to control the light application. For example, the proxy can be determined in a first cycle before commencement of the light application to determine a baseline value, and then repeated intermittently. The value of the proxy determined in each subsequent measurement cycle can be compared to the baseline value.

[0031] The push pulses are applied with the circuit 50 in the second state mentioned above, with switch 60 closed, so that the push pulses actuate the entire piezoelectric layer 40 to emit ultrasound. The ultrasound generated in each push pulse desirably is a sinusoidal signal with almost all of the signal power within a narrow band of frequencies centered at or near a continuity frequency f_c of the ultrasonic lens 16. Desirably, the acoustic stack (piezoelectric layer 40 and coupling and backing layers) is constructed so that the layer is resonant at f_c . The push pulses are generated in response to a drive signal applied by drive circuit 53 while circuit 50 is in the second state mentioned above, with switch 60 closed. The ultrasound of the push pulses is generated by the entire piezoelectric layer 40, and thus is directed through all of the refractive surface portions 32 and 34a-34c of the lens. At each refractive surface portion, the ultrasound is refracted according to Snell's law towards the focal point FP of the lens. By focusing the ultrasound from the entire transducer, the lens maximizes the ultrasonic power applied to a single small region of the cornea surrounding the axis 12 and thus increases the deflection at the axis. This facilitates measurement of the deflection or difference in flight time used as the proxy for stiffness of the cornea. The Fresnel lens provides this focusing action in a thin configuration. The thickness T of the device (Fig. 1), from the forward extremity of lens 16 to the outside of the contact lens shell 10, desirably is on the order of a few mm, as, for example 5 mm or less, more preferably 4 mm or less and most preferably 3 mm or less.

[0032] Because the lens is phase-continuous, the ultrasound passing through each refractive surface portion each refractive surface portion will remain in-phase with ultrasound passing through the other refractive surface portions, so that the ultrasound passes through the lens, into the medium and into the cornea efficiently. However, this is only true for ultrasound within a narrow frequency band centered on f_c . If ultrasound outside of this narrow band was transmitted through multiple refractive surface portions, it would not remain in phase, and destructive interference would occur. Stated another way, the phase-continuous ultrasonic lens operates as a frequency-selective filter with a narrow passband centered on each continuity frequency f_c . The passband of a phase-continuous lens represents the band of frequencies where destructive interference either does not occur at all (in an ideal case) or occurs to such a limited extent that a substantial portion of the ultrasonic power into the medium remains after losses due to destructive interference. For example, the passband can be taken as the band of frequencies f_c such that for frequencies within the passband, destructive interference causes attenuation of 3db or less. In an ideal case, in where all of the discontinuities in the lens have exactly the same step distance D and thus the same continuity frequency f_c , and where the ultrasonic power is a pure sinusoidal vibration at this f_c , there is no destructive interference and thus perfect continuity. However, it is not essential to achieve perfect continuity. The system operates in a phase-continuous manner so long as attenuation caused by destructive interference is limited, desirably to 3db attenuation or less.

[0033] The monitoring pulses are applied, and the echoes are received, while the circuit 50 is in the first state discussed above, with switch 60 open. Thus, only the central portion of the piezoelectric layer 40, aligned with the central electrode 44 is active in these operations. The monitoring pulses desirably are very brief to allow for precise measurement of the time of flight. The monitoring pulses typically are created by the controller actuating pulse circuit 51 to apply a short, high amplitude voltage spike to central electrode 44; other signals such as a half-cycle or a single cycle of a sine wave can be used. The monitoring pulses are significantly shorter in duration than the push pulses. The brief pulses will include components in a wide band of frequencies. The ultrasonic echoes returned from the cornea after application of each monitoring pulse will include components in the same wide band of frequencies. However, because only the central part of the transducer is active, the ultrasound of the monitoring pulses will be transmitted entirely or almost entirely through the

central refractive surface portion 32. The ultrasonic echoes of the monitoring pulses also will be transmitted efficiently through the central refractive surface portion 32 and through the lens to the central portion of the piezoelectric layer. In this condition, the lens does not act as a frequency-selective filter; all of the components of the monitoring pulse and the echo will be efficiently transmitted. Although the power output of transducer 30 will be reduced because a portion of the piezoelectric layer is inactive, this does not pose a problem because the power in the monitoring pulses need only be enough to yield a detectable echo.

[0034] As discussed above, in the embodiment of Figs. 1-4, the continuity frequency of the ultrasonic lens depends in part on the medium used in contact with the lens. A further aspect of the invention provides a kit including the structure together with the medium. Yet another aspect of the invention provides the structure in conjunction with labelling specifying the medium.

[0035] A system according to a further embodiment of the invention, partially depicted in Fig. 6, incorporates a Fresnel lens 116 generally similar to the lens discussed above with reference to Figs 1-4. In this embodiment as well, a surface of the lens includes a first or central refractive surface portion 131 which is disposed at the central axis 112 of the lens, and additional refractive portions 134a, 134b and 134c, which are annular and surround the central refractive portion 132. However, lens 116 is not phase-continuous; the discontinuities between the various refractive portions define various step distances, selected without regard for any particular coherence frequency. In this embodiment as well, the ultrasonic transducer includes a layer of piezoelectric material 140 having a first common ground electrode 142 on a front face of the layer. The rear face of the transducer again has a first electrode 144 aligned with the first or central refractive portion 132. In place of the unitary peripheral electrode 46 (Figs. 2 and 4), the transducer of Fig. 6 has a plurality of annular additional electrodes 146a, 146b and 146c on the rear face. Additional electrodes 146a, 146b and 146c are aligned with additional refractive surface portions 134a, 134b and 134c, respectively. Thus, the portion of the transducer 130 aligned with each refractive surface portion can be driven independently of the other portions.

[0036] The electrical circuit 150 in this embodiment includes a pulse circuit 151, drive circuit 153, switch 160 and controller 164 similar to the corresponding elements of the circuit discussed above with reference to Fig. 5. Circuit 150 also includes phase shifting elements such as delay lines 101a, 101b and 101c connected to the output of drive circuit

153. In the first or monitoring state of circuit 150, with switch 160 open, the pulse circuit 151 is connected to first electrode 144 but is not connected to additional electrodes 146a, 146b and 146c. Thus, circuit 150 cooperates with the central portion of the transducer to send brief monitoring pulses of ultrasound through the central refractive surface portion 132 of the lens, and to receive the resulting echo pulses. In the second state, the drive circuit 153 again produces a drive signal having a narrower bandwidth than the monitoring pulses. The phase shifters 101a-101c yield three replicates of this drive signal differing in phase from one another, so that there are four replicates in all, including the original signal provided by drive circuit 153 and the replicates provided by the delay lines. One of the four replicates is directed to the first or central electrode 144 via switch 160, whereas each of the other replicates is directed to one of the additional electrodes 146a-146c. Thus, each portion of the transducer will emit ultrasound differing in phase from the ultrasound emitted by the other portions of the transducer. The delay lines are adjusted so that the phase differences between the replicates of the drive signal compensates for the differences in phase introduced by discontinuities 135. For example, if the discontinuity 135a at the juncture of the first or central refractive surface portion 132 and the adjacent refractive surface portion 134c has a step height which would cause ultrasound passing through surface portion 134a to be advanced in phase by 57° relative to ultrasound passing through surface portion 132, delay line 101a is adjusted to retard the phase of the drive signal to electrode 146a by 57° relative to the drive signal replicate delivered to central electrode 144. The required phase differences can be calculated based on measured step heights, the drive frequency and the velocity of ultrasound in the material of lens 116 and in the medium in contact with the refractive surface portions. Alternatively, the required phase differences can be determined by measuring the ultrasonic power delivered to the focal point and adjusting the delay lines to maximize the delivered power.

[0037] In both the embodiment of Figs. 1-5 and the embodiment of Fig. 6, the electrical circuit 50 or 150 cooperates with the transducer and with the lens to deliver phase-continuous ultrasound through multiple refractive surface portions of the lens when the circuit is in the second state discussed above, and to direct pulses through one refractive surface portion in the first or monitoring state.

[0038] The features discussed above can be varied. For example, in the embodiments discussed above, the first refractive surface portion which is used to transmit the broadband

monitoring pulses is the center surface portion 32 or 132. In a variant (not shown), another surface portion may be used. For example, in the embodiment of Fig. 6, surface portion 134c may be employed as the first surface portion which is connected to the pulse circuit in the first or monitoring state of the system.

[0039] In the embodiments discussed above, the entire layer is driven in the second state, while applying the push pulses of ultrasound. However, this is not essential. For example, in the embodiment of Figs. 1-5, switch 60 could be omitted so that the drive is never connected to the central electrode 44, but is connected only to the peripheral electrode 46 in the second state

[0040] The number of refractive surface portions in the lens can be varied; the lens may have as few as two refractive surface portions or any greater number of refractive surface portions. Also, the shapes of the refractive surface portions can be varied. For example, the refractive surface portions need not be portions of a spherical surface, but instead may be portions of a parabolic surface. In the embodiments discussed above, the speed of sound in the coupling medium in contact with the refractive surface portions is slower than the speed of sound in material of lens 16. In another embodiment, this relationship may be reversed. In this case, in order to focus the ultrasound, the refractive surface portions will be convex instead of concave.

[0041] In the embodiment of Figs. 1-4, the refractive surface portions face away from the transducer. However, the orientation of the lens can be reversed, so that the front surface of the lens bearing the refractive surface portions faces toward the transducer. A transmission medium such as a liquid or gel would be disposed between the transducer and the lens so that the lens would be acoustically coupled to the front surface of the transducer through this medium. The rear surface of the lens, facing away from the transducer may be a plane surface, a continuous refractive surface, or another Fresnel refractive surface, desirably having the same continuity frequency. In this variant, the continuity frequency f_c at the front surface would be determined by the acoustic velocities of the transmission medium and the lens material.

[0042] In a corneal treatment device, it is not essential that an optically scattering element which also serves as an acoustic lens be configured as a Fresnel lens. For example, the optically scattering element could have a continuous refractive surface instead of the discrete refractive surface portions discussed above. In this embodiment, the entire ultrasonic

transducer may be driven as a unit, and may have unitary electrodes covering the front and rear surfaces of the piezoelectric layer. However, in this case it is still desirable to disconnect the drive circuit components used to apply the push pulses (as, for example, drive circuit 53 of Fig. 5) when operating the device in a monitoring mode to emit brief monitoring pulses and to detect the echoes of these pulses, so as to avoid electrical loading the transducer in this mode.

[0043] In the embodiments discussed above, the lens is formed as a unitary element from a single material. However, the lens may be formed as a composite as, for example, from a first layer of a material which is optically scattering and which transmits ultrasound and a separate second layer of a material which transmits ultrasound and light but is not optically scattering.. For example, the optically scattering material may be disposed between the transducer and the second layer and may as an ultrasonic coupling layer.

[0044] In the embodiments discussed above, the lens and ultrasonic transducer are mounted to a structure which rests on the eye of a living subject, so that the lens is aligned with the cornea. However, other means for holding these elements can be used. For example, a frame may hold the subject's head in a fixed position, and a support may be fixed to the frame to hold these elements.

[0045] The combination of an ultrasonic Fresnel lens having multiple refractive surface portions, a transducer having plural portions and an electrical circuit which can actuate the transducer either to send ultrasound in a narrow frequency band through multiple refractive surface portions or to send ultrasound having a broader frequency band through one surface portion can be used in many applications other than corneal crosslinking as, for example, in sensing and measuring applications such as sonar and ultrasonic measurement of the physical properties of a target. In those applications, the lens need not be optically scattering or optically transmissive. The refractive surface portions need not be in the form of concentric circular elements. For example, the refractive surface portions may be elements of cylindrical surfaces so as to focus the ultrasound in a linear region of the target, rather than at a point.

[0046] As these and other variations and combinations of the features described above can be used, the foregoing description should be taken as illustrating, rather than as limiting, the present invention.

CLAIMS:

1. An ultrasonic system comprising:
 - (a) an ultrasonic Fresnel lens having oppositely-facing front and rear surfaces, the front surface of the lens including a plurality of discrete refractive portions;
 - (b) an ultrasonic transducer acoustically coupled to one of the front and rear surfaces of the lens, the ultrasonic transducer including a first part aligned with a first one of the refractive portions and a second part aligned with one or more additional ones of the refractive portions;
 - (c) an electrical circuit cooperating with the first part of the transducer but not with the second part of the transducer when the circuit is in a first state and cooperating with the second part of the transducer when the circuit is in a second state.
2. A system as claimed in claim 1 wherein the electrical circuit cooperates with both the first part of the transducer and the second part of the transducer when the electrical circuit is in the second state.
3. A system as claimed in claim 1 or claim 2 wherein the electrical circuit is operative in the first state to apply and detect pulsatile signals having a first bandwidth and is operative in the second state to apply a drive signal having a second bandwidth narrower than the first bandwidth.
4. A system as claimed in claim 3 wherein the ultrasonic lens is a phase-continuous ultrasonic lens having a passband further comprising an ultrasound-transmissive medium in contact with the front surface of the lens, wherein the electrical circuit is operative to apply the drive signal at a continuity frequency within the passband of the lens.
5. A system as claimed in claim 3 wherein the ultrasonic lens is a phase-discontinuous ultrasonic lens and wherein the electrical circuit is operative to apply the drive signal as a plurality of phase-shifted replicates to parts of the transducer aligned with different ones of the plurality of refractive surfaces so that the phase shifts compensate for phase discontinuity between the plurality of refractive surfaces.

6. A system as claimed in any of claims 3-5 wherein the electrical circuit includes a pulse circuit and a drive circuit, the pulse circuit being active and being connected to the first part of the transducer and disconnected from the second part of the transducer when the system is in the first state, the drive circuit being connected to both the first and second parts of the transducer when the system is in the second state, the drive circuit being inactive and disconnected from the first part of the transducer when the system is in the first state.

7. A system as claimed in any of the preceding claims wherein the ultrasonic transducer includes at least one piezoelectric element.

8. A system as claimed in claim 7 wherein the at least one piezoelectric element includes a layer of piezoelectric material extending within the first and second parts of the transducer, the layer having a front surface facing toward the lens and a rear surface facing away from the lens, and one or more electrodes overlying each of the surfaces of the layer, the one or more electrodes on at least one of the surfaces of the layer including a first-part electrode overlying the layer in the first part of the transducer and one or more second-part electrodes covering the layer in the second part of the transducer.

9. A system as claimed in claim 8 wherein the one or more electrodes overlying the front surface of the piezoelectric layer includes a unitary electrode overlying the layer in the first and second parts of the transducer.

10. A system as claimed in any of the preceding claims wherein the lens includes a central element defining one of the refractive surfaces and one or more peripheral elements at least partially surrounding the center element, each of the peripheral elements defining another one of the refractive surfaces.

11. A system as claimed in claim 9 wherein the central element is disposed on a central axis and each of the peripheral elements is annular and concentric with the central axis, and wherein each of the refractive surfaces is a surface of revolution around the central axis.

12. A system as claimed in claim 10 wherein the central element defines the first refractive surface and the first part of the transducer is aligned with the central axis, and wherein the lens is constructed and arranged to focus ultrasound onto a location in front of the lens on the central axis.

13. Apparatus for measuring a physical property of the cornea of the eye of a living subject comprising a system as claimed in any of the preceding claims and a structure adapted to rest on an anterior surface of the eye, the lens being mounted to the structure so that the lens overlies the cornea when the structure rests on the eye.

14. Apparatus as claimed in claim 10 wherein the lens is optically scattering and ultrasonically transmissive, the apparatus further comprising an optical element in optical communication with the lens, the optical element being operative to direct light into the lens so that light scattered by the lens will pass into the eye.

15. An ultrasonic lens formed from an ultrasonically transmissive, optically scattering material, the lens having oppositely-facing front and rear surfaces, the lens being constructed and arranged to focus ultrasound passing through the lens into a focal region forward of the front surface and to scatter light passing through the lens.

16. A lens as recited in paragraph 15 wherein the lens is a Fresnel lens, at least one of the front and rear surfaces of the lens including a plurality of discrete refractive surface portions.

17. A lens as recited in paragraph 16 wherein the lens is a phase-continuous Fresnel lens.

18. Apparatus for corneal crosslinking comprising:

(a) a lens as claimed in claim 16 or claim 17;

(b) means for holding the lens in alignment with the cornea of the eye of a living subject so that the front surface of the lens faces toward the eye and the focal region is disposed within the cornea;

(c) an optical element in optical communication with the lens, the optical element being operative to direct light into the lens so that light scattered by the lens will pass through the front surface of the lens into the cornea; and

(d) an ultrasonic transducer disposed to the rear of the lens and arranged to emit ultrasound through the lens so that the ultrasound emitted by the transducer will pass into the focal region.

19. Apparatus as claimed in claim 18 wherein the means for holding the lens includes a structure having a base surface adapted to rest on an anterior surface of the eye, the lens and the transducer being mounted to the structure.

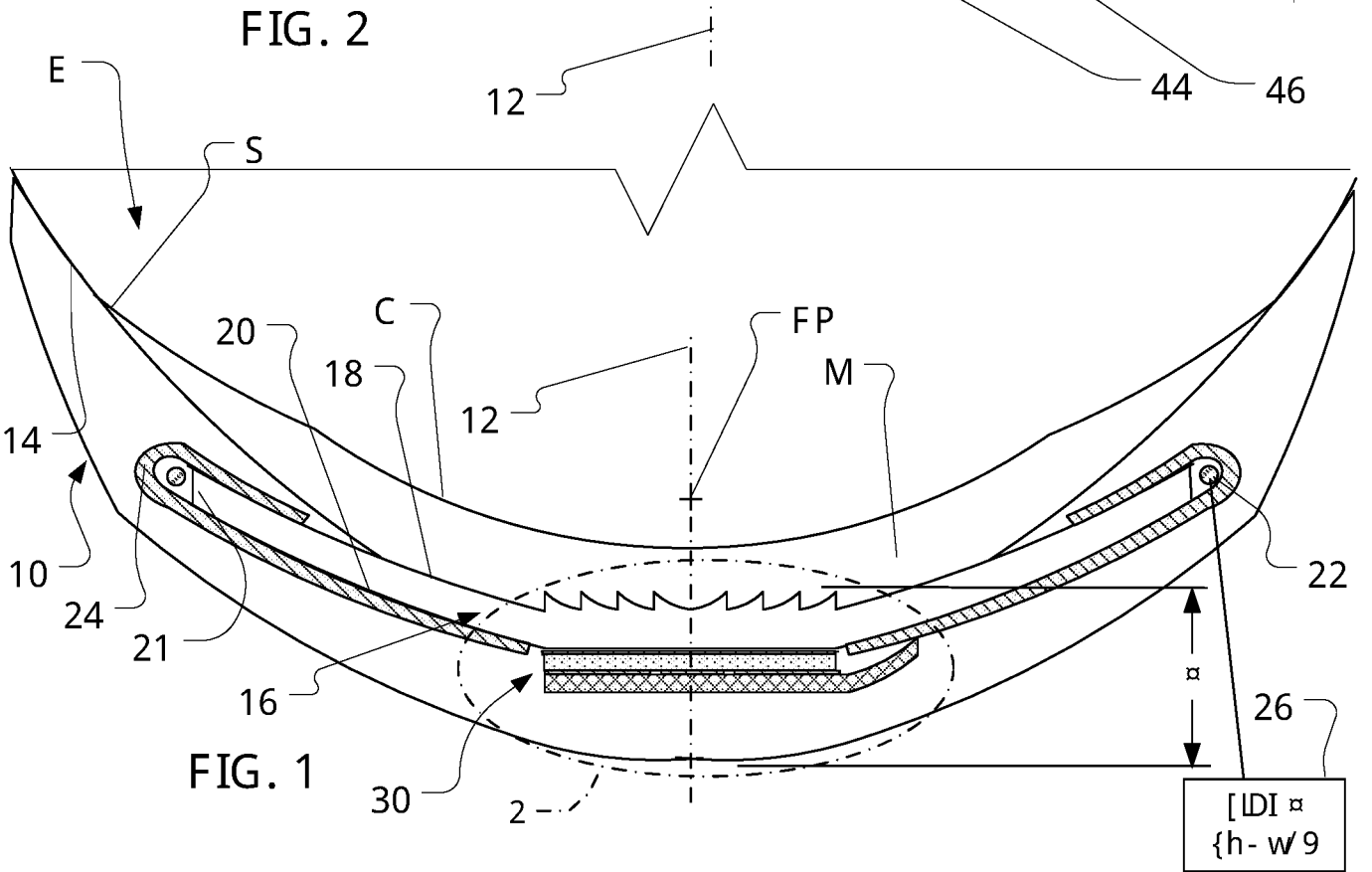
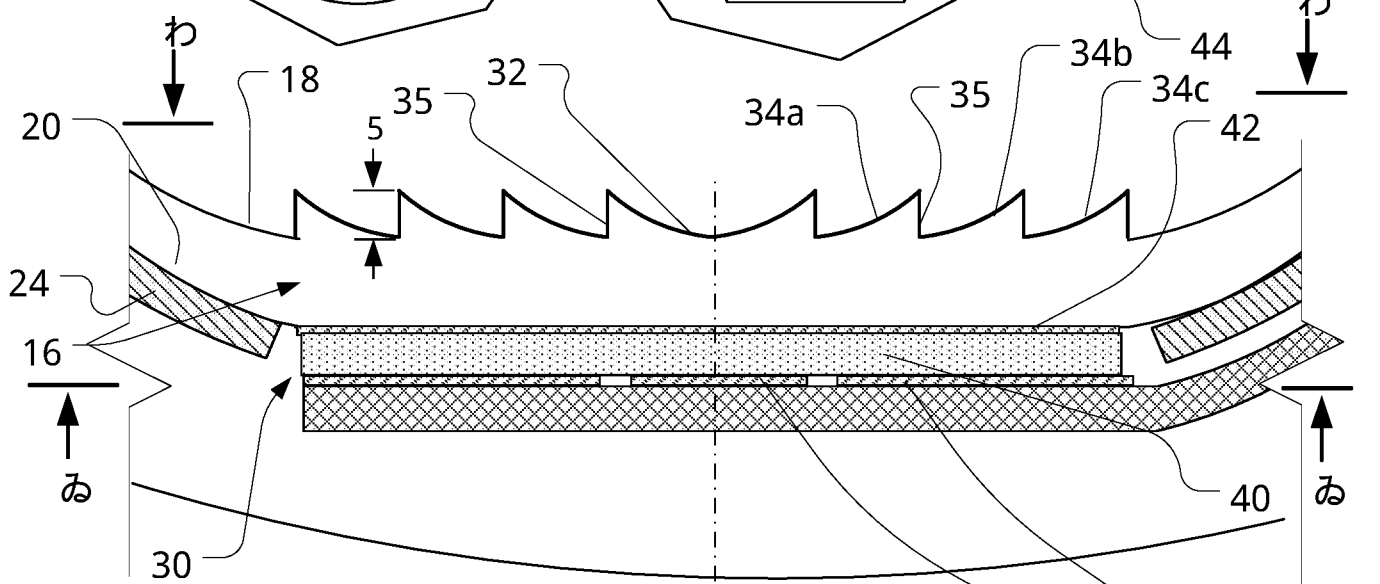
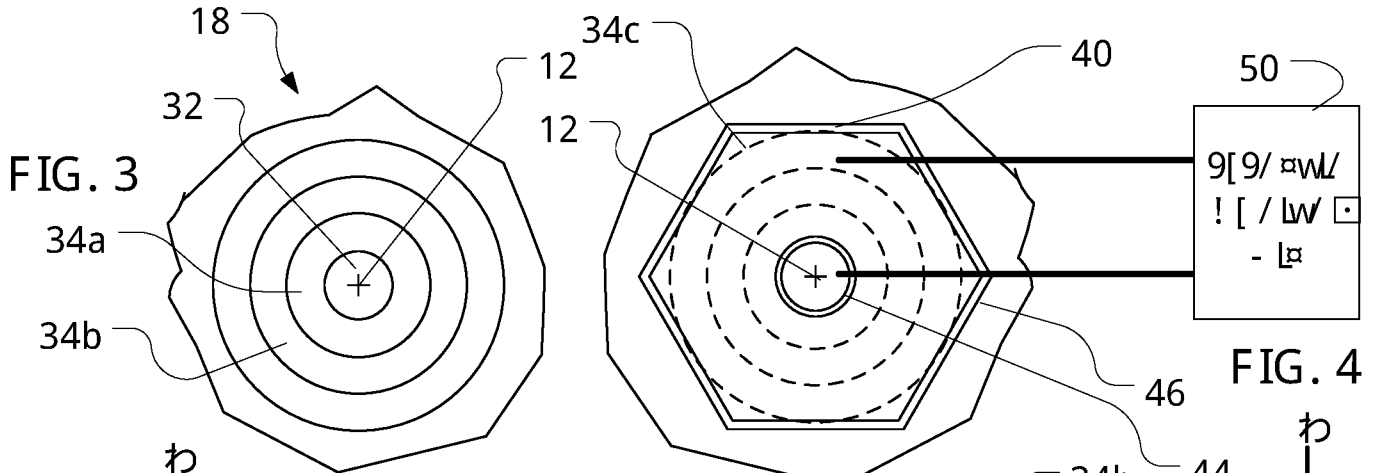
20. Apparatus as claimed in claim 18 wherein the lens has a central axis, the refractive surface portions of the lens including a central refractive surface portion extending across the central axis and a plurality of peripheral refractive surface portions encircling the central refractive surface portion, and wherein the ultrasonic transducer includes a central part aligned with the central refractive surface portion and a peripheral part aligned with the peripheral refractive surface portions.

21. Apparatus as claimed in claim 20 further comprising an electrical circuit connected to the ultrasonic transducer, the circuit being operative to apply pulsatile monitoring signals having a first bandwidth to the central part of the transducer and detect signals from the central part of the transducer, and to apply a drive signal having a second bandwidth narrower than the first bandwidth to the peripheral part of the transducer.

22. A method of corneal crosslinking comprising the steps of:

(a) directing light into a cornea of an eye of a living subject through a optically scattering, ultrasonically transmissive ultrasonic lens so as to cause crosslinking within the cornea; and

(b) passing ultrasound through the lens so that the lens focuses the ultrasound into a focal region within the cornea.



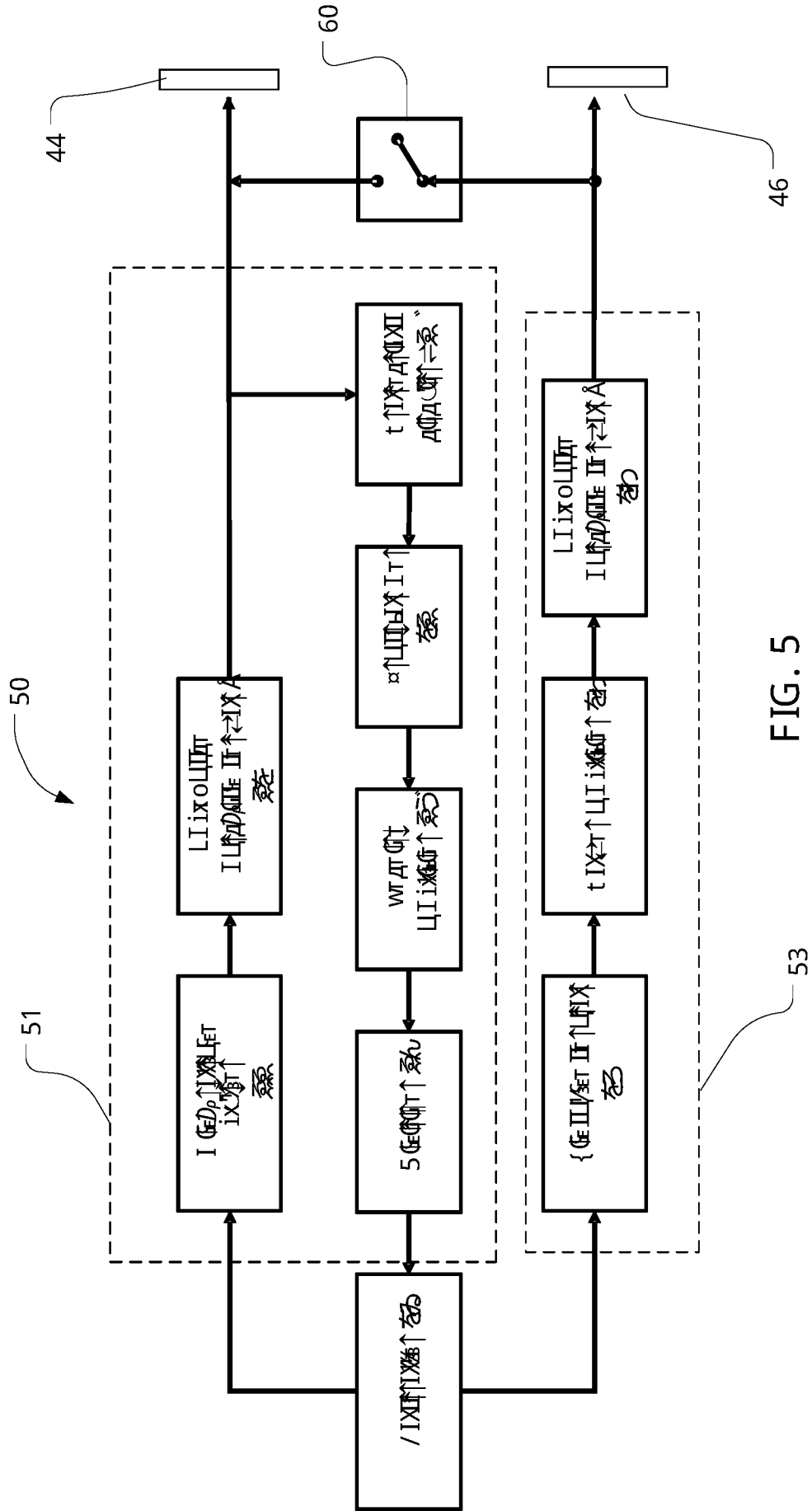


FIG. 5

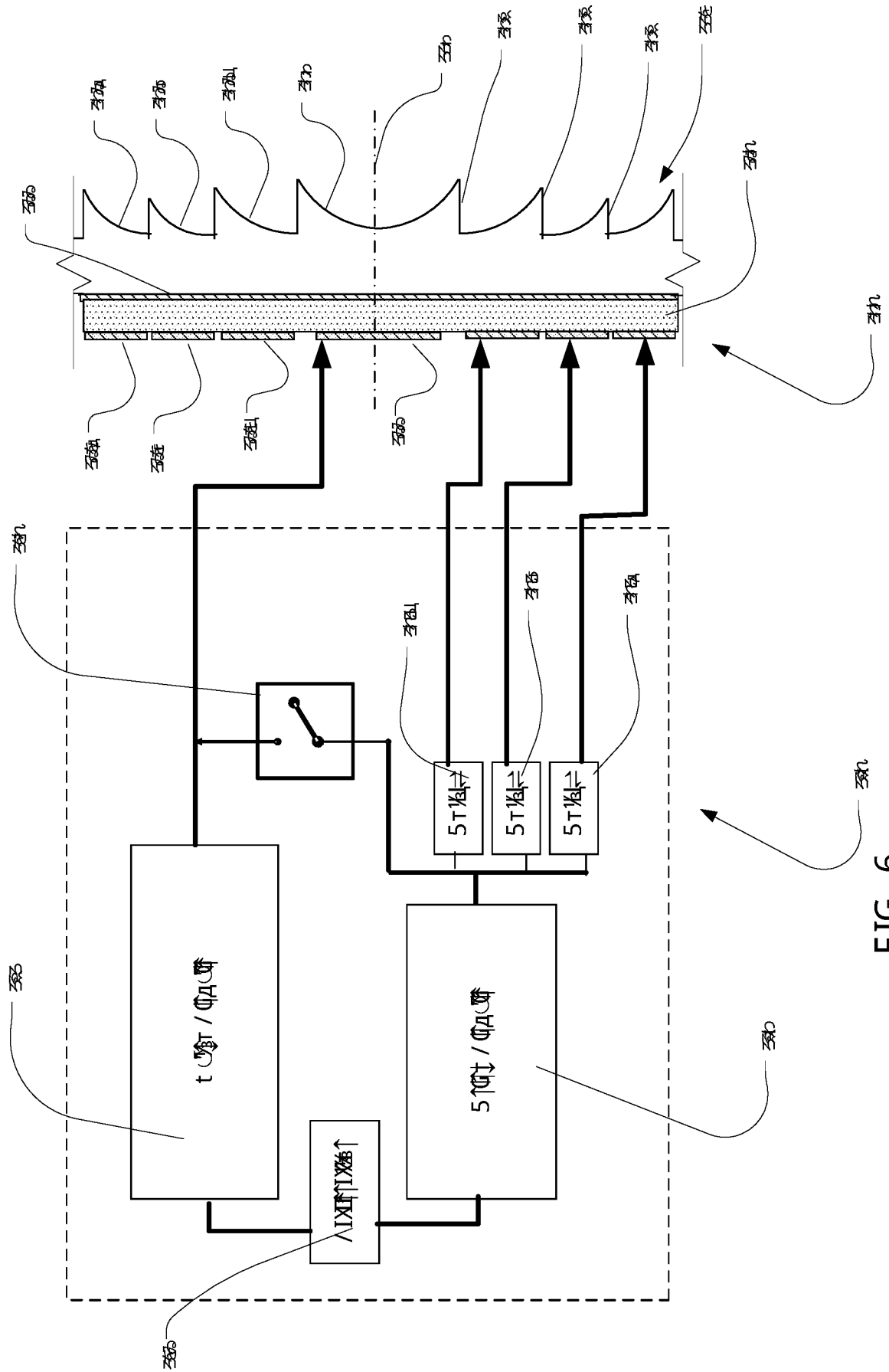


FIG. 6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2020/033736

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-12

Remark on Protest

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2020/033736

A. CLASSIFICATION OF SUBJECT MATTER
INV. B06B1/06 B06B1/02 G10K11/30
ADD.
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED
Minimum documentation searched (classification system followed by classification symbols)
B06B G10K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	JP H08 193987 A (NIPPON DENSO CO) 30 July 1996 (1996-07-30)	1-3,5-12
Y	paragraph [0006] - paragraph [0040]; claim 1; figures 1-4	4
Y	----- US 5 938 608 A (BIEGER JOHANNES [DE] ET AL) 17 August 1999 (1999-08-17) column 4 - column 5; figures 1,2	4
A	----- US 5 882 309 A (CHIAO RICHARD YUNG [US] ET AL) 16 March 1999 (1999-03-16) figures 4A,5A	1-3,6
A	----- US 2018/317950 A1 (SINELNIKOV YEGOR [US]) 8 November 2018 (2018-11-08) paragraphs [0077], [0078], [0098]; figures 4,31,32	1-3,6

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier application or patent but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- "&" document member of the same patent family

Date of the actual completion of the international search 3 August 2020	Date of mailing of the international search report 02/10/2020
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Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer Gassmann, Martin
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2020/033736

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			US 2018317950 A1 08-11-2018
			WO 2011146139 A2 24-11-2011

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-12

Ultrasonic system with an ultrasonic lens wherein an electric circuit cooperates with different parts of the ultrasonic transducer

2. claims: 13-22

Ultrasonic lens wherein lens optically scatters light that passes through the lens
