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(54) Title: APPARATUS AND TECHNIQUE FOR THE TREATMENT OF GALLSTONES AND KIDNEY- STONES

(57) Abstract: Apparatus for treating medical conditions such as a gallstone or kidney stone in a patient, comprising a transmitter operable to focus sound waves on the medical condition within the patient to cause a reduction in the medical condition, a detector operable to receive a treatment sound signal generated in the process of the reduction of the medical condition, and a signal processor adapted to provide an output signal to an operator indicative of the advocacy of the treatment of the medical condition dependent on the treatment sound signal detected by the detector.

Apparatus and technique for the treatment of gallstones and kidney-stones

The invention relates to apparatus and methods for treating medical conditions comprising build up of bodies treatable using ultrasound, such as gallstones and kidney-stones.

Gallstones and kidney-stones are a common problem, and can be extremely painful and indeed debilitating until they are diagnosed and treated.

The common method for treating gallstones is surgery, and for kidney-stones is shock-wave lithotripsy; this involves focussing a high-powered acoustic shock wave onto the stones, through the abdomen. A series of pulses breaks the stones up into small pieces that can subsequently passed through urination.

One of the difficulties of applying this technique is the accuracy that most systems can achieve in hitting the stone. Not focussing the shock wave onto the stone will, firstly increase the treatment time unduly, will decrease the efficacy of the treatment, and will increase damage to the tissue surrounding the stone. The beam is commonly focussed using either x-rays or diagnostic ultrasound to determine the accurate position of the stone, however as the patient moves, or as the stone moves or disintegrates within the patient, this focus position will need to be changed, which is not particularly easy throughout a single treatment. Moreover, the treatment commonly lasts for several 10's of minutes, and may need to be repeated several times until the stones are sufficiently broken-up.

One of the main problems with this technique arises with the passing of the stone fragments through the urinary system. This can be painful, and there is a risk of fragments lodging in the urinary tracts. This is potentially dangerous, and requires surgery to dislodge them.

Gallstones are not as easy to treat as kidney stones, requiring surgery to remove them, as well as the tissue that they are lodged in. Shock wave lithotripsy is not commonly used to treat gallstones, as there isn't an easy mechanism to remove or pass the stone fragments after treatment. Surgery is possible with most patients (although there is naturally an inconvenience, pain and significant costs), however with some patients surgery would be dangerous, and therefore cannot be used. This leaves the patient with a debilitating, painful, and potentially a fatal condition.

The new apparatus and treatment technique described uses a technique where stones are disintegrated into powder using a combination of ultrasonic frequencies, having particular novelty in respect of the delivery and monitoring of the ultrasound.

Aspects and features of the invention are set out in the dependent claims hereto.

Embodiments of the invention will now be described, by way of example only, with reference to the accompanying drawings, in which:

Figure 1 is a schematic view of detected ultrasonic signal and three component parts of that signal;

Figure 2 is a schematic drawing of the detected ultra sonic signal using apparatus according to the invention and various Fourier transforms of that signal;

Figure 3 comprises parts A and B showing the ability of the apparatus to provide an ultrasonic sectoral scan of a patient thereby to view the position of the focus of transmitted ultrasonic waves;

Figure 4 is a schematic block diagram of a first embodiment of an apparatus according to the invention; and

Figure 5 is a schematic block diagram of apparatus according to a second embodiment of the invention.

Referring initially to the apparatus shown in Figure 4, apparatus 10 according to the invention is for the treatment of a medical condition such as gallstones and/or kidney stones. The medical conditions include ailments susceptible to treatment by ultrasound, such as hard deposits including uric acid, urates, calcium slats such as calcium oxalate and/or calcium phosphate, magnesium phosphate, silica, alumina, systine, xanthine, fibrin, cholesterol, fatty acids, bile pigments, . the apparatus 10 comprises a high power transmitter driver 12 coupled to a transmitter 14 in the form of transducer for emitting sound waves and in particular ultrasonic sound waves you interlay patient. Apparatus 10 further comprises a single detector 16 in particular an ultrasonic transducer for receiving ultrasonic sound waves in the patient and passing a signal to amplify 18. Apparatus 10 further comprises a filter 20, an output display 24 and a sound apple box 26. Sound apple box 26 preferably comprises a mixer 28 coupled to the filter 20, a carrier wave generator 30, an amplifier 32 and a loudspeaker 34. Also shown in Figure 4 is the prior art configuration of an X-ray assembly which is described, is very difficult for an operator (such as a surgeon) to use in order to obtain real time positioning of the medical condition M such as a gallstone or kidney stone throughout any treatment procedure. However, the X-ray equipment can be used to set up the patient initially for proceeding to use the ultrasonic apparatus 10.

Referring to Figure 5, apparatus 10' is substantially similar to apparatus 10 shown in Figure 4 except a phased-array and stone-decay monitoring transducer is used in the form of the second transducer or detector 16'. This is coupled to amplifier 36 which is able to provide a sectoral scan, or ultrasound image, as shown in Figures 3A and 3B, to be displayed to an operator (surgeon) on display 38.

Referring to Figure 1, the ultrasonic signal detector by transducer 16 or 16' is shown as amplitude versus time. A transform into the frequency domain, such as via a Fourier transformation shows that the ultrasonic signal detected by transducer 16, 16' comprises fundamentally three components namely (a) the basic ultrasonic frequencies apply such as a 50kl and 300kl signal, (b) harmonics of these fundamental frequencies as created through non-linear processes in the interaction of the fundamental frequencies with tissue in the patient, and (c) a broad spectrum from the disintegration of the stones resulting from the efficacy of the treatment in the application of the ultrasonic signals from the primary transducer (transmitter 40).

Accordingly, referring to Figure 2, it can be seen that the ultrasonic signal in the time domain can be seen as all three components super imposed as shown in image filter 20 can be a band pass filter so purely to the harmonics as shown in Figure 2c thereby to generate a signal shown in Figure 2d of the harmonics only which result only from interactions of the ultrasonic signal emitted by transmitter 14, close to the focus of the ultrasonic, by doing an inverse Fourier transform, an amplitude versus time signal as shown in Figure 2e which can be used to provide an output to an operator of the proximity of the focused beam to the medical condition.

The technique mixes 2 high-power ultrasonic beams, of different frequencies, and the interaction between them on the stone is to erode the surface of the stone into a fine powder. The powder particles are sufficiently small to be easily passed from the body using natural processes; via the urinary tract for kidney stones, and into the alimentary canal for gallstones.

Whilst the 2 beams (which may, or may not be produced from the same ultrasonic transducer) are commonly driven in "pulses", these pulses are sufficiently regular. To appear to the operator / surgeon/ technician as a quasi-continuous wave.

As the pulses are predominantly ultrasonic rather than a single acoustic pulse, they can be more tightly focussed, allowing more energy to be applied to the offending stone rather than to the surrounding tissue and fluids, increasing the efficiency of stone reduction, and minimising damage to other tissue.

Particular innovation centres around an improved method of monitoring the ultrasonic beam, and the interaction between the ultrasonic beam and the stones. This firstly allows much better control over the accuracy of the focus (in real-time), and secondly allows the operator to modify the parameters of the ultrasonic field in real-time to optimise the efficiency of breaking down the stones.

The monitoring technique relies on the detection of acoustic and ultrasonic signals produced by the interaction of the applied ultrasonic beam and the tissue /stone within the body. When the ultrasonic energy enters the body, there will be three sources of ultrasonic energy radiating from the stone, and from the surrounding tissue:

The first will simply be a reflected signal at the same frequency as the applied ultrasonic field. Similar ultrasound will also be scatter/reflected throughout the insonified tissue, and picked up by a receiving transducer, making it difficult to use this ultrasound alone to give information as to the position or state of the stone. A sketch of the frequency spectra from this source is given in figure 1A

The second source is generated as a non-linear interaction between the ultrasound and its environment, this predominantly produces "harmonics" of the applied ultrasound (at known, specific frequencies). Such harmonics arise only close to the focus of the ultrasonic field. As the frequencies of such harmonics are different to the frequencies of the applied ultrasound, simple electronic filtering techniques allow such harmonics to be easily isolated and identified. A sketch of the frequency spectra from this source is given in figure 1B.

The third source will be acoustic/ultrasonic energy generated by the disintegration of the stones, this will be over a continuous range of frequencies, and again can be easily isolated and identified by filtering out the other frequencies described above.

Both the frequency spectrum, and the amplitude of this sound will depend on the interaction between the impinging ultrasonic field and the stone. A sketch of the frequency spectra from this source is given in figure 1C.
A simplified sketch showing the effect of filtering is shown in figure 2

Hence we have three separate types of ultrasound, which can be easily separated electronically;
one arising from throughout the insonified field,
the second arising only at the focus of the field,
the third originating only when the field is disintegrating the stone.

This gives information on the position of the focus, the position of the stone (relative to the position of the focus), and the nature of the interaction of the ultrasonic field and the stone (for example how fast it is disintegrating).

In its simplest embodiment, the technique described in this invention can look at the third source of acoustic energy alone (that arising from the disintegration of the stone), using a single receiver. The signal can either be displayed on a suitable visual display (as a frequency spectra, or a simple amplitude bar), or can be represented by an audible signal, (possibly using frequency mixing with a variable carrier wave, such as is found in a "bat detector"). This tells the operator when the focus of the therapeutic ultrasonic beam is on the stone, and how well the disintegration of the stone is progressing. The operator can, for example move the focus slightly from side-to-side to maximise the signal, "fine-tuning" the focus. The operator can also modify the ultrasonic source (changing the amplitude, frequency and pulse-length) to optimise the disintegration of the stones. The operator will also know when the stones have gone (the signal will cease!)

In further, more complicated embodiments, the 3 signals may be used in conjunction with diagnostic ultrasonic imaging technology (phased-array transducers), and equipment similar to the equipment used for standard ultrasonic imaging may be used for this purpose.

In one such embodiment, whilst the high-power ultrasonic field is being used to erode the stone, standard ultrasonic image of the stone and surrounding tissue may be obtained (pulses may need to be locked to distinguish the ultrasound from the diagnostic transducer, from the high power beam).
The diagnostic transducer (or a separate imaging ultrasonic transducer) would also be used to image the focus of the ultrasonic beam (using electronic frequency-filtering as described above to separate this ultrasonic source from the others), and this would be superimposed on the standard image, perhaps in another colour. This is akin to the Doppler measurements that are used to image blood flow in the body.

Furthermore, the signal arising from the erosion of the stones could also be separated using appropriate frequency-filtering, and superimposed on the base image in another colour – the stones would appear to "light up" on the screen when successful erosion was taking place. Such signals are shown in Figures 3A and 3B

In further embodiments, the diagnostic transducer and the high-power transducers could be integrated into a single unit.

In further embodiments, the focusing and alignment of the high power ultrasonic source may be performed either manually or automatically (using a motorised jig)

In further embodiments, the focusing and alignment of the high-power ultrasonic source may be adjusted electronically (if the source is built as a phased-array)

In further embodiments, the diagnostic techniques may be used in 2-D and 3-D modes

A typical embodiment of the simplest arrangement described in this patent application is given in Figure 4.

Here it can be seen that the problematic stones M within the patient are therapeutically insonified by the high-power transducer in order to break them up into a powder. The initial alignment and monitoring of the stones is achieved by an x-ray system (although a separate phased array ultrasonic system may be used in place of the x-ray system). When the stones M are being successfully treated by the high-power ultrasonic beam, ultrasound is given off across a range of frequencies (as described previously), which is picked up by the receiving transducer. The output from the transducer is first amplified, and then filtered to detect only the sound generated by the disintegration of the stones. This signal is then displayed on an output device (such as a simple meter), but may also be input into a “sound output box”, where the signal (at ultrasonic frequencies) is converted into audible sound by mixing it with a carrier wave. The operator (surgeon manipulating the transmitting transducer) then has real feedback on the operation of the system, which he (or she) can use to optimise the positioning and focus of the transmitting transducer, and the transmitter-driver parameters to produce the best possible treatment.

Figure 5 shows a further embodiment where the second transducer is now a combined phased-array and stone-decay monitoring transducer. This allows the surgeon to image the stones using ultrasound, eliminating the need for an x-ray system. This system can also form an image *using only the ultrasound generated by the disintegration of the stones*. This can show exactly which part of the stones are being disintegrated, allowing the operator more information to optimise the treatment further.

CLAIMS

1. Apparatus for treating a medical condition such as a gallstone or a kidney stone in a patient, comprising a transmitter operable to focus sound waves on the medical condition within the patient to cause a reduction in the medical condition, a detector operable to receive a treatment sound signal generated in the process of the reduction of the medical condition, and a signal processor adapted to provide an output signal to an operator indicative of the efficacy of the treatment of the medical condition dependent on the treatment sound signal detected by the detector.

2. Apparatus according to claim 1 wherein a transmitter is adapted to emit sound waves at two or more discreet frequencies which sound waves operably to effect a gradual abrasion of the medical condition in use.

3. Apparatus according to claim 2 wherein the transmitter is adapted to emit sound waves in the ultrasonic frequency range.

4. Apparatus according to preceding claim 2 or 3 wherein the discreet frequencies are separated by about 100kHz or more.

5. Apparatus according to any preceding claim wherein the transmitter is adapted to emit a first sound wave having a frequency in the range of 20 kHz to 100 kHz, and a second sound wave in the frequency range of 100 kHz to 1000 kHz.

6. Apparatus according to claim 5 wherein the transmitter is adapted to emit a first sound wave having a frequency in the order of 40 kHz to 90 kHz and preferably 50 kHz to 60 kHz, and a second sound wave in the order of 100 kHz to 500 kHz and preferably in the order 300 kHz.

7. Apparatus according to any preceding claim wherein the transmitter is adapted to emit pulsed sound waves preferably regularly pulsed in a quasi -

continuous manner such as having a quasi-continuous visual manner having a pulse frequency greater than 16 pulses per second, or an audio manner.

8. Apparatus according to any preceding claim wherein the signal processor is adapted to distinguish different signals detected by the detector in order to filter out unwanted signals such as any signal generated by the detector representative of the frequency of sound waves emitted by the transmitter.

9. Apparatus according to claim 8 wherein signal processor is adapted to select, for example using a band pass filter, any signal detected by the detector representative of harmonic frequencies of the sound waves emitted by the transmitter and to emit an output signal based on the selected signal to enable an operator to direct the sound waves from the transmitter more accurately on the medical condition through feedback to the operator based on an output signal from the signal processor.

10. Apparatus according to any preceding claim comprising a user interface adapted to provide an audible signal to the operator representative of the output signal from the signal processor thereby to indicate to operator the efficacy of the treatment of the medical condition.

11. Apparatus according to claim 10 wherein the audible signal is only generated when the treatment is being effective.

12. Apparatus according to any preceding claim comprising a user interface having a display adapted to provide a visual representation of the efficacy of the treatment in accordance with the output signal from the single processor.

13. Apparatus according to any preceding claim wherein the detector is adapted to receive signals over a broad range of frequencies and a signal processor is adapted to provide a visual representation of an ultrasonic image

of the patient in use and/or of an output signal indicative of the efficacy of the treatment.

14. Apparatus according to any preceding claim comprising a user interface enabling an operator to adjust the operating conditions including one or more of a first or second sound wave frequency emitted by the transmitter, the amplitude of the first or second sound wave emitted by the transmitter, the pulse rate of the first or second sound wave emitted by the transmitter, the pulse width of the first or second sound wave emitted by the transmitter, the direction of the transmission of the transmitter, the focus of the transmitter, and improve the advocacy of the treatment through monitoring output signal from the single processor dependent on the advocacy of the treatment of the medical condition.

15. A method of treating a medical condition such as a gallstone or a kidney stone in a patient, comprising the steps of focusing sound waves on the medical condition within the patient to cause a reduction in the medical condition, detecting a treatment sound signal generated in the process of the reduction of the medical condition, and generating an output signal to an operator indicative of the efficacy of the treatment of the medical condition dependent on the treatment sound signal.

16. Use of apparatus according to any of claims 1 to 14 in a method of treating a medical condition such as a gallstone or kidney stone.

17. Use according to claim 16 wherein the patient is human.

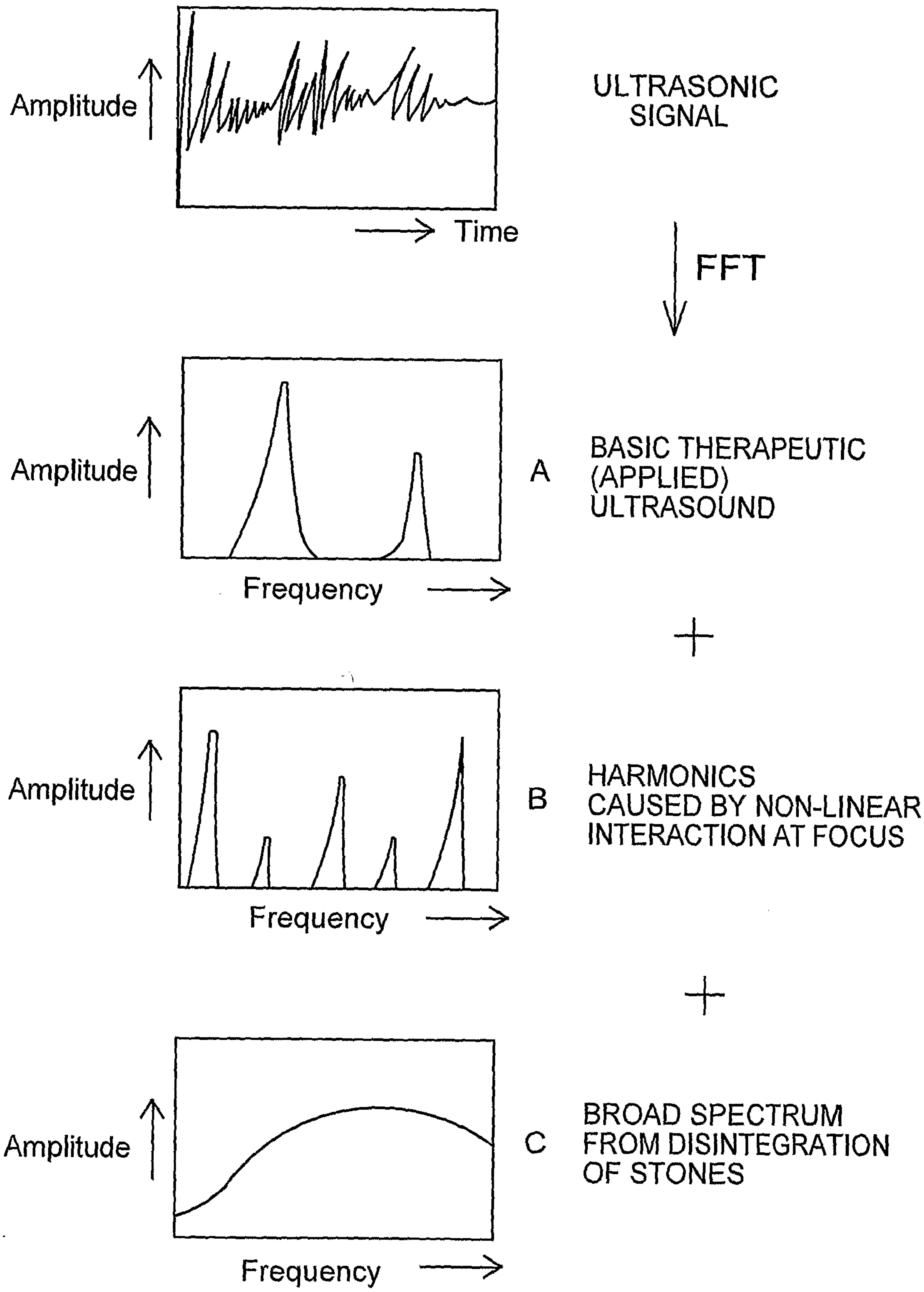
Amplitude
Time
ULTRASONIC SIGNAL
FFT
Amplitude
Frequency
A
BASIC THERAPEUTIC (APPLIED) ULTRASOUND
+
Amplitude
Frequency
B
HARMONICS CAUSED BY NON-LINEAR INTERACTION AT FOCUS
+
Amplitude
Frequency
C
BROAD SPECTRUM FROM DISINTEGRATION OF STONES

FIGURE 1

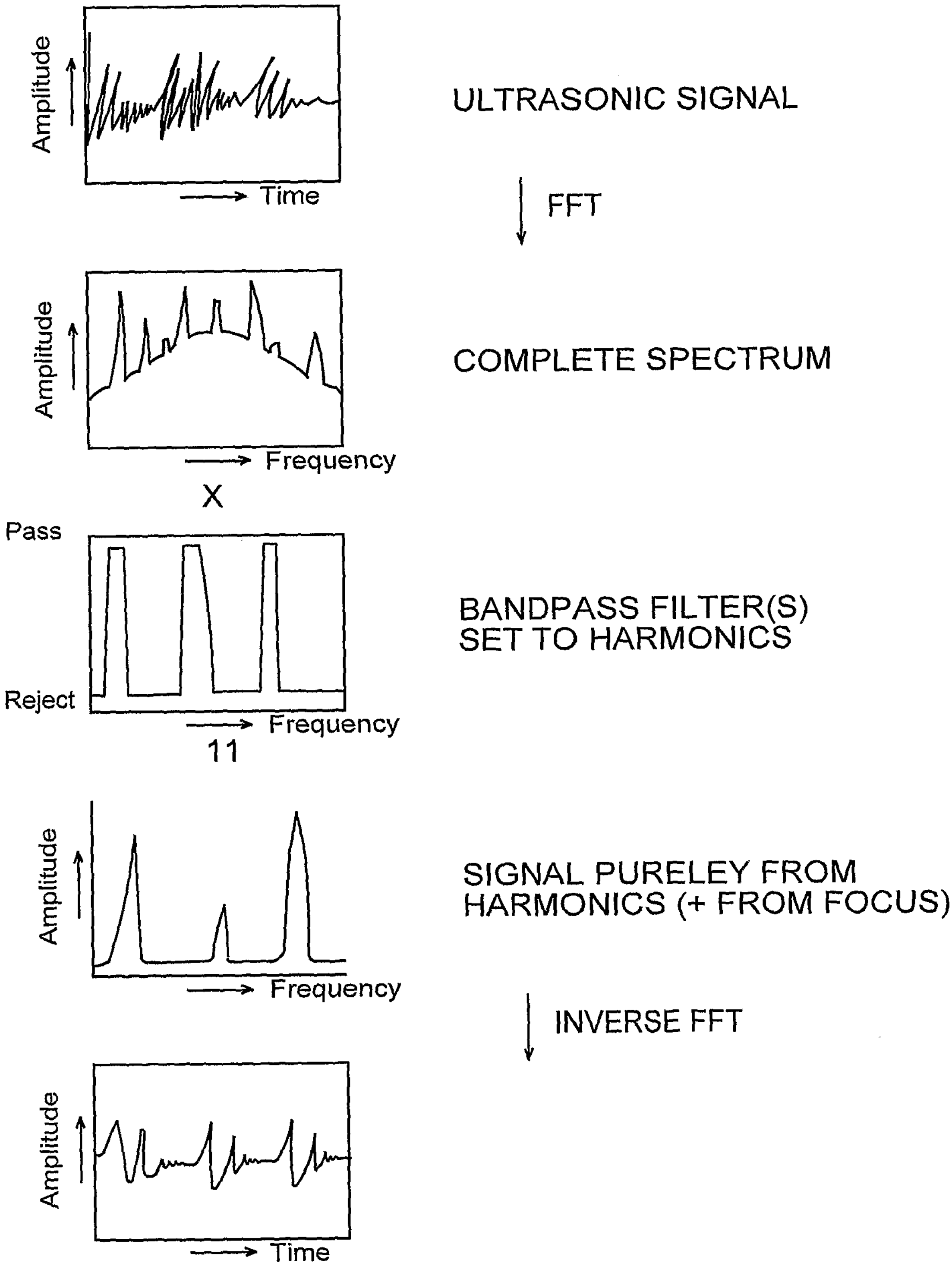
Amplitude
Time
ULTRASONIC SIGNAL
FFT
Amplitude
Frequency
COMPLETE SPECTRUM
X
Pass
Reject
Frequency
11
BANDPASS FILTER(S)
SET TO HARMONICS
Amplitude
Frequency
SIGNAL PURELEY FROM
HARMONICS (+ FROM FOCUS)
INVERSE FFT
Amplitude
Time

FIGURE 2

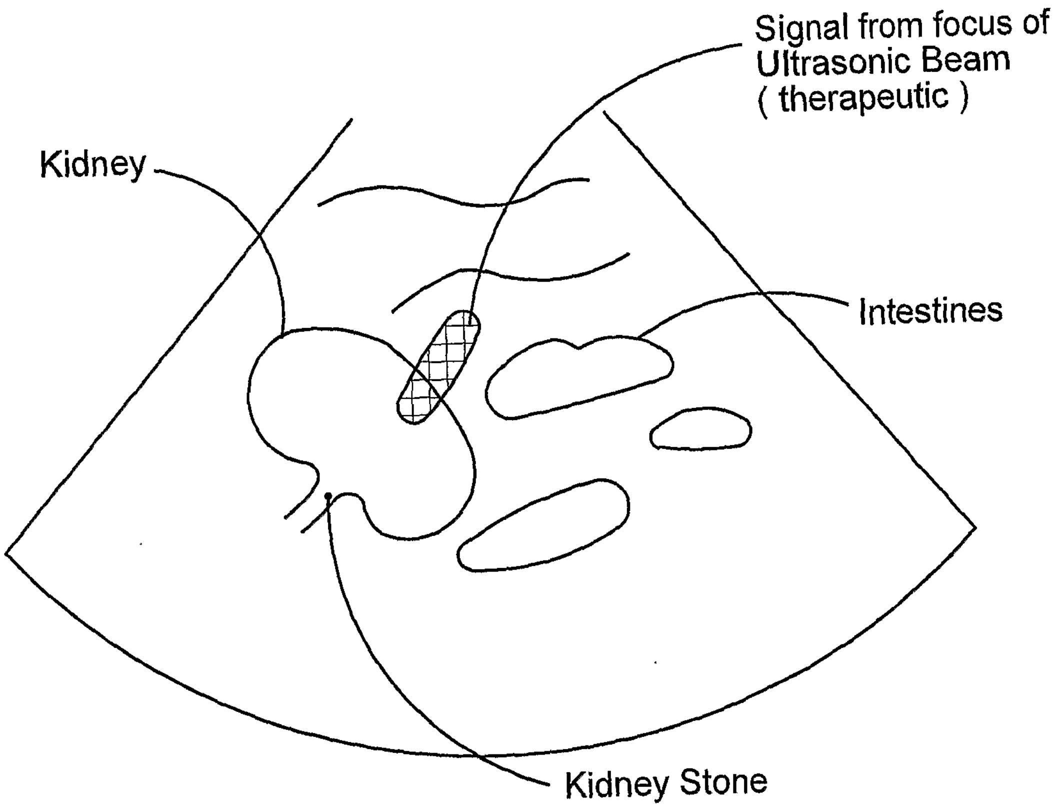

IMAGE RECEIVED WHEN THERAPEUTIC FOCUS NOT ON KIDNEY STONE

FIGURE 3A

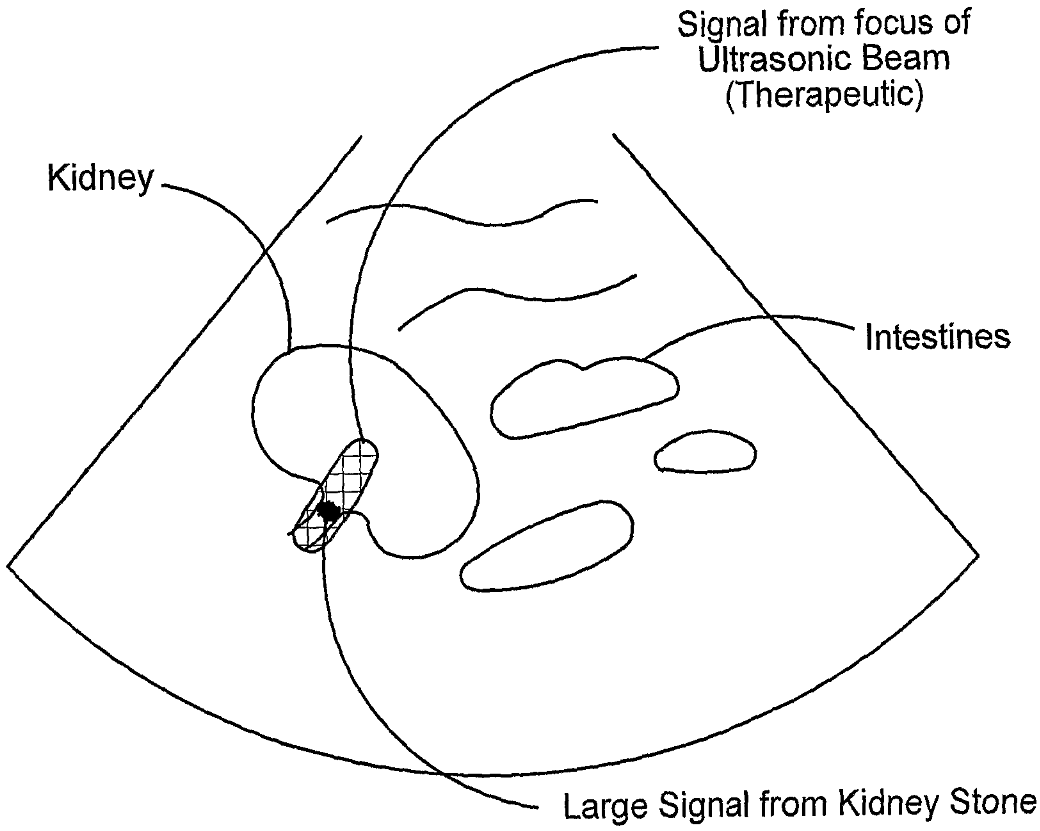

IMAGE WHEN THERAPEUTIC FOCUS
ON KIDNEY STONE AND
EROSION TAKING PLACE

FIGURE 3B

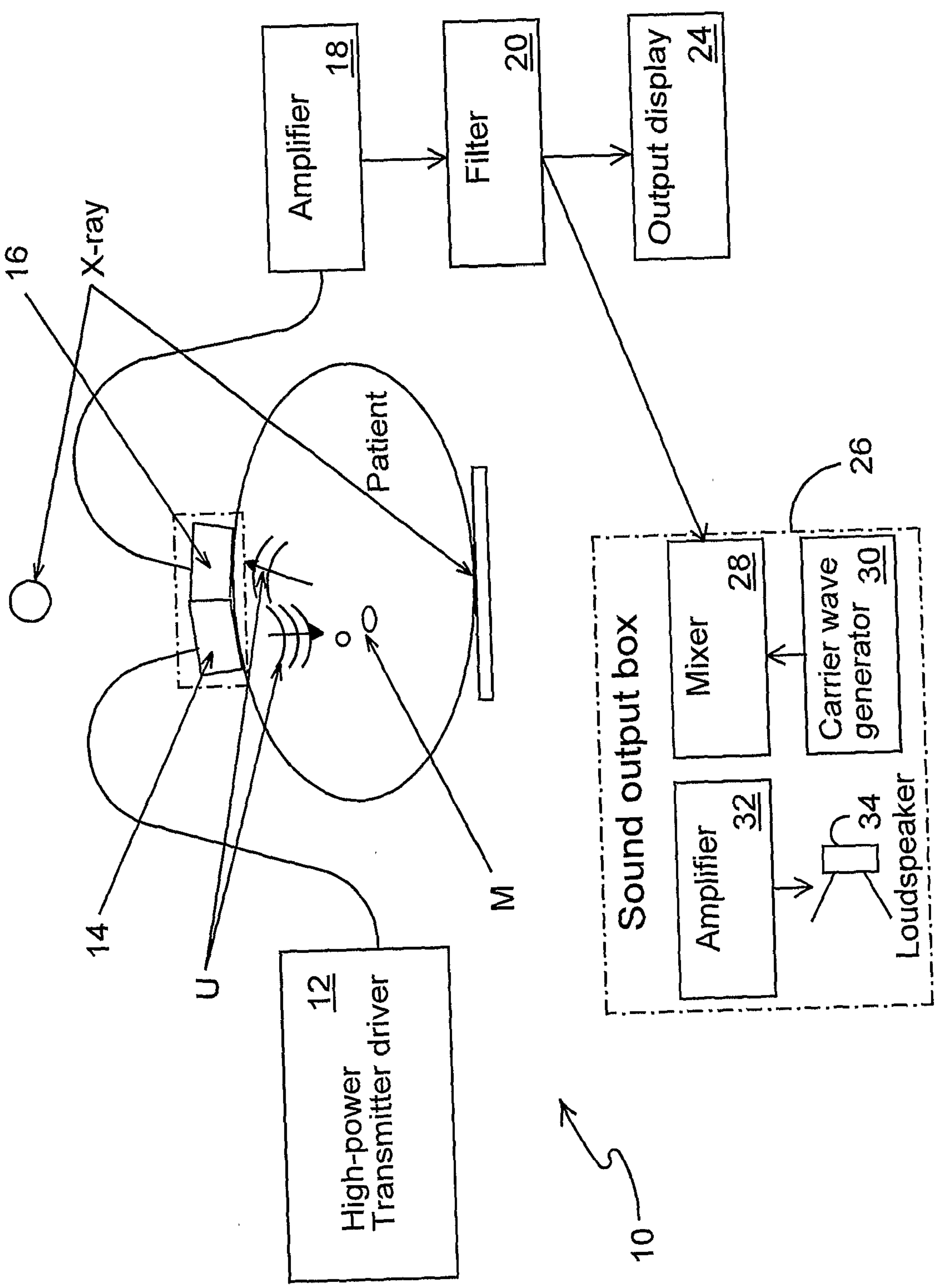
16
X-ray
Amplifier 18
Filter 20
Output display 24
Patient
26
Sound output box
Mixer 28
Carrier wave generator 30
Amplifier 32
34
Loudspeaker
14
U
M
High-power Transmitter driver 12
10

FIGURE 4

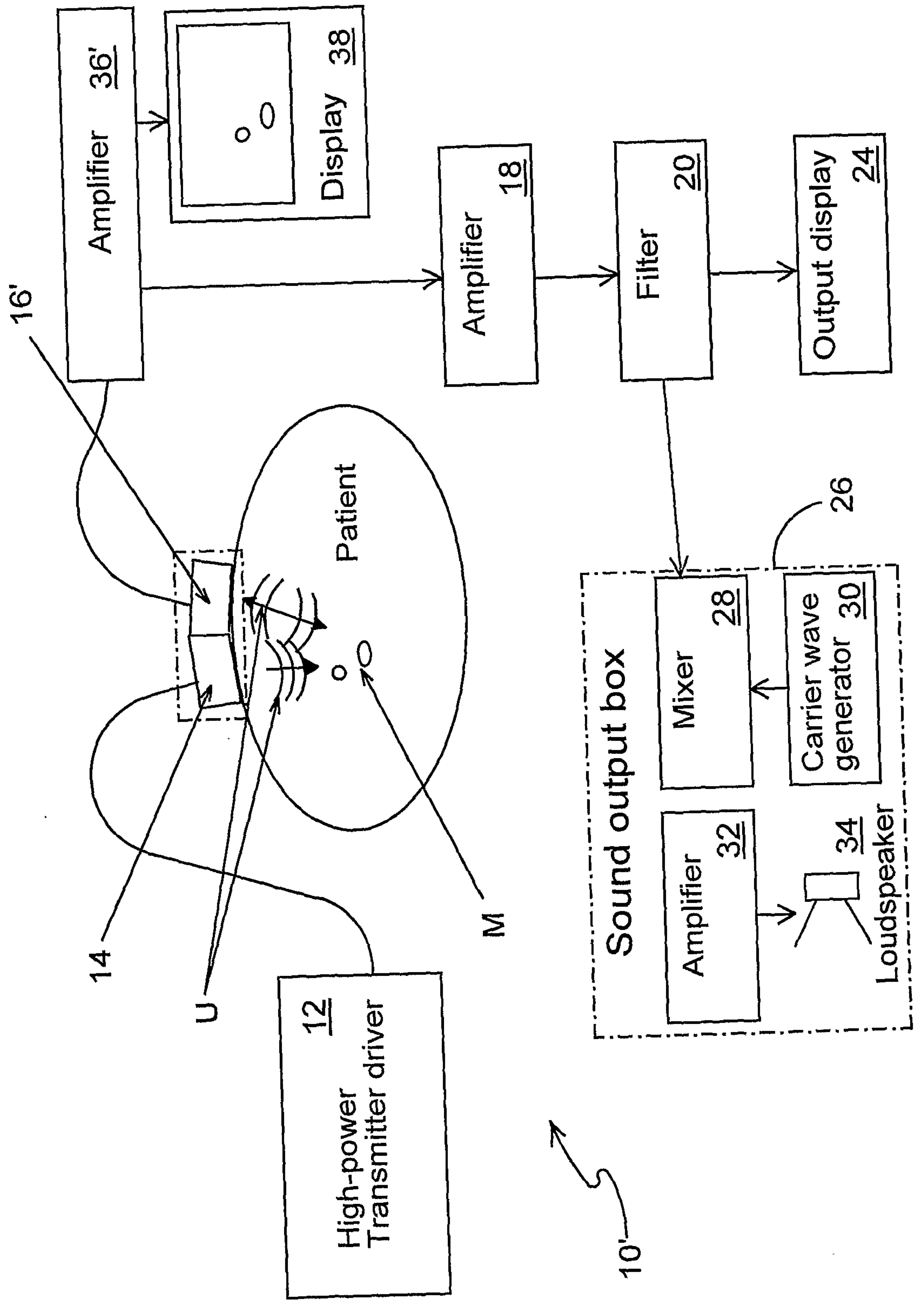
Amplifier 36'
Display 38
Amplifier 18
Filter 20
Output display 24
16'
Patient
26
Sound output box
Mixer 28
Carrier wave generator 30
Amplifier 32
34
Loudspeaker
14
U
M
High-power Transmitter driver 12
10'

FIGURE 5