

(12) **UK Patent Application** (19) **GB** (11) **2 157 828 A**

(43) Application published 30 Oct 1985

(21) Application No **8510070**

(22) Date of filing **19 Apr 1985**

(30) Priority data

(31) **8410215**
8430914

(32) **19 Apr 1984**
7 Dec 1984

(33) **GB**

(51) INT CL⁴

G01N 29/06 A61B 8/00

(52) Domestic classification

G1G MD

(56) Documents cited

GB 1462147 **EP A 0083973**

(58) Field of search

G1G

(71) Applicants

Jan Lesny,
Tarrants, Grange Road, Wareham, Dorset BH20 5AJ.
Joseph Aindow,
Brewery Cottage, 6 High Street, Sydling St Nicholas,
Dorchester, Dorset DT2 9PB

(72) Inventors

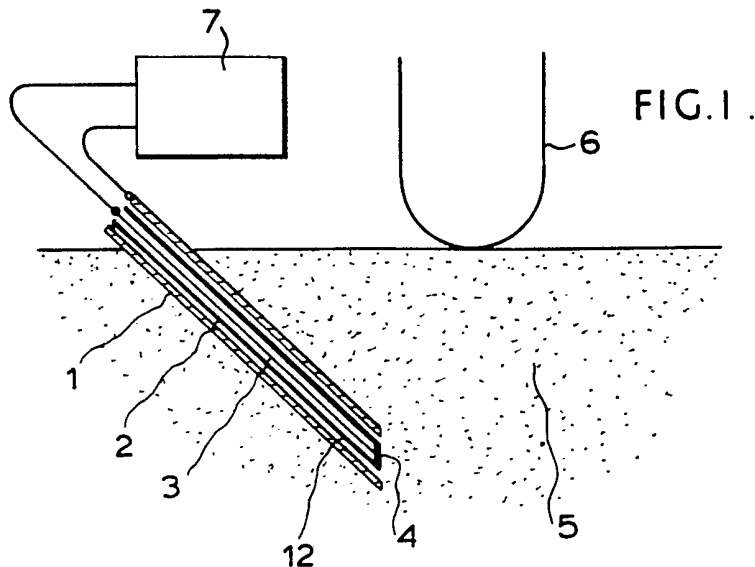
Jan Lesny
Joseph Aindow

(74) Agent and/or Address for Service

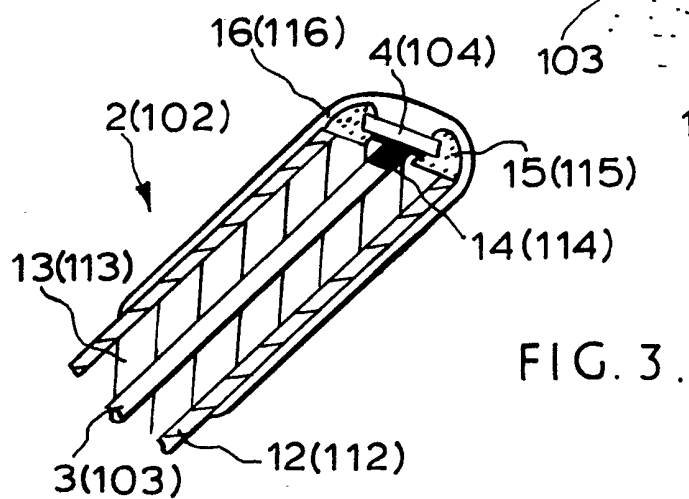
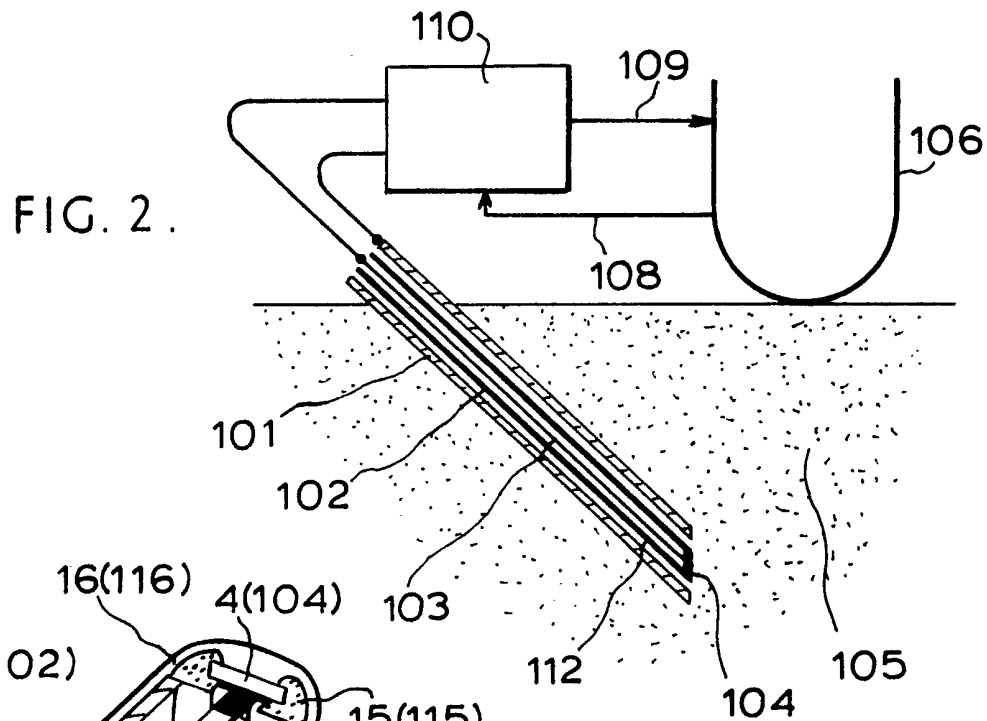
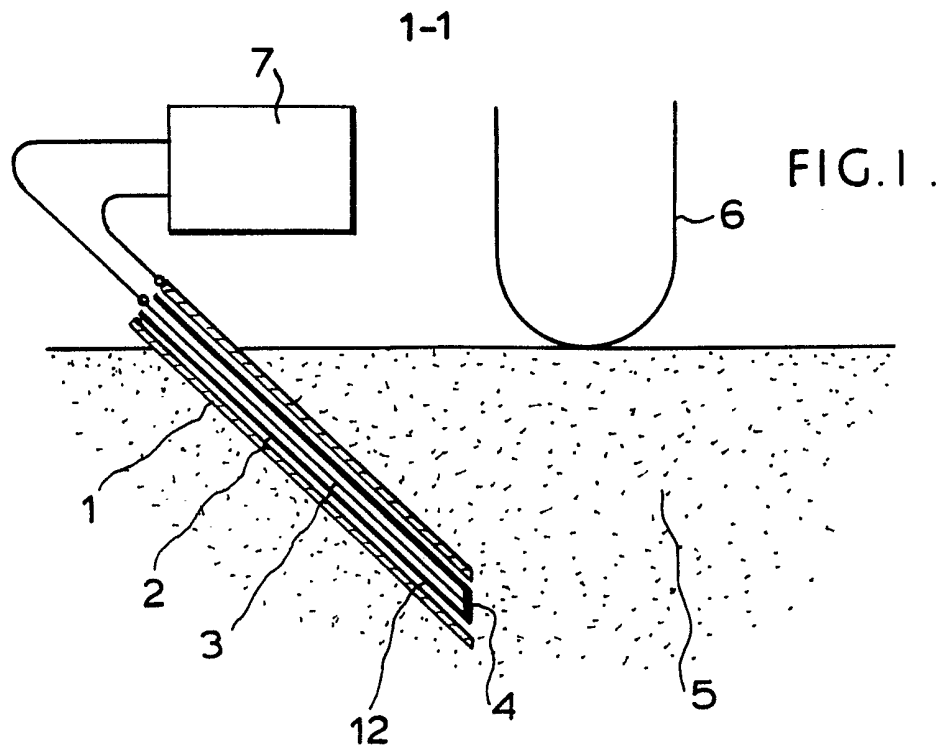
Marks & Clerk,
57-60 Lincoln's Inn Fields, London WC2A 3LS

(54) **Ultrasonic imaging apparatus and surgical instrument**

(57) An invasive instrument is provided with an ultrasonic transducer (4) which is responsive to ultrasonics 6 used for imaging. The instrument provides an active response by means of which the image formed by a scanner may be enhanced. The active response signal may be emitted as an ultrasonic pulse for detection by the imaging scanner (6), or may comprise an electrical signal which is electrically correlated with the scanning ultrasonic beam to provide location information. A method of making the instrument is also disclosed.



GB 2 157 828 A



SPECIFICATION

Ultrasonic apparatus and method

5 This invention relates to an ultrasonic apparatus and method for use in conjunction with invasive procedures used in surgical and medical investigations, treatment or diagnosis, in research and in related fields.

10 In procedures involving the insertion of an instrument into a human or animal body, it is often very important for the position of the instrument to be accurately known. The use of ultrasonic instruments, in particular imaging
15 scanners, to guide the insertion of surgical instruments such as puncture needles or catheters during invasive medical procedures is known. However, the imaging system relies on detection of passive echos from the instru-
20 ments, and there are serious problems in distinguishing these echos from those produced by scattering or reflection within the body tissue itself. Attempts have been made to enhance the echos by roughening the tips
25 of the instruments, but this produces little or no improvement in the image.

According to the present invention, an invasive instrument is provided with an ultrasonic transponder responsive to the ultrasonics used
30 for imaging. Thus, the instrument provides an active response, by means of which the image is enhanced. The active response may comprise a coded signal permitting precise and unequivocal location of the relevant part or
35 parts of the instrument within the body tissue. The active response signal may be emitted as an ultrasonic pulse for detection by the imaging scanner, or may comprise an electrical signal which is electronically correlated with
40 the scanning ultrasonic beam to provide location information.

According to the invention in a first aspect, there is provided an invasive instrument for providing an active response to an ultrasonic
45 imaging signal, comprising a hollow member for insertion, in use, in a patient, a transducer positionable at a predetermined position in the hollow member and being connected to means for feeding electrical signals to and
50 from the transducer, the transducer being responsive to the ultrasonic signal for providing a signal indicative of said predetermined position and the member being positionable, in use, independent of the position of the
55 source of the ultrasonic signal.

According to the invention in a second aspect, there is provided an invasive instrument for providing an active response to an ultrasonic imaging signal comprising a hollow
60 member for insertion, in use, in a patient, a transducer positionable at a predetermined position in the hollow member and being connected to means for feeding electrical signals to and from the transducer, the trans-
65 ducer being responsive to the ultrasonic signal

for providing a signal indicative of said predetermined position and further comprising a transponder unit for sensing detection of the ultrasonic signal by the transducer and returning an electrical pulse to the transducer for conversion to a further ultrasonic signal detectable by an ultrasonic imaging device.

70 According to the invention in a third aspect, there is provided a method of forming a transducer assembly for an invasive instrument comprising the steps of:

75 providing a support containing an electrical conductor
mounting a PVDF transducer element on
80 the conductor so as to form an electrical connection to one surface of the element
applying electrically insulating material to insulate the surface opposed to said one surface from said one surface
85 sputtering an electrically conducting material over the element and at least part of the support; and
electroplating a metallic layer on top of the conducting material.

90 Preferably, there is provided one or more small ultrasonic transducer elements mounted on the invasive part of a puncture needle, catheter or other invasive instrument (or on an associated stylet or guide wire) of a construction such that electrical signals can be fed to
95 and from the transducer element or elements.

In a first, preferred form, each transducer element forms part of an electronic system such that when the ultrasonic beam of an
100 ultrasonic imaging scanner interacts with the transducer element, the latter produces a preferably controllable and coded active ultrasonic echo pulse, which is detected and decoded by the imaging scanner thereby permitting accurate and unequivocal location of the
105 relevant part or parts of the instrument within the body tissue.

Preferably, the transducer is connected electrically to an external electronic transponder
110 unit which detects the electrical signal produced by the transducer on interaction with the ultrasonic beam, and responds by transducer which converts the electrical pulse into ultrasonic energy of an appropriate spectral
115 content which is then radiated and part of which is intercepted by the interrogating ultrasonic scanner.

In a second preferred form, each transducer element forms part of an electronic system
120 such that when the ultrasonic beam of an ultrasonic imaging scanner interacts with the transducer element, the latter produces a signal pulse, which is detected and applied through correlation circuitry to the imaging
125 scanner thereby permitting accurate and unequivocal location of the relevant part or parts of the instrument within the body tissue.

The transducer is connected electrically to an external electronic detector and delay unit
130 which detects the electrical signal produced

by the transducer on interaction with the ultrasonic beam, and responds by sending a predetermined electrical excitation pulse to the interrogating ultrasonic scanner.

- 5 The invention permits greatly enhanced visualisation of ultrasonically guided surgical instruments.

The invention is applicable to a wide range of instruments used in surgical and medical investigations, diagnosis, treatment and associated research, for example puncture needles, catheters and endoscopes, used for example for aspiration of liquids, taking biopsies and cytological samples, positioning capsules for taking small bowel biopsies, ductography, selective arteriography, phlebography, embolisation, drug administration and cardiac catheterisation.

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

Figure 1 is a schematic representation of a first embodiment,

25 Figure 2 is a schematic representation of a second embodiment,

Figure 3 shows a preferred form of the stylet of Figures 1 and 2 in more detail.

Figure 1 shows a surgical instrument comprising a hollow puncture needle 1 together with an associated stylet 2 which consists of a hollow needle 12 of smaller diameter with an inner conductor 3 mounted coaxially. This instrument is shown being inserted into body tissue 5 under the guidance of an ultrasonic imaging scanner 6.

The stylet has a miniature ultrasonic transducer (receiver/transmitter) element 4 mounted on its tip, so that electrical signals can be fed to and from the transducer element. When this instrument is introduced into the body tissue, the ultrasound beam of the scanner 6 interacts with the transducer element 4. The ultrasonic beam causes the transducer element to produce an electrical signal which is fed to an associated external electronic transponder unit 7 which acknowledges detection of the signal by returning a predetermined electrical excitation pulse to the transducer element which converts the electrical pulse into ultrasonic energy of an appropriate spectral content, which is radiated by the transducer element and part of which is intercepted by the interrogating ultrasonic imaging scanner 6. The scanner then processes the received signal, so that the image produced includes a clear and accurate visualisation of the instrument tip carrying the transducer element.

60 The excitation pulse and therefore the ultrasonic signal generated by the transducer element may be encoded in such a way that the scanner can identify it and display it in an unequivocal manner. In this case, the scanner is provided with means for decoding the

coded signal.

70 Figure 2 shows a second embodiment of the invention in which like components are designated by the same reference numerals used with reference to Figure 1, with the addition of 100.

In this embodiment, when this instrument is introduced into the body tissue, the ultrasound beam of the scanner 6 interacts with the transducer element 4. The ultrasonic beam causes the transducer element to produce an electrical signal which is fed to an associated external electronic correlation unit 110. The correlation unit 110 is connected to the scanner to receive synchronisation and timing signals 108 and to transmit an imaging pulse 109.

In operation, the correlation unit 110 monitors and quantifies the time delay between the firing of the ultrasonic transmitter of the scanner, and the arrival of the corresponding acoustic pulse at the transducer on the tip of the needle. On the basis of this time delay information, and measurement of the exact moment at which the acoustic pulse arrived at the needle tip transducer, the correlation unit 110, inserts into the electronic circuitry of the scanner, an electronic pulse of appropriate nature, and at the appropriate time, to cause the scanner to produce an image signal representing the position of the needle tip as determined from the time delay. The scanner then processes the received signal, so that the scanner image produced includes a clear and accurate visualisation of the instrument tip carrying the transducer element.

100 The image pulse 9 may be encoded in such a way that the scanner can identify it and display it in an unequivocal manner as a representation of the needle. In this case, the scanner is provided with means for decoding the coded signal.

The instrument described with reference to Figures 1 and 2 may carry multiple transducer elements, for example spaced along its length.

110 The transducer 4, 104 itself can be of any convenient construction small enough to be fitted to the instrument in question. One particularly convenient form of transducer is a piezoelectric plastics film transducer made of e.g. polyvinyl vinylidene difluoride (PVDF). Transducers of this material can be very small and can be cut and shaped to fit a particular instrument. Alternatively the transducer may be fabricated from a piezoelectric ceramic e.g. lead zirconate titanate (PZT), or any other suitable material.

A preferred fabrication technique for the stylet will now be described, with reference to 125 Figure 3 which shows the inner conductor 3 (103) surrounded, within the hollow needle 12 (112) by an epoxy resin 13 (113). The PVDF element 4 (104) is mounted on the central conductor 3 (103) by means of a small dab of silver loaded epoxy 14 (114). A thin

film of varnish 15 (115) is then applied to the edges of the element 4 (104) to ensure electrical isolation of the front and back faces of the element 4 (104). A thin film of gold is then sputtered over the entire outer surface of the needle tip to provide electrical conductivity and a protective layer of one or more metals 16 (116) is then electroplated onto the sputtered layer. Preferably the electroplated layer is formed by a layer of nickel of 30 mm thick followed by a 10 mm thick layer of gold for corrosion resistance.

CLAIMS

1. An invasive instrument for providing an active response to an ultrasonic imaging signal, comprising a hollow member for insertion, in use, in a patient, a transducer positionable at a predetermined position in the hollow member and being connected to means for feeding electrical signals to and from the transducer, the transducer being responsive to the ultrasonic signal for providing a signal indicative of said predetermined position and the member being positionable, in use, independent of the position of the source of the ultrasonic signal.

2. An instrument as claimed in Claim 1, wherein the transducer is mounted on a support or guide.

3. An instrument as claimed in Claim 2, wherein the support is a hollow needle and the signal feeding means comprises a conductor disposed within the needle.

4. An instrument as claimed in Claim 1, wherein the transducer is mounted on the member at said predetermined position.

5. An instrument as claimed in any one of the preceding Claims, wherein the hollow member is a hyperdermic needle.

6. An instrument as claimed in any one of Claims 1 to 4, wherein the member is a catheter.

7. An instrument as claimed in any one of the preceding Claims, wherein the predetermined position is the tip of the hollow member.

8. An instrument as claimed in any one of the preceding Claims, wherein the transducer is connected to a transponder unit for sensing detection of the ultrasonic signal by the transducer and returning an electrical pulse to the transducer for conversion to a further ultrasonic signal detectable by an ultrasonic imaging device.

9. An instrument as claimed in any one of Claims 1 to 7, wherein the transducer is connected to a correlation unit connectable to the source of the ultrasonic signal, for measuring a time delay between the transmission of the ultrasonic signal and the detection thereof by the transducer, the time delay being indicative of said predetermined position, and for providing an output signal indicative of said predetermined position.

10. An instrument as claimed in any one of the preceding Claims wherein the transducer is formed from polyvinyl vinylidene difluoride.

11. An instrument as claimed in any one of Claims 1 to 9, wherein the transducer is formed from lead zirconate titanate.

12. An instrument as claimed in any one of the preceding Claims, further comprising at least one further transducer, the transducers being disposed at different said predetermined positions.

13. Ultrasonic apparatus comprising an invasive instrument as claimed in any one of the preceding Claims and further comprising an ultrasonic source and imaging device.

14. An invasive instrument for providing an active response to an ultrasonic imaging signal comprising a hollow member for insertion, in use, in a patient, a transducer positionable at a predetermined position in the hollow member and being connected to means for feeding electrical signals to and from the transducer, the transducer being responsive to the ultrasonic signal for providing a signal indicative of said predetermined position and further comprising a transponder unit for sensing detection of the ultrasonic signal by the transducer and returning an electrical pulse to the transducer for conversion to a further ultrasonic signal detectable by an ultrasonic imaging device.

15. A method of forming a transducer assembly for an invasive instrument comprising the steps of:

providing a support containing an electrical conductor

mounting a PVDF transducer element on the conductor so as to form an electrical connection to one surface of the element

applying electrically insulating material to insulate the surface opposed to said one surface from said one surface

sputtering an electrically conducting material over the element and at least part of the support; and

electroplating a metallic layer on top of the conducting material.

16. An invasive instrument substantially as hereinbefore described with reference to Figure 1 and, optionally, Figure 3 of the accompanying drawings.

17. An invasive instrument substantially as hereinbefore described with reference to Figure 2 and, optionally, Figure 3 of the accompanying drawings.

18. Ultrasonic apparatus substantially as hereinbefore described with reference to Figure 1 and, optionally, Figure 3 of the accompanying drawings.

19. Ultrasonic apparatus substantially as hereinbefore described with reference to Figure 2 and, optionally, Figure 3 of the accompanying drawings.

20. A method of forming a transducer element for an invasive instrument substantially

as hereinbefore described with reference to
Figure 3 of the accompanying drawings.

Printed in the United Kingdom for
Her Majesty's Stationery Office, Dd 8818935, 1985, 4235.
Published at The Patent Office, 25 Southampton Buildings,
London, WC2A 1AY, from which copies may be obtained.