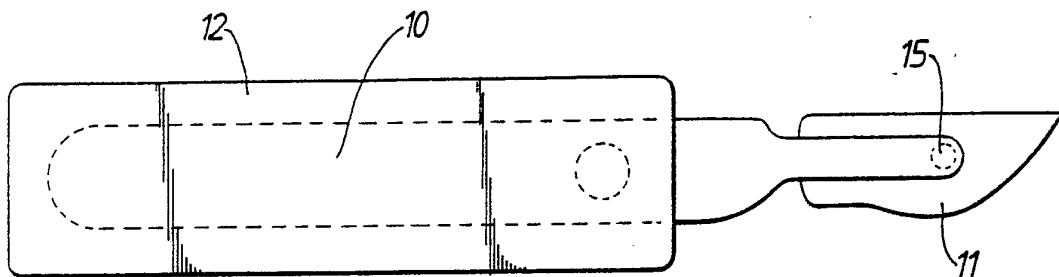




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification⁴ : A61B 5/06, 19/00</p>	<p>A1</p>	<p>(11) International Publication Number: WO 88/ 00811 (43) International Publication Date: 11 February 1988 (11.02.88)</p>
<p>(21) International Application Number: PCT/GB87/00551 (22) International Filing Date: 3 August 1987 (03.08.87) (31) Priority Application Numbers: 8619107 8709279 (32) Priority Dates: 5 August 1986 (05.08.86) 16 April 1987 (16.04.87) (33) Priority Country: GB (71) Applicant (for all designated States except US): UNIVERSITY OF WALES COLLEGE OF MEDICINE [GB/GB]; Heath Park, Cardiff CF4 4XN (GB). (72) Inventors; and (75) Inventors/Applicants (for US only) : MARKS, Ronald [GB/GB]; 12 Pen-y-lan Place, Pen-y-lan, Cardiff CF2 5HE (GB). EDWARDS, Christopher [GB/GB]; 137 Bwlch Road, Sairwater, Cardiff (GB).</p>		<p>(74) Agents: WYNNE-JONES, John, Vaughan et al.; Wynne-Jones, Laine & James, Morgan Arcade Chambers, 33 St. Mary Street, Cardiff CF1 2AB (GB). (81) Designated States: AT (European patent), AU, BE (European patent), CH (European patent), DE (European patent), FR (European patent), GB (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent), US. Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>

(54) Title: PROXIMITY DETECTOR



(57) Abstract

A surgical or medical implement including a proximity detector to indicate the distance from an internal organ or member such as an artery. In one form the invention is applied to a surgical scalpel (12) with an audio transducer in contact with the blade (11) and connected to an electrical circuit (18) for providing a warning signal. In another form the invention is applied to a hypodermic syringe (50) with a transducer (60) in contact with the needle (56) and connected through circuitry (62) with a warning lamp or buzzer (63, 64).

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	FR	France	ML	Mali
AU	Australia	GA	Gabon	MR	Mauritania
BB	Barbados	GB	United Kingdom	MW	Malawi
BE	Belgium	HU	Hungary	NL	Netherlands
BG	Bulgaria	IT	Italy	NO	Norway
BJ	Benin	JP	Japan	RO	Romania
BR	Brazil	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic	KR	Republic of Korea	SE	Sweden
CG	Congo	LI	Liechtenstein	SN	Senegal
CH	Switzerland	LK	Sri Lanka	SU	Soviet Union
CM	Cameroon	LU	Luxembourg	TD	Chad
DE	Germany, Federal Republic of	MC	Monaco	TG	Togo
DK	Denmark	MG	Madagascar	US	United States of America
FI	Finland				

- 1 -

"Proximity Detector"

This invention relates to a proximity detector which is primarily, though not exclusively, applicable to surgical or medical implements.

In surgical operations there is a risk, however careful the surgeon may be, of accidentally incising or damaging parts of the body such as arteries, viscera or nerves. Likewise when giving an injection by means of a hypodermic needle or the like, there may be a similar risk of causing such damage, but more importantly the invention can be applied in a contrary sense to assist in penetrating the artery.

Accordingly, it is one object of the invention to provide an instrument with means for producing a warning or control signal which will assist the surgeon or medical personnel in avoiding such damage, and/or in locating an internal target such as an artery.

From one aspect the invention consists in a proximity detector for use with a surgical or medical instrument or the like, comprising an audio transducer positioned on or adjacent to the instrument

- 2 -

or a part thereof for detecting sounds or changes
in pressure levels in the surrounding zone, and a
response or actuator system coupled to the transducer
to provide an output related to the position of the
5 instrument relative to another object or body of
interest, such as an artery.

In one preferred form of the invention the
detector is designed to sense pulses created or
existing within the body being operated upon, and
10 by appropriate electronic circuitry to sense or
measure the proximity of the body from the source
of the pulsing input to the transducer.

For example, in the case of a blood artery,
the arterial pulses produce cyclic sound signals
15 which can be detected by an audio-electronic
transducer. In some preferred systems according
to the invention the detector is arranged in
conjunction with a surgical implement, the audio
transducer being mounted on or in contact with the
20 cutting blade or other tool. Alternatively, in
the case of a hypodermic needle or syringe the
transducer may be positioned in good acoustic contact
with the needle.

To reduce or eliminate extraneous "noise"
25 or other pressure variations, the transducer is
preferably coupled or connected to a comparator

- 3 -

circuit having a second input derived from a different point on the body of the patient or other zone, such that the comparator output is representative of the local sound signals only.

5 In any case, the apparatus preferably includes an amplifier coupled to the transducer and means responsive to the output of the amplifier to determine the distance between the implement and a pre-selected object.

10 In some forms of the invention the apparatus includes an audible, visual or tactile warning device to indicate proximity of the instrument to an artery or viscera. Alternatively, there may be an automatic control system or actuator for positively preventing
15 further incision or penetration by the implement.

 According to another preferred feature of the invention, the apparatus includes a radio transmission link between the audio transducer and a remote comparator, or warning, indicating or control
20 device.

 As previously mentioned the invention may be applied to a hypodermic syringe and needle, in which case the detector is used to assist the user in finding and penetrating an artery rather than
25 avoiding it.

- 4 -

Broadly stated from this aspect the invention consists in a hypodermic syringe and needle including an audio transducer acoustically coupled with the needle to sense pressure changes or vibrations in
5 tissue adjacent to the needle.

As applied to a hypodermic syringe and needle it is often useful or important for the user to know that the tip of the needle is in the proper position for making an injection, often into an
10 artery. Thus the transducer is preferably arranged to detect and indicate proximity of the needle to an artery, and it may be arranged to detect when the needle has actually penetrated an artery.

In a particular preferred construction the
15 transducer is located in close contact with the base of the needle so that vibrations experienced at the tip of the needle are conveyed along the length of the needle and by direct or indirect contact to the transducer.

20 It is of advantage that the invention can be applied to existing standard syringes and needles and in a particular preferred arrangement the syringe is located at least partly within a holder which has an aperture through which the needle projects and the

- 5 -

holder also incorporates an amplifier, a visible or audible warning indicator and a battery or other power source.

The invention may be performed in various ways and three specific embodiments, with a number of possible modifications, will now be described by way of example with reference to the accompanying drawings, in which:-

Figure 1 is a diagrammatic illustration of a surgeon's scalpel in a handle or holder, and provided with a miniature acoustic transducer according to the invention,

Figure 2 is a very diagrammatic illustration of the essential components of the transducer system,

Figure 3 is a diagram illustrating the essentials of the electronic circuit,

Figure 4 is an exploded view illustrating the same constructional elements in a typical example,

Figure 5 is a further diagram illustrating the associated electronic comparator warning circuit coupled to an E.C.G. (electro-cardiograph) instrument,

Figure 6 is a further diagram illustrating a possible modification with the sensor separate from the blade of the instrument,

Figure 7 is a diagrammatic cross-section

- 6 -

through the implement on the lines VII - VII in Figure 6, and

Figure 8 is a diagrammatic sectional elevation through a modified hypodermic syringe and needle
5 according to the invention.

In the first example the invention is applied to a surgeon's scalpel as illustrated at 10, having a knife or blade 11, usually formed of stainless steel. In this example the handle of the scalpel
10 is positioned in a holder 12 which is provided with a closure or lid 9 and an audio transducer 13 pressed into close contact with the handle of the scalpel so as to detect any sound or other vibrations. This transducer is conveniently a piezo-electric crystal
15 or ceramic such as a p.z.t (lead zirconate titanate) ceramic transducer.

Alternatively, the transducer may be positioned as shown at 15 directly on the blade or other part of the scalpel. The transducer is electrically
20 coupled to circuitry illustrated at 18 and in more detail in Figure 3, which includes a preamplifier 19, an R.F. oscillator 20, a modulator 21, R.F. amplifier 22 and a small ferrite transmitting aerial
23. The handle 12 also includes a small battery 25
25 for the electronic circuit.

In the diagrammatic illustration of Figure

- 7 -

4 the scalpel handle 10 is mounted in a holder 12
of box or trough shape and is clamped in position
in contact with the audio transducer 13, which is
spring-urged into contact with the handle. The
5 scalpel itself with its blade 11 can be removed
to be sterilised and replaced, or it may be
disposable, and the holder 12 with the transducer
and other elements of the circuit of 18 is
preferably separate from the instrument and need
10 not therefore be treated as disposable.

The information transmitted by the antenna
23 will include all vibrations or sounds picked up
by the transducer and this will include, for example,
noise created by the actual cutting action of the
15 scalpel through tissue. In some cases that sound
itself may be sufficient to trigger a warning signal,
in which case the warning circuit merely includes a
level detector sensitive to the volume of sound
received.

20 In a preferred construction, however, the
detector relies on the sounds and vibrations created
by the pulsing flow of blood in the artery or viscera
and the apparatus includes the further equipment
illustrated in Figure 5. This is positioned adjacent
25 to but not physically connected to the surgeon's
scalpel and includes a receiving antenna 30, an

- 8 -

amplifier 31, E.C.G. (Electro-Cardiograph) input 32, a comparator or lock-in amplifier 33, output amplifier 34 and warning or control circuit 35. The lock-in amplifier 33 compares the signal received from the
5 E.C.G. with the signal transmitted between the radio link 23,30, eliminates extraneous "noise" and thus detects only the vibrations of interest, in this case the artery pulse, and then responds to a pre-selected level which is related to the distance between the
10 scalpel blade and the actual artery. At the required level of proximity the alarm is activated.

In the alternative illustrated in Figures 6 and 7 the instrument comprises a detachable blade 40, mounted in a blade carrier 41 with the proximity
15 sensor or probe 42 positioned above the carrier and close to the blade but not in direct contact. In this case the instrument includes an automatic withdrawal mechanism comprising a plunger 45 movable lengthwise by a hydraulic, mechanical or electrical
20 actuator 46, preferably with a return spring. The plunger has a pair of inclined cam slots 47 engaged by pins 48 attached to the blade, and on receipt of the warning signal from the output element of the comparator circuit, the plunger is triggered to
25 cause the blade 40 to withdraw into the holder 41.

- 9 -

In the example of Figure 8 the invention is applied to a standard hypodermic syringe assembly comprising a cylinder 50 having a cover or closure 51 at its rear end with an aperture to receive the rod 52 of the piston 53. At the other end of the cylinder a further opening is provided to receive and locate the base of the hypodermic needle 56. The needle is normally secured permanently to the cylinder and is disposable as one unit or it may be removable.

In accordance with the invention the cylinder 50 is located within a holder 58 which is also generally cylindrical and has an end wall 59 formed with an aperture through which the needle projects. This end wall also supports an acoustic transducer 60 which in this example is a generally flat annular disc designed to make intimate contact with the base of the needle when in position thus allowing good acoustic transmission from the needle to the transducer. The holder also includes an electronic compartment 62 which may comprise a miniaturised amplifier coupled with a volume or amplitude threshold detector arranged to provide an output signal when the volume of sound or vibration reaching the transducer reaches a predetermined value. The

- 10 -

output of this signalling circuit is connected to a warning or indicator device such as a small L.E.D. light 63 and/or an audible warning buzzer 64. These are preferably positioned on lateral projections
5 from the holder so as to give a clear warning to the person using the syringe and the threshold level is preferably set or adjusted to a value which corresponds to the tip of the needle penetrating the wall of an artery. This then indicates that
10 the needle is in proper position for the injection. Alternatively the circuit may be set or adjusted to give warning that the tip of the needle is in close proximity with an artery.

It will be appreciated that the holder and
15 related components may be manufactured separately from a standard syringe and designed to be readily coupled thereto, for example by simply inserting the syringe and needle into the holder.

It will be understood that the invention can
20 thus be applied to detect the proximity of vascular or visceral structures in general or blood vessels or nerves, or other sensitive parts of the body and the associated sensing circuitry may be designed and adjusted to operate at any required distance or
25 indeed to detect or prevent incision or cutting into a body up to or beyond any pre-set depth.

- 11 -

CLAIMS

1. A proximity detector for use with a surgical instrument or the like, comprising an audio transducer positioned on or adjacent to the instrument or a part thereof for detecting sounds or changes
5 in pressure levels in the surrounding zone, and a response or actuator system coupled to the transducer to provide an output related to the position of the instrument relative to another object or body of interest.
- 10 2. A proximity detector according to Claim 1, in conjunction with a surgical implement, the audio transducer being mounted on or in contact with the cutting blade or other tool.
- 15 3. A detector according to Claim 1 or Claim 2, in which the transducer is coupled or connected to a comparator circuit having a second input derived from a different point on the body of the patient or other zone.
- 20 4. A detector according to any of the preceding claims, including an amplifier coupled to the transducer and means responsive to the output of the amplifier to determine the distance between the implement and a pre-selected object.

- 12 -

5. A detector according to any of the preceding claims in conjunction with an audible, visual or tactile warning device to indicate proximity of the instrument to an artery or viscera.

5 6. A detector according to any of the preceding claims, including a radio transmission link between the audio transducer and a remote comparator, or warning, indicating or control device.

10 7. A hypodermic syringe and needle including an audio transducer acoustically coupled with the needle to sense pressure changes or vibrations in tissue adjacent to the needle.

15 8. A syringe and needle according to Claim 7, in which the transducer is connected to a signalling device to indicate the proximity of the needle to an object creating pressure changes or vibrations.

20 9. A syringe and needle according to Claim 8, in which the transducer is coupled through an amplifier to an audible or visible signalling device positioned on or attached to the syringe.

10. A syringe and needle according to any of the preceding Claims 7-9, in which the transducer is arranged to detect and indicate proximity of the needle to an artery.

- 13 -

11. A syringe according to Claim 10, in which the transducer and its associated circuit are arranged to detect and indicate that the needle has penetrated an artery.

5 12. A syringe according to any of the preceding Claims 7-11, in which the transducer is located in close contact with the base of the needle so that vibrations experienced at the tip of the needle are conveyed along the length of the needle
10 and by direct or indirect contact to the transducer.

13. A syringe and needle according to any of the preceding Claims 7-12, in which the syringe is located at least partly within a holder which has an aperture through which the needle projects and
15 the holder also incorporates an amplifier, a visible or audible warning indicator and a battery or other power source.

14. A warning or indicating device for use with a hypodermic syringe and needle comprising a
20 holder or support adapted to be attached to the syringe or needle, having an audio transducer arranged to be in good acoustic contact with the needle, an amplifying circuit for generating a warning signal in response to the output from the transducer, a
25 battery or other power source, and an audible or visual warning device.

1/3

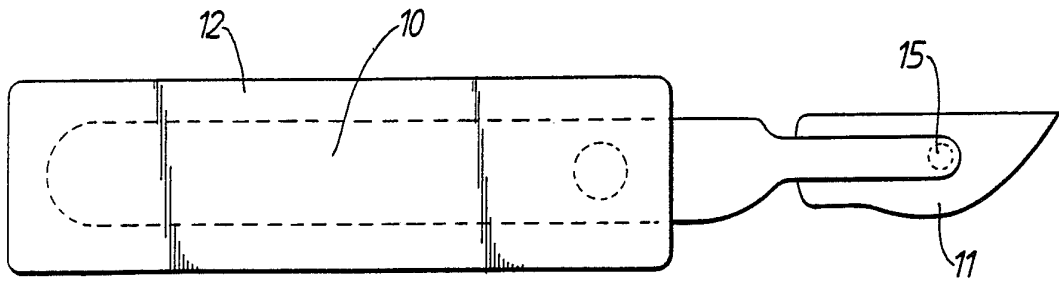


FIG. 1.

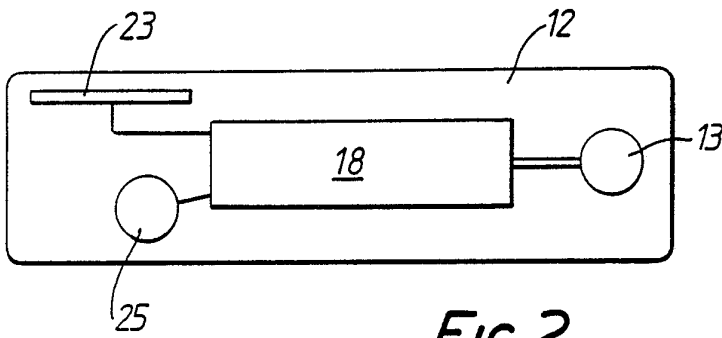


FIG. 2.

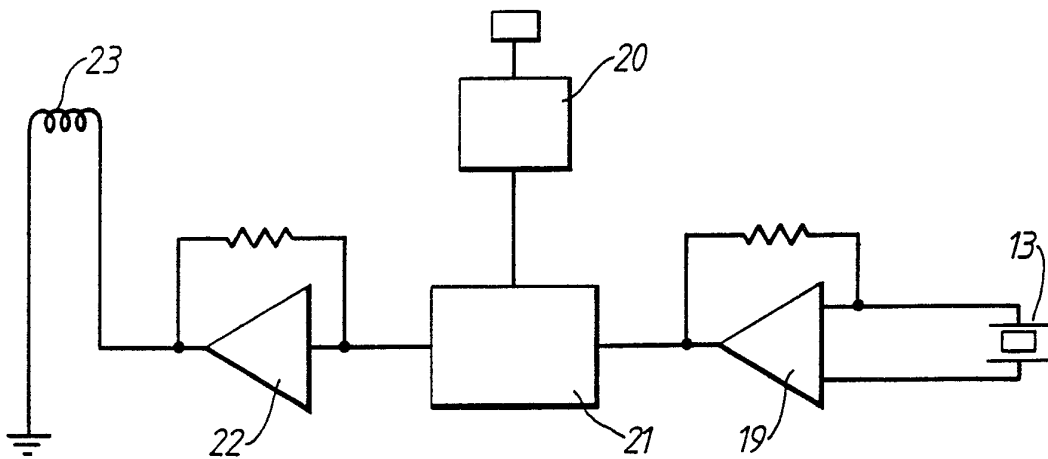


FIG. 3.

2/3

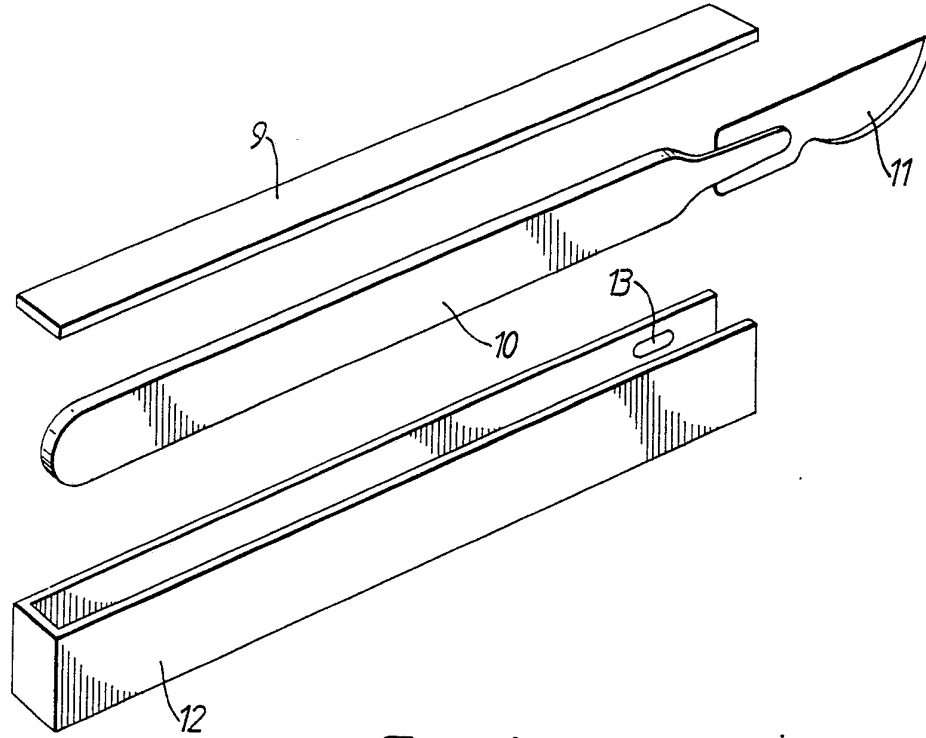


FIG. 4.

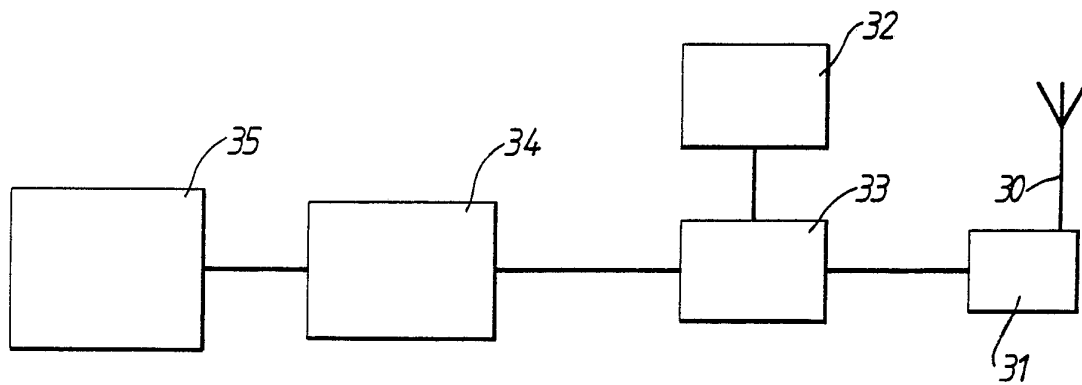


FIG. 5.

3/3

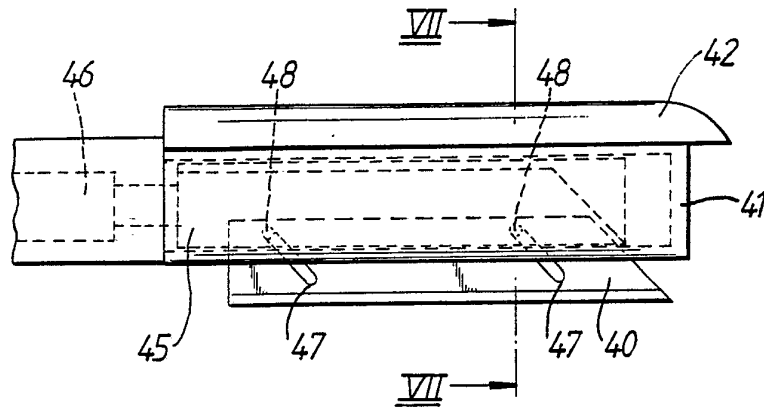


FIG. 6.

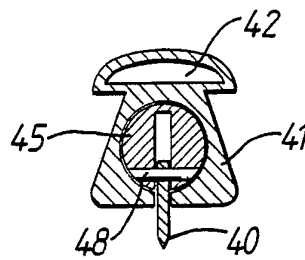


FIG. 7.

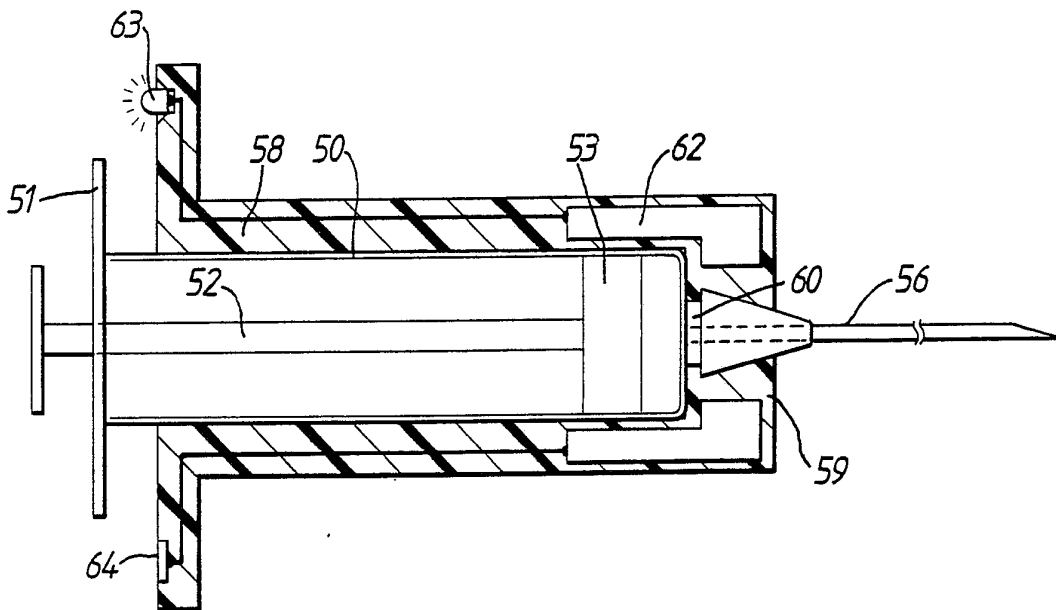
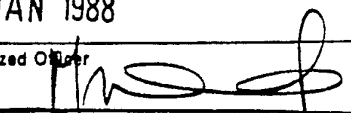


FIG. 8.

INTERNATIONAL SEARCH REPORT

International Application No PCT/GB 87/00551

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶		
According to International Patent Classification (IPC) or to both National Classification and IPC		
IPC ⁴ : A 61 B 5/06; A 61 B 19/00		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System	Classification Symbols	
IPC ⁴	A 61 B	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸		
III. DOCUMENTS CONSIDERED TO BE RELEVANT ⁹		
Category ⁹	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
Y	BE, A, 897885 (INTECH SYSTEMS CORP.) 16 January 1984 see page 5, line 30 - page 7, line 1; claims 1-4,7,8,14; figures 1-3 --	1-3
Y	GB, A, 2142163 (MICROSURGICAL EQUIPMENT LTD) 9 January 1985 see page 1, lines 90-113; claims 1,2; figure 1 --	1-3
A	FR, A, 2136492 (HEWLETT-PACKARD) 22 December 1972 see page 4, line 16 - page 5, line 20; claims 1,2,10; figure 1 --	1-3
A,P	EP, A, 0190719 (FUKUTOME et al.) 13 August 1986 see page 9, line 14 - page 10, line 16; page 12, line 16 - page 13, line 7; claims 1-3; figure 4 --	7-14
A	US, A, 4175567 (PATEL) 27 November 1979 see column 2, lines 31-54; claims 1-3; figures 1-3,9,10	7-9,12-14
<p>¹⁰ Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"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)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"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</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"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.</p> <p>"&" document member of the same patent family</p>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
6th November 1987	08 JAN 1988	
International Searching Authority	Signature of Authorized Officer	
EUROPEAN PATENT OFFICE	M. VAN MOL 	

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON

INTERNATIONAL APPLICATION NO. PCT/GB 87/00551 (SA 18139)

This Annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 14/11/87.

The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
BE-A- 897885	16/01/84	None	
GB-A- 2142163	09/01/85	JP-A- 60014847 US-A- 4637393	25/01/85 20/01/87
FR-A- 2136492	22/12/72	DE-A, B 2215543 US-A- 3762397 GB-A- 1388129	09/11/72 02/10/73 26/03/75
EP-A- 0190719	13/08/86	JP-A- 61181472	14/08/86
US-A- 4175567	27/11/79	CA-A- 1078286	27/05/80

For more details about this annex :
see Official Journal of the European Patent Office, No. 12/82