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(54) Title: STAND-OFF CELL FOR AN ULTRASONIC SCANNER HEAD (57) Abstract A stand-off cell (2) for an ultrasonic scanner head (1) has a slit (3) in which a biopsy needle (4) can be guided. The whole introduction will therefore take place in the supervision area (8, 8') of the scanner head (1) so that the needle can be guided in a scanner manner when making a biopsy. The stand-off cell (2) can be made of a plastics with the same acoustic impedance as tissue and can therefore be manufactured very cheaply. After the needle (4) is introduced the stand-off cell (2) can be removed as the needle (4) slides out through the slit (3). This makes the biopsy easier and makes it possible to utilize the scanner 7 head in the best way.

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- 1 STAND-OFF CELL FOR AN ULTRASONIC SCANNER HEAD.
- 5 The invention relates to a stand-off cell for an ultrasonic scanner head which stand-off cell is mounted so that it can be disconnected, on the scanner head by a clutch facing and is in contact with the patient through a contact surface and which furthermore has a number of free surfaces.
- In medical diagnostics one is often interested in making a so-called biopsy. I.e. that one by means of a needle takes a sample from the patient. The placing of the needle is often critical, wherefore one is interested in being able to determine this exactly. This applies for example when taking samples of the amniotic fluid.
- The supervision of the placing of the needle has been tried by means of ultrasonic scanning where emitted ultrasonic impulses are reflected from the needle and its surroundings and are used for making pictures i.e. by means of a micro computer and a cathode ray tube.

Ordinary scanner heads consist of a row of transducer elements placed in line. As an example one can mention the scanner head which is described in US Patent

Specification No. 4.346.717. Such scanner heads have the drawback, when used for biopsy that one cannot supervise the first 20-50 mm of the area into which the needle is introduced. This is due to the fact that the needle first has to be lead diagonally in



1 under the scanner head before it gets into its supervision area.

In order to avoid this drawback it is known from for example German Patent Specification No. 2.906.474 to use special biopsy heads. They consist of an ordinary linear scanner head through which a canal for introducing the needle has been made. However, in order to make room for this canal one has to remove a number of transducer elements in the centre of the head. This creates an area that the scanner head is unable to supervise and this will often be inconvenient when introducing the needle. These special biopsy heads furthermore have the drawback that they are very expensive. The even cost more than a normal scanner head.

If one wishes to supervise an area ultrasonically, which area lies close to the surface of the body, it is furthermore known from for example british Patent Application No. 2.009.563 to use a spacer unit between the scanner itself and the body.

The aim of the invention is to disclose a stand-off
cell for a conventional scanner head so that this will
be capable of supervising the whole course of the
needle in the patient at a biopsy and this is according to the invention achieved in that the stand-off
cell is provided with a slit for engaging a needle
or a hypodermic needle and that the slit extends between the contact surface and one of the free surfaces.



1 As the stand-off cell is made of a material with almost the same acoustic impedance as tissue it will be possible to register the whole course of the needle "through" this. Due to the slit the needle will first

penetrate into the patient in a place which lies within the supervision area of the scanner head. In that the needle is placed in a slit it is furthermore achieved that the scanner head with the stand-off cell can be removed from the needle without pul-

ling the needle out of the patient. This makes it possible to perform an easier biopsy just as it makes it possible to utilize the scanner head better. This is now only used during the placing of the needle itself. The stand-off cell can in a simple manner be

made of a suitable plastics, and will therefore be very cheap. Thus it becomes possible to be free to dispose of a suitable number of stand-off cells which makes it possible to use any scanner head optimum for many different purposes.

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A stand-off cell according to the invention is characteristic in that the contact surface is parallel with the clutch facing. For many purposes this is a suitable and very simple execution of a stand-off cell.

If the stand-off cell, as dealt with in claim 3, has one or more reflection surfaces it becomes possible to make stand-off cells where the ultrasonic wave course is "broken" inside the stand-off cell. This can be convenient where the biopsy has to be made in places not very accessible.

A stand-off cell according to the invention can be,



as dealt with in claim 4, characteristic in that the contact surface stands at right angles to the clutch facing. If the ultrasonic waves are now sent horizon-tally against a reflection surface, which makes up an angle of 45° at the contact surface, a 90° deflection of the ultrasonic waves is obtained. Thus it becomes possible to introduce a needle in the centre of an ultrasonic field under a large number of angles, and for example also at a right angle to the contact sur-

By mounting a guide organ, as dealt with in claim 5, in front of the needle a good control of this is obtained.

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By the in claim 6 referred to guide organs which can be disconnected and are adjustable it is obtained that the needle easily can be placed in well-defined angles in proportion to the contact surface, and that the 20 stand-off cell in a simple manner can be removed from the needle.

It may be expedient as mentioned in claim 7 to make the slit in a needle-guide organ which is secured to 25 the stand-off cell so that it can be disconnected, as the scanner head 6 itself with the stand-off cell that can easily be removed from the needle and the needleguide organ.

- The invention will in the following be described more closely with a reference to the drawing, where
 - fig. 1 shows a scanner head with a stand-off cell according to the invention seen in section,



- fig. 2 shows a stand-off cell according to the invention with guide organs for the needle,
- fig, 3 shows a second embodiment for a stand-off cell according to the invention,
 - fig. 4 shows another embodiment for the invention,
- fig. 5 shows an embodiment for the invention, where the scanner head forms an angle of 45° with the contact surface,
- 15 fig. 6 shows another embodiment for the invention, and
 - fig. 7 shows a needle-guide organ seen in section along the line VII-VII on fig. 6.
- On fig. 1 an ordinary scanner head 1 is seen. To this there is attached a stand-off cell 2 according to the invention at the clutch facing 5. Between the stand-off cell 2 and the scanner head 1 a thin layer of a suitable paste has been put, which ensures a good acoustic clutching between the parts. The same paste can suitably be used between the stand-off cell 2 and the patient.
- The stand-off cell 2 is made of a plastics with an acoustic impedance, which essentially is the same as that of the patient's tissue. The plastics must furthermore have a poor damping of the ultrasonic waves. It has thus turned out that elastic materials



often have a too large damping of the ultrasonic waves wherefore the stand-off cell can be made of a possibly liquid-filled plastics. So one can obtain an efficient transmission of acoustic energy without inconvenient reflections at the transition between the surfaces.

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The biopsy needle 4 is lead through the slit 3 which is designed between the free side face 9 and the contact surface 7. As can be seen from fig. 1 the needle first enters the patient in the supervision area of the scanner head which is defined by the lines 8 and 8' on fig. 1. The slit 3 furthermore supports the needle 4 during its introduction into the patient. When the needle 4 is fully introduced one can without further measures remove the scanner head 1 and the stand-off cell 2 as the needle can be removed through the slit.

The shape of the stand-off cell can be very simple, which makes a very cheap production of it possible, e.g. by machining processes. Moreover, it will be simple to produce stand-off cells for any conceivable scanner head.

On fig. 2 it can be seen how a stand-off cell 2

according to the invention can be supplied with needle-guide organs 10. These can e.g. consist of a tube with a strap for supporting the needle. Hereby a very safe guiding of the biopsy needle is made possible. The guide organs 10 can be adjustable at various angles with the contact surface, and can of course be made in many other ways than the one shown here. If the needle-guide organs 10 are connected to the stand-off cell 2 in such a manner that they can be released, said stand-off cell will be capable of



1 being released for other use without removing the biopsy needle from the patient.

On fig. 3 a stand-off cell is seen, where the contact surface 7 and the clutch facing 5 stand at right angles to each other.

With different presentation of the slit 3 a large area of variation can be obtained for the angle of the needle by the patient. As the acoustic impedance in air is very different to the acoustic impedance in the stand-off cell, an area, which is turned horizontally against the clutch facing 5 will be deflected 90° of the reflection surface 11. The ultrasonic area will thus be directed vertically down into the patient and it becomes possible to lead the needle vertically down in the centre of the sound area. This gives a very precise and effecient control of the needle, and at the same time this embodiment is very material saving.

On fig. 4 and 5 stand-off cells 2 are seen where the sound area is reflected one or a number of times at the reflection surfaces 12, 13 and 14. It is simple to manufacture such reflection surfaces as they can consist of surfaces for air chambers, openings or metal surfaces. The difference of the acoustic impedance will so ensure total reflection. One can thus manufacture special stand-off cells for places that are difficult to reach or where accuracy is particularly important. It also becomes possible to give the area a favourable direction and to let the needle 4 follow this.



- 1 On fig. 6 and 7 it is seen how the needle can be lead in a needle-guide organ 15, which is secured to the stand-off cell 2 by means of pegs and which can be disconnected.
- 5 The stand-off cell according to the invention may possibly be made in innumerable ways according to the task the stand-off cell is to be used to perform. The stand-off cell can also easily be adjusted to any scanner head. Thus, it will be possible for a hospital ward to own a large number of scanner heads so that every biopsy can be done quickly and precisely and with a minimum of malaise and risk for the patient.
- of the fact that the ultrasonic waves at the transition between the stand-off cell and the patient will change course be refracted due to the difference in acoustic impedance between the stand-off cell and the tissue. This refraction can be used in such a way that the transducer itself can form an angle which is different from 90° with the patient's skin even if one wishes the ultrasonic waves to penetrate fairly perpendicular into the patient.
- Hereby, it becomes possible to lead a hypodermic needle into the patient precisely in the centre of the sound area without the needle having to pass through the transducer itself and thus disturb the picture.



9 CLAIMS

- 1 1. Stand-off cell (2) for an ultrasonic scanner head (1), which stand-off cell is mounted on the scanner head by a clutch facing (5) in such a manner that it can be disconnected, and is in contact with the patient through a contact surface (7), and which furthermore has a number of free surfaces, c h a r a c t erized in that the stand-off cell (2) is supplied with a slit (3) for engaging a needle (4) or a hypodermic needle and that the slit (3) extends between the part of the contact surface (7), which is placed in the supervision area of the scanner head (1), and one of its free surfaces (9).
- 2. Stand-off cell according to claims 1-2, c h a r15 a c t e r i z e d in that the stand-off cell (2) has
 at least one reflection surface (11, 12, 13, 14) for
 ultrasonic waves.
- 4. Stand-off cell according to claim 3, c h a r a c20 t e r i z e d in that the contact surface (7) stands
 at right angles to the clutch facing (5).
- 5. Stand-off cell according to claims 1-4, c h a r-a c t e r i z e d in that there at the slit (3) is
 25 mounted guide organs (10) for the needle (4).
- 6. Stand-off cell according to claim 5, c h a r a cterized in that the guide organs (10) are mounted in such a manner on the stand-off cell (2)
 30 that they can be disconnected and/or are adjustable.
 - 7. Stand-off cell according to claims 1-6, c h a rac t e r i z e d in that the slit (3) is placed in a needle-guide organ (15) mounted on the stand-off



1	cell	(2)	in	such	a	manner	that	it	can	Ъe	disconnected.
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8. Stand-off cell according to one or more of the above claims, c h a r a c t e r i z e d in that it is made so that the refraction at the surface between

5 the stand-off cell and the patient is used for controlled refraction of the ultrasonic waves.

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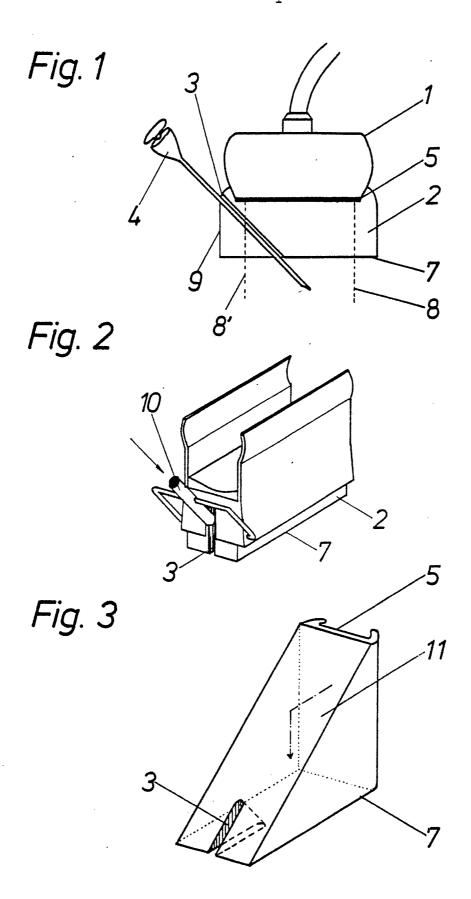
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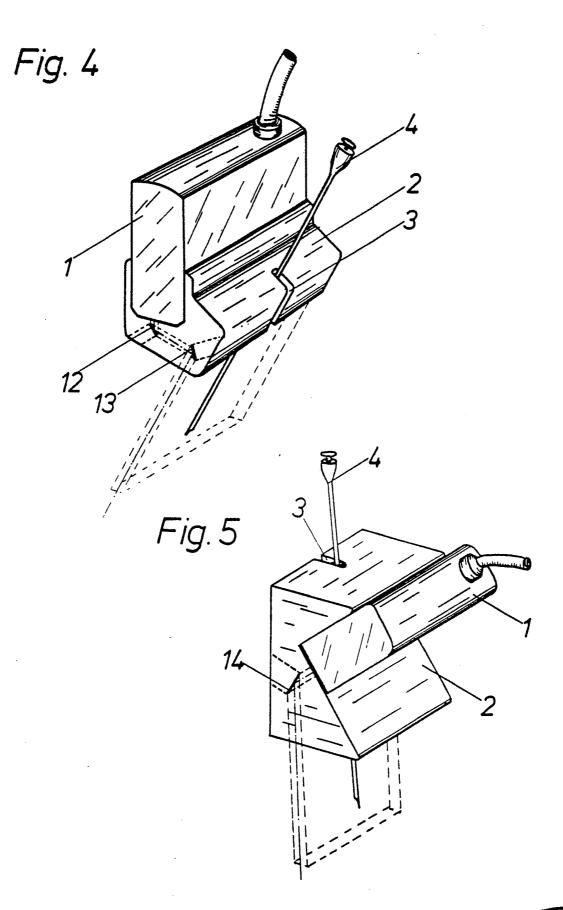




Fig. 6

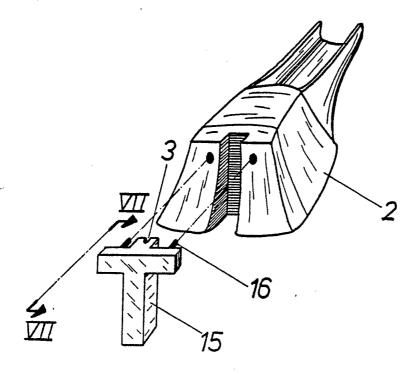
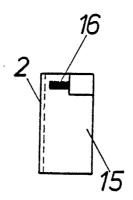


Fig. 7





INTERNATIONAL SEARCH REPORT

International Application No PCT/DK84/00011

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) 8 According to International Patent Classification (IPC) or to both National Classification and IPC 3 A 61 B 10/00 II. FIELDS SEARCHED Minimum Documentation Searched 4 Classification System Classification Symbols IPC 3 A 61 B 10/00 US CL 128:2R, 2B, 630, 653, 660 Documentation Searched other than Minimum Documentation to the Extent that such Documents are included in the Fields Searched 6 SE, NO, DK, FI classes as above III. DOCUMENTS CONSIDERED TO BE RELEVANT 14 Relevant to Claim No. 18 Citation of Document, 16 with indication, where appropriate, of the relevant passages 17 Category * Α DE, B2, 2 906 474 (TOKYO SHIBAURA DENKI K.K.) 27 November 1980 USA, A, 4 346 717 (HAERTEN) 31 August 1982 5,6 Α 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 * Special categories of cited documents: 15 document defining the general state of the art which is not considered to be of particular relevance invention earlier document but published on or after the international filing date "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step "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) 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 "O" document referring to an oral disclosure, use, exhibition or document published prior to the international filing date but later than the priority date claimed "&" document member of the same patent family IV. CERTIFICATION Date of the Actual Completion of the International Search # Date of Mailing of this international Search Report * 1984 -04- 1 8 1984-04-04 International Searching Authority 1 Signature of Authorized Office umas tilder Gunnar Swedish Patent Office

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