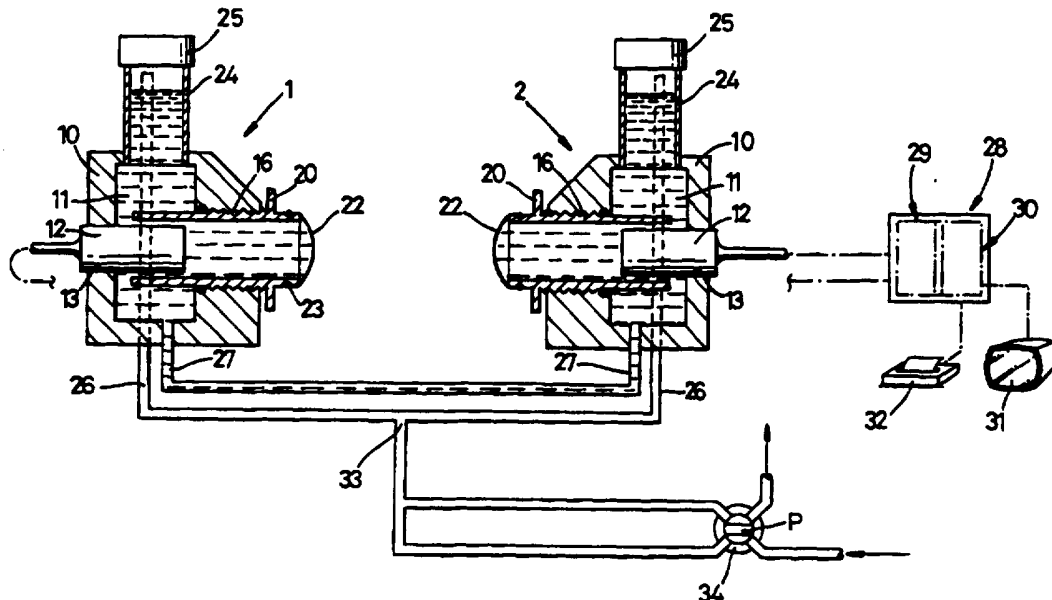


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(54) Title: OSTEOPOROSIS APPARATUS



(57) Abstract

Osteoporosis apparatus for measuring ultrasonic characteristic(s) of a patient's bone comprises: two ultrasonic transducers (12) spacedly arranged in respective head (1, 2) in the apparatus for ultrasonic transmission from one to the other; circuitry (29, 30, 31) for controlling transmission from the one transducer, measuring the reception at the other and providing an output indicative of the ultrasonic characteristic(s); the apparatus including: a fluid system having two diaphragms (22) arranged in the respective heads so that there is a fluid path from each transducer to its diaphragm and a gap between the diaphragms which is occupied in use by a patient's bone.

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OSTEOPOROSIS APPARATUSThe Field of the Invention

The present invention relates to apparatus for the
5 detection and measurement of osteoporosis.

Background of the Invention

It is known that detection of the attenuation and
transmissibility of ultrasound through bone is a useful
10 measure of osteoporosis. Conveniently the measurement is
made on the heel bone, as a large bone surrounded by little
flesh.

Two main types of apparatus are used. In one, a foot
15 bath is used. It has a pair of transducers fixedly arranged
in opposite sidewalls of the bath. One transducer is for
transmission and the other is a receiver. The bath is
filled with water. This apparatus produces repeatable
results, but suffers from poor portability and a relatively
20 long time - of the order of 20 minutes - to stabilise before
use, whilst the water is de-gassed and heated to blood
temperature.

In the second type of apparatus, the transducers are
25 movable towards and away from each other, by means of a
mechanism able to relay their separation to detection
circuitry. The transducers directly abut the patient's skin
at the heel. This apparatus is more readily portable, but
has less good reproduceability.

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The Invention

The object of the present invention is to provide
apparatus having the repeatability of the water bath
apparatus and the portability of the dry apparatus.

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According to the invention there is provided osteoporosis apparatus for measuring ultrasonic characteristic(s) of a patient's bone, the apparatus comprising:

5 two ultrasonic transducers spacedly arranged in respective heads in the apparatus for ultrasonic transmission from one to the other;

10 circuitry for controlling transmission from the one transducer, measuring the reception at the other and providing an output indicative of the ultrasonic characteristic(s); the apparatus including:

15 a fluid system having two diaphragms arranged in the respective heads so that there is a fluid path from each transducer to its diaphragm and a gap between the diaphragms which is occupied in use by a patient's bone.

It is envisageable that the spacing of the transducers in the apparatus is adjustable to provide a standard length of fluid path. However, in the preferred embodiment, the 20 spacing of the transducers in the apparatus is fixed and the diaphragms are adjustable to accommodate differing thicknesses of patients' bones, since the transmission of ultrasound through water occurs with little attenuation and a predictable velocity which can be allowed for.

25 Preferably the fluid system is adapted to be pressurised for adjustment of the diaphragms by inflation against the patient. The diaphragms can be mounted on annular supports, with outer annular sleeves provided around 30 the supports for limiting radial inflation of the diaphragms. Conveniently, the diaphragms are carried on respective tubes - including the annular supports - the tubes being able to be advanced for adjustment of the apparatus to suit patients having differing bone 35 thicknesses.

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In one alternative, the tubes are threaded and adapted for diaphragm advance by screw action. Alternatively, the tubes are resilient for extension under fluid pressure for diaphragm advance. In this case, the tubes can have concertina formations for their resilient extension.

It is envisaged that the fluid system may be divided into separate portions, one for each transducer. However, the fluid system preferably includes a fluid interconnection between the fluid paths to each transducer for diaphragm pressure equalisation, with the interconnection being arranged to avoid ultrasound transmission along it.

The fluid system may be open, with diaphragms' flexibility under the system's own hydraulic head biasing them into contact with the patient. However, again it is preferred that it is closed or closable and provided with means for pressurisation, whereby the diaphragms can be urged into contact with the patient. The arrangement provides that there is little in the ultrasound path between the transducers other than water and the patient's heel bone, with the diaphragms being in good air excluding contact with the patient's skin. Conveniently, the pressurisation means is an air pump arranged to pump air into a region of the fluid system higher than the transducers and the diaphragms.

Preferably, the apparatus includes a sensor for sensing the temperature of the fluid and the circuitry is adapted to compensate the measurements for the temperature.

Conveniently the fluid used in the system is water, but of a quantity able to reach operating conditions in a short period of the order of one minute. Alternatively other

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liquids such as a castor oil may be used.

Whilst two transducers are preferred, it is conceivable that an array of more than two may be used.

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The Drawings

To help understanding of the invention, a specific embodiment thereof will now be described by way of example and with reference to the accompanying drawings, in which:

10 Figure 1 is a diagrammatic view of osteoporosis apparatus of the invention,

Figure 2 is a similar view of measurement heads of the apparatus of Figure 1 in fully retracted and fully extended positions,

15 Figure 3 is view on a large scale of one measurement head,

Figure 4 is a diagrammatic perspective view of a second osteoporosis apparatus according to the invention and

20 Figure 5 is a cross-sectional side view of one of the heads of the second apparatus.

Preferred Embodiment

The apparatus shown in the drawings has two essentially identical heads 1,2, one only of which will first be
25 described in detail with particular reference to Figure 1. Each head has a body 10 defining a central reservoir 11. To one side of the reservoir, an ultrasonic transducer 12 is fluid tightly fixed in a bore 13 in the body. Opposite the transducer, the body has a threaded bore 14 with an O-ring
30 groove 15 adjacent the reservoir. A tubular member 16 is threaded in the bore 14. It has a plain inner section 17 on which an O-ring 18 in the groove 15 acts to prevent escape of fluid along the bore 14. The outer end 19 of the tube has a knurled adjusting wheel 20 and an external groove 21
35 at the terminal end of the tube. An elastomeric material

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diaphragm 22 with a bead 23 is fluid tightly stretched across the mouth of the tube with its bead engaged in the groove 21.

5 An upper extension 24 of the body forms an upper reservoir and is sealed by a cap 25. A pressurisation tube 26 extends from the top of the extension. Also an interconnection tube 27 extends from the bottom of the reservoir.

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Referring now to Figure 1, the pressurisation tubes 26 of the two heads 1,2 are connected together as are the interconnection tubes. The two transducers are connected to a control unit 28. The unit includes circuitry 29 for
15 controlling transmission from the one transducer, further circuitry 30 for measuring the reception at the other transducer. A display 31 and a printer 32 are provided for showing an output indicative of the ultrasonic characteristic(s). The pressurisation tubes are connected
20 via a Tee piece 33 to a three position valve 34. In one position P, that shown in Figure 1, the tubes 26 are isolated from the ambient for transport of the apparatus. In a second position, for set up, the tubes are connected to the ambient atmosphere. In the third position, the tubes
25 are connected to low pressure gas, typically nitrogen at 0.06bar (1psig), for use of the apparatus to make a measurement. At all times the reservoirs are connected by the interconnection tubes 27. The heads are held at a fixed distance apart by a frame 35, shown diagrammatically as a
30 heel support.

In use, the reservoirs are filled with water or other fluid having a high transmissibility to ultrasound. The fluid finds its own level via the interconnection tube so
35 that the levels in the two reservoirs are the same. It

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should be noted that since the interconnection tubes extend from the reservoirs remote from the active front faces of the transducers, they do not provide a ready path for ultrasound between the heads. Referring to Figure 2, the diaphragm tubes 16 are screwed in or out to bring the diaphragms 22 into contact with the heel H of a patient supported on the frame 35, the upper position in Figure 3 being for a thick heel and the lower for a thin heel. To ensure good ultrasound transmission, an acoustic gel is applied between the diaphragms and the heel. With the diaphragms in contact with the heel via the gel, the valve 34 is turned to its third - pressure - position. The applied pressure stretches the diaphragms 22 into firm contact with the heel excluding air from between them the patients skin. The control unit then operates the transducers as transmitter and receiver to measure the transmissibility and attenuation property to ultrasound of the heel, that is to say of its bone, which occupies the majority of the space between the diaphragms.

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After measurement, the valve 34 is adjusted to correct the tubes 26 to ambient, removing pressure from the diaphragms 22. The knurled wheels 20 may be used to withdraw the tubes 16 from the heel, allowing the patient's foot to be withdrawn.

Second Embodiment

Referring now to Figures 4 and 5, the apparatus there-shown has heads 101,102, which are similar to the heads 1,2 with transducers 112, except that their tubes 116 are of flexible material, with a concertina circumferential ridges 140. These allow the tubes to extend under applied pressure. The ends of the tubes carry diaphragms 122 with beads 123 engaged in grooves 121. Surrounding the latter are short sleeves 141, which each extend a short distance

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beyond the free surface of its diaphragm when un-pressurised. The heads are interconnected by a reservoir tube 142 above and connected to them by branches 143 that extend down from the reservoir 142. This arrangement
5 provides that any air in the heads rises into the reservoir, which as a filler cap 144 and a connection 145 for a flexible tube 146 leading to a bulb-type, manual inflator 147.

10 In use, the patient's heel is positioned between the heads 101,102 and the reservoir is pressurised. The diaphragms are extended towards the heel, both by their own stretching and concertina extension of the tubes 116. Radial stretching of the diaphragms is inhibited by the
15 sleeves 141. The bulb is pumped until the diaphragms are in firm contact with the heel. Then measurements are taken. The air pumped in is allowed to escape at the bulb for release of the heel, the connection 145 being at a high point on the reservoir. Thus the air in it collects at the
20 connector 145.

A temperature sensor 148, typically a thermistor, is provided for measuring the temperature of the water. This allows an adjustment for temperature dependent speed of
25 sound in the water to be made to the measurements of ultrasonic characteristics of the heel. For this adjustment, the length of the water path between the transducers, of the order of 75mm, can be assumed to be constant. The heel is assumed to have a nominal thickness
30 of 40mm. Alternatively its thickness can be measured and the ultrasonic measurements interpreted accordingly.

Variant of the Second Embodiment

In a non-illustrated variant, the reservoir tube is
35 divided in two, with the two parts being mounted for

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movement towards each other. With this arrangement, the two diaphragms can be advanced close to the heel before pressurisation; and then pressurised for contact with the heel. Since the two heads are hydraulically separate, each diaphragm must be separately pressurised. This can be effected by connection to individual manometer tubes, to which water is added to provide a determined head for each diaphragm.

10 Further it is envisaged that each diaphragm and concertina bellows may be a single moulding of resilient plastics material. It can be connected to its head by a peripheral bead engaging in a circumferential groove in the head in the manner of the diaphragms 22,122.

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CLAIMS:

1. Osteoporosis apparatus for measuring ultrasonic characteristic(s) of a patient's bone, the apparatus comprising:
 - 5 two ultrasonic transducers spacedly arranged in respective heads in the apparatus for ultrasonic transmission from one to the other;
circuitry for controlling transmission from the one transducer, measuring the reception at the other and
10 providing an output indicative of the ultrasonic characteristic(s); the apparatus including:
a fluid system having two diaphragms arranged in the respective heads so that there is a fluid path from each transducer to its diaphragm and a gap between the diaphragms
15 which is occupied in use by a patient's bone.
 2. Osteoporosis apparatus as claimed in claim 1, wherein the spacing of the transducers in the apparatus is adjustable to provide a standard length of fluid path.
 3. Osteoporosis apparatus as claimed in claim 1, wherein
20 the spacing of the transducers in the apparatus is fixed and the diaphragms are adjustable to accommodate differing thicknesses of patients' bones.
 4. Osteoporosis apparatus as claimed in claim 3, wherein the fluid system is adapted to be pressurised for adjustment
25 of the diaphragms by inflation against the patient.
 5. Osteoporosis apparatus as claimed in claim 4, wherein the diaphragms are mounted on annular supports and outer annular sleeves are provided around the supports for limiting radial inflation of the diaphragms.
 - 30 6. Osteoporosis apparatus as claimed in claim 3, claim 4 or claim 5, wherein the diaphragms are carried on respective tubes - including the annular supports where provided - the tubes being able to be advanced for adjustment of the apparatus to suit patients having differing bone
35 thicknesses.

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7. Osteoporosis apparatus as claimed in claim 6, wherein the tubes are threaded and adapted for diaphragm advance by screw action.
8. Osteoporosis apparatus as claimed in claim 6, wherein
5 the tubes are resilient for extension under fluid pressure for diaphragm advance.
9. Osteoporosis apparatus as claimed in claim 8, wherein the tubes have concertina formations for their resilient extension.
- 10 10. Osteoporosis apparatus as claimed in claim 9, wherein each diaphragm and respective concertina formations is formed as a single moulding of resilient plastics material and includes a peripheral bead engaging in a circumferential groove in the respective head for securing of the diaphragm
15 to the head.
11. Osteoporosis apparatus as claimed in any preceding claim, wherein the fluid system is divided into separate portions, one for each transducer.
12. Osteoporosis apparatus as claimed in any one of claims
20 1 to 10, wherein the fluid system includes a fluid interconnection between the fluid paths to each transducer for diaphragm pressure equalisation, with the interconnection being arranged to avoid ultrasound transmission along it.
- 25 13. Osteoporosis apparatus as claimed in any preceding claim, wherein the fluid system is open, with diaphragms' flexibility under the system's own hydraulic head biasing them into contact with the patient.
14. Osteoporosis apparatus as claimed in any one of claims
30 1 to 12, wherein the fluid system is closed or closable and provided with means for pressurisation, whereby the diaphragms can be urged into contact with the patient.
15. Osteoporosis apparatus as claimed in claim 14, wherein the pressurisation means is an air pump arranged to pump air
35 into a region of the fluid system higher than the

transducers and the diaphragms.

16. Osteoporosis apparatus as claimed in any preceding claim, including a sensor for sensing the temperature of the fluid and the circuitry is adapted to compensate the
5 measurements for the temperature.

17. Osteoporosis apparatus as claimed in any preceding claim, wherein the fluid is water.

18. Osteoporosis apparatus as claimed in claim 17, wherein the volume of the fluid system is such that the quantity of
10 water contained in it is able to reach temperature in a short period of time of the order of magnitude of one minute.

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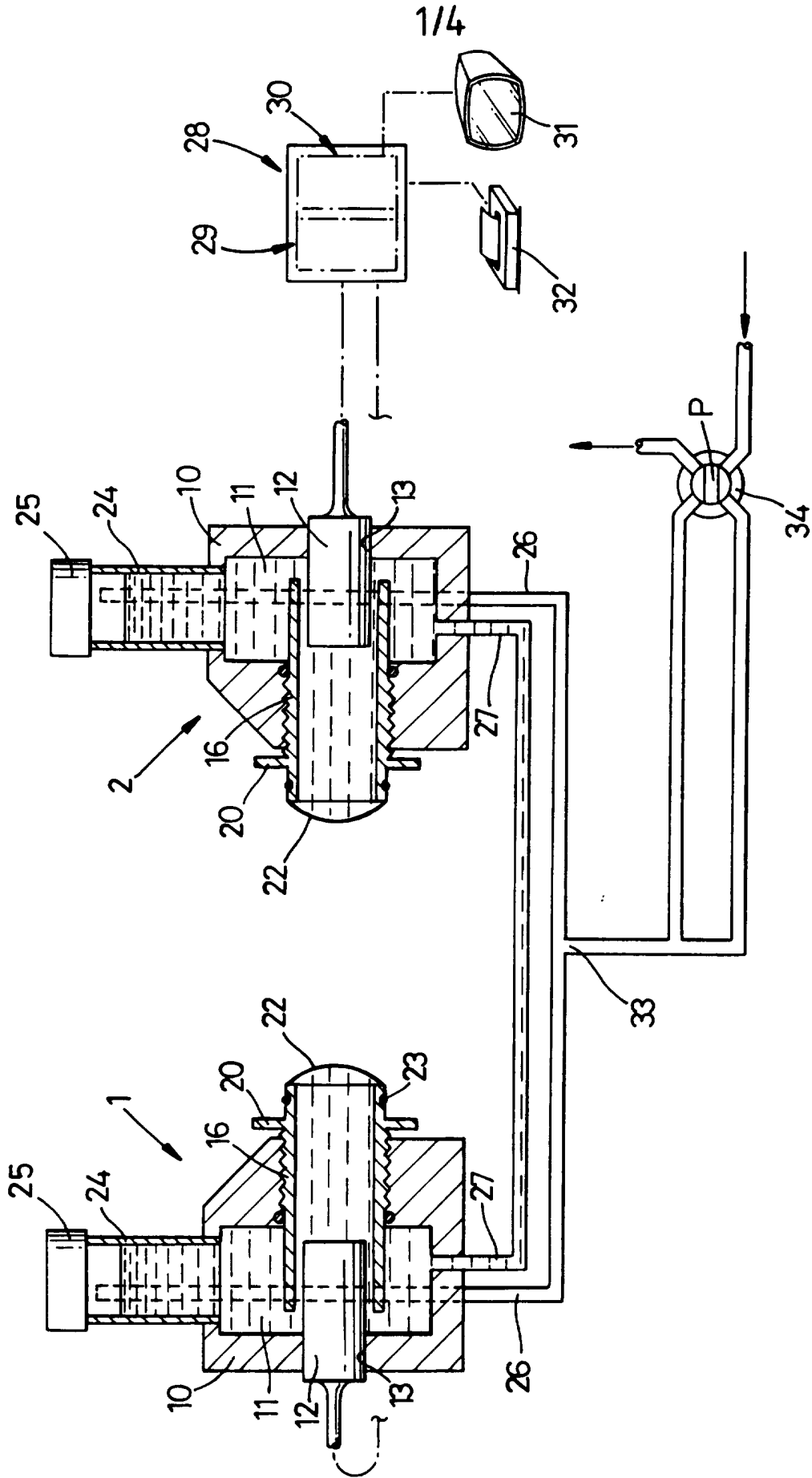


Fig.1

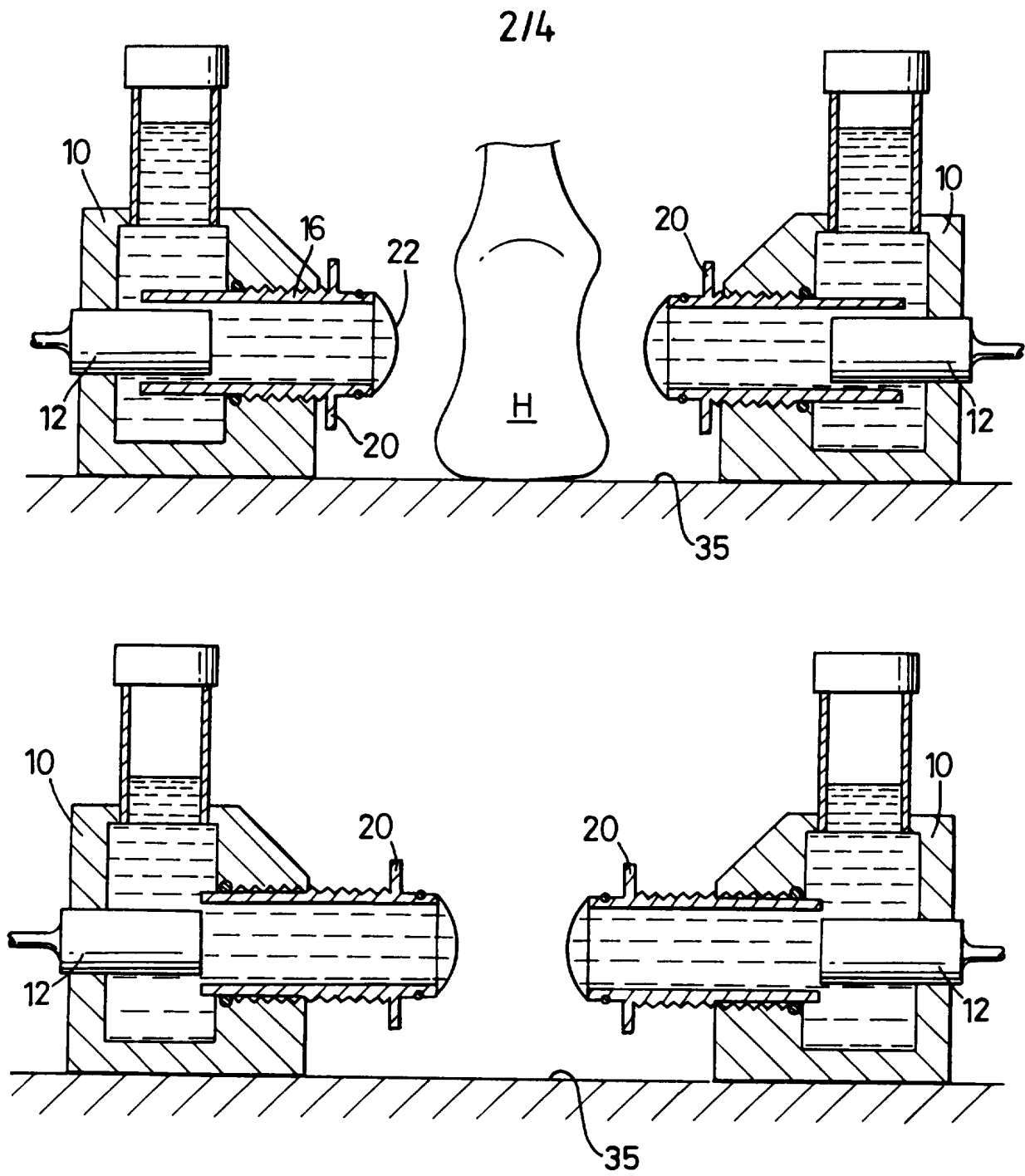


Fig. 2

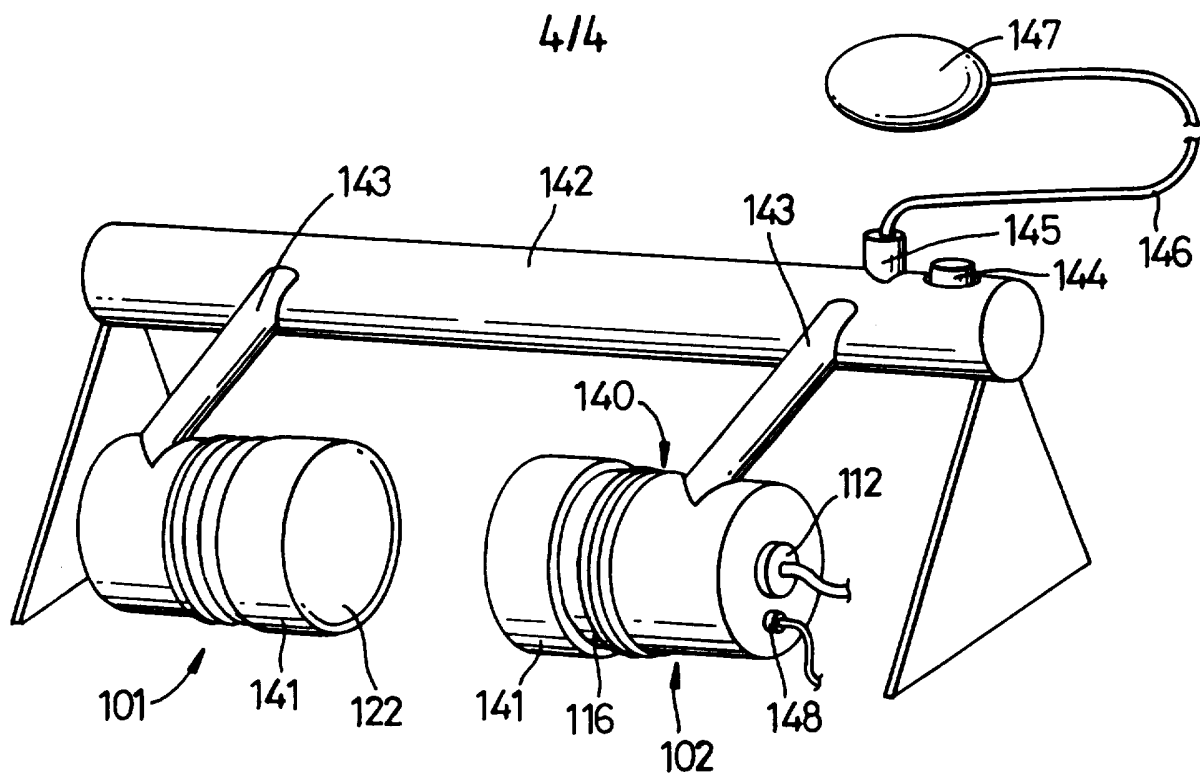


Fig. 4

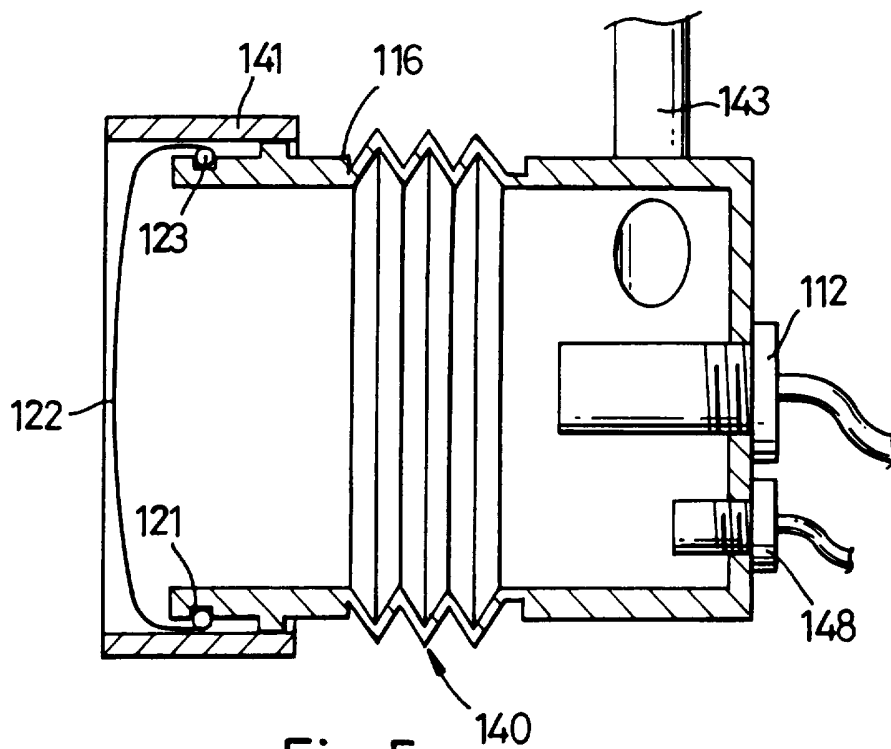


Fig. 5

INTERNATIONAL SEARCH REPORT

International Application No.
PCT/GB 95/01747

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B8/08 A61B8/00

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)
IPC 6 A61B G10K G01N

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 practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US,A,5 134 999 (OSIPOV) 4 August 1992 see column 2, line 20 - column 3, line 7 see figures 1,2	1
A	---	2,4-6, 11,14,17
A	EP,A,0 585 492 (MEDICANO SYSTEMS LTD.) 9 March 1994 see abstract see page 15, line 29 - line 48 see figures 18A,B	1,16
A	EP,A,0 045 265 (DORY) 3 February 1982 see page 13, line 18 - page 15, line 2 see figure 8	4,5,7
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Date of the actual completion of the international search

26 October 1995

Date of mailing of the international search report

17. 11. 95

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INTERNATIONAL SEARCH REPORT

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP,A,0 480 554 (LUNAR CORPORATION) 15 April 1992 see column 4, line 47 - column 5, line 26 see column 7, line 18 - column 8, line 12 see column 17, line 17 - column 19, line 54 see figures 1,10 see figure 1 ---	1-3,16, 17
A	EP,A,0 404 121 (KABUSHIKI KAISHA TOSHIBA) 27 December 1990 see column 5, line 6 - column 8, line 45 see figures 2-8C -----	8,9,16, 17

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No PCT/GB 95/01747
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A-5134999	04-08-92	EP-A- 0516353 JP-A- 5237101	02-12-92 17-09-93

EP-A-585492	09-03-94	CA-A- 2076137	14-02-94

EP-A-45265	03-02-82	FR-A- 2487664 FR-A- 2487665 JP-C- 1488037 JP-A- 57057541 JP-B- 63036255 US-A- 4418698	05-02-82 05-02-82 23-03-89 06-04-82 19-07-88 06-12-83

EP-A-480554	15-04-92	US-A- 5042489	27-08-91

EP-A-404121	27-12-90	JP-A- 3023854 DE-D- 69017765 US-A- 5095907	31-01-91 20-04-95 17-03-92
