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#### (54) Title: APPARATUS FOR COLLECTING A SAMPLE

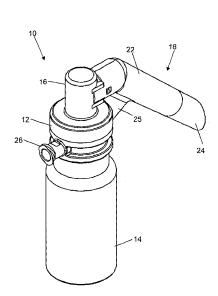


Figure 1

(57) Abstract: Apparatus (10) for collecting a sample, the apparatus (10) comprising: a body (12) having attachment means for releasably attaching the body (12) to a sample collection vessel (14); a spout (18) having at one end a sample inlet (24) and at the other end a sample outlet, the sample outlet being arranged to deposit a sample received at the sample inlet (24) into the sample collection vessel (14); and a suction inlet (26) for connecting a suction source to the apparatus (10), the suction inlet (26) being in fluid communication with the sample outlet of the spout (18) such that when suction is applied at the suction inlet (26) negative pressure is created in the spout (18) to draw the sample into the sample inlet (24).



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— with international search report (Art. 21(3))

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# APPARATUS FOR COLLECTING A SAMPLE

## Technical Field

The present invention relates to apparatus for collecting a sample such as a biological sample.

# Background to the Invention

In many clinical processes for diagnosing infection and disease it is necessary to collect a sample of a bodily fluid for analysis. The equipment used for collecting the required sample typically varies depending on the sample to be collected. For example, where a sample of stool is to be collected a spoon, spatula or the like is often used to scoop a sample of the stool into a collection vial, whilst collection of pus or sputum typically involves using a sponge or gauze to absorb a sample.

It is acknowledged that existing sample collection techniques are unsatisfactory for a number of reasons. For example, collection of stool samples using a spoon, spatula or the like risks contamination of both the sample and the individual collecting the sample. Contamination of the sample increases the risk of inaccurate analysis results leading to misdiagnosis, whilst contamination of the individual collecting the sample increases the risk of infection of that individual and of the wider public.

Similarly, existing methods of collecting samples of pus or sputum can lead to contamination of the sample, which can lead to problems of inaccurate analysis and misdiagnosis, and contamination of the individual collecting the sample, increasing the risk of infection of the individual and of the wider public.

Accordingly there is a need for an improved apparatus for collecting a sample which reduces the risk of contamination of the sample and of a user of the apparatus.

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#### Summary of Invention

According to a first aspect of the present invention there is provided apparatus for collecting a sample, the apparatus comprising: a body having attachment means for releasably attaching the body to a sample collection vessel; a spout having at one end a sample inlet and at the other end a sample outlet, the sample outlet being arranged to deposit a sample received at the sample inlet into the sample collection vessel; and a suction inlet for connecting a suction source to the apparatus, the suction inlet being in fluid communication with the sample outlet of the spout such that when suction is applied at the suction inlet negative pressure is created in the spout to draw the sample into the sample inlet.

The apparatus of the present invention enables samples to be collected more safely and hygienically than has hitherto been possible. Using the apparatus of the present invention reduces the risk of contamination to the sample and to the user compared to known sample collection techniques, and therefore the risk of incorrect analysis and misdiagnosis is reduced, as is the risk of infection to the user of the apparatus and to the wider public. Additionally, the apparatus can be used to collect a specific volume of a sample, which is useful, for example, when a defined volume of sample is required for a subsequent testing or diagnosis procedure, or when more than one testing diagnostic procedure is to be undertaken using the sample.

The spout may be angled downwardly with respect to a lateral axis of the body when the apparatus is in an upright orientation.

The sample inlet may be angled with respect to a longitudinal axis of the spout. This permits the sample inlet to be positioned directly above the substance to be sampled,

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thereby maximising the area of the inlet that is exposed to the substance and improving the efficiency of sample collection.

The spout may be substantially inflexible.

The suction inlet may be positioned below the level of the spout, when the apparatus is in an upright orientation.

The apparatus may further comprise a conduit which communicates with the spout, the conduit having an open end which is arranged to be received in the sample collection vessel.

The body may be provided with means defining a channel which communicates with the suction inlet and with the open end of the conduit.

The means defining the channel may comprise a tube which depends from the body and is co-axial with the conduit, such that the channel is formed between an inner wall of the tube and an outer wall of the conduit.

The tube may extend beyond a distal end of the conduit.

The body may be generally cylindrical. This enables the body to be compatible with standard sample collection vials.

According to a second aspect of the present invention there is provided a kit comprising apparatus according to the first aspect of the invention, a sample collection vessel and a suction source.

The suction source may comprise a syringe.

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The kit may further comprise a lid for the sample collection vessel.

The kit may further comprise a case for receiving the apparatus, vessel, suction source and lid.

The case may be provided with receiving means for receiving the apparatus, vessel, suction source and lid.

The receiving means may comprise pre-formed indentations in the case.

## Brief Description of the Drawings

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

Figure 1 is a schematic perspective representation of a sample collection device incorporating apparatus according to an embodiment of the present invention;

Figure 2 is a side view of the device illustrated in Figure 1;

Figure 3 is a cross-sectional representation of the device illustrated in Figures 1 and 2;

Figure 4 is a detailed view of a section of the device illustrated in Figure 3;

Figure 5 is a schematic perspective representation of a sample collection kit including the sample collection device illustrated in Figures 1 to 3; and

Figure 6 illustrates a method for using a sample collection kit including the sample collection device illustrated in Figures 1 to 3.

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### Description of the Embodiments

Referring to Figures 1 and 2, a sample collection device is shown generally at 10. The sample collection device in this example has a generally cylindrical body 12 which is releasably attachable to a sample collection vessel, which in this example is a vial 14, for example by means of a snap-fit connection or co-operating internal and external screw threads on the body 12 and on a rim of the sample collection vial 14 respectively.

A generally hollow enclosed head portion 16 projects from an upper part of the body 12, and a generally hollow spout 18 extends outwardly of the head portion 16. As can be seen from Figures 1 and 2, the spout 18 has first generally cylindrical portion 20 which projects radially outwardly of the head portion 16 of the body 12 and a second generally cylindrical portion 22 which in this example is angled downwardly with respect to a lateral axis of the body 12, (and with respect to a longitudinal axis of the first portion 20) when the sample collection vial 14 is in an upright orientation.

The outwardly projecting first portion 20 of the spout 18 ensures that the angled second portion 22 does not foul the body 12 or the sample collection vial 14. The first and second portions 20, 22 of the spout 18 are both hollow and open-ended, to permit fluid to flow through them into the hollow head portion 16, as is described in detail below.

The second generally cylindrical portion 22 of the spout 18 is truncated, that is to say its open end is angled with respect to a longitudinal axis of the second portion, to form an inlet 24 of the spout 18. The angled inlet 24, in conjunction with the angled second portion 22 of the spout 18, increases the efficiency of the device 10, as is described in detail below.

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In the embodiment illustrated in Figures 1 to 3, the spout 18 is supported by a buttress formation 25 which extends between an underside of the spout 18 and an edge of the body 12. The buttress formation 25 adds stability to the device 10 and prevents the spout 18 from snapping if a downwardly directed force is applied to the spout 18. However, it will be appreciated that the buttress formation 25 is not essential and can be omitted if desired.

From the foregoing description and drawings it will be appreciated that in one embodiment the spout 18 is substantially inflexible, such that in use of the device 10 the spout 18 will not bend.

The body 12 is provided with an inlet port 26, which is positioned in this example on an opposite side of the body 12 to the spout 18. In this example, the inlet port 26 is positioned below the level of the spout 18 (when the sample collection vial 14 is in the upright position shown in Figures 1 and 2), and has means such as an internal screw thread or snap fitting for securely receiving an outlet of a source of suction such as a syringe, suction pump or the like. It will be appreciated, however, that the inlet port could equally be positioned above the level of the spout 18, or at the same level as the spout 18.

The internal structure and operation of the device 10 will now be described with reference to the cross-sectional view of Figure 3.

As can be seen in Figure 3, the hollow first portion 20 of the spout 18 communicates with a hollow, generally cylindrical internal conduit 28 which extends downwardly from an interior of the head portion 16 such that when the body 12 is attached to the sample collection vial 14 an open distal end of the conduit 28 is located in an interior of the sample collection vial 14. Thus the second and first portions 22, 20 of the spout 18 and

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the conduit 28 constitute a fluid flow path from the inlet 24 to the interior of the sample collection vial 14.

The body 12 is provided with a downwardly extending hollow generally cylindrical tube 30. The tube 30 is coaxial with the internal conduit 28 and is disposed outside of the conduit 28 such that a channel 32 is formed between an outer wall of the conduit and an inner wall of the tube 30. The tube 30 extends beyond the open distal end of the conduit 28 and terminates in an open end 34, such that when the body 12 is attached to the sample collection vial 14 the open end 34 of the tube 30 is located in the interior of the vial 14, at a level below that of the open distal end of the conduit 28. This arrangement of the open end of the tube 28 being positioned at a level below the open distal end of the conduit 30 ensures that a sample drops out of the inner conduit 30 without fouling the outer tube 28, leaving the outer tube 28 clean so that when the head portion 16 of the device 10 is removed from the collection vial 14 the risk of contamination if the user touches the outer tube 28 is reduced.

The channel 32 formed between the inner wall of the tube 30 and the outer wall of the conduit 28 communicates with the inlet port 26 such that when a source of suction such as a syringe, suction pump or the like is connected to the inlet port 26, and activated, negative pressure develops in the region near the open distal end of the conduit 28, which has the effect of creating negative pressure in the spout 18 to draw a sample to be collected through the spout 18 to be deposited in the sample collection vial 14.

The angled inlet 24 and the angled second portion of the spout 18 improve the efficiency of the device 10, as the they enable the inlet 24 of the spout 18 to be positioned directly over a substance from which a sample is to be taken without having to hold the device 10 at an angle which is too large with respect to the upright position illustrated in Figures 1 to 3. Thus, when a source of suction such as a syringe or suction pump is applied to the

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inlet port 26 suction is not lost due to the angle at which the device 10 must be held in use.

It will be appreciated that alternative configurations of the spout 18 and the inlet 24 could achieve the same result. For example, the spout 18 could project radially outwardly of the head portion 16, with the inlet 24 being angled downwardly with respect to the radially outwardly projecting spout 18, such that when the device 10 is rotated such that the spout 18 slopes upwardly the inlet 24 can be positioned directly above a substance from which a sample is to be collected.

In some embodiments, the spout 18 may be provided with a one-way valve, to prevent any residue of the sample from dribbling out of the spout. The one way valve may take the form of a flap which is hingedly attached to an inner surface of the spout 18, such that when suction is applied the flap opens, and when the suction ceases the flap returns to its closed position (in which it may abut against a stop) under the action of gravity.

Referring now to the detailed view of Figure 4, it can be seen that to ensure that the device 10 is fluid-tight, a first O-ring 36 of a material such as rubber is received between an outer upper side of the tube 30 and an inner surface of the body 12, to seal the interface between the body 12 and the tube 30 to prevent leakage of air or other fluid through gaps that may exist between the body 12 and the tube 30. Second and third O-rings 38, 40 are provided at positions where the spout 18 interfaces with the body 12, again to help to prevent leakage of air or fluid through gaps that may exist between the body 12 and the spout 18.

Referring next to Figure 5, a kit for collecting samples for use in hospitals, surgeries and other medical facilities is shown generally at 50. The kit 50 includes many of the elements described above in relation to Figures 1 to 3, so the same reference numerals

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will be used for elements that are common to the kit 50 of Figure 5 and the sample collection device 10 of Figures 1 to 3.

The kit 50 comprises a case or tray 52 having pre-formed indentations or other receiving formations for receiving the various elements of the kit 50. The kit 50 is provided with the sample collection device 10 illustrated in Figures 1 to 3, including the sample collection vial 14 and the body 12. Additionally, the kit 50 is provided with a lid 54 for sealing the sample collection vial 14 after a sample has been collected, and with a syringe 56 which acts as the source of suction for the sample collection device 10. Thus, the kit 10 includes all of the equipment required to collect and store a sample.

A method of using the sample collection device 10 and the kit 50 is illustrated in Figure 6. In a first step 60, the sample collection vial 14 and the body 12 are removed from their respective indentations in the tray 52, and the body 12 is secured to the sample collection vial 14 by means of complementary screw threads on the body and the sample collection vial, or by a snap fit engagement between the body 12 and the sample collection vial 14, for example.

In a second step 62, the syringe 56 is removed from its indentation in the tray 52 and is securely attached to the inlet port 16, for example by interengaging complementary screw threads of an outlet of the syringe 56 and the inlet port 16, or by a snap fit engagement between the outlet of the syringe 56 and the inlet port 16.

In the next step 64 the device 10 is positioned over the substance from which a sample is to be collected. As can be seen from Figure 5, the truncated spout 18 of the device 10 enables the device 10 to be positioned over the substance to be sampled without coming into contact with the substance to be sampled, which reduces the risk of contamination of the sample, and of contamination of the user of the device 10. Additionally, the angle of

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the inlet 24 of the of the spout 18 allows the inlet 24 to be positioned directly over the substance to be sampled, thereby exposing the whole of the area of the inlet 24 to the substance to be sampled to improve the efficiency with which a sample can be collected.

With the inlet 24 of the spout 18 of the device 10 in position the plunger of the syringe 56 is withdrawn. This creates suction, generating negative pressure in the spout and causing a sample of the substance to be drawn through the inlet 24, the spout 18, and the conduit 28 to be deposited in the sample collection vial 14.

The device 10 can be used to collect a specific volume of a sample by withdrawing the plunger of the syringe by a specific distance which causes the specific amount of the sample to be collected in the sample collection vial 14. This is useful, for example, when a defined volume of sample is required for a subsequent testing or diagnosis procedure, or when more than one testing diagnostic procedure is to be undertaken using the sample.

The syringe may be marked with markings indicating the positions to which the plunger must be withdrawn to collect particular volumes of a sample. For example, the syringe may be marked with markings such as 5ml, 10ml, 15ml to indicate the positions to which the plunger must be withdrawn to collect those volumes of the sample. It is to be noted, however, that the markings on the syringe may not correspond to the volume of the syringe with the plunger at the marked positions, i.e. there may not be a one to one mapping between the volume displaced by the plunger of the syringe and the volume of sample collected.

In step 4, shown at 66, the device 10 is moved to a position in which the sample collection vial 14 is generally upright, and the quantity of the collected sample is checked. If the quantity of sample collected is within acceptable lower and upper limits, as shown at 68 in Figure 5, the sample collection vial 14 is detached from the body 12

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and the lid 54 is securely attached to the sample collection vial 14, as is shown at 70 and 72 in Figure 5. To reduce the risk of spilling the sample the sample collection vial 14 may be received in the indentation for the lid 54 in the tray 52 (or another indentation), as shown at 72 in Figure 5, whilst the body 12 and syringe 56 are hygienically disposed of, as shown at 74 in Figure 5.

The design of the device 10 is such that it is not possible to overfill the sample collection vial 14, which helps to reduce the risk of spillage when the sample collection vial 14 is disengaged from the body 12 and subsequently handled.

It will be appreciated that the device 10 and kit 50 described above and illustrated in Figures 1 to 5 enable samples to be collected more safely and hygienically than has hitherto been possible. Using the device 10 reduces the risk of contamination to the sample and to the user compared to known sample collection techniques, and therefore the risk of incorrect analysis and misdiagnosis is reduced, as is the risk of infection to the user of the device 10 and to the wider public.

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#### **CLAIMS**

1. Apparatus for collecting a sample, the apparatus comprising:

a body having attachment means for releasably attaching the body to a sample collection vessel;

a spout having at one end a sample inlet and at the other end a sample outlet, the sample outlet being arranged to deposit a sample received at the sample inlet into the sample collection vessel; and

a suction inlet for connecting a suction source to the apparatus, the suction inlet being in fluid communication with the sample outlet of the spout such that when suction is applied at the suction inlet negative pressure is created in the spout to draw the sample into the sample inlet.

- 2. Apparatus according to claim 1 wherein the spout is angled downwardly with respect to a lateral axis of the body when the apparatus is in an upright orientation.
- 3. Apparatus according to claim 1 or claim 2 wherein the sample inlet is angled with respect to a longitudinal axis of the spout.
- 4. Apparatus according to any one of the preceding claims wherein the spout is substantially inflexible.
- 5. Apparatus according to any one of claims 1 to 3 wherein the suction inlet is positioned below the level of the spout, when the apparatus is in an upright orientation.
- 6. Apparatus according to any one of the preceding claims further comprising a conduit which communicates with the spout, the conduit having an open end which is arranged to be received in the sample collection vessel.

- 7. Apparatus according to claim wherein the body is provided with means defining a channel which communicates with the suction inlet and with the open end of the conduit.
- 8. Apparatus according to claim 7 wherein the means defining the channel comprise a tube which depends from the body and is co-axial with the conduit, such that the channel is formed between an inner wall of the tube and an outer wall of the conduit.
- 9. Apparatus according to claim 8 wherein the tube extends beyond a distal end of the conduit.
- 10. Apparatus according to any one of the preceding claims wherein the body is generally cylindrical.
- 11. A kit comprising apparatus according to any one of the preceding claims, a sample collection vessel and a suction source.
- 12. A kit according to claim 11 wherein the suction source comprises a syringe.
- 13. A kit according to claim 11 or claim 12 further comprising a lid for the sample collection vessel.
- 14. A kit according to claim 13 further comprising a case for receiving the apparatus, vessel, suction source and lid.
- 15. A kit according to claim 14 wherein the case is provided with receiving means for receiving the apparatus, vessel, suction source and lid.
- 16. A kit according to claim 15 wherein the receiving means comprises pre-formed indentations in the case.

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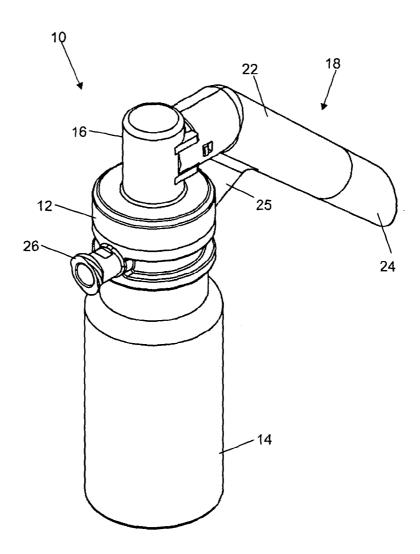


Figure 1

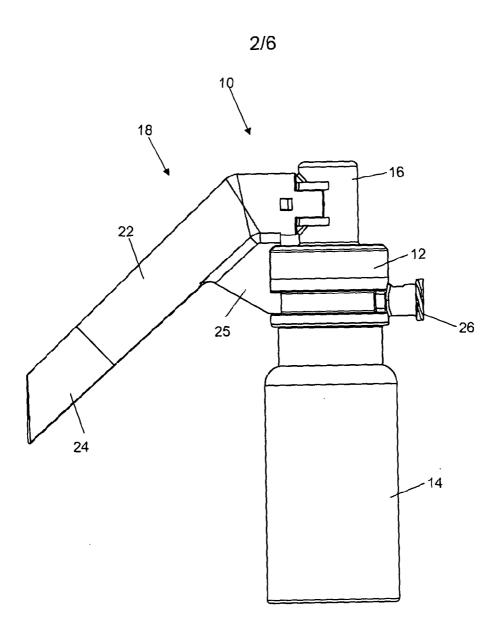


Figure 2

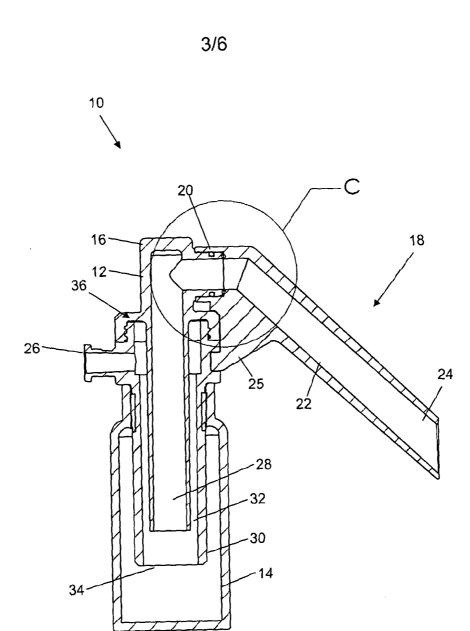


Figure 3

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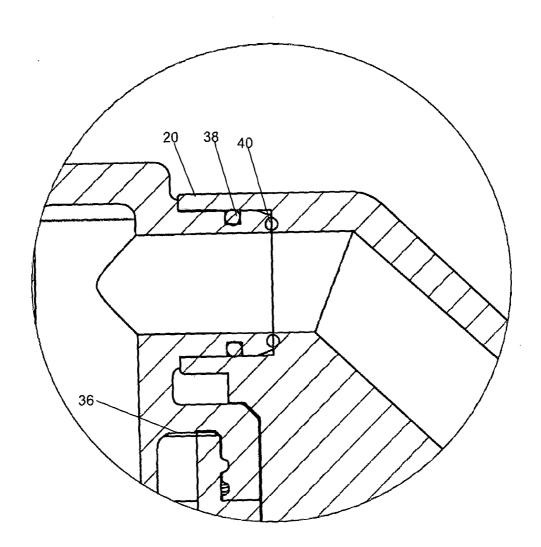


Figure 4



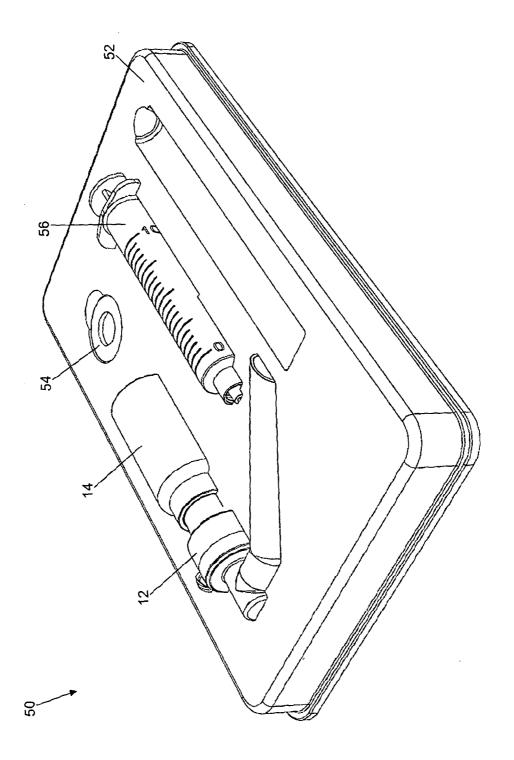
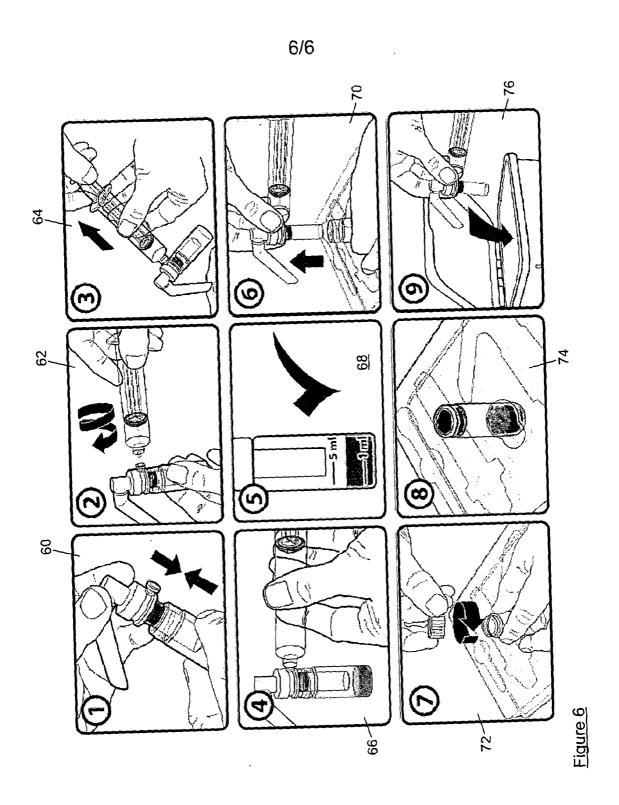


Figure 5



## **INTERNATIONAL SEARCH REPORT**

International application No PCT/GB2012/000534

A. CLASSIFICATION OF SUBJECT MATTER INV. A61B10/00 A61M1/00 ADD.

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)

A61B A61M

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 practicable, search terms used)

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X Further documents are listed in the continuation of Box C.	X See patent family annex.			
* Special categories of cited documents :  "A" document defining the general state of the art which is not considered	"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			
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17 August 2012	31/08/2012			
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Information on patent family members

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