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(71) Applicant *(for all designated States except US)*: **SIEMENS HEATHCARE DIAGNOSTICS INC.** [US/US]; 511 Benedict Avenue, Tarrytown, NY 10591 (US).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **MICHAEL, Avdenko** [US/US]; 42 Yorktown Drive, Rochester, NY 14616 (US).

(74) Agents: **YUAN, Chien** et al.; Siemens Corporation, Intellectual Property Department, 170 Wood Avenue South, Iselin, NJ 08830 (US).

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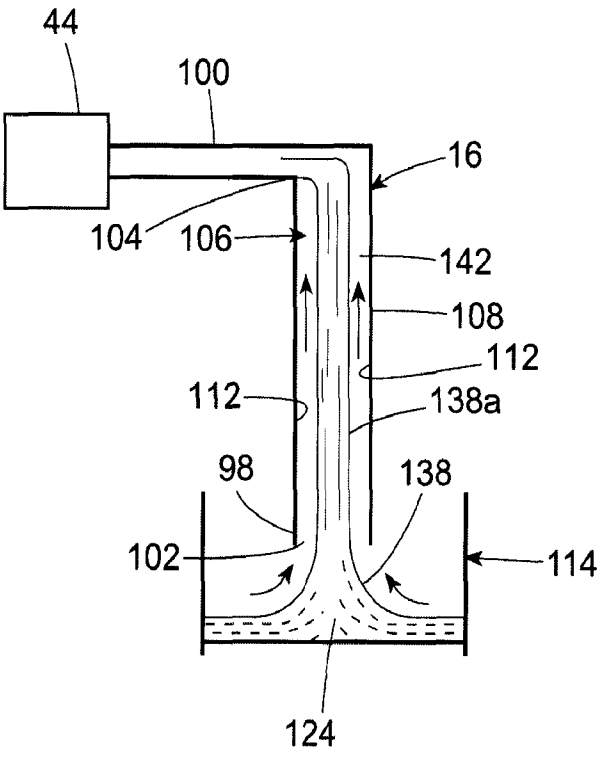
[Continued on next page]

(54) Title: WATERSPOUT ASPIRATION SYSTEM

FIG. 5



(57) Abstract: An aspiration probe, having a predetermined level of suction pressure, moves at a predetermined rate of descent toward the surface of liquid in a vessel. When the inlet end of the probe is at predetermined distance from the liquid surface in the vessel, the suction pressure produces an upwelling stream of liquid that is drawn into the probe, and at the same time, a protective inner annular sheath of air is formed at the inner surface of the probe extending from the inlet opening to the outlet opening of the probe that completely surrounds the upwelling stream of liquid, thereby preventing the upwelling liquid from contacting the inner surface of the probe.

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NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declaration under Rule 4.17:

— *of inventorship (Rule 4.17(iv))*

Published:

— *with international search report*

WATERSPOUT ASPIRATION SYSTEM

FIELD OF THE INVENTION

[001] This invention relates to devices and methods for removing liquid from a vessel in amounts that can be precisely controlled, especially liquids involved in the analysis of body fluids such as blood serum and urine. More specifically, the invention relates to a device and method for aspirating liquid from a vessel wherein the liquid being aspirated does not contact the inner or outer surfaces of an aspiration probe at the inlet end of the probe.

BACKGROUND OF THE INVENTION

[002] During laboratory analysis of biological substances, such as blood or urine, the biological substance that is tested for a particular patient is generally contained in an individual sample vessel. The sample vessel is housed in an automated analytical apparatus, generally referred to as an immuno-assay system. The analytical apparatus usually contains a plurality of sample vessels.

[003] At some stage of the analytical process, other additives can be introduced either into the original sample vessel or into a secondary vessel into which was transferred some of the original sample liquid containing the biological substance, such as liquid reagents, solid phase reagent, diluents, and wash liquids. The biological substance with the additives in the vessel is referred to as a "reaction mixture," and the vessel may be referred to as a "reaction vessel."

[004] The aspiration or removal of a relatively small amount of liquid reaction mixture is generally done as part of the analytical process to provide a precise predetermined amount of the post-reaction sample

material for analysis. This is done to each of a successive number of reaction vessels in the analytical apparatus. The aspirated liquid is usually discarded. Such removal of contaminated wash liquid typically occurs as part of separation and rinsing of a solid phase reagent such as beads or magnetic particles. The remaining bound analyte and solid phase components of the original reaction mixture in each individual reaction vessel are then used for a specific analytical test.

[005] Thus, the reactants remaining in each sample vessel are then delivered to one or more processing stations for testing in the sample analysis section of the immuno-assay system.

[006] Each specific analytical test of the precise amount of reaction mixture present in the reaction vessel involves at least one chemical reaction with one or more reagents. These tests or assays are for drugs, hormones, cardiac markers, allergies and infectious diseases, and nucleic acid-based assays, such as for human immunodeficiency virus (HIV) and hepatitis. The chemical reactions provide data that forms the basis for sample analysis information that is ultimately furnished to a physician or patient.

[007] Some assays require detection of as low as 100 molecules of analyte. If only one or several molecules of analyte are carried over to another sample, the carryover from a test sample from a diseased patient could trigger a false positive in the test sample from a healthy patient.

[008] An aspiration or suction device such as a syringe or probe is commonly used to aspirate liquid from the sample vessel in predetermined controlled amounts.

[009] U.S. Patent 5,639,426 to *Kerr et al* discloses a single probe that is used to perform aspiration and dispense measured amounts of test samples from a plurality of sample vessels in an automated immuno-assay sample analysis testing system. Because the same probe is used repetitively for the aspiration and dispensation of test samples from more

than one sample vessel in rapid succession, there exists the problem of residue carryover of liquid test sample from one sample vessel to another or subsequent sample vessel. Residue carryover is a problem because it can cause contamination of a subsequent patient test sample in a subsequent sample vessel that uses the same single probe.

[010] In general, each sample or reaction vessel contains a liquid test sample from a different patient or different ingredients. Therefore, the carryover of the contents from one sample vessel to another sample vessel can cause contamination of a subsequent liquid test sample, and have an adverse effect on test accuracy. This can lead to the generation of erroneous analytical data during sample analysis. The risk of carryover contamination is a deterrent to using the same aspiration probe for successive aspiration cycles with a plurality of sample vessels.

[011] *Kerr et al* attempts to deal with the problem of carryover contamination of the probe by using a rinsing fluid that is flushed through the probe after each cycle of aspiration and dispensation to minimize the possibility of carryover before introducing the same probe into another liquid test sample in a subsequent sample vessel. However, rinsing and/or washing the probe does not assure the elimination of carryover contamination, and is complicated, time consuming and expensive.

[012] Another way of dealing with the problem of carryover contamination is to replace the aspiration probe with a new probe each time a liquid test sample is aspirated from a different sample vessel. The replacement of probes each time an aspiration is performed on a different sample vessel is also expensive, time consuming and complicated.

[013] U.S. Patent 3,853,011 to *Baumann* discloses a suction conduit in Figs 1 and 2 for removal of a liquid 10 from a receptacle 2 wherein the suction conduit 12 does not contact the liquid 10 in the receptacle 2. As can be seen from Fig 2, the liquid stream 10 that enters the suction conduit 12 contacts the inner walls of the conduit 12 at the

point of entry 12a. A suction or vacuum force at the inlet end 12a of the conduit initiates an upward flow of liquid 10 from the receptacle 2 into the suction conduit 12. The suction conduit 12 does not contact the liquid 10 in the receptacle 2. However, the liquid drawn into the suction conduit 12 contacts the inner surface of the suction conduit from the open end or point of entry 12a.

[014] When the suction conduit in *Baumann* is used with different fluid receptacles in successive cycles of aspiration, ambient air is drawn through the suction conduit to prevent portions of the removed sample, such as drops, from being discharged by gravity from the suction conduit 12 into the receptacle 2. The ambient air also serves to dry the inner wall surface of the suction conduit 12.

[015] However, even when the suction conduit in *Baumann* is dried, there can be a residue or film of dried liquid remaining on the inner surface of the suction conduit that can cause carryover contamination during successive use of the same suction conduit to aspirate a different liquid sample from a subsequent receptacle. The different liquid sample entering the same suction conduit from a subsequent receptacle can solubilize the dried film or residue that remains on the inner walls of the suction conduit from the previous liquid test sample that was drawn into the suction conduit from the previous receptacle.

[016] *Baumann* does not address the problem of carryover contamination caused by the liquefication of carryover residue on the inner surface of the suction conduit caused by a subsequent liquid test sample that has been drawn into the suction conduit from a subsequent receptacle during a subsequent aspiration or suction removal of a subsequent liquid test sample.

[017] It would thus be desirable to implement a suction conduit or aspiration probe that can be used repetitively to remove liquid test sample

from a vessel, in predetermined controlled amounts, from a plurality of sample vessels in successive sequence without carryover contamination.

[018] In order to do this, there should be no contact whatsoever of aspirated liquid from any sample vessel among a plurality of successive sample vessels, even molecularly with the inner surface, outer surface, or inlet end of the suction or aspiration probe. The regime of no contact is preferably for an upward longitudinal distance from the inlet end of the aspiration probe, equal to at least 5 times the inside diameter of the aspiration probe.

[019] The successful implementation of such an aspiration probe would substantially eliminate the carryover contamination that is attributable to use of a common aspiration probe for successively aspirating liquid from a plurality of sample vessels.

DESCRIPTION OF THE DRAWINGS

[020] In the accompanying drawings,

[021] Fig. 1 is a simplified schematic view of a waterspout aspiration system incorporating one embodiment of the invention;

[022] Fig. 2 is a simplified schematic view of a waterspout aspiration system incorporating another embodiment of the invention;

[023] Fig. 3 is a simplified fragmentary elevational view of a suction probe used in either embodiment of the waterspout aspiration system;

[024] Fig. 4 is a view similar to Fig. 3 at the inception of an aspiration cycle; and,

[025] Fig. 5 is a view similar to Fig. 3 during an aspiration cycle.

[026] Corresponding reference numbers indicate corresponding parts throughout the several views of the drawings.

DETAILED DESCRIPTION OF THE INVENTION

[027] Referring to the drawings, one embodiment of the waterspout aspiration system is generally indicated by the reference number 10 in Fig. 1.

[028] The system 10 includes a plurality of aspiration probes 16 connected in series to a tube 20 provided with a suitable known two-way valve 22. The flow tube 20 has an outlet end 24 that communicates with a tank or waste reservoir 26 which can be used for accumulation of waste materials 28. A level sensor 30 is provided with the tank 26 to monitor the level of liquid and any other waste materials 28 that accumulate in the tank 26. The tank 26 also includes an upper space 32 that is not occupied by any waste material.

[029] Another tube 34 has one end 36 connected to the tank 26 and an opposite end 42 connected to a pressure regulated vacuum pump 44 having any suitable known pressure regulator (not shown).

[030] An air filter 50 of any suitable known construction is connected to the tube 34 between the vacuum pump 44 and the tank 26. Pressure sensors 52 and 54 are also connected to the tube 34 upstream and downstream of the air filter 50.

[031] The portion of the system 10 between the downstream ends of aspiration probes 16 to the inlet 42 of vacuum pump 44 are a pneumatically closed system.

[032] Vacuum is thus provided by the pump 44 to the probes 16 via the tube 34, the unoccupied tank space 32 and the tube 20. Any air, liquid or other material that passes into the tube 20 also passes into the tank 26 where unusable liquid or particulate material accumulates as the waste material 28 and can be collected for disposal. Pressure regulated air is drawn into the probes 16 under the influence of the vacuum pump 44 passes through the flow tube 20, the tank 26, the flow tube 34 and the

pressure sensors 52 and 54 as well as the air filter 50. Thus, the pressure conditions at the probes 16 produced by the pump 44 can be precisely monitored by the pressure sensors 52 and 54.

[033] Another embodiment of the waterspout aspiration system is generally indicated by the reference number 60 in Fig. 2. The system 60 includes a plurality of the aspiration probes 16 connected in parallel to an exit tube 62 via a manifold 64. Each of the aspiration probes 16 is connected via separate flow tubes 70, 72, 74, 76, 78, 80, 82 and 84 to the manifold 64 for common communication with the exit tube 62.

[034] The exit tube 62 has an outlet end 88 that communicates with a waste reservoir 90 similar to the waste reservoir 26 of the system 10 in Fig. 1. A two-way valve 96 similar to the two-way valve 22 of the system 10 is connected to the exit tube 62 between the manifold 64 and the outlet end 88.

[035] The remaining structure of the system 60 is identical to that of the system 10 as indicated by the corresponding reference numbers in Fig 2.

[036] The systems 10 and 60 operate in substantially the same manner. For simplification purposes in describing system operation, the system 10 of Fig. 1 is shown with one aspiration probe 16 in direct connection with the vacuum pump 44 via the flow tube 100 in Fig. 3. It should also be noted that the waterspout aspiration systems 10 and 60 are operable with aspiration probes 16 of lesser quantity than that shown, including only one aspiration probe 16.

[037] The probe 16 (Figure 3) includes an inlet end 98 having an inlet opening 102 an outlet opening 104, an interior space 106, an outer surface 108, an inner surface 112, and a diameter *d*.

[038] The probe 16 is positioned in alignment with a vessel 114, that can be a tray or other conventional sample or reaction vessel having sidewalls 118 and a bottom wall 120. A supply of liquid 124, such as a

test sample that contains blood serum and a solid phase reagent, is provided in the vessel 114. The liquid 124 has a top surface or meniscus 126.

[039] During an aspiration cycle, the axis 130 of the probe 16 is concentrically aligned with the axis 132 of the vessel 114, and movement of the probe 16 relative to the vessel 114 or movement of the vessel 114 relative to the probe 16 are coaxial. Although not shown, the probe 16 can be provided with conventional means for raising and lowering the probe 16 relative to the vessel 114. Alternatively, the vessel 114 can be provided with conventional means for raising or lowering the vessel 114 relative to the probe 16. This description will refer to movement of the probe 16 relative to the vessel 114, although similar results are obtainable with movement of the vessel 114 relative to the probe 16.

[040] A suction or vacuum pressure is induced in the aspiration probe 16 by the vacuum pump 44 to provide a predetermined level of suction at the inlet end 98 of the probe 16 (for example, approximately 1.5 psig). The vacuum pressure in the probe 16 results in a high velocity air flow (for example, approximately 200 kilometers per hour or 120 miles per hour) into the inlet opening 102 of the probe 16.

[041] The aspiration probe 16 is moved downwardly in a suitable known manner at a controllable steady rate toward the meniscus 126 such that when the inlet end 98 of the probe 16 is at a predetermined distance "D" from the meniscus 126, the high velocity air flow into the inlet end 98 creates high-drag shear forces on the meniscus 126 below the inlet end 98.

[042] The predetermined distance D = $0.2d$ to $2d$, preferably about $0.5d$ to about $1d$, wherein d = the inside diameter of the probe. The high-drag shear forces lift the liquid from the meniscus 126 into the inlet opening 102, in the form of a conical mound or upwelling liquid 138, as shown in the simplified schematic diagram in Fig. 4.

[043] The upwelling liquid 138, as it rises into the aspiration probe 16, under the described pressure conditions becomes a relatively narrow and constricted upwelling stream 138a as shown in simplified schematic form in Fig 5. The constricted upwelling stream 138a is completely and uninterruptedly surrounded by a protective high velocity air sheath 142 that extends longitudinally upward from the inlet opening 102 for a distance equal to at least 5 times the inside diameter of the aspiration probe 16.

[044] The constricted liquid upwelling stream 138a flows directly into the inlet opening 102 and into the interior space 106 of the probe 16 without contacting the inner surface 112 or the outer surface 108 of the probe 16.

[045] In order to accomplish this effect, a flow rate ratio, *FRR*, within the probe 16 is established that varies from about 0.001 to about 0.06, preferably about 0.005 to about 0.01, wherein

$$FRR = \frac{V_p}{V_l + V_a}$$

wherein,

V_p = total volume of liquid passing through the probe;

V_a = total volume of air passing through the probe.

[046] The formation of the upwelling 138 and the flow of the constricted liquid upwelling stream 138a into the inlet end 98 of the probe occur rapidly such that the transition of the upwelling from the representations shown in Figs. 4 and 5 is substantially instantaneous.

[047] In a particular embodiment, by regulating the suction pressure applied at the inlet end 98 of the probe 16 to approximately 1.5 psig, an annular protective inner sheath of air 142 will form between the inner surface 112 of the probe 16 and the constricted liquid upwelling stream 138a that extends upward longitudinally from the inlet opening

102 for a distance equal to at least five times the inside diameter of the aspiration probe 16, and preferably to the outlet opening 104.

[048] The protective inner sheath of air 142 totally and completely prevents the upwelling liquid 138 and the constricted liquid upwelling stream 138a from contacting the inner surface 112, the inlet end 98 and any other part of the probe 16.

[049] Thus, there is absolutely no contact between the aspirated fluid 124 in the upwelling liquid stream 138 and upwelling stream 138a and the probe 16 during aspiration of fluid 124 from the vessel 114. Since there is no contact of fluid 124 with the inlet end 98 or any other part of the aspiration probe 16 during aspiration, there will be no carryover of sample-containing fluid 124 to another reaction vessel (not shown) when the aspiration probe 16 is subsequently used in rapid sequence with another or subsequent reaction vessel in rapid succession. The subsequent reaction vessel (not shown) contains reactants that are different in composition from the sample fluid 124 in the vessel 114.

[050] With this arrangement, there is no need to change or replace, or wash the probe 16 between successive aspirations from different sample vessels containing different serum or liquid, since carryover contamination does not occur.

[051] Although various dimensional configurations and specifications for the waterspout aspiration system are possible, it has been found that the results described above are obtainable with an aspiration probe 16 that is approximately 8 cm long with about a 1.35 millimeter inside diameter (*d*). The upwelling 138 becomes established when the inlet end 98 is at a distance (D) of approximately 1 millimeter from the meniscus 126.

[052] A downward movement of the probe 16 of one centimeter/second toward the meniscus 126 will ensure that the distance (D) between the inlet end 98 and the receding meniscus 126 remains

substantially constant during aspiration. It typically takes about 2 ½ seconds to aspirate one milliliter of liquid from a representative sample vessel, and about 4 to about 20 seconds for the aspiration cycle to proceed in rapid succession from one sample vessel to the next sample vessel.

[053] As various changes can be made in the above constructions and methods without departing from the scope of the invention, it is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative and not in a limiting sense.

What is claimed is:

1. A method for aspirating liquid from a plurality of vessels in rapid succession with an aspiration probe, wherein the aspirated liquid does not contact any part of the aspiration probe, thereby avoiding carryover contamination of the vessels, comprising:

(a) concentrically aligning a first central axis of an aspiration probe having an inner surface, an outer surface, an inlet end, an inlet opening, an outlet opening, and an inner diameter *d* with a second central axis of a vessel of liquid, wherein the inlet end of the aspiration probe is spaced at a first predetermined distance D from the surface of the liquid in the vessel;

(b) moving the aspiration probe concentrically toward the surface of the liquid in the vessel such that the inlet end of the aspiration probe approaches the surface of the liquid in the vessel at a predetermined rate of descent;

(c) establishing a sufficient suction pressure in the aspiration probe to cause the liquid at the surface of the vessel at the second central axis to form an upwelling stream of liquid to enter the inlet end of the probe completely and uninterruptedly surrounded by a protective annular sheath of air extending upward longitudinally from the inlet opening of the aspiration probe for a distance equal to at least five times the inside diameter of the aspiration probe, thereby avoiding liquid carryover contamination and enabling the aspiration probe to proceed in rapid succession to a subsequent vessel to repeat the process of aspiration without carryover contamination.

2. The method of claim 1, wherein the vessels contain biological samples or derivatives of substances selected from the group

consisting of blood, urine, cerebrospinal fluid, amniotic fluid, and any biological materials that contain nucleic acids.

3. The method of claim 1, wherein the vessels are housed in an automated analytical apparatus.

4. The method of claim 3, wherein the vessels contain biological samples from different patients.

5. The method of claim 1 wherein the aspiration probe is approximately 8cm long with an inside diameter of about 1.35 millimeters, and the suction pressure is about 1.5 psig.

6. The method of claim 1, wherein the ratio of total volume of liquid passing through the probe to the total volume of liquid and air passing through the probe varies from about 0.001 to about 0.06.

7. The method of claim 1, wherein the distance (D) remains substantially constant during the aspiration until a predetermined amount of liquid is aspirated from the vessel.

8. The method of claim 3, wherein the automated analytical apparatus is an immuno-assay system.

9. The method of claim 1, wherein the protective annular sheath of air is established by a sufficient flow rate ratio (FRR) wherein,

$$FRR = \frac{V_p}{V_p + V_a}$$

wherein,

V_p = total volume of liquid passing through the probe; and

V_a = total volume of air passing through the probe.10.

The method of claim 9, wherein the FRR varies from about 0.001 to about 0.06.

11. The method of claim 1, wherein the rate of descent is fixed.

12. The method of claim 1, wherein the rate of descent is variable.

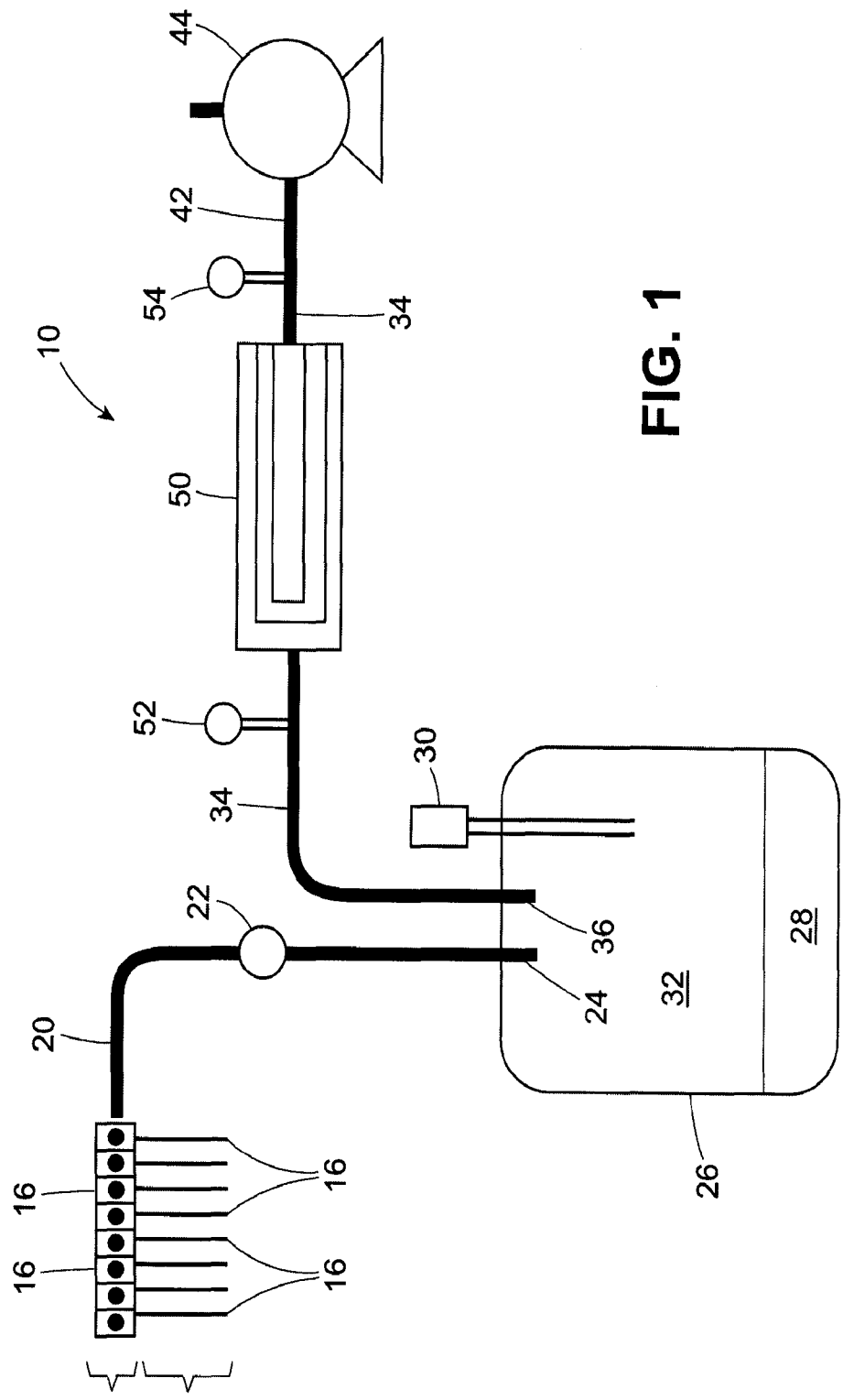

FIG. 1

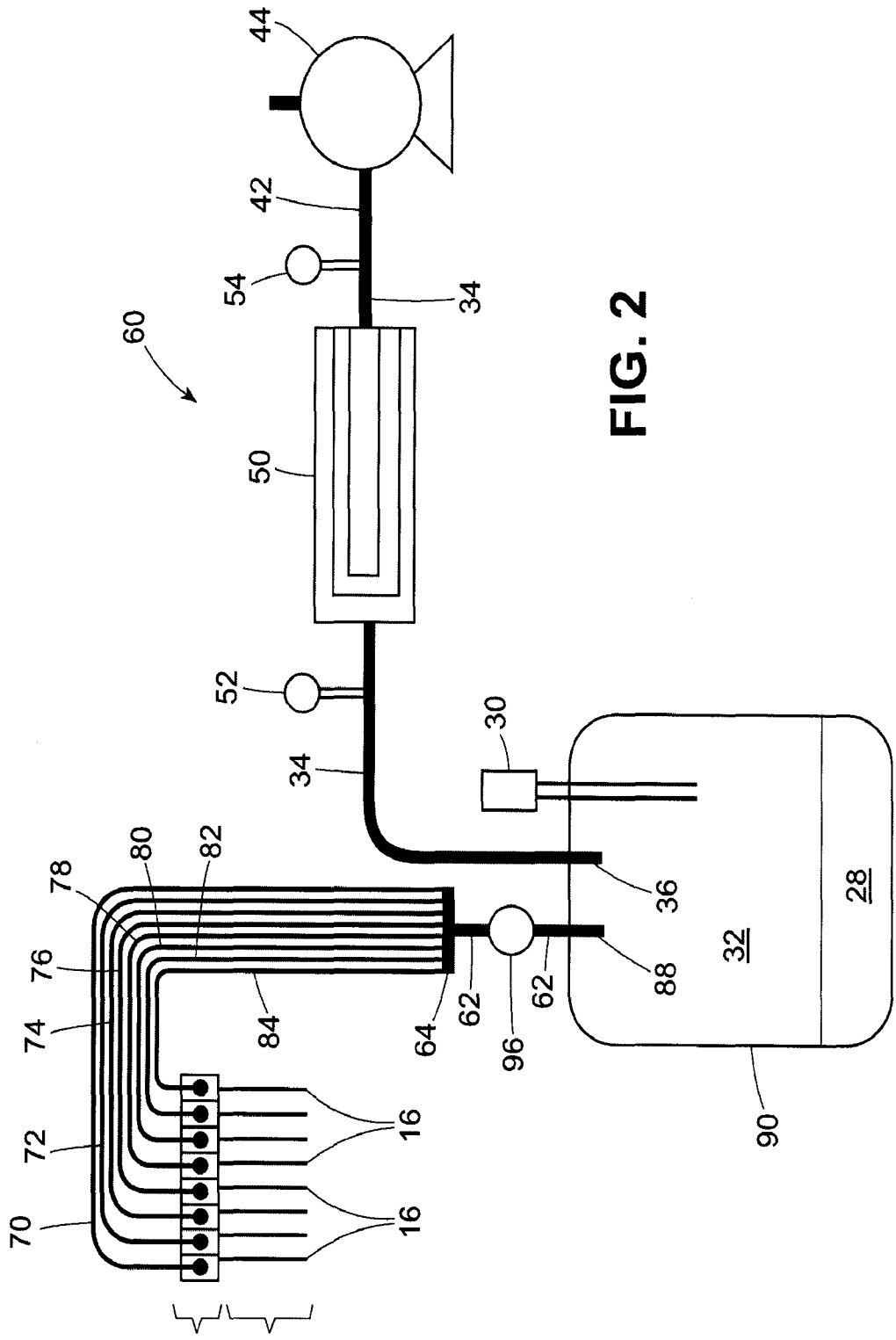
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FIG. 2

FIG. 4

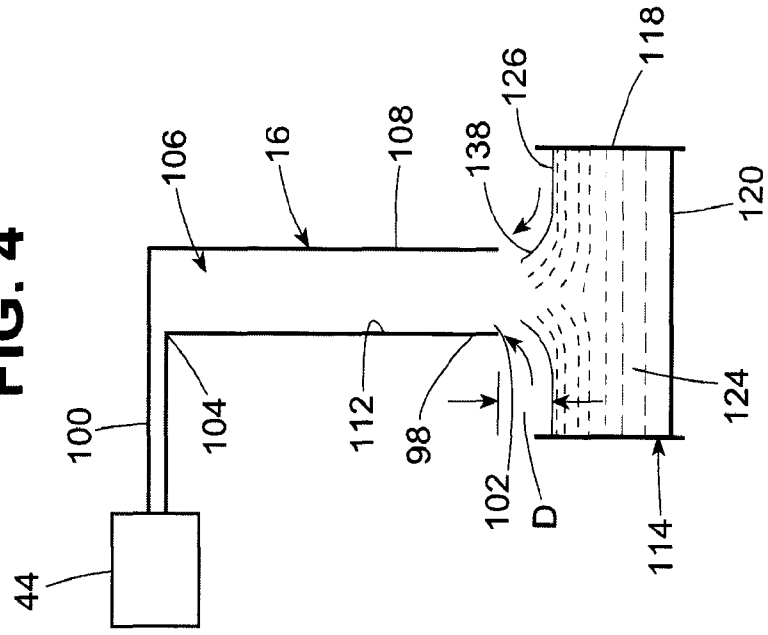
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FIG. 3

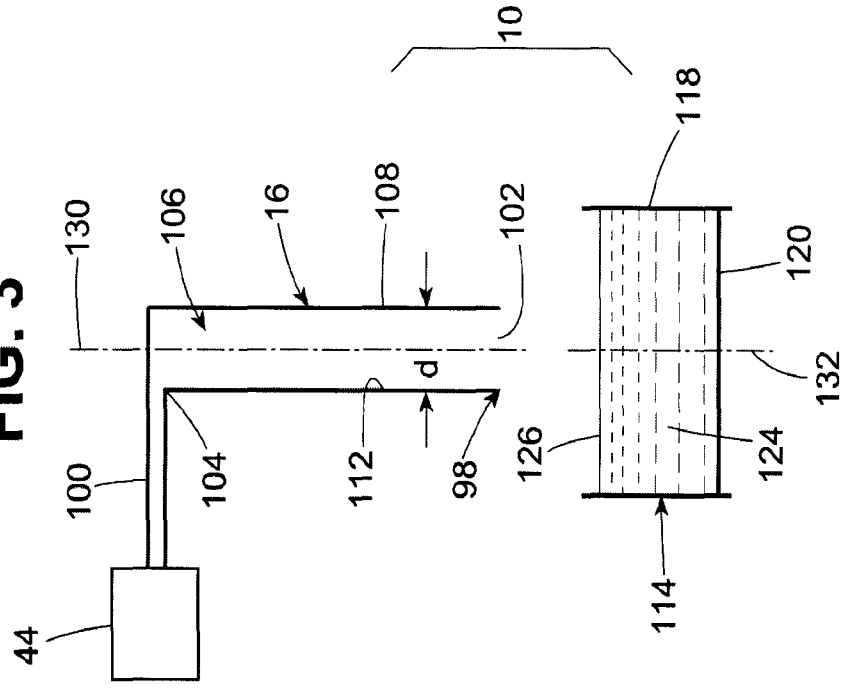
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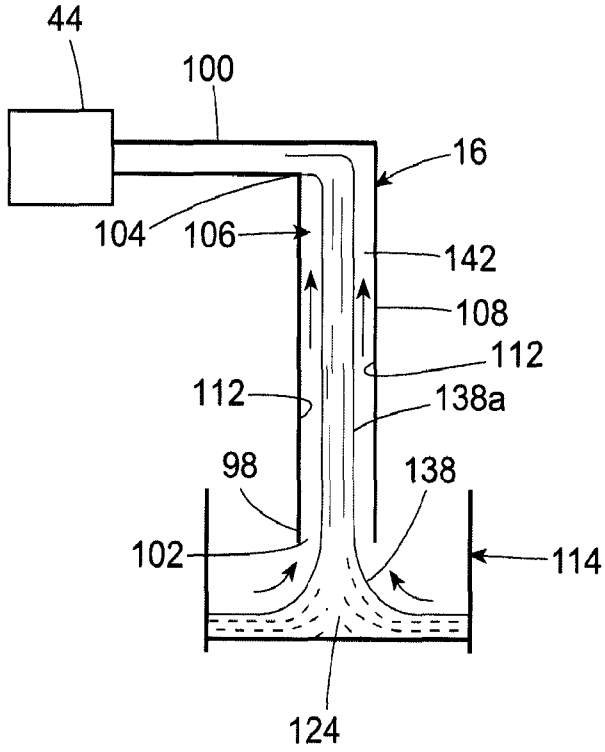
FIG. 5



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 08/82379

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - B01L 3/02 (2008.04)
USPC - 422/100
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)
USPC - 422/100

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 422/50, 68.1, 99, 119; 73/432.1, 863, 863.32, 863.81, 864.01, 864.11, 864.21, 864.22, 864.23, 864.24, 864.35, 864.81, 866; 141/14, 16, 18, 35, 36, 234, 237, 250, 270, 275, 285, 392. (see continuation sheet)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWEST(USPT,PGPB,EPAB,JPAB); Dialogweb (344, 347, 348, 349, 371, 652, 654, 345, 351, 315, 35, 440); Google Patents; Google Scholar; USPTO online (term search).
Terms: (see continuation sheet)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4,121,466 A (REICHLER, et al.) 24 October 1978 (24.10.1978), entire document, especially abstract; col. 2, ln 3-13; col. 4, ln 13-16; col. 4, ln 27-29; col. 4, ln 43-47; FIGS. 1, 5.	1-12
Y	US 4,117,047 A (HANNECART) 26 September 1978 (26.09.1978), entire document, especially col. 3, ln 14-41; FIG. 1.	1-12
Y	US 4,984,475 A (UFFENHEIMER, et al.) 15 January 1991 (15.01.1991), col. 2, ln 20-29; col. 10, ln 34-59.	2, 5, 8
Y	US 4,629,703 A (UFFENHEIMER) 16 December 1986 (16.12.1986), col. 1, ln 22-26.	4
Y	US 3,635,819 A (KAISER) 18 January 1972 (18.01.1972), col. 8, ln 20-25.	6, 9, 10
Y	US 5,463,895 A (BRENTZ) 7 November 1995 (07.11.1995), col. 2, ln 62 to col. 3, ln 37.	5
A	US 4,259,291 A (SMYTHE) 31 March 1981 (31.03.1981), entire document.	1
A	US 4,347,875 A (COLUMBUS) 7 September 1982 (07.09.1982), abstract.	1
A	US 5,550,059 A (BOGER, et al.) 27 August 1996 (27.08.1996), entire document, especially abstract; col. 5, ln 4-5; col. 5, ln 35-51; col. 7, ln 32-55.	1, 3, 5

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
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"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"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
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"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
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
14 December 2008 (14.12.2008)	24 DEC 2008
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (April 2007)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 08/82379

Continuation of B - Fields Searched

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched:

IPC(8) - B01L 3/00, 3/02; G01N 1/00, 1/14, 1/20, 1/24, 33/00, 33/48 G01N 35/00, 35/10; G01F 11/00; B67C 3/00; B65B 3/00, 3/04, 37/00, 37/06 (2008.04).

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

waterspout, pipette, probe, pipe, capillary, upwelling, column, cylinder, cylindrical, vacuum, reduced pressure, aspirat$, sheath, suction, evacuate, evacuation, cushion, layer, sleeve, tube, tubular, contaminat$, liquid, annular, immunoassay, multivariate, assay, analysis, surface, air, touch, touchless, contact, plurality, multiple, vessels, samples, carryover, blood, urine, cerebrospinal, amniotic, DNA, nucleic