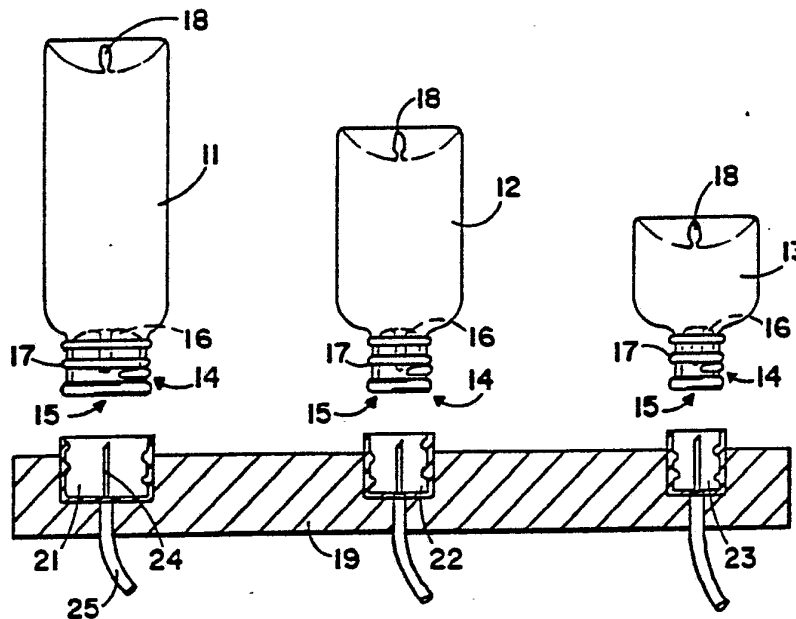




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<p>(21) International Application Number: PCT/US82/01194 (22) International Filing Date: 31 August 1982 (31.08.82) (31) Priority Application Number: 297,650 (32) Priority Date: 31 August 1981 (31.08.81) (33) Priority Country: US (71) Applicant: BECKMAN INSTRUMENTS, INC. [US/US]; 2500 Harbor Boulevard, Fullerton, CA 92634 (US). (72) Inventor: HARRIS, Arthur, Milton ; 3349 West Park Road, Hollywood, FL 33021 (US). (74) Agents: STEINMEYER, R., J. et al.; Beckman Instruments, Inc., 2500 Harbor Boulevard, Fullerton, CA 92634 (US).</p>		<p>(81) Designated States: DE (European patent), FR (European patent), GB (European patent), JP. Published <i>With international search report.</i></p>

(54) Title: REAGENT STORAGE AND DELIVERY SYSTEM



(57) Abstract

A reagent storage and delivery apparatus. The invention includes containers (11, 12, 13) with elastomeric septums (16) in the mouth portions (15) thereof. When attached to a supporting rack (19), a hollow needle (24) on the supporting rack (19) pierces the elastomeric septums (15) and allows the reagent to be dispensed from the containers (11, 12, 13) through the needle (24).

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-1-

REAGENT STORAGE AND DELIVERY SYSTEMBackground of the InventionField of the Invention

The invention relates to the field of contain-
5 ing apparatus. More particularly, the invention relates
to a container system which includes a means for dispens-
ing a substance from the containers. By way of further
characterization, but not by way of limitation thereto,
the invention includes at least one container which is
10 secured to a rack wherein, upon securing the container to
the rack, a seal on the container is pierced to allow the
liquid within the container to be drained therefrom.

Description of the Prior Art

In analytical instruments, such as medical
15 instrumentation, samples of body fluids are combined with
reagents or other substances and tested for specific
components and percentages thereof. It is important,
when utilizing these reagents or substances, that the
reagents be kept sterile and free from contamination. In
20 addition, the substances must be stored when not in
use. Many instruments employ refillable reservoirs into
which the new reagent is added. Many other instruments
employ reagent bottles into which tubing may be inserted
and pumps are used to pump out the liquids or other sub-
25 stances to be used. While these arrangements are suited
for their intended purpose, it would be desirable to have
a containment system wherein the bottles of reagents may
be inserted onto or removed from the instrument easily,
with no or minimal leakage, and stored safely.

30 Long-term storage of the reagents is done in a
refrigerated atmosphere and thus the storage system used
for the reagents must allow for easy and rapid insertion



-2-

onto and removal from the instrument. In addition, the reagents must be kept substantially sealed within the container to prevent leakage and contamination.

Summary of the Invention

5 The invention is an apparatus for supplying one or more substances to an analytical instrument. It includes at least one container defining an interior of predetermined volume with a neck portion having an opening through the container communicating with the interior. A sealing means is insertable into the mouth. A supporting means onto which the container is secured includes a means for piercing the sealing means when the container is secured to the supporting means.

10

The supporting means includes a rack having receptacles to engage and secure the containers by engaging with a neck portion on the containers. The receptacles include a hollow needle to pierce the septum which seals the opening in the neck portion of the container. When the containers are secured to the supporting rack, the hollow needle extends through the septum such that an inlet in the needle allows the reagent or other substance in the container to flow from the container through the needle and into an analytical instrument.

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Brief Description of the Drawings

25 Fig. 1 is a partially sectioned view of the containers and the supporting rack;

Fig. 2 is a sectional view of the container secured to the rack;

Fig. 3 is a view of the containers in a separate storage rack; and

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-3-

Fig. 4 shows a container with a collapsible liner therein.

Description of the Preferred Embodiment

Referring to Fig. 1, a plurality of containers 5 11, 12, and 13 each have a neck portion 14 defining a mouth 15 into which a septum 16 is inserted. Neck portions 14 include threads 17 on the outside thereof. Containers 11, 12, and 13 also include a frangible vent 10 tab 18. Containers 11, 12, and 13 each define an interior of predetermined volume. A supporting rack 19 includes container caps 21, 22, and 23, respectively, 15 sized to fit containers 11, 12, and 13. Caps 21, 22, and 23 are attached to supporting rack 19. Caps 21, 22, and 23 include threaded portions on the interior of the caps for engagement with threaded neck portions 14 on contain- 20 ers 11, 12, and 13. Caps 21, 22, and 23 also include a hollow needle 24 preferably at the center of each cap. A conduit 25 is connected to hollow needle 24.

Referring to Fig. 2, the attachment of a con- 25 tainer to supporting rack 19 is shown. For purposes of illustration, this attachment will be described with reference to container 11, but it should be expressly understood that containers 12 and 13 are attached in a like 30 manner. Neck portion 14 of container 11 is threadably engaged with cap 21, itself attached to supporting rack 19. Septum 16 seals a liquid or other substance within the interior of container 11. Hollow needle 24 penetrates septum 16 and extends into the interior of container 11 such that an inlet 26 in hollow needle 24 communicates with the predetermined volume in container 11 allowing the liquid to flow therethrough. Conduit 25 is 35 attached to hollow needle 24.

-4-

Referring to Fig. 3, containers 11, 12, and 13 may be placed in a separate storage rack 27 to allow storage of the reagents apart from the analytical instrument. Containers 11, 12, and 13 include holes 28 left by the removal of the frangible vent tab 18 (Fig. 1).

Referring to Fig. 4, a container 29 is shown including a collapsible liner 31 in the interior predetermined volume of container 29. In this alternate embodiment, as with the previously described containers 11, 12, and 13, the threaded neck portion 14 may be attached to a supporting rack 19. Septum 16 is configured as described above.

Mode of Operation

Referring to Figs. 1 and 2, containers 11, 12, and 13 define predetermined volumes into which a reagent or other substance is placed. Septum 16, fitting in mouth 15 of neck portions 14, provides a liquid and airtight seal such that the reagent or other substance enclosed in containers 11, 12, and 13 is prevented from escaping. Septums 16 are made of an elastomeric material such as silicone rubber such that, when containers 11, 12, and 13 are screwed into caps 21, 22, and 23, respectively, needles 24 pierce septum 16 and extend into the interior defined by the containers. This is more clearly shown in Fig. 2 where container 11 is shown in place as screwed into cap 21. Reagent is conducted from container 11 to a reaction site (not shown) through hollow needle 24 and conduit 25. To equalize the pressure between the exterior and interior of container 11, frangible valve 18 is opened, such as by breaking the tab, so as to permit uniform flow of reagent.

The containers shown in Fig. 1 may be removed from rack 19 without leakage of the contents of contain-



-5-

ers 11, 12 or 13. That is, if, for example, at the end of a day all the reagents are not used from containers 11, 12, or 13, then the containers may be removed to be stored in a refrigerated environment or other suitable location. Upon unscrewing containers 11, 12, and 13, needle 24 will be pulled back through septum 16. Because of the elastomeric nature of septum 16, however, the elastomeric material will fill the space formally occupied by the needle and thus the hole punched by the needle 24 will be effectively sealed.

In the container illustrated in Figs. 1 and 2, once the frangible vent is opened a hole is formed in the container bottom. Thus, if the contents of the container is not completely used and the container is to be stored for reuse, the container may be placed in a suitable holding means for storage such as storage rack 27 to keep the bottles turned neck down as shown in Fig. 3. This rack may then be placed into the desired storage location. This rack is similar to rack 19 except that no needles are included to penetrate septum 16.

Alternatively to the frangible vent tab 18 shown in Fig. 1, as shown in Fig. 4 a collapsible liner 31 can be used in a container 29, eliminating the need for venting container 29. That is, as reagent is drawn from collapsible liner 31, no air is needed to equalize the pressure inside the liner and thus venting is unnecessary. Container 29 is otherwise identical to containers 11, 12 and 13 including septum 16 and threaded neck portion 14, the structure and function of which have been described in connection with Figs. 1 and 2.

In addition to the convenience of disposable bottles and ease of handling, the invention provides a safe contamination-free package for reagents to ensure



-6-

reproducible results when employed with an analytical instrument. In addition, the removability of the containers from the rack allows them to be placed into a storage rack if all the reagent is not used. Different
5 size threads may be used on each container and corresponding cap. In this way correct placement of each container on the supporting rack may be assured. Alternatively, color coding could be used. The resealable septum prevents leakage when the containers are removed from
10 the supporting rack. The collapsible liner may also be made opaque such that light-sensitive reagents may be protected.

While a silicone rubber septum has been disclosed, it should be understood that any elastomeric
15 material would be suitable for use as a septum. Additionally, while threads have been used to secure the containers to the rack, it should be understood that any type of fastening means such as clamps, snap fit, or press fit may be used. In addition, while a hollow
20 needle has been disclosed as a means for piercing the septum, it should be expressly understood that any type of piercing means may be employed such as a knife, etc. Additionally, the hole in the hollow needle, while preferably placed on the side, may be advantageously placed
25 in various positions on the needle in order to facilitate flow of the reagent from the container. Also, while frangible vent tabs have been disclosed to vent the containers, it should be understood that any type of vent may be employed such as removable plugs, a double needle,
30 etc.

While particular forms of the invention have been disclosed with respect to a preferred embodiment thereof, it is not to be so limited as changes and modifications may be made without departing from the full
35 intended scope of the invention.



-7-

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. Apparatus supplying one or more substances to an analytical instrument comprising:
 - 5 at least one container, each said container defining an interior of predetermined volume and including an opening communicating with said interior;
 - means, cooperative with each said container, for supporting each said container;
 - 10 means, insertible into said opening, for substantially sealing said interior;
 - means, cooperative with each said container and said supporting means, for securing each
 - 15 said container to said supporting means; and
 - means, connected to said supporting means and communicable with said interior, for conducting said substances from said contain-
 - 20 er.

2. Apparatus according to claim 1 wherein said supporting means includes:
 - a supporting rack; and
 - at least one cap connected to said rack, said
 - 25 cap adapted to receive said at least one container.

3. Apparatus according to claim 1 wherein said sealing means includes an elastomeric septum.

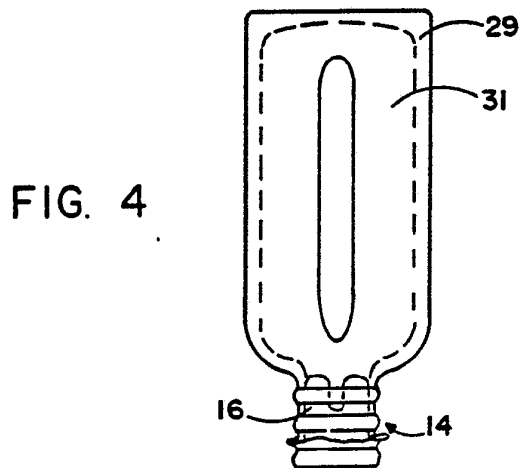
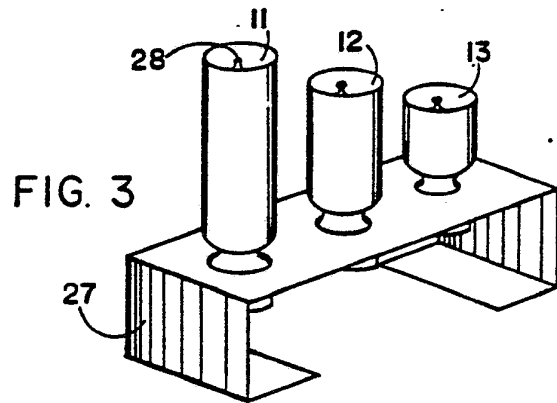
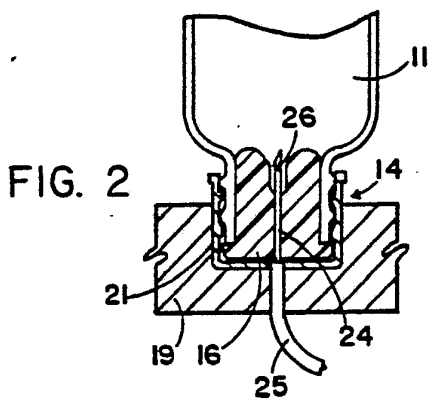
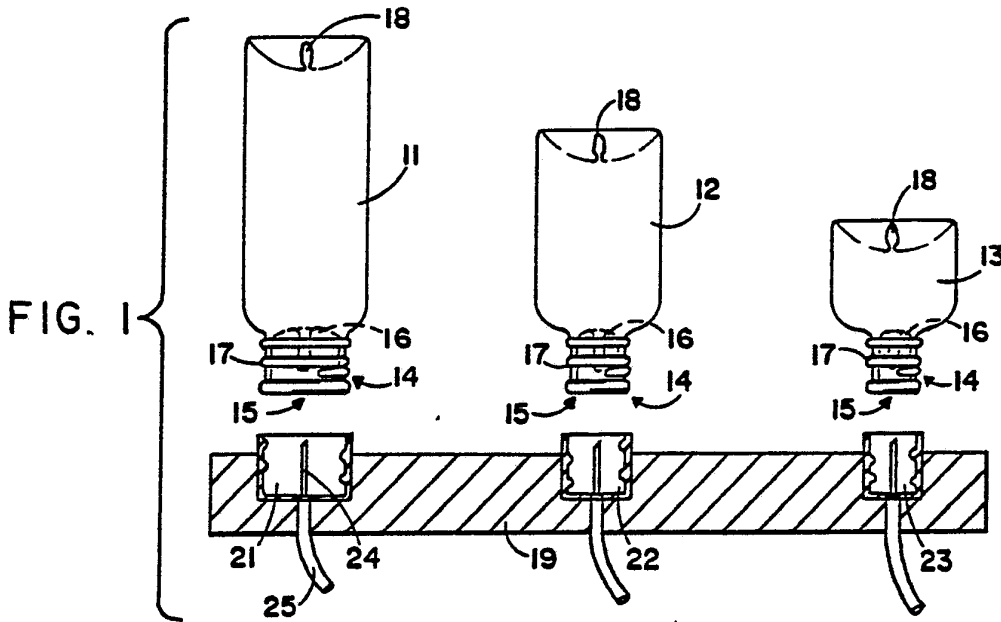
4. Apparatus according to claim 1 wherein said securing means includes mating threaded portions on said
- 30 container and said supporting means.



5. Apparatus according to claim 1 wherein said conducting means includes a needle connected to said supporting means, said needle oriented to pierce said sealing means when said container is secured to said supporting means.
6. Apparatus according to claim 5 wherein said needle includes:
an at least partially hollow needle communicating with said predetermined volume, one end of said hollow needle configured to penetrate said sealing means and the other end of said hollow needle connectible to an analytical instrument; and
said hollow needle including at least one inlet communicating with said predetermined volume.
7. Apparatus according to claim 6 wherein said at least one inlet is on a side wall of said hollow needle.
8. Apparatus according to claim 1 wherein said container includes a concave bottom portion opposite to said opening, said concave bottom including a frangible vent thereon.
9. Apparatus according to claim 1 wherein said container includes a deformable, flexible, liner within said predetermined volume.
10. A liquid storage and delivery system comprising:
a supporting rack;
at least one container defining an interior of predetermined volume, each such container including a neck portion having an open-

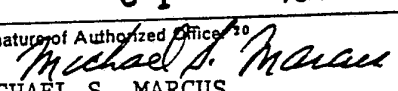
-9-

- ing, said neck portion including an engageable area matable with an engageable area on said supporting rack;
an elastomeric septum insertible into the opening of each said container; and
at least one needle, adjacent said engageable area on said rack and communicating with said interior.
- 5
11. Apparatus according to claim 10 wherein said needle includes:
- 10
- an at least partially hollow needle communicating with said interior, one end of said hollow needle configured to penetrate said elastomeric septum and the other end of said hollow needle connectible to an analytical instrument; and
- 15
- said hollow needle including at least one inlet for communication with said interior.
12. Apparatus according to claim 11 wherein said at least one inlet is on a side wall of said hollow needle.
- 20
13. Apparatus according to claim 10 wherein said container includes a concave bottom portion opposite to said open mouth portion, said concave bottom portion including a frangible vent thereon.
- 25
14. Apparatus according to claim 10 wherein said container includes a deformable, flexible liner within said predetermined volume.
15. Apparatus according to claim 10 wherein said engageable area includes mating threads on said neck portion and said supporting rack.
- 30



INTERNATIONAL SEARCH REPORT

International Application No PCT/US82/01194

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ³				
According to International Patent Classification (IPC) or to both National Classification and IPC ³				
GOIN 37/00 BOLL 9/00 B 67B 7/24				
II. FIELDS SEARCHED				
Minimum Documentation Searched ⁴				
Classification System	Classification Symbols			
U.S.	422/81,82,99,101,102,104; 128/214G,215,272,272.3; 215/1C,11E,21R,247; 222/83.5,88,91,215			
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁵				
III. DOCUMENTS CONSIDERED TO BE RELEVANT ¹⁴				
Category ⁶	Citation of Document, ¹⁶ with indication, where appropriate, of the relevant passages ¹⁷	Relevant to Claim No. ¹⁸		
X,P	US,X,P, 4,306,667, PUBLISHED 22 DECEMBER 1981, SEDAM ET AL.	1-3,5,6,10,11		
X	US,X, 4,063,460, PUBLISHED 20 DECEMBER 1977, SUENSSON.	1,3,5		
Y,P	US,Y,P, 4,306,667, PUBLISHED 22 DECEMBER 1981, SEDAM ET AL.	4,7-9,12-15		
Y	US,Y, 4,234,103, PUBLISHED 11 NOVEMBER 1980, STROBL, JR., ET AL.	1-6,8,10,11,13, 15		
Y	US,Y, 3,186,599, PUBLISHED 01 JUNE 1965, LEVINSON ET AL.	1-6,8,10,11,13, 15		
Y	US,Y, 2,628,130, PUBLISHED 10 FEBRUARY 1953, KNAPP.	1-6,8,10,11,13, 15		
Y	US,Y, 4,063,460, PUBLISHED 20 DECEMBER 1977, SVENSSON.	7-12		
Y	US,Y, 2,911,123, PUBLISHED 03 NOVEMBER 1959, SACCOMANNO.	7,12		
Y	US,Y, 2,438,024, PUBLISHED 16 MARCH 1948, STRANSKY.	7,12		
Y	US,Y, 4,236,647, PUBLISHED 02 DECEMBER 1980, KOTTURAN.	9,14		
A	US,A, 4,098,431, PUBLISHED 04 JULY 1978, PALMER ET AL.	1,2		
<table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none; vertical-align: top;"> <p>¹⁵ Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </td> <td style="width: 50%; border: none; vertical-align: top;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p> </td> </tr> </table>			<p>¹⁵ Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p>	<p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p>
<p>¹⁵ Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p>	<p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p>			
IV. CERTIFICATION				
Date of the Actual Completion of the International Search ¹	Date of Mailing of this International Search Report ²			
29 OCTOBER 1982	01 DEC 1982			
International Searching Authority ¹	Signature of Authorized Officer ¹⁹			
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