United States Patent

[11] 3,630,191

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[21] Appl. No. **830,185**
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[45] Patented **Dec. 28, 1971**

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Continuation-in-part of application Ser. No. 803,031, Feb. 27, 1969, now abandoned. This application May 15, 1969, Ser. No. 830,185

[54] APPARATUS AND METHOD FOR FILLING CAPILLARY TUBING WITH FLUIDS

21 Claims, 9 Drawing Figs.

[52] **U.S. Cl.** **128/2,** 128/276
[51] **Int. Cl.** **A61b 5/00,** A61m 1/00
[50] **Field of Search** 128/2, 276, 297, 299, 302, 272; 73/425.6, 425.4

[56] **References Cited**

UNITED STATES PATENTS

1,594,370	8/1926	Kubota	73/425.6
1,124,285	1/1915	Brown	128/276
2,290,857	7/1942	Booye et al.	128/276
3,332,288	7/1967	Mladenovich	73/425.6

FOREIGN PATENTS

124,141	3/1945	Canada	128/272
596,496	4/1925	France	128/272
121,038	10/1929	Germany	128/272
158,727	3/1954	Australia	128/276

Primary Examiner—Warner H. Camp
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ABSTRACT: A plurality of lengths of evacuated capillary tubing having their ends sealed is mounted in a container with one end protruding from the closure of the container. The closure has a well formed by an upper collar, the small upper sections of the lengths of tubing extending through the closure and the well and being scored at the bottom of the well above the transverse wall or plug thereat. When used, blood or the like fluid is deposited in the well, the upper end of each protruding section of the lengths is given a lateral strain so that the portion breaks off under the surface of the fluid, and the vacuum in the hollow bore of the length of capillary tubing draws the fluid into itself. The lateral strain is effected manually or by means of a cap engaged on the closure and having an extension entering the well.

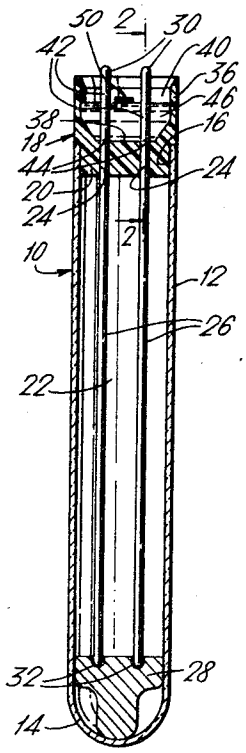


Fig. 1.

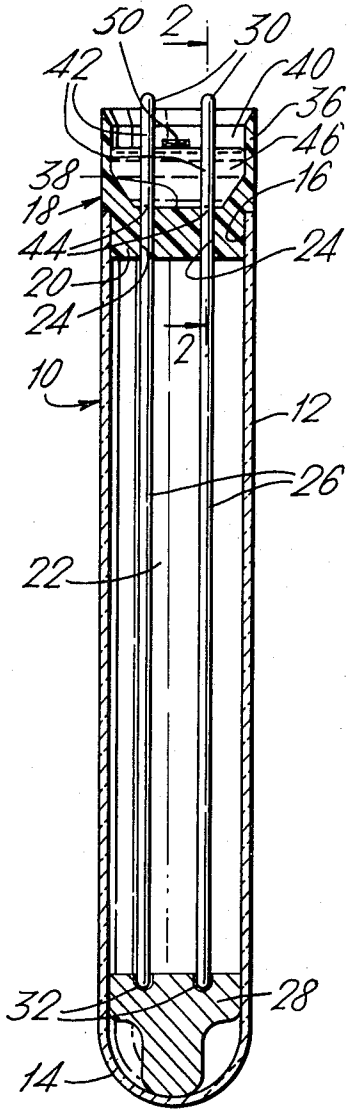


Fig. 2.

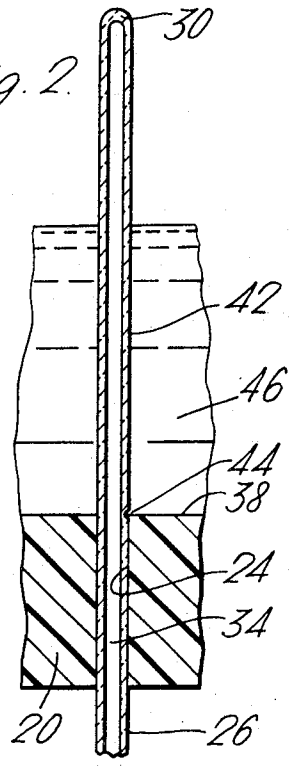
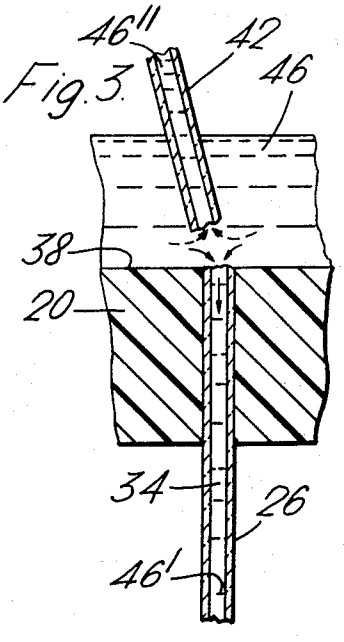


Fig. 3.



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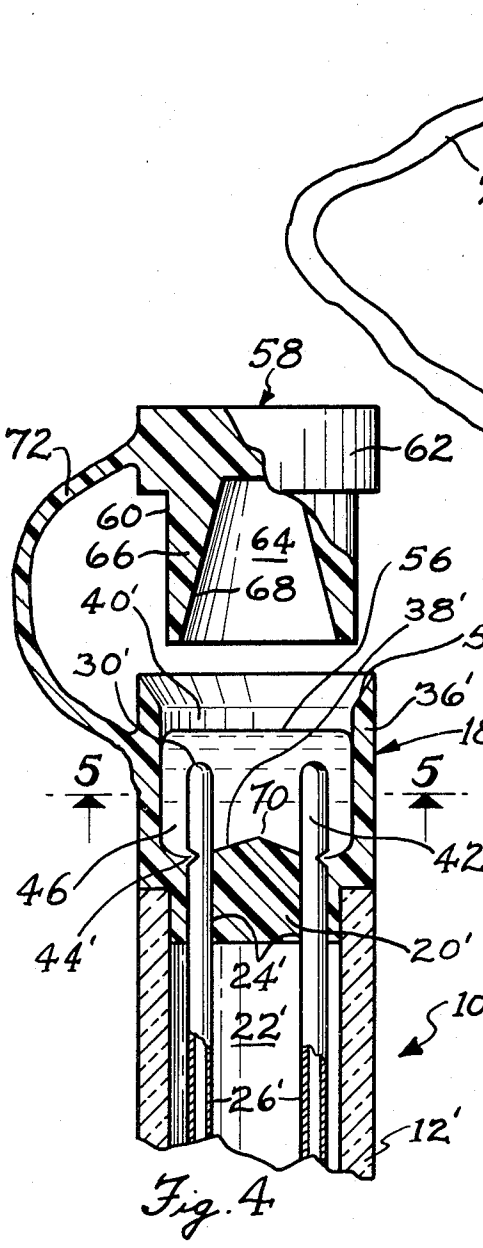

Fig. 4

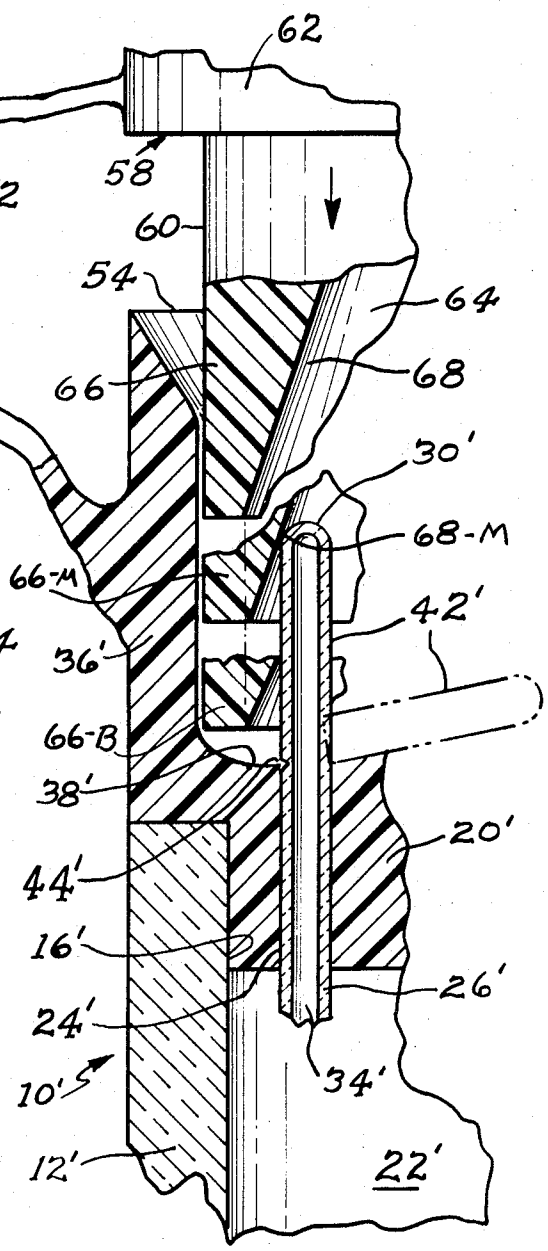

Fig. 6

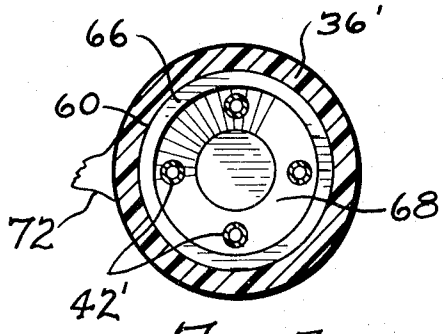

Fig. 5

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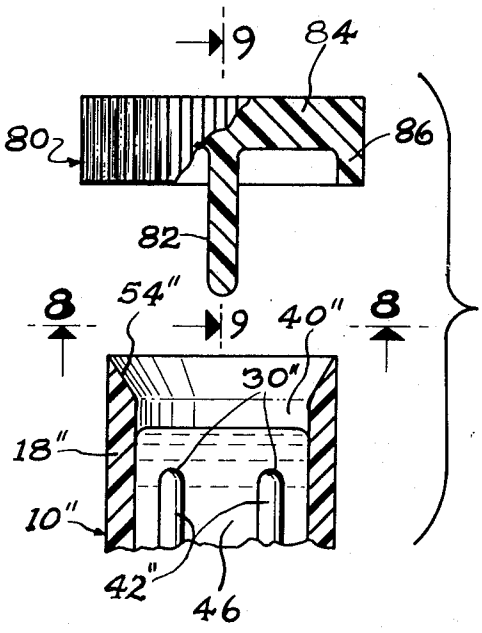

Fig. 7

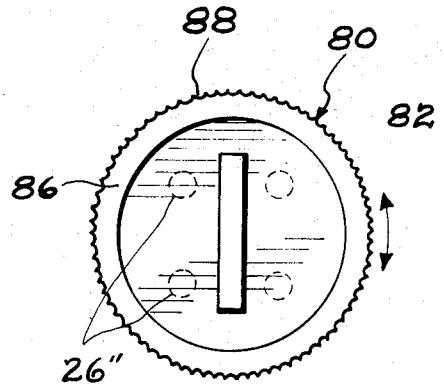

Fig. 8

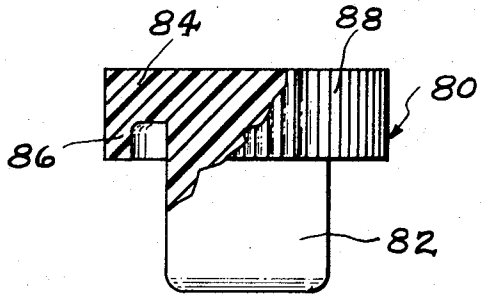

Fig. 9

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APPARATUS AND METHOD FOR FILLING CAPILLARY TUBING WITH FLUIDS

RELATION TO OTHER APPLICATIONS

This application is a continuation-in-part of an application of the same title, Ser. No. 803,031 filed Feb. 27, 1969 and now abandoned.

The basic concept of utilizing accurately bored lengths of capillary tubing to represent predetermined volumes of sample liquid for making dilutions is disclosed in application Ser. No. 472,294, now U.S. Pat. No. 3,475,125.

The method of filling long lengths of capillary tubing with some biological fluid such as blood by having a vacuum in the lengths is disclosed in copending application, Ser. No. 781,386 **filed Dec.** 5, 1968 and now abandoned. Certain apparatus for accomplishing the filling of the lengths at the bedside of a patient are disclosed and claimed in the same application.

BACKGROUND OF THE INVENTION

The invention herein is concerned with one phase of a technique which represents a new philosophical approach to the gathering and testing of fluids generally. This technique is explained in the two applications which are mentioned above, but will be briefly set forth hereinafter.

Considering the routine testing of blood, the presently used techniques revolve around the drawing of venous blood from a patient at bedside, spinning it in its container within a centrifuge to pack the cells at one end of the container, and then making tests on the serum which stands above the packed cells. The percentile relationship of cells to serum represents an index known as the hematocrit, but for the most parts the processing and testing is accomplished with the serum alone.

Venous blood has in recent times been drawn from a vein by the use of a vacuum container or vessel that has an elastomeric closure that can be pierced by a double-ended cannula carried in a socket into which the vessel fits. The vessel is not unlike a conventional test tube having the closure at its otherwise open end. Ordinarily, this method is feasible because it provides a substantial quantity of blood from the usual type of patient. Application Ser. No. 781,386 uses a vessel similar to that which is known, but instead of the simple vessel, there is an assemblage of lengths of capillary and its upper end open and disposed in fairly close spaced relation to the closure of the vessel. The lengths of tubing are evacuated, and the open ends of the hollow bores are thus able to draw blood into these bores when it is drawn into the interior of the vessel.

The vacuum vessel without the assemblage of capillary tubing lengths is well known.

After the capillary tubing lengths are filled, and while still in the vessel, they are all spun in a centrifuge to pack the red blood cells at the sealed ends. The lengths are then removed from the vessel, and the serum portions are cut into sections of predetermined length, each of which has a known volume of the serum therein. The closed ends having the packed cells are not used, but remain in place to permit handling of the capillary tubing lengths with ease. The short serum sections can be emptied into containers along with diluent or reagents for making testing samples. Thereafter the necessary tests are performed on samples withdrawn from the containers.

The amounts of fluids which are used in the technique that has been described in connection with the lengths of capillary tubing are quite small and hence economical of the fluids being tested. The approach to the technique using capillary tubing lengths is geared to the use of small quantities. Large amounts of venous blood are normally available from most patients, in which case gathering whole blood is not too difficult. Often the fluids which are drawn are not available in large quantities and in these circumstances, techniques which use very small volumes are desirable. It is under these circumstances that the capillary tube method of processing becomes additionally advantageous.

In the case of patients whose veins have collapsed, infants and small children, and under other circumstances, it is not possible to obtain a vena puncture for the purpose of drawing blood. In these instances, capillary blood is collected from small punctures made in the ear, the finger or other convenient place. The blood is then expressed by pressure of the technician's fingers and the blood is collected in a small vial or in capillary tubing that has one end placed in contact with the emerging blood.

Many problems arise in this method because the blood resulting is in small quantity for ordinary testing techniques geared to handle large volumes. Capillary tubing of the conventional variety is sometimes used to gather this expressed blood, but must be carefully handled and maintained in a horizontal position at all times. Where the technician wants to obtain as much blood as possible, the pressure applied may be excessive and result in body fluids other than blood being expressed with the blood.

According to the invention herein, the amount of blood which need be drawn is very small, and the vena puncture is not needed. The blood is drawn into the lengths of capillary tubing without any difficulty and is available for further processing. Because the lengths are each maintained with one closed end, even after filling and during cutting, no critical handling techniques are required.

It is essential to understand that the use of biological fluid is not to be considered a limitation. The invention covers any type of fluid which is capable of being entrained in capillary tubing lengths. The example described is particularly related to the gathering of blood as a field where the invention is particularly useful.

SUMMARY OF THE INVENTION

According to the invention herein, a vessel is provided which is similar to that of the copending application Ser. No. 781,386 but there is no need for vacuum to exist in the vessel. A plurality of lengths of capillary tubing is evacuated by any suitable technique and the ends sealed as by heat. Each length is scored close to one end and pressed into suitable openings provided in a plastic or elastomeric member which will serve several functions. It supports an assembly of lengths of capillary tubing; it serves as a stopper for a vessel within which the principal portions of the lengths of tubing are disposed; and it has an annular upstanding wall or collar which forms a well to receive the blood sample therein. The bottom of the well is defined by a transverse wall or plug having the openings into which the lengths of capillary tubing are engaged. The score of each length is preferably located at the upper surface of the bottom wall or slightly above the said surface so that when the protruding tips are broken off the hollow bores of the lengths still held in the transverse wall will open into the bottom of the well.

In use, the technician makes the capillary vessel cut or puncture and expresses the resulting blood into the well of a device having an assemblage of capillary tubing lengths therein. When sufficient blood has entered the well, the technician grasps the protruding sealed ends and breaks them off one after the other. Since this results in the open bores being exposed below the surface of the blood, the vacuum in the lengths of capillary tubing will draw the blood into their respective bores, and the device thereafter may be centrifuged and further processed as explained above.

In one form of the invention, a cap is engaged over the end of the well and a depending extension of the cap enters the well to contact the ends protruding therein to break them off. The cap keeps the well closed after the ends are fractured and the lengths of capillary tubing have been filled with the biological liquid. The fracture of the ends is achieved in one case by the wedging action of the extension and in another case by twisting the cap. In the latter embodiment the extension comprises a blade which sweeps through the well during the twisting of the cap, thereby engaging and laterally straining the end sections of the lengths of capillary tubing.

In both of the above forms of the invention, the protruding end sections may terminate substantially below the upper entrance of the well so that if desired the well entrance may be pressed directly against the puncture of the patient, as for example, against the flesh of the finger surrounding the puncture, to capture all of the flow without any interference resulting with protruding capillary tube ends.

In using the invention with any other liquid, the sample liquid is deposited in the well from any source, and the procedure is as above-described in connection with blood.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a sectional view taken through a device constructed in accordance with the invention;

FIG. 2 is a fragmentary sectional view on an exaggerated scale taken generally along the line 2—2 of FIG. 1 and in the indicated direction; and

FIG. 3 is a view similar to that of FIG. 2 but in this case the upper section of the length of capillary tubing has been broken off and fluid has been drawn into the resulting pieces;

FIG. 4 is a median fragmentary sectional view taken through another form of the invention with portions broken away;

FIG. 5 is a sectional view taken generally along the line 5—5 of FIG. 4 and in the direction indicated;

FIG. 6 is a fragmentary sectional view on an enlarged scale, showing diagrammatically the operation of the device of FIG. 4;

FIG. 7 is a fragmentary sectional view of the upper end of a further form of the invention;

FIG. 8 is a bottom plan view of the cap of FIG. 7 taken generally along the plane 8—8 of FIG. 7 and looking upward;

FIG. 9 is a sectional view taken generally along the line 9—9 of FIG. 7 and in the direction indicated.

DESCRIPTION OF THE PREFERRED EMBODIMENT

In FIG. 1 there is illustrated, in section, a device 10 which is constructed in accordance with the invention. The container or vessel 12 is in the form of a simple test tube having a closed bottom end 14 and a mouth at 16. A closure member 18 is engaged in the mouth 16 and serves several functions.

The closure member 18 is formed of molded flexible and/or resilient material, such as a synthetic resin or an elastomeric compound. A preferred material is polyethylene, a readily available plastic easily molded. It has a transverse wall or plug 20 which closes off the inner chamber 22 within the vessel 12. Axially extending openings 24 are provided in the transverse wall 20 and within each such opening there is sealingly engaged a length of capillary tubing, two such lengths being shown in the drawing at 26. The major portions of these lengths are disposed in the chamber 22 and hence protected by the vessel 12, rendering the device easy to handle and use. A spacing plug 28 may be provided to prevent undue movement of capillary lengths 26 inside of the chamber 22.

Each length is sealed at its upper and lower ends, as for example, by heat, the sealed upper ends being designated 30 and the sealed lower ends 32. The hollow bores 34 of the lengths of capillary tubing are fully evacuated before sealing the same, so that when the maker sells the device it has the vacuum sealed into the lengths.

The closure member 18 has an integral upstanding annular collar or wall 36 that extends a substantial distance above the upper surface 38 of the transverse wall 20, thereby providing a well 40 in the top of the closure member 18 capable of carrying a small quantity of liquid. A small section 42 of each length 26 is arranged to protrude through its opening 24 in the transverse wall 20 and pass through the well 40 so that its end 30 is at or slightly above the top of the collar 36. The lengths of tubing 26 are all scored at 44 which is chosen to be located at the surface 38 or slightly above such surface.

In use, the technician makes a puncture or cut in the patient's finger or ear or other part of the body, and permits the extruding blood to fall into the well 40. Pressure may be applied to force the blood to flow. After a short time a small quantity of blood is collected in the well 40, this being indicated as the fluid 46 in the drawing. The technician at this time grasps the end 30 of each length of tubing 26 and applies a lateral strain thereat. This forces the length to break at the score line 44 so that the upper section 42 separates, as shown in FIG. 3. Since this break occurs below the upper surface of the blood 46, and thereafter exposes the inner bore 34 of the tubing, the vacuum within the bore draws the blood into said bore. This is shown in FIG. 3 at 46' and 46''. The majority of the length 26 will remain mounted in the closure member 18 and the blood 46' that is drawn into its bore 34 will be used for testing. The short section 42 obviously will have some vacuum on its interior as well, and some of the blood 46 will be drawn into this section as shown at 46'' but will be discarded along with the section. The useful blood is indicated by solid arrows in FIG. 3 entering the remaining portion of the length 26, while a small quantity is indicated by the broken arrows entering the discarded section 42.

After the device 10 is in the condition described with the lengths of capillary tubing all filled with blood 46' the device is further processed as described above, that is, centrifuged, divided into smaller lengths, etc.

It will be understood that although only two lengths 26 are illustrated in the drawing, any desired number may be mounted in an assemblage as illustrated. The spacer 28 may be of any other suitable form, such as a mass of some plastic material in the lower closed end 14 with the ends 32 engaged in such mass.

To assure complete filling of the lengths 26, the well 40 conveniently may have indicia as at 50 in the form of a mark or ridge molded on the inside of the wall 36 showing the liquid level which must be reached by the sample 46 to assure filling of the total number of lengths 26 utilized.

FIGS. 4 through 9 illustrate two forms of the apparatus of the invention which eliminate the need for manual breaking of the upper ends of the lengths of capillary tubing. Several advantages are achieved by these embodiments.

Often it is desirable to press the well at the top of the closure member into engagement with the finger or other part of the body where the puncture has been made for the purpose of collecting the capillary blood. In the case of the arrangement described in connection with the embodiment 10, the closure member 18 has the ends 30 protruding from the well 40 to facilitate easy manual breakage after the well has been filled with the blood 46. If pressed against a finger, the ends 30 interfere and may well be broken off. The shortening of the protruding portions 42 make manual breaking difficult, especially since the said protruding portions may well be fully immersed in the blood sample. Any manual attempts at breakage will be difficult and result in the soiling of equipment and personnel, and in addition will contaminate the blood sample.

These problems are overcome and additional advantages provided in the structures of FIGS. 4 through 9.

In FIGS. 4, 5 and 6, the reference characters used to designate parts of the apparatus 10 will also be used where applicable to equivalent parts, but the numerals will be primed. The blood sample is designated 46.

The apparatus 10' provides the container or vessel 12' which may be glass or plastic, having the molded closure member 18' of a construction slightly different than the closure member 18. It is formed of polyethylene or similar synthetic plastic resin, has a transverse wall or plug 20' which is engaged in the mouth 16' of the vessel 12' closing off the inner chamber 22', and has the axially extending openings 24' within which are engaged the lengths of capillary tubing 26'. Each length is evacuated on its interior 34' and has its ends sealed as at 30', there being scores at 44' where the upper portions 42' enter the well 40' defined by the plug 20' and the annular wall 36'. The principal difference between the device 10' and the device 10 as thus far described is that the ends 30' are disposed a substantial distance below the upper entrance 54 of the well 40'. As in the case of the entrance of the well

40, the entrance 54 has an internal chamfer or taper, but in the case of the device 10' this chamfer serves two purposes. It enables the said end 54 to be tightly pressed against a patient's finger to collect blood, and it serves as a pilot for the cap to be described.

It will be seen from FIG. 4 that when the blood sample 46 is collected, its surface 56 will be above the ends 30' in most cases. In order to break the sections 42' at their scores 44', a cap 58 is provided. This cap has a cylindrical body portion 60 and an upper flange or head 62 integrally molded therewith. The interior of the body portion 60 is provided with a frustoconical bore 64 so that the resulting annular wall 66 has an internal wedging surface 68 that decreases in internal diameter from bottom to top as viewed in the illustrations of FIGS. 4 and 6. The outer diameter of the body portion 60 is such that the cap 58 easily may be engaged in the well 40' and be held therein as a covering device. The axial length of the body portion 60 is such that it will enter the well a substantial distance, principally determined by the relationship with the free ends 42' of the lengths of capillary tubing 26'.

After having drawn a sample 46, the technician grasps the cap 58 by the head and inserts the body portion 60 into the well 40', this condition being illustrated in FIG. 6 at the top of the view. As the cap 58 is pushed downward into the well 40, the wall 66 moves to the position designated 66–M which will be above the base 38' of the well 40'. The direction of movement is indicated by the arrow. The fragment of the cap 58 in the center of the view illustrates the position 66–M in the middle of the movement, at which point the surface 68 has moved into engagement with the upper ends 30' of all of the upper sections 42'. The simultaneous engagement of all upper ends 30' is not essential. The engagement may be successive or in groups. There is no need for dimensioning the upper sections 42' with great accuracy or precision. The only requirement is that all ends should be engaged by the surface 68 before the cap 58 bottoms.

Further movement of the cap 58 downward applies substantial lateral pressure on the ends 30' due to the wedging action of the surface 68 and breaks the upper section 42' at the score 44'. This is illustrated by the fragment of the cap 58 at the bottom of its movement in FIG. 6, the position being designated 66–B. The broken fragment of the length of capillary tubing is shown in phantom lines in FIG. 6 lying on the bottom of the well 40'.

With the fracture of the upper sections 42' at their scores 44' the lengths 26' will be filled with the fluid 46. A crown at 70 on the surface 38' will aid in draining the sample 46 toward the opened lengths of tubing 26'.

The cap 58 serves to keep the sample 46 clean and prevents evaporation of any kind. It confines the remanent sample and the broken glass ends 42'. While it is not necessary to do so, the cap 58 may be integrally molded with the closure member 18' and be connected therewith through a narrow connector 72. This prevents loss of the cap 58 and makes the device 10' quite easy to handle and use.

One requirement of the structure 10' is that the upper sections 42' must be located in a pattern which is susceptible of engagement with the tapered surface 68 when the cap 58 is pressed home. The simplest arrangement is one in which the axes of the lengths of tubing 26' lie on a circle coaxial with the surface 68, but having a diameter which will place the ends 30' properly so that movement of the cap 58 will engage all of them. In FIG. 5 the bottom of the cap 58 is shown in a plan view with the location of an arrangement of four lengths of tubing properly oriented for ensuring engagement with the surface 68 and consequent breakage. The invention is not limited to the particular arrangement or any specific number of lengths of tubing.

Although described as a glass tube, the container 12' may be of synthetic resin also, but preferably having somewhat more stiffness than polyethylene. It is appreciated that there is no need for the container being sealed since there is no vacuum within the chamber 22'.

FIGS. 7, 8 and 9 illustrate a form 10'' of the invention which utilizes a cap somewhat different than that of the device 10'. In this case the cap 80 is provided with a central flat blade 82 integral with the top 84, the blade being arranged to enter the well 40''. The top 84 has a depending peripheral annular flange 86 that engages over the outside of the closure member 18'' and the outer surface of the flange 86 may be knurled as shown at 88. The blood sample 46 is collected in the same way as in the case of the device 10', the ends 30'' being substantially below the surface of the entrance 54''. Thereafter the technician applies the cap 80.

In applying the cap 80, the technician preferably will guide the blade 82 to enter the well 40'' between the upper sections 42'', and for this purpose, there may be some form of guide (not shown) provided. Practically, there is no difficulty in doing this, since the breakage of the ends during the introduction of the blade 82 is not harmful. After the cap 80 has been fully engaged, the technician merely rotates the same, the fingers grasping the knurled surface 88. This causes the blade 82 to sweep through the well 40'' breaking off the upper sections 42'' to permit the blood sample to enter the remaining lengths of capillary tubing. In FIG. 8, an arrangement of four lengths of tubing is shown in broken lines at 26'' which will result in effective location for breakage by rotation of the cap 80.

Variations are capable of being made without departing from the spirit or scope of the invention as defined in the appended claims. Especially, no limitation is intended by the description of methods of handling biological fluids.

What is desired to be secured by Letters Patent of the United States is:

1. The method of filling a capillary tubing length with blood or other fluid and retaining such fluid in the length which comprises forming a length of tubing with its interior hollow bore evacuated, its ends sealed and its surface scored at a location between its ends, immersing at least the portion of the length which is scored in a quantity of said fluid and breaking the length at said score below the surface of said quantity of fluid to permit the vacuum to draw fluid into the hollow bores of the resulting pieces.

2. The method of filling a capillary tubing length with blood or other fluid and retaining such fluid in the length which comprises: forming a length of tubing with vacuum on its interior and with its ends sealed, scoring the length adjacent one end thereof, collecting said fluid in a well having the tubing protruding through the well with the score in the well adjacent the bottom of said well, applying lateral pressure on said end to cause the upper section of the length to break off at the score line and fluid in the well to be drawn into the portion of the length below the well.

3. The method as claimed in claim 2 in which the well mounts a plurality of such lengths of tubing and each has its upper section broken off in succession until all of the lower portions are filled with said fluid.

4. The method as claimed in claim 2 in which the well mounts a plurality of such lengths of tubing and the upper sections thereof are broken off in pairs.

5. The method as claimed in claim 2 in which the well mounts a plurality of such lengths of tubing and each has its upper section broken off substantially simultaneously.

6. The method as claimed in claim 5 in which the well is enclosed at the time the upper sections are broken off.

7. The method as claimed in claim 4 in which the well is enclosed prior to breaking off the upper sections of the lengths of tubing.

8. Apparatus for filling capillary tubing with quantities of fluid, comprising:

A. a vessel having a closed lower end and open at its upper end to provide a mouth,

B. a closure member secured to the mouth and having

i. a transverse plug closing the mouth,

ii. an annular upstanding wall above the plug and forming a well,

C. a plurality of lengths of capillary tubing, each length

i. having its opposite ends sealed,

ii. the hollow bore of each length being evacuated,

iii. being sealingly engaged through the plug with the major portion of the length disposed on the interior of the vessel, and a small upper section protruding upwardly through the well,

iv. and having a score line on its outer surface at the location where it emerges into the well from said plug,

whereby when fluid is in said well and said upper section of a length is broken off at said score, the vacuum will draw said fluid at least into the major portion of said length.

9. The apparatus as claimed in claim **8** in which said closure member is an integral member and together with said lengths of capillary tubing provide an assemblage that is readily installed within or removed from said vessel irrespective of whether the upper sections are broken off.

10. The apparatus as claimed in claim **8** in which the plug has an upper surface that provides the bottom floor of the said well, and the said score line of each length is disposed substantially at said surface.

11. The apparatus as claimed in claim **8** in which the upper sections are of such length as to protrude somewhat above the upper end of said well enabling the user to grasp the same without touching the fluid in the well when said well is filled.

12. The apparatus as claimed in claim **8** in which said upper sections are shorter than the length of the well so that the mouth of the well may be pressed against a source of fluid without contacting the ends of said upper sections.

13. The apparatus as claimed in claim **12** which includes means adapted to be inserted into said well to engage and break said upper sections.

14. The apparatus as claimed in claim **13** in which said last means has a cap for enclosing said well.

15. The apparatus as claimed in claim **13** in which said inserted means is a blade adapted to be rotated to sweep said well.

16. The apparatus as claimed in claim **14** in which said inserted means is a blade adapted to be rotated to sweep said well be twisting said cap.

17. The apparatus as claimed in claim **14** in which said lengths of capillary tubing are arranged in a circle and the inserted means comprise a wedging wall formation adapted to engage the ends of the upper sections while said cap is being applied to the top of the well and exert lateral force against the same for breaking same at said score lines.

18. The apparatus as claimed in claim **17** in which the wedging wall formation has a frustoconical surface.

19. The apparatus as claimed in claim **17** in which the wedging wall formation has a frustoconical interior surface.

20. The apparatus as claimed in claim **10** in which said lengths of capillary tubing are arranged in a circle.

21. The apparatus as claimed in claim **20** in which the floor of the well has a central crown which slopes down toward the circle defined by the upper sections emerging from said floor.

* * * * *

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UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,630,191 Dated December 28,1971

Inventor(s) SAUL R. GILFORD

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Column 1, line 45, Between "capillary" and "and" insert --tubing within the vessel, each having its lower end sealed--

Signed and sealed this 26th day of September 1972.

(SEAL)
Attest:

EDWARD M.FLETCHER,JR.
Attesting Officer

ROBERT GOTTSCHALK
Commissioner of Patents