Jan. 11, 1966 T. H. GEWECKE 3,228,395

BLOOD BAG TRANSFUSION UNIT WITH PRESSURE CHAMBER

Filed Nov. 10, 1961 2 Sheets-Sheet 1

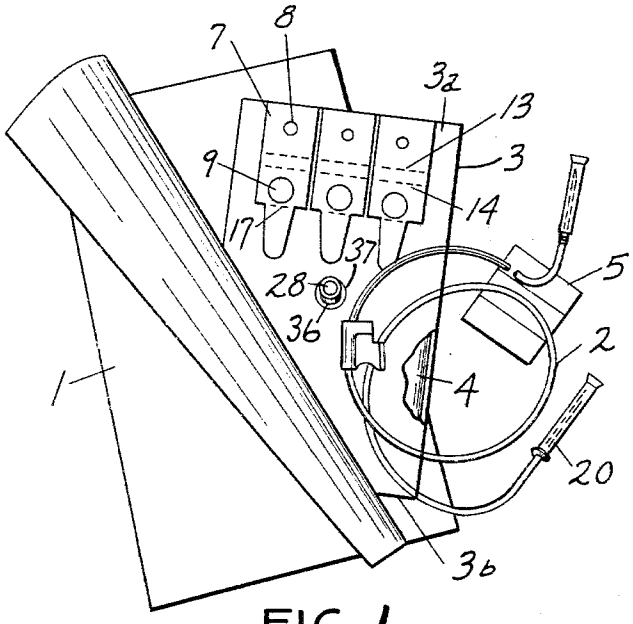


FIG. 1

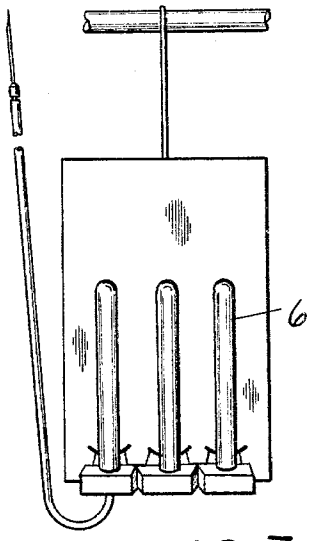


FIG. 3

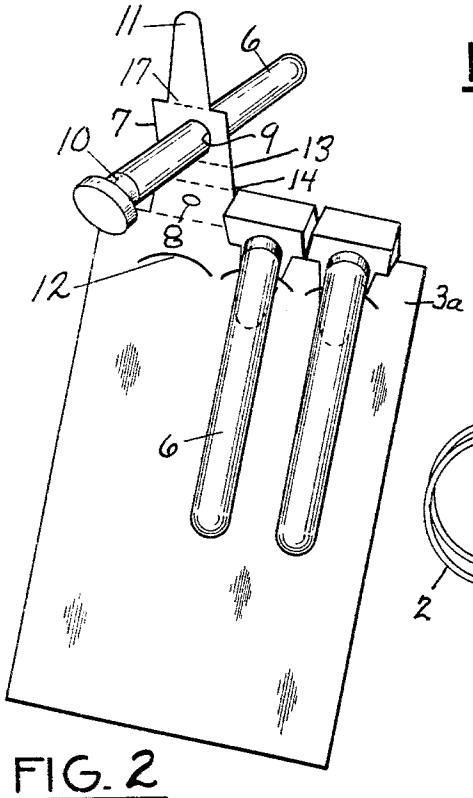
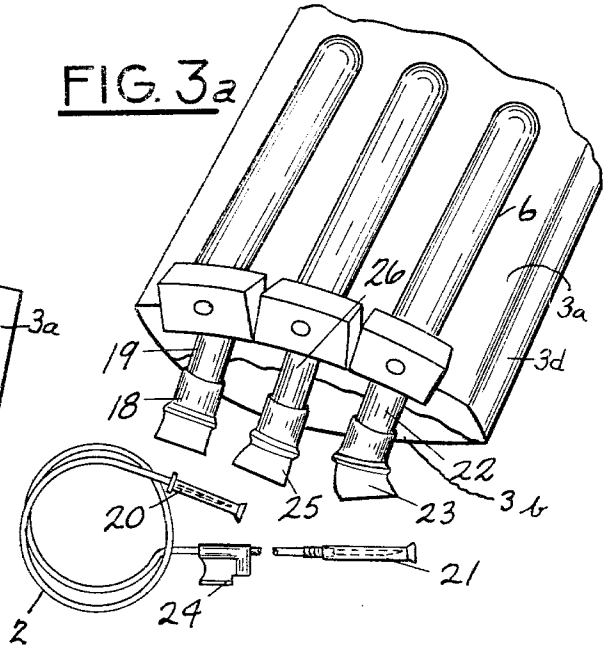


FIG. 2

FIG. 3a



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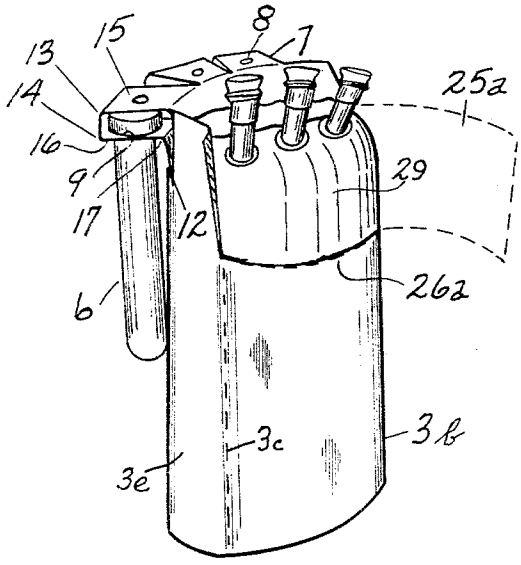


FIG. 4

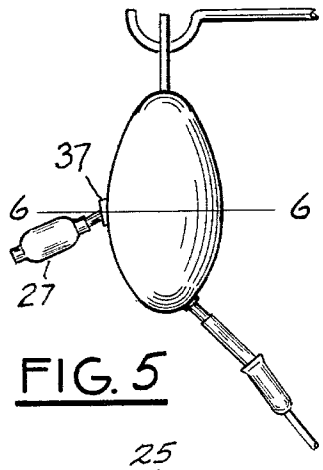


FIG. 5

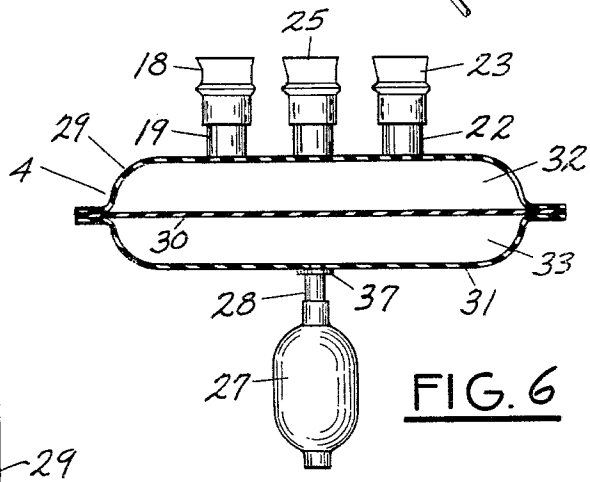


FIG. 6

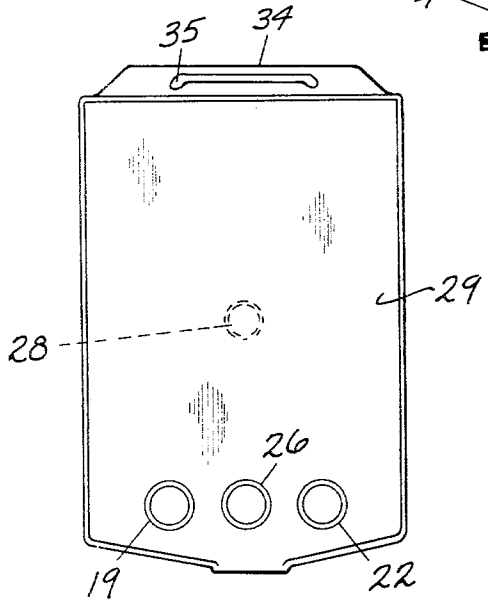


FIG. 7

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BLOOD BAG TRANSFUSION UNIT WITH PRESSURE CHAMBER

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Filed Nov. 10, 1961, Ser. No. 151,518
9 Claims. (Cl. 128—214)

This application claims subject matter disclosed but not claimed in copending Patent 3,054,401, issued September 18, 1962.

This invention is an expandable unit for the collection, storage and administration of blood. In a preferred form, the blood bag is made of flexible plastic and is housed during collection and storage in an elongated open ended container made of flexible but not expandable material such as paperboard of rectangular transverse cross section which controls the amount of blood drawn and stands upright during storage. The container has external tabs for supporting the pilot and serology tubes. One side of the container is adapted to receive data identifying the blood and part of the other side may be torn off to permit observation of the blood during storage without disturbing the side carrying the data. A flexible plastic wall sealed to the outside of the blood bag provides an air chamber separate from the blood chamber through which pressure may be applied for pressure administration of the blood.

In the drawing, FIG. 1 shows the unit and its package, FIG. 2 shows the structure for supporting the pilot and serology tubes, FIG. 3 shows the unit in a collection position, FIG. 3*a* is a partial perspective of this unit, FIG. 4 shows the unit in storage position, FIG. 5 shows the unit in position for transfusion, FIG. 6 is diagrammatic section on line 6—6 of FIG. 5, and FIG. 7 is a view of the blood bag.

The unit is packaged in a hermetically sealed foil wrapper **1** which is not opened until immediately before blood collection. The wrapper contains a blood collection set donor tube **2**, labels **5** for the pilot and serology tubes, and a flat open ended flexible cardboard container **3** of rectangular transverse cross section housing a flat plastic bag **4**. The container has two wide sides **3***a* ,**3***b* connected at opposite vertical edges by narrow sides **3***d* (FIG. 3*a*) and **3***e* (FIG. 4.) One side **3***a* of the cardboard container **3**, the bag **4** and the labels **5** are pre-numbered with the same identifying number providing positive identification for the blood. The bag is held flatwise between the parallel front and back sides **3***a* and **3***b* of the container **3**.

The first step in preparing the bag for blood collection is to attach the labels **5** to the pilot and serology tubes **6** and to mount the tubes in tear off tabs **7** hinged to the upper edge of side **3***a* of the cardboard container **3**. Depending upon the particular hospital requirements, there will be from one to three of the tubes **6** and there are accordingly three tabs **7**. Each of the tabs has a small opening **8** adjacent the upper edge of side **3***a* of container **3** and a larger opening **9** spaced below opening **8**. The tubes **6** are inserted as shown in FIG. 2 by inserting the tube through the tab from the back until the rubber closure **10** is gripped in the opening **9**. The tab is then folded downward and the free end **11** inserted in curved slot **12** which holds the tab in a tamper-proof manner so that glue is not required on the tab. This brings the upper end of the closure **10** directly below the opening **8** in the tab. The tabs have fold lines **13**, **14** and **17** which accurately center the closure **10** below the opening **8**. The curved slots **12** are positioned so that in the folded position the tabs have upper and lower walls **15**, **16** which

are parallel to each other (FIG. 4) with the lower wall **16** even with the slot **12**. The tabs lock into the curved slots **12** to provide a tamper-proof closure for the tubes. This ends the preliminary preparation of the bag.

For blood collection, the tamper-proof protector **18** is torn off one of the sterile inlets **19** of the blood collection bag and the flanged needle **20** at one end of the donor tube **2** is inserted in the inlet port **19**. The blood collection bag contains the required amount of ACD solution NIH formula "A." By squeezing the flexible sides **3***a* and **3***b* of the container, air may be expelled from the donor tube **2** and the tube filled with the anticoagulant solution. The bag is then placed below the donor and the needle **21** at the other end of the donor tube inserted in a vein of the donor. When the full unit of blood has been drawn, further expansion of the bag is prevented by the container **3**. This automatically terminates the flow at the desired quantity, e.g. 552 ml., (72 ml. ACD solution and 480 ml. of blood) ±3% and prevents over bleeding the donor. If the bag were outside the container **3**, it would hold more than a unit of blood and some measuring device would be necessary to determine the contents. The container **3** serves as the measuring device because it confines the expansion of the bag. A second sterile inlet port **22** with a protective cap **23** is provided in case the full unit is not obtained from the first phlebotomy.

At the completion of bleeding, clamp **24** is closed and the container **3** is set in an upright position. The flanged needle **20** is removed from the inlet **19** and there is sufficient blood between the needle and the clamp **24** to fill one, or all three of the pilot and serology tubes **6** in accordance with the hospital requirements. Filling the tubes is by inserting the needle **20** through the hole **8** into the closure **10** of each tube. A panel **25***a* at the upper end of side **3***b* of the carton **3** may now be removed by tearing off along perforated lines **26***a*, thus providing full view of plasma down to the red cell layer. This does not interfere with side **3***a* which carries identifying data for the blood. The unit is self standing in an upright position on its lower end permitting easy and convenient refrigerator storage, eliminating the need for a separate rack during storage.

For transfusing whole blood, the unit is inverted several times to resuspend the cells. The remaining lower part (FIG. 4) of side **3***b* of the container is torn off along perforated lines **3***c*. Tamper-proof protector **25** is torn off the outlet **26** and any administration set is connected to the outlet in the usual manner. If pressure is desired, a pressure bulb **27** is connected to the inlet **28** to the pressure chamber, supplying pressure to the entire blood bag unit without fear of air embolism.

As shown in FIGS. 6 and 7, the unit is made of three sheets **29**, **30** and **31** of limp flexible plastic. The sheets are arranged one on top of the other and are heat sealed around the peripheral edges at the sides and ends providing a flexible walled blood chamber **32** on one side of the wall **30** and a flexible walled pressure chamber **33** on the opposite side of the wall **30**. At a suitable point in the wall **31** is sealed the pressure inlet tube **28**. Adjacent the lower edge of the wall **29** are heat sealed the blood inlet tubes **19** and **22** and the blood outlet tube **26**. At the end opposite the blood inlet and outlet tubes the three sheets are heat sealed together to provide a rim **34** with suspension holds **35**. In FIG. 6, the bag is shown as having a generally rectangular transverse cross section. This is a diagrammatic view. Before collection, the bag would be quite flat because the contents would consist solely of the small amount of liquid anti-coagulant. After collection of a unit of blood, the limp plastic sheets **29** and **31** of the bag would be expanded against

the inner surfaces of the sides 3*a*, 3*b* of the container and would be substantially in the position illustrated in FIG. 6. The center sheet **30** would, however, be pushed against the inner surface of outer sheet **31** and would not be in the center position illustrated. The removal of the side 3*b* of the container and the application of air pressure causes the bag to assume the generally rounded shape shown in FIG. 5.

The pressure inlet tube **28** extends through opening **36** in wall 3*a* of the container **3** and has an anchoring washer **37** sealed to tube **28**. This holds the bag in position before it is filled and also holds side 3*a* of the container on the tube during transfusion. Side 3*a* contains the critical identifying data for the blood and also carries the identifying number which appears on the bag and on the labels for the pilot and serology tubes.

What is claimed as new is:

1. Blood collection equipment comprising a flat open ended flexible cardboard container of rectangular transverse cross section of volume corresponding to a unit of blood and having two opposed wide sides connected by two narrow sides, a flexible wall plastic blood bag in the rectangular carton, said bag having a blood chamber and a pressure chamber integral with the blood chamber, an inlet to the blood chamber at one end of the container, an inlet to the pressure chamber extending out through one of the wide sides of the container and anchoring the bag within the container, and the other of the wide sides having along its upper edge a tear-off panel exposing the blood plasma down to the red corpuscle line when the container is stored in an upright position, and said container with the bag filled adapted to stand stably in an upright position on its lower end.

2. Blood collection equipment comprising a flat tubular cardboard container having spaced opposed sides, a flat flexible wall plastic blood bag within the container, said bag comprising three vertically extending flexible plastic walls arranged one on top of the other and sealed together around the edges and providing a blood chamber on one side of the center wall and a pressure chamber on the opposite side of the center wall, the walls of the bag being generally parallel to said sides of the container and substantially collapsed when the bag is empty, an inlet to the outer wall of the pressure chamber extending out through one side of the container and anchoring the empty blood bag in the container, said one side of the container being adapted to receive data identifying the blood, the other side of the container having an upper tear-off panel exposing the plasma down to the red corpuscle line when the container is stored upright and a lower tear-off panel exposing the bag for transfusion without disturbing the side of the container receiving the data identifying the blood, said container with the bag filled adapted to stand stably in an upright position on its lower end, and inlet and outlet fittings to the blood chamber accessible through one end of the container.

3. Blood collection equipment comprising a flat tubular cardboard container having spaced opposed sides, a flat flexible wall plastic blood bag within the container, said bag comprising three vertically extending flexible plastic walls arranged one on top of the other and sealed together around the edges and providing a blood chamber on one side of the center wall and a pressure chamber on the opposite side of the center wall, the walls of the bag being generally parallel to said sides of the container and substantially collapsed when the bag is empty, an inlet to the outer wall of the pressure chamber extending out through one side of the container and anchoring the empty blood bag in the container, said one side of the container being adapted to receive data identifying the blood, the other side of the container being arranged to be torn off to expose the bag for transfusion without disturbing the side of the container receiving the data identifying the blood, said container with the bag filled adapted to stand stably in an upright position on its lower end, and inlet and outlet fittings to the blood chamber accessible through one end of the container.

4. Prepackaged blood collection equipment comprising a flat rectangular cardboard container of volume corresponding to a unit of blood, said container having two opposed wide sides connected by two narrow sides, a flexible wall plastic blood bag packed in the rectangular container in empty condition ready to receive blood, said bag having a blood chamber and a pressure chamber integral with the blood chamber, an inlet to the blood chamber at one end of the container, an inlet to the pressure chamber extending out through one of the wide sides of the container and anchoring the bag within the container so it will remain in place during the preparation for and collection of the blood, and the other of the wide sides being arranged to be torn off to expose the bag for transfusion but without interfering with said one of the wide sides which is adapted to receive data identifying the blood.

5. Prepackaged collection equipment comprising a flat open ended tubular flexible cardboard container of rectangular transverse cross section and of volume corresponding to a unit of blood and having two opposed wide sides connected by two narrow sides, a flat flexible plastic blood bag having an inlet connection for a donor extending out the upper end of the container, said bag having three spaced walls of limp flexible plastic arranged one on top of the other and sealed to each other around the peripheral side and end edges and providing a blood chamber on one side of the center wall and a pressure chamber on the opposite side of the center wall, the walls of the bag being substantially collapsed when the bag is empty, means supporting the empty bag flatwise in the container with the spaced walls between and presented to the wide sides of the container, said walls of the blood bag being arranged to expand against the wide sides of the container as the bag is filled and the container serving to limit the expansion of the walls of the blood bag and to thereby limit the quantity of blood to the desired unit volume, said container with the bag filled adapted to stand stably in an upright position on its lower end, and an outlet connection to the blood chamber for transfusion extending out the upper end of the container.

6. Prepackaged blood collection equipment comprising a flat tubular cardboard container having spaced opposed sides, a flat flexible wall plastic blood bag in the container having walls substantially collapsed and presented toward said sides when the bag is empty, said walls expanding against the sides of the container as the bag is filled, means for anchoring one of the walls of the empty bag to one of the sides, said one of the sides being adapted to receive data identifying the blood, a flexible tab connected on one end to an upper part of said one of the spaced sides of the container, said tab having an upper section extending out away from the container and then downward to a lower section spaced below the upper section and extending back toward the container and releasably secured to the container, the lower section having a hole large enough to hold a pilot tube, a pilot tube in said lower section with its closure below and presented toward the upper section, the upper section having an access hole of smaller diameter than the pilot tube and registering with the closure of a pilot tube supported in the lower section through which the pilot tube may be filled, said container with the bag filled adapted to stand stably in an upright position on its lower end, and inlet and outlet fittings to the blood bag accessible through one end of the container.

7. Prepackaged blood collection equipment comprising a flat open ended tubular cardboard container of a volume corresponding to a unit of blood, said container having opposed sides, a flexible plastic blood bag packed in the container in empty condition ready to collect blood, said bag in the empty condition comprising a plurality of limp flexible plastic walls arranged one on top of the

other and sealed to each other around the peripheral side and end edges and providing a blood chamber on one side of the center wall and a pressure chamber on the opposite side of the center wall, the walls of the bag being between and generally parallel to said sides of the container, one side of the container being adapted to receive data identifying the blood, means for anchoring one wall of the empty bag to said one side of the container so it will remain in place within the container during preparation for and collection of blood, the walls of the blood bag being ararnged to expand against the side of the container as the bag is filled and the container sides serving to limit the expansion of the walls of the blood bag and to thereby limit the quantity of blood to the desired unit.

8. Prepackaged blood collection equipment comprising a tubular cardboard container of a volume corresponding to a unit of blood, said container having opposed sides, a flexible plastic blood bag packed in the container in empty condition ready to collect blood, said bag comprising three flexible plastic walls arranged one on top of the other and sealed together around the edges and providing a blood chamber on one side of the center wall and a pressure chamber on the opposite side of the center wall, the walls in the empty condition of the bag being between and generally parallel to said sides of the container, an inlet to the outer fall of the pressure chamber extending out through one side of the container and anchoring the blood bag in the container, and inlet and outlet fittings to the blood chamber accessible through one end of the container.

9. Blood transfusion equipment comprising a tubular cardboard container adapted to stand stably on its lower end, a blood bag, means anchoring the blood bag in the container, a tear-off tab connected at one end to an upper part of the container, said tab having an upper section extending out away from the container and then downward and joining a lower section spaced below the

upper section and extending back toward the container, said container having a slot through which said lower section extends to anchor it to the container, the lower section having a hole large enough to hold a pilot tube, a pilot tube in the lower section with its closure below and presented toward the upper section and the upper section having an access hole of smaller diameter than the pilot tube registering with the closure of a pilot tube supported in the lower section through which the pilot tube may be filled.

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