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APPARATUS FOR EXCHANGING BODY FLUIDS

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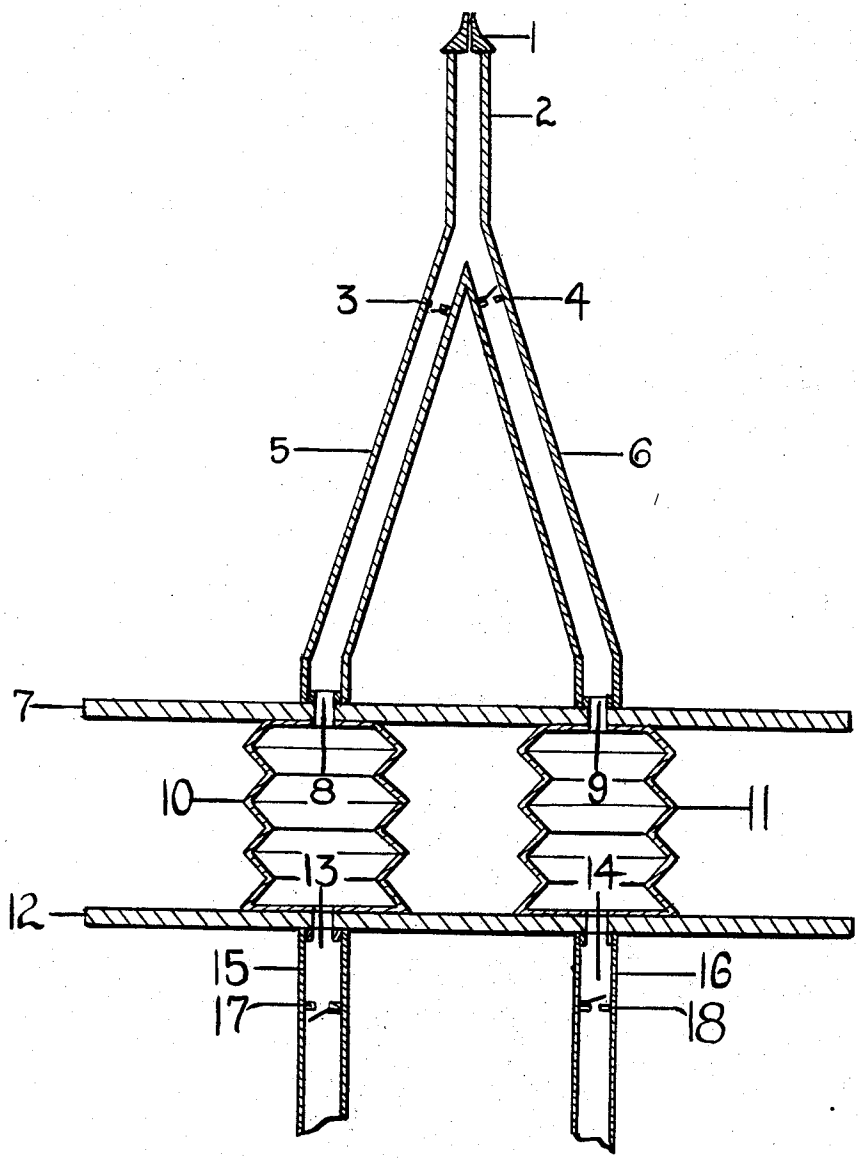

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APPARATUS FOR EXCHANGING BODY FLUIDS

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ABSTRACT OF THE DISCLOSURE

This invention relates to a method and apparatus suitable for the removal of fluid from vital or non-vital systems and its co-incident replacement therein. Specifically, this disposable device of plastic is suitable for effecting substitution of blood in a new-born infant by uninterrupted procedure. It is an exchange transfuser consisting of a flexible Y-shaped tube having its stem adapted for connection to the infant and its outflow and inflow branches equipped each with a bellows pump rigidly coupled together and adapted for manual operation.

In particular this invention is of significance to those skilled in the art of medicine and surgery who may be responsible for carrying out such clinical procedures as exchange transfusion or irrigation.

In the first instance, such procedure is required when the blood of a new-born child is known to have derived the anti Rh factor agglutinin from its mother; a condition which develops from the following causes. Corpuscles in the blood of 85% of the white race contain agglutinogen, a substance found in the blood of Rhesus monkeys; this type of blood is said to be Rh positive. The remaining 15% whose blood does not possess aggultinogen are said have type Rh negative blood.

The blood of a new-born child may contain the Rh positive factor agglutinogen inherited from the father, while the mother's blood may be Rh negative. In such a case red cells have escaped from the foetus into the blood of the mother during pregnancy and stimulated the production of anti-Rh factor in her tissue cells.

The mother suffers no ill effects, but the foetus, having derived the anti-Rh factor from the blood of the mother, is seriously affected by the cell-destructive or hemolytic action of the agglutinin; the condition is known as erythroblastosis foetalis and is usually fatal.

To avoid fatal consequences of the blood of the new born child so threatened is withdrawn by means of a syringe, replacement of the blood being made immediately.

During the cycle of exchange transfusion the syringe holding the blood must be disconnected from time to time for introduction of anticoagulant such as heparin and then reconnected to the intravenous needle usually inserted into the umbilical vein. The procedure is time-consuming and can be precarious to the life of the child who would be in less danger if the cycle of exchange transfusion were carried out more quickly and simply; this, we claim, our invention makes possible.

In the second instance, similarly operated, this apparatus is also suitable for use during irrigation of the bladder. For this application the inlet port of the delivery bellows is connected to a reservoir of irrigation fluid such as isotonic saline or other antiseptic solution, the output orifice of the same unit is connected to catheter which is introduced into the bladder through the urethra. The outlet port of the removal bellows is connected to a tube which discharges, as in the procedure of exchange transfusion, the waste fluid into a container.

The present apparatus used in the procedure of exchange transfusion employs a syringe fitted with a three-way stop-cock, one way communicating between the syringe and the vein and carrying new blood towards the vein or removing unwanted blood from the vein, a second way communicating between the syringe and the new blood supply and a third way communicating between the syringe and the waste container. The four cycles of blood flow which can be carried out by manipulating the stop-cock as described are:

	Position
(1) Inject blood into vein	1
(2) Withdraw waste blood from vein	1
(3) Eject waste blood from syringe	2
(4) Draw in new blood from reservoir	3

Instead of using, as is now practised, one syringe adapted for 4-cycle operation which must be successively emptied and refilled, we prefer to use the double bellows-type device which during one compression and one relaxation cycle carries out the four functions described. Two hands are required to manipulate the syringe, one hand only the bellows device.

Two plastic bellows of approximately 20 cc. capacity each are mounted between the parallel surfaces of two flat, oblong rigid plates; each unit has an orifice at each end to which a plastic tube is firmly fitted. The bellows units are mounted side by side between the flat plates to which they are attached. Each orifice of the bellows units is so formed as to communicate through a hole in the plate with one of the four tubes which is attached thereto.

When the bellows is successively relaxed and compressed new blood is drawn into one orifice and ejected from the opposite orifice respectively. A one-way valve opening forward in each tube allows the blood to flow from the supply bottle to the needle adapter.

By grasping the two parallel plates between the thumb and fingers, both bellows units may be compressed and relaxed simultaneously.

The second bellows unit is similarly fitted with a tube at each end through one of which the unwanted blood is drawn from the patient and discharged through the other into a waste container by the same successive relaxing and compressing cycle. The withdrawal line is also equipped with a one-way valve in each tube so oriented as to prevent the return of the unwanted blood to the needle-adapter.

Both the new blood conduit and the unwanted blood conduit carry blood in opposite directions but each is connected to the needle-adapter through a branched "Y" fitting. When blood is being propelled through the needle the bellows assembly is under compression thereby closing the valve in the exhaust leg of the "Y" and preventing the new blood from being diverted directly into the waste container.

The flow-rate at which the blood passes into the patient is determined by the internal diameter of the needle which is being used. Any excessive pressure applied by the operator causes the bellows plates to deviate from parallel. Such excessive pressure is extremely difficult to apply, because the two bellows units, being of equal volumetric capacity, not only balance each other's movement, but also, in so doing, ensure that the patient's blood system remains in hemodynamic balance with the supply and drainage lines.

This is explained by the fact that as the bellows unit in the new blood delivery line relaxes and draws in its next aliquot from the supply bottle, the bellows in the collection line also relaxes by the same amount, thereby removing an identically equal volume of unwanted blood from the patient. In the next part of the cycle these two equal volumes are discharged simultaneously in opposite directions one through the needle adapter and the other through a "waste" tube.

When a system carrying live blood is interrupted by

disconnection and reconnection, the blood thereby exposed to air not only becomes unsterile but is likely to clot. Clots so formed may then be accidentally returned by the pumping action to the patient's system, with embarrassing and sometimes fatal results. It is therefore most desirable that such apparatus be replaced by a system that does not require to be disconnected and re-connected during operation. Such improvement and added safety-factor is incorporated in our invention as already described.

Also, the presently available method requires the surgeon to measure successive aliquots of about 10–15 cc. of blood, a procedure which depends for its success on the absence of human error, and not on automatic equilibration of the hydraulic system which our invention provides.

The complete assembly can be made of a plastic material such as polyvinyl chloride at a cost low enough to permit of its being discarded after use. Before use it can be contained sterile and hermetically sealed inside a plastic package.

Referring to the drawing it will be seen that

FIG. 1 shows a diagrammatic view of the apparatus wherein, needle adapter tip **1** froms the termination of the common tube **2** which branches into one-way valve openings **3** and **4** into collection tube **5** and delivery tube **6** respectively. Flat mounting plate **7** has holes **8** and **9** communicating respectively with orifices in collection and delivery bellows units **10** and **11**. Flat mounting plate **12** has holes **13** and **14** also communicating with orifices in collection and delivery bellows units **10** and **11** respectively. Collection bellows **10** communicates with discharge tube **15** which is fitted with one-way valve **17** and delivery bellows **11** communicates with blood-supply tube **16** which is fitted with one-way valve **18**. The apparatus is designed to be operated with one hand. The operator is therefore able to stabilize the patient in position. Bellows **10** and **11** are first compressed and tubes **16** and **15** connected to blood supply and discharge vessels respectively. Bellows are then relaxed, valve **18** opens and **17** closes and blood flows from supply into delivery tube **6**. Compressing the bellows then opens valve **4** and closes valve **3** so that needle and common tube **2** may be filled. Needle is inserted into vein and bellows relaxed. Valves **4** and **17** close, valves **3** and **18** open while bellows **10** and **11** are controllably filled with discharge and replacement blood respectively. The following compression stroke causes valves **4** and **17** to open and valves **3** and **18** to close while replacement blood is controllably delivered into the vein and waste blood discharged.

We submit that our invention embodies the advantages described, such as simplicity of operation, safety, sterility and low cost, and, what is most vital, that clots cannot form and be pumped back into the patient. These measurably advance the frontiers of the science of pediatric technology.

Having described our invention in detail and illustrated by drawings its structure and appearance we claim:

1. A pumping device for use during surgical liquid exchange procedures on the body, such as blood exchange transfusions or bladder irrigations consisting of first a delivery bellows unit and second a collection bellows unit having each an inlet and an outlet orifice in axial alignment, each of said bellows units being so formed in an accordian-like configuration of resilient plastic material as to remain in extended form when relaxed, said delivery and collection bellows units being coupled together by a first flat plate of rigid material having openings formed therethrough within which the said delivery outlet and collection inlet orifices are connected to delivery and collection tubes respectively which are in turn connected together at a common junction to from a single terminal tube, the end of said terminal tube being provided with means for attachment to the body, together with a second flat plate of rigid material having openings formed therethrough within which the said delivery inlet orifice and the said collection outlet orifice are firmly attached terminating thereafter each in a tube, the delivery inlet tube having a valve means therein opening only in a direction toward the delivery bellows and the collection outlet tube having a valve means therein opening only in the direction away from the collection bellows, the delivery outlet tube having a valve means therein opening only in a direction away from the delivery bellows and the collection inlet tube having a valve means therein opening only in a direction toward the collection bellows, said first and second flat plates being adapted to move freely in parallel relationship to and from each other. Whereby treatment liquids may be infused into, and discharged from the body simultaneously by compression and expansion of both bellows units when said flat plates are moved toward and away from each other.

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