A Negative Pressure Alarm for Use in Neonatal Extracorporeal Membrane Oxygenation

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Abstract

(*J. Extra-Corpor. Technol.* 20(2):63–66) The following is a design for a simple, inexpensive negative pressure alarm, with specific applications in neonatal Extracorporeal Membrane Oxygenation (ECMO).

In a typical roller pump driven ECMO system, if the pump flow rate exceeds the heart's venous return, or if for any reason there is insufficient blood flow into the tubing system, the negative pressure alarm disables the pump and activates alarms.

The unavailability of such a modular device, through commercial manufacturers, has facilitated the need for ECMO centers to fabricate their own alarm systems.

Introduction

Extracorporeal Membrane Oxygenation (ECMO) is the term generally used to describe the use of extracorporeal blood circulation and gas exchange to provide life support for newborn infants that are suffering from life threatening respiratory dysfunctions. The procedure has been used successfully for the last ten years, and has seen much wider use in the last three. Prime candidates are those patients who do not respond optimally to medical and ventilatory treatment[1].

As of this writing, there are approximately forty ECMO centers in the United States and Europe.[2] Many hospitals are interested in offering this treatment, but are unable to for various reasons. One of these reasons is the commercial unavailability of a negative pressure alarm system, a component deemed necessary in all ECMO systems.[3]

A typical ECMO system, as shown in Figure 1, incorporates many disposable and reuseable components, among the latter, a negative pressure alarm. If for any reason there is insufficient blood flow into the ECMO system, a blood-filled reservoir will collapse. This causes a microswitch to be activated, which shuts the roller pump down and activates both audible and visual alarms. Disabling the pump prevents a vacuum from being drawn on the venous side (blood input) of the system.[4]

Some hospitals who are fortunate enough to be able to design and build their own negative pressure alarms have done so. Most of these alarm systems have been designed around the SciMed R-50-1 "venous blood reservoir,"[a] a limited production, disposable 50 ml silicone "bladder" that has many potential problems, the most notable of which is the sheer volume. Building the necessary sensing mechanism and the associated electronics around this reservoir is not an easy task.

The design detailed in this paper is an attempt to simplify the negative pressure alarm/reservoir combination. The hardware involved is chaste in construction and relatively inexpensive to produce (approximately $240.00 in parts, see Table 1). The associated disposable reservoir is readily available commercially, and is both lower in volume and much less expensive than the SciMed product.

This alarm system can be adapted to most roller pump-driven neonatal ECMO systems currently in use. It has been used clinically in this hospital, with a similar design used in over fifty ECMO cases.

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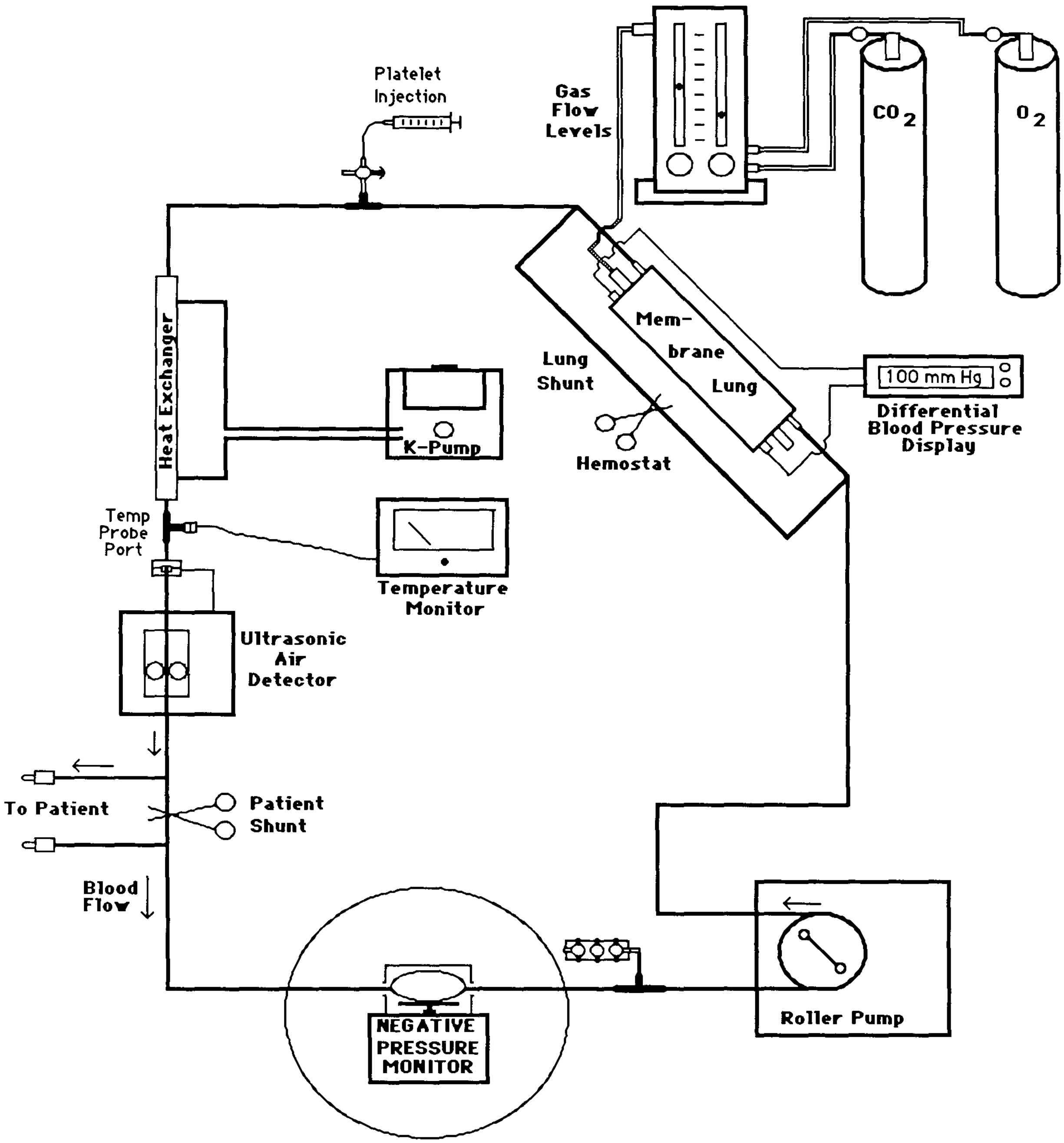

Figure 1: ECMO System Block Diagram

Materials and Methods

The negative pressure alarm detailed in this paper has been designed around the Gambro "arterial pillow"[b] (see Figure 2), a 5 ml polyvinylchloride reservoir readily available as part of the G500 hemodialysis blood line (list price under $20.00, compared to $188.00 for the SciMed "venous blood reservoir"). The G500-type bloodlines for the Gambro AK-10 hemodialysis system are also available from a number of other manufacturers, such as Travenol and Cobe. A product comparable to the Gambro pillow is the Lifemed© B87-021-39 "pillow with side

b Gambro, Newport News, VA, 23607

c Lifemed, Compton, CA 90220

Table 1

Parts List (with approximate prices)

F1—FUSE, 4A slo-blo, Littlefuse (Des Plaines, IL., 60016) #313004, @ $0.55 w/panel mount fuse holder, #345613, @ $1.32.

T1—TRANSFORMER, 12v, 2A, SPC Technologies (Bensenville, IL., 60106) type R-1900, @ $11.70.

B1—BRIDGE RECTIFIER, GTE Sylvania (Waltham, MA., 02154), # ECG 5309 @ $2.19.

C1—CAPACITOR, electrolytic, 2100 uf @ 35 vdc, Sprague (North Adams, MA., 01247) #212G035GJ6 @ $3.22.

S1—SWITCH ASSEMBLY, #KO-4511A, @ $144.00; **HEAD ASSEMBLY,** #KO4510A @ $16.20; and **O-RING,** #100 318 054 @ $2.30 (Gambro, Newport News, VA., 23607).

K1—RELAY, contact rating 5 A @ 120 vac; coil 12 v, 24 ohms; DPDT Potter & Brumfield (Princeton, IN., 47671) #KUP14D15 @ $9.63; with mating 8 pin socket, #27E121 @ $3.53.

NE 1—NEON INDICATOR, red Leecraft (Long Island City, NY., 11101) #32-2111 @ $2.93.

AC OUTLET—Hospital Grade, parallel blade with "V" ground, 125 vac, 15A Hubbell (Bridgeport, CT., 06602) #5256 @ $11.00; **AC PLUG with POWER CORD**—Hospital Grade front plug, Hubbell #8215C, @ $9.52; w/16-3 type SJT power cord @ $0.50 per foot.

SONALERT, 6-28 vdc, 3-14 mA, P.R. Mallory & Co., Inc. (Indianapolis, IN., 46206) #SC 628, @ $9.43.

ENCLOSURE—BUD Industries (Willoughby, OH., 44094) type CU-347 (7" × 3" × 5"), @ $15.20.

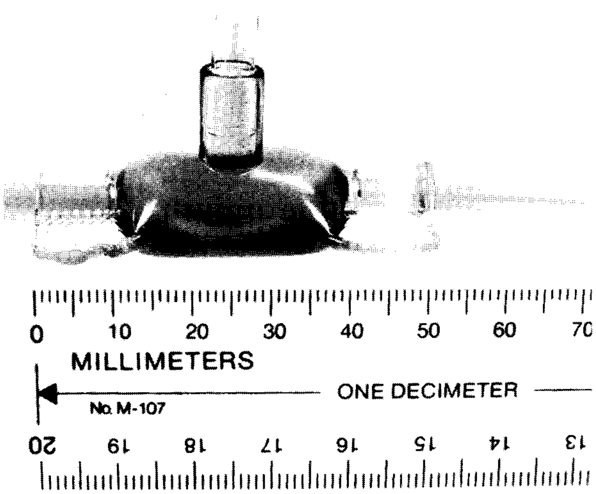

Figure 2: "Arterial Pillow"

port," which can be purchased singly for approximately $190.00 per thousand.

The pillow is streamlined in design to facilitate laminar flow and has little dead space where blood could clot. The manufacturer has specified negligible resistance to blood flow at rates up to 650 ml/min. It's 3/16" I.D. tubing connections can be incorporated into a larger size tubing system with appropriate adaptors. The pillow has a 3 inch long, 1/8" I.D. tubing stem molded into its body for the purpose of saline priming. For ECMO, a stopcock can be installed on this line and used for injection of packed red blood cells and plasma.

In the ECMO system shown in Figure 1, the roller pump is powered by the negative pressure alarm through relay K1 (Figure 3). The negative pressure alarm itself is an electromechanical device which monitors blood volume of the pillow. In the event of a negative pressure situation, the pillow will collapse, at which time a plunger-activated microswitch (with adjustable sensitivity) stops the roller pump, and activates both audible (2.9 KHz continuous tone, 70db Sonalert) and visual (red neon) alarms. When the problem is resolved and the reservoir refills, the spring-loaded microswitch automatically resets and reactivates the pump for continued normal operation.[5]

One of the most attractive features of this design is the incorporation of the commercially available (from Gambro) pillow housing/sensor switch assembly ("S1", see Parts List, Table 1). Together with the pillow, this assembly affords great sensitivity, which is continually adjustable by rotating the platform on which the pillow rests, i.e., threading it up or down the plunger shaft. The switch assembly incorporates an alarm bypass mode (inherent in the original manufacturer's design) which is activated by pulling the platform forward into a detented position.[6] In this situation, the pump is allowed to function, even if the pillow is collapsed.

The schematic diagram shown in Figure 3 gives a good indication of how extremely basic and simple the design is. Any electronics technician should be able to fabricate the entire device with a minimum of effort. All parts (other than the Gambro switch assembly) can be pur-

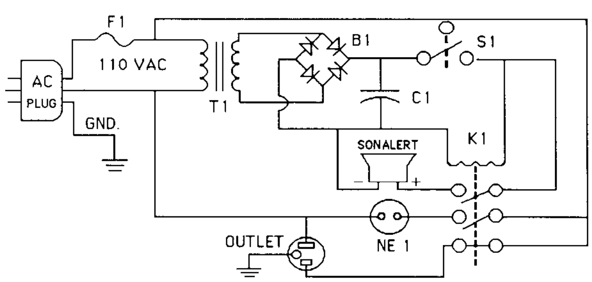

Figure 3: Schematic Diagram of Negative Pressure Alarm

chased through an electronics supply company (such as Newark Electronics, Chicago, IL).

A suggestion for the physical construction of the negative pressure alarm is shown in Figure 4. All of the components can be mounted in a relatively small enclosure, (the one shown is made of cast aluminum) with heavy rubber feet for stability.

Discussion

As long as an occlusion type roller pump is used to drive an ECMO system, the presence of a negative pressure alarm is necessary for both patient safety and success of the therapy.

The negative pressure alarm described in this paper offers an alternative to the "bladder box"[4] type pump controller. It is of a straightforward design, making it easy and economical to build. Used in conjunction with the Gambro "arterial pillow," the system affords great sensitivity, accuracy, and dependability. It has been used clinically at this hospital, with a similar design used in over fifty ECMO cases.

A further step in automating an ECMO system is the use of the negative pressure alarm in servoregulating roller pump speed. The RPM of certain pumps can be controlled by sensory signals originating at the negative pressure pillow, obtained from a pressure transducer or linear potentiometer. This does, of course, require modification of the pump electronics.

Currently, there is a tremendous amount of room for improvement in the ECMO field. Innovations, both major and minor, are being made on a continual basis, albeit slowly, by all the ECMO centers and a handful of manufacturers. Until such time as industry intervenes and markets an ECMO 'machine', hospitals involved in this life-saving procedure should continue to share ideas, working for the refinement of ECMO technology. Hopefully this will lead to a safer and more user-friendly ECMO system.

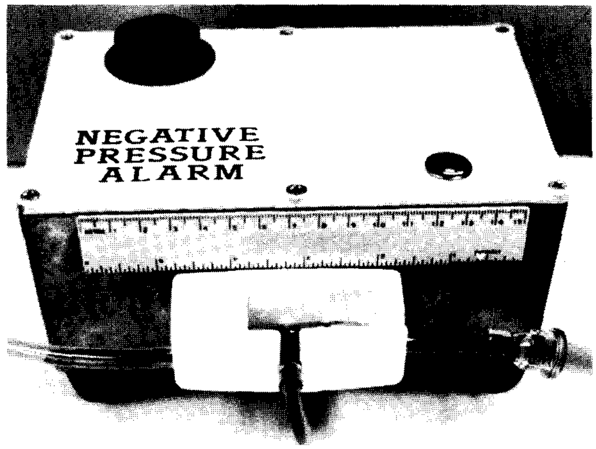

Figure 4: Negative Pressure Alarm

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