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QUARTERLY PROGRESS REPORT
BIOMEDICAL ENGINEERING SUPPORT

Contract E(11-1)-2155-16

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Third Quarterly Report

for

February 16, 1975 to May 15, 1975

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SUMMARY:

During the quarter covered by this progress report (February 16, 1975 to May 15, 1975), one implantation experiment was conducted to continue development of surgical procedures as well as to assess the overall performance and adequacy of the ERDA Blood Pump and ventricles. This experiment was directed primarily at determining and evaluating pump and ventricular efficiency, improving surgical procedures and evaluating the application of a stainless strap encompassing the ventricles to prevent possible interference during pumping from surrounding tissue and organs.

Experiment No. 18 (ERDA) was scheduled as a long-term experiment in a 110 kg male Holstein calf. The electric motor was implanted in the abdomen which powered ERDA Blood Pump No. 2 via a 3/16" flexible drive shaft.

During the experiment, after implantation of the ERDA Artificial Heart System and initial operation, and just as the calf was being taken off heart-lung bypass, the implanted electric motor stopped operating. In spite of efforts to reinstate operation, the electric motor continued to operate sporadically. Subsequent analysis of the motor after termination of the experiment revealed moisture and corrosion products which were sporadically short circuiting the motor. Two new electric motors have been obtained and are presently being prepared for future experiments. Both of these motors will be available during future experiments to preclude animal loss due to electric motor failure.

Mr. Lee Smith has devoted 80% of his time to this contract during the reporting period. Furthermore, Dr. Gary Sandquist has devoted 33% of his time to the contract during the quarter and Dr. Don Olsen has devoted 25% of his time to the contract during the quarter. Contract requirements are thus being filled.

I. SUMMARY REPORT ON TOTAL ARTIFICIAL HEART
REPLACEMENT EXPERIMENT ERDA 18

Experiment (TH 75 C 14 ERDA 18): Conducted on May 29, 1975

Experiment No. 18 was planned as a long-term sterile experiment to evaluate the ERDA Blood Pump, a device to prevent ventricle obstruction, the reinforced flexible drive shaft and casing, and to improve surgical procedures. ERDA Blood Pump No. 2 was used with Avcothane Elastomer-51 ventricles and a smooth intimal surface. The ventricles were fitted with Bjork-Shiley pyrolytic carbon valves. This ERDA Blood Pump was also fitted with a stainless steel strap encompassing the flexible ventricle dome to prevent obstruction of ventricle motion. The Blood Pump was to be driven via the flexible shaft by a water cooled electric motor implanted in the abdomen.

The Blood Pump and drive shaft assembly were sterilized with ethylene oxide prior to surgery. The calf was anesthetized with Brevane followed by fluothane. Parameters to be monitored during the course of the experiment were aortic pressure, central venous pressure, left arterial pressures, right arterial pressures and pulmonary arterial pressures. Other parameters measured were motor speed, torque, electric motor temperature and vacuum maintained inside the Blood Pump.

Surgical Procedure: The calf was a 110 kg male Holstein calf in very good health. The implantation team consisted of Drs. Don Olsen, Clifford Kwan-Gett, Vittorio Ceccarelli and Mr. Chris Kesler, with Lowana Reese (surgical nurse) handling the instruments. The sternal split surgical procedure was uneventful, the heart was removed and the atrial cuffs and Dacron and vascular grafts were sutured using the standard procedure. The intramuscular pocket for the

electrical driving motor had been prepared in advance of heparinization, as usual. The ERDA Blood Pump had a stainless steel metal strap encompassing the collapsible dome, in an effort to keep these domes from being impinged upon by the thorax of the calf. This strap, like the Blood Pump, had been covered with polyurethane. The two components were wired together with bare stainless steel wire. The Blood Pump was connected (in the usual procedure) to the flexible drive shaft, which was tunneled from the thoracic cavity to the sternum, very close to the zyphoid cartilage. The driveshaft continued back into the pocket previously prepared to receive the electric motor. The umbilical cord from the electric motor was passed through the transcutaneous incision and the electric motor was connected to the flexible drive shaft. The motor was powered momentarily to ensure correct connection to the Blood Pump.

The left atrium and aorta were connected first, followed by the right atrium and the pulmonary artery. Blood returning to the left atrium by way of the bronchial arteries was sufficient to fill the left ventricle and the tourniquet around the inferior vena cava line was loosened to fill the right ventricle. The Statinsky was removed from the pulmonary artery and aorta, and the pump was started. The chest was immediately filled with 2 - 2½ liters of saline to submerge the atrial cuffs, and the tourniquet was loosened on the superior vena cava cannula and the azygous vein. The ERDA pump began pumping as the cardio-pulmonary bypass was weaned. All parameters seemed stable and no serious leaks developed (some belt loops on the atrial and pulmonary quick connects had to be tied down with umbilical tape). The inferior vena cava return line and the superior vena cava return line were removed and protamine sulfate started. After approximately 75 cc of the protamine sulfate containing

saline had been administered the Blood Pump stopped. The pusher cups were free and it was determined that current was being drawn by the electric motor. The surgeons immediately stopped the protamine sulfate and hand massaged the pusher cups, pushing them from right to left side, maintaining very low aortic pressure. After approximately 2 minutes of being unable to get the Blood Pump started again the superior vena cava line was returned in place and the calf was returned to partial bypass. A rapid attempt was made to evaluate the problem. It was found that when the electric motor was disconnected from the drive shaft, the motor would run. However, the torque generated by the electric motor was inadequate for full perfusion. A hemostat was placed on the motor end of the drive shaft and the Blood Pump could be continuously rotated, the least resistance encountered during the spring loaded right ventricular systole. The flexible drive shaft was removed and examined and found satisfactory. However, every time the motor was rejoined to the drive shaft, it would cease running. Then for some unknown reason the pump started functioning again. After 2 or 3 minutes the calf was taken off bypass and the surgeons started the protamine sulfate and began placing the chest drains in preparation of closing the thorax. The arterial cannula was removed after all of the blood within the blood oxygenator was recovered. Again, the electric motor stopped, and attempts to restart were unsuccessful. It was too late to return to cardio-pulmonary bypass because of the administration of the protamine sulfate and the fact that the tubes had all been removed from the surgery table. So, the experiment was terminated. Then for some unknown reason the Blood Pump began functioning again. At this point it was suggested that the pump be allowed to operate in the animal until it was discovered why operation was sporadic. Dr. Kwan-Gett increased the resistance

in the aorta and the motor did not stall out even when high resistance was applied to the left ventricular outflow tract. Dr. Olsen turned off both the electrocautery units and as he unplugged the second ground plate from the one electrocautery units, the electric motor stalled. It became apparent that the electric motor could be grounded at will by contacting the electrocautery ground plate to either the electrocautery or the stainless steel table containing the power supply for the electric motor. Obviously there were electrical shorts in the system. Furthermore, it was apparent that a short within the electric motor itself existed. Thus, electrical current would go through the power control module into the electric motor, down the drive shaft, into the Blood Pump and from the Blood Pump out into the body ground, returning to the electrocautery unit. Subsequent analysis and assessment of the situation pointed to essentially two grounding paths, one within the electric motor and the other between the Blood Pump itself and the body of the calf.

CONCLUSION

After removal of the electric motor from the calf, the motor was carefully disassembled. Moisture and corrosion products were found within the encapsulated motor. Preliminary tests showed that these contaminants were capable of short circuiting the motor and producing sporadic operation.

Two new electric motors have been obtained and tested. They are now being fitted with cooling coils, tested and encapsulated. The additional motor will provide a backup unit which will be available during future ERDA Total Heart Replacement Experiments.

II. STORAGE FACILITY FOR PLUTONIUM-238 HEAT SOURCE

The storage room at the Institute for Biomedical Engineering's Saint Mark's facility has been completed, i.e. refurbished, equipped and instrumented for receiving and storing the PuO_2 heat sources used in the ERDA Artificial Heart System. The monitoring system for indication of forced entry, high radiation or fire in the storage room is operational and is now being tested monthly for satisfactory long-term operation.

During a recent visit by Westinghouse personnel, i.e. Mr. Don Roberts and Dave Puchot, at Saint Mark's an examination was made of the proposed rooms and facilities to be used in testing, preparing and implanting the thermal convertor with an implaced PuO_2 heat source in an experimental animal. Some modifications of the Westinghouse equipment seems necessary to accomplish such an animal experiment and these modifications are in progress.