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July 28, 1972

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RE: Annual Report (AT 11-1 - 2155-5)

Dear Dr. Mott:

Enclosed are five copies of the Annual Report for the above contract for the year 1971-72. We would appreciate your reviewing this report - make the necessary corrections or suggestions and return to us. We will then mail you ten corrected copies.

Sincerely yours,

Francis M. Donovan, Jr., Ph.D.

FMD:mj
Encl. (5)

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ANNUAL REPORT

TITLE: BIOMEDICAL ENGINEERING SUPPORT

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July 15, 1972

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ABSTRACT

The purpose of this research was to provide the artificial heart design information necessary for the proper development of an implantable nuclear power supply for the artificial heart. A Kwan-Gett hemispherical artificial heart made of silicone rubber was attached to a mock circulation instrumented with pressure, volume and flow transducers and measurements made of power input to the artificial heart at various locations, source of power losses and efficiencies of the artificial heart under a variety of pumping conditions, volumetric efficiency, pressure required to move the diaphragm of the artificial heart, required motion of the heart diaphragm and pumping characteristics of the artificial heart. The in vitro measurements have been verified by in vivo experiments in calves. The preliminary design of a pumping chamber for the nuclear powered heart has been completed.

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INTRODUCTION

At the present time, nuclear engines are being designed and developed by several groups in the United States to provide a totally implantable power supply for the artificial heart. The design information concerning the power and forces required by the artificial heart which is necessary for the proper design of an implantable power supply is not available in the literature. The purpose of this research was to provide the required design information which includes the power input, source of power losses and efficiencies of the artificial heart under a variety of pumping conditions, volumetric efficiency, forces required to move the diaphragm of the artificial heart, required motion of the heart diaphragm, the pump characteristics of the artificial heart, measured power input to the artificial heart in calves, pumping characteristics of the artificial heart in calves, predicted average input power, peak power, and daily power profile of the artificial heart in human. The Kwan-Gett hemispherical artificial heart (1) made of silicone rubber and equipped with flap inflow and tricuspid outflow valves was used for this research.

A preliminary design of the pump chamber of the nuclear powered artificial heart has been conceived at the University of Utah and is being developed in cooperation with Westinghouse Astronuclear Laboratory.

THERMODYNAMICS OF THE ARTIFICIAL HEART

METHODS:

I. In Vitro Determination of Power Force, Efficiency and Pump Characteristics of the Artificial Heart.

A schematic diagram of a Kwan-Gett artificial ventricle is shown in Figure 1. The artificial heart replaces the natural heart inside the chest, and is driven by compressed air which is supplied by an external power unit via two 3/8 inch internal diameter 6ft Tygon tubes (one for each ventricle) which pass through the chest wall. The following powers were measured in vitro for the left artificial ventricle (refer to Figure 1):

1. Power input to the air drive line
2. Power input to the air chamber
3. Power input to the diaphragm
4. Power output from the diaphragm to the blood
5. Power input to the arterial blood

A venturi meter combined with an analog computer (Figure 2) was used to measure the input power to the air drive line. The differential pressure transducer measured the pressure drop in the venturi meter and produced a signal which was converted by the function generator into a flow signal. The multiplier produced a power signal ($\dot{E}_a$) from the air pressure (P_a) and flow (Q_a) signals according to the equation:

$$\dot{E}_a = Q_a P_a \quad (\text{Equation 1})$$

Since only the input power was of interest, a switching circuit was used to set Q_a equal to zero during backflow of air from the system. Figure 3 shows

air flow rate, air pressure and power wave forms at the distal end of the air drive line (location 1 of figure 1).

The power input to the air chamber was measured by moving the venturi meter to the proximal end of the air drive line (location 2 of figure 1).

The power transfer across the moving boundary of a cyclic system is given by the equation:

$$\dot{E} = R \int P dV \quad (\text{Equation 2})$$

where R is the cycle frequency

P is the pressure in the system

V is the volume of the system

The symbol $\int$ refers to integration over one complete cycle.

Equation 2 was used to calculate the power input to the diaphragm (location 3 of figure 1) by setting R equal to the heart rate, measuring P in the air chamber with a transducer and using a volume sensing mock circulation to determine V. A schematic diagram of the mock circulation is shown in figure 4. Fluid is pumped into the arterial reservoir by the artificial heart, drains through the resistance valve and flow-meter into the venous reservoir and finally returns from the venous reservoir back to the heart. The mock circulatory system is rigid, but the arterial compliance is maintained at 1 ml/mmHg and the venous compliance at 25 ml/mmHg by air pockets in the reservoirs. Since the entire system is rigid except for the heart diaphragm, any change in the volume of fluid in the heart will result in an exact change in volume of fluid in the mock circulation and in the volume of air in the air pockets. Because of the frequency of oscillation of volume of the air chambers (70 to 120 cpm), the process is essentially adiabatic so that the pressure volume relationship of the air is:

$$P_a = (C_1/V_a)^r \quad (\text{Equation 3})$$

when P = absolute air pressure

V_a = air volume

r = specific heat ratio for air

C_1 = constant

Because of the relatively small changes in volume, the relationship can be approximated with an error of about 1% by the equation:

$$P_a = C_2 V_a \quad (\text{Equation 4})$$

The change of air volume of the air chambers was determined by measuring the pressure changes in the air pockets and adding the signals. The resulting volume signal was a direct indication of the amount of fluid in the artificial heart and because of the relatively rigid housing of the heart, a direct indication of the volume of air in the air chamber of the heart. The air volume and air pressure signals were placed on the vertical and horizontal axes of an oscilloscope and a photographic record of the resulting P-V diagram integrated over one cycle with a polar planimeter.

The same procedure was used to determine the power output from the diaphragm to the blood. The variation of volume of the artificial heart with time is shown in Figure 5. A typical pressure-volume diagram of the blood chamber of the artificial heart is shown in Figure 6.

The power input to the arterial blood was calculated by the equation:

$$\dot{E}_A = \bar{P}_A \bar{Q}_A \quad (\text{Equation 5})$$

where

$\bar{P}_A$ is the mean arterial pressure

$\bar{Q}_A$ is the mean arterial flow rate

This equation as written is valid only for non-pulsatile flow, but it is commonly used to calculate cardiac output power. A calculation by the author using a mean pressure of 100 mmHg and a pulse width of 40 mmHg with a sinusoidal arterial pulse wave and constant arterial resistance indicated that the calculated power is about 8% less than the true power. Even though the error exists in Equation 5, it was used because power calculations in vivo are commonly done this way, and the predicted power requirements of the artificial heart in humans were determined using this equation. The arterial pressure in the mock circulation is shown in Figure 7.

II. Power Input to the Artificial Heart and Pumping Characteristics in Calves.

In order to verify the mock circulation measurements, an artificial heart of exactly the same design was implanted in an 84 Kg female calf and measurements made of femoral venous and femoral arterial pressure, distal air drive line pressure for right and left ventricles, average power input, instantaneous power input and instantaneous air flow rate into the air drive line of the left ventricle. The animal survived for 117 hours and was terminated because of a severe chest infection. A sample of the measurements is shown in Figure 8 which was recorded at 82 hours after total heart replacement. Corresponding measurements on the mock circulation are shown in Figure 9. The similarities in these figures clearly indicate the behavior of the artificial heart in vivo is essentially the same as in vitro. The cardiac output of the artificial heart in this particular animal was estimated by comparison with the mock circulation data. A more direct method of determining

cardiac output of the artificial heart in calves was developed and used in subsequent experiments.

A photograph of the typical air pressure wave form measured at the distal end of the air drive line of an artificial heart which is pumping at less than maximum output is shown in Figure 10. The solenoid valve in the drive system opens at point A which is the beginning of systole. The air pressure builds up to a level sufficient to begin moving the heart diaphragm at point B. The heart empties during the period from B to C where the diaphragm reaches the end of its stroke and the air pressure begins once again to increase rapidly. The solenoid valve closes at point D which is the beginning of diastole. For given conditions in the drive system and fixed heart rate, the time interval B-C is determined by the arterial pressure and the cardiac output. The second derivative with respect to time was produced electronically in order to make the determination of the time interval (t) easier and the entire system calibrated on the mock circulation. A typical calibration curve relating t and arterial pressure to cardiac output is shown in Figure 11. Once the calibrated artificial heart was implanted in an animal, the cardiac output was determined by measuring arterial pressure and t .

The cardiac output and arterial pressure measurements were used to calculate output power of the artificial heart. The in vitro determinations of efficiency were used to calculate power input to the diaphragm of the artificial heart in vivo.

III. Predicted Average Input Power, Peak Power and Daily Power Profile of the Artificial Heart in Humans.

Because of the scarcity of data in the literature relating cardiac output to various types of normal activities in humans, an indirect method

of predicting cardiac output was used. A linear relationship between cardiac output and oxygen consumption has been found by several investigators (2) (3) (4). The rate of change of cardiac output with oxygen consumption was determined from data presented by Guyton (2) and is given by Equation 6.

$$\frac{dQ}{d\dot{V}_{O_2}} = 6.9 \frac{1/\text{min}}{1/\text{min (STPD)}} \quad (\text{Equation 6})$$

where Q is the cardiac output

$\dot{V}_{O_2}$ is the rate of oxygen consumption.

Since the metabolic energy equivalent of oxygen is 4.825 K cal/l, the rate of change of cardiac output with metabolic energy utilization is 6.9/4.825 or 1.43 l/min/Kcal/min. The normal resting cardiac output for adult men has been found to be approximately 6 l/min (2). The cardiac output for various activities was calculated by adding the output required for activity to the resting value as in Equation 7.

$$Q = 1.43\dot{E}_m + 6 \quad 1/\text{min} \quad (\text{Equation 7})$$

where $\dot{E}_m$ is the metabolic energy utilization in excess of the basal metabolism. A daily activity profile was established for a hypothetical 25 year old 68 Kg 173 cm man and a 25 year old 60 Kg 165cm woman based on the reference man and woman described by the Food and Agricultural Organization of the United Nations (5). The metabolic energy requirement of each activity was obtained from references (6) and (7) and the corresponding cardiac output calculated from Equation 7. The power required to drive the artificial heart was calculated from the equation:

$$\dot{E}_h = \frac{Q (P_A + P_P)}{\quad} \quad (\text{Equation 8})$$

where P_A is the aortic pressure

P_p is the pulmonary artery pressure

is the efficiency of the heart.

Mean aortic pressures of 100 mmHg and mean pulmonary artery pressures of 15 mmHg were used in calculating the power. Experimentally measured efficiencies were used. The variations in average power requirements of the artificial heart with weight and with age were calculated from metabolic data given in Reference (7).

RESULTS

All of the in vitro results presented are for a 7 cm diameter hemispherical Kwan-Gett artificial left ventricle made of smooth silicone rubber using a flap inflow valve and tricuspid outflow valve operating at 120 beats per minute with a systolic duration of 42% of the cardiac cycle and an air drive supply pressure of alternate 310 mmHg and 0 mmHg. Except where indicated, mean arterial pressures of 100 mmHg were maintained. The fluid used in the mock circulation was a mixture of 33% Glycerin in water to match the viscosity of blood.

The response of cardiac output of the artificial heart to atrial pressure and arterial pressure is shown in Figure 12. Note that no external control is used so that the response shown is intrinsic in the design of the artificial ventricle.

The average power input to the 5 locations of Figure 1 is shown in Figure 13 as a function of cardiac output. The large power loss between the input to the air drive line and the input to the diaphragm represents the energy wasted in simply compressing the air in the drive lines and air chambers of the heart. The input power to the diaphragm represents the power required to move the heart diaphragm regardless of the method of operating the heart (pneumatically, hydraulically, electrically or mechanically). The power loss in the diaphragm is probably caused by the hysteresis and viscous effects of the material in the diaphragm. The power loss between the diaphragm and arterial blood is caused by fluid frictional losses and valve regurgitation.

The efficiency of the artificial heart as measured at three different locations is shown in Figure 14. The efficiency as measured at the input to

the diaphragm is defined by Equation 9:

$$\text{Efficiency} = \frac{100 (\text{power input to arterial blood})}{\text{Power input to the diaphragm}} \% \quad (\text{Equation 9})$$

The efficiencies at the other two locations are defined in a similar manner. The efficiency measured at the input to the diaphragm is of the greatest interest because this is the efficiency seen by any type of drive system. In the normal range of cardiac outputs of 6 to 12 l/min this efficiency is about 72%. As indicated by the efficiency measured at the output from the diaphragm, about 20% of the power output from the diaphragm is lost in fluid friction and valve regurgitation. The low efficiency measured at the input to the air drive line is a result of using a compressible gas to drive the heart. The effect of arterial pressure on efficiency is shown in Figure 15.

The volumetric efficiency shown in Figure 16 is defined by Equation 10:

$$\text{Volumetric Efficiency} = \frac{100 (\text{cardiac Output})}{\text{Heart Rate} \times \text{Stroke Volume}} \% \quad (\text{Equation 10})$$

In the normal range of cardiac outputs, the volumetric efficiency is relatively constant. The decrease of volumetric efficiency with increasing or decreasing arterial pressure is probably due to the fact that the systolic duration was optimized for peak cardiac output at an arterial pressure of 100 mmHg. The volumetric efficiency of about 90% for arterial pressure of 100 mmHg and the efficiency as measured at the output from the diaphragm of 80% indicate that about one-half of the power loss in the blood chamber of the heart is caused by regurgitation and the rest is caused by fluid friction.

The maximum blood chamber pressures shown in Figure 17 represent the maximum pressure against which the diaphragm must move, regardless of the method used to drive the heart. These curves indicate that in the normal range of cardiac outputs, the pressure drop across the outflow valve is

relatively constant.

The cardiac outputs measured in five total heart replacements in calves are shown in Figure 18.

The power requirements of the artificial left ventricle in five calves are shown in Figure 19.

Tables I and II list the daily proposed activity profile, metabolic energy requirements, cardiac output profile and power profile for the adult male and female human. The powers refer to input power to the artificial heart diaphragm. The power profiles are shown graphically in Figures 20 and 21. The predicted variation of average power requirements of the artificial heart in humans with age and with body weight is shown in Figures 22 and 23.

PRELIMINARY DESIGN OF PUMP CHAMBERS FOR THE
NUCLEAR POWERED ARTIFICIAL HEART

The preliminary artificial heart design shown in Figure 24 was conceived at the University of Utah. The design has been developed jointly by the University of Utah and Westinghouse Astronuclear Laboratory - another contractor to the Atomic Energy Commission on the Artificial Heart - to the device shown in Figure 25 and in detail in Figure 26. Both of these figures are reproduced from the Westinghouse Astronuclear Laboratory quarterly progress report covering the period March 1, to May 31, 1972 (WANL-3043-3) AEC Contract No. AT(11-1)-3043.

The heart consists of a metal ring through which the necessary drive shafts pass and to which flexible ventricles are attached. Each ventricle consists of a sac attached at one side to the mechanical actuator. The actuator moves back and forth along the axis of the heart. This produces alternating pulse in the left and right ventricles.

The heart operates at a fixed rate of 120 beats/minute. Response to Starling's law is accomplished by allowing the stroke volume to change in response to changes in atrial pressure. The housing of the heart is flexible so that it will partially collapse if the heart is only partially filled during diastole. This also provides the reference pressure to the chest cavity so that no other compliance bag is necessary. The heart is designed for a maximum cardiac output of 12 l/min.

The location and shape of the inflow and outflow connectors is shown in Figure 27 which is a photograph of a plaster model of the heart. Figure 28 shows a photograph of the plaster model in the chest of a dead calf.

A silicone rubber pumping chamber is currently under construction with bench testing to begin in August.

SUMMARY

The in vitro measurements indicate that the efficiency as measured at the diaphragm of the Kwan-Gett artificial heart is relatively constant at 72% over the normal range of cardiac output of 6 to 12 l/min. Except for the large loss in the drive air, there are no large power losses in the artificial heart. The volumetric efficiency of the artificial heart is approximately 90% over the normal range of cardiac output for normal arterial pressures.

The in vitro measurements compare very well with comparable in vivo results. The output of the total artificial heart in five calf experiments averages about 7 l/min with periodic increases to 10 l/min and decreases to 4 l/min. The average power input to the artificial left heart diaphragm in calves is about 2 watt with a maximum of 4 watt and a minimum of 0.8 watt. It was assumed that the power required for the right ventricle is 15/100 of the power required by the left ventricle because of the relationship of pulmonary artery pressure to aortic pressure. Based on this assumption, the average power required for the total artificial heart in calves is about 2.3 watt with a maximum of 4.6 watt and a minimum of 0.9 watt.

Calculations of cardiac output for different types of activity based on metabolic and nutritional data in the literature, combined with the experimentally measured artificial heart efficiencies, indicate that the average power required by a 25 year old, 68 Kg, 173 cm male human leading a relatively active life is 2.7 watt with a maximum power requirement during moderate exercise of 4.1 watt. For the 25 year old, 60 Kg, 165 cm female, the average power is 2.4 watt and the maximum power is 3.3 watt. In both the male and female, nutritional data indicate that the average power requirements of the artificial heart decrease slightly with age and

increase slightly with body weight.

Preliminary design of a mechanically driven sac type artificial heart has been completed. A pumping sac is currently under construction with bench testing to begin in August 1972.

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TABLE I

ACTIVITY, ENERGY, OUTPUT AND POWER PROFILES FOR MALE

(Age 25 years, Height 173 cm, Weight 68 kg)

ACTIVITY	DURATION (Hours)	RATE OF ENERGY UTILIZATION (Kcal/min)	CARDIAC OUTPUT (L/min)	POWER REQUIRED TO DRIVE ARTIFICIAL		
				RIGHT VENTRICLE (Watt)	LEFT VENTRICLE (Watt)	TOTAL HEART (Watt)
Sleep	8	0	6	0.28	1.83	2.11
Dressing, Etc.	1	2.12	9.03	0.42	2.80	3.22
Driving	$\frac{1}{2}$	1.62	8.32	0.39	2.56	2.95
Moderate Work	4	1.82	8.6	0.40	2.65	3.05
Walking	$\frac{1}{4}$	3.12	10.5	0.49	3.25	3.74
Lunch	$\frac{1}{2}$	0.26	6.37	0.30	1.97	2.27
Walking	$\frac{1}{4}$	3.12	10.5	0.49	3.25	3.74
Moderate Work	4	1.82	8.6	0.40	2.65	3.05
Driving	$\frac{1}{2}$	1.62	8.32	0.39	2.56	2.95
Moderate Exercise	1	3.82	11.5	0.54	3.54	4.08
Dinner	1	0.26	6.37	0.30	1.97	2.27
Relaxation	3	0.82	7.17	0.33	2.21	2.54

Aortic Pressure 100 mmHg
Pulmonary Art. Pressure 15 mmHg
Basal Metabolic Energy 1700 Kcal/day

Artificial heart efficiency 72%
Average Power Requirement 2.7 watt
Total Metabolic Energy 3294 Kcal/day

TABLE 21

ACTIVITY, ENERGY, OUTPUT AND POWER PROFILES FOR FEMALE

(Age 25 years, Height 165 cm, Weight 60 Kg)

ACTIVITY	DURATION (Hours)	RATE OF ENERGY UTILIZATION (Kcal/min)	CARDIAC OUTPUT (L/min)	POWER REQUIRED TO DRIVE ARTIFICIAL		
				RIGHT VENTRICLE (Watt)	LEFT VENTRICLE (Watt)	TOTAL HEART (Watt)
Sleep	8	0	6	0.28	1.83	2.11
Dressing, Etc.	1	2.32	9.32	0.43	2.88	3.31
Domestic Work	5	0.5	6.72	0.31	2.06	2.37
Lunch	1	0.26	6.37	0.30	1.97	2.27
Driving	$\frac{1}{4}$	1.62	8.32	0.38	2.56	2.94
Walking	1	1.86	8.66	0.40	2.68	3.08
Driving	$\frac{1}{4}$	1.62	8.32	0.38	2.56	2.94
Domestic Work	2	0.5	6.72	0.31	2.06	2.37
Dinner	1	0.26	6.37	0.30	1.97	2.27
Domestic Work	$\frac{1}{2}$	0.5	6.72	0.31	2.06	2.37
Exercise	1	2.0	8.86	0.41	2.74	3.15
Relaxation	3	0.5	6.72	0.31	2.06	2.37

Aortic Pressure 100 mmHg
 Pulmonary Art. Pressure 15 mmHg
 Basal Metabolic Energy 1480 Kcal/Day

Artificial Heart Efficiency 72%
 Average Power Requirement 2.4 watt
 Total Metabolic Energy 2304 Kcal/day

FIGURE 1

AIR LINE POWER MEASUREMENT SYSTEM

FIGURE 2

DISTAL AIR DRIVE LINE

FIGURE 3

VOLUME MEASURING MOCK CIRCULATION

FIGURE 4

VOLUME OF BLOOD CHAMBER

FIGURE 5

FIGURE 6

ARTERIAL PRESSURE

FIGURE 7

ARTIFICIAL HEART DATA FROM CALF

FIGURE 8

ARTIFICIAL HEART DATA FROM MOCK CIRCULATION

FIGURE 9

PRESSURE AT THE DISTAL END OF THE AIR DRIVE LINE

PRESSURE (mmHg)

200

100

0

A

B

C

D

TIME (sec)

0.1

FIGURE 10

CARDIAC OUTPUT CALIBRATION CURVE

FIGURE 11

CARDIAC OUTPUT RESPONSE

FIGURE 12

FIGURE 13

FIGURE 14

EFFECT OF ARTERIAL PRESSURE ON POWER EFFICIENCY AT INPUT TO DIAPHRAGM

FIGURE 15

FIGURE 16

FIGURE 17

CARDIAC OUTPUT OF THE
ARTIFICIAL HEART IN CALVES

FIGURE 18

PUMPING TIME OF ARTIFICIAL HEART - HRS.

AVERAGE POWER INPUT TO DIAPHRAGM
OF LEFT VENTRICLE

FIGURE 19

TOTAL ARTIFICIAL HEART POWER PROFILE
FOR 25 YEAR OLD, 68 Kg, 173 cm MALE

FIGURE 20

TOTAL ARTIFICIAL HEART POWER PROFILE
FOR 25 YEAR OLD, 60 Kg, 165 cm FEMALE

FIGURE 21

TOTAL ARTIFICIAL HEART AVERAGE
POWER VARIATION WITH AGE

FIGURE 22

TOTAL ARTIFICIAL HEART AVERAGE
POWER VARIATION WITH BODY WEIGHT

FIGURE 23

MECHANICALLY DRIVEN ARTIFICIAL HEART

ALL DIMENSIONS ARE IN CENTIMETERS

STROKE VOLUME = 111 ml

DRAWN TO DOUBLE SCALE

STROKE LENGTH = 3.88 cm

FIGURE 24

F. M. Donovan Jr. 2/18/72

FIGURE 25

FIGURE 26

FIGURE 27

FIGURE 28