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Technical note

Integrated unit for programmable control of the 21F Hemopump and registration of physiological signals

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1 Introduction

A RECENT innovation in heart assist devices is the Hemopump (BUTLER *et al.*, 1990; KUNST and ALSTÉ, 1992; WAMPLER *et al.*, 1988), a miniature intra-ventricular blood pump for the support of a failing heart where functional recovery is expected within days. Indications of a failing heart include failure to wean from cardiopulmonary bypass, cardiogenic shock following acute myocardial infarction and high-risk coronary angioplasty (LOISANCE *et al.*, 1990; WAMPLER *et al.*, 1988; WIEBALCK *et al.*, 1993).

The clinical application of the Hemopump to support a failing heart and coronary circulation is still experimental. Major questions concerning its application include the ability to maintain systemic circulation with the Hemopump with its limited maximal flow of approximately 3.5 l min^{-1} , the role of the Hemopump in causing

haemolysis, and the optimal protocol for weaning from the device (WIEBALCK *et al.*, 1993). Furthermore, there is still considerable discussion whether assist pumps should exert their effect with continuous or pulsatile flow (UNGER *et al.*, 1985; YADA *et al.*, 1983). To study such questions, it is preferable that any assist pump can be operated in two ways. This aroused our interest in extending the Hemopump control system to being able to generate various pulsatile flow wave forms.

Our personal interest in the experimental application of the Hemopump was also focused on quantifying the left ventricular pumping function while the ventricle is being assisted by the Hemopump. As this device is meant for a short-term application, the period of weaning from the device may be reduced when the left ventricular pumping function can be quantified at any moment and when signs of recovery can thus be continuously monitored.

Research topics as described above require a system for controlling the Hemopump flow and by which physiological signals (for example, left ventricular pressure and flow) can be recorded and analysed. Such a system is described in this work. The console for controlling the Hemopump in the clinic was found unsuitable under our experimental constraints. Although we realise that our research interest resulted in more specific constraints for controlling the Hemopump, we believe that the basic design of this system is of a more general interest, thus being of use in related research.

2 Architecture

The experimental conditions originating from our research objectives and experimental set-up led to the following functional specifications.

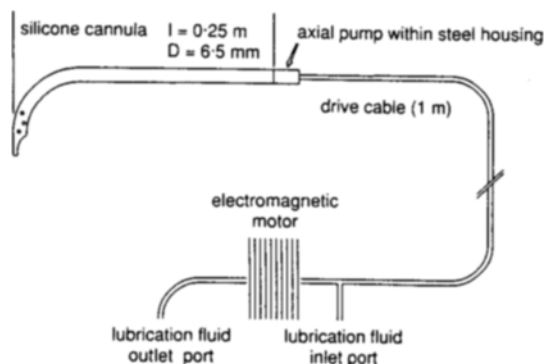


Fig. 1 Schematic representation of the Hemopump

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(a) Continuous adjustment of rotational speed of the Hemopump between 0 and 500 revolutions per second (rev s^{-1}); the clinical console with the Hemopump provides only seven speeds between 17 500 and 28 000 rev min^{-1} (290–470 rev s^{-1}). A possibility of continuous adjustment in that range is not available.

(b) Instantaneous downward reductions in rotational speed synchronous or asynchronous to autonomous heart activity; in our experimental set-up we analysed perturbations in left ventricular pressure caused by significant ECG-synchronised reductions in Hemopump flow (flow-step response). The Hemopump is a continuous flow pump, and thus unlike other types of assist devices, its pumping activity does not need to be synchronised to the autonomous heart activity. It is therefore obvious that the clinical console does not possess a synchronisation feature.

(c) Multichannel data acquisition synchronous or asynchronous to heart activity; in our experimental set-up the ECG was recorded and analysed on-line for R-wave occurrence. On detection of the R-wave, the Hemopump rotational speed could be altered when the experimental protocol required.

(d) Implementation of a user-defined protocol prescribing and generating Hemopump rotational speed as a function of time or heart beat number, and selection of the data channels to be recorded and analysed.

3 Implementation

3.1 Hemopump system

The 21F Hemopump system*, schematically represented in Fig. 1, consists of an axial pump (6 mm diameter, 12 mm length) within a silicone cannula (25 cm length, 6.5 mm inner diameter, 7 mm outer diameter). The axial pump is connected to a steel drive cable incorporated in a double lumen catheter, through which a lubrication fluid is purged. Rotation of the cable and the pump is performed by an electromagnetic motor which, in clinical operation, is placed outside the body. The Hemopump enters the body through the femoral artery and is moved up the descending aorta and the aortic arch until the flexible tip of the cannula passes the aortic valve. Blood is sucked into the cannula and flows out into the aorta.

3.2 Hemopump motor

The Hemopump is operated by a permanent magnet synchronous motor. The stator of this motor contains three coils with which a rotating magnetic field can be generated. The frequency of the control signal applied (either voltage or current) determines the rotational speed. An important characteristic of a permanent synchronous motor is that either the rotor rotates at the rotational speed applied or it does not rotate at all. Additional information on permanent magnet synchronous motors can be found elsewhere (MURPHY, 1989 and SLEMON, 1992).

The motor is operated at 24 V at all rotational frequencies. Motor current I is approximately inversely proportional to rotational speed n due to the self-induction of the stator coils. For reasons of simplicity, we operate the motor under open-loop control, which is suitable for stand-alone operation, gradual increases in rotational speed and instantaneous reductions in rotational speed. During clinical operation, sudden stalling of the motor is not allowed, and thus it is operated under closed-loop control,

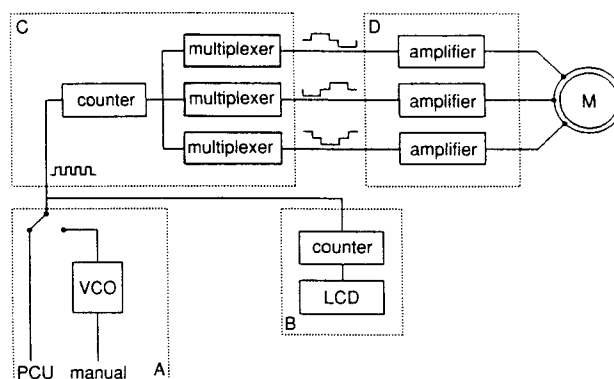


Fig. 2 Block diagram of electronic circuitry for controlling motor rotational speed; (a) pulse train (0–5 V) generated by the personal computer unit (PCU) or by manually adjustable voltage-controlled oscillator (VCO); (b) rotational speed determined and shown on an LCD; (c) digital circuitry for creation of stator coil control signals; (d) control signals amplified to ± 24 V and connected to motor (M)

where stalling is prevented by monitoring the phase angle between the rotating magnetic field and the rotor.

3.3 Data acquisition and control of Hemopump rotational speed

An MS-DOS personal computer was extended with a multi-purpose analogue/digital/digital/analogue (AD/DA) converter card. Such an AD/DA card facilitates multi-channel data acquisition. Furthermore, control signals for controlling the Hemopump rotational speed can be generated. Appropriate software allows the implementation of user-defined protocols which, for example, control the Hemopump rotational speed according to a specific protocol and which provide the tools for data acquisition and analysis.

4 Realisation

Fig. 2 shows a block diagram of the electronic circuitry to provide the Hemopump motor with the appropriate control signals. The circuitry was realised with commercially available components. The rotational speed was determined by a pulse train (Fig. 2a), either generated by a manually adjustable voltage-controlled oscillator (VCO) or an external pulse generator; in our case, this was the MS-DOS personal computer. The pulses of the pulse train are counted for 1 s and the resulting number, specifying the Hemopump rotational speed, is shown on a liquid crystal display (LCD) (Fig. 2b). Fig. 2c shows the digital circuitry for the creation of the stator coil control signals. A combination of a counter and three multiplexers converts the pulse train to three identical signals, 120° phase-shifted. Fig. 2d is used for the power amplification of the control signals and provides the necessary stator coil current (limited to 1A DC).

Data acquisition and control of the Hemopump rotational speed was performed with an MS-DOS personal computer† extended with a multi-purpose AD/DA converter card‡. The converter card contains 16 single-ended or eight differential analogue input ports (± 10 V), two analogue output ports, two digital input/output ports, and five multi-purpose software-controllable timers. Timer 3 (mode D) was used to generate a pulse-train for control of

* Johnson & Johnson Interventional Systems

† Olivetti M24, 8086 CPU
‡ RT1815A, Analog Devices

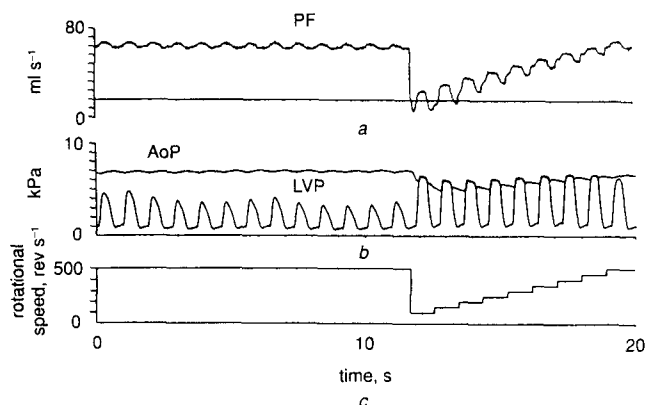


Fig. 3 Example of the application of the system *in vivo* in sheep; (a) PF = pump flow; (b) AoP = aortic pressure; LVP = left ventricular pressure; (c) time course of Hemopump rotational speed

the Hemopump rotational speed. Timers 4 and 5 were used to control multiplexed data acquisition, which means that the input channels are digitised sequentially, needing 25 μ s per channel. Timer 4 (mode E) controls the sample frequency. Timer 5 (mode J) controls the actual digitisation process for each sample. The conversion accuracy is 12 bits.

Software was developed to control data acquisition and the Hemopump rotational speed (the foreground process), and to implement user-defined experimental protocols and data analysis tools (the background process). The functions of the background process are not relevant here. The foreground process was built within an interrupt structure. Following a hardware interrupt activated at the user-defined clock-generated sample frequency, the instructions listed in the interrupt service routine are processed. The processing of these instructions mainly limit the maximum sample frequency.

4.1 Specifications

In water, with this system, the Hemopump rotational speed could be varied continuously between 0 and 700 rev s^{-1} . In blood, the upper limit was approximately 650 rev s^{-1} .

Instantaneous reductions in rotational speed could be realised for reductions as large as 500–1 rev s^{-1} . Reduction of pump flow following a virtually instantaneous reduction in rotational speed was observed to be completed within 100 ms. Instantaneous increases in rotational speed with an estimated rise time of less than 1 ms could be realised for steps as large as 50 rev s^{-1} .

The maximum sample frequency for the digitisation of data depends on the number of data channels to be digitised and the amount of additional instructions to be handled during an interrupt. For example, with an interrupt frequency of 200 Hz, within the interrupt service routine it was possible to perform detection of the R-wave in the ECG, change the Hemopump rotational speed according to the experimental protocol if necessary, and perform 8-channel data acquisition without any problem.

R-wave detection was accomplished in real-time by thresholding the ECG submitted to one of the analogue

input ports, which proved to be useful when the ECG was free of base-line drift after high-pass filtering. The threshold could be adjusted manually.

An example of the application of the system described above in our experimental set-up is shown in Fig. 3. In sheep, changes in left ventricular pressure resulting from changes in the Hemopump flow were analysed to determine ventricular function. After opening the thorax, the Hemopump was inserted into the left ventricle. The pump output was returned to the circulation through a Dacron graft, in which an electromagnetic flow meter was mounted. During short-term ischaemia of the circumflex branch of the left coronary artery, the response of left ventricular pressure to an instantaneous reduction in Hemopump rotational speed and subsequent incremental steps of 25 rev s^{-1} was investigated. Recordings are shown in Fig. 3 of aortic and left ventricular pressure, pump flow and the time course of the Hemopump rotational speed. Changes in the Hemopump rotational speed were triggered by the real-time detected R-wave of the ECG.

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Hemopump is a registered trademark.

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