

## Design, Construction, and Testing of a Manually Portable Prototype Device for Prolonged Cryostorage of Hearts

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**Background:** Hearts used in transplantation are perfused only once, which limits their preservation to about four hours. No lightweight device exists to allow for intermittent perfusion.

**Methods:** This is a report of a manually portable, lightweight heart-preservation device (under 20 lbs.) capable of intermittently perfusing hearts under cryostorage (4° and 6° C). The basic container has a 16 quart/0.5 cubic feet capacity and an empty weight of 8 lbs., 5 oz. It uses a 2 lb., 5 oz. OEM 720 Series high-precision peristaltic pump – capable of speeds of 10 to 265 RPMs. Electronic touch screen programming allows at different infusion schedules. The device was tested using pig hearts.

**Results:** The device performed faultlessly for up to 12 hours, keeping the organ cold (5°) and perfusing exact

amounts during the preservation period. Electronic programming can set a wide range of perfusion schedules and maintain accurate injections until the solution reservoirs are empty. Intermittently reperfused hearts reached cardioplegic temperature within an hour, and remained so throughout six hours of observation. The fully loaded device is easily hand carried.

**Conclusion:** This new design will offer many advantages over previous designs. Once the sterility issues are solved, it may have clinical applications.

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**Key words:** portable, device, cryostorage, hearts

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### Introduction

A prototype of a manually portable, lightweight heart-preservation and transportation device has been built at the University of Minnesota through the cooperative efforts of the Department of Surgery, Division of Cardiothoracic Surgery; the Department of Mechanical Engineering; and the Department of Electrical and Computer Engineering. This device maintains a temperature between 4° and 6° C for cold storage of the heart, allowing for intermittent perfusion during transportation. The basic container is a cooler with a capacity of 16 quarts/0.5 cubic feet and an empty weight of 8 lbs., 5 oz. It uses a 2 lb., 5 oz. OEM 720 Series high-precision peristaltic infusion pump, which is operated by 12-volt DC current and is capable of pump speeds of 10 to 265 RPMs. Electronic programming via a

touch screen allows the pump to perform at least 10 different infusion schedules. Using pig hearts, we tested the device for reliability in maintaining accurate temperatures and adhering to precise fluid-injection schedules for up to 12 hours.

### Methods

The aim of our study was to construct a portable device that can be carried by hand to perfuse, store, and transport hearts for human transplants. The device consists of the following components: a) containers to store the preservation solution, which is injected into the heart to maintain its viability; b) an electrically operated pump infusion system, which can be electronically programmed as desired to maintain constant and reliable cycles of perfusion; and, c) the organ storage container, in which the heart can be kept refrigerated until it is retrieved in the surgical suite at the time of implantation.

The device is lightweight (less than 20 lbs.), for easy transportation by plane, car, or ambulance. If necessary, an individual can hand-carry the operational device from the organ donation site to the medical facility where the heart would be implanted in the recipient.

The device operates using either 110-120 volts AC (VAC) current, or during transportation, 12 volts DC (VDC) current. It does not use ice, but rather solid-state

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electrically operated plates. Another important feature allows the used perfusate to fall into a waste chamber so that it is not recirculated.

We tested the device for its ability to maintain steady cold temperatures below 15° C and for to enable direct monitoring of the heart temperature while in the container. We also measured the amount of preservation solution after every predetermined injection to the heart, to assess reliability.

All donor animals involved in this study received humane care in compliance with principles of laboratory animal care formulated by the National Society for Medical Research and the Guide for the Care and Use of Laboratory Animals prepared by the National Academy of Sciences and published by the National Institutes of Health (publication # 96-03). Their use was approved by the Institutional Animal Care and Use Committee (IACUC) at the University of Minnesota, code # 0212A37706. This approval was renewed every year. The last accreditation by the AAALAC was March 2001. The assurance compliance number is A3456.

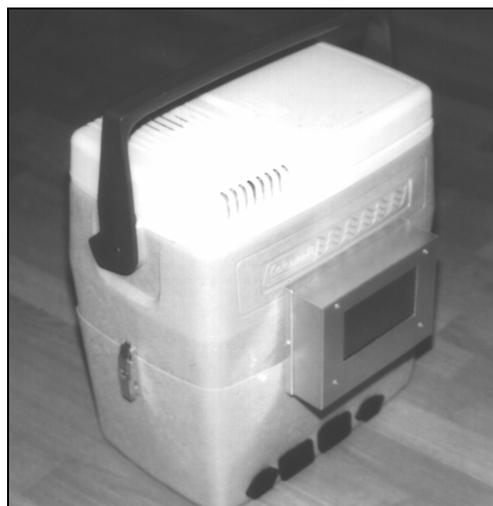
## Description of the Components

### Main Container

A cooling unit with a 16-quart capacity was chosen, in order to accommodate the preservation solution containers, the peristaltic pump, the electrical circuitry, and the ventilator fans. A Coleman<sup>1</sup> cooler seemed to fulfill all our requirements (Figure 1). This cooler has an empty weight of 8 lbs., 5 oz. It is powered by 12 volt DC current, and can be plugged into the cigarette lighter outlet of the transporting vehicle. We tested the cooler under various conditions to determine if it was adequate for our purposes.

### Pump

We considered and evaluated many pumps, and selected a Swedish-manufactured peristaltic pump purchased from Pump Express/Alitea AB, Advanced Flow Systems, LTD<sup>2</sup>, that weighs just 2 lbs., 12 oz. We picked a Series 720 that could accurately provide flow rates between 0.07 and 960 ml/min., depending on RPMs and tube size. This pump delivers a continuous pressure of 20 pounds per square inch (PSI) and intermittent pressure of 35 PSI; it is capable of up to 50 PSI. The motor requires 15 to 30 VDC at 5 watts, and can run on 12 VDC current. The pump we installed in our device has a motor controller and a small meter attached, so that RPMs can be read by a computer. The pump is secured inside the cooler within a Lexan<sup>3</sup>



**Fig. 1-A:** Our manually portable heart preservation device. The touch screen is mounted on the front of the container. At the front and bottom are the electrical receptacles for 220 volts AC, 120 volts AC, 20 volts DC, and 12 volts DC. Each receptacle has a different configuration to prevent error when connecting the electrical supply.



**Fig. 1-B:** Half of the lid is open to reveal the peristaltic pump for organ perfusion. The device has a double bottom; the electronic components are contained in the lower portion. The total weight of the device loaded is 18 lbs.

clear polycarbonate box. The preservation solution containers are connected to the perfusion pump with 1/4" and 1/16" Tigon tubing.

1 Coleman Co., Inc., P. O. Box 2931, Dept. 586, Wichita, KS 67201

2 Pump Express, 4733 N. Kelso Ave., Chicago, IL 60630

3 General Electric Company, 1 Independence Way, Princeton, NJ 08540-6620

## Heart Container

The heart container consists of a polyvinyl chloride (PVC) plastic bag that retains its flexibility at temperatures down to 5° C. The bag is provided with a mesh lining, which is secured to both sides of the bag opening. This mesh suspends the heart off the bottom of the container, in order to prevent the waste fluid coming out of the coronary sinus from continuing to bathe the heart. The bag has two ports at the bottom to allow the waste fluid to drain into a separate container.

## Power Supply

The perfusion pump and the refrigerating system of the cooler require a 12 VDC current. During transportation, the cooler is connected to this power supply, which is commonly available in cars and ambulances. Medical aircraft and helicopters, however, have outlets for 120 volts, to allow them to use standard medical equipment. The only time a DC-to-DC step-down converter would be necessary is if the heart were to be transported in a plane where the current is 28 VDC; a separate step-down converter would then be needed to change the current to 12 VDC.

With our electrical design, the device is continually powered throughout the entire period of storage and transportation – whether in a hospital, an ambulance, a car, or some type of medical aircraft.

## Circuit Board

The circuit board was designed by the Department of Electrical and Computer Engineering on a Macintosh computer using a program called MCCAD PCV-1. Figure 1 shows the gold-etched circuit board; the connectors are identified by letters corresponding to the table.

The microcontroller on the circuit board is a Mosaic Industries<sup>4</sup> QED embedded controller board, measuring 3.2 in. x 4 in. x 1.5 in. and weighing 3.5 oz. An important feature of the microcontroller is its ability to retain its programming when disconnected from 12 VDC power. The controller contains a real-time clock with a battery backup, so it is possible to unplug the heart preservation device from its power source in the middle of a cycle without disrupting the programming. After power has been restored, the unit will resume the cycle as if it had not been interrupted, or it will start a new cycle if the elapsed time is longer than one complete cycle.

The electrical components of the device are connected to the main circuit board, which has two functions: a) to distribute power to the motor controller microprocessor and electronic cooling fans, and b) to connect the components in an appropriate sequence, i.e., the optical encoder

to the microcontroller and the microcontroller to the motor controller.

For input and programming, we built a touch screen display into the outside of the container. This touch screen allows the user to program the device to automatically perform the different schedules of perfusion which may be specified for various organs and rates of perfusion. The electrical components of the device connected to the microcontroller are the motor controller and the optical encoder.

The motor is initially controlled by an analog output from the QED board, which sends a signal to a relay to switch the motor controller on and off, or to adjust the direction and speed of the flow. After flow has started, the optical encoder on the pump sends a digital signal to the microcontroller, which uses this information to regulate the flow of fluid or to adjust the speed of the motor.

Figure 2 shows the touch screen, mounted in a protective metal case on the outside of the cooler. The entire electrical system lies in a separate compartment at the bottom of the cooler. Tiny fans cool the electronics, which may produce heat during operation.



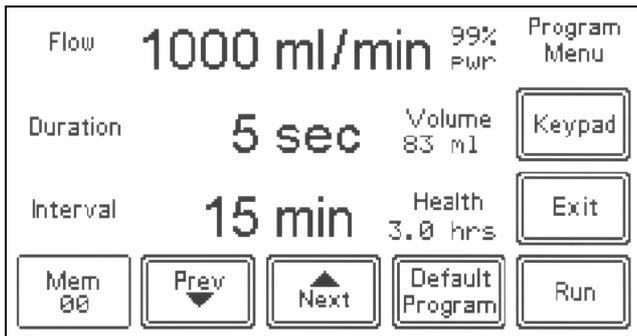
**Fig. 2:** Actual display of the touch screen main menu before the perfusion parameters have been programmed.

## Programmability

The basic microcontroller program for transporting hearts is based on information obtained from animal research. These basic settings can also be changed by the user to achieve optimum perfusion results. Such changes might be necessary for a number of factors – for instance, the type of preservation solution being used, the size of the heart, etc.

When the device is first powered on, a splash screen is displayed. Touching anywhere on the screen will display the main menu. The main menu shows the current date and time, the elapsed time of the previous preservation run, and three buttons that control the preservation program (Figure 3).

<sup>4</sup> Mosaic Industries, Inc., 5437 Central Ave, Ste. #1, Newark, CA 94560



**Fig. 3:** Displayed parameters for a theoretical case: the flow (1000 ml/min), the duration of the injection (5 seconds, 83 ml/5 sec), and the interval between injections (15 minutes).

To begin the preservation program, the “Begin Program” button is pressed. The display will show the frame of the button highlighted. On releasing the button, the display will revert to its normal state, and the requested function will be performed. With the program showing on the screen, the user can select the frequency of injections, the interval between injections, the amount of fluid per injection, and the duration of the infusion. Once these choices have been selected, the machine will automatically perform the required function until the fluid in the containers has been completely used.

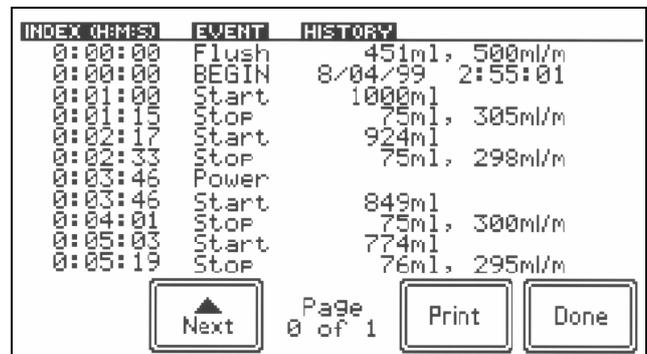
### Electronic Control

The electronic system that controls the operation of the peristaltic pump is housed in a flat insulated chamber occupying the entire floor of the cooler, separate from the main chamber in which the heart and the fluid are stored. The electronic operating system is cooled and ventilated through lateral vents by miniature fans. The board is easily programmed using a cable link connected to a personal computer. Built-in programming tools include an interactive debugger, multitasking, and executive and comprehensive libraries of device-driver functions (including drawing and plotting functions for 125x240-pixel touch screen graphics displays.) A battery-backed write-protected RAM (random-access memory) eliminates the need for PROM (programmable read-only memory) burning. This board provides for up to 512k on-board memory and 60 I/O (input/output) lines (including keypad and graphics display interfaces, timer controlled I/O, 16 analog inputs, 8 analog outputs, quad high-current drivers, and dual serial ports). The touch screen display is connected to the board at the bottom of the device by means of a flexible ribbon cable. An entire list of components of the device is available as a separate manual.

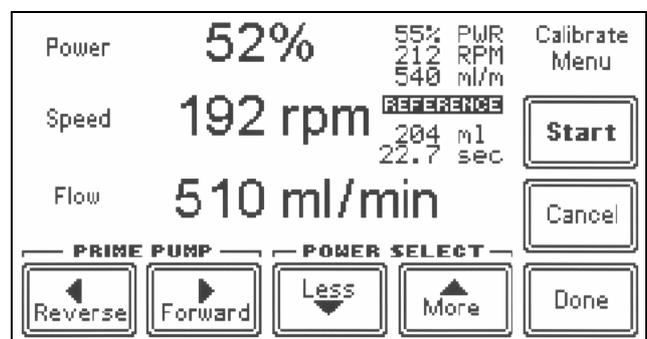
### Program Operation

First, the tubing system is primed by manual control using the touch screen. After the air is vented from the tubing, it is connected to the cannula previously secured in the aortic root of the heart. At this point, the heart has already been flushed at the organ donation site with the protective solution and de-aired. Once the tubing system is connected, the desired infusion schedule can be selected using the touch screen. The display shows milliliters per minute, the target flow rate during perfusion, and the calculated power needed to achieve this flow rate (low [0.5%] to high [100%]). It also shows the interval, the flush flow (ml/min), and the flush amount (Figures 4 and 5).

Once the first injection is completed, the screen displays a countdown timer, which shows in minutes and seconds the interval until the next perfusion is scheduled to begin. Pressing “Stop” ends the program and returns the micro-controller to its neutral operating state. The program will



**Fig. 4:** Initial flush injections of 500 ml and the total amount of fluid in the bags before the intermittent recycling injection is started (line 3). The following lines show the amount of solution used for each injection, as well as a running total of the remaining amount of available solution.



**Fig. 5:** Additional parameters shown for a theoretical case: the percentage of power needed to inject the requested amount of solution (52%), the speed of injection for the volume specified (192 rpm to inject 204 ml in 22.7 sec), and the flow (510 ml/min). All parameters may be changed, as desired, by using the touch screen before beginning the perfusion schedule.

also automatically stop if there is less than 10 ml of fluid in the container holding the protective solution.

The amount of perfusion fluid per injection can be selected from the screen at 15, 30, 50, 100, 150, or 200 ml. We corroborated the calibration of these settings by in vitro measurement of the amount of fluid actually coming out of the pump. These settings were established as accurate and reproducible under any normal usage conditions using any volume or duration of infusion.

When the donor heart reaches the medical facility, the perfusion is stopped. At this point, it is safe to remove the heart from the device. The screen will display the start and end dates and times, as well as the elapsed time. Thus the user receives accurate clinical data regarding the exact time of ischemia from the moment the heart was placed in the device until it was removed.

### **Loss of Power**

In the event of a electrical power loss while a program is running, the program will resume execution when power is restored. If one or more perfusion cycles were missed during the outage, the program will immediately perform one perfusion cycle. The program will then resume the programmed operation, waiting for the previously selected interval to pass before starting the next perfusion.

If the power loss occurs during a perfusion cycle, that cycle will be ignored and will not be repeated when power is restored. However, the interval until the next perfusion is determined from the start of the cycle that was interrupted.

### **Clock Set**

Our device uses a 24-hour clock that will, at some point, need to be set or reset. This is done by pressing the "Clock Set" button on the service menu. The user can then use the touch screen to highlight the item to change. Up and down arrows increase and decrease the values for the date and time settings. Once the screen shows the correct time and date, pressing the "Set" button will set the clock and will return the user to the service menu.

## **Results**

### **Cooler Efficiency**

We tested the Coleman cooler to determine if it could maintain the temperature of a pre-cooled cardioplegic solution within a specific target range over a long period. We also determined the amount of time needed to achieve the target temperature range. We tested the cooler when it was empty and when it contained 2-liter bags of solution. When the ambient temperature was 20 °C, it took 60 minutes for the temperature in the container to reach 5°C. The temperature subsequently stabilized at  $5.3 \pm 0.2^\circ\text{C}$  during a period of 6 hours.

When the perfusate was previously cooled to 4.5°C by overnight refrigeration, the temperature of the perfusate remained steady at 2.5°C throughout the same 6 hours. When the bags of perfusate were at room temperature (not pre-cooled before they were placed into the cooler), they did not reach the target temperature after 80 minutes of storage. When the cooler was placed outdoors at an ambient temperature of 28.3 °C, it was able to maintain the temperature of the bags of solution within an acceptable range of 4°C to 6°C. However, we noted a slight trend to drift from 4°C to about 6°C over a 4-hour period.

Finally, we also tested the insulation properties of the cooler when no power was applied. The unpowered cooler was exposed to an ambient temperature of 20°C, and 2000 ml of 2°C cardioplegic solution was placed in the bags. At the end of 4 hours, the temperature in the solution was still as low as 8°C. Thus, the insulating properties of the cooler were proven adequate for our purposes.

Our tests of the cooling system demonstrated that even when the cooler had been kept in the sun for as long as 6 hours, it reliably maintained the desired temperature range of the heart and the perfusate – as long as all items placed in the cooler had been previously cooled.

We also determined that the temperature of the donor heart would not pose a problem. The donor heart is usually flushed with a 1000 ml solution of cold preservation fluid at the time it is harvested. Therefore, it is already hypothermic before it is placed in the cooler.

### **Heart Sizes**

We used pig hearts, given the similarity of their weight and anatomy to adult human hearts, to determine all the measurements of temperature and flow rate for perfusing and storing human hearts. The average weight of a normal human heart typically varies between 283 and 340 g. Our device's heart container will accommodate a heart of up to 400 g. In our testing, we used pigs weighing from 42 to 50 kg, with heart weights between 280 and 374 g (mean = 328 g). The heart container easily held those sizes.

### **Monitoring and In Vivo Testing**

We inserted a temperature needle probe into the inter-ventricular septum for monitoring purposes. The infusing cannula in the ascending aorta was clamped and connected to the perfusion tubing from the peristaltic pump, with meticulous care being taken to eliminate all air bubbles from the system. The electronically controlled infusion system was then programmed to perfuse the pig heart with the chosen solution every 30 minutes for a total of 6 hours.

Temperature needle probes were placed inside the device as follows: 1) one in the cardioplegic solution; 2) one floating in the center of the large chamber; 3) one floating at the opposite end of the container; 4) one inserted into the inter-ventricular septum of the heart; 5) one in the chamber containing the donor heart; and, 6) one at the bottom of the

large container. These probes had a capability of measuring a temperature range between  $-40^{\circ}$  and  $80^{\circ}\text{C}$ . Each probe was connected to an independent thermometer to obtain continuous readings during the study. Table I shows the measurements obtained from 16 consecutive experiments to test the temperature variability of the device. Figure 2 shows the interventricular septum temperatures of the heart undergoing intermittent perfusion every 30 minutes for a total of 6 hours. Those readings are compared to the temperatures of the interventricular septum of the heart undergoing no perfusion – in which case one single injection of cold solution is administered to the heart and the heart is stored for six hours. There was a statistically significant difference between them. On average, the reperfused heart maintained a temperature between  $4.9^{\circ}$  and  $7.5^{\circ}\text{C}$ .

### Other Temperatures

To test the variability of the temperatures within the device as well as within the heart, we infused 100 ml crystalloid cardioplegia solution every 30 minutes throughout the preservation period. Figure 6 shows the interventricular septum temperature at 30-minute intervals during intermittent perfusion versus similar timed temperature measurements when no reperfusion has taken place. The temperature of the cardioplegic solution showed a slight drift to a colder level.

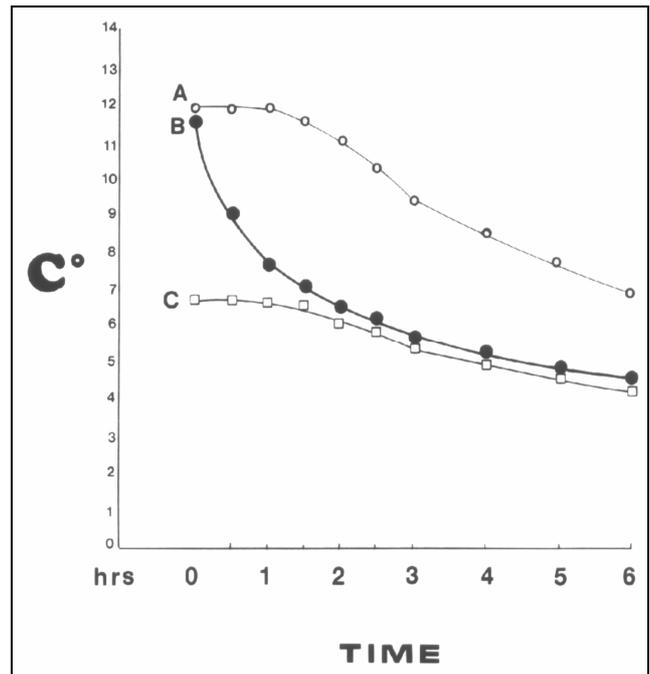
The temperature curve shows that the myocardial temperature of a heart that is reperfused every 30 minutes drops rather rapidly from a baseline of  $11.4^{\circ}\text{C}$ , to  $7.7^{\circ}\text{C}$  at the end of the first hour, to  $6.5^{\circ}\text{C}$  at the end of the second hour, and to  $4.7^{\circ}\text{C}$  at the end of the sixth hour. The rate of myocardial cooling during the first 2 hours might be important, but this is unknown at this point.

In comparison, if the heart is kept in the device without undergoing reperfusion, the myocardial temperature remains relatively high during the first 2 hours. The subsequent rate of temperature drop is much slower, reaching only  $6.5^{\circ}\text{C}$  at the end of the sixth hour.

Each measurement shown on the graph reflects the results of storing 10 hearts without changing our technique. Figure 7 shows the temperature in the various chambers of the device. The heart container maintained an adequate temperature throughout the preservation period, varying from  $5^{\circ}$  to  $9^{\circ}\text{C}$ . Traces 2, 5, and 6 chart the temperature change in the main chamber of the device.

If the device was not opened during the storage period, the temperature in the main chamber steadily decreases from an average of  $8.5^{\circ}\text{C}$  to about  $4.7^{\circ}\text{C}$  at the end of six hours. Depending on the solution chosen for preservation, however, the infusions may not need to be given but every 45 or 60 minutes to maintain adequate temperature. Future experiments are needed.

Our tests of the basic function of our device indicated that intermittent perfusion of the heart during storage provided rapidly-achieved low temperatures to preserve the organ.



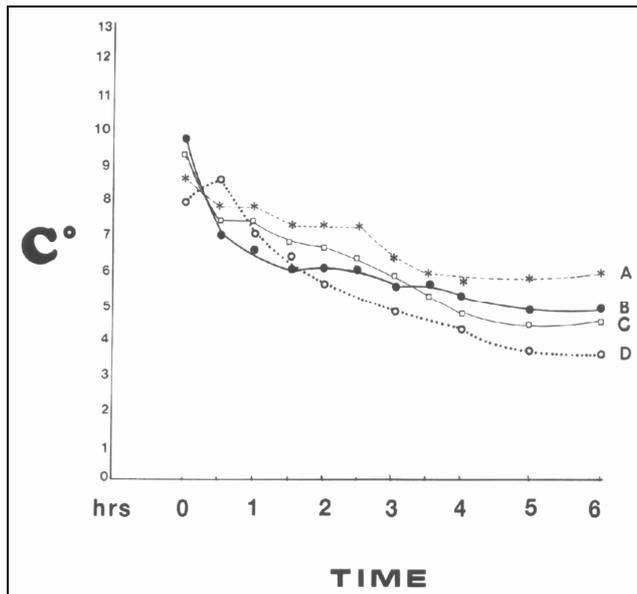
**Fig. 6:** Temperature changes recorded at 3 locations inside the device over 6 hours. A) Nonperfused heart simply stored for 6 hours after one single injection of 1000 ml crystalloid cardioplegia. Cooling of the heart takes place slowly, and the myocardium remains warmer than the cardioplegia even at the end of 6 hours. B) Heart intermittently perfused every half-hour following the initial injection. Tracing shows more rapid cooling of the heart, reaching cardioplegia temperature levels at the end of the first hour. Temperature of the heart in both settings was recorded from the probe positioned in the interventricular septum. C) Temperature registered from the cardioplegic solution during the same period of time.

### Discussion

The design and construction of our device was made possible through the cooperation of several departments in different colleges within a large university. The device is portable, lightweight, and easily programmable, with precise electronic reperfusion controls. The current clinical method is to flush the donor heart and store it in an ice chest for transportation – without subsequent reperfusion. Any heart held in a similar ischemic state for more than 4 hours shows functional deterioration (1, 2).

An improved preservation method is desirable to surmount the following limitations: time to transport the heart from donor to recipient; time to do an elective operation; time to obtain tissue-typing data on the donor heart and to find the best recipient; time to gain anonymity for the heart donor and thus to reduce undesirable publicity; and perhaps time to resuscitate a heart that has been rendered unsuitable for an immediate transplantation because of antemortem arrest.

When cardioplegia is used in standard cardiac operations, the protective solution needs to be reinfused at spe-



**Fig. 7:** Temperatures recorded from various compartments inside the device during a 6-hour period. A) Probe positioned at the bottom of the main chamber. B) Temperatures measured within the heart container without touching the organ or the walls of the receptacle. C) Temperatures measured at the mid-level of the main container. D) Temperatures at the top of the container under the lid.

specific intervals to maintain the viability of the heart muscle. Several publications have shown that the viability of an organ can be maintained for extended periods by reperfusing it with a protective solution, such as cold blood cardioplegia (3, 4), HTK [Bretschneider] solution (5, 6), Wisconsin solution (6, 7), oxygenated GIK solution (8), and others (9). Our device will allow a protective solution to be precisely infused into a stored organ at intervals. More studies are needed to elucidate this point.

The idea of a portable device for heart preservation goes back to the original designs by Wicomb et al. (10) published in 1982. Despite the claim that their device was portable, it proved to be cumbersome. The portability of a device can be defined in many ways. A 100-pound cart mounted on wheels carrying oxygen tanks and reservoirs for protective solution may be considered portable, but it is not at all practical for manual transportation, and certainly does not approach the portability of the ice-filled Igloo<sup>5</sup> containers currently being used. The portable unit described by Wicomb et al. entailed circulating the same perfusate continuously through the heart. It necessitated the use of an oxygen tank and was very large and heavy. Their original machine also used regular-sized roller pumps, which further contributed to its weight, size, and impracticality. An updated version of their system was described later (11). It entailed a new method of continuously infusing the heart by gravity, which eliminated the

need for the standard roller pump infusion. Under low pressures, however, the effectiveness of the updated version in providing adequate perfusion of the heart was questionable.

Other machines for portable use were described in 1998 by Hassanein et al. (12), and by Oshima et al. (13, 14). Both of their machines were roughly the size of an ECMO (extracorporeal membrane oxygenation) machine placed on wheels. Therefore, both could be moved, but neither was portable in the practical sense that it could be hand-carried. Another portable hypothermic perfusion device – similar to the designs used for the transportation of kidneys – was described by Hill (15) and manufactured by Waters Instruments<sup>6</sup>. This system, however, lacked programmability.

New designs described by Bunegin et al. (16) used a non-electrical low-pressure continuous perfusion machine, which, theoretically, could also be activated intermittently. Their system, however, did not allow for precise pressures and flows injected at pre-programmed periods. It was also large, with an oxygenation apparatus to keep the organ viable. It is not being used at the present time. Other devices in the past include a design by Minten (17), Fahy (18), and McGhee (19), all of which were designed primarily for transportation of kidneys.

Our device is the first to encompass controlled intermittent perfusion and cold storage of an organ, while also maintaining a small size, a low weight, and guaranteed hand-carried portability. We still need to address the issue of how to maintain sterility. Nevertheless, our device allows the transplant team to determine and control optimal injection timing, frequency, and volume for various types of cardioplegic solution.

In conclusion, we believe that this prototype device has many advantages over previous designs. 1) it is able to preserve the heart under hypothermic conditions that are constant and reproducible; 2) the heart is not left to bathe in the same solution with which it has been perfused; 3) it does not use ice, but rather solid-state cooling plates, which makes it lighter; 4) intermittent perfusion can be set at will, depending on optimal intervals of reperfusion; and, 5) these intervals, as well as other settings, can be electronically programmed ahead of time to provide ideal parameters for the particular organ.

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<sup>5</sup> Westar Capital, 949 South Coast Dr., Ste. #650, Costa Mesa, CA 92626

<sup>6</sup> Waters Instruments, Inc., 13705 26th Ave. N., Ste. #102, Plymouth, MN 55441

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