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PC/104 *in the* MEDICAL FIELD

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PICTURED
LIVE ORGAN CARRIER/PRESERVATION SYSTEM (LOCS)

PC/104-based kidney preservation machine: A virtual collaborative venture

By Doug Stead

As the medical and surgical fields advance in terms of techniques for saving lives, so must technology advance to meet the ever-increasing need for supportive equipment and supplies. Transplant surgery is one area where dependable and easy-to-operate equipment is necessary in the operating room and where critical containers are necessary to preserve the life-saving organs. The following article describes how Tri-M Engineering and its partners developed a high-tech kidney preservation machine using PC/104 to assist medical professionals in transporting live organs and to assist operating-room teams with monitoring and transplanting kidneys successfully to needy patients.

Establishing the design and partnerships

Trans-Med Corporation of Elk River, MN collaborated with Tri-M Systems Inc., of Port Coquitlam, BC, for the development of the computer hardware and software control monitoring system(s) in their kidney preservation machine - the Live Organ Carrier/Preservation System (LOCS). Tri-M subsequently created a larger virtual partnership, using a coordinated and collaborative business model, to bring together the widely varied technical skill sets needed to bring such a product to fruition. SanDragon Design in Richmond, BC, was given responsibility for sensor and hardware integration, while the system's application software was developed in California.

Trans-Med Corporation's LOCS is built around the PC/104 standard for embedded x86 hardware. The GUI touch-screen control and monitoring software is written in "C" atop the real-time operating system VxWorks. The PC/104 embedded stack manages an internal battery power system while accepting input power of various voltages. Simultaneously, this hardware/software combination monitors and controls the flow, temperature, and pressure of a special perfusate solution. This solution, also manufactured by TransMed, is pumped through one or both donor kidneys in a pulsatile fashion, mimicking the human heart.

The Live Organ Carrier/ Preservation System

Trans-Med's LOCS is a patented organ preservation system used to maintain and transport human kidneys for transplantation. The system acts as the donor organ's temporary heart and life support system by circulating a patented perfusion solution, Trans-Med's Belzer-MPS, through the donor kidneys to preserve and maintain organ viability, normally for 20-48 hours. In clinical studies, a combination of this method and the use of the Belzer MPS solution preserved kidneys successfully for five days. The same group conducted an ancillary study with animals, accomplishing seven days of successful preservation.

The embedded PC/104 computer monitors and controls the preservation functions while recording pressure, temperature, and flow data. The data streams are used for evaluating the up-to-the-second viability of the donor organ between harvesting and implantation. Additionally, this data is stored for post-transplant clinical and statistical studies of preservation methods. The PC/104 computer is configured to work in conjunction with Trans-Med's proprietary boards to monitor each parameter, and when preset alarm set points are detected, it will initiate an audible alarm in addition to generating automated notification via network, Internet, or wireless communications.

Figure 1

The perfusate solution is circulated through the kidneys by the system's cam and bladder pump, which simulate pulsatile, heart-action flow, maintaining a rate of sixty beats per minute. In addition, the pump regulates the flow of perfusion solution allowing preservation of kidneys donated by the smallest child to the largest adult. A separate circulation system chills the perfusate. A disposable closed system cassette, which includes a bladder pump, connecting circulation tubes, a heat exchanger, and integrated sensors for pressure and temperature, maintains the donor organs and perfusate in a sterile environment.

System operation is initiated when the kidneys are received from the donor and terminates when the organs are transplanted. Figure 1 shows the LOCS, ready to run.

PC/104 hardware description

Two primary concerns drove the choice of hardware components in the LOCS system: electrical power consumption and available space.

The most important concern was power, from two aspects: efficiency when running on its own internal batteries, and adaptability when running on various sources of external power.

The LOCS has to be able to run continuously for many hours on its batteries; for example, when a regular commercial passenger flight is transporting the organ. The current version of the LOCS has about 125 watt-hours in its batteries. Therefore, for 10 hours of portable operation, the average power consumption must be lower than 12.5 watts. That's quite a difficult target to hit, given the necessary electronics:

- At least a 100 MHz or so x86. PC-class CPU
- One 12-VDC motor (the heart pump). running full time
- Two more DC motors (coolant. air), running occasionally An LCD display screen, backlight, and touch screen
- A hard disk for data storage. running occasionally
- Proprietary sensors and control circuitry
- Multiple internal DC voltage levels, e.g., 5V for the CPU, digital circuits, and disk drive, and ± 12V for the analog sensor amplifiers

On the other hand, external power sources can vary widely. For example, it can conic from a stable but noisy 12VDC or more, from a lighter adapter in a car, taxi, or ambulance, or a semi-regulated 12-24VDC from a 110 or 220VAC at 60 or 50 Hz for a wall adapter/transformer. The LOCS internal power supply has to be able to generate the necessary DC voltages for its CPU and sensor/control circuits, no matter what the external voltage source is... and it must be able to charge the internal batteries simultaneously, too.

Clearly, an efficient, quiet, flexible DC-DC converter power supply and battery charger is needed in the LOCS.

Tri-M Engineering's HESC-104 High Efficiency Power Supply is ideal. It converts 6-40VDC input to ±5 and ±12VDC at up to 95 percent efficiency, does it quietly (< 20mV ripple), can charge many battery types (SLA, NiMh. NiCd, Li-Ion), and the LOCS CPU can fully control it over the PC/104 bus.

The CPU board in the LOCS must use as little power as possible, yet run fast enough to do the necessary software processing tasks and have sufficient I/O capability to support the LOCS peripherals, controls, and sensors. Tri-M 's MZI04-EV CPU board is ideal for the main processor. It provides:

- A 586 class x86 CPU running at selectable speeds of 33/66/100/128 MHz
- Onboard LCD/Ethernet/USB/EIDE interfaces, all of which are needed for the LOCS
- The rest of a full PC-compatible platform, e.g.. floppy disk controller. serial/ parallel ports. SXGA CRT controller. etc.
- Up to 64 Mbytes of fast SDRAM. and a DiskOnChip of up to 288 Mbytes
- Many useful embedded PC features, such as watchdog timer, fail-safe booting. etc.

Figure 3

Best of all, the MZ104-EV uses only about 3W of power, on average. See Figure 2 for an illustration of the LOCS hardware block diagram.
The space available inside the LOCS was dictated by the case design (see Figure 3). which in turn was driven by the need for the LOCS to be easily portable and able to fit on an airplane or car seat. This maximum size had to accommodate Trans-Med's patented. disposable sterile container, which contains one or two kidneys, and is recessed in an insulated cooling chamber for cooling the perfusate.

The space left for the electronics hardware core, including battery for backup, is about 750 cu. in. at the front of the case - less than 50 percent of the overall case volume.

Both Tri-M modules are fully compliant to the PC/104 standard, so they are about as space-efficient as possible. One other module, the A/D and DIO board, is PC/104, too, and the hard disk mounts in the PC/104 stack (see Figure 4). The rest of the electronics, including proprietary boards custom designed for Trans-Med, mount under the PC/104 stack on the back wall of the electronics cavity or on the front panel. Plans are set to redesign as many of the custom electronics boards as possible onto PC/104 modules, so that final assembly will be fast and easy.

LOCS software

The VxWorks image of the system software boots off a DOS partition on the hard drive. VxLoad.com (a DOS program) loads BOOTROM.SYS (a miniVxWorks System); BOOTROM.SYS then loads the system image either from the hard disk or over the LAN from a development system during development and testing. Although the system currently boots from DOS, potentially it could boot directly out of the MZ104-EV's onboard Flash, or out of a DOS partition on the EV's

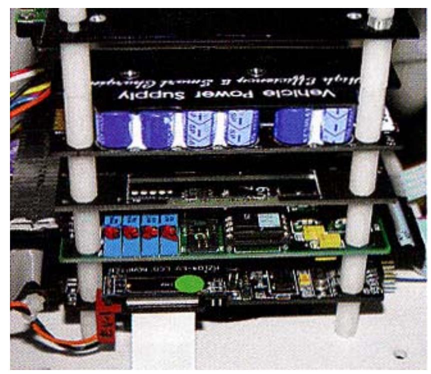

Figure 4

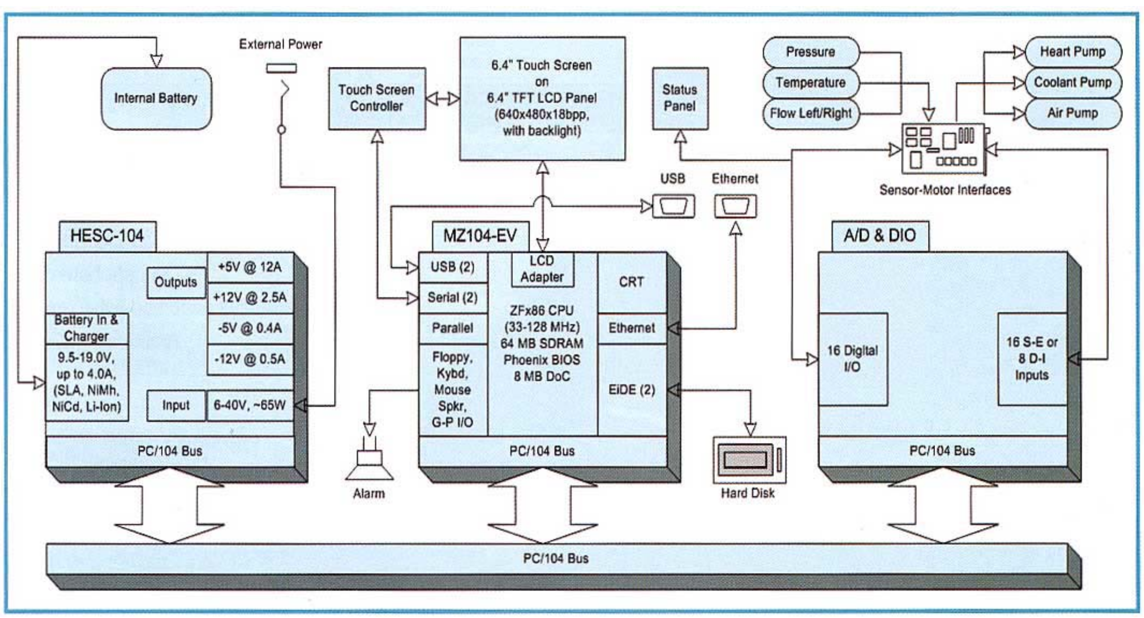

Figure 2

DiskOnChip. See Figure 5 for a LOCS system block diagram.

The EV's ZFx86 processor chip provides a 100 percent PC-compatible environment, so it was possible to run standard PC software during development. A custom BSP for the ZFx86 was not necessary, as the standard 486 BSP worked right out of the box. Once up, VxWorks switches into a 32-bit flat programming environment and makes use of all the SDRAM on the EV board.

The LOCS can run freestanding or can be fully monitored and controlled from a remote or nearby external PC running a custom LOCS remote front-panel console/monitor, Visual Basic application. A Wind River FTP server task and a custom written UDP handler task run under VxWorks on the LOCS. The FTP server allows LAN access to selected portions of the LOCS hard disk via CuteFTP and Visual Basic. The FTP server can also serve up HTML report pages to an Internet browser. UDP is used for message passing to and from the Visual Basic front panel hosted on a PC.

Under VxWorks, Custom software drives the LCD display and touch screen. The 69000 video chip on the EV board allows simultaneous CRT and LCD displays, which is convenient during development. Custom graphics software allows the design of the human interface our way; and it allows software redraw or animation of part of the action while leaving the remainder of the screen static.

The software provides a help push button on each screen. That help can be context-sensitive, depending on the state of the screen when the button is touched. Additionally, touching the title of any screen brings up a general-purpose navigation screen, which allows the LOCS operator to go to any control or display screen with ease.

All sensor data is saved for future reporting and analysis. At the end of a transplant cycle, the data can be uploaded and archived. Data samples are buffered in the sensor interface hardware and then periodically read by the system software, causing data input to be a low overhead operation. The raw data is then buffered in the EV's SDRAM and, periodically, the hard disk is spun up and the data saved on it. Using RAM buffering to reduce power consumption is easy when you have 64 Mbytes of onboard SDRAM.

The raw sensor data is scaled into medical units (mmHg, degrees C, cc/min) according to the appropriate calibration values for the current set of sensors. The scaled data - live real-time values, or previously recorded values played back from the hard disk - can be displayed in numeric tables, or as waveforms on a graphic screen.

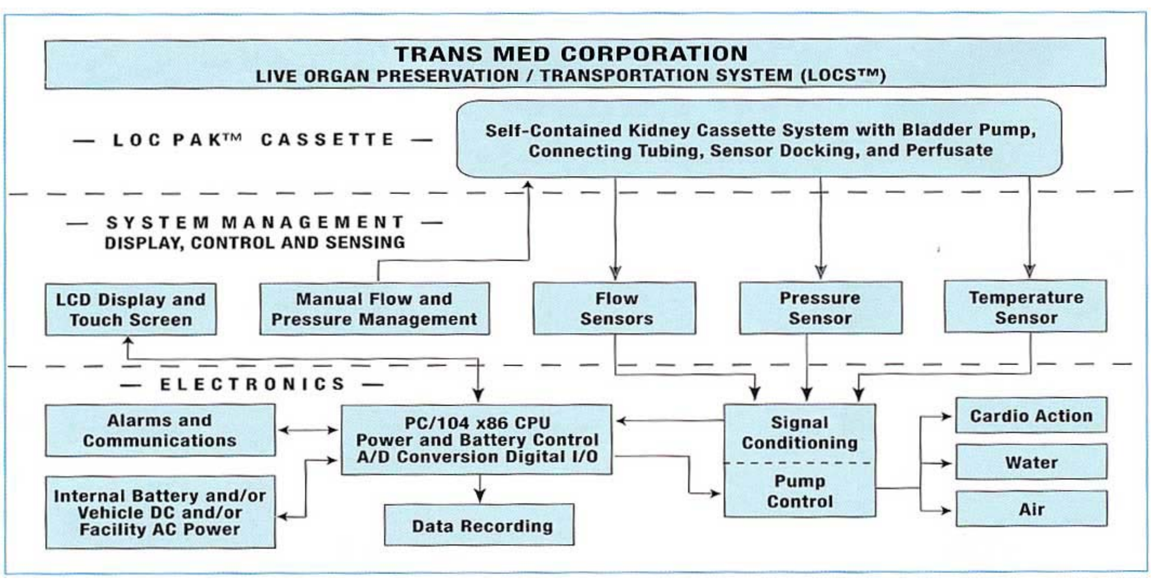

Figure 5

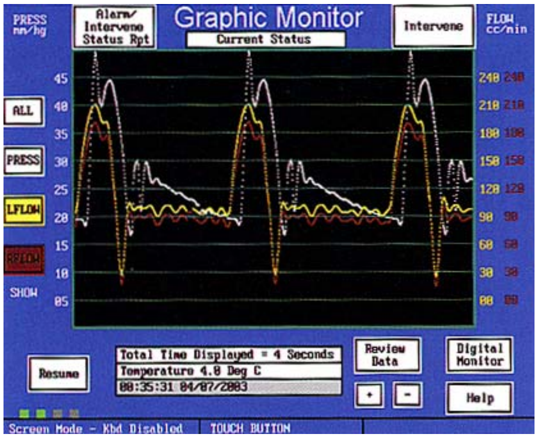

Figure 6

Operator-set alarm limits are constantly checked in case human intervention is needed. There are LEDs that show current motor/pump status in the lower left of the screen, and active prompting and status in the three text fields at the bottom of the screen. See Figure 6. which shows the pulsatile waveforms and status data on the graphic monitor screen.

Business case

In 1998, there were 8748 kidney transplants in the United States. By 2002, this number had increased to 14,731. Despite this increase, the past and current supply of transplantable kidneys has not met the demand. Herein lies a very serious problem and a significant business opportunity.

Kidneys accounted for 58.4 percent of all organ transplants in the United States during 2001. On April 11 this year, the American organ transplant authority - The United Network for Organ Sharing (UNOS) - revealed that there were 54,901 people waiting for kidney transplants in the United States, yet the total kidney transplants the previous year numbered only 14,731. Of those kidney transplants in 2002, 58 percent or 8497, were retrieved from non-living donors.

One possibility in resolving the viable kidney organ supply and demand problem would simply be to retrieve more kidneys. Needless to say, that is a lot easier said than done.

However, the technology combined in the LOCS machine has the potential to alleviate the problem dramatically by increasing the available pool of potential donors by including those who are dead on arrival at a hospital, but where the heart has stopped beating for less than 30 minutes.

The LOCS machine is extremely useful to this preservation process for several reasons. It maximizes the preservation time available for transporting and maintaining kidneys. In addition, it helps allay the two problems that are the principal focus of the transplant community right now. The LOCS machine assists significantly in avoiding Delayed Graft Function (DGF) by stimulating the organs with pulsatile perfusion as well as nourishing them. More than 98 percent of transplanted perfused kidneys do experience immediate function. The LOCS is instrumental in enhancing the survivability, and more robust viability, of Non-Heart Beating Donor (NHBD) organs that have been obtained a significant time after death occurs.

In fact, an NHBD kidney must be perfused before transplantation. This is a prime market for the LOCS machine, and it is substantial. Further, it represents a good deal less than half of the worldwide market - a market already available to Trans-Med since they service it currently with their perfusion solution.

The use of the perfusion and the control and monitoring technology incorporated in the LOCS machine also reduces patient hospital time dramatically by reducing the need for post-operative medical intervention such as repeated dialysis, and thereby helps shorten the required stay in the hospital. These functions are widely recognized, and the increased acceptance and use of the technology that the LOCS machine incorporates establishes an important market while, at the same time, offers hope and a better life for thousands.

Doug Stead is a successful entrepreneur whose companies throughout the last 25 years have engaged in the design, manufacture, and marketing of embedded computer solutions for industrial and hostile environments. He also contributes considerable effort to protecting children, serving on the Board of Directors for the American Anti-Child Pornography Organization as well as the International Society for the Policing of Cyber Space.

Tri-M Systems Inc. provides hardware and turnkey solutions for embedded systems, specializing in PC/104 products. The company was founded by Doug Stead in 1983. Since then, Tri-M has provided the utmost in customer service and quality products. The company manufactures a wide range of products and offers extensive design, engineering, and other technical services for standard, semi-custom, and custom requirements through its engineering partners Tri-M Engineering Inc.

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