

# Abstracts Presented at 26th International Conference

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## Biomedical Information and Cardiopulmonary Bypass Computerization

### APPLICATIONS OF A LAPTOP MICROCOMPUTER DURING CARDIOPULMONARY BYPASS

Suzanne Lorenzo Wilt,\* Jeffrey Silvershein

A "user friendly" microcomputer generated data management system designed for on-sight documentation and immediate analysis of patient parameters during cardiopulmonary bypass is presented. The program is a macro-driven template for use with Lotus 1-2-3 (ver. 2.0) on IBM PC/XT/AT or compatible such as the Zenith 183 Laptop computer used in this report. Automatic calculation of data requiring minimal input includes kilos, centimeters, body surface area, blood flow, fluid balance, heparin, protamine, and mannitol dose, systemic vascular resistance (SVR). Also included is auto-computation of documented minimum, maximum and average pressure, blood flow, oxygen flow/percent, temperature, activated clotting time and SVR. Basic file functions are easily performed such as saving, retrieving, deleting and report generation. Data base management capabilities include sorting by contents of fields, searching for specific records and graphing of selected parameters. The use of a computer generated perfusion record has become a valuable tool in the tracking and evaluation of important patient parameters during cardiopulmonary bypass.

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### AN INEXPENSIVE REAL-TIME COMPUTER SYSTEM FOR CARDIAC SURGERY

Charles Frank Jerabek,\* Howard Walton, Ernest Sugden

We have developed an inexpensive mobile computer system for the operating room. This system utilizes an IBM AT computer, 1200 baud modem, wide carriage dot matrix printer, serial interface card and Adalab-PC data acquisition hardware for continuous patient monitoring and data storage.

The computer currently interfaces with the main monitor, blood gas machine, heart-lung machine and five

Yellow Springs 400 series temperature probes. Flexibility has been built into the software to allow for the use of inline blood gas monitors, centrifugal pumps and up to sixteen continuously recorded parameters. Case data is stored under the patient's hospital number in ASCII disk files and can be transferred to the hospital main-frame computer for detailed statistical analysis.

Patient data is displayed on a color monitor during the case and is automatically printed as a permanent record when the patient leaves the surgery suite. Detailed information, calculated values, pressure trend graphs, temperature trend graphs and event timers are available through single keystroke commands which change the screen on display.

The software is written by a perfusionist in the easily understood and modified BASIC programming language. Under experimental conditions this program has been used to control the heart-lung machine through the use of established algorithms.

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### PERFUSION ERROR CAUSE REMOVAL: THE PERFUSION CASE CONFERENCE

Charles M. Tyndal, Jr.,\* Richard G. Berryessa

Prevention of accidents is one of the fundamental elements of perfusion quality. Unfortunately, errors and accidents frequently occur during cardiopulmonary bypass. A recent retrospective survey of perfusionists identified some common accidents. We have previously reported a method of developing protocols to prevent and treat the ten most common perfusion related problems.

Until we reach the day when perfusion accidents no longer occur, we need to be able to systematically evaluate failures and prevent their recurrence.

We have developed a non-judgemental forum to discuss, analyze, and prevent variances or unusual circumstances that occur during cardiopulmonary bypass. We hold a monthly case conference where we discuss

all cases from which we can learn something—interesting cases and cases during which there was a departure from protocol.

The purpose of this paper is to discuss the development of a case conference and to outline the format and benefits of such an Error Cause Removal program.

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## **THE BIOMEDICAL TECHNOLOGY/INFORMATION EXPLOSION: FIND YOURSELF A FOXHOLE**

Charles M. Tyndal, Jr.,\* Richard G. Berryessa

Approximately 5500 biomedical papers are published every day and the half-life of this information is currently only 3-4 years. Therefore, is not only important but nearly impossible to keep up-to-date on the literature relating to one's field.

This paper will propose a Journal Club (JC) format designed for perfusionists. Our experience with JC the last three years encourages us to share what we have learned about design, scheduling, benefits, pitfalls, and the evolution of a JC. We will suggest a list of 50+ journals that represent a cross section of the literature from disciplines affecting perfusionists. We will discuss techniques for surveying the literature, reporting at JC, recording participation, and creating a database for reference. JC is the best way to stay current with new information in our field and the benefits justify the effort required.

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## **Cardiopulmonary Bypass Oxygenation Systems**

### **CLINICAL EVALUATION OF BENTLEY 10 PLUS**

Joseph W. Basha,\* J.J. Sternleib, V.O. Bjork, T.W. Gabrielson, V.J. Hodges

**PURPOSE:** This is the first clinical report evaluating the accuracy, safety and operative simplicity of the new BENTLEY 10 PLUS (B10+) bubble oxygenator to control pO<sub>2</sub> and pCO<sub>2</sub> independently. **METHOD:** 11 patients undergoing CPB were randomly selected. The Bentley Gas Stat (BGS) was used to obtain blood gas values during CPB at five minute intervals, (N=270). BGS calibration values were recorded. Confirming blood gas samples were sent to the hospital laboratory at approx. 15 minute intervals to insure accuracy of the BGS. Adjustments to the Gas Flow Controller (GFC) and Total Gas Flow (TGF) were made to maintain the pO<sub>2</sub> and pCO<sub>2</sub> within predetermined ranges, 100-150 torr and 38-42 torr, respectively. Number of adjustments required to maintain values within ranges, GFC settings, TGF settings, Hgb., and visual signs of hemolysis (hemoglobinurea) were charted. **RESULTS:**

	pO <sub>2</sub> +	pCO <sub>2</sub> +	pO <sub>2</sub> **+	pCO <sub>2</sub> **+
RANGE	83-450 torr	37-48 torr	105-149 torr*	38-41 torr*
MEAN	143 torr	39.8 torr	135 torr*	39.5 torr
% (N) in RANGE	80%	95%	100%	100%

(+)Values uncorrected. (\*\*)At removal of Aortic Cross Clamp. (\*)Significant for oxygen-free radicals.

There were approximately 15 adjustments per case. No visual signs of hemolysis. **CONCLUSION:** The B10+ unique gas flow control mechanism and central filming

chamber enables the user to independently control pO<sub>2</sub> and pCO<sub>2</sub> during CPB; thus, A) maintain blood gases within physiologic ranges, B) reduce micro-gaseous emboli emmission, C) potentially reduce deleterious effect of oxygen-free radicals on the myocardium at Aortic Cross Clamp removal, D) reduce blood trauma and E) allow blood gas control similar to a membrane at significantly less cost. Use of a continuous on-line blood gas analyzer is recommended with this oxygenator.

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### **POOR BLOOD MIXING IN THE SHILEY HARDSHELL VENOUS RESERVOIR PROVEN BY CHANGES IN HAEMATOLOGICAL DATA ON DIFFERENT VOLUME LEVELS**

Ellen M.J. Retera,\* Dick S. de Jong, Willem R.M. Dassen, Olaf C.K.M. Penn

Low values in hematological data at the end of cardiopulmonary bypass (CPB) brought us to the hypotheses that this could be caused by a visible poor blood mixing phenomenon in the Shiley Hardshell Venous Reservoir. To study this, we designed an instrument enabling us to take blood samples from the venous reservoir at a level of 1000ml (A), 500ml (B), and

100ml (C). During CPB we took blood samples from the levels, A, B, and C and from the venous line (D) in a group of 20 patients. The first set of samples was taken 10 minutes after the aorta was occluded and cardioplegia was administered. Successive samplings took place at half hour intervals. The last samples were taken just shortly after removal of the aortic cross-clamp. We detected a marked decrease in the value of the hematocrit (Ht) at level A which dropped from 23.7% (SD 2.8) to 6.5% (SD 7.3) within 30 minutes. This showed to be a significant difference compared with the previous value and the values at the other sampling points ( $p < 0.001$ ), which were respectively B:24.7% (SD 2.9), C:25.1% (SD 2.8) and D:24.0% (SD 2.6). The values of B, C and D showed no significant changes. This difference in Ht at level A versus level B, C and D remained until the aortic crossclamp was removed, at which moment mixing in the reservoir appeared due to short time volume changes. It is concluded that poor mixing of blood occurs in the Shiley HSVR. However, we could not prove in this study that unexpected low values in hematological data at the end of CPB are due to this phenomenon.

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## **EXPANDED USE OF THE COBE VPCML OXYGENATOR**

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James R. Kauten

The Variable Prime Cobe Membrane Lung (VPCML) is a membrane gas exchange device originally developed for the short term cardiopulmonary support of infants and small adults. A particular advantage is its low static priming volume of 425 cc. To assess the efficacy of the VPCML in heavier patients, we used it for 123 consecutive adult patients weighing 46-113 kg. (mean  $78 \pm 15$  kg.). Arterial and venous blood gases were obtained simultaneously at maximum hypothermia and during rewarming.

Venous  $pO_2$  was used to assess the adequacy of perfusion. Mean venous  $pO_2$  during rewarming between the 60-70 kg. groups ( $n=22$ ) and the 90-100 kg. group ( $n=17$ ) was  $38.26 \pm 8.59$  mm Hg and  $37.54 \pm 5.98$  mm Hg respectively ( $p=NS$ ). Our results, with a mean flow of  $4.25 \pm 0.49$  LPM, showed excellent gas exchange during rewarming and at maximum hypothermia regardless of weight range.

In summary, our experience with the VPCML oxygenator demonstrates its ability to safely and efficiently oxygenate a wide range of adult patients while keeping priming volume to a minimum.

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## **THE USE OF A HOLLOW FIBER MEMBRANE OXYGENATOR FOR EXTENDED EXTRACORPOREAL SUPPORT**

W.B. Pelley,\* D.D. Taylor, C.F. Butler

There is a small percentage of patients, who having undergone cardiac surgery, are unable to be weaned from CPB. Some reports in the literature seem to indicate some success with extended extracorporeal support (EECS). In an effort to reduce the amount of supplies needed and the resulting confusion of utilizing a completely different oxygenator, a hollow fiber membrane oxygenator (HFMO) was selected as the oxygenator of choice for an EECS system.

The HFMO for EECS has been utilized on 5 patients in the past 12 months. Two patients were weaned from the system and all patients expired within 30 days. The HFMO performed adequately with respect to gas exchange and circulatory support. However, as EECS approached 15 hours, there was evidence of plasma leakage across the membrane fibers. While there appeared to be no decrease in gas exchange, two HFMO's were replaced because of the leakage.

We conclude that the HFMO for EECS may not be adequate for support periods above 12 to 15 hours.

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## **AN EXPERIMENTAL EVALUATION OF THE CAPIOX 1.6 AND 5.4 m<sup>2</sup> MEMBRANE OXYGENATORS FOR AIR REMOVAL EFFICIENCY IN THE CONVENTIONAL AND INVERTED POSITIONS**

Richard B. Berryessa,\* Charles M. Tyndal,  
Devona Osbourn

Membrane oxygenators (MO) do not create bubbles but most will transmit bubbles which are common in venous reservoir bags (VRB). We previously reported the elimination of arterial micro air in the 0.8 m<sup>2</sup> Capiiox when operated in the inverted position with an open purge line. This same lung failed to remove micro air when operated in the conventional orientation.

The purpose of this study was to test the effectiveness of

the Capiox as a bubble trap in lungs with a larger surface area (Subgroup A-1.6 m<sup>2</sup>) (Subgroup B-5.4m<sup>2</sup>) and at higher flows.

Two test circuits were constructed for each size lung (Group I-conventional orientation) (Group II-inverted). The circuits were primed with diluted, out-dated human blood (Hct. 20±2%). Ten injections of air (5cc) were done for each lung in both test positions. A bubble counter on the outlet side of the lung was used to count bubbles passed through the membrane oxygenator following the air challenge.

Thirty second bubble counts were significantly higher (p<.001) in Group I than in Group II for both size

lungs and in all bubble sizes (n=10). There were no bubbles >30μ in Group II lungs while in Group I lungs [1.6m<sup>2</sup> / 5.4m<sup>2</sup>] they were: 39.4±20.02 / 30.7±7.8 (21-30μ), 23.6±11.66 / 19.6±7.93 (31-40μ), 18.8±9.13 / 13.4±4.03 (41-50μ), 14.5±7.53 / 21.1±2.99 (51-60μ), 10.7±6.38 / 10.1±3.18 (61-70μ), 8.6±3.47 / 7.5±3.5 (71-80μ), 7.9±3.51 / 5.7±2.91 (81-90μ), and 17.7±14.67 / 50.0±4.52 (>90μ). The inverted orientation of both the Capiox 1.6 and 5.4 with an open purge line was superior to the conventional orientation. As a bubble trap, both performed comparably to an arterial filter.

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## Heparinization During Extra-Corporeal Circulation

### HEPARIN COATED HOLLOW-FIBER OXYGENATOR WITHOUT SYSTEMIC HEPARINIZATION IN COMPARISON TO CLASSIC BUBBLE AND MEMBRANE OXYGENATORS

Ludwig von Segesser,\* Marko Turina

Heparin surface coated hollow-fiber oxygenators and tubing sets were evaluated without systemic heparinization (SURFACE) in comparison to conventional uncoated membrane (PLATE) and BUBBLE oxygenators and tubing sets with systemic heparinization (ACT > 400s).

Thirteen dogs were perfused for 6 hours with a mean flow of 100 ml/kg min and either SURFACE (42±9kg), PLATE (38±12kg) or BUBBLE oxygenators (41±18: NS) by cavo-aortic cannulation after median sternotomy. Besides continuous monitoring of hemodynamics, blood samples for blood gas, biochemical and hematological analyses were taken before, after mixing and every 30 minutes thereafter:

	BEFORE BYPASS		6 HOURS BYPASS			
	SURFACE	PLATE	BUBBLE	SURFACE	PLATE	BUBBLE
pH arterial	7.3±0.1	7.4±0.1	7.4±0.2	7.4±0.0	7.3±0.2	7.4±0.1
saturation	92±1	92±4	85±8	72±5	72±9	56±10
venous % hematocrite	36±3	34±4	38±7	19±2	15±5	17±2
plasma hemo globin g/l	0.1±0.0	0.1±0.1	0.2±0.1	0.6±0.6	2.0±0.5	5.7±0.9

Plasma hemoglobin production was significantly lower in heparin coated equipment (p<0.005) which allowed cardiopulmonary bypass without systemic heparinization and therefore without return of shed blood.

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### EXTENDED EXTRACORPOREAL SUPPORT UTILIZING MINIMAL HEPARIN AND ILOPROST

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Iloprost (ZK36374), a prostacyclin analogue, has been shown to preserve platelet ultrastructure and reactivity. In an effort to reduce adverse platelet alterations, iloprost was utilized in three patients undergoing extended extracorporeal support (EECS).

EECS times ranged from 21 to 46 hours. One patient was able to be weaned from EECS. Iloprost allowed EECS in one patient who was heparin sensitive. All three patients demonstrated no platelet aggregation when challenged by ADP during iloprost infusion. Platelet reactivity returned to normal in the patient who was successfully weaned from EECS after iloprost was discontinued. Iloprost allowed EECS to be performed with minimal heparinization.

We conclude that minimal heparinization and iloprost may be a valuable addition for those patients requiring extended extracorporeal support.

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### DEMONSTRATION OF HEPARIN REVERSAL WITH REDUCED PROTAMINE ADMINISTRATION USING AN AUTOMATED PROTAMINE DOSE ASSAY: A COMPARISON OF TWO METHODS

Dennis C. Rivard,\* Steven J. Thompson

Systemic heparinization is required in procedures uti-

lizing extracorporeal circulation. Once this procedure is complete, heparinization must be reversed. The drug to neutralize heparin is protamine sulfate. The complications associated with protamine administration are well documented. An accurate and safe method of determining optimal dose is a clinically desirable tool.

A comparison study of 317 patients was performed using two different methods of protamine dose determinations. The first method utilized the classic Bull heparin dose-activated clotting time (ACT) curve determined prior to bypass. The second method consisted of a protamine titration curve constructed using a Hemochron CA 510 tube containing diatomaceous

earth and a PDA 699 tube containing a known amount of lyophilized protamine. The intercept of the protamine titration curve with the baseline ACT was multiplied by patient fluid volume to determine protamine dose. All ACT determinations utilized an automated technique.

A comparison of the two methods showed that 95% of the sample ( $p < 0.001$ ) returned to an ACT baseline with a decreased protamine administration using the protamine titration assay.

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## Physiologic and On-line Monitoring During Cardiopulmonary Bypass

### COMPARISON OF THE RESPONSE TIME OF VARIOUS ON-LINE SENSORS FOR MONITORING BLOOD GASES, pH AND O<sub>2</sub> DURING CARDIOPULMONARY BYPASS

J.B. Riley,\* R.W. Fletcher, H.R. Hoerr, C. Bell, J.C. Crowley

The rise times and decay times of the currently available, continuous blood gas and pH monitors' sensors were evaluated at 37°C and 25°C.

An *IN VITRO* human blood circuit was employed to apply step functions in pH, pCO<sub>2</sub>, and pO<sub>2</sub> to the monitor sensors. The 10 to 90% response and the time to respond (reach 10% response) for the sensors are as follows:

Device:	Sensor:	25°C			37°C		
		DT	RT	TR	DT	RT	TR
Oxy SAT 1	sO <sub>2</sub>		NS		45	45	10
Oxy-SAT 2	sO <sub>2</sub>	45	45	10	45	45	10
GEM-6	all	times = 30-220 (discrete)					
Gas STAT	pH	164	344	65	145	263	65
	pCO <sub>2</sub>	283	186	35	184	133	30
	pO <sub>2</sub>	165	172	40	132	131	65
CD I 300	pH	155	252	58	169	283	62
	pCO <sub>2</sub>	279	230	59	208	184	41
	pO <sub>2</sub>	162	252	33	195	190	19
Orange Medical	pO <sub>2</sub>		NS		72	110	21
Cardiomet 4000	pH	132	265	45	99	207	42
	pCO <sub>2</sub>	150	139	28	124	98	36
	pO <sub>2</sub>	129	133	17	159	120	8

where: DT = decay time (sec.), RT = rise time, TR = time to respond during RT, and NS = not studied

Continuous monitors for CPB have inherent measurable response delays. The inherent delay in the sterile diffusion barriers of the sensor flow-through connec-

tors is probably the greatest source of interference in accuracy studies involving discrete sampling versus continuous sampling techniques during CPB.

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### A TECHNIQUE TO IMPROVE THE ESTIMATION OF HEMOGLOBIN PERCENT OXYGEN SATURATION DURING CARDIOPULMONARY BYPASS

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Algorithms that estimate hemoglobin percent O<sub>2</sub> saturation (%Hb•O<sub>2</sub>) from pH, pO<sub>2</sub>, and temperature assume a normal patient hemoglobin P<sub>50</sub> equal to about 27 mmHg. Ischemic cardiac and peripheral vascular disease patients do not have P<sub>50</sub>s near normal.

A new continuous pH and blood gas monitor allows the user to evaluate and employ the patient's pre-CPB P<sub>50</sub> to estimate the subsequent %Hb•O<sub>2</sub>. The P<sub>50</sub> %Hb•O<sub>2</sub> algorithm estimate was calculated retrospectively for a normal patient blood gas data set and the % error between the estimate and a cooximeter measurement correlated well with the patient P<sub>50</sub> ( $r = .972$ ).

The patient P<sub>50</sub> %Hb•O<sub>2</sub> algorithm estimate was compared to simultaneous in line %Hb•O<sub>2</sub> readings ( $r = .88$ ), a cooximeter measurement ( $r = .68$ ), and a blood gas analyzer %Hb•O<sub>2</sub> (normal P<sub>50</sub>) estimate ( $r = .48$ ). To employ a pre-CPB patient P<sub>50</sub> value to estimate %Hb•O<sub>2</sub> improves the predicting power of a %Hb•O<sub>2</sub> estimating algorithm during CPB.

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## CLINICAL EVALUATION OF CARDIOMET 4000

J.W. Basha,\* V.O. Bjork, J.J. Sternlieb

**PURPOSE:** Clinically evaluate a new, continuous, on-line blood gas analyzer, Cardiomet 4000 (C4000), for accuracy, safety, user friendliness. **METHOD:** 32 patients undergoing CPB were randomly selected. Approximately 105 blood samples were drawn and analyzed by the hospital blood gas laboratory. The Bentley Gas Stat (BGS) was used as an on-line reference. The parameters of the C4000 and BGS were recorded simultaneous to the drawing of blood samples. Calibration (cal.) times and sensor insertion procedures were noted. Lab results were evaluated for bias and precision (B/P). The bias of both on-line systems were subject to a t-test analysis for significance. **RESULTS:** Significant level = 0.001.

Device	pH Bias/Precision	pCO <sub>2</sub> B/P	pO <sub>2</sub> B/P
C4000	0.003/0.028	0.059/2.8 mmHg	-7.1/43.7 mmHg
BGS	**0.28/0.505	*0.13/4.4 mmHg	**29.5/44.7 mmHg

\*not significant    \*\*significant

Daily cal. time for the C4000 was 5 min. Full cal. time 15 min. (apx. once/wk.) Design of C4000 connector allows for sensor insertions and removal during CPB. **CONCLUSION:** The C4000 demonstrated a clinically acceptable bias and precision in the measured parameters pH, pCO<sub>2</sub>, pO<sub>2</sub> and required minimal calibration and set-up time during daily use. The C4000 stainless steel reinforced gas/ion window design provides a pressure barrier (17PSI) thus: A) allows for sensor calibration verification at any time, B) allows for sensor insertion after onset of CPB in emergency applications, and C) eliminates sensor placement as requirement for membrane integrity.

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## LACTIC ACID LEVELS DURING PEDIATRIC CARDIOPULMONARY BYPASS FOLLOWING BLOOD AND NON-BLOOD PRIMES

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David R. Clarke, David N. Campbell

With the increasing concern over patient exposure to donor blood, we undertook a study to determine whether the exclusion of red blood cells from the pump prime for pediatric cardiopulmonary bypass surgical procedures would contribute to the development of metabolic acidosis by either decreasing O<sub>2</sub> carrying capacity or diluting plasma buffers with a crystalloid solutions. We compared a cellular blood prime (fresh-frozen plasma and red blood cells) and a non-blood prime (Isolyte E and serum albumin).

Lactic acid and venous saturation levels were used to evaluate effects of the two types of priming solutions. Lactic acid samples were drawn two minutes after bypass was initiated, and two minutes after cross clamp removal (or two minutes after bypass was resumed on circulatory arrest cases) and two minutes before coming off bypass. Venous saturation samples were taken at random times during the procedures. For cases using the clear prime, we were more aggressive in our blood conservation techniques.

The two-way analysis of variance revealed that there was a significant increase in lactic acid levels in both bypass groups as CPB progressed (p=.000000887. n=13). There was not a significant difference between priming group values at any one period during CPB (p=.7756). The only difference between groups 1 (n=15) and 11 was the bypass hematocrits, number of donor blood exposures and patient cooling times. The two-way ANOVA "Interaction" p value (p=.6117) strongly suggests that this was a clean study. These findings are supported by the comparability of the exsanguination times and venous saturations.

Our study results indicated that an Isolyte E and serum albumin prime did not increase the pediatric patient's lactic acid levels over a blood prime, but does reduce patient donor exposures.

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## CLINICAL EVALUATION OF THE OXYSAT 2 MONITORING SYSTEM

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A clinical study was undertaken to determine the accuracy of the Oxysat 2 monitoring system. A series of 25 patients undergoing cardiopulmonary bypass were studied to compare venous saturation and hematocrit results with standard laboratory values. Samples were analyzed using the Auto Crit Centrifuge and the Corning 2500 Co-Oximeter. Upon analysis of the data, graphs plotting correlation of hematocrit values demonstrated a r<sup>2</sup> value of 0.67595 between Oxysat 2 and Corning 2500. Graphs plotting correlation of percent hematocrit using the Auto Crit Centrifuge and Corning 2500, the usual laboratory standard, show an r<sup>2</sup> value of 0.94119. Further analysis of graphs plotting correlation of venous saturation using the Oxysat 2 and the Corning 2500 indicated an r<sup>2</sup> of 0.86597. This study indicated a statistically good correlation of the saturation values using the Oxysat 2 while only a statistically moderate correlation was achieved using hematocrit results.

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## Extra-Corporeal Circuit Equipment, Devices and Techniques

### A QUICK CANULATION SYSTEM

D. Roux,\* G. Fournial, Y. Glock, P. Dalous, P. Puel

The classic method of placing and affixing the aortic extracorporeal canulae and the venous canulae have always struck us as impractical, long and needing assistance. The device that we have created has been used primarily for emergency operation rather than for controlled surgery. This device is adaptable to all types of extracorporeal canulae. This system is equipped with a ring at its base to grip the thread around the canulae thus ensuring its tightness. The thread is then slipped into a self locking-excentric Device: the tension of the thread is maintained by a spring. The whole system is joined to the extracorporeal canulae by a semi-circular elastic clip.

This prototype is made of stainless steel. We have been using it in our department for over a year and it has given complete satisfaction.

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### THREE SPECIAL CLAMPS FOR FIXING ECC TUBES TO OPERATIVE FIELDS

D. Roux,\* R. Barthelemy, G. Fournial, Y. Glock, P. Dalous, P. Puel

Conventional fixation devices of ECC tubes on operative fields are unsatisfactory because their attachment is long unreliable and open to infection. We have put together three forceps which can be used on woven or non-woven operative fields as the pinchers are atraumatic.

There are two independent forceps for the arterial and venous tubes allowing a rapid and reliable fixation, as well a mobility of the tubes during the operation especially during coronary bypass on the right coronary.

The third forcep has three fixation points. The first is to hold the filter vertical on the cardioplegia tube, to allow it to fulfill its role as a bubble trap. The three other points are for the aspiratory tubes; the length of each tube is regulated in function of its use thus avoiding unnecessary congestion of the operative field.

These three forceps are adapted to adult ECC tube and

have a standard diameter of :  $\frac{3}{4}$ " for arterial  
 $\frac{1}{2}$ " for venous  
 $\frac{1}{4}$ " for the aspirations

There is also a model adapted to child ECC. We have been using the technique in our department for a year and we have never encountered any problems.

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### PORTABLE BYPASS FOR THE PROCUREMENT OF ORGANS USED IN HEART AND LUNG TRANSPLANTS

P.E. Jones

In July 1985, a method of organ procurement was devised using a portable cardio-pulmonary bypass machine. Up to July 1985 all donors were transferred to Harefield Hospital for organ removal, only 7 were performed by this method. On the introduction of the portable device, 25 more organ transplants were done, a significant increase in organ availability. To date 114 organ procurements have been performed, not only in Great Britain and Northern Ireland, but also in Europe, with the longest ischemic time being 4 hours 45 minutes.

The following is a detailed description of what was used to develop the portable machine, the use of a bubble oxygenator, cardiomy reservoir, and a cooling system, which allows the user to cool the donor down to a temperature of 6 degrees centigrade oesophageal, and approximately 8 degrees nasopharyngeal.

It is believed that this method can help other procurement teams, namely the liver and kidneys because of the total body cooling. This device has also been used on two occasions for the treatment of Pulmonary Embolism, where the operation was carried out at a non-cardiac hospital, and the transfer of such a patient would have led to the patients demise.

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### ANESTHETIC WASTE GAS MANAGEMENT FOR HOLLOW FIBER MEMBRANE OXYGENATORS

G.A. Justison

Breathing of anesthetic waste gas has been shown to be harmful to operating room personnel. Improper use of

scavenging systems with hollow Fiber Membrane Oxygenators (HFMO) has been associated with arterial embolism. This study looked at the efficacy of a continuously vented active scavenge system. Environmental room air was tested for the presence of halogenated agents at 1, 3, and 6 foot radius from the HFMO. Presence of waste gas was measured using gas flows from 0.5 to 10 LPM and anesthetic gas concentrations from 0.5 to 5 percent of the total gas flow. Analysis shows that the continuously vented scavenge system maintains the environmental level below the recommended level of 2 ppm.

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### **CLINICAL EVALUATION OF A NEW PUMP INTERFACE MODULE (PIM) SAFETY DEVICE**

Susan P. Tornabene,\* Angelo Iatridis, David Westbrook, Robert Dyga, Mark Miller

The Pump Interface Module (PIM) is a new safety device intended to be used in conjunction with a COBE Air Emboli Protection System (AEPS), and a roller or centrifugal pump. The PIM is a special relay device that, upon receiving an alarm signal from the AEPS, interrupts line voltage thus stopping the arterial pumphead. The purpose of this clinical trial evaluation was to verify the utility and user advantages of the PIM when employed with a variety of pumps. The study first involved *EX-VIVO* tests using the bovine model. These tests looked at different AEPS positioning, different blood flows, and simulation of a variety of clinical conditions. The clinical study evaluated the PIM using five different types of pumps during 160 open heart procedures. The pumps used were a Cinco (n=28), Sarns 5000 (n=47), Sarns 7000 (n=33), Biomedicus 520 (n=27), and Biomedicus 540 (n=25). In all instances, the PIM immediately stopped the arterial pumphead when an alarm signal was received from the AEPS system. The PIM is an effective and practical safety device for use with the tested pumps.

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### **LONG-TERM CLINICAL USE OF NOVACOR LEFT VENTRICULAR ASSIST DEVICE AS A BRIDGE-TO-TRANSPLANT**

James J. Ramsey,\* William H. Frist, John W. Hammon, Jr., Walter H. Merrill, James R. Stewart and Harvey W. Bender, Jr.

The Novacor left ventricular assist device (NLVAD) is an electrical, implantable pulsatile device under Food and Drug Administration investigational protocol. The purpose is to review the 33-day bridge-to-transplant course of a patient presenting in cardiogenic shock after acute myocardial infarction who could not be weaned from bypass after emergency coronary artery revascularization.

Cardiac output was satisfactory during the entire 33 day period:  $4.2 \pm 0.8$  l/min ( $\pm$  SD) during the first week,  $6.3 \pm 0.9$  thereafter. Haptoglobin remained low ( $30 \pm 4$  mg%), suggesting mild hemolysis, but plasma hemoglobin remained normal throughout and the patient required only 600 ml of blood after the first two postoperative days. Renal impairment (peak creatinine = 2.9 mg/dl on day three) was attributed to preoperative hypotension and resolved by day seven. The clinical course included pneumonia and hypoxic encephalopathy, both of which resolved. There were no thromboembolic complications or device-related infections. The patient underwent orthotopic cardiac transplantation on day 33.

This case demonstrates the long-term clinical efficacy and safety of the NLVAD in the setting of cardiogenic shock after massive myocardial infarction as a bridge-to-transplant support system.

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### **A NEW APPROACH IN THE REGULATION OF THE PARTIAL PRESSURE IN CARDIOTOMY SUCTION DURING OPEN HEART SURGERY**

Willem R. Dassen,\* Jan Geilen

During open heart surgery, the drainage of cardiomy is sometimes interrupted by occlusion of the suction tip or vent against cardiac or thoracic tissue, causing a rise in partial vacuum in the suction system, which may lead to increased hemolysis. Mechanical safety valves can be used to avoid this. However the use of such valves is limited for negative pressure regulation on fixed levels. In order to control the existing or created pressure we decided to develop an electronic system capable of monitoring the pressures and to adjust them to a selected level. If this level is reached, an electromagnetic valve is opened, titrating air into the system until the partial pressure has dropped to 80% of the preselected value. The electronic approach also offers the possibility to make use of the signal as a feedback to control the vacuum by controlling the rotations of the roller pump. Furthermore the signal can be used for trend registration or application in hemodynamic calculations. This vacuum regulation system enables the perfusionist to minimize possible destruction of blood



elements in the cardiotomy suction system and to devote his attention to the physiological state of the patient rather than to the equipment.

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### **MORE THAN TURNING KNOBS: THE EXPANDING ROLE OF THE CLINICAL PERFUSIONIST**

Irvin B. Birenbaum, Dennis C. Rivard, Steven J. Thompson, Robert C. Baldwin, Jr., Candace L. Banchieri, Michael S. Harple

The practice of clinical cardiovascular perfusion has experienced major changes in scope since its inception over thirty years ago. The tasks of today's clinical perfusionist may include not only the usual life support of patients undergoing cardiac surgery, but also such diverse duties as IABP therapy, VAD life support, artificial heart management, blood salvage for auto-transfusion, rapid fluid administration, ECMO therapy, liver transplantation, circulatory support for cardiac arrest, and perfusion for distant heart-lung procurement for transplantation.

All of these duties are practiced by the perfusion team of the Johns Hopkins Medical Institutions. Except for the normal surgical tasks of a perfusionist, these tasks have been assumed by the perfusion team over a recent three year period with no increase in staff. Certain managerial and team strategies were necessary to achieve this without sacrificing either patient safety or staff morale.

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### **CRYSTALLOID CARDIOPLEGIA VERSUS OXYGENATED CRYSTALLOID CARDIOPLEGIA IN THE ISOLATED RAT HEART**

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Elective cardiac arrest with hypothermic potassium cardioplegic solution is now the primary method of

myocardial protection in the majority of centres. To determine if the protection afforded by crystalloid potassium cardioplegic solution could be enhanced by the addition of oxygen to the solution, 12 rat hearts were studied using the isolated retroperfused heart model, with a 2 hour ischaemic arrest at 20°C.

Group I hearts (n=6) received our standard crystalloid cardioplegic solution every 30 minutes of the arrest. Group II (n=6) were treated identically except that the crystalloid cardioplegic solution was oxygenated prior to delivery. Pre-arrest (control) and post-arrest coronary effluent enzyme levels, heart rate and coronary vascular resistance were determined. In addition the time to spontaneous defibrillation was measured.

Control coronary effluent lactate dehydrogenase (LD) was significantly elevated in group II ( $p < 0.05$ ). There was no significant difference in the other control parameters.

Post-arrest coronary effluent creatine kinase (CK) in group I and group II hearts were  $640.67 \pm 263.234$  and  $107.513 \pm 43.892$  ( $\pm$  SEM), respectively ( $p < 0.05$ ). The post-arrest heart rate was  $200.6 \pm 13.836$  and  $244.25 \pm 13.448$ , respectively ( $p < 0.05$ ). One heart failed to spontaneously defibrillate and one heart had an irregular rhythm, both were in group I. Time to spontaneous defibrillation was  $58.4 \pm 5.7$  for group I and  $44.67 \pm 2.704$  for group II, ( $p < 0.05$ ). Post-arrest coronary effluent LD for group I and group II were  $442.34 \pm 180.727$  and  $100.07 \pm 32.076$  and showed no significant difference ( $p = 0.06$ ).

This study demonstrates that at 20°C, (our upper clinically acceptable temperature for ischaemic arrest), markers of ischaemic injury (particularly enzyme leakage) are significantly improved. Although the post-arrest LD did not show significance it should be noted that the control LD was elevated in group II. These findings lead us to conclude that the addition of oxygen to the cardioplegic solution may enhance its efficiency in protecting the heart from ischaemic arrest.

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## Expanding Clinical Perfusionists Roles and Procedures

### LOW VOLUME, ISOLATED *IN SITU* LUNG PERFUSION: RESULTS OF STUDIES OF METABOLIC STABILITY

Annette Basile-Borgia,\* D. Eugene Rannels, Dennis R. Williams

Non-ventilatory lung functions involve uptake and release of compounds across the pulmonary vascular bed. Alterations in these functions may be readily assessed in an isolated, ventilated, small mammal lung perfusion preparation. A previously documented preparation is known to maintain metabolic stability of *IN SITU* rat lungs for at least 240 minutes. The model, developed by Watkins and Rannels, requires a rotating drum oxygenator which necessitates the use of 100 ml of perfusate buffer. The effects of 100 ml dilution limit the ability to measure uptake and release of metabolites because increased sensitivity of assay procedures or more prolonged experiments are required. A recently developed preparation proved to require only 25 ml of recirculating perfusate, clearly reducing substrate and metabolite dilution, and enhancing the investigators ability to detect changes in pulmonary metabolism. The intent of this study was to test the vascular permeability and metabolic stability of this low volume lung perfusion model. Results indicate that a stable, low volume, isolated lung preparation is feasible as evidenced by studies on vascular permeability. Metabolic stability of the model was demonstrated by results of glucose uptake, lactate production, and protein synthesis. The clinical importance of isolated organ perfusion is discussed.

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### SURVEY OF BLOOD CONSERVATION TECHNIQUES DURING OPEN HEART SURGERY

Joseph J. Sistino

The shortage of a safe and adequate blood supply for open heart surgery has prompted the development and institution of numerous blood conservation and autotransfusion techniques. A survey was conducted of 60 hospitals in the Northeastern United States to determine the frequency of application, as well as the resultant effect on banked blood usage.

A total of 37 surveys were completed for a response rate of 62%. This represents an annual caseload of

23,449 open heart cases which is more than 10% of the total number of open hearts performed annually in the U.S.

The following techniques were used during adult cases to conserve blood:

No blood in prime	95%
Membrane oxygenator	67%
Chest drainage autotransfusion	40%
Autotransfusion of suction blood	40%
Pre-bypass volume removal	18%
Hemoconcentrator	8%

Post bypass techniques for recovery of residual pump blood were also surveyed. The following techniques were employed:

Centrifugation	54%
Blood bag collection	31%
Discarded	11%
Hemoconcentration	4%

Kendall's Tau-b correlation coefficients showed a significant association between autotransfusion of suctioned blood ( $p < .05$ ) and decreasing reported blood use as well as priming volume and blood use ( $p < .05$ ), although correlations were of small magnitude. When usage was compared across units of packed red cells, for several blood conservation techniques greater usage was reported in the groups that used the smallest amount of blood.

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### ASSESSMENT OF DEPTH OF ANESTHESIA DURING CARDIOPULMONARY BYPASS

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Despite recent advances in the anesthetic management of patients undergoing open heart surgery (OHS), little is known concerning depth of anesthesia in the presence of variable surgical stimuli. The present study was designed to evaluate anesthetic depth during hypothermic cardiopulmonary bypass utilizing continuous monitoring of lower esophageal contractility. Tertiary esophageal contractions are stress-related and their presence during cardiopulmonary bypass may indicate inadequate depth of anesthesia. The responses to inappropriate depth of anesthesia may correlate with increased post operative morbidity<sup>4</sup> or awareness.<sup>5</sup> The present study was designed to (1) evaluate the depth of anesthesia during hypothermic cardiopulmo-

nary bypass (2) compare lower esophageal contractility (LEC) with other parameters available to assess depth of anesthesia: mean arterial pressure/perfusion flow/temperature and electroencephalogram (EEG) and somatosensory evoked potential (SEP) measurements.

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## **SEPARATION OF CONJOINED TWINS UTILIZING CARDIOPULMONARY BYPASS**

Candace L. Banchieri, Steven J. Thompson, Dennis C. Rivard

The incidence of conjoined twins occurs once in every two million live births. Successful separation has occurred in 50% of these patients. Previous attempts to separate twins at the sagittal sinus have resulted in death. On September 5, 1987, the team at Johns Hopkins Hospital was the first to successfully separate conjoined twins at the sagittal sinus. One key to this success was the use of cardiopulmonary bypass, deep hypothermia, and circulatory arrest.

Each patient was cannulated with a 14 Fr. aortic cannula and a 22 Fr. venous cannula in the right atrium. They were then connected to completely separate cardiopulmonary bypass circuits. Cardiopulmonary bypass was initiated utilizing a roller pump, pediatric membrane oxygenator with integral cardiotomy, and an arterial filter. The twins were cooled to 20°C. in preparation for circulatory arrest. During circulatory arrest, separation occurred and repair was accomplished utilizing direct suture and pericardial patches. When repair was complete, cardiopulmonary bypass was resumed and rewarming begun. At a rectal temperature of 33°C. cardiopulmonary bypass was discontinued.

The two major benefits of extracorporeal circulation in this procedure were maintaining hemodynamic stability and the ability of regulate metabolic demands. The use of cardiopulmonary bypass was a solution to the obstacles presented. The ability to control blood flow, temperature, and volume resulted in a successful separation of these patients.

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## **INTRA AORTIC BALLOON COUNTERPULSATION FOR THE TREATMENT OF ISCHEMIC STROKE**

Richard Berryessa,\* Bruce I. Tranmer, Charles M. Tyndal, Raymond L. Iacobacci

Colloid volume expansion in a stroke model has been shown to increase cerebral blood flow (CBF) in ischemic brain but is hazardous to use in patients because of associated cardiovascular disease.

This study was designed to see if Intra-Aortic Balloon Counterpulsation (IABC), in an animal with a normal heart, would increase CBF and EEG activity in the ischemic brain.

Unilateral cerebral ischemia was produced in baboons (n=9) after right middle cerebral artery (MCA) occlusion. A 12 cc intra-aortic balloon catheter was introduced into the descending aorta via the femoral artery prior to MCA occlusion. The balloon was positioned distal to the origin of the left subclavian artery and following MCA occlusion was inflated with each R wave on the ECG. Cardiac output (C.O.), CBF (by Hydrogen wash-out), computer mapped EEG (CME), and hemodynamic data were collected before and during the three hour post-stroke period.

IABC produced a significant increase in pulse pressure from  $54.7 \pm 21$  to  $70.6 \pm 33$  mmHg ( $p = .043$ ). No significant change was produced in C.O., mean arterial pressure, or CBF. Although the CME improved and the right (ischemic) hemisphere CBF did increase slightly from  $16.9 \pm 6.5$  to  $18.3 \pm 8.3$  cc/100 gm/min the CBF changes were not significant ( $p = .295$ ).

We believe that the desired increase in CBF was not achieved partly because the animals were only 3-4 years old and were difficult to stroke. We also believe that there is merit to a follow-up study in older primates where IABC is used to protect the heart from the deleterious effects of volume expansion. Perhaps volume expansion with IABC will be safer and more effective than either treatment modality alone.

(All data reported as mean  $\pm$  standard deviation)

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