



North Carolina Department of Health and Human Services  
Division of Health Service Regulation

Pat McCrory  
Governor

Aldona Z. Wos, M.D.  
Ambassador (Ret.)  
Secretary DHHS

Drexdal Pratt  
Division Director

July 24, 2015

Dee Jay Zerman, Director, Regulatory Planning  
James T. Hedrick Building  
211 Friday Center Drive, Suite G015  
Chapel Hill NC 27517

**Exempt from Review – Replacement Equipment**

**Record #:** 1659  
**Facility Name:** UNC Hospitals  
**FID #:** 923517  
**Business Name:** University of North Carolina Hospitals at Chapel Hill  
**Business #:** 1946  
**Project Description:** Replace heart-lung bypass machine  
**County:** Orange

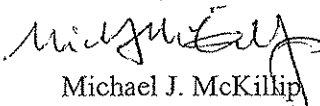
Dear Ms. Zerman:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of July 15, 2015, the above referenced proposal is exempt from certificate of need review in accordance with G.S 131E-184(7). Therefore, you may proceed to acquire, without a certificate of need, the Sorin S5 heart-lung bypass machine. This determination is based on your representations that the unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need.

Moreover, you need to contact the Agency's Acute and Home Care Licensure and Certification Section to determine if they have any requirements for development of the proposed project.

It should be noted that the Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this office and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

  
Michael J. McKillip  
Project Analyst

  
Martha J. Frisone,  
Assistant Chief, Certificate of Need

cc: Assistant Chief, Healthcare Planning  
Acute and Home Care Licensure and Certification Section, DHSR



Healthcare Planning and Certificate of Need Section  
www.ncdhhs.gov

Telephone: 919-855-3873 • Fax: 919-715-4413  
Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603  
Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704  
An Equal Opportunity/ Affirmative Action Employer





UNC  
HOSPITALS



Hedrick Building  
211 Friday Center Drive, Suite G015  
Chapel Hill, NC 27517

July 15, 2015

Michael J. McKillip, Project Analyst  
Certificate of Need Section  
Division of Health Service Regulation, DHHS  
Mail Service Center 2704  
Raleigh, NC 27699-2704

RE: Request for Exemption / Replacement of an existing heart-lung bypass machine /  
UNC Hospitals

Dear Mr. McKillip:

UNC Hospitals is planning to replace an existing heart-lung bypass machine and is requesting a determination that the replacement of this equipment is exempt from review pursuant to NCGS §131E-184(7). The existing heart-lung bypass machine was placed into service in 2001, and remains in use. The age of this machine is making it difficult to obtain replacement parts for repairs.

We are supplying the following information that the CON Section has requested in the past as a part of its general information request for an equipment replacement exemption.

1. A comparison of the existing and replacement equipment, using the format in the following table:

*Equipment Comparisons*

|   | <i>Existing Equipment</i> | <i>Replacement Equipment</i> |
|---|---------------------------|------------------------------|
| <i>Type of Equipment (List each component)</i>    | Heart-Lung machine        | Heart-Lung machine           |
| <i>Manufacturer of Equipment</i>                  | Sarns/Terumo              | Sorin                        |
| <i>Tesla Rating for MRIs</i>                      | N/A                       | N/A                          |
| <i>Model Number</i>                               | Model 8000                | Sorin S5                     |
| <i>Serial number</i>                              | S/N 1766 (base)           | Not yet available            |
| <i>Provider's Method of Identifying Equipment</i> | By model & serial #s      | By model & serial #s         |
| <i>Specify if Mobile or Fixed</i>                 | Portable                  | Portable                     |
| <i>Mobile Trailer Serial Number/VIN #</i>         | Not applicable            | Not applicable               |
| <i>Mobile Tractor Serial Number/VIN #</i>         | Not applicable            | Not applicable               |
| <i>Date of Acquisition of Each Component</i>      | 2001                      | Projected 2015               |

|  |                         |                    |
|--|-------------------------|--------------------|
| <i>Does Provider Hold Title to Equipment or Have a Capital Lease?</i>            | UNCH owns               | UNCH owns          |
| <i>Specify if Equipment Was/Is New or Used When Acquired</i>                     | New                     | Will be new        |
| <i>Total Capital Cost of Project (Including Construction, etc.) &lt;Ex 4&gt;</i> | Approx. \$101,005       | \$242,335          |
| <i>Total Cost of Equipment</i>   | Approx. \$101,005       | \$242,335          |
| <i>Fair Market Value of Equipment</i>  | N/A (no trade-in value) | \$242,335          |
| <i>Net Purchase Price of Equipment</i>   | N/A                     | \$242,335          |
| <i>Locations Where Operated</i>  | UNC Hospitals           | UNC Hospitals      |
| <i>Number of Days In Use/To be Used in N.C. Per Year</i>                         | 365 days                | 365 days           |
| <i>% of Change in Patient Charges (by Procedure)</i>                             | N/A                     | No change          |
| <i>% of Change in Per Procedure Operating Expenses (by Procedure)</i>            | N/A                     | No change          |
| <i>Type of Procedures Currently performed on Existing Equipment</i>              | Open heart surgery      | N/A                |
| <i>Type of Procedures New Equipment is Capable of Performing</i>                 | N/A                     | Open heart surgery |

2. *A description of the basic technology and functions of the existing and replacement equipment, including the diagnostic and treatment purposes for which the equipment is used or capable of being used.*

*Response:* The machine to be replaced is a Sarns Terumo Model 8000 pump. The original brochure, quote and purchase order are not available. Exhibit 1 contains a similar brochure and similar quote for the existing Sarns 8000. UNC Hospitals plans to replace this pump with the Sorin S5 pump. The current equipment and the replacement equipment will perform the same basic functions. Both are pumps which during open heart surgery take over the pumping action of the heart. Attached to the heart lung machine is an oxygenator (not included in the purchase) which performs the functions of the lungs. The replacement equipment has computer control of the pump heads which offer safety features to reduce the potential of strokes. The electrical components in the replacement equipment are protected from damage from fluids. The manufacturer is no longer producing the existing Sarns 8000, and as a result will soon discontinue support for the Sarns 8000 machines.

3. *Brochures or letters from the vendors describing the capabilities of the existing equipment and the replacement equipment.*

*Response:* A copy of a brochure and a quote for a similar Sarns 8000 unit is attached as Exhibit 1 as the original purchase order, brochure, and quote are not available. A copy of a brochure from the vendor describing the proposed replacement Sorin S5 pump is attached as Exhibit 2.

4. *A copy of the purchase order for the existing equipment, including all components and original purchase price.*

*Response:* A copy of the similar brochure and quote is attached as Exhibit 1 as the original items are not available.

5. *A copy of the title, if any, for the existing equipment or the capital lease for the existing equipment.*

*Response:* Not applicable. The existing equipment does not have a title and is not leased.

6. *If the replacement equipment is to be leased, a copy of the proposed lease that transfers substantially all the benefits and risks inherent in the ownership of the equipment to the lessee of the equipment, in accordance with criteria in Generally Accepted Accounting Principles (GAAP).*

*Response:* Not applicable. The replacement equipment will not be leased.

7. *If the replacement equipment is to be purchased, a copy of the proposed purchase order or quotation, including the amount of the purchase price before discounts and trade-in allowance.*

*Response:* A copy of the quote received from Sorin for the replacement pump is attached as Exhibit 3. The existing machine has no trade-in value because the vendors are not interested in taking possession of the existing equipment due to its age.

8. *A letter from the person taking possession of the existing equipment that acknowledges the existing equipment will be permanently removed from North Carolina, will no longer be exempt from requirements of the North Carolina Certificate of Need law, and will not be used in North Carolina without first obtaining a new certificate of need.*

*Response:* As a State Agency we have two options for the disposal of equipment. The first is by trade-in on the purchase of replacement equipment. However, due to the advanced age of this equipment Sarns is not interested in taking possession of this equipment. Since this specific machine is being phased out by the manufacturer, the vendor will no longer guarantee replacement parts and will no longer execute full service contracts for repair of the machine. The second option available to us as a State Agency is disposal through State Surplus Property or transfer to a non-patient care department. Upon replacement, the existing Sarns 8000 pump will be surplus to the School of Medicine. The equipment is still useful for education and research, so it will be surplus to Dr. Kiser's Simulation Lab in the School of Medicine for predominately training and simulation purposes.

9. *Documentation that the existing equipment is currently in use and has not been taken out of service.*

*Response:* UNC Hospitals currently has four heart lung bypass machines in use as identified on our most recent Licensure Renewal Application form. See Exhibit 4 for a copy of the page of the 2015 Licensure Renewal Application form pertaining to heart-lung bypass machines.

Exhibit 5 contains a completed 'Proposed Total Capital Cost of Project' form which projects the total capital cost of this replacement project to be \$242,335 for the Sorin S5 machine. The total project cost includes all costs required to make the unit operational.

Please do not hesitate to contact me at 984-974-1210 if you need any additional information. Thank you for your prompt consideration of this matter.

Sincerely,

Dee Jay Zerman, Director of Regulatory Planning  
UNC HCS

**3M HEALTH CARE**  
**Sarns and CDI Products**  
6200 JACKSON RD.  
ANN ARBOR, MI 48103

313-663-4145/800-262-3304  
FAX: 734-741-6181

DATE: 5/26/99 *SIMILAR EXISTING MACHINE*

TO: Franklin Boone Sr.  
Chief of Perfusion  
UNC Hospital

# PAGE 5  
(INCLUDING COVER)  
FAX NO: 919-966-3475

FROM: **Mike Cuddington**  
**Contract Administrator**

PHONE: 800-262-3304 x6382  
734-741-6382

REFERENCE: Proposal No. 201206

MESSAGE:

Per your request please see the updated proposal reflecting the  
current date. If you have any questions please feel free to call me.

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
Sincerely,  
Mike Cuddington  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**3M Proposal**

May 26, 1999

Franklin Boone, Sr.  
 Chief Of Perfusion  
 UNC Hospital  
 101 Manning Drive  
 Chapel Hill NC 27514

Proposal No. 201206

For 3M™ Sarns™ 8000 Perfusion System

| Qty          | Product No.    | Description                    |             | Amount              |
|--------------|----------------|--------------------------------|-------------|---------------------|
| 1            | 98-0702-0644-0 | 16401 Base 5 Unit 115V         | \$15,000.00 | \$15,000.00         |
| 5            | 98-0702-0647-3 | 16402 Roller Pump 115V         | \$10,600.00 | \$53,000.00         |
| 1            | 98-0702-0660-6 | 16404 Safety Monitor           | \$0.00      | \$0.00              |
| 1            | 98-0702-0842-0 | 5773 Air Sensor 3/8x3/32       | \$0.00      | \$0.00              |
| 1            | 98-0702-0860-2 | 5799 Level Sensor Pads 100/Pk  | \$0.00      | \$0.00              |
| 1            | 98-0702-0267-0 | 164278 Ultrasonic Gel          | \$0.00      | \$0.00              |
| 1            | 98-0702-0655-6 | 16413 Arterial Monitor         | \$4,000.00  | \$4,000.00          |
| 1            | 98-0702-0654-9 | 16414 Cardioplegia Monitor     | \$5,000.00  | \$5,000.00          |
| 1            | 98-0702-0692-9 | 16421 Monitor Mounting Arm     | \$690.00    | \$690.00            |
| 1            | 98-0702-0657-2 | 16416 Pulse Module System 8000 | \$5,500.00  | \$5,500.00          |
| 1            | 98-0702-0722-4 | 16422 Battery Module 115V      | \$7,500.00  | \$7,500.00          |
| 1            | 98-0702-0664-8 | 16420 Lamp System 8000         | \$690.00    | \$690.00            |
| 1            | 98-0702-0659-8 | 16418 Electronic Occluder      | \$6,650.00  | \$6,650.00          |
| 1            | 78-8066-6721-4 | 16433301 Pressure Transducer   | \$1,400.00  | \$1,400.00          |
| 1            | 98-0702-0211-8 | 16066100 Pressure Mntng Kit    | \$0.00      | \$0.00              |
| 1            | 98-0702-0353-8 | 22300030 Transducer Holder     | \$0.00      | \$0.00              |
| 1            | 98-0702-0252-2 | 164235 Sechrist Blender        | \$1,575.00  | \$1,575.00          |
| <b>TOTAL</b> |                |                                |             | <b>\$101,005.00</b> |

**3M**

Health Care  
 Cardiovascular Systems  
 SARNS™ AND CDI™ PRODUCTS

6200 Jackson Road  
 PO Box 1247  
 Ann Arbor, MI 48103-1247  
 USA

800 521 2818 Tel  
 313 663 4145 Tel  
 800 292 6551 Fax

Proposal No. C005624  
5/26/99  
Page: 2

*Warranty*

Please note that this equipment comes with a warranty covering all repairs, parts and labor for the first 12 months following delivery. Prices contained in this proposal are valid for 60 days.

*Terms*

The terms of this proposal are net 30 days, F.O.B., Ann Arbor, Michigan. (Please allow 45 days from receipt of the order to commence shipment.)

If you have any questions regarding this proposal, you may contact either of the following persons at 800-262-3304: Randy D. Pence, Cardiovascular Systems account representative, extension 6028  
Mike Cuddington, Contract Administrator, extension 6382

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**3M**

Health Care  
Cardiovascular Systems  
SARNS™ AND CDT™ PRODUCTS

8200 Jackson Road  
PO Box 1247  
Ann Arbor, MI 48103-1247  
USA

800 521 2818 Tel  
313 663 4145 Tel  
800 292 6551 Fax

3M Health Care/3M Health Care  
Standard Cardiovascular Products

**Terms and Conditions**

**1. Invoicing and Payment:**

All prices are F.O.B. 3M Health Care, point of shipment (hereafter referred to as 3M Health Care) unless otherwise stated in the proposal. All invoices will be dated at or after the date of shipment. All invoices are payable in full within thirty (30) days of the date of invoice.

**2. Shipment and Risk of Loss:**

3M Health Care makes every effort to meet any shipping dates specified in Buyer's purchase orders, but 3M Health Care does not guarantee to meet any particular shipping deadlines. 3M Health Care will, however, promptly notify Buyer of any delays in processing Buyer's order. Buyer's only remedy for late shipment is to cancel the order. A written notice of cancellation must arrive at 3M Health Care before the Product is actually shipped. Unless instructed otherwise in writing, 3M Health Care will ship via the most economical route and method available, freight prepaid and added to the invoice. Risk of loss passes to Buyer at the F.O.B. point. Title transfers only when Buyer has fully paid for the products.

**3. Excusable Delay:**

3M Health Care makes every effort possible not to delay your shipment. However, we cannot be held responsible due to causes beyond 3M Health Care reasonable control.

**4. Limited Warranty; Remedies Limited:**

3M Health Care will repair or replace free of charge any part found to be defective in workmanship or material during one year from the date of shipment. This warranty does not apply to filters, light bulbs, fuses or other expendable items, or to those parts damaged by improper use or by accident. Any parts found to be defective due to lack of maintenance in accordance with 3M Health Care Operators Manuals, or as a result of unauthorized repair, will be repaired or replaced at service rates in effect at that time. *This warranty is expressly in lieu of all other warranties expressed or implied, including any implied warranty of merchantability or fitness for a particular purpose.* 3M Health Care shall not be liable under any circumstances, for any consequential, incidental, or indirect damages or expenses associated with this warranted product or its use.

**5. Buyer's Duty to Inspect:**

Buyer will promptly inspect any shipment of Products received from 3M Health Care and will promptly notify 3M Health Care. The notice must specify the defects in detail; any defect present but not specified is waived. After sending the notice, Buyer will follow 3M Health Care return

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**3M**

Health Care  
Cardiovascular Systems  
Sarns™ AND CDI™ PRODUCTS

6200 Jackson Road  
PO Box 1247  
Ann Arbor, MI 48103-1247  
USA

800 262 3304 Tel  
734 663 4145 Tel  
734 741 6181 Fax



goods policy then in effect, or any specific and reasonable instructions which 3M Health Care may issue. Buyer will allow 3M Health Care to inspect any allegedly defective goods at Buyer's site. For any goods which 3M Health Care determines are defective, Buyer will follow 3M Health Care instructions and either return the goods to 3M Health Care, with 3M Health Care responsible for the return freight, or dispose of the goods in a safe manner (approved by 3M Health Care), at no charge to 3M Health Care. Any goods not rejected within thirty (30) days of delivery are accepted.

#### 6. Use of 3M Health Care Names and Trademarks:

Buyer will make no use whatsoever of 3M Health Care name without 3M Health Care written permission. The decision to grant or withhold permission is within 3M Health Care sole discretion. Buyer will not use or reproduce any of 3M Health Care trademarks in any manner without 3M Health Care prior written approval. To request this approval, Buyer must forward to 3M Health Care a complete and accurate specimen copy of the proposed use. If in its sole discretion, 3M Health Care chooses to approve the use, the use is subject to any revisions which 3M Health Care may choose to make on the specimen.

#### 7. No Assignment OR Delegation:

Buyer may not assign its rights or delegate its duties under these Terms and Conditions.

#### 8. Entire Agreement; No Waiver; Governing Law:

These Terms and Conditions state the complete understanding between 3M Health Care and Buyer on this subject and replace any previous statements, communications or understandings, whether oral or written. Any reference to Buyer's purchase order number is solely a matter of administrative convenience to Buyer. These Terms and Conditions cannot be modified except by a signed writing. A course of dealing or of performance does not effect a waiver or modification unless ratified in writing. A party's failure to exercise a right in one instance does not waive that party's right to later exercise that right. Any questions, claims or disputes concerning these Terms and Conditions or this sale are governed by the laws of Delaware.

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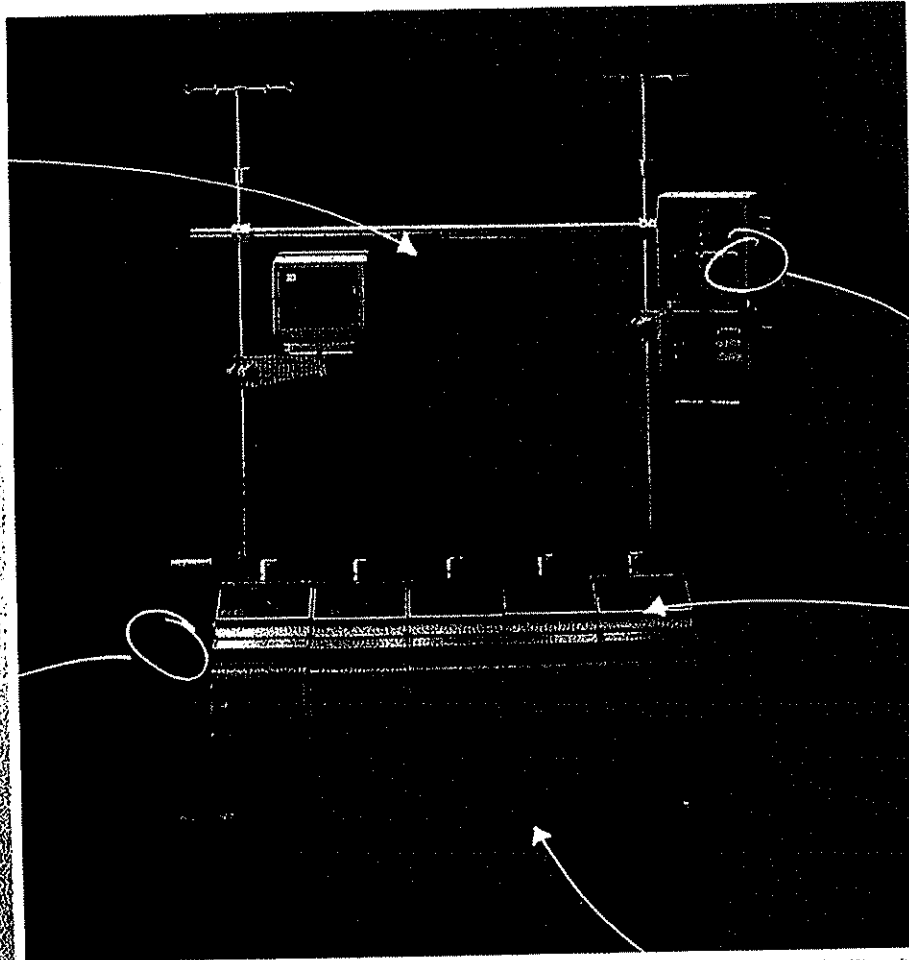
**3M**

Health Care  
Cardiovascular Systems  
Sarns™ AND CDI™ PRODUCTS

6200 Jackson Road  
PO Box 1247  
Ann Arbor, MI 48103-1247  
USA

800 262 3304 Tel  
734 663 4145 Tel  
734 741 6181 Fax

# Build a system to your specs.



*I want  
the instrument  
tray*

*I want to  
control the  
cardiopulmonary  
machine*

*I only  
want one*

*I want  
the electronic  
occluder*

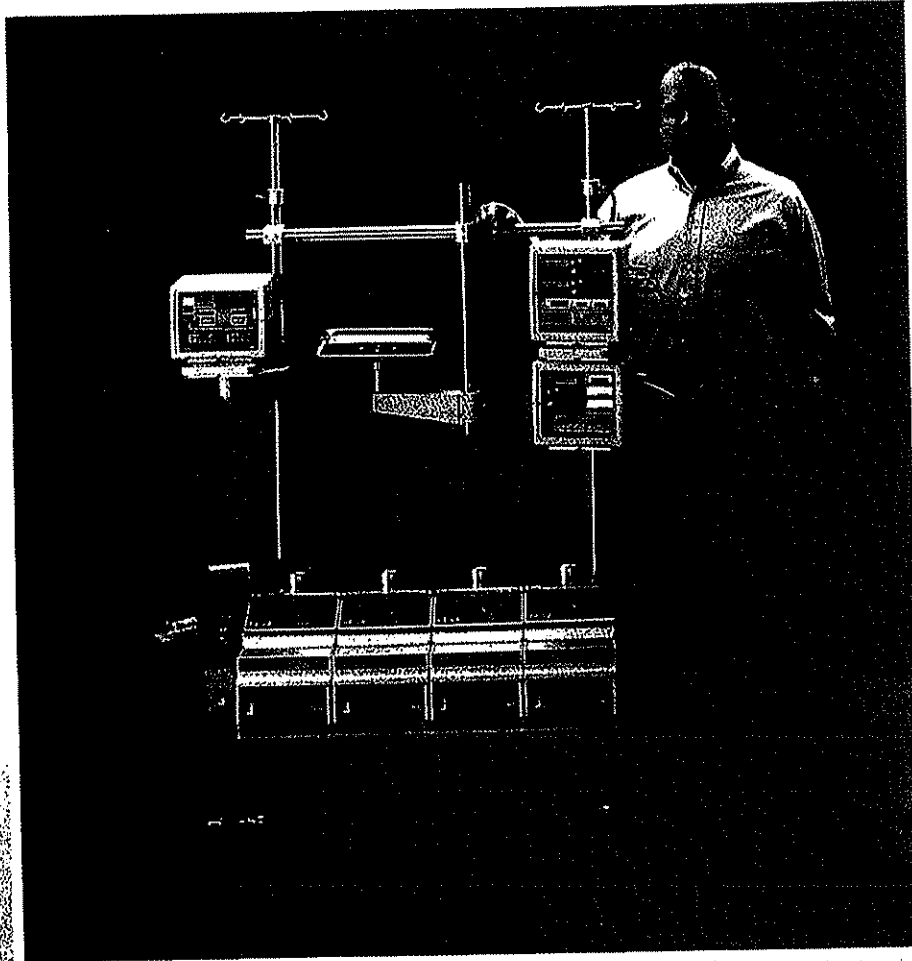
*I need  
battery backup*

Sarns 8000 modular perfusion system



**3M**  
HealthCare

# Build your own Sarns™ 8000 modular perfusion system.



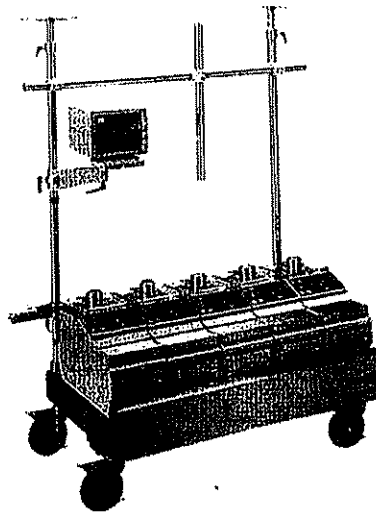
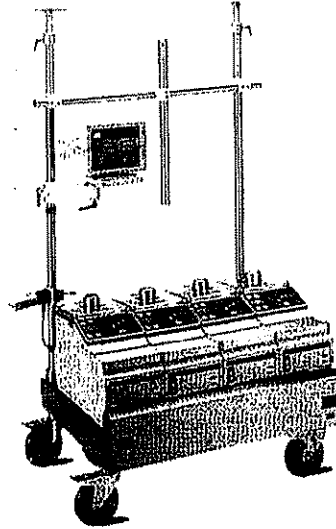
## Start with a solid foundation...

This flexible, modular perfusion system offers a four- or five-pump base with easily interchanged pumpheads. The Sarns<sup>®</sup> 8000 modular perfusion system can be upgraded after purchase to include additional equipment as needed.

**Safety monitoring** is achieved with air bubble and level detection modules. Under specific arterial pressure alarm conditions, the safety module stops both the arterial and cardioplegia pumps immediately.

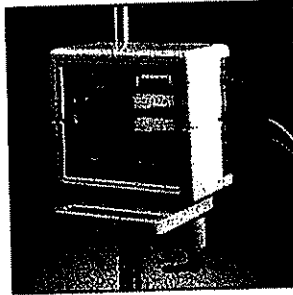
**Proven pump design** has been used in Sarns perfusion systems for tens of thousands of open-heart surgeries. The base has been designed to accommodate roller or centrifugal pumps at any position. Each pump plugs into its own circuit and can be connected to the safety module.

**Attentive service** includes installation, set-up, calibration and periodic maintenance by Sarns service experts. Initial product support is backed by a 24-hour helpline and a wide spectrum of service contracts.

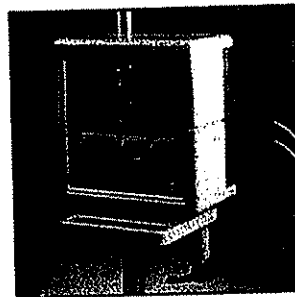


## Add the features you want.

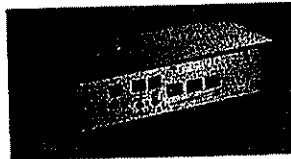
Arterial monitor integrates one pressure display, three temperature displays and two separate timers into a single, easy-to-watch module. Specific arterial overpressure conditions will automatically stop arterial and cardioplegia pumps.



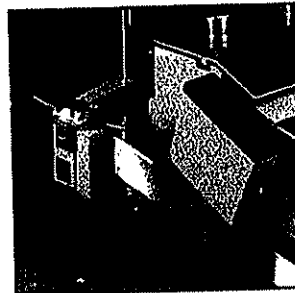
Cardioplegia monitor devotes two pressure displays, three temperature displays and two timers to the cardioplegia circuit. An overpressure alarm will stop the cardioplegia pump for antegrade and/or retrograde delivery.



Automatic battery backup supplies uninterrupted power to two pumps, all safety systems and accessories for 25 minutes. Built into the pump base, the battery conserves scarce OR space.

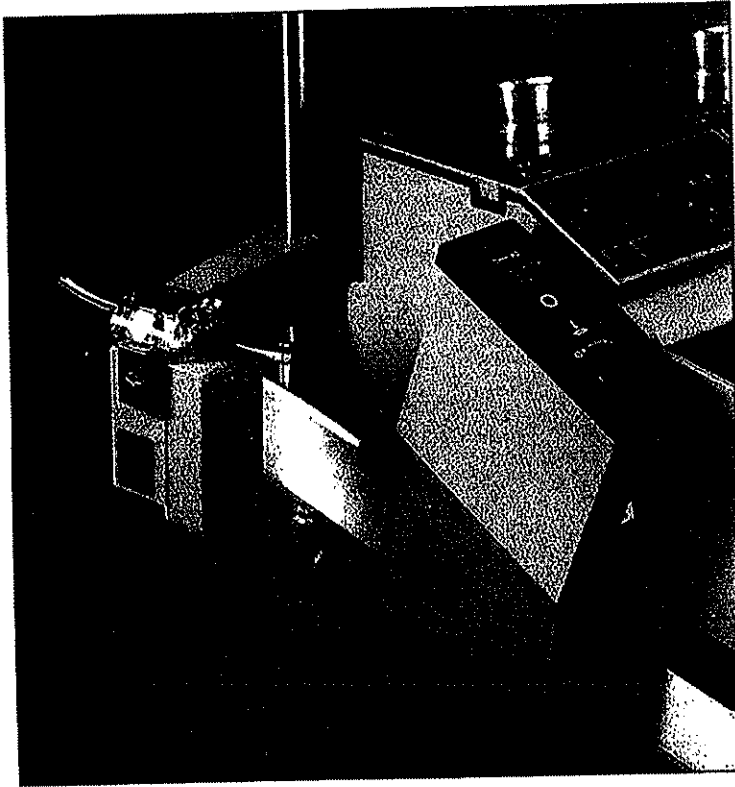


Precise, electronic occluder controls venous flow more accurately and conveniently than conventional means.



## Electronic occluder

Sarns 8000 modular perfusion system



**Accurate venous flow** is controlled with a precise electronic occluder that can be set exactly to achieve any desired occlusion. The occluder responds promptly to any control changes, and the open and close switches have a very fast response time.

**Quick self-calibration** automatically determines tube wall thickness after the tubing is placed in the occluder head and the close switch is pressed.

**Good visibility** of the blood flow path is allowed by the see-through tubing clamp.

**Convenient mounting** and cable storage keep your work zone familiar and uncluttered. Put the occluder on the left or right to suit your needs.

# Electronic occluder specifications

Catalog number 16418

## Operating parameters

|                     |  |
|---------------------|--|
| Tubing requirements | 1/4 in. (6.4 mm) ID x 1/16 in. (1.6 mm) wall   |
| Minimum             | 1/2 in. (12.7 mm) ID x 3/32 in. (2.4 mm) wall  |
| Maximum             |  |
| Display range       | 0-99% of maximum venous flow   |
| Display accuracy    | The occluder will display accurately ( $\pm 12\%$ ) only when using 1/2 in. or 3/8 in. ID tubing with the blood at 20°-40° C and with a vertical height of 20-36 in. (50.8-91.4 cm) from the fluid level in the venous reservoir to the level of the patient.* |

## Physical description

|   | Occluder module    | Occluder head     |
|---|--------------------|-------------------|
| Depth                                   | 8.5 in. (21.6 cm)  | 8.0 in. (20.3 cm) |
| Width                                   | 3.0 in. (7.6 cm)   | 6.5 in. (16.5 cm) |
| Height                                  | 7.7 in. (19.6 cm)  | 3.0 in. (7.6 cm)  |
| Weight                                  | 3.6 lbs. (1.6 kg)  | 6.2 lbs. (2.8 kg) |
| Total system weight (including bracket) | 12.6 lbs. (5.7 kg) |                   |

## Environmental conditions

|                       |                                       |
|-----------------------|---------------------------------------|
| Operating temperature | 10°-40° C                             |
| Relative humidity     | <95% relative humidity, noncondensing |

For more information about the 8000 electronic occluder, contact your Sarns representative or call 800/521-2818. In Michigan, call 313/663-4145.

See product inserts for indications, contraindications, instructions for use and warnings.

\*Sarns" is a registered trademark of 3M.

## Sarns 3M Health Care

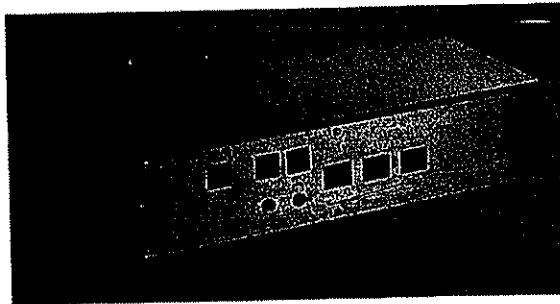
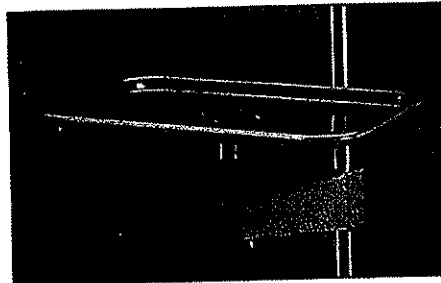
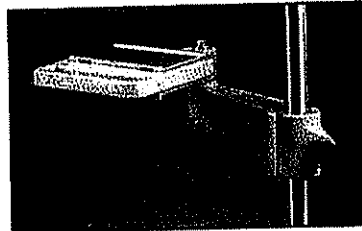
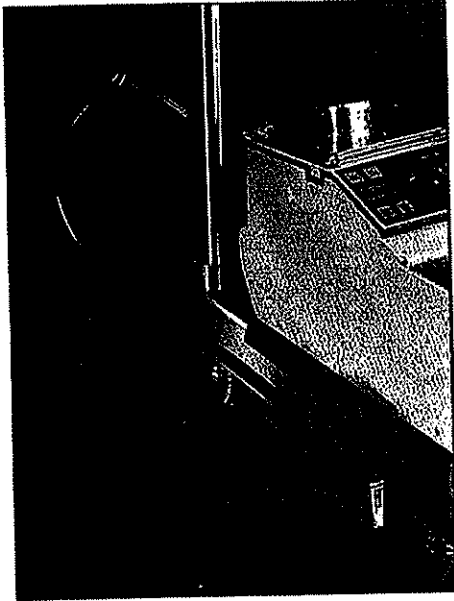
6200 Jackson Road, Ann Arbor, MI 48103 USA  
Phone: 800/521-2818 or 313/663-4145  
FAX: 313/663-7981 Telex: 4930456 SARINC

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## Accessories

### Sarns 8000 modular perfusion system



**Automatic battery backup** provides power to two pumps, all safety systems and accessories for 25 minutes. Switchover from main power to battery backup is automatic and immediate, providing an uninterrupted power supply. The battery unit is built into the pump base to conserve valuable OR space and can be recharged automatically when the system is operating with wall power.

**High-intensity quartz lamp** can be connected on either end of the base to illuminate the oxygenator. Power to the lamp will be uninterrupted if the battery module is installed.

**Positionable instrument tray** organizes supplies for more efficient perfusion management.

**Adjustable mounting arm** for arterial and cardioplegia monitors offers maximum positioning flexibility.



# Accessories specifications

| Description  | Catalog numbers |
|--|-----------------|
| Battery module~ supplies uninterrupted power to two pumps, all safety systems and accessories for 25 minutes |                 |
| 115V   | 16422           |
| 220-240V   | 16415           |
| 100V   | 16423           |
| Lamp   | 16420           |
| Mounting arms  |                 |
| Short, with 5/8 in. (1.6 cm) pole  | 16505801        |
| Long, with 5/8 in. (1.6 cm) pole   | 16505901        |
| For 8000 monitors  | 16421           |
| Instrument tray, includes long mounting arm  | 16434101        |
| Writing surface (pole mounted)   | 4404            |
| Extension Arm  | 16425           |
| Cross Bar Kit, 3 ft.   | 16426           |
| Cross Bar Kit, 4 ft.   | 16427           |
| Blender  | 164235          |

For more information about 8000 system accessories, contact your Sarns representative or call 800/521-2818. In Michigan, call 313/663-4145.

See product inserts for indications, contraindications, instructions for use and warnings.

"Sarns" is a registered trademark of 3M.

## Sarns 3M Health Care

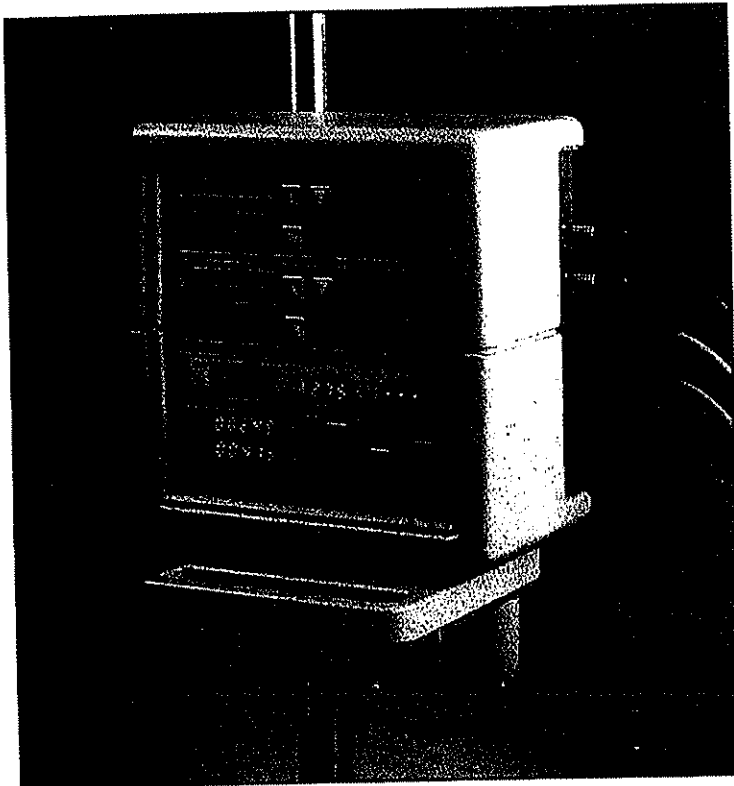
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## Cardioplegia monitor

Sarns 8000 modular perfusion system



**Dedicated cardioplegia monitor** uses two pressure displays, three temperature displays and two timers.

**User-set alerts and alarms** warn of overpressure or actually stop the cardioplegia pump. The system retains the settings for the next power up.

**Automatic pump stop** will occur for antegrade and/or retrograde delivery under specific overpressure conditions.

**Adjustable audio volume** can be set to your preference.

**Convenient timers** track the length of each cardioplegia infusion as well as time between infusions.

# Cardioplegia monitor specifications

Catalog number  
(Mounting arm ordered separately)

16414

---

## Operating parameters

|  |   |
|--|---|
| Temperature monitoring range           | 0°–49.9° C, with $\pm 0.3^\circ$ C display accuracy and 0.1° C resolution   |
| Pressure monitoring range (2 channels) | -45–990 mmHg  |
| Alert range (each channel)             | 0–980 in 10 mmHg increments; default = 300 mmHg   |
| Alarm range (each channel)             | 10–990 in 10 mmHg increments; default = 360 mmHg  |
| Timers                                 | Two digital timers (displaying hours, minutes and seconds) measure the duration of cardioplegia delivery and the time between deliveries. |

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## Environmental conditions

|                       |                                       |
|-----------------------|---------------------------------------|
| Operating temperature | 10°–40° C                             |
| Relative humidity     | <95% relative humidity, noncondensing |

For more information about the 8000 cardioplegia monitor, contact your Sarns representative or call **800/521-2818**. In Michigan, call 313/663-4145.

See product inserts for indications, contraindications, instructions for use and warnings.

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## Sarns 3M Health Care

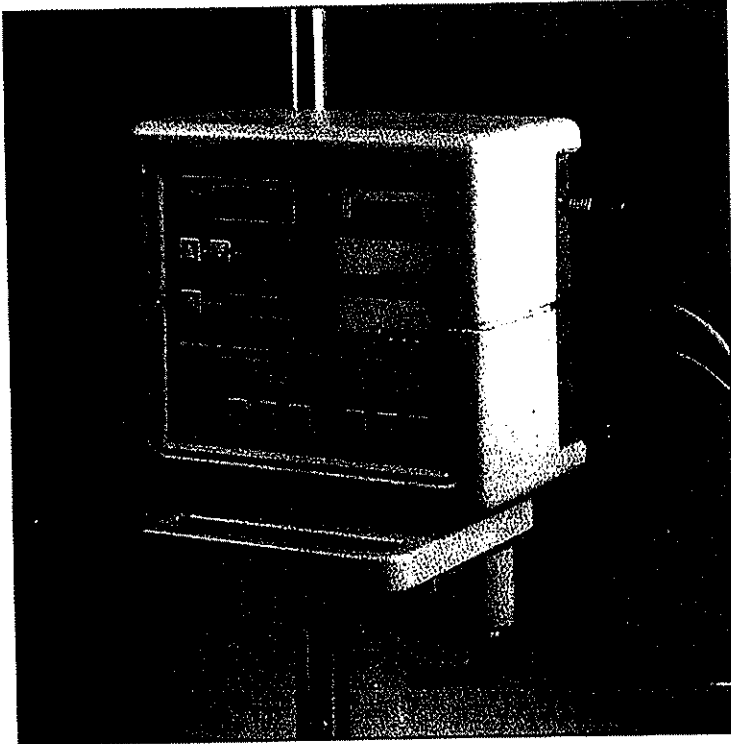
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# Arterial monitor

Sarns 8000 modular perfusion system



**Easy-to-watch integrated display** for one pressure, three temperatures and two timers simplifies arterial monitoring. A well-organized control panel combines accurate digital displays with user-friendly membrane switches.

**Convenient transducer connections** for temperatures and pressure are made on the right side of the monitor. A flexible mounting arm positions the module according to personal preference.

**User-set alerts and alarms** warn of impending overpressure with visual and audio signals or actually stop the arterial pump. The system retains the settings and recalls them after the next power up.

**Adjustable audio volume** adequately warns users without startling them.

# Arterial monitor specifications

Catalog number  
(Mounting arm ordered separately)

16413

---

## Operating parameters

|  |  |
|--|--|
| Temperature monitoring range<br>(For YSI* 400-type probes) | 0°–49.9° C, with $\pm 0.3^\circ$ C display accuracy<br>and 0.1° C resolution   |
| Pressure monitoring range                                  | -45–990 mmHg   |
| Alert range  | 0–990 in 10 mmHg increments; default = 300 mmHg  |
| Alarm range  | 10–990 in 10 mmHg increments; default = 360 mmHg   |
| Timers   | Two independent timers, each with start, stop<br>and reset switches, with hours, minutes and seconds<br>up to 9 hours, 59 minutes, 59 seconds. |

---

## Environmental conditions

|                       |                                       |
|-----------------------|---------------------------------------|
| Operating temperature | 10°–40° C                             |
| Relative humidity     | <95% relative humidity, noncondensing |

\*Yellow Springs Instrument Company, Yellow Springs, Ohio

For more information about the 8000 arterial monitor,  
contact your Sarns representative or call **800/521-2818**.  
In Michigan, call 313/663-4145.

See product inserts for indications, contraindications,  
instructions for use and warnings.

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## Sarns 3M Health Care

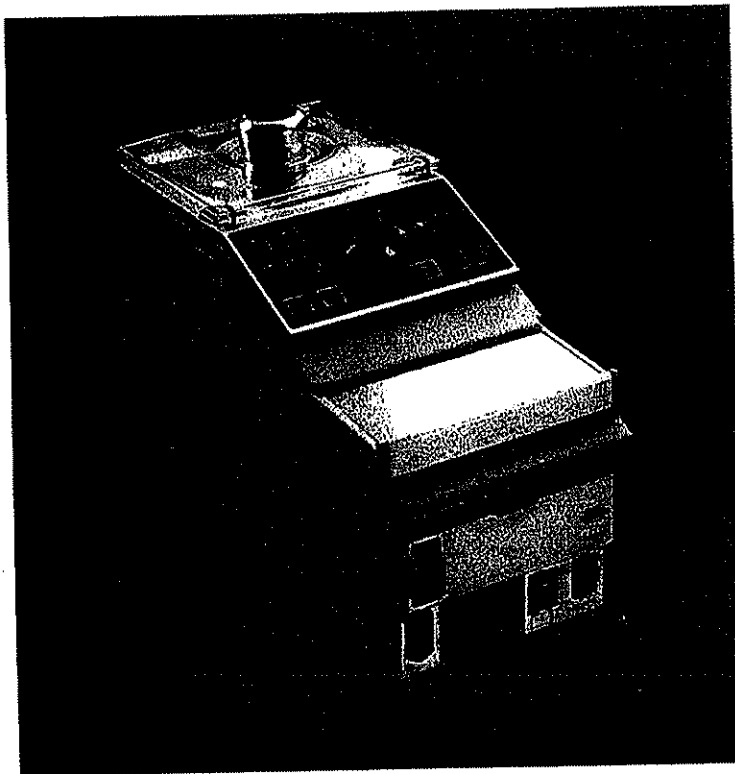
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# Universal roller pump

Sarns 8000 modular perfusion system



**Powerful portable pump** consists of a microprocessor-controlled peristaltic pump in a spill-proof enclosure with its own power supply. The compact module has handles for easy lifting.

**Accurate speed control** from 1 RPM all the way up to 250 RPM and flow rates of 9.9 L/min. Response is excellent under a wide range of clinical conditions, temperatures and loads.

**Precise digital readouts** display flow rates in LPM or RPM. The pump automatically calculates and displays flow rates for various tubing sizes, including 4:1, 2:1 and 1:1 cardioplegia tubing. Helpful advisory information appears in the control panel message area.

**On-the-fly occlusion adjustment** permits fine tuning while the pump is running, yet allows quick tube removal if necessary. Interchangeable inserts for the tube clamps slide out easily for quick replacement.

**Multiple checks of pump speed**, including an accurate optical tachometer that measures pump speed directly from the drive shaft, quickly alert the operator to unlikely events such as overspeed, tachometer loss, pump jam or belt slip.

**Intentional controls** require that dual forward, reverse and computer switches be pushed simultaneously to ensure deliberate activation. The control panel is angled and color coded for maximum efficiency.

**Cover interlock** helps prevent spills into the pump head and pump jams because the pump operates only when the cover is closed.

# Pump specifications

---

## Electrical power

|   | 115 V Pump                         | 220-240 V Pump                     | 100 V Pump                    |
|---|------------------------------------|------------------------------------|-------------------------------|
| Voltage   | 103.5-126.5 V~<br>(115 V, nominal) | 198-264 V~<br>(220-240 V, nominal) | 90-110 V~<br>(100 V, nominal) |
| Frequency   | 50/60 Hz                           | 50/60 Hz                           | 50/60 Hz                      |
| Current rating,<br>fully loaded system<br>Continuous flow | 1.4 amps                           | 0.7 amps                           | 1.6 amps                      |
| Catalog numbers<br>Roller pump                            | 16402                              | 16407                              | 16411                         |

---

## Physical description

| Dimensions | Roller pump        |
|------------|--------------------|
| Height     | 8.2 in. (20.8 cm)  |
| Width      | 19.7 in. (50.0 cm) |
| Depth      | 14.0 in. (35.6 cm) |
| Weight     | 50 lbs (22.6 kg)   |

---

## Environmental conditions

|                       |                                       |
|-----------------------|---------------------------------------|
| Operating temperature | 10°-40° C                             |
| Relative humidity     | <95% relative humidity, noncondensing |

For more information about 8000 modular roller pumps, contact your Sarns representative or call **800/521-2818**. In Michigan, call 313/663-4145.

See product inserts for indications, contraindications, instructions for use and warnings.

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### Sarns 3M Health Care

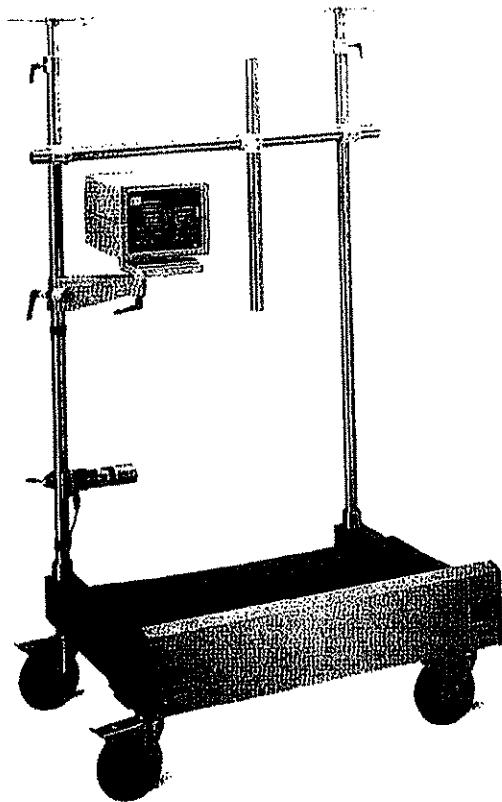
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## Pump base and safety monitor

Sarns 8000 modular perfusion system



**Solid stainless-steel base** with recessed top securely holds four or five modular pumps that can be exchanged quickly in an emergency. The removable polyethylene cover shields the unit from spills.

**Unique safety monitor** can be set to stop the designated arterial and cardioplegia pumps in the event of air detection or low reservoir level. An adjustable mounting arm offers maximum positioning flexibility.

**Logical alerts and alarms** combine audible and visual indications compatible with the seriousness of the situation. Activated alarms stop the arterial and cardioplegia pumps.

**Protected power cords** behind the front access door connect each pump to the base. All electrical connections are protected from spills but easily accessible behind the door.

**Future expansion** is always an option because the 8000 base is designed to integrate the modular components of the future. Be confident that each acquisition—from additional monitors to battery backup to electronic occluder—already has its place.

**Sturdy poles** make it easy to mount monitors and additional equipment. After the monitor brackets are mounted, the monitors simply slide into place.

**Superb maneuverability** is assured by four easy-to-roll casters that can be locked to prevent rolling or swiveling.



# Pump base specifications

## Electrical power

|  | 115 V Base                         | 220-240 V Base                     | 100 V Base                    |
|--|------------------------------------|------------------------------------|-------------------------------|
| Voltage                                | 103.5-126.5 V~<br>(115 V, nominal) | 198-264 V~<br>(220-240 V, nominal) | 90-110 V~<br>(100 V, nominal) |
| Frequency                              | 50/60 Hz                           | 50/60 Hz                           | 50/60 Hz                      |
| Current rating,<br>fully loaded system |                                    |                                    |                               |
| 4-pump base                            | 13 amps                            | 6 amps                             | 14 amps                       |
| 5-pump base                            | 15 amps                            | 7 amps                             | 16 amps                       |
| Catalog numbers                        |                                    |                                    |                               |
| 4-pump base                            | 16400                              | 16405                              | 16409                         |
| 5-pump base                            | 16401                              | 16406                              | 16410                         |
| Battery module                         | 16422                              | 16415                              | 16423                         |

## Environmental conditions

|                       |  |
|-----------------------|--|
| Operating temperature | 10°-40° C                                |
| Relative humidity     | <95% relative humidity,<br>noncondensing |

Emergency power The optional 8000 system battery module will power the arterial pump (operating in continuous mode), the monitors, occluder and lamp for 40 minutes. When the cardioplegia pump also is operating on battery power, the battery time available will decrease to 25 minutes.

## Base

|            | 4-pump base        | 5-pump base         |
|------------|--------------------|---------------------|
| Dimensions |                    |                     |
| Height     | 25.8 in. (65.5 cm) | 25.8 in. (65.5 cm)  |
| Width      | 33.3 in. (84.5 cm) | 41.6 in. (105.6 cm) |
| Depth      | 26.5 in. (67.3 cm) | 26.5 in. (67.3 cm)  |

\* Height from floor to top of roller pump when mounted on base

## Extra poles and brackets

| Description                             | Catalog numbers |
|---|-----------------|
| * Cross bar for 4-pump base (standard)  | 16426           |
| ** Cross bar for 5-pump base (standard) | 16427           |
| * ** 2' pole (standard)                 | 16553301        |
| 3' pole (optional)                      | 16548101        |
| 4' pole (optional)                      | 16553401        |
| Arm for mounting additional monitor     | 16421           |
| Extension arm for extra pole            | 16425           |

\* One included standard with 4-pump base

\*\* One included standard with 5-pump base.

# Safety monitor specifications

## Description

Monitor, including mounting arm,  
standard with all bases

Catalog number  
16404

## Infrared air detection

|                    | 1/4 in. sensor   | 3/8 in. sensor  |
|--------------------|--|---|
| Tubing requirement | 1/4 in. (6.4 mm) ID x<br>1/16 in. (1.6 mm) wall  | 3/8 in. (9.5 mm) ID x<br>3/32 in. (2.4 mm) wall   |
| Sensor performance | Detects bubbles of $\geq 0.5$ mL<br>at flow rates up to 3 L/min<br>in blood with a hematocrit<br>of 15-40% | Detects bubbles of $\geq 1$ mL at<br>flow rates up to 6 L/min in<br>blood with a hematocrit<br>of 15-40%. |
| Catalog numbers    | 15020  | 13540   |

## Ultrasonic level detection

|                                 |  |
|---------------------------------|--|
| Fluid level                     | Level detection occurs when the fluid level in the reservoir is within $\pm 0.2$ in. (0.5 cm) from the horizontal center line of the level sensor pad. |
| Reservoir                       | Functions only with clear hard-shell reservoirs that have a wall thickness of 0.03-0.10 in. (0.8-2.5 mm)   |
| Performance                     | Alert and alarm signals function properly with clear priming solutions or blood of any hematocrit.   |
| Catalog numbers                 |  |
| Level sensor transducers        | 16458601   |
| Level sensor pads (20 sets/box) | 16432901   |

For more information about the 8000 modular perfusion system, contact your Sarns representative or call 800/521-2818. In Michigan, call 313/663-4145.

See product inserts for indications, contraindications, instructions for use and warnings.

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## Sarns 3M Health Care

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## Sarns 8000 modular perfusion system...

Build a Sarns 8000 perfusion system by selecting components to suit your patient safety, clinical performance and budget needs...now and in the future.

In standard configuration, your system will:

- Pump blood using roller or centrifugal pump technology in a four- or five-pump configuration.
- Detect gross air bubbles and stop the arterial and cardioplegia pumps under specific alarm conditions.
- Warn when the rigid reservoir blood levels reach an operator-set minimum and stop the arterial and cardioplegia pumps under specific alarm conditions.
- Accommodate auxiliary equipment through two outlets, one of which is switched to safety systems.
- Allow retrofitting of additional capabilities after purchase.

With optional capabilities, your 8000 system will:

- Monitor arterial pressure, three temperatures and two times.
- Display two cardioplegia pressures, three temperatures and two times.
- Control venous line occlusion.
- Supply uninterrupted backup power for two pumps and all safety systems for 25 minutes.

For more information about the 8000 modular perfusion system, contact your local sales representative or call 800/821-2818. In New York, call 315/663-4145.

For medical contraindications, contraindications, and other information, see the manual.

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Sarns  
3M Health Care

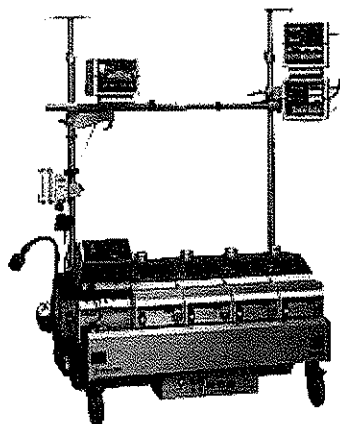
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Fax: 315/663-7991 / 315/663-4830/456-SARINC

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# SARNS™ 8000

- Complete 4 Pump Open Heart System
- Modular design makes a custom system affordable
- Built for reliability and durability
- It is indicated for use in extracorporeal circulation of blood for arterial perfusion, regional perfusion and cardiopulmonary bypass procedures only.



Typical Manufacturer's Picture

## Specifications

### Electrical Power Requirements

|                                     | 115 V Bases  | 220-240 V Bases | 100V Bases |
|-------------------------------------|--------------|-----------------|------------|
| Voltage                             | ~103-126.5 V | 198-264         | ~90-110    |
| Frequency                           | 50/60 Hz     | 50/60 Hz        | 50/60 Hz   |
| Circuit Breaker Protection          | 16 amps      | 8 amps          | 16 amps    |
| Fully Loaded System Current Rating: |              |                 |            |
| 4 pump base                         | 13 amps      | 6 amps          | 14 amps    |
| 5 pump base                         | 15 amps      | 7 amps          | 16 amps    |

### Electrical Power Performance

Leakage Current: <100 microamperes for 115 V and 100 V bases (fully loaded); <200 microamperes for 220-240 V bases (fully loaded). The maximum leakage current for the base without pumps is 45 microamperes for all input voltages. Ground resistance: 0.1 ohms maximum for all bases. Emergency power: 8000 system battery (two 12 volt, sealed gel cell batteries) will power the arterial pump (operating in continuous mode), the monitors, occluder and lamp for 40 minutes; when the arterial pump is operated in pulsatile mode or the cardioplegia pump is also operating on battery power, the battery time available will diminish to 25 minutes. The base is tested for high potential: 1200V~ for 100-115 VAC units; 1500V~ for 220-240 VAC units.

### Physical characteristics

|             | 4 Pumps Unit       | 5 Pumps Unit       |
|-------------|--------------------|--------------------|
| Base Height | 25.8" (65.5 cm)    | 25.8" (65.5 cm)    |
| Width       | 33.3" (84.5 cm)    | 41.6" (105.6 cm)   |
| Depth       | 26.5" (67.3 cm)    | 26.5" (67.3 cm)    |
| Weight      | 330 lbs (149.5 kg) | 380 lbs (172.1 kg) |

|        |                  |
|--------|------------------|
| Pump   | Roller           |
| Height | 14" (35.6 cm)    |
| Width  | 8.2" (20.8 cm)   |
| Depth  | 19.7" (50 cm)    |
| Weight | 50 lbs (22.6 kg) |

Telescope pole: 1.30" (3.3 cm) diameter, 6-7 feet (1.8 – 1.9 m) height.

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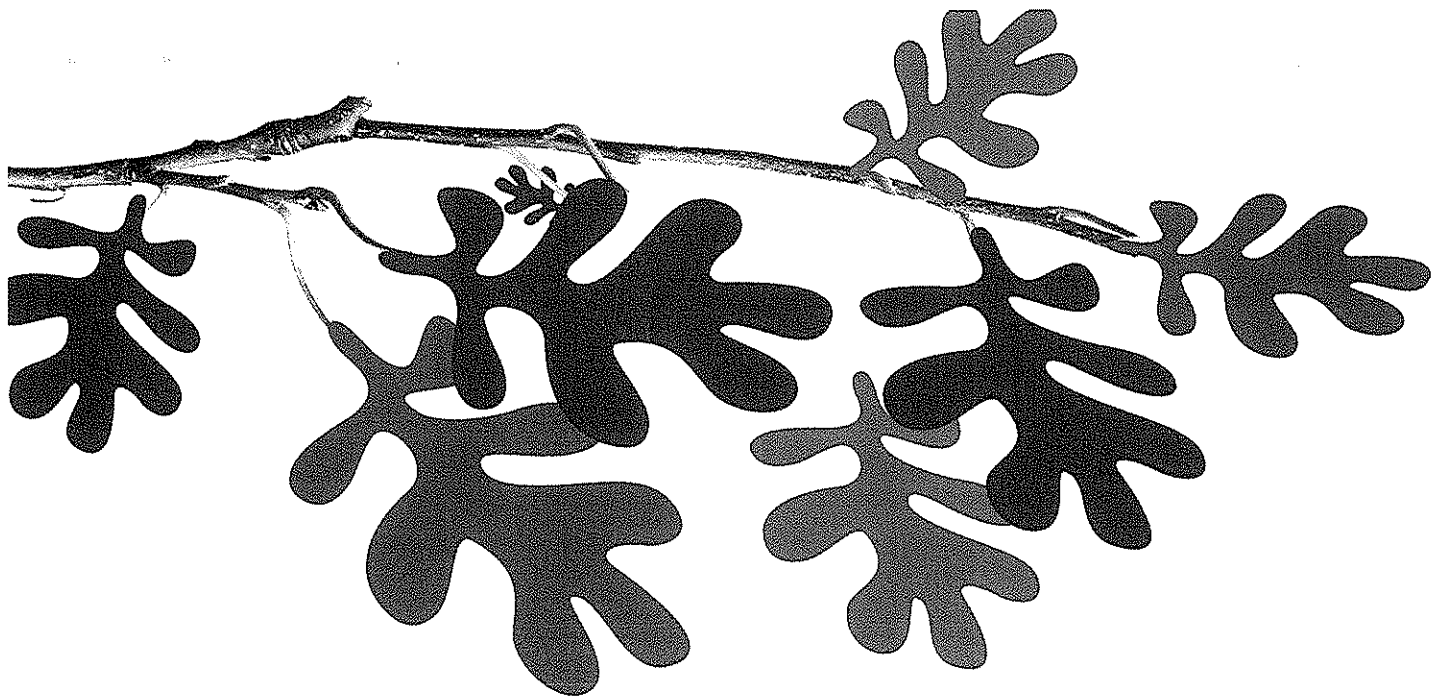
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 **SORIN** | 55™

EXTRACORPOREAL EXCELLENCE





## OUR FIFTH-GENERATION MODULAR HEART-LUNG MACHINE HAS COMPLETELY REWRITTEN THE STANDARDS FOR FUNCTIONALITY, FLEXIBILITY AND QUALITY.

The S5™ is in a class by itself. The innovation represents the culmination of more than 30 years of experience in extracorporeal perfusion system design and manufacturing. Its solid construction and sophisticated feature set reflect input from professionals operating in real world conditions.

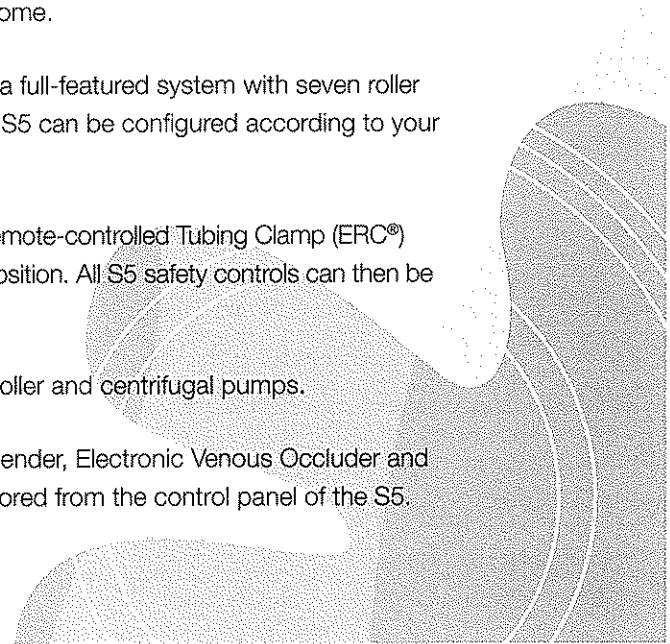
For the perfusionist who demands intelligent, functional ergonomics and reliable safety systems, the S5 delivers. Its refined modular design permits the quick and easy exchange of individual components in even the most challenging of environments. Software based upgrades that can be implemented at any time will allow your system to remain state-of-the-art for many years to come.

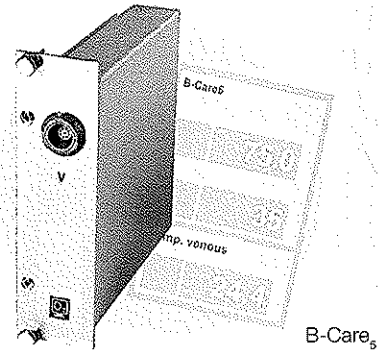
From a small, compact HLM equipped with three roller pumps to a full-featured system with seven roller pumps and the full range of control and monitoring functions, the S5 can be configured according to your individual requirements and budget considerations.

The renowned integrated Centrifugal Pump (SCP) and Electronic Remote-controlled Tubing Clamp (ERC®) can be easily integrated into the S5 without consuming a console position. All S5 safety controls can then be applied to the SCP.

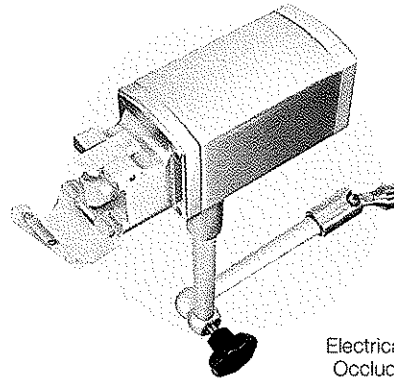
The S5 is now available with pulsatile flow capability for both the roller and centrifugal pumps.

The high performing and quiet 3T heater/cooler, Electronic Gas Blender, Electronic Venous Occluder and B-Care<sub>s</sub> Sat/Hct monitor can be remotely controlled and/or monitored from the control panel of the S5.

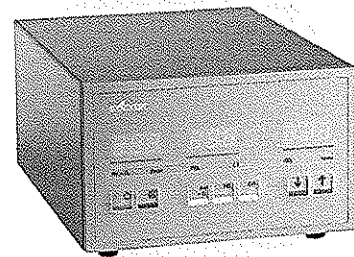




B-Care<sub>s</sub>



Electrical Venous Occluder (EVO)

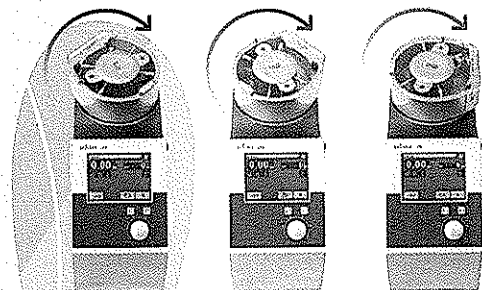


Electronic Gas Blender (EGB)

## ERGONOMICS

In today's OR, available space is at a premium, which is why we've designed the S5 with 20% smaller outward dimensions as compared to the SIII.

The angled pump displays, flexible mast system and other available options for mast mounting will ensure that your pump can be optimized to exceed your ergonomic needs.



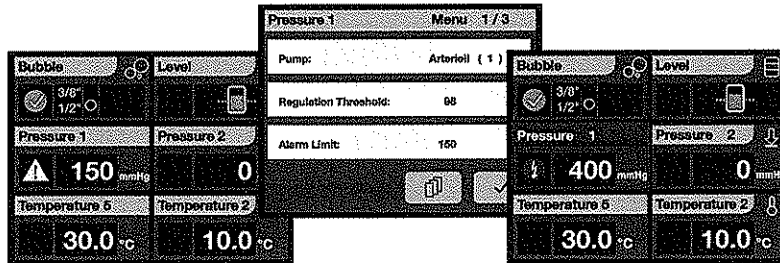
Roller Pumps

## QUALITY AND DURABILITY

Optimizing operational safety was paramount in the design of S5. Only parts made of the highest quality materials with the lowest failure rates and greatest possible resistance to wear and tear are used. The care taken in the selection of the materials and parts used contributes to reducing the operating costs and increasing the durability of the system.

Sorin Group is a leader in the innovation of cardiovascular perfusion products. Our unsurpassed manufacturing experience and customer-driven design excellence will ensure that your investment meets your highest expectations in quality, performance, safety and simplicity.

## Control Panel Views



## SAFETY

All of the warnings and automated alarms of the S5 system—some of which are acoustically differentiable—are recorded and listed chronologically on the system display. All pertinent information is clearly displayed, and critical situations can be quickly detected and cleared.

In the event of power failure, the uninterruptible power supply (UPS) enables further operation for up to 130 minutes. The remaining time is continually indicated on the battery status display.

## TECHNOLOGY

Micro processors contained within the various modules ensure that each component functions as designed, in real-time. In addition, each module is completely replaceable and interchangeable.

No other perfusion system can match S5's new, high-resolution TFT displays. This new technology enables the perfusionist to easily view displayed values from greater distances and at an angle of up to 140 degrees.

The menu system is clearly structured and guides you quickly and intuitively through the set-up menus to the desired touchscreen display. The use of descriptive system displays eliminates guesswork and makes the perfusionist's job easier.

The brushless, direct-drive motor of the roller pumps runs extremely quiet. Speed adjustments are performed via an incremental encoder. The technology is maintenance-free, assuring lower operating costs.

## FLEXIBILITY

The S5 was designed to meet the diverse needs of today's hospital—while keeping pace with changing demands.

It can be operated with as few as three and as many as seven roller pumps and a centrifugal pump. Two newly developed mast roller pumps (150 mm or 85 mm diameter) enable positioning in close proximity to the patient. The pump heads can easily be rotated through a range of 180 degrees and self-lock into position for convenient optimization of the tubing circuit.

The S5 mast system consists of three vertically and one horizontally moveable mast for mounting external devices and disposables.



# DATA MANAGEMENT SYSTEM

The Data Management System (DMS) offers a new standard of convenience for the surgical team. The fully integrated system with its easy-to-use interface provides valuable tools for conducting correlation studies or trends analysis and managing the perfusion record.

Each of the system's components work to help you achieve excellent performance, as well as an unprecedented level of convenience.

## DATA PAD<sup>®</sup> TOUCH SCREEN

DataPad is a drip proof, medical grade tablet PC mounted directly on the Sorin perfusion system. The touch screen interface enables fast and easy manual entries without use of a keyboard or mouse.

## DMS CHARTING SYSTEM

DMS automatically records all values and events of the heart-lung machine and external devices (e.g. patient monitor, blood gas analyzer, ACT meter and cerebral oximetry). This innovative charting system can also provide data storage for all hospital operating rooms in one central database, thereby avoiding inconsistent data inventory and enabling data compilation for studies and analysis. Data transfer is provided in different formats for easy processing in other programs (Excel, Access, dBase, etc.).


DMS is HL7 compatible to align perfusion data with Electronic Health Record compliance.





## ORDERING INFORMATION

|  |          |  |                 |
|--|----------|--|-----------------|
| <b>S5 Consoles with E/P Pack and Standard Mast System</b>  |          | <b>SCP Centrifugal pump system (for S5 system exclusively)</b> | <b>60-00-50</b> |
| S5 Console 3 position  | 48-30-00 | SCP Drive unit   | 60-01-00        |
| S5 Console 4 position  | 48-40-00 | SCP Control panel  | 60-02-50        |
| S5 Console 5 position  | 48-50-00 | Emergency hand crank   | 60-01-50        |
| <b>S5 System Components</b>  |          | Flow sensor 3/8"   | 96-414-120      |
| S5 3-slot system panel   | 28-95-03 | ERC Electrical Remote-Controlled tubing clamp                  | 60-05-60        |
| S5 4-slot system panel   | 28-95-00 | Electronic Gas Blender (EGB)                                   | 25-28-67        |
| S5 5-slot system panel   | 28-95-01 | Electronic Venous Occluder (EVO)                               | 12-80-00        |
| S5 6-slot system panel   | 28-95-04 | B-Care <sub>s</sub> Sat/Hct Monitor                            | 25-60-00        |
| S5 Control and display module  | 28-95-10 | DMS with Server and Online License                             | 24-10-90        |
| S5 Blank module  | 28-95-30 | DMS with Online License  | 24-10-95        |
| S5 Roller pump 150 (S5 RP 150)   | 10-80-00 | S5 Pressure sensor module (2-channel)                          | 22-20-20        |
| S5 Double roller pump 85 (S5 DRP 85)   | 10-85-00 | S5 Temperature sensor module (4-channel)                       | 20-30-20        |
| Large S5 mast roller pump 150  | 50-80-00 | S5 Level sensor module, complete                               | 23-40-00        |
| S5 Mast roller pump 85 (S5 MRP 85) includes 1 pump and control panel   | 50-80-70 | Holder for level sensor  | 75-521-548      |
| 2 S5 Mast roller pump 85 (2 S5 MRP 85) includes 2 pumps and control panel  | 50-80-60 | S5 Bubble sensor module, complete                              | 23-45-00        |
| 2 S5 Mast roller pumps 85 with coupling (2 S5 MRP 85)  | 50-80-62 | S5 Cardioplegia sensor module                                  | 27-80-20        |
| S5 Mast extension system includes telescoping mast, 2 sets of horizontal joining arms, short vertical mast locking arm for transport | 50-45-00 | S5 Interface module with 4 serial ports, RS-232                | 29-02-50        |
| S5 Tubing clamp "Variolock" RP 150 (included with RP 150)  | 10-81-30 | S5 Shelf 3 position  | 48-31-10        |
|  |          | S5 Shelf 4 position  | 48-41-10        |
|  |          | S5 Shelf 5 position  | 48-51-10        |
|  |          | S5 LED lamp  | 35-05-60        |

 THIS BROCHURE WAS PRINTED ON RECYCLED PAPER.



SORIN GROUP USA, INC.  
14401 W. 65TH WAY, ARVADA, CO 80004  
800.221.7943 • 303.467.6525 FAX  
WWW.SORINGROUP-USA.COM

CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.  
TRADEMARK USED HEREIN ARE OWNED BY OR LICENSED TO SORIN GROUP USA, INC.

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Via E-Mail: ggriffin@unch.unc.edu

June 8, 2015

Mr. Greg Griffin CCP  
Chief Perfusionist  
University of North Carolina Hospital  
101 Manning Drive  
Chapel Hill, NC 27514  
Account: 910778  
Contract Number: OP91077820150605.2

**RE: S5 Heart Lung Perfusion System Outright Purchase Proposal**

Dear Mr. Griffin:

As requested through Adam Clark, the Sorin Group USA, Inc. Account Executive in your area, we are pleased to make the following proposal for the S5 Heart Lung Perfusion System. This proposal will become invalid if not accepted by October 8, 2015.

Our terms are Net 30, and Sorin Group USA, Inc. prepays freight and adds to the invoice. This proposal is confidential between Sorin Group USA, Inc. and University of North Carolina Hospital ("Customer"), and disclosure of the information it contains will render it null and void. Notwithstanding the foregoing, this proposal may be disclosed to such representatives, advisors and affiliates of Customer as have a need to know such information for the sole purpose of assisting Customer in evaluating the proposal, and for no other purpose (it being understood that such representatives, advisors and affiliates shall be informed by Customer of the confidential nature of such information and shall be directed by Customer and shall agree to treat such information confidentially).

If you accept the terms and conditions (see attached Standard Terms and Conditions) of this proposal for the purchase of the quoted equipment, please fax or mail your Purchase Order **referencing your contract number on the Purchase Order** to the undersigned, Fax No. (303) 467-6590. The mailing address is referenced in the terms and conditions under ordering information.

Our records indicate that you are not affiliated with a GPO (Group Purchasing Organization) member with whom Sorin Group USA, Inc. currently has a pricing arrangement. If this is incorrect, please note your GPO membership in the spaces provided and fax to (303) 467-6590. This will help Sorin Group USA, Inc. to determine that the pricing we have established does not exceed pricing we have negotiated with your GPO. If you are a member of more than one GPO, please note your commitment for pricing for all the GPO contracted items for purchase from Sorin Group USA, Inc.

We welcome the opportunity to supply and support your equipment needs in the coming years. If you have any questions or if I can be of any further assistance, please contact me at (800) 221-7943, extension 6296, or Adam Clark, voice mailbox # 5015.

Sincerely,

Sorin Group USA, Inc.

Danielle Danenhauer  
Contract Administrator

Enclosure

cc: Adam Clark, Sorin Group USA, Inc. Senior Account Executive  
Ted Cowles, Sorin Group USA, Inc. Regional Manager

Contract # OP91077820150605.2  
Sorin Group USA, Inc.  
14401 W. 65th Way  
Arvada, CO 80004-3599  
United States of America

T: 303 425-5508  
800 221-7943  
F: 303 467-6590

June 8, 2015

**S5 HEART LUNG PERFUSION SYSTEM  
 OUTRIGHT PURCHASE PROPOSAL  
 FOR  
 University of North Carolina Hospital in Chapel Hill, NC**
**S5 HEART LUNG PERFUSION SYSTEM:**

| <i>Catalog No.</i>                                  | <i>Description</i>   | <i>Quantity<br/>Per System</i> |
|---|--|--------------------------------|
| <b><i>S5 Consoles</i></b>                           |  |                                |
| 48-30-00  | 3-Pump console (includes: Timer, power supply, emergency power supply, electronic and power supply pack and mast system) | 1                              |
| 45-09-10  | Cable holding and organizing system  | 1                              |
| 45-09-11  | Cable holding and organizing system  | 1                              |
| 43-42-61  | Cap for fast clamp (6 pcs.)  | 1                              |
| <b><i>S5 Pump Modules</i></b>                       |  |                                |
| 10-80-00  | Single roller pump   | 3                              |
| 50-80-00  | Mast roller pump 150 (incl. mast mountable pump and control panel)   | 2                              |
| 10-84-60  | Pump Tray for RP150  | 1                              |
| 10-84-64  | Double Pump Tray   | 1                              |
| 50-80-99  | Color Knob Set   | 1                              |
| 50-45-15  | Mast Extension Pole  | 1                              |
| <b><i>Variolock Tubing Gate and Accessories</i></b> |  |                                |
| 10-81-30  | Tubing Gate  | 5                              |
| 10-61-94  | Tubing Variolock 4:1 SILVER  | 1                              |
| <b><i>S5 Control Desk</i></b>                       |  |                                |
| 28-95-00  | 4-slot system Panel  | 1                              |
| 28-95-10  | Display Module   | 4                              |
| <b><i>S5 Control Devices and Monitors</i></b>       |  |                                |
| 22-20-20  | Pressure sensor module (2 channel)   | 1                              |
| 20-30-20  | Temperature sensor module (4 channels) for YSI probes  | 1                              |
| 23-40-00  | Level Sensor (incl. 23-27-40, 23-27-41)  | 1                              |
| 75-521-548  | Holder (required for Level Sensor II 23-27-40)   | 1                              |
| 23-27-60  | Mounting pads, Level sensor II   | 1                              |
| 23-45-00  | 3/8" Bubble sensor module w/420 mm holder, incl. (23-07-50, 23-26-96, 23-45-20 and 96-06-10)                             | 1                              |
| 10-07-48  | Tubing insert, metal, 3/8 X 3/32, BLUE   | 1                              |
| 27-80-20  | Cardioplegia Sensor Module   | 1                              |
| 23-07-40  | 1/4" Bubble Sensor (pediatric or cardioplegia)   | 1                              |
| 10-07-45  | Tubing insert, metal, 1/4 X 1/16, RED  | 1                              |
| <b><i>S5 Accessories - Masts and Crosstrays</i></b> |  |                                |
| 48-31-19  | Crosstray 3 position W/Power Outlet  | 1                              |
| <b><i>Venous Line Occluders</i></b>                 |  |                                |
| 12-80-00  | Electronic Line Clamp (incl. 12-80-10 & 28-95-70)  | 1                              |
| <b><i>S5 Miscellaneous</i></b>                      |  |                                |
| 35-05-70  | Led Lamp 24V   | 2                              |
| 10-07-49  | Tubing insert, metal, 1/2 X 1/16, SILVER   | 1                              |
| 29-02-70  | Single Port Interface DDDD module for connection to competitive DMS Devices  | 1                              |
| 0264-2049   | Abbott Transpac IV Pressure Transducer Cable   | 3                              |
| <b>Each System Net Price</b>                        |  | <b>\$241,355.00*</b>           |
| <b>Freight Charges Per System</b>                   |  | <b>\$980.00</b>                |
| <b>Extended Amount for Each System with Freight</b> |  | <b>\$242,335.00*</b>           |

\*Price does not include applicable taxes.

**SORIN GROUP USA, INC.**  
**STANDARD TERMS AND CONDITIONS**

|  |  |
|--|--|
| <b>PRICE &amp; PAYMENT TERMS:</b>        | Payment terms subject to approved credit. Taxes, if owed, shall be added to the invoice amount. Tax exemption certificates must be submitted to Sorin Group USA, Inc. prior to placement of orders. All prices are subject to an annual increase set by Sorin Group USA, Inc. at its sole discretion. Credit Cards will not be accepted for payment of amounts owed.   |
| <b>METHOD OF SHIPMENT AND FREIGHT:</b>   | Equipment and Disposable Products shall be shipped and delivered to Customer via surface transportation. Sorin Group USA, Inc. prepays freight and adds to the invoice. Freight charges for Equipment may be billed to the Customer separately.  |
| <b>TITLE &amp; RISK OF LOSS:</b>         | Title of, and risk of loss to, Equipment and/or Disposables shall transfer to Customer upon shipment.  |
| <b>ORDER QUANTITIES:</b>                 | Made to order, custom packs require a minimum order quantity of one case. Federal regulations prohibit the sale of incomplete case quantities.   |
| <b>RETURNED GOODS:</b>                   | Returned goods will be accepted only with prior written authorization from Sorin Group USA, Inc. and in accordance with such authorization. Items must be returned freight prepaid and accompanied by Sorin Group USA, Inc.'s Returned Materials Authorization form. Items to be returned must be in ORIGINAL UNOPENED cartons, have original labels, be in a saleable condition and are subject to a twenty-five percent (25%) re-stocking charge. Goods held over twelve (12) months from the date of invoicing, abused or custom items, chemical concentrates, and items identified as non-returnable or that have deteriorated due to a cause beyond Sorin Group USA, Inc.'s control, may not be returned.   |
| <b>DAMAGED SHIPMENTS:</b>                | Damage or shortage should be noted on the freight bill. If damage is observed after opening, notify the transportation company and request a <b>hidden damage report</b> . No adjustment, credit or duplicate shipment can be made until written documentation is received by Sorin Group USA, Inc.  |
| <b>LIMITED WARRANTY:</b>                 | For a period of twelve (12) months from the date of installation of Equipment, Sorin Group USA, Inc. will at its option repair or replace (free of charge) Equipment that Sorin Group USA, Inc. finds defective in materials or workmanship. For a period of twelve (12) months from the date of the invoice, Sorin Group USA, Inc. will replace (free of charge) Disposable Products which Sorin Group USA, Inc. finds defective in materials or workmanship. For a period of ninety (90) days from the date of the invoice, Sorin Group USA, Inc. will repair or replace (free of charge) spare parts that Sorin Group USA, Inc. finds defective in materials or workmanship. Sorin Group USA, Inc. is not responsible for, and shall have no obligation with respect to, any failure caused by normal wear and tear, misuse, unauthorized alterations, accident, neglect, use of nonstandard accessory attachments, and/or improper maintenance. Sorin Group USA, Inc. does not verify the safety or efficacy, and makes no warranties - expressed or implied - with respect to any non-Sorin Group USA, Inc. components included at Customer's request or any components or products used other than as expressly intended by their manufacturer. <b>THIS LIMITED WARRANTY CONTAINS THE CUSTOMER'S EXCLUSIVE REMEDIES. SORIN GROUP USA, INC. SHALL NOT BE LIABLE FOR ANY INCIDENTAL, SPECIAL OR CONSEQUENTIAL DAMAGES ARISING FROM THE USE OF ITS PRODUCTS. SORIN GROUP USA, INC. DOES NOT GIVE ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.</b> |
| <b>ORDERING INFORMATION:</b>             | Orders may be placed by phone, facsimile, e-mail or mail to Sorin Group USA, Inc. at:<br><br>Sorin Group USA, Inc.<br>Attn.: Customer Service Department<br>14401 W. 65 <sup>th</sup> Way<br>Arvada, Colorado 80004-3599<br>(800) 650-2623 Toll-Free Phone<br>(800) 323-4031 Fax<br><a href="mailto:customerservice@Sorin.com">customerservice@Sorin.com</a><br><br>Normal business hours are 6:00 a.m. to 5:00 p.m., MST, Monday through Friday. Purchase Order numbers are required at the time the order is placed.   |
| <b>DELIVERY:</b>                         | Stock products will be delivered in 7-10 days after receipt of order (ARO).  |
| <b>DISTRIBUTORS:</b>                     | Sorin Group USA, Inc. is not responsible for any fees associated with placement of orders through JIT suppliers, distributors, or warehouses.  |
| <b>MODIFICATION AND LEGAL COMPLIANCE</b> | Customer shall not modify or alter the products in any way without the prior written approval of Sorin Group USA, Inc. Customer shall conduct its business in compliance with all applicable laws, statutes and ordinances and shall comply with all applicable governmental rules and regulations in force with respect to the products.<br><br>Sorin will make available technical training opportunities for health care practitioners on the use of Sorin medical devices purchased by you. Should health care practitioners choose to receive such training, Sorin may pay the reasonable travel and lodging expenses, including meals, to all health care practitioners who reasonably require such training and use or recommend the use of Sorin products. Training and education of your employees, agents or others who implant or utilize Sorin medical devices purchased by you will enable informed medical decisions about the use or recommendation for use of Sorin products with patients.  |
| <b>SUBSTITUTION:</b>                     | Sorin Group USA, Inc. reserves the right to discontinue products that may be covered by this Agreement. Should any product covered by this Agreement become obsolete during the term of this Agreement, Sorin Group USA, Inc. will notify the Customer and offer substitute product, if available.   |
| <b>FORCE MAJEURE:</b>                    | Sorin Group USA, Inc. shall not be liable for any delays in delivery from any cause beyond its control including, without limitation, acts of GOD, fire, flood, strike, lockout, factory shutdown, supply shortage, priority request, riot, war or embargo. In the event of shortage of supply of materials or goods for any reason, Sorin Group USA, Inc. may allocate its available supply among itself and its Customers in a manner determined by Sorin Group USA, Inc. in its sole discretion.  |
| <b>PAST DUE ACCOUNTS:</b>                | Customer shall pay Sorin Group USA, Inc. the lesser of interest at the rate of one and one-half percent (1.5%) per month or the highest rate permitted by applicable law on all invoices thirty (30) days past due. Customer agrees to pay all reasonable attorneys' fees and expenses incurred by Sorin Group USA, Inc. in enforcing its rights hereunder.  |
| <b>PRODUCT TRACEABILITY:</b>             | Customer is responsible to maintain product traceability for each individual product delivered by Sorin Group USA, Inc. Customer will comply with any product recalls initiated by Sorin Group USA, Inc. and will notify Sorin Group USA, Inc. of any Customer complaints on Sorin Group USA, Inc.'s products.   |
| <b>DISCOUNTS FROM LIST PRICE:</b>        | The parties understand that for purposes of 42 C.F.R. § 1001.952(h), any reduction in the amount charged Customer from list price is a "discount or other reduction in price" to Customer. The Customer shall report the discount or reduction in price and provide other requested information to any state or federal program which provides cost or charge-based reimbursement to Customer for products and supplies covered by this Agreement in accordance with applicable governmental regulations.  |
| <b>INDEMNIFICATION:</b>                  | Customer agrees to hold Sorin Group USA, Inc., and its employees, officers, directors, agents, successors and assigns harmless from and against any and all losses, claims and damages (including reasonable fees and expenses of counsel), as they are incurred, which arise out of or are related to any claim by a third party of personal injury or other loss to the third party caused by alleged negligence on the part of the Customer or its employees, agents, or assigns. This provision shall survive expiration or termination of this Agreement.   |
| <b>TERM:</b>                             | Unless there is a specific termination provision in a document signed by Customer and Sorin Group USA, Inc., Sorin Group USA, Inc. may terminate this Agreement and its obligations to Customer at any time upon one hundred twenty (120) days advance written notice to Customer and immediately upon written notice to Customer if Customer fails to pay Sorin Group USA, Inc. when due any amount it owes Sorin Group USA, Inc. or otherwise breaches these Standard Terms and Conditions. Termination or expiration of this Agreement shall not affect Customer's obligation to pay Sorin Group USA, Inc. all amounts it owes Sorin Group USA, Inc. (including interest and attorneys' fees) nor shall it affect any provision intended to survive expiration or termination.  |
| <b>STANDARD TERMS AND CONDITIONS:</b>    | These Standard Terms and Conditions supersede any provisions, terms and/or conditions contained in any purchase order or other writing submitted by Customer to Sorin Group USA, Inc. and the provisions, terms and/or conditions of any such purchase order or other writing submitted by Customer are of no force or effect. These Standard Terms and Conditions shall be construed and enforced in accordance with the laws of the State of Colorado.   |

**ADDITIONAL INFORMATION REQUIRED FOR EQUIPMENT TO BE SHIPPED TO CUSTOMER'S LOCATION**

**Customer Contact Information**

| Department                              | Phone | Contact name | Alternate Contact |
|---|-------|--------------|-------------------|
| Shipping/Receiving                      |       |              |                   |
| Perfusion/Surgery/ECMO<br>O.R. Director |       |              |                   |
| Biomedical Engineering                  |       |              |                   |
| Purchasing                              |       |              |                   |

**Customer Shipping Information**

Customer PO Number: \_\_\_\_\_ Facility Medical License Number: \_\_\_\_\_

Equipment Shipping Address:

|   |  |     |
|---|--|-----|
|   |  |     |
| Hospital Name                                 |  |     |
|   |  |     |
| Street Address                                |  |     |
|   |  |     |
| City  | State  | Zip |
| <input type="checkbox"/> Appointment Required | <input type="checkbox"/> Lift gate               |     |
| <input type="checkbox"/> Inside Delivery      | <input type="checkbox"/> Other (Please describe) |     |

**Please include these special delivery instructions requirements on your Purchase Order.**



**GPO Membership Confirmation**  
**For**  
**University of North Carolina Hospital in Chapel Hill, NC**  
**Account: 910778**

|  |  |
|--|--|
| <p><b>GPO Membership Commitment</b> (Please note that SORIN GROUP USA, INC. currently has contracted pricing only with the GPO's listed below). Please choose only one, if applicable.</p> <p><input type="checkbox"/> Carolina Shared Services</p> <p><input type="checkbox"/> Cooperative Services of Florida</p> <p><input type="checkbox"/> HCA (Hospital Corporation of America)</p> <p><input type="checkbox"/> HPA (Healthcare Purchasing Alliance)</p> <p><input type="checkbox"/> HPG (HealthTrust Purchasing Group)</p> <p><input type="checkbox"/> Premier</p> <p><input type="checkbox"/> PSCS (Providers Supply Chain Services)</p> | <hr/> <p>(Buyer: Full Corporate Name)</p> <hr/> <p>(Signature)</p> <hr/> <p>(Name - Please Print or Type)</p> <hr/> <p>(Title)</p> <hr/> <p>(Date)</p> |
|--|--|

**You only need to complete and return this page if Sorin Group USA, Inc. does not have your correct GPO affiliation on the cover page. Please complete the above information and fax this page to (303) 467-6590.**

2015 Renewal Application for Hospital:  
**University of North Carolina Hospitals**

**CORRECTED 1/15**

License No: **H0157**  
 Facility ID: **923517**

All responses should pertain to October 1, 2013 through September 30, 2014.

**7. Specialized Cardiac Services** (for questions, call 855-3865 [Medical Facilities Planning])

| <b>(a) Cardiac Catheterization</b>   | <b>Diagnostic Cardiac Catheterization ICD-9</b><br>37.21, 37.22, 37.23, 37.25 <del>XX</del>  | <b>Interventional Cardiac Catheterization ICD-9</b><br>00.66, 99.10, 36.06, 36.07, 36.09; 35.52, 35.71, 35.96 |
|--|--|---|
| 1. Number of Units of Fixed Equipment  | <b>3 ADULT + 1 PEDIATRIC</b>   |   |
| 2. Number of Procedures* Performed in Fixed Units on Patients Age 14 and younger | <b>109</b>   | <b>59</b>   |
| 3. Number of Procedures* Performed in Fixed Units on Patients Age 15 and older   | <b>1412</b>  | <b>1053</b>   |
| 4. Number of Procedures* Performed in Mobile Units                               |  |   |
|  | <b>Electro-physiology ICF-9</b><br>37.26, 37.27, 37.34, 37.70, 37.71, 37.72, 37.73, 37.74, 37.75, 37.76, 37.77, 37.79, 37.80, 37.81, 37.82, 37.83, 37.85, 37.86, 37.87, 37.89, 37.94, 37.95, 37.96, 37.97, 37.98, 37.99, 00.50, 00.51, 00.52, 00.53, 00.54 |   |
| 5. Number of Units of Fixed Equipment  | <b>2</b>   |   |
| 6. Number of Procedures on Dedicated EP Equipment                                | <b>978</b>   |   |

\*A procedure is defined to be one visit or trip by a patient to a catheterization laboratory for a single or multiple catheterizations. Count each visit once, regardless of the number of diagnostic, interventional, and/or EP catheterizations performed within that visit.

Name of Mobile Vendor: \_\_\_\_\_

Number of 8-hour days per week the mobile unit is onsite: \_\_\_\_\_ 8-hour days per week.

(Examples: Monday through Friday for 8 hours per day is 5 8-hour days per week. Monday, Wednesday, & Friday for 4 hours per day is 1.5 8-hour days per week)

| <b>(b) Open Heart Surgery</b>  | <b>Number of Machines/Procedures</b> |
|--|--------------------------------------|
| 1. Number of Heart-Lung Bypass Machines  | <b>4</b>                             |
| 2. Total Annual Number of Open Heart Surgery Procedures Utilizing Heart-Lung Bypass Machine                | <b>390</b>                           |
| 3. Total Annual Number of Open Heart Surgery Procedures done without utilizing a Heart-Lung Bypass Machine | <b>167</b>                           |
| 4. Total Open Heart Surgery Procedures (2. + 3.)   | <b>557</b>                           |
| <b>Procedures on Patients Age 14 and younger</b>   |                                      |
| 5. Of total in #2, Number of Procedures on Patients Age 14 & younger                                       | <b>101</b>                           |
| 6. Of total in #3, Number of Procedures on Patients Age 14 & younger                                       | <b>11</b>                            |

~~XX~~ DOES NOT INCLUDE 668 DIAG. CATHS PERFORMED ON SAME DAY AS INTERVENTIONAL  
 Revised 08/2014 CATHS (6 AGE 0-14 & 662 AGE 15+).

**CORRECTED**

PROPOSED TOTAL CAPITAL COST OF PROJECT

A. Site Costs

|  |    |   |
|--|----|---|
| (1) Full purchase price of land          | \$ | 0 |
| Acres _____ Price per Acre \$ _____      |    |   |
| (2) Closing costs                        | \$ | 0 |
| (3) Site Inspection and Survey           | \$ | 0 |
| (4) Legal fees and subsoil investigation | \$ | 0 |
| (5) Site Preparation Costs               |    |   |
| Soil Borings                             | \$ | 0 |
| Clearing - Earthwork                     | \$ | 0 |
| Fine Grade for Slab                      | \$ | 0 |
| Roads - Paving                           | \$ | 0 |
| Concrete Sidewalks                       | \$ | 0 |
| Water and Sewer                          | \$ | 0 |
| Footing Excavation                       | \$ | 0 |
| Footing Backfill                         | \$ | 0 |
| Termite Treatment                        | \$ | 0 |
| Other (Specify)                          | \$ | 0 |
| Sub-Total Site Preparation Costs         | \$ | 0 |
| (6) Other (Specify)                      | \$ | 0 |
| (7) <b>Sub-Total Site Costs</b>          | \$ | 0 |

B. Construction Contract

|   |    |   |
|---|----|---|
| (8) Cost of Materials                       |    |   |
| General Requirements                        | \$ | 0 |
| Concrete/Masonry                            | \$ | 0 |
| Woods/Doors & Windows/Finishes              | \$ | 0 |
| Thermal & Moisture Protection               | \$ | 0 |
| Equipment/Specialty Items                   | \$ | 0 |
| Mechanical/Electrical                       | \$ | 0 |
| Other (Unit Strut Support)                  | \$ | 0 |
| Sub-Total Cost of Materials                 | \$ | 0 |
| (9) Cost of Labor                           | \$ | 0 |
| (10) Other (Specify)                        | \$ | 0 |
| Firestopping                                | \$ | 0 |
| Asbestos Abatement                          | \$ | 0 |
| Window Upgrade                              | \$ | 0 |
| HVAC Upgrade                                | \$ | 0 |
| (11) <b>Sub-Total Construction Contract</b> | \$ | 0 |

C. Miscellaneous Project Costs

|   |    |         |
|---|----|---------|
| (12) Building Purchase                                    | \$ | 0       |
| (13) Fixed Equipment Purchase                             | \$ | 0       |
| (14) Movable Equipment Purchase                           | \$ | 242,335 |
| (15) Furniture  | \$ | 0       |
| (16) Landscaping  | \$ | 0       |
| (17) Consultant Fees                                      |    |         |
| Architect and Engineering Fees                            | \$ | 0       |
| Legal Fees  | \$ | 0       |
| Market Analysis   | \$ | 0       |
| Other (Structural fee)                                    | \$ | 0       |
| Other (Specify)   | \$ | 0       |
| Sub-Total Consultant Fees                                 | \$ | 0       |
| (18) Financing Costs (e.g. Bond, Loan, etc.)              | \$ | 0       |
| (19) Interest During Construction                         | \$ | 0       |
| (20) Other (Specify)                                      | \$ | 0       |
| (21) <b>Sub-Total Miscellaneous</b>                       |    | 242,335 |
| (22) <b>Total Capital Cost of Project (Sum A-C above)</b> | \$ | 242,335 |

I certify that, to the best of my knowledge, the above construction related costs of the proposed project named above are complete and correct.

\_\_\_\_\_  
Signature of Licensed Architect or Engineer

I assure that, to the best of my knowledge, the above capital costs for the proposed project are complete and correct and that it is my intent to carry out the proposed project as described.

*James St. Phillips, Jr. VP Penix Services*  
\_\_\_\_\_  
Assistant Director of Operations  
(Title & Signature of Office Authorized to Represent Provider/Company)