NC DEPARTMENT OF
HEALTH AND HUMAN SERVICES

ROY COOPER • Governor
KODY H. KINSLEY • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

March 24, 2022

Gary S. Qualls
gary.qualls@klgates.com

No Review

Record #:	**3848**
Date of Request:	March 16, 2022
Facility Name:	Atrium Health Pineville
FID #:	110878
Business Name:	The Charlotte-Mecklenburg Hospital Authority
Business #:	1770
Project Description:	Relocate a replacement heart/lung bypass machine from Carolinas Medical Center to Atrium Health Pineville
County:	Mecklenburg

Dear Mr. Qualls:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your correspondence regarding the project described above. Based on the CON law **in effect on the date of this response to your request,** the project as described is not governed by, and therefore, does not currently require a certificate of need. If the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective. Please see the Agency's Exempt from Review determination (Record #3847) regarding the replacement of the heart/lung bypass machine being relocated from Carolinas Medical Center to Atrium Health Pineville.

This determination is binding only for the facts represented in your correspondence. If changes are made in the project or in the facts provided in the correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office.

Please do not hesitate to contact this office if you have any questions.

Sincerely,

Julie M. Faenza

Julie M. Faenza, Project Analyst

Micheala Mitchell

Micheala Mitchell, Chief

cc. Acute and Home Care Licensure and Certification

K&L GATES

March 16, 2022

Gary S. Qualls
D 919.466.1182
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gary.qualls@klgates.com

Via E-Mail
Micheala Mitchell, Chief
Julie Faenza, Project Analyst
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
N.C. Department of Health and Human Services
809 Ruggles Drive
Raleigh, NC 27603

Re: Replacement Equipment Exemption and Material Compliance / No Review Request for Replacing and Relocating Heart-Lung Bypass Machine from CMHA's CMC Campus to CMHA's Pineville Campus

Dear Ms. Mitchell and Ms. Faenza:

The Charlotte-Mecklenburg Hospital Authority d/b/a Atrium Health ("CMHA") asks the Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section (the "Agency") to make the two rulings described below for its wholly owned facilities and operating divisions, Carolinas Medical Center ("CMC") and Atrium Health Pineville ("AH Pineville").

The Exemption Notice in Part I describes how CMHA will replace one CMHA-owned and operated Heart-Lung Bypass Unit ("Bypass Unit") at CMC with another existing, comparable Bypass Unit at CMC.

The Material Compliance / No Review Request in Part II asks the Agency to confirm that no Certificate of Need ("CON") is required in order for CMHA to relocate that replaced Bypass Unit from one existing CMHA wholly owned facility and operating division to another (i.e., from CMC to AH Pineville). The relocation of this Bypass Unit will not increase CMHA's Bypass Unit complement or the Bypass Unit complement in Mecklenburg County.[1]

[1] We characterize Step 2 as, alternatively, a Material Compliance / No Review Request for the following reasons. Step 2 is most accurately called a Material Compliance Request if the "Old Bypass Unit" being replaced (or its predecessors units) were obtained pursuant to a CON, as opposed to being grandfathered under the CON Law. Because CMHA has owned the Old Bypass Unit (or its predecessors units) so long, CMHA's records do not reflect whether this particular unit originated from a CON or predated CON

A summary of each step is described immediately below. A more detailed description of each step is then provided in Parts I and II below.

Summary of Step #1

1. In Step #1, CMHA seeks a replacement equipment exemption to replace the "Old Bypass Unit" at CMC with a new Bypass Unit (the "Replacement Bypass Unit" or "Replacement Equipment") for under $2 Million. See N.C. Gen. Stat. § 131E-184(a)(7) and 131E-176(22a).

Summary of Step #2

2. CMHA next seeks a material compliance or (in the alternative) a no review determination to relocate the Replacement Bypass Unit to the AH Pineville Campus. The act of relocating the Replacement Bypass Unit does not constitute a "purchase" or "acquisition" since CMHA: (a) owns it when it is located at CMC; and (b) will still own it when it is made operational at AH Pineville.

I. Step #1 -- The Replacement Equipment Exemption.

CMHA first seeks a replacement equipment exemption to replace CMC's "Old Bypass Unit" with the Replacement Bypass Unit. The Old Bypass Unit is a LivaNova S5 Heart Lung Perfusion System. The Replacement Bypass Unit is also the same make and model of LivaNova S5 Heart Lung Perfusion System, just newer. See Exhibit B (cost quote for Replacement Bypass Unit); Exhibit C (brochure for Replacement Bypass Unit); Exhibit D (CON Equipment Comparison Form). CMHA's acquisition of this Replacement Bypass Unit is exempt as described below.

A. Section 184(a)(7) Exemption

The General Assembly has chosen to exempt certain, otherwise reviewable events from CON review. Among those exemptions is the acquisition of "replacement equipment," as provided in N.C. Gen. Stat. § 131E-184(a)(7), set forth below:

> (a) Except as provided in subsection (b), the Department shall exempt from certificate of need review a new institutional health service if it receives prior written notice from the entity proposing the new institutional health service, which notice includes an explanation of why the new institutional health service is required, for any of the following: .
>
> * * *
>
> (7) To provide replacement equipment.

---

requirements for heart-lung bypass machines. For example, 1996 SMFP excerpts show that CMHA already owned and operated seven (7) bypass units at CMC in that reporting year. See Exhibit A.

The CON Law then defines "replacement equipment," as follows:

> "Replacement equipment" means equipment that costs less than two million dollars ($2,000,000) and is purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced.

See N.C. Gen. Stat. § 131E-176(22a).

Therefore, to qualify for this exemption, the replacement equipment must cost less than $2 Million and be "comparable" to the equipment it replaces and must be "sold or otherwise disposed of when replaced." As described below, CMHA's proposal qualifies for this exemption.

B. Comparable Equipment

The CON rule codified as 10A N.C.A.C. 14C.0303 (the "Regulation") reads as follows:

> 10A NCAC 14C.0303 REPLACEMENT EQUIPMENT
>
> (a) This Rule defines the terms used in the definition of "replacement equipment" set forth in G.S. 131E-176(22a).
>
> (b) "Currently in use" means that the equipment to be replaced has been used by the person requesting the exemption at least 10 times to provide a health service during the 12 months prior to the date the written notice required by G.S. 131E-184(a) is submitted to the CON Section.
>
> (c) Replacement equipment is not "comparable" if:
>
> (1) the replacement equipment to be acquired is capable of providing a health service that the equipment to be replaced cannot provide; or
>
> (2) the equipment to be replaced was acquired less than 12 months prior to the date the written notice required by G.S. 131E-184(a) is submitted to the CON Section and it was refurbished or reconditioned when it was acquired by the person requesting the exemption.

10A N.C.A.C. 14C.0303(c).

CMHA used the Old Bypass Unit at CMC to perform over 30 procedures in FY 2021, thus satisfying Subsection (b). CMHA intends to use the Replacement Bypass Unit for the same health service as the Old Bypass Unit, open heart surgery, thus satisfying Subsection (c)(1). Moreover, the Old Bypass Unit was acquired in 2011, thus satisfying Subsection (c)(2). See Exhibit D. For further equipment comparison points, please refer to Exhibit D (CON Equipment Comparison Chart).

C. Cost of the Replacement Equipment

CMHA will incur $193,380.56 in total capital costs to acquire and make operational the Replacement Bypass Unit. See Exhibits B and D. As the brochure in Exhibit C illustrates, this Bypass Unit is relatively small, moveable equipment, which does not require "installation" as would a larger piece of equipment (e.g., MRI scanner). Thus, the capital costs associated with the replacement are far less than the $2 Million threshold in N.C. Gen. Stat. § 131E-176(22a).

D. Disposal of the Old Bypass Unit

CMHA commits to dispose of the Old Bypass Unit and not operate it again in North Carolina. See N.C. Gen. Stat. § 131E-176(22a).

II. Step #2 -- The Material Compliance / No Review Request.

This Material Compliance / No Review Request in Part II asks the Agency to confirm that no CON is required in order for CMHA to relocate the CMHA-owned and operated Replacement Bypass Unit from the CMC Campus to the AH Pineville Campus. As underscored in Part I(C) above, the Replacement Bypass Unit is a relatively small, moveable equipment unit, which does not require "installation" as would a larger piece of equipment. See Exhibits C. Thus, there are no additional relocation costs involved in the relocation from the CMC Campus to the AH Pineville Campus.

Upon relocation, the Replacement Bypass Unit will then be operated as a full-time heart-lung bypass unit at AH Pineville. After the relocation: (a) CMC will have six (6) heart-lung bypass units (five full-time units and one backup unit); and (b) AH Pineville will have three (3) heart-lung bypass units (two full-time units and one backup unit).

There is precedent for the relocation of CON *per se* reviewable equipment from one wholly owned hospital to another wholly owned hospital in the same county (and thus the same service area).

In two September 29, 2017 material compliance and replacement equipment exemption determinations, the Agency approved CMHA to relocate and replace cardiac catheterization equipment from CMHA's University Campus to its CMC Campus. See Exhibit E.

Relatedly, in an August 5, 2015 determination, the Agency approved Novant Health to relocate and replace cardiac catheterization unit from Novant Health Presbyterian Medical Center ("Presbyterian") to Novant Health Matthews Medical Center ("Matthews"). See Exhibit 3 to Exhibit E (Ex. E-3, Bates Nos. 17-18). In requesting the relocation, Novant pointed out that both Presbyterian and Matthews were within the Novant Health corporate family and were both located in Mecklenburg County (and thus the same cardiac cath service area). See Ex. E-4, Bates Nos. 19-24. That Agency analysis fits CMHA here even better than it fit Novant in the foregoing scenario. In the Novant situation, Presby and Matthews were owned by two separate Novant Health subsidiaries, but were under Novant Health ownership at the parent level. Here, CMC and AH Pineville are both operating units of CMHA, with both located in Mecklenburg County. Thus, CMC and AH Pineville are operated within the same entity.

Thus, as with the requests approved in Exhibit E (and discussed above), CMHA's proposed Bypass Relocation Project here is not CON reviewable.

Conclusion

Based on the foregoing information, CMHA asks the Agency to make the following two conclusions:

1. Find that the replacement equipment transaction described in Part I above is exempt from CON review under N.C. Gen. Stat. § 131E-184(a)(7); and

2. Find that relocating the Replacement Bypass Unit from one existing CMHA Mecklenburg County hospital campus to another (not increasing CMHA's Bypass Unit complement) materially complies with the CON for CMC's Old Bypass Unit or is otherwise not reviewable.

We thank you for your consideration of this notice.

Sincerely,

Gary S. Qualls

Gary S. Qualls

Exhibits

A. Excerpts from the 1996 SMFP

B. Cost Quote for Replacement Bypass Unit

C. Brochure for Replacement Bypass Unit

D. CON Comparison Form

E. Material Compliance and Exemption Approvals, Request for Such Approvals, and Exhibits Thereto for CMHA to Relocate Cardia Cath Equipment from CMHA's CMC Campus to CMHA's University Campus (Bates Nos. 1 – 29)

Exhibit A

EXHIBIT

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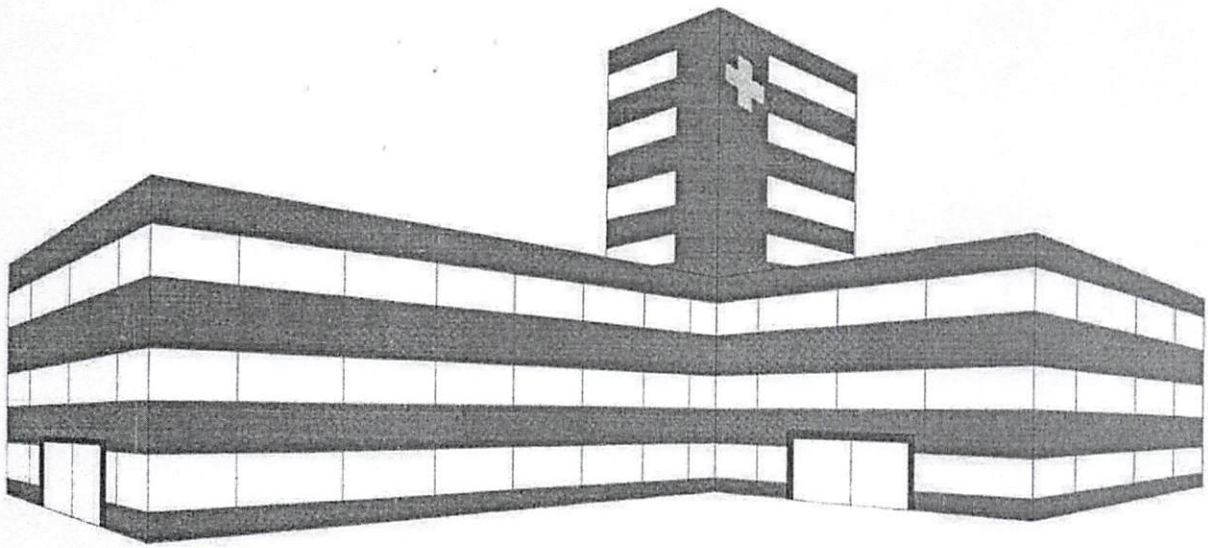
A

The 1996 State Medical Facilities Plan



North Carolina State Health Coordinating Council
Medical Facilities Planning Section
Division of Facility Services
North Carolina Department of Human Resources

The following table displays 1996 heart-lung bypass machine capacity and utilization:

Table 8B. Heart-Lung Bypass Machine Capacity and Volume

Hospital	Heart-Lung Bypass Machine	Open Heart Surgical Operating Rooms	Machine Procedure Capacity	1996 Procedures	Machine Excess Capacity	% Utilization of Machine
Duke	8	* 5	3200	** 1713	1487	53.5%
Carolinas	7	6	2800	** 1475	1325	52.7%
Baptist	5	* 3	2000	** 917	1083	45.9%
UNC	4	* 2	1600	** 482	1118	30.1%
Wake	6	* 6	2400	1025	1375	42.7%
Mercy	3	2	1200	388	812	32.3%
Mission	5	* 5	2000	1077	923	53.9%
Moses Cone	4	* 4	1600	1016	584	63.5%
Pitt	5	* 3	2000	** 1129	871	56.5%
Presbyterian	4	3	1600	845	755	52.8%
Forsyth	3	3	1200	769	431	64.1%
New Hanover	3	* 2	1200	643	557	53.6%
Rex	6	2	2400	431	1969	18.0%
Frye	2	2	800	614	186	76.8%
Durham	2	* 1	800	170	630	21.3%
Moore	2	* 1	800	273	527	34.1%
High Point	2	2	800	309	491	38.6%
Craven	2	* 1	800	126	674	15.8%
Cabarrus	* 1	* 1	400	318	82	79.5%
Cape Fear Valley	* 1	* 1	400	283	117	70.8%
T O T A L	75	55	30,000	14,003	15,997	46.7%

* Plus a back-up

** Adult procedures plus Pediatric procedures x2

Exhibit B

EXHIBIT
tabbies
B

LivaNova
Health innovation that matters

S5 HEART LUNG PERFUSION SYSTEM
OUTRIGHT PURCHASE PROPOSAL
For
Atrium Health
In
Charlotte, NC

S5 HEART LUNG PERFUSION SYSTEM:

Catalog No.	Description	Quantity Per System	Price Per Each
48-40-00Z	SRD S5 CONSOLE FOR 4 PUMP	1	$29,860.30
45-09-11	S5 CABLE HOLDING SYS 25MM MAST	1	$341.12
45-95-14USA	S5 PRO SYS. IFU USA	1	$0.00
45-09-10	SRD S5 CABLE HOLDING SYS	1	$324.72
43-42-61	CAP FOR QUICK CLAMP	1	$341.12
10-80-00Z	SRD S5 SINGLE ROLLER PUMP 150	3	$17,962.10
10-81-30	S5 VARIOLOCK TUB CLAMP RP150	3	$911.02
10-85-00Z	S5 DOUBLE ROLLER PUMP 85	1	$29,236.28
10-86-55	"""S5 TUBING CLAMP 1/8""" X 1/16"""""""	2	$60.68
60-00-60Z	CP5 CENTRIFUGAL PUMP	1	$26,964.88
45-90-75USA	OPS MANUAL, CP5	1	$0.00
10-84-64	S5 DRIP TRAY DOUBLE PUMP	1	$234.52
10-84-60	SRD S5 DRIP TRAY ROLLER PUMP	1	$114.80
50-80-99	S5 COLOR CODE SET	1	$41.82
28-95-00	SRD S5 4-SLOT SYSTEM PANEL	1	$6,046.68
28-95-10Z	SRD S5 CONTROL DISPLAY MODULE	4	$2,135.28
20-30-20Z	SRD S5 TEMP SENSOR MODULE	1	$2,757.66
22-20-20Z	SRD S5 PRESSURE SENSOR MODULE	1	$3,576.84
27-80-20Z	S5 CARDIOPLEGIA SENSOR MODULE	1	$5,238.16
23-41-00	LEVEL-3 SET COMPLETE S5	1	$4,452.60
23-45-10Z	S5 3/8" BUBBLE MODULE W/620MM	1	$6,294.32
10-07-48	METAL INSERTS BLUE	1	$534.64
48-41-10	SRD S5 CROSSTRAY FOR 4 PUMP	1	$2,220.56
050350000	PAS SECHRIST 3500 CP-G	1	$2,638.76
050350100	SECHRIST IV308 HOSE AIR 14 FT	1	$186.96
050350200	SECHRIST IV309 HOSE OXY 14 FT	1	$163.18
10-07-49	METAL INSERTS PLAIN	1	$534.64
10-86-59	"""S5 TUBING CLAMP 3/16 X 1/16"""""""	1	$62.32
10-86-55	"""S5 TUBING CLAMP 1/8""" X 1/16"""""""	1	$60.68
10-86-56	"""S5 TUBING CLAMP 1/4""" X 1/16"""""""	1	$72.98
35-05-80	CONSOLE LAMP LED	1	$1,213.60
0395-2049	SPD TRUWAVE XDUCER CABLE	2	$292.72
48-51-20	S5 PUMP/SPACER 5 PUMP CONSOLE	1	$3,343.14
23-41-51	100PC ADHESIVE PAD LV-3 SENSOR	1	$656.00
		Net Price Per Each System	**$193,380.56**

LivaNova

Health innovation that matters

LIVANOVA
STANDARD TERMS AND CONDITIONS

PRICE & PAYMENT TERMS:	Payment terms are net thirty (30) days. Product prices do not include applicable taxes or freight charges. Payment terms subject to approved credit. Taxes, if owed, shall be added to the invoice amount. Tax exemption certificates must be submitted to LivaNova prior to placement of orders. All prices are subject to an annual increase set by LivaNova at its sole discretion.
METHOD OF SHIPMENT AND FREIGHT:	Equipment and Disposable Products shall be shipped and delivered to Customer via surface transportation. LivaNova prepays freight and adds to the invoice. Freight charges for Equipment may be billed to the Customer separately.
TITLE & RISK OF LOSS:	Title of, and risk of loss to, Equipment and/or Disposables shall transfer to Customer upon shipment.
ORDER QUANTITIES:	Made to order, custom packs require a minimum order quantity of one case. Federal regulations prohibit the sale of incomplete case quantities.
RETURNED GOODS:	Subject to Purchaser obtaining a corresponding Returned Goods Authorization number in accordance with LivaNova's Return Policy, any unused and unopened Implantable and/or Disposable in its original packaging and condition may be returned to LivaNova within 14 calendar days of their receipt or 90 calendar days from receipt for Equipment and Spare Parts. A $250 reprocessing/restocking fee shall be charged for each return of Implantables to LivaNova. A 10% reprocessing/restocking fee shall be charged for each return of Disposables, Equipment and/or Spare Parts to LivaNova. Items must be returned freight prepaid and within 30 calendar days once the Return Authorization number is issued. Items to be returned must be in ORIGINAL UNOPENED cartons, have original labels and be in a saleable condition. Expired products, abused or damaged items, custom items, chemical concentrates, and items identified as non-returnable or that have deteriorated due to a cause beyond LivaNova's control, may not be returned.
DAMAGED SHIPMENTS:	Damage or shortage should be noted on the freight bill. If damage is observed after opening, notify the transportation company and request a hidden damage report. No adjustment, credit or duplicate shipment can be made until written documentation is received by LivaNova. LivaNova must receive documentation within 2 days of product receipt.
LIMITED WARRANTY:	For a period of twelve (12) months from the date of installation of Equipment, LivaNova will at its option repair or replace (free of charge) Equipment that LivaNova finds defective in materials or workmanship. For a period of twelve (12) months from the date of the invoice, LivaNova will replace (free of charge) Disposable Products which LivaNova finds defective in materials or workmanship. For a period of ninety (90) days from the date of the invoice, LivaNova will repair or replace (free of charge) spare parts that LivaNova finds defective in materials or workmanship. LivaNova 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. LivaNova does not verify the safety or efficacy, and makes no warranties - expressed or implied - with respect to any non- LivaNova components included at Customer's request or any components or products used other than as expressly intended by their manufacturer. **THIS LIMITED WARRANTY CONTAINS THE CUSTOMER'S EXCLUSIVE REMEDIES. LIVANOVA SHALL NOT BE LIABLE FOR ANY INCIDENTAL, SPECIAL OR CONSEQUENTIAL DAMAGES ARISING FROM THE USE OF ITS PRODUCTS. LIVANOVA DOES NOT GIVE ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.**
ORDERING INFORMATION:	Orders may be placed by phone, facsimile, e-mail or mail to LivaNova at: LivaNova USA, Inc. Attn.: Customer Service Department 100 Cyberonics Blvd. Houston, TX 77058 (866) 332-1375 Toll-Free Phone (800) 539-0092 Fax CustomerService.US@livanova.com Normal business hours are 7:30 a.m. to 5:30 p.m., Central Time Zone, Monday through Friday. Purchase Order numbers are required at the time the order is placed.
DELIVERY:	Stock products will be delivered in 7-10 days after receipt of order (ARO).
DISTRIBUTORS:	LivaNova is not responsible for any fees associated with placement of orders through JIT suppliers, distributors, or warehouses.
MODIFICATION AND LEGAL COMPLIANCE	Customer shall not modify or alter the products in any way without the prior written approval of LivaNova. 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.
SUBSTITUTION:	LivaNova 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, LivaNova will notify the Customer and offer substitute product, if available.
FORCE MAJEURE:	LivaNova 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, LivaNova may allocate its available supply among itself and its Customers in a manner determined by LivaNova in its sole discretion.
PAST DUE ACCOUNTS:	Customer shall pay LivaNova 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 LivaNova in enforcing its rights hereunder.
PRODUCT TRACEABILITY:	Customer is responsible to maintain product traceability for each individual product delivered by LivaNova Customer will comply with any product recalls initiated by LivaNova and will notify LivaNova of any Customer complaints on LivaNova products.
DISCOUNTS FROM LIST PRICE:	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.
INDEMNIFICATION:	Customer agrees to hold LivaNova, 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.
TERM:	Unless there is a specific termination provision in a document signed by Customer and LivaNova, LivaNova 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 LivaNova when due any amount it owes LivaNova or otherwise breaches these Standard Terms and Conditions. Termination or expiration of this Agreement shall not affect Customer's obligation to pay LivaNova all amounts it owes LivaNova (including interest and attorneys' fees) nor shall it affect any provision intended to survive expiration or termination.
STANDARD TERMS AND CONDITIONS:	In the event of a conflict between the terms and conditions of this Agreement and the terms and conditions of, printed on, or referenced in any purchase order, order acknowledgement, invoice, or similar document, the terms and conditions of the Agreement shall take precedence. This Agreement shall be construed and enforced in accordance with the laws of the State of Texas.

Exhibit C

SORIN | S5

EXHIBIT
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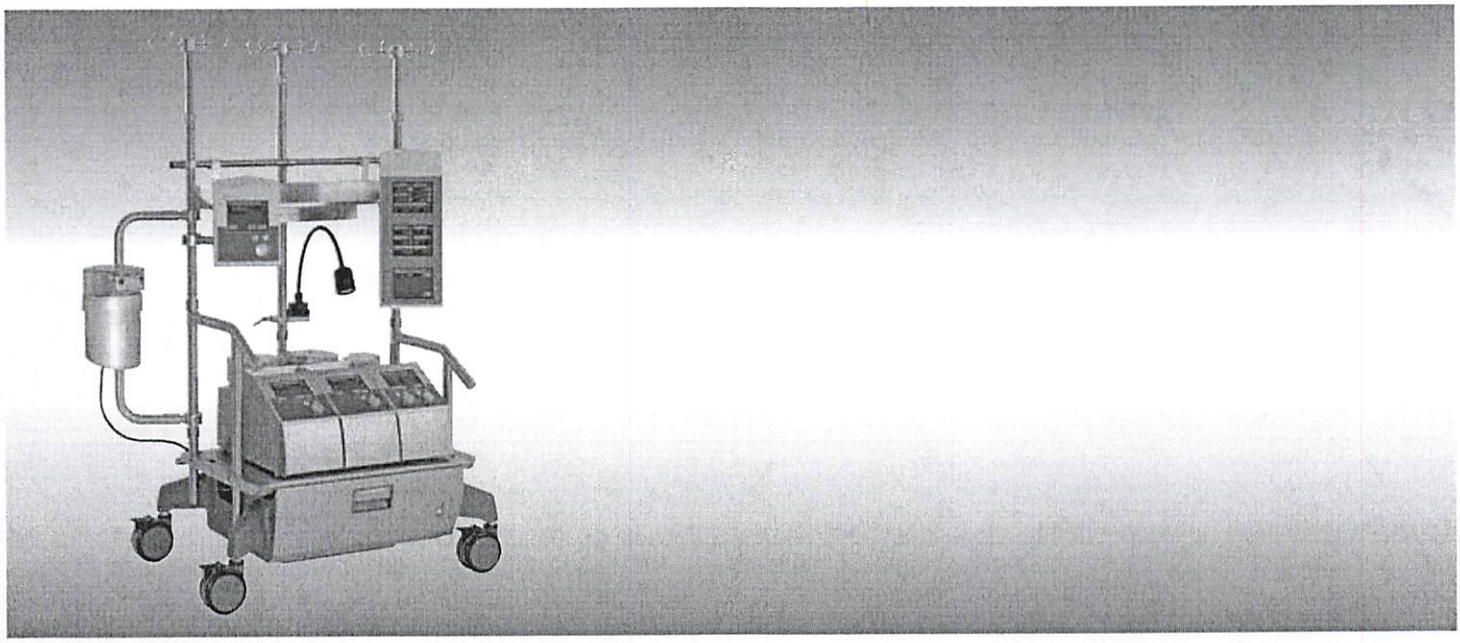
C



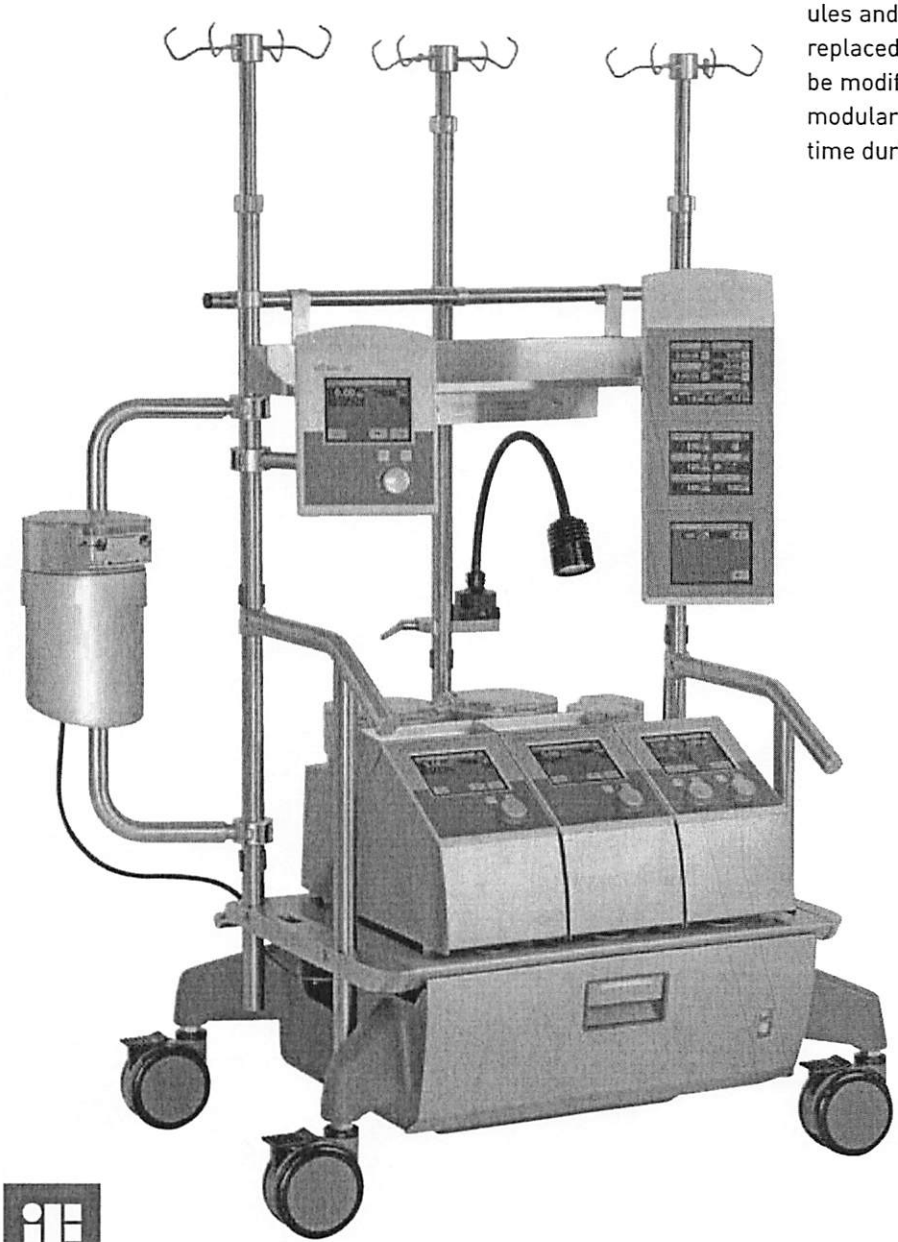
READY TO MEET ANY CHALLENGE

CARDIAC SURGERY SOLUTIONS

INDEX

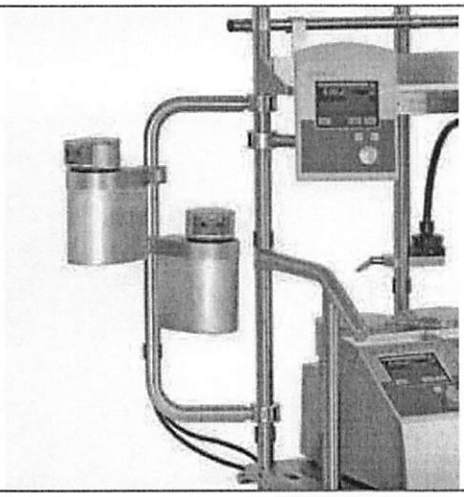
READY TO MEET ANY CHALLENGE

The concept
The S5 heart-lung-machine has a modular design.
The individual components, modules and accessories can be easily replaced, the overall system can be modified and extended, and the modular structure saves valuable time during routine maintenance.



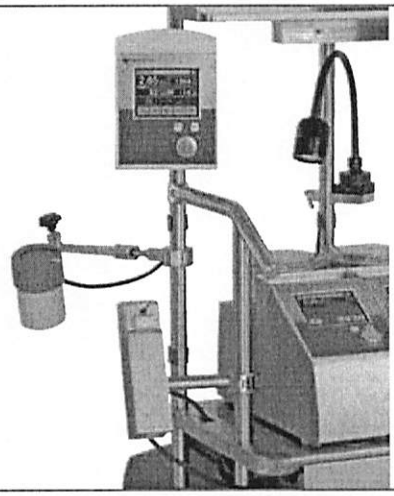
product
design
award

2006



S5 mast roller pump 85 with "C"-shaped holder

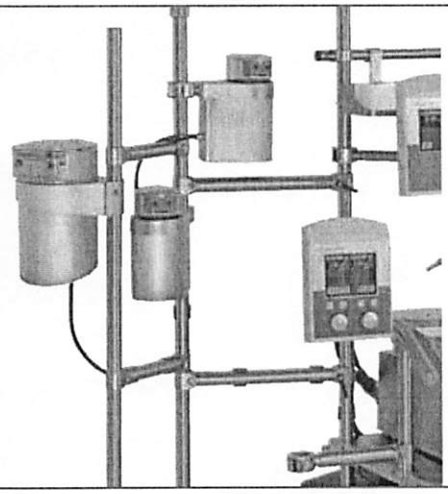
This version of the S5 mast roller pump system was specially designed for operators who infrequently perform paediatric and infant/neonate perfusion. The pumps can be placed closer to the patient leading to a reduction in tubing length and priming volume – a positive effect that is important for paediatric and infant/neonate perfusion, but also for other applications with low flow rates.



CP5 centrifugal pump system for S5

Versatility: the centrifugal pump can be mounted quickly onto a mast and integrated into the available system saving space.

The CP5 uses the monitoring and control units that are already part of the system.



Mast system extension with S5 mast roller pump 150 / two S5 mast roller pumps 85

The S5 roller pumps are mounted on two masts that are connected to an adjustable swivel arm. The control units of the pump heads are mounted separately on the mast system of the console. Convenient fast clamp connectors allow the mast roller pumps to be mounted/removed quickly.

Console

S5 console
The console housing accommodates and protects the entire electronics of the E/P pack including the central power supply and the uninterruptible emergency power supply. The four castors of the console can be locked separately.

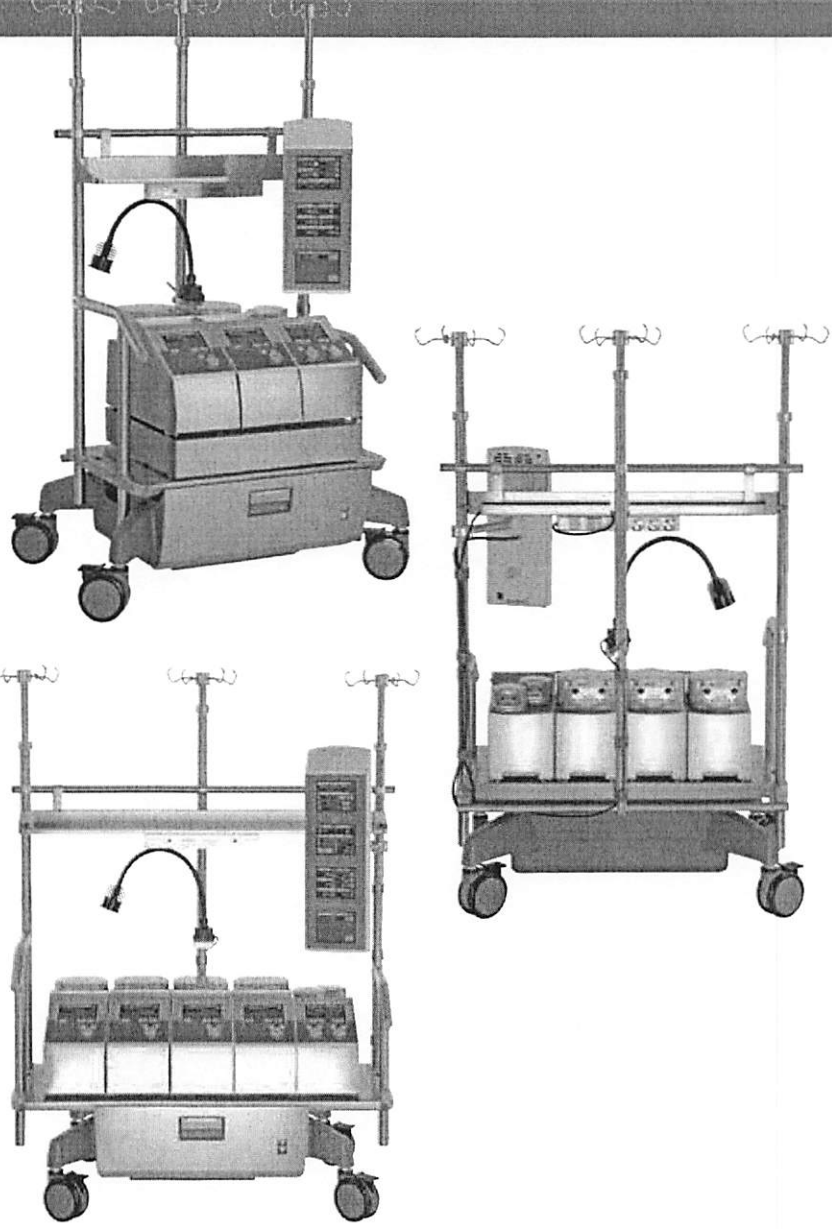
S5 pump table
This stainless steel pump table is screwed to the console. Stainless steel pins on the pump table are used for mounting and securing the pump housing. Pump tables for 3, 4 or 5 pumps can be supplied.

S5 standard mast system
The standard mast system is fixed to the console and includes:

Two fixed telescope masts and an adjustable vertical mast with an infusion rack. The masts can be used for mounting the S5 system panel and additional accessories and disposables. The height of all masts can be adjusted.

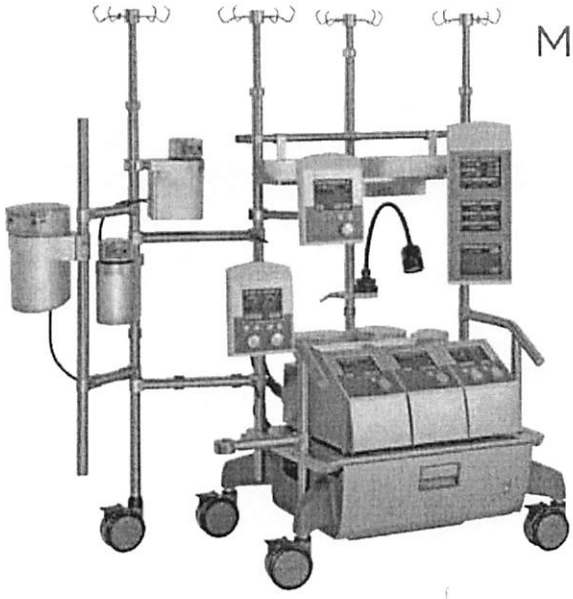
Two height-adjustable push bars on the left and right side of the console can be used when transporting the S5. They can also be used for mounting accessories.

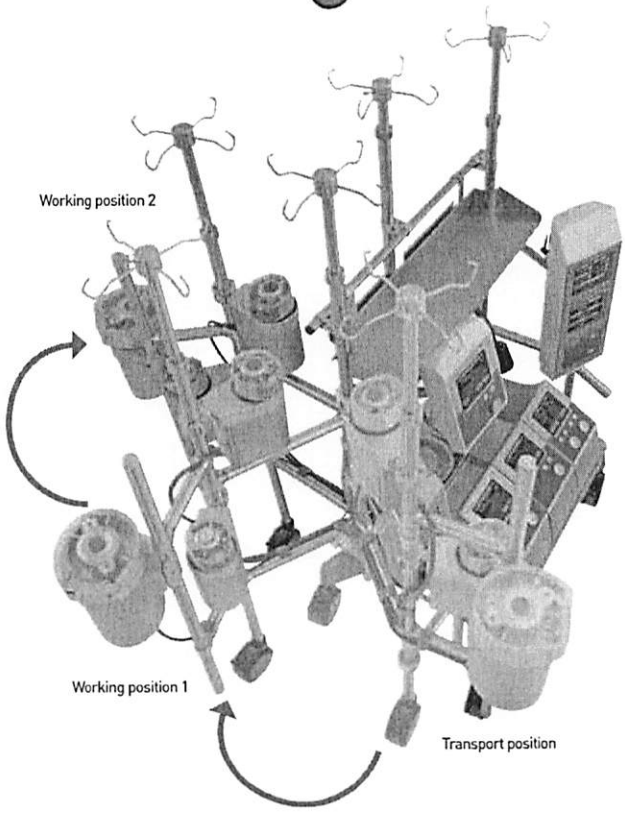
A horizontal mast stabilises the mast system.



Product desigantion	Part number		
Consoles with E/P pack and standard mast system	3-position	4-position	5-position
S5 console	48-30-00	48-40-00	48-50-00
Mast systems	Size 3	Size 4	Size 5
Telescope mast with infusion rack	all sizes: 48-30-50		
Telescope mast, movable with infusion rack	all sizes: 48-30-51		
Push bar (horizontal)	all sizes: 48-30-57		
Push bar mast (vertical)	all sizes: 48-30-67		
"C"-shaped holder	all sizes: 50-70-57		
Horizontal mast	48-30-77	48-30-78	48-30-79
Crossbar for movable mast (horizontal)	48-30-81	48-30-82	48-30-83

Mast System Extension





S5 Mast System Extension

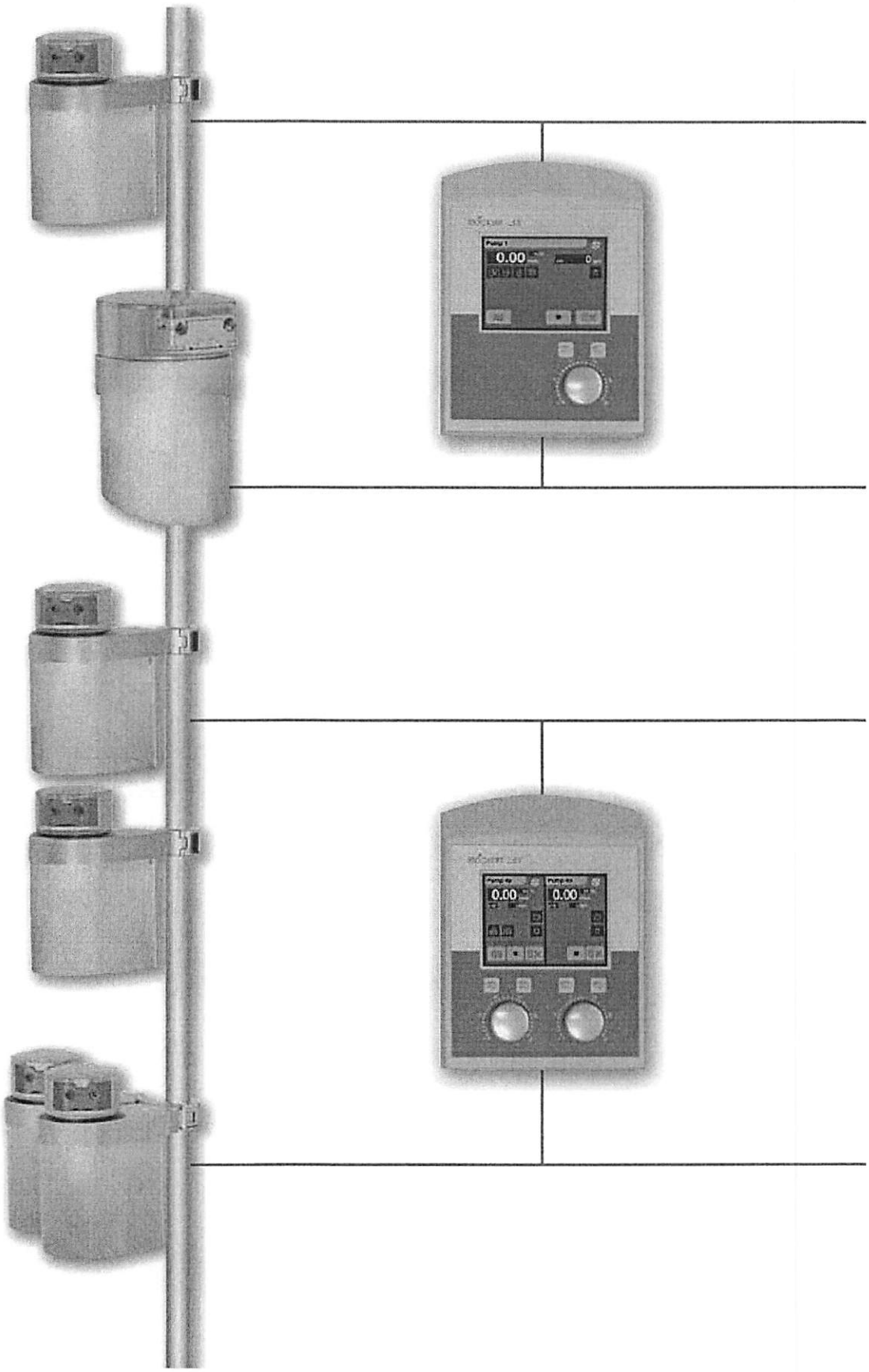
The S5 mast system extension can accommodate up to 3 mast roller pumps. The separate control units are mounted away from the pump heads on the console mast system. The mast system extension can be mounted on the left or on the right side of the console and folded prior to transport. A supporting castor is used to stabilise the mast system. The mast system extension can be used to place the pumps, oxygenator and tubing set right beside the patient.

The mast system extension

- is for paediatric and infant/neonate perfusion.
- can be operated right beside the patient
- can be swivelled and is user friendly

Product desigantion	Part number
S5 mast system extension consisting of:	50-45-00
Swivel telescope mast with infusion rack and castor	50-45-05
2 swivel arms	50-45-10
Vertical mast (including 2 horizontal masts)	50-45-15
Transport locking arm	50-45-20

Mast Roller Pumps



Mast Roller Pumps

Product designation	Part number
Mast roller pump system 85 consisting of:	50-80-70
1x mast roller pump 85 (connection cable supplied)	10-88-60
Control panel for mast roller pump 150/85 (connection cable supplied)	28-95-80

Product designation	Part number
Mast roller pump system 150 consisting of:	50-80-00
Mast roller pump 150 (connection cable supplied)	10-88-00
Control panel for mast roller pump 150/85 (connection cable supplied)	28-95-80

Product designation	Part number
Mast roller pump system 85 consisting of:	50-80-60
2x mast roller pumps 85 (connection cable supplied)	10-88-60
Control panel for mast roller pump 85 (connection cable supplied)	28-95-85

Product designation	Part number
Mast roller pump system with 2 MRP 85 consisting of:	50-80-62
2x mast roller pumps 85 (connection cable supplied)	10-88-60
Control panel for 2 mast roller pumps 85 (connection cable supplied)	28-95-85
Double holder (fixed)	

Two mast roller pumps, with 85 and 150 mm diameters respectively, are available for specialised applications. The small double pump, which is controlled from a single control panel, has some special features.

The holders that were specially developed for the mast roller pump are equipped with practical fast clamp connectors for quick and easy mounting/removal. They can be quickly and easily mounted to/removed from the mast. The corrosion-proof stainless steel pump housing is easily cleaned.

MRP 85

- user friendly
- whenever a robust design and trouble-free upgrading are required

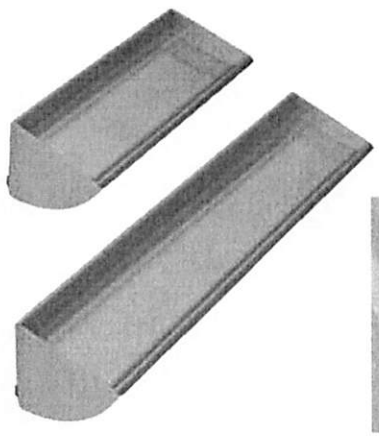
Roller pumps

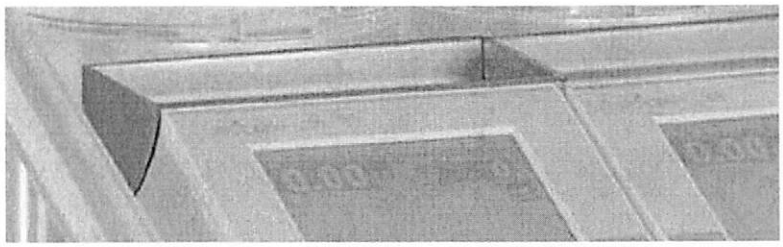
S5 roller pump
The S5 roller pump with a 150 mm diameter is used primarily for the arterial blood flow during cardiotomy suction and venting.

S5 double roller pump
The S5 double roller pump combines two roller pumps with a diameter of 85 mm in a single housing. Both roller pumps can be operated and controlled independently. The double roller pump is especially suitable for paediatric/neonate perfusion, as a cardioplegia pump or as a cardiotomy suction and venting pump.

The roller pumps are the most important elements of the S5 perfusion system. Every pump has an independent control system and its own pump control panel that is operated using a high-contrast colour touch screen. The pumps can be individually configured, i.e. the monitoring functions can be individually assigned to each pump and displayed on the touch screen.

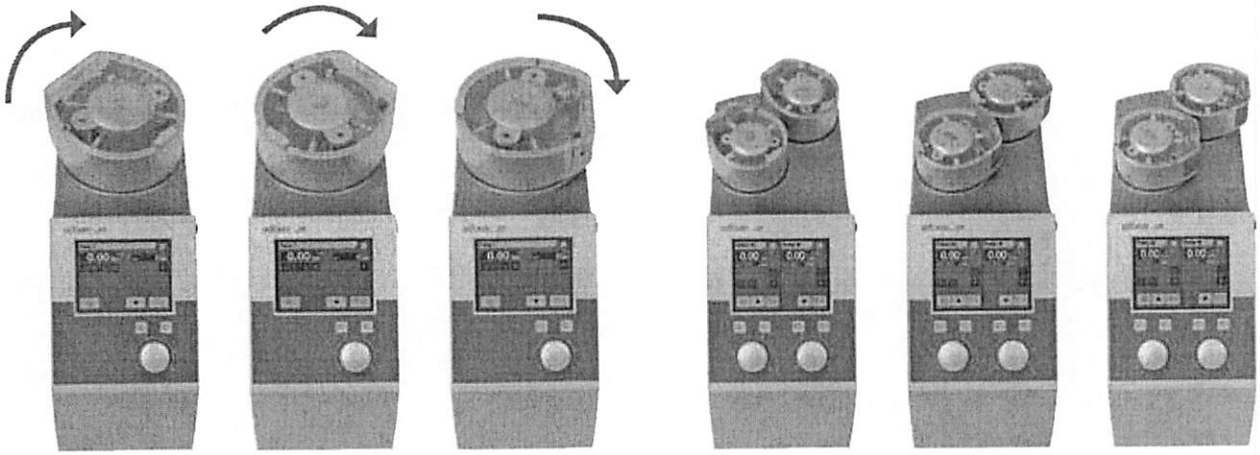
An innovative, hard-wearing setting knob (incremental shaft encoder) is used to adjust the set speed electronically. A maximum of five roller pumps can be placed on the console pump table and connected to the E/P pack. The optimised pump head geometry (horseshoe shaped) keeps pressure peaks during operation to a minimum.





Product advantages

- For perfect positioning relative to the surgical site, the pump heads can be rotated 180° (RP 150) or 240° (RP 85). Rotation is carried out in increments of 15° (self-locking).
- The pump head design facilitates quick and easy insertion of the pump tubing.
- The Master-follower mode regulates the flow of the follower pump according to the set flow ratio of the master pump.
- Each pump can be operated in continuous or pulse mode.
- Large digital displays of the speed and/or the flow rate provide a quick overview of the current pump speed.
- Quick orientation: the monitoring functions and current pump status are displayed on the touch screen when an alarm is triggered.
- All pump parameters can be entered using the clearly-structured menu navigation on the pump touch screen.
- If two Override keys are pressed simultaneously, the monitoring functions assigned to a pump are overridden.
- Every pump has a stop link function. This function can be connected to the arterial pump. If the arterial pump stops, the stop link pump also stops.



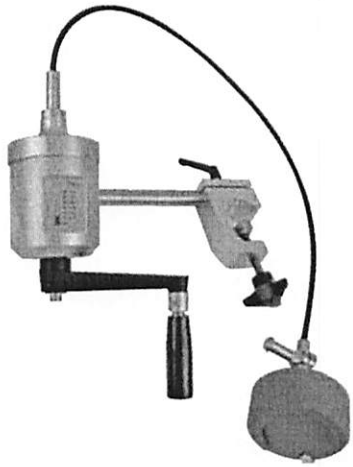
Product designation	Part number
S5 roller pump 150 / S5 RP 150	10-80-00
S5 double roller pump 85 / S5 DRP 85	10-85-00

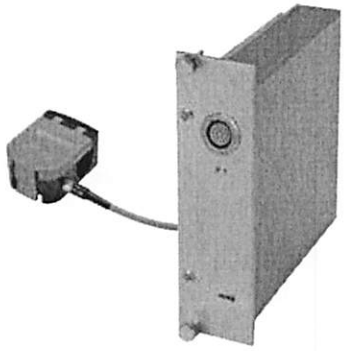
CP5 CENTRIFUGAL PUMP

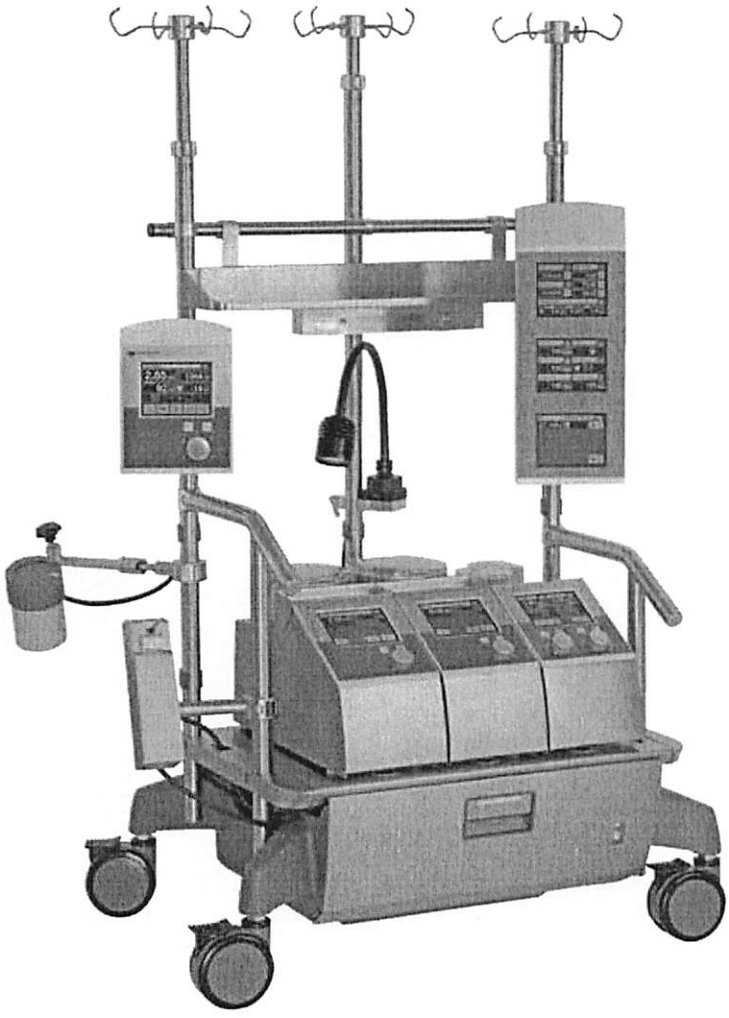
This established centrifugal pump system provides the S5 operator with flexibility. The mast assembly saves space, no additional space is needed on the console.

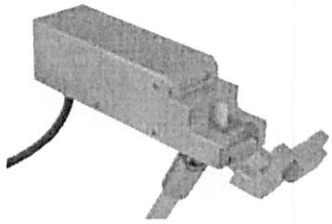
The overall system is delivered complete with drive unit, control panel, connection cable, sensor module for flow measurement, flow sensor and emergency system.

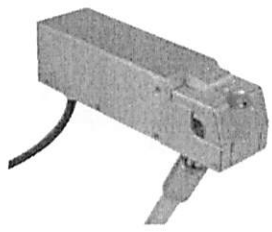
The ERC closes the arterial line in a fraction of a second if an alarm is triggered (e.g. retrograde flow, level or bubble alarm), keeping the danger of air delivery to a minimum.

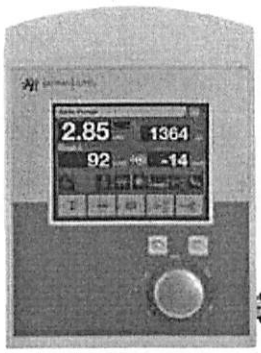




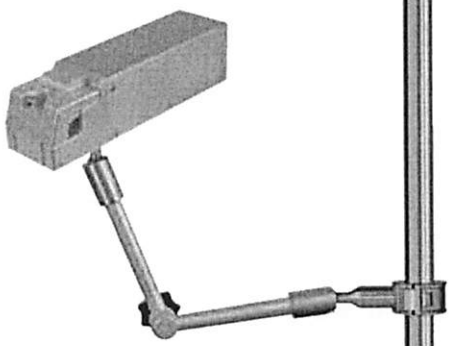








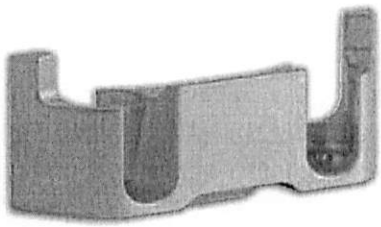
Product designation	Part number
CP5 (only for S5|C5) consisting of:	60-00-60
CP5 drive unit (with cable)	60-01-04
Pump control panel (with holder)	60-02-60
Emergency system (complete)	60-01-35
Flow sensor (3/8")	96-414-140
Flow measurement sensor module	25-60-70

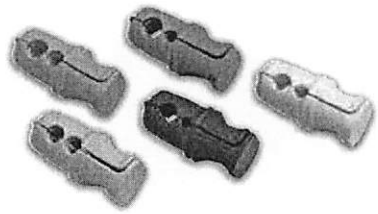


Product designation	Part number
Electrical remote-controlled tubing clamp consisting of: tubing clamp, 3-joint mast holder with fast clamp connector, 500 mm	60-05-60
Electrical remote-controlled tubing clamp consisting of: tubing clamp, 3-joint mast holder with fast clamp connector, 620 mm	60-05-65

Tubing clamps

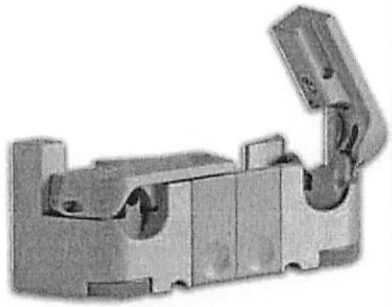
Tubing clamp inserts are available for all tubing sizes. They are inserted into the tubing clamp block of the pump heads.
Special cardioplegia tubing clamp inserts allow two tubes with different diameters to be safely and simultaneously connected to the roller pump heads. They are available for flow ratios from 1:1 to 8:1.





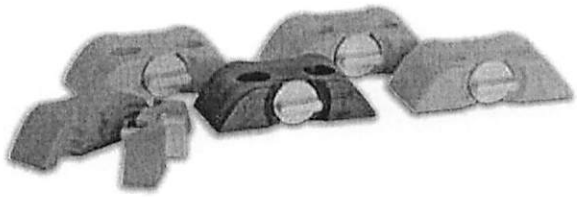
Product designation				Part number
Tubing clamp block RP 150 (included in RP 150, 10-80-00)				10-81-35
Tubing clamp inserts for tubing clamp block RP 150				
	1/4" x 1/16"	red		10-64-15
	1/4" x 3/32" 5/16" x 1/16"	yellow		10-64-25
	3/8" x 1/16" 5/16" x 3/32"	black		10-64-40
	3/8" x 3/32"	blue		10-64-50
	1/2" x 3/32"	green		10-64-65
	1/8" x 1/16"	violet		10-64-05
	3/16" x 1/16"	mint-green		10-64-10
	1/2" x 1/16"	grey		10-64-55
Tubing clamp inserts for cardioplegia RP 150				
	3/16" x 1/16" 3/16" x 1/16"	light grey	1:1	10-64-70
	1/4" x 1/16" 1/4" x 1/16"	light brown	1:1	10-64-71
	3/16" x 1/16" 1/8" x 1/16"	white	2:1	10-64-72
	1/4" x 1/16" 3/16" x 1/16"	light blue	2:1	10-64-74
	1/4" x 1/16" 1/8" x 1/16"	turquoise	4:1	10-64-76
	17/64" x 1/16" 3/32" x 1/16"	brown	8:1	10-64-78

Variolock tubing clamp module
The Variolock tubing clamp module was developed for the heads of roller pumps. A large range of tubing clamp inserts for single and double (e.g. for cardioplegia delivery) tubing configuration are available.



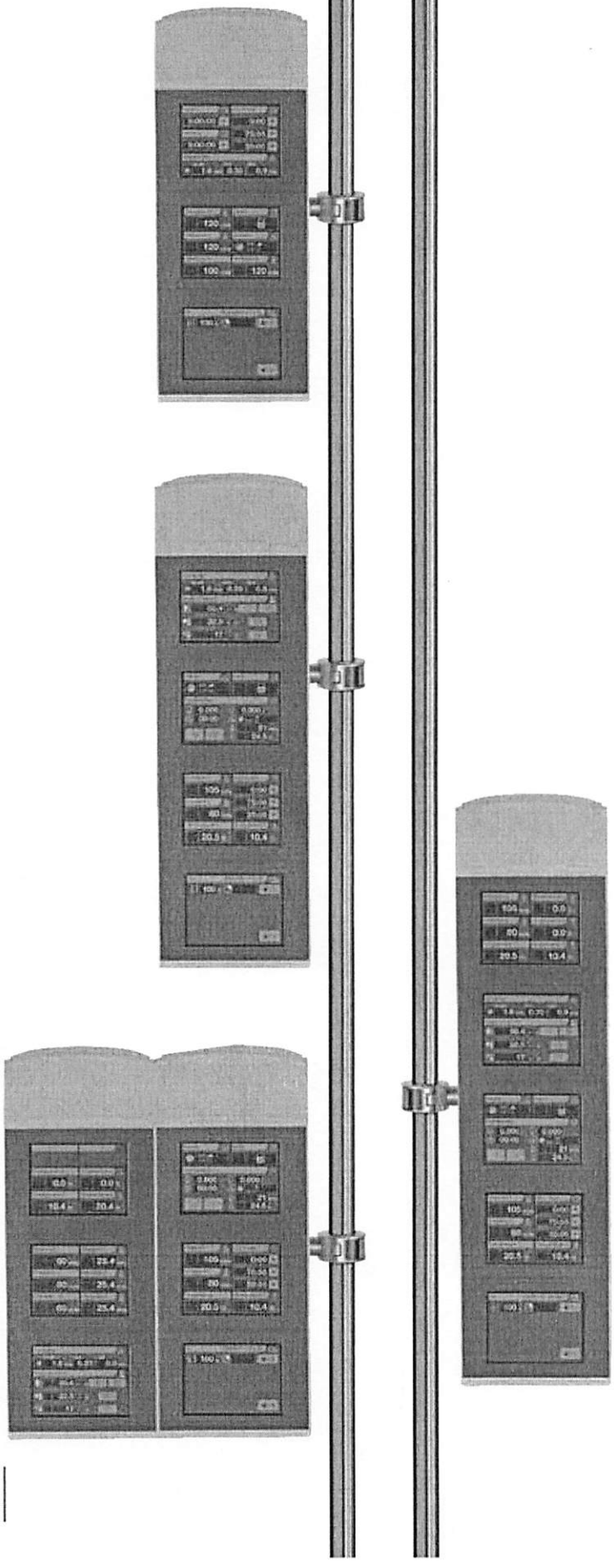
Product designation				Part number
Variolock tubing clamp module RP 150 (optional)				10-81-30
Tubing clamp inserts for Variolock				
included (in 10-81-30)	1/4" x 1/16" 1/4" x 3/32" 5/16" x 1/16" 3/8" x 1/16" 5/16" x 3/32" 3/8" x 3/32"	red (small)		10-61-73
	3/8" x 3/32" 1/2" x 1/16" 1/2" x 3/32"	blue (large)		10-61-72
Tubing clamp inserts for Variolock for cardioplegia				
optional	1/4" x 1/16" 1/4" x 1/16"		1:1	10-61-91
	1/4" x 1/16" 3/16" x 1/16"		2:1	10-61-92
	1/4" x 1/16" 1/8" x 1/16"		4:1	10-61-93

Tubing clamp block DRP 85
Tubing clamp blocks that can take tubing sizes up to 5/16" x 1/16" have been developed for the small roller pump.



Product designation			Part number
Tubing clamp block DRP 85 (included in DRP 85, 10-85-00)			
included	1/4" x 1/16"	red	10-86-56
	1/4" x 3/32"	yellow	10-86-57
	5/16" x 3/32"	black	10-86-58
optional	1/8" x 1/16"	violet	10-86-55
	3/16" x 1/16"	mint-green	10-86-59

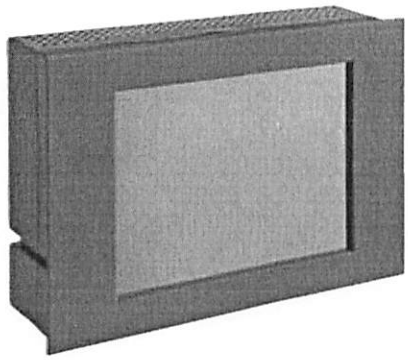
SYSTEM PANEL

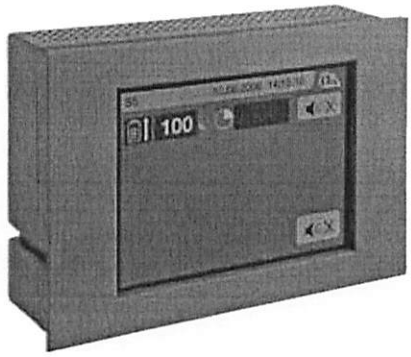


S5 system panel
The S5 system panel contains the display and control modules for all of the monitoring, control and measuring devices and is, alongside the pump control panel, another interface between the operator and the S5 System. The system panel can be mounted on the left or right mast of the standard mast system as required.

The holder with ball joint can be swivelled into any desired position.

System panels with 3 to 6 slots accommodate the control and monitoring modules. All display and control modules can be replaced during operation if a fault occurs. The data is displayed unchanged on the replacement module.





S5 blank module
If not all of the slots are taken up by display and control modules and adding additional monitoring parameters should remain an option, the inexpensive blank module can be used as a placeholder.

S5 display and control module
All display and control modules are physically identical but each one is controlled by its own separate microprocessor. The high-contrast TFT display has a restrained colour scheme and a clear display structure. The display layout is determined by the chosen control and monitoring function. All pump control and monitoring function settings - with a few exceptions - are entered using the control module touch screens. A user-friendly menu guides the operator through all setting parameters.

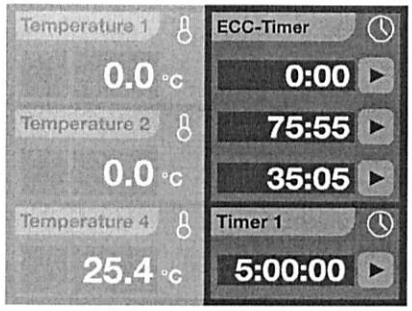
Product designation	Part number
S5 system components	
3-position S5 system panel 3 display and control modules	28-95-03
4-position S5 system panel 4 display and control modules	28-95-00
5-position S5 system panel 5 display and control modules	28-95-01
6-position S5 system panel 6 display and control modules	28-95-04
1 display and control module	28-95-10
Blank module	28-95-30

Timer

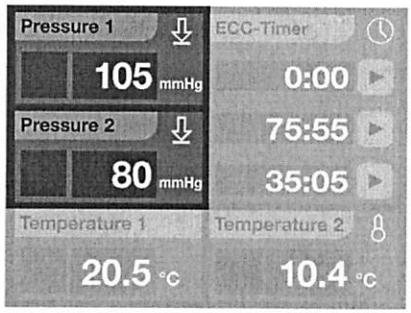
Three timers that work independently of each other can measure the duration of three simultaneous separate processes, for example the complete bypass time or the aortic cross-clamping time.

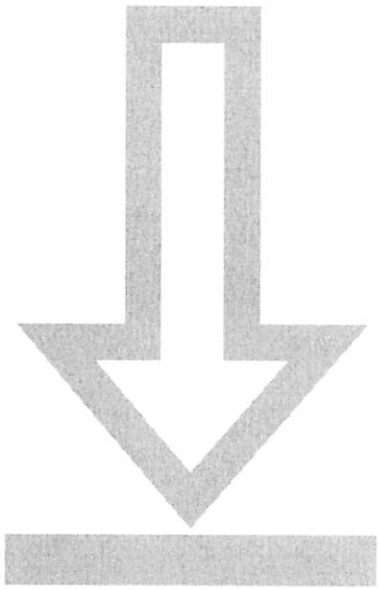
- The timers can be started and stopped individually.
- It is possible to carry out cumulative measurements with each timer.
- The measurement range for each timer is 999 min 59 sec.

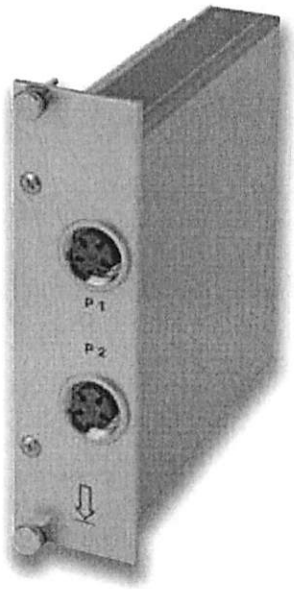
A fourth timer can (depending on the setting) count upwards or downwards for a maximum of 10 hours or 600 minutes (optional, available on request).



PRESSURE CONTROL







The double pressure sensor module is used for:

Measuring and displaying the pressure in the extracorporeal circuit. The display range extends from -200 mmHg to +800 mmHg. The values can be displayed in either mmHg or kPa.

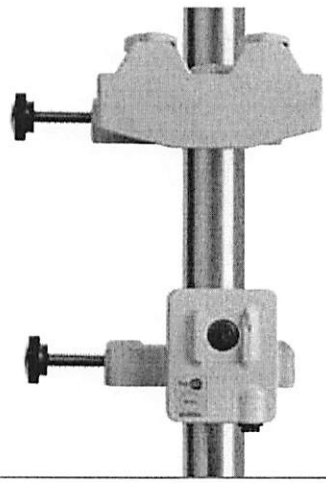
Limiting the pressure by stopping the pump (monitoring mode) when the preset pressure (stop limit) has been reached.

Controlling perfusion with constant adjustable pressure (set value) through automatic variation of the pump speed (control mode).

The double pressure sensor module allows the operator to control two pumps independently of one another. The control and display-module of the system panel is used for setting parameters and adjusting the zero-point. The pressure transducer and transducer holder are required accessories.

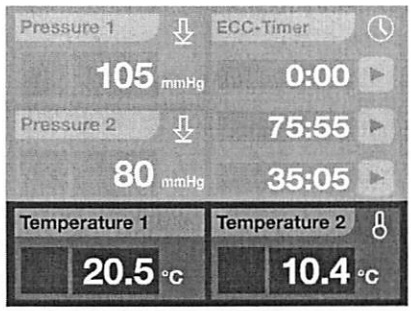
Product designation	Part number
Sensor module 2-channel pressure monitor	22-20-20

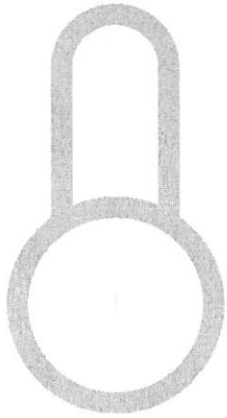
Sensors and accessories (optional)	Part number
Medex transducer (MX 960)	45-04-03
Cable for Medex transducer	45-04-15
Holder for one Medex transducer	45-04-16
Holder for 2 Medex transducers	45-04-17



Temperature monitor

- The temperature monitor allows the simultaneous measurement and display of up to four temperatures. One temperature sensor module channel is reserved for cardioplegia control.
- An upper and a lower temperature limit can be set. The values are set on the control and display module on the system panel.
- An outstanding feature of the measuring channels is their measurement precision.
- If the temperature limit is reached, visual and acoustic alarms are triggered.
- Temperature probes (listed under "Accessories") are required to operate the monitor.



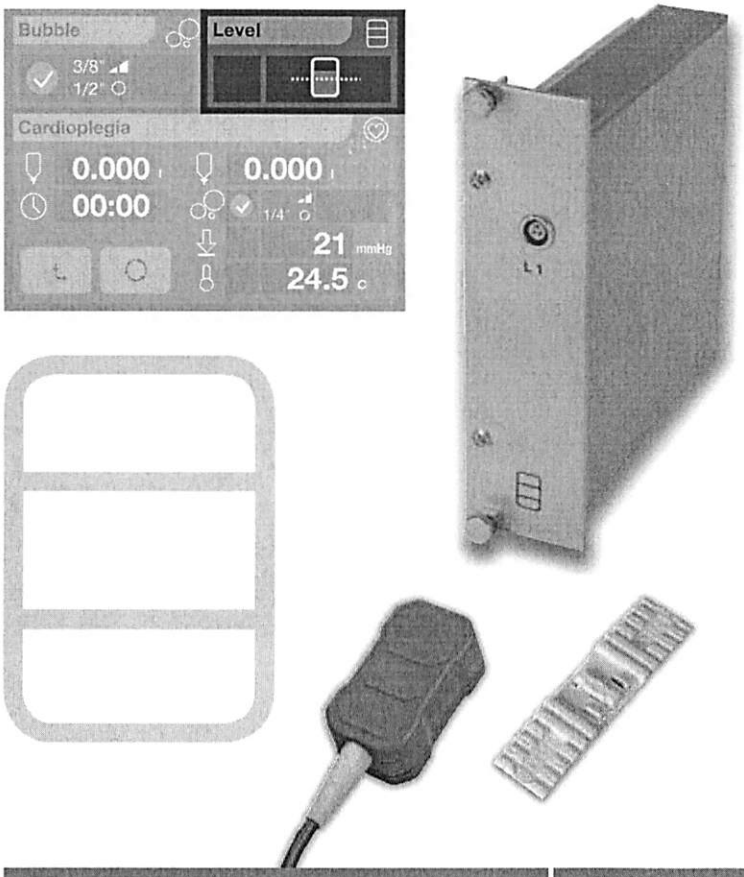


Product designation	Part number
Sensor module 4-channel temperature monitor	20-30-20

Accessories (optional)	Part number
Temperature probes for direct measurement in the oxygenator (optional)	
For SORIN GROUP oxygenators	45-03-10
For Dideco oxygenators	45-03-11
For MEDTRONIC oxygenators	45-03-30

Accessories (optional)	Part number
Vinyl probe for oesophageal or rectal temperature, Ø 5.0 mm	45-03-21
Thin, flexible temperature probe (used as 45-03-21), Ø 3.3 mm, 165 mm long	45-03-22
Surface temperature probe: one side made of epoxy, the other made of stainless steel	45-03-25

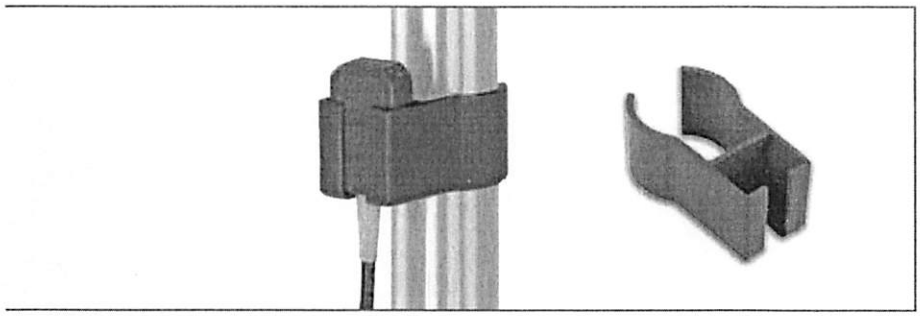
LEVEL CONTROL



Product designation	Part number
Sensor module level control	23-40-00

Sensors and accessories (included)	Part number
Level sensor	23-27-40
Adhesive sensor holder(100 units)	23-27-41

Accessories (optional)	Part number
Level sensor holder	75-521-548



- The level monitor controls the blood level in the oxygenator/ reservoir.

- The level sensor is mounted on special disposable, adhesive mounting strips which are attached to the reservoir or oxygenator. The sensor can be used with most hardshell oxygenators and reservoirs.

- The sensor is based on the effect the liquid level has on high-frequency, electromagnetic waves in an electric oscillating circuit. Using this method, interference caused by electromagnetic or external light sources and residual liquid on the oxygenator's wall is avoided.

Two operating modes can be used for level monitoring and control:

- In monitoring mode, the sensor is attached to the minimum filling level. If the current blood level drops below the set minimum level, a visual and acoustic alarm is triggered and the pump stops. The level icon switches to red. As soon as the blood level rises above the minimum level, the alarm is cleared automatically and the pump restarts. The level icon turns green.

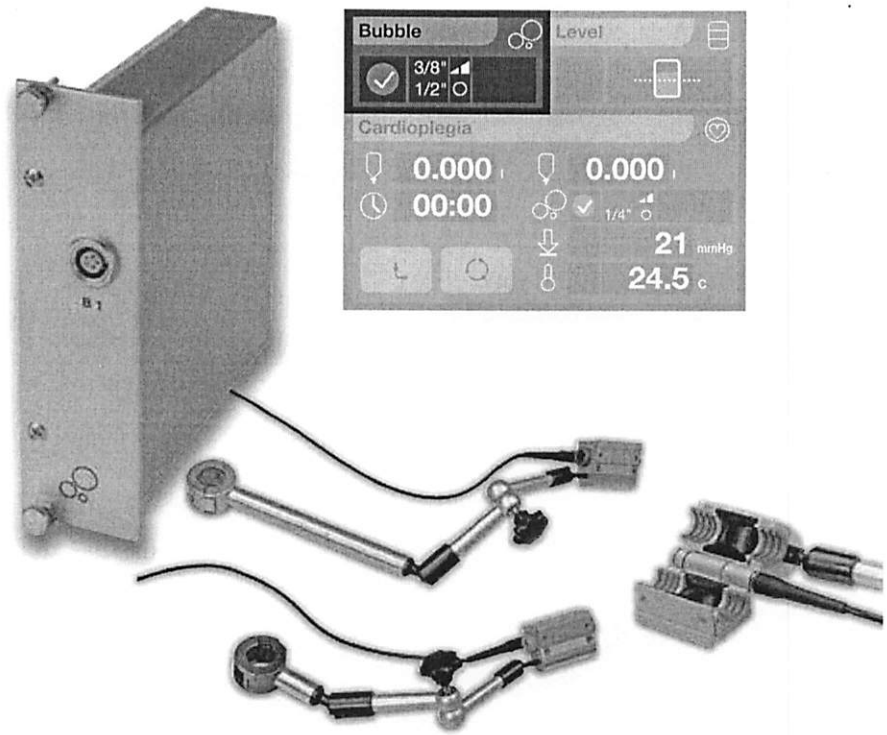
- In control mode, the sensor is attached to the set filling level. By automatically controlling the pump's rotational speed, the set blood level in the reservoir can be kept constant. The display is yellow.

Bubble detector

This monitoring device detects air bubbles and micro-bubbles in the extracorporeal circuit.

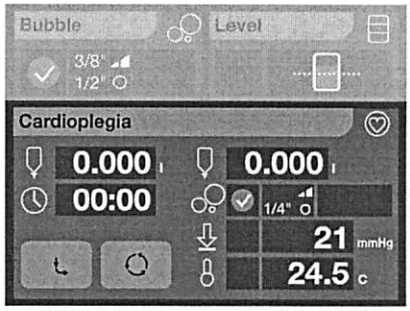
This function requires a sensor module and the corresponding sensor. The scope of delivery includes a bubble detector that can be used for 3/8" tubing. Alternatively, 1/2" and 1/4" sensors are available.

- The 3-joint mast holder with a fast clamp connector allows the bubble sensor to be positioned at the tubing system.
- If air bubbles are detected, a visual and acoustic alarm is triggered and the connected pump stops.
- You can set three different bubble detection alarm thresholds (4 mm, 5 mm and 6.5 mm Ø).
- The micro-bubble detection function can also be activated.



Product designation	Part number
Sensor Module Bubble Detector consists of: One bubble sensor **3/8"** (9.56 mm) (23-07-50) and one 3-joint mast holder, **420 mm** (23-26-96)	23-45-00
Sensor Module Bubble Detector consists of: One bubble sensor **1/4"** (6.35 mm) (23-07-40) and one 3-joint mast holder, **420 mm** (23-26-96)	23-45-01
Sensor Module Bubble Detector consists of: One bubble sensor **1/2"** (12.7 mm) (23-07-45) and one 3-joint mast holder, **420 mm** (23-26-96)	23-45-02
Sensor Module Bubble Detector consists of: One bubble sensor **3/8"** (9.56 mm) (23-07-50) and one 3-joint mast holder, **620 mm** (23-26-91)	23-45-10
Sensor Module Bubble Detector consists of: One bubble sensor **1/4"** (6.35 mm) (23-07-40) and one 3-joint mast holder, **620 mm** (23-26-91)	23-45-11
Sensor Module Bubble Detector consists of: One bubble sensor **1/2"** (12.7 mm) (23-07-45) and one 3-joint mast holder, **620 mm** (23-26-91)	23-45-12
Ultrasound gel (required for 3/8" or 1/2") 250 ml	96-06-10

CARDIOPLEGIA CONTROL



This unit can be used with a RP 150 or a DRP 85 to deliver cardioplegic solutions or blood cardioplegia during an operation. The operator can choose between two operating modes that can be selected in the menu of the control and display module.

Manual operation
The operator can start and stop the pump. The dose volume to be delivered counts up on the volume display (beginning at 0).

Automatic operation
In this operational mode an exact preset dose is delivered. In this case the volume display starts at the preset dose and counts down to 0. Then the pump stops.

- The integrated timer automatically starts during a pump stop regardless of operational mode and records the ischaemia time.
- The (total) volume delivered since the start of cardioplegia is accumulated and displayed.
- Two roller pumps are particularly suited to blood cardioplegia delivery.
- The cardioplegia sensor module has its own connectors for a bubble sensor and a pressure transducer.
- As soon as the sensor detects bubbles, the cardioplegia pump stops automatically and the cardioplegia delivery is interrupted. At the same time, the visual and acoustic alarms are triggered.
- When the preset pressure (stop limit) has been exceeded, the cardioplegia pump stops and cardioplegia delivery is interrupted. At the same time, the visual and acoustic alarms are triggered (monitoring mode). The control mode can also be set.

Product designation	Part number
Sensor module cardioplegia control	27-80-20

Sensors and accessories (optional)	Part number
Medex transducer (MX 960)	45-04-03
Cable for Medex transducer	45-04-15
Holder for one Medex transducer	45-04-16
Holder for 2 Medex transducers	45-04-17
Bubble sensor	
1/4" (6.35 mm)	23-07-40
1/2" (12.7 mm)	23-07-45
3/8" (9.56 mm)	23-07-50
Ultrasound gel (only required for 23-07-45 or 23-07-50), 250 ml bottle	96-06-10
3-joint mast holder with fast clamp connectors for 2 sensors, 620 mm	23-26-91
3-joint mast holder with fast clamp connectors for 2 sensors, 420 mm	23-26-96

B-CARE$_5$

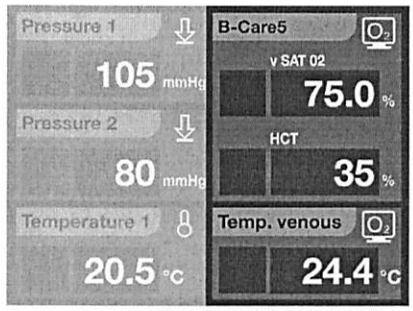
The In-Line Monitoring System for 3 vital parameters

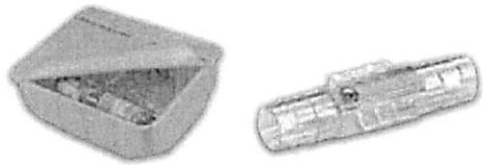
Sorin B-Care$_5$ is the first in-line monitor fully integrated into a heart-lung machine.

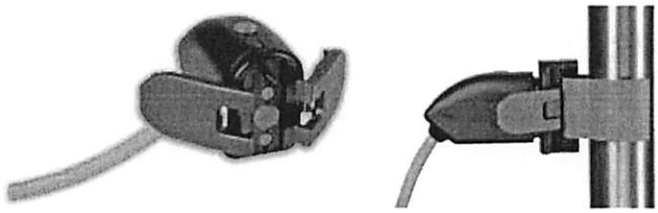
Vital parameters, i.e., venous saturation, haematocrit and venous temperature are measured and shown on a display and control module (DCM) of the S5 system panel. This new S5 sensor module is plugged into the E/P pack of the S5 perfusion system, eliminating the need of an external blood monitor. Moreover, all measured blood values are automatically transferred to the Data Management System via the S5's internal data communication system.

Venous Connector
The venous connector is available either separately packaged and sterile or pre-connected in a customised tubing system.

Venous Sensor
Sorin B-Care$_5$ performs an automatic self-test upon power-up of the S5 (no intervention required by the user). The venous sensor features an optical sensor to measure signals determining the venous saturation (Sat %) and the haematocrit (Hct %). An integrated thermistor reads the actual venous blood temperature.





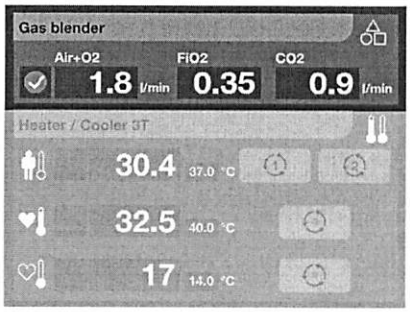


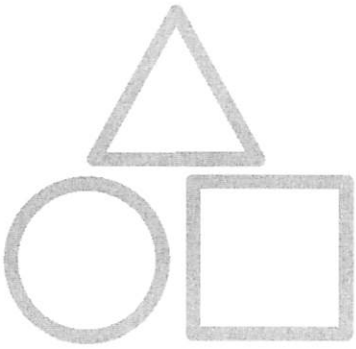
Product designation	Part number
Sorin B-Care$_5$	25-60-00

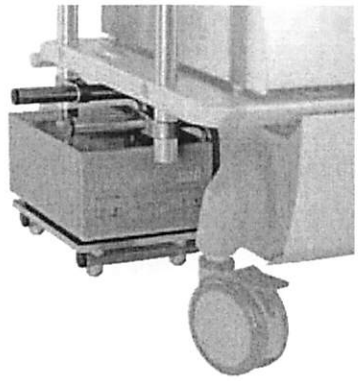
Sensors and accessories (optional)	Part number
Sorin B-Care$_5$ sensor module (venous)	25-60-20
Venous sensor (complete)	97-231-059
Holder for measuring head (reference element)	25-60-30

Connectors	
Sorin Group 1/2" venous measuring connector 10 units (sterile)	05171
Sorin Group 3/8" venous measuring connector 10 units (sterile)	05172
Kit for 1/4" venous connector	080099

Electronic gas blender







Product designation	Part number
Electronic gas blender (10 l/min)	25-28-67
Electronic gas blender (5 l/min)	25-28-68
Electronic gas blender (2 l/min)	25-28-69

Accessories (optional)	Part number
Standard holder (straight, with fast clamp connector)	55-91-50
Holder (U-shaped with plate, only compatible with 4- and 5-position consoles)	25-40-70

The electronic gas blender allows to set, monitor and display the gas flows required for extracorporeal circulation. The preset values (i.e. the total flow including Air + O2, FiO2 and CO2) can be set independently and are displayed on both the gas blender and the display and control panel.

The actual values and the set values are continuously compared. Additionally, the actual value is measured by 2 independent sensors and an alarm is triggered if a deviation between the 2 values is detected.

The remote control on the display and control module can be used to change the set values for Air + O2, FiO2 and CO2 from gas flow to blood flow. The operator is made aware of the actual values exceeding or dropping below the set values by acoustic and visual signals.

The electronic gas blender is available in three different versions:

- Electronic gas blender (10 l/min) for adult perfusion
- Electronic gas blender (5 l/min) for paediatric perfusion
- Electronic gas blender (2 l/min) for infant/neonate perfusion

Scope of delivery:

- Electronic gas blender
- Connection cable for E/P pack (length: 2 m)
- 4 connectors (Air, O2, CO2, total gas flow)

Venous line clamp

Venous Line Clamps with Mechanical Remote Control

The venous line clamp has a mechanical remote control.

It has a lightweight design. If the clamp head is fixed to another part of the venous tubing system, it might well be necessary to support the clamp head with a joint holder.

The 1 m Bowden cable connects the clamp head with the control unit and transfers settings entered on the control unit immediately to the clamping lever in the clamp head. The control unit is mounted on one of the S5's push bars (right or left – depending on the system arrangement and/or ease of use). The coarse and fine setting knobs are used for setting the tubing diameter and regulating the venous return flow quickly.

An overview of the remote-controlled venous line clamp's advantages:

- The separate control unit and line clamp facilitates a flexible assembly.
- Unlike an electronic line clamp, this clamp does not have to be calibrated and is always ready for use.
- The structural design of the line clamp means that the clamped line can be visually monitored at all times.

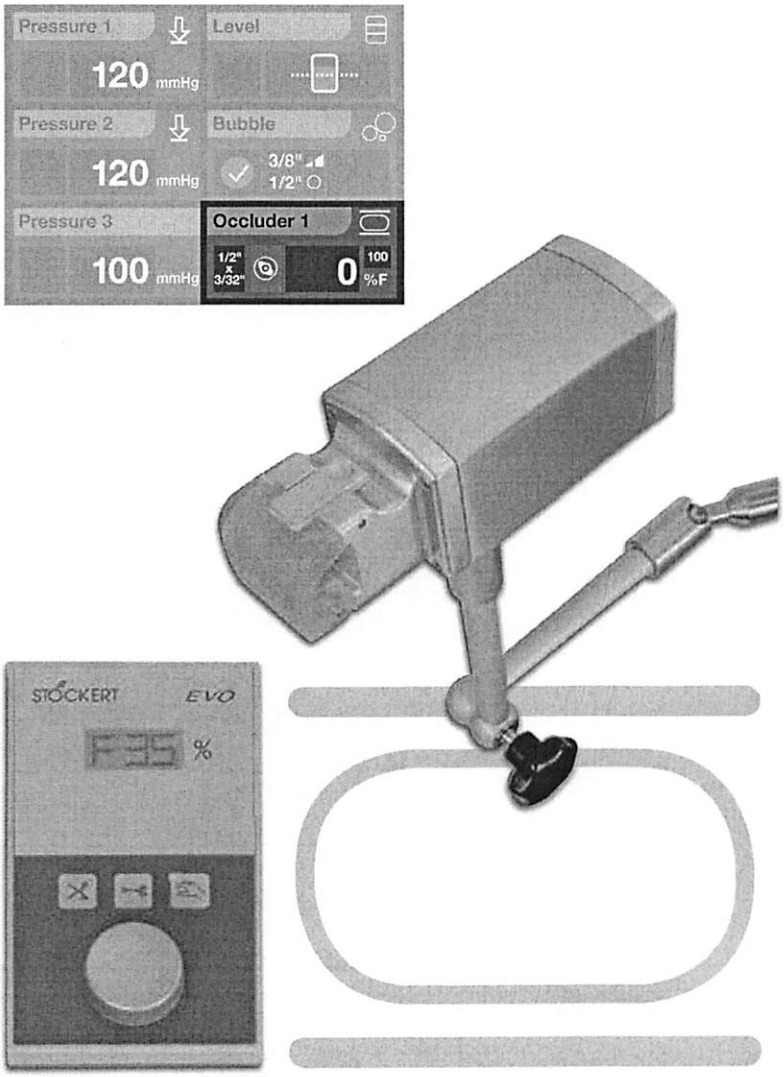
Product designation	Part number
Venous line clamp remote control	12-40-00

3-joint mast holder for venous line clamp	Part number
With fast clamp connector (586 mm)	12-30-90
With fast clamp connector (386 mm)	12-30-95
Mast adapter for mounting the control unit on the vertical mast	12-05-80

Tubing Inserts in sets with 4 pcs. each (incl.)		Part number
ø 1/4" x 1/16"	red	10-07-20
ø 3/8" x 3/32"	blue	10-07-23
ø 1/2" x 3/32"	green	10-07-25

Tubing Inserts in sets with 4 pcs. each (opt.)		Part number
ø 1/4" x 3/32"	yellow	10-07-21
ø 3/8" x 1/16"	black	10-07-22
ø 1/2" x 1/16"	grey	10-07-24
ø 5/8" x 3/32"	brown	10-07-26
ø 1/8" x 1/16"	violet	10-07-27
ø 3/16" x 1/16"	turquoise	10-07-28

EVO - Electrical venous occluder



The clamp closes automatically when the stop link function to the arterial pump is activated, if the latter has been stopped by monitoring functions in case of an alarm or is stopped manually. When the arterial pump starts up, the EVO opens to the most recently specified set value. An override of the stop link function is possible at any time, directly at the EVO operating unit.

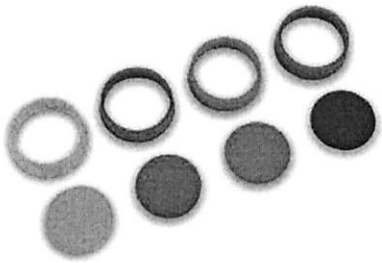
Use the relevant keys or the setting knob on the EVO operating unit to open and close. When the setting knob is turned, there is audible clicking and locking into place. Different ranges can be selected for a fine adjustment.

- Ergonomic operation when initiating and ending ECC
- The set value can be preset when the occluder is closed and the stop link function is activated
- Audible clicking and locking into place make you doubly aware of setting knob adjustments
- A choice of fine adjustment from < 40% in 10% steps
- The stop link delay for a level alarm is adjustable from 0 to 60 seconds

Product designation	Part number
Electrical venous occluder consists of:	12-80-00
Occluder (with mast holder)	12-80-10
Control unit	28-95-70

Accessories

Colour coding set
To ensure the control panel is safely assigned to the mast roller pump, a colour coding set is available.



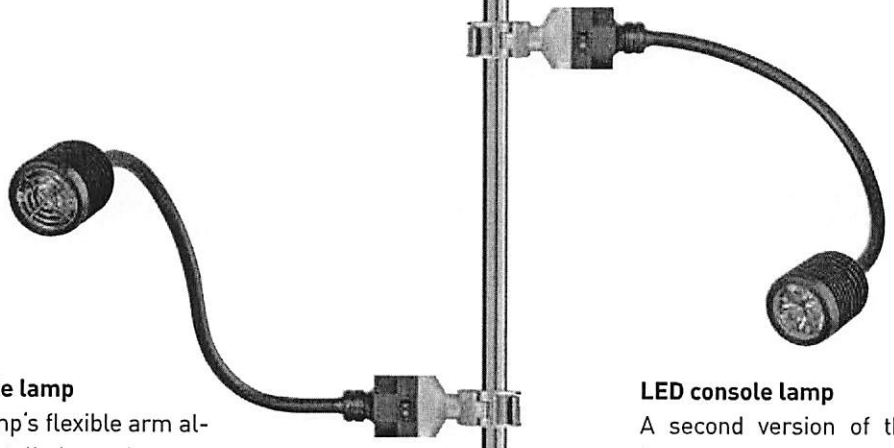
Cable holders
Cable holders are used for the secure and correct routing of cables and tubing on the mast system. The holders can be installed anywhere on the mast system. Available in sets of 6.

Perfusionist's chair
This comfortable chair helps the operator maintain a healthy posture. The ergonomic swivel design is mounted on 5 self-locking castors. The back and seat height are adjustable. It is suitable for the operating theatre and easy to clean.

S3 to S5 adapter cable
The adapter cable is used for connecting S3 accessories (SCP, ERC, gas blender) to the S5 System.

Product designation	Part number
Colour coding set	50-80-99
Cable holders / 6 clips Ø 33 mm mast diameter	45-09-10
Cable holders / 6 clips Ø 25 mm mast diameter	45-09-11
Perfusionist's chair	41-02-98
S3 to S5 adapter cable	45-12-00

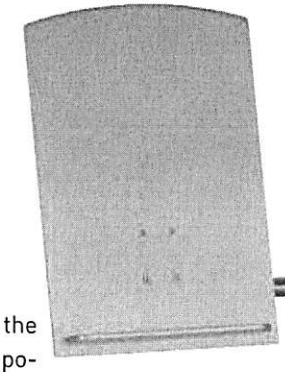
Accessories



Halogen console lamp
The console lamp's flexible arm allows it to be installed anywhere on the mast system. The console lamp is connected to the central power supply. In the case of a power failure, the lamp is powered by the uninterruptible emergency power supply.

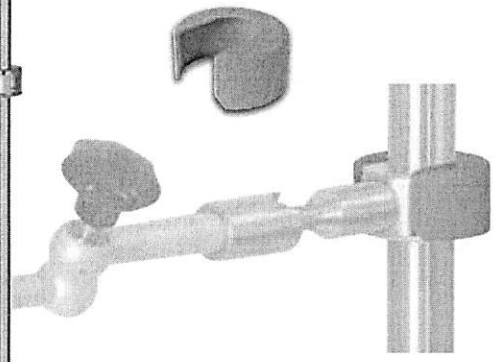
LED console lamp
A second version of the console lamp uses LEDs. Some major advantages of LEDs are:

- Powerful luminosity
- Longevity
- Energy efficiency
- Minimum heating of lamp



Writing desk DIN A4
This writing desk is mounted on the console using a stable arm. The position and tilt can be set individually by the operator.

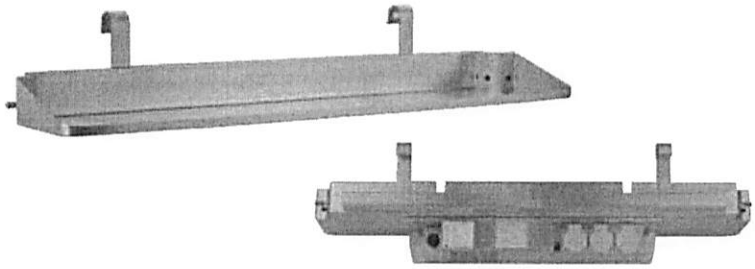
Cover for fast clamp connectors
These convenient covers safeguard the fast clamp connectors against unintentional opening and protect against spilled liquid.



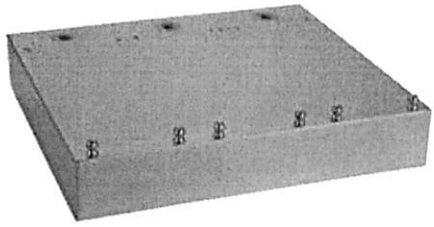
Product designation	Part number
Halogen console lamp	35-05-50
LED console lamp	35-05-70
Writing desk DIN A4	48-04-00
Cover for fast clamp connectors (set of 6 pieces)	43-42-61

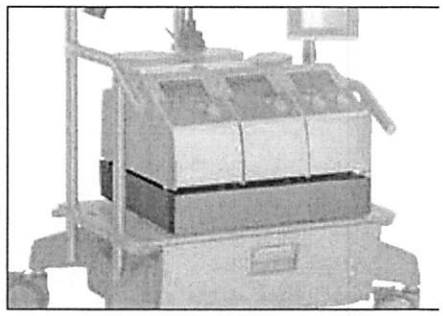
Accessories

S5 shelf
This versatile shelf is available in three sizes (for 3-, 4- and 5-position pump tables). It can be supplied with or without a AC outlet strip.



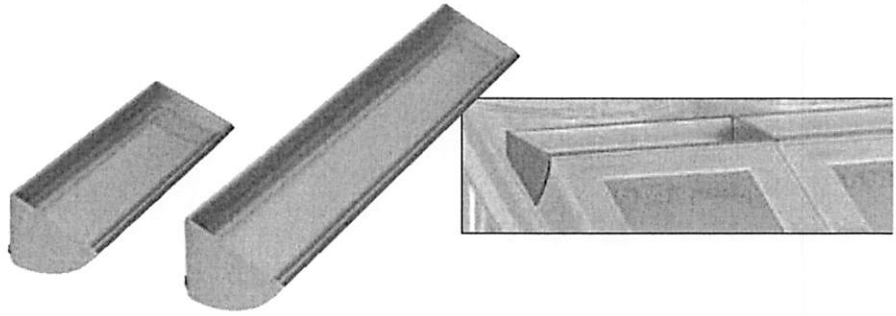
S5 pump spacer
The S5 roller pumps for 3-, 4- and 5-position pump tables can be raised by 10 cm using the pump spacer.





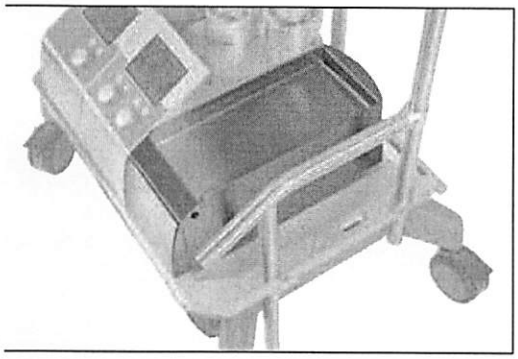
S5 plexiglas display protector
This cover protects the roller pump displays against falling objects.

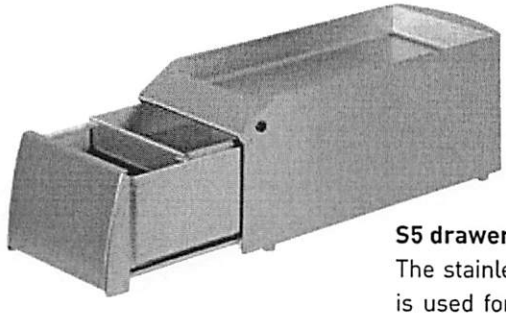
S5 shelf for roller pump 150
A stainless steel shelf for storing small parts is available for every roller pump. A longer version for 2 roller pumps is also available. For technical reasons, a shelf is not available for the double roller pump.



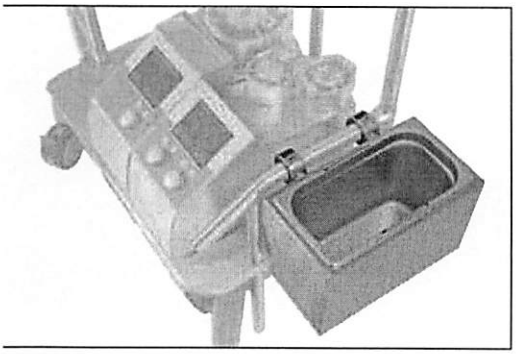
Product designation	Part number		
	3-position	4-position	5-position
S5 shelf with AC outlet strip	48-31-19	48-41-19	48-51-19
S5 shelf without AC outlet strip	48-31-10	48-41-10	48-51-10
S5 pump spacer	48-31-20	48-41-20	48-51-20
S5 plexiglas display protector	48-31-30	48-41-30	48-51-30
S5 shelf for roller pump 150	all sizes: 10-84-60		
S5 shelf for 2 roller pumps 150	all sizes: 10-64-84		

Accessories

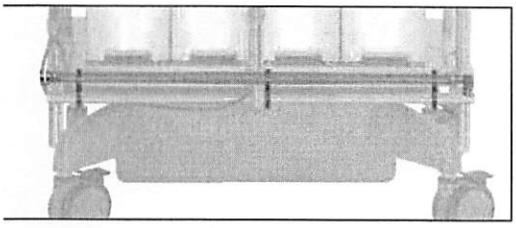


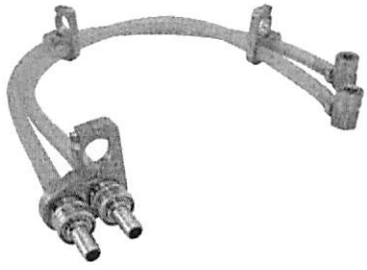


S5 drawer module
The stainless steel drawer module is used for storing utensils. It has an easy-access drawer on tracks with a stop to prevent it from falling out. There is an additional sliding tray inside the drawer. The drawer module occupies a single pump space on the console.



S5 ice container
Infusion bags and bottles (for example cardioplegic solutions) can be cooled and stored in the S5 ice container. It consists of an outside casing and a stainless steel insert. The chilled bottles etc. are always within reach if the ice container is mounted on the right or left push bar of the S5!





S5 tubing guide holder
The tubing guide consists of a 6-m length of PVC tubing with connectors and 3 holders for securing to the horizontal crossbar of the movable mast. The holder lifts the tubing clear of the floor so that it is not squashed under the castors of the console. The floor is also easier to clean without tangled tubing and the danger of being tripped.

Product designation	Part number
S5 drawer module	48-41-70
S5 ice container	16-05-40
S5 tubing guide holder incl. connectors and a 6-m length of PVC tubing	16-05-60

Heater-cooler 3T

The Heater-Cooler 3T facilitates the precise and fast regulation of the patient's blood temperature and the temperature of the cardioplegic solution regardless of the hot/cold water supply in the operating theatre.

The device has 3 separate water tanks and 3 water circuits that can be used simultaneously. Circuits 1 and 2 use an identical preset temperature and are mainly used to control the patient's temperature.

Circuit 3, which has a separate cold water and warm water tank, is specially designed for cooling and heating blood and/or cardioplegic solutions. Cold water and warm water tanks with the relevant preset temperatures are available during operation at all times.

Heating-cooling blankets connected to the heater-cooler provide an additional support for regulating the patient's blood temperature. The device is operated and monitored from its own control panel or, alternatively, from the display and control modules on the system panel (see illustration).

Product advantages:

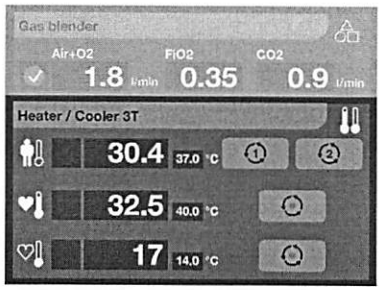
- The low tank volume makes short pre-cooling/pre-heating times possible.
- Separate cold and warm water tanks allow the operator to switch between warm and cold cardioplegia spontaneously.
- The patient and cardioplegia circuits can be switched off separately when not in use. This improves the other circuit's heating and cooling performance.
- An independent safety system stops the water temperature reaching critical values.
- The pump suction stage ensures that the heat exchanger and tubing are purged.

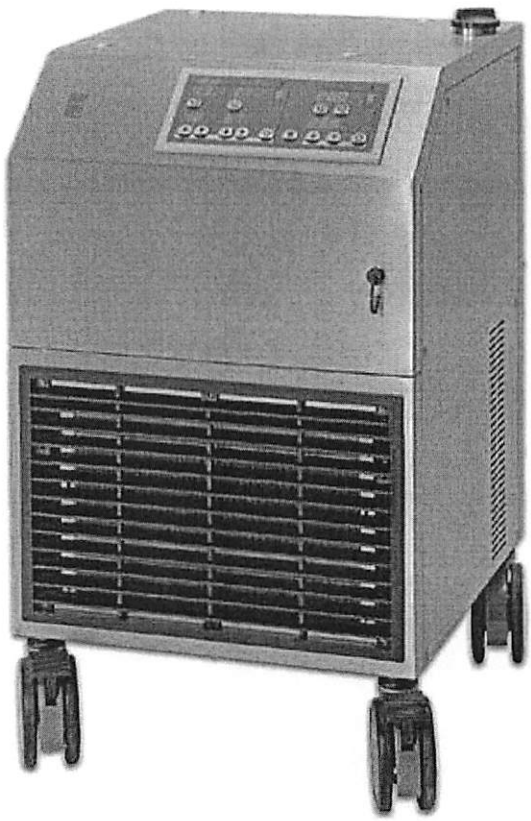
Product designation	Part number
Heater-cooler 3T, 230 V	16-02-80

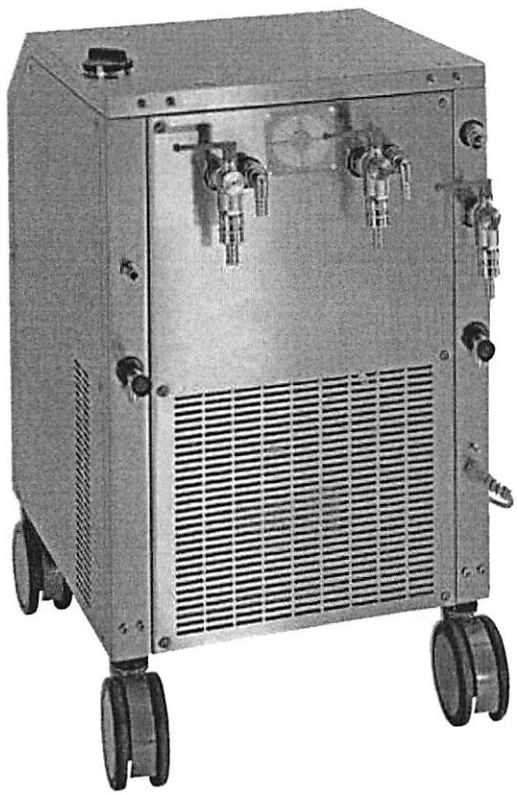
Accessories (included)	Part number
Cable for connection to the S5 System, 6-m	45-12-16

Accessories (optional)	Part number
Heating-cooling blanket for adults (55 x 150 cm)	16-10-50
Heating-cooling blanket for children (55 x 90 cm)	16-10-51
Tubing set for heating-cooling blanket	16-10-55
1 adapter connector set for blanket	16-10-10

Heater-cooler 3T







SORIN CONNECT

Sorin CONNECT is an innovative and intuitive Perfusion charting system focused on real time and retrospective calculations and trending tools to assist with data management during and after CPB.

CONNECT offers a combination of intelligently designed software and hardware to support your perfusion and documentation goals. CONNECT ensures data integrity for an efficient, effective and automated electronic charting system.

The CONNECT Manager application manages all case data in one central database and allows access to the information by the Perfusion team at anytime. Manager can be used for printing or exporting case reports as well as for conducting data analysis with the included statistics tool.

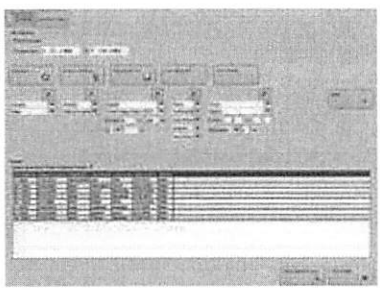
The CONNECT Recorder application effortlessly collects customized patient and case information during CPB. Information from the heart lung machine and other devices in the operating room are displayed in a variety of chart and table formats to optimize viewing preferences. Comments, drugs and volumes are easily entered into the case record via quick entry touch of the innovative tag cloud feature.

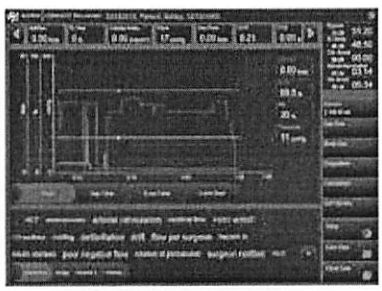
CONNECT Recorder operates on a touch screen datapad, custom designed as a drip proof, medical grade tablet PC that mounts onto the Sorin heart lung machine. The touch screen interface enables fast and easy case event entries and patient specific documentation via on screen virtual keyboards, pull down lists and customized data tables. The datapad standard configuration includes built in wireless and LAN connections for transfer of case data and customized settings across the hospital network.

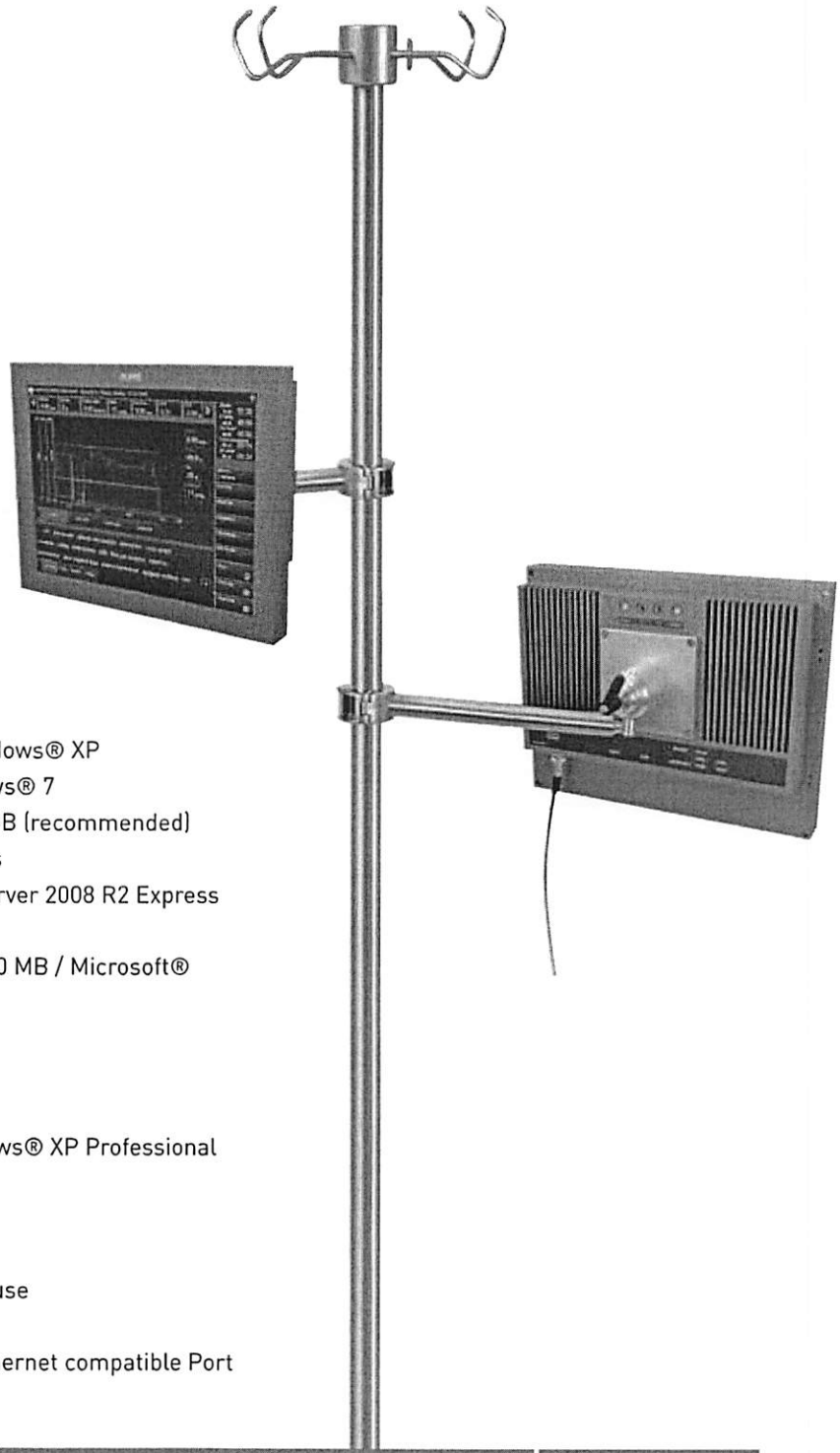
Once the case has been completed, the case record may be transferred between Manager and Recorder via USB drive, across the hospital network with a LAN connection or by utilizing the integrated wireless feature. The record can then be printed, exported to a location on the hospital network and retained in the database for statistical analysis, export and reporting at anytime.

Designed with Goal Directed Perfusion in Mind

- GDP Monitor feature for real time calculation of DO2, VO2 and VCO2 values
- Dedicated fluid balance chart for focus on the hemodilution footprint
- Embedded Quality Scores feature for practice improvement initiatives
- Electronic connection to Sorin ATS devices to integrate ATS information into the Perfusion record
- Clinical statistics and Inventory reporting tool
- Paperless or printed user defined case reports
- Easy customization for tailoring Connect to Perfusion practice preferences
- Customizable charts and tables for real time and retrospective data trending and analysis
- Connect is a registered medical device







Specifications

CONNECT Manager

- Operating system: Microsoft® Windows® XP service pack 3 / Microsoft® Windows® 7
- Random access memory (RAM): 1 GB (recommended)
- Screen resolution: 1024 x 768 pixels
- Database used: Microsoft® SQL Server 2008 R2 Express (recommended)
- Free hard disk space - software: 120 MB / Microsoft® SQL Server 2008 R2
- Express database: 12 GB

Datapad for CONNECT Recorder

Operating system: Microsoft® Windows® XP Professional

- Intel® Core™ 2 Duo processor
- SO-DIMM DDR1-RAM 2 GByte
- 1x COM Port (COM1), TTL Level
- 2x PS/2 Ports for Keyboard and Mouse
- 4x USB 2.0 Ports (EHCI)
- 1x IEEE 802.3u 100Base-Tx Fast Ethernet compatible Port

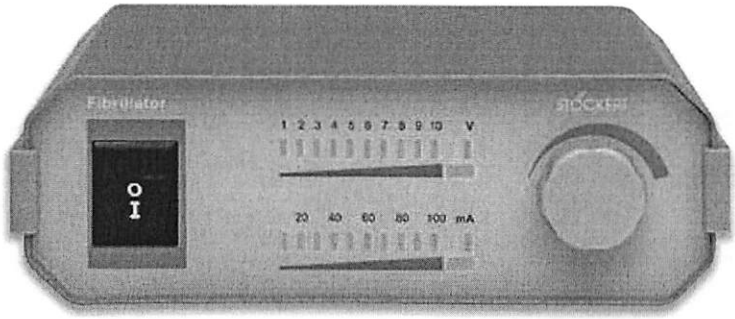
Product designation	Part number
Sorin Connect Manager	24-90-30
Sorin Connect Recorder	24-90-45

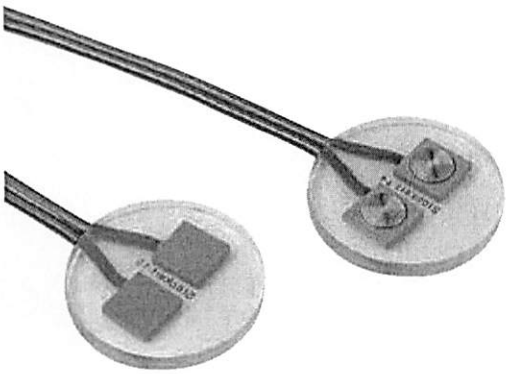
Additional packages for upgrades from DMS are available, please contact your local Sorin Group representative for more details.

Fibrillator

Fibrillator

Applying AC voltage to the myocardium is one way of inducing cardiac arrest. The Fibrillator Fi 20 M supplies the necessary AC voltage. The device is CE certified. When switched on, the output voltage is always set to 0 V. The setting range for the output voltage extends from 0V to 10V~, 50 Hz. The electrodes can be sterilised and reused repeatedly.





Product designation	Part number
Fibrillator Fi 20 M	28-10-80

Accessories (included)	Part number
Electrode, both sides conducting	28-10-15*

Accessories (optional)	Part number
Electrode, one side conducting	28-10-20*
Electrode, for children	28-10-25*
Potential equalization cable (5 m)	45-10-50

* The fibrillator electrodes are connected to the unit via 4 metres of highly flexible silicone cable.

Technical Specifications

1. Dimensions, Weights, Operating Conditions

1.1 Console

Height (to the surface of the pump cover)	640 mm
Depth	600 mm

Console	3-position	4-position	5-position
Width (incl. push bars)	745 mm	890 mm	1073 mm
Weight	83.4 kg	86.3 kg	89.5 kg

Operating conditions	
Operating temperature	+ 10 °C ... + 40 °C
Storage temperature	0 °C ... + 40 °C
Relative humidity (operating and storing)	30% ... 75%

1.2 Masts

Maximum permissible load	
Maximum total load on mast system	45 kg
Maximum load on a mast	20 kg [1]

Mast system extension (optional)	
Maximum load on the telescope mast	40 kg
Maximum load on the vertical mast	11.5 kg

1.3 Pumps

	Roller pump 150	Double roller pump 85	Mast roller pump 150	Mast roller pump 85	2 mast roller pumps 85
Height	285 mm	257 mm	289 mm	237 mm	237 mm
Width	180 mm	180 mm	178 mm	116 mm	260 mm
Depth	485 mm	485 mm	299 mm	175 mm [3]	200 mm [5]
Weight	15 kg	12 kg	11.9 kg [2]	5 kg [2]	11 kg [4]

Pump specifications	Roller pump	Double roller pump
Diameter of pump raceway Ø	150 mm	85 mm
Diameter of occlusion roller Ø	30.5 mm	15 mm

Speed range	0 to 250 rpm (clockwise, counterclockwise)	
Deviation in speed accuracy	±1% of the terminal value 250 rpm plus ±0.5% of set value	
Speed deviation in the event of a fault (Detection of faulty speed from 30 rpm)	during continuous operation: +15% max.; 2 revolutions max. until pump stops	
Direction of rotation	Clockwise/counterclockwise	Clockwise/counterclockwise

Concentricity		
Pump raceway	0.03 mm	0.03 mm
Occlusion symmetry	0.03 mm	0.03 mm
Occlusion rollers	0.015 mm	0.015 mm

Displays	Roller pump	Double roller pump
rpm display range	0 to 250 rpm	0 to 250 rpm
Resolution	1 rpm	1 rpm
l/min display range (flow)		
1/8"	0 to 0.83 l/min	0 to 0.44 l/min
3/16"	0 to 1.79 l/min	0 to 0.93 l/min
1/4"	0 to 3.12 l/min	0 to 1.57 l/min
5/16"	0 to 4.70 l/min	0 to 2.33 l/min
3/8"	0 to 6.50 l/min	0
1/2"	0 to 11.2 l/min	0

[1] max. swivel arm 200 mm; [2] with fast clamp connector; [3] without fast clamp connector;
[4] with double holder; [5] without double holder

Deviation of speed slave pump	max. 1 percentage point of the flow ratio setting

Power supply	Roller pump	Double roller pump
Operating voltage	24 V DC	24 V DC
Power consumption	160 W	160 W

1.4 System Panel

	For 3 display and control modules	For 4 display and control modules	For 5 display and control modules	For 6 display and control modules
Height	475 mm	590 mm	723 mm	475 mm
Width	184 mm	184 mm	184 mm	375 mm
Depth (without mast holder)	94 mm	94 mm	94 mm	94 mm
Weight (without display and control module)	3.9 kg	4.5 kg	5.1 kg	7 kg

	Display and control module	Control module for mast roller pumps
Height	125 mm	260 mm
Width	179 mm	190 mm
Depth 4	8 mm	100 mm
Weight	0.5 kg	3.5 kg [6]

2. Electrical Specifications

2.1 Electronics and Power Pack

Input voltages	100 V ~to 240 V~; 50 / 60 Hz
Permissible mains voltage fluctuation	± 10%
Maximum power consumption (standard equipment)	1000 W

2.2 UPS and Batteries

Operating time of UPS	
At 400 W output power	20 minutes
At 160 W output power	90 minutes
Charging time	12-15 hours

2.3 System Panel

Display and control module / touch screen	
Operating voltage	24 V
Power consumption	45 W
Pixel Failure Class	Conformity with Pixel Failure Class III

2.4 Shelf with AC Outlet

	3-/4-/5-position
Weight - shelf	approx. 6.5 kg
Maximum load - shelf	8 kg
Number of sockets	4
Protection	at 230/240 V: Circuit breaker 2 A at 110/115 V: Circuit breaker 2 A
Load rating	2 A maximum in total
Sum of leakage currents	500 µA max. in total

[6] with holder

Level	
Alarm limit (level sensor) for oxygenators/reservoirs made of rigid polycarbonate, wall thickness at sensor position 3 mm max.	Level display of the sensor holder ±10 mm

Pressure	
Measurement range mmHg	-200 mmHg to +800
Resolution	1 mmHg

Cardioplegia	
Pressure measurement range	-200 mmHg to +800 mmHg
Resolution	1 mmHg

Temperature monitor	
Display range	0 °C to +50 °C

Timer	
Counting range	0 - 999 min 59 sec

Timer (optional)	
Counting range	0 - 10 h (up and down)

2.5 Modules and Sensors

Level sensor module	
Alarm limit (level sensor) for oxygenators/reservoirs made of rigid polycarbonate, wall thickness at sensor position 3 mm max.	Level display of the sensor holder ±10 mm

Sensor module for bubble detector	
Alarm limit (bubble sensor) at ⩾ 15 rpm 1/2" and 3/8"	Air volume: 0.144 cm^3 (Ø 6.5 mm) Air volume: 0.065 cm^3 (Ø 5.0 mm) Air volume: 0.034 cm^3 (Ø 4.0 mm)

Sensor module 2 channel pressure monitor	
Accuracy	± 5 mmHg
Zero point adjustment range	± 100 mmHg
Gain adjustment range (matching)	± 20%
Input resistance	100 kΩ
Output voltage to pressure transducer	< 10 V

Cardioplegia sensor module	
Volume control Setting range Accuracy of dosage	 0 to 2 liter ± 10%, min. ± 20 ml
Pressure monitor	See sensor module 2 channel pressure monitor
Bubble detector	See alarm limit of the bubble sensor

Sensor module 4 channel temperature monitor	
Temperature measurement range	0 °C to +50 °C
Resolution	0.1 °C
Accuracy (without sensors)	0.0 °C - 25.0 °C ± 0.2 °C 25.0 °C - 45.0 °C ± 0.1 °C 45.0 °C - 50.0 °C ± 0.2 °C

Exhibit D

EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type (e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotriptor, MRI, PET, Simulator, CT Scanner, etc.)	Heart-Lung Bypass Machine	Heart-Lung Bypass Machine
Manufacturer	LivaNova	LivaNova
Model name/number	SRD S5 Heart Lung Perfusion System	SRD S5 Heart Lung Perfusion System
Other method of identifying the equipment (e.g., Serial Number, VIN #)	48E01770	Not Available Until Installed
Is the equipment mobile or fixed?	Mobile	Mobile
Date of acquisition	2011	2022
Was the existing equipment new or used when acquired? / Is the replacement equipment new or used?	New	New
Total projected capital cost of the project	NA	$193,380.56
Total cost of the equipment	Not available due to system transition	$193,380.56
Location of the equipment	Carolinas Medical Center	Atrium Health Pineville
Document that the existing equipment is currently in use	729 open heart surgery procedures utilizing a heart-lung bypass machine were performed at CMC during FFY2021	NA
Will the replacement equipment result in any increase in the **average charge per procedure**?	NA	No
If so, provide the increase as a percent of the current average charge per procedure	NA	NA
Will the replacement equipment result in any increase in the **average operating expense per procedure**?	NA	No
If so, provide the increase as a percent of the current average operating expense per procedure	NA	NA
Type of procedures performed on the existing equipment	Heart-Lung Bypass	NA
Type of procedures the replacement equipment will perform	NA	Heart-Lung Bypass

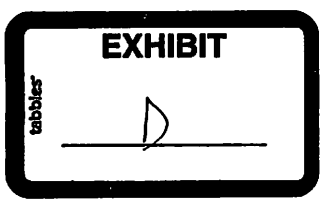


Exhibit E

EXHIBIT
tabbies
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE
DIRECTOR

September 29, 2017

Gary S. Qualls
K&L Gates
430 Davis Drive, Suite 400
Morrisville, NC 27560

Material Compliance Approval

Project ID #:	F-6384-01
Facility:	Carolinas HealthCare System (CHS) University
Project Description:	Change site of one unit of cardiac catheterization equipment from CHS University to Carolinas Medical Center (CMC)
County:	Mecklenburg
FID #:	923516

Dear Mr. Qualls:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) has determined that the change proposed in your letter of September 7, 2017 is in material compliance with representations made in the application. This change includes changing the site of one unit of cardiac catheterization equipment from CHS University to CMC where it will be located in Cardiology Room 8. The EP unit located in that room will become a cardiac catheterization unit. Upon completion, CHS University will have zero cardiac catheterization units and CMC will have nine cardiac catheterization units on its license. However, you should contact the Agency's Construction Section to determine if they have any requirements pertinent to the proposed change.

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. Please refer to the Project ID # and Facility ID # (FID) in all correspondence.

Sincerely,

Gloria C. Hale
Project Analyst

Martha J. Frisone
Chief, Healthcare Planning and
Certificate of Need Section

cc: Construction Section, DHSR
Acute and Home Care, Licensure and Certification Section, DHSR
Sharetta Blackwell, Program Assistant, Healthcare Planning, DHSR

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE
DIRECTOR

September 29, 2017

Gary S. Qualls
K&L Gates
430 Davis Drive, Suite 400
Morrisville, North Carolina 27560

Exempt from Review – Replacement Equipment

Record #:	**2387**
Facility Name:	Carolinas Medical Center (CMC)
FID #:	943070
Business Name:	The Charlotte-Mecklenburg Hospital Authority
Business #:	1770
Project Description:	Replace the existing unit of equipment at Carolinas Healthcare System (CHS) University that had been used to provide cardiac catheterization services by having a vendor remove it, rebuild it and install it in Room 1 at CMC to be used to provide EP services
County:	Mecklenburg

Dear Mr. Qualls:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of September 7, 2017, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(a)(7). Therefore, you may proceed to replace the existing unit of equipment at CHS University that had been used to provide cardiac catheterization services by having a vendor remove it, rebuild it and install it in Room 1 at CMC to be used to provide EP services. Please see the Agency's Material Compliance Approval letter dated September 29, 2017 regarding the change of site of one unit of cardiac catheterization equipment from CHS University to CMC.

Moreover, you need to contact the Agency's Construction and Acute and Home Care Licensure and Certification Sections 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,

Gloria C. Hale

Gloria C. Hale
Project Analyst

for

Martha J. Frisone
Chief, Healthcare Planning and
Certificate of Need

cc: Construction Section, DHSR
Acute and Home Care Licensure and Certification Section, DHSR
Sharetta Blackwell, Program Assistant, Healthcare Planning, DHSR

K&L GATES

Correct date

September 7, 2017

Gary S. Qualls
D 919.466.1182
F 919.516.2182
gary.qualls@klgates.com

Via Hand Delivery
Martha J. Frisone, Chief
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
N.C. Department of Health and Human Services
809 Ruggles Drive
Raleigh, NC 27603

Dear Martha:

The Charlotte-Mecklenburg Hospital Authority ("CMHA") d/b/a Carolinas Medical Center ("CMC") and d/b/a CHS University seeks the two rulings described below. The Material Compliance Request in Part I merely asks to assign the Cardiac Catheterization ("Cardiac Cath") CON Rights from one existing CMHA Equipment Unit to another (not increasing CMHA's Cardiac Cath Unit complement). The Exemption Notice in Part II then describes how CMHA will take one of its existing electrophysiology ("EP") Equipment Units and physically replace it with another existing, comparable CMHA EP Equipment Unit. A summary of each step is described immediately below. A more detailed description of each step is provided in Parts I and II below.

Summary of Step #1

1. CMHA seeks a material compliance determination to relocate the Cardiac Catheterization Equipment Unit CON Rights CMHA currently has for the University Campus Cardiac Cath Unit to an existing EP Unit currently housed in Cardiology Room 8 ("Room 8") at CMC. That existing EP Unit in CMC Room 8 will become CMHA's New Cardiac Cath Unit to supplant the old University Campus Cardiac Cath Unit. This will effectively be the substitution of the Cardiac Cath CON rights from one of CMHA's current equipment units to another of CMHA's current equipment units. This is couched as a material compliance request instead of a replacement equipment exemption because the equipment to be used as Cardiac Cath Equipment in CMC Room 8 is not being "purchased." See N.C. Gen. Stat. 131E-176(22a).

Summary of Step #2

2. In Step #2, CMHA seeks a replacement equipment exemption to replace the Old University Campus Cardiac Cath Unit (which -- after Step #1 -- will no longer be a Cardiac Cath Unit with Cardiac Cath CON Rights) and replace it with an EP Unit at CMC in Cardiology Room 1 ("Room 1") for under $2 Million (CMC Room 1 currently houses no medical equipment).

I. Step #1 -- The Material Compliance Request.

As described above, CMHA first seeks a material compliance determination to relocate the Cardiac Cath CON Rights currently assigned to the University Campus Cardiac Cath Unit to an existing EP Unit in CMC Room 8. That existing EP Unit in CMC Room 8 will become CMHA's New Cardiac Cath Unit to supplant the old University Campus Cardiac Cath Unit.[1] Since CMHA already owns the EP Unit in CMC Room 8 (to which the Cardiac Cath CON Rights are being assigned), this is a substitution of CON rights as opposed to a replacement equipment exemption. The equipment to be used as Cardiac Cath Equipment in CMC Room 8 is not being purchased, and thus does not trigger the replacement equipment definition under N.C. Gen. Stat. 131E-176(22a).

We have included floor plans showing the following:

- Exhibits 1A and 1B show macro and micro views of where the University Campus Cardiac Cath Unit is situated.

- Exhibits 2A, 2B, and 2C show macro and micro views of CMC Room 8, which will now house CMHA's New Cardiac Cath Unit.

There is precedent for the relocation of Cardiac Cath Equipment and associated CON Rights from one wholly owned hospital to another wholly owned hospital in the same county (and thus the same Cardiac Cath Service Area). In an August 5, 2015 material compliance determination, the Agency approved Novant Health to relocate and replace a Cardiac Cath Unit from Novant Health Presbyterian Medical Center ("Presbyterian") to Novant Health Matthews Medical Center ("Matthews"). See Exhibit 3.

[1] This New Cardiac Cath Unit will be the 8th Cardiac Cath Unit on the CMC Campus and will be the 9th Cardiac Cath Unit under CMC's license (given that one Cardiac Cath Unit on the CMC license is housed on the Mercy Campus). After this transaction is effectuated, the University Campus will no longer house any Cardiac Cath Units.

In requesting the relocation, Novant pointed out that both Presbyterian and Matthews were within the Novant Health corporate family and were both located in Mecklenburg County (and thus the same Cardiac Cath Service Area). See Exhibit 4.

That analysis fits CMHA here even better than it fit Novant in the foregoing scenario. In the Novant situation, Presby and Matthews were owned by two separate Novant Health subsidiaries, but were under Novant Health ownership at the parent level. Here, CMC and CHS University are both operating units of CMHA and are both located in Mecklenburg County. Thus, CMC and CHS University are operated within the same entity.

Thus, neither the substitution component nor the relocation component of this material compliance project is CON reviewable.

II. Step #2 -- The Replacement Equipment Exemption.

As also described above, CMHA next seeks (in Step #2) a replacement equipment exemption to replace the physical piece of equipment that was formerly used as the University Campus Cardiac Cath Unit (the "Old University Cath Unit" or the "Existing Equipment"). CMHA will replace the Existing Equipment with an EP Unit at CMC in Room 1 for under $2 Million (CMC Room 1 currently houses no medical equipment).

After Step #1 above, the Old University Cath Unit loses its status as "Cardiac Catheterization Equipment" under N.C. Gen. Stat. 131E-176(2f) and thus no longer has CON Rights to perform "Cardiac Catheterization Services under N.C. Gen. Stat. 131E-176(2g). Thus, after Step #1, the Old University Cath Unit will be stripped of its Cardiac Cath CON Rights and will now be comparable to the New EP Equipment in CMC Room 1 because the remaining capabilities of the Old University Cath Unit are now limited to EP (and other angiographic capabilities) as opposed to Cardiac Cath Services capabilities pursuant to Cardiac Cath CON Rights. Exhibits 5A and 5B show macro and micro views, respectively, of CMC Room 1, which will now house CMHA's Replacement EP Unit.

A. **Section 184(a)(7) Exemption**

The General Assembly has chosen to exempt certain, otherwise reviewable events from CON review. Among those exemptions is the acquisition of "replacement equipment," as provided in N.C. Gen. Stat. § 131E-184(a)(7), set forth below:

> (a) Except as provided in subsection (b), the Department shall exempt from certificate of need review a new institutional health service if it receives prior written notice from the entity proposing the new institutional health service, which notice includes an explanation of why the new institutional health service is required, for any of the following:
>
> * * *
>
> (7) To provide replacement equipment.

The CON Law then defines "replacement equipment," as follows:

> "Replacement equipment" means equipment that costs less than two million dollars ($2,000,000) and is purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced.

See N.C. Gen. Stat. § 131E-176(22a).

Therefore, to qualify for this exemption, the replacement equipment must cost less than $2 Million and be "comparable" to the equipment it replaces and must be "sold or otherwise disposed of when replaced." As described below, CMHA's proposal qualifies for this exemption.

B. **Comparable Equipment**

The CON rule codified as 10A N.C.A.C. 14C.0303 (the "Regulation") defines "comparable medical equipment" in Subsection (c) as follows:

> "Comparable medical equipment" means equipment which is functionally similar and which is used for the same diagnostic or treatment purposes.

10A N.C.A.C. 14C.0303(c).

CMHA intends to use the Replacement Equipment for substantially the same types of treatments for which the Existing Equipment will be capable after Step #1 is consummated. As described above, after Step #1, the Old University Cath Unit will be comparable to the New EP Equipment in CMC Room 1 because the remaining capabilities of the Old University Cath Unit are now limited to EP (and other angiographic capabilities) as opposed to Cardiac Cath Services capabilities pursuant to Cardiac Cath CON Rights. The Replacement Equipment is therefore "comparable medical equipment" as defined in Subsection (c) of the Regulation.

Furthermore, CMHA does not intend to increase patient charges or per procedure operating expenses within the first 12 months after its acquisition. For further equipment comparison, please refer to Exhibit 9, the Equipment Comparison Chart.

Subsection (d) of the Regulation further provides that the Replacement Equipment is comparable to the Existing Equipment if:

(1) the Replacement Equipment has the same technology as the Existing Equipment, although it may possess expanded capabilities due to technological improvements;

(2) the Replacement Equipment is functionally similar and is used for the same diagnostic or treatment purposes as the Existing Equipment and is not used to provide a new health service; and

(3) acquisition of the Replacement Equipment does not result in more than a 10% increase in patient charges or per procedure operating expenses within the first twelve months after the Replacement Equipment is acquired.

10A N.C.A.C. 14C.0303(d).

The Replacement Equipment will meet all three of the tests set out in Subsection (d). The Replacement Equipment satisfies the technology and functionality tests in Subsection (1) and (2) as discussed above and identified in the Comparison Chart. See Exhibit 9. Moreover, CMHA represents that use of the Replacement Equipment will not result in the types of expense or charge increase described in Subsection (d)(3).

C. Cost of the Replacement Equipment

The total costs are $1,962,116.59 to acquire, install, and make operational the Replacement EP Unit (the "Replacement Equipment") and all items to be placed in CMC Room #1. The line item component costs are set forth in Exhibit 6 (Proposed Total Capital Cost Sheet). The Quote for the Replacement Equipment by itself is attached as Exhibit 7. The Quotes for other equipment items to be placed in Room #1 are included in Exhibit 8.

Thus, the costs are less than the $2 Million threshold in N.C. Gen. Stat. § 131E-176(22a), even if one counts all items to be placed in CMC Room #1 and the related construction costs.

D. Equipment Being Replaced is Currently in Use

The Existing Equipment is currently in use at CHS University, identified as the University Campus Cardiac Cath Unit described in detail in Part I above.

CONCLUSION

Based on the foregoing information, CMHA asks the Agency to make the following two rulings:

1. Find that assigning the Cardiac Cath CON Rights from one existing CMHA Equipment Unit to another (not increasing CMHA's Cardiac Cath Unit complement) materially complies with the CON for the CHS University Cardiac Cath Unit.

2. Find that the replacement equipment transaction described in Part II above is exempt from CON review under N.C. Gen. Stat. § 131E-184(a)(7).

We thank you for your consideration of this notice.

Sincerely,

Gary S. Qualls

Gary S. Qualls

Exhibits

1A. Macro view of University Campus Cardiac Cath Unit

1B. Micro view of University Campus Cardiac Cath Unit

2A. Macro view of CMC Room 8, which will now house CMHA's New Cardiac Cath Unit.

2B. Micro view of CMC Room 8, which will now house CMHA's New Cardiac Cath Unit.

2C. Enlarged micro view of CMC Room 8, which will now house CMHA's New Cardiac Cath Unit.

3. August 5, 2015 Material Compliance Letter approving Novant Health to relocate and replace a Cardiac Cath Unit from Novant Health Presbyterian Medical Center to Novant Health Matthews Medical Center.

4. July 16, 2015 Request by Novant Health to relocate and replace a Cardiac Cath Unit from Novant Health Presbyterian Medical Center to Novant Health Matthews Medical Center.

5A. Macro views of CMC Room 1, which will now house CMHA's Replacement EP Unit.

5B. Micro views of CMC Room 1, which will now house CMHA's Replacement EP Unit.

6. Proposed Total Capital Cost Sheet for CMC Room 1

7A. EP Replacement Equipment Quote

7B. EP Replacement Equipment Brochure

7C. EP Replacement Equipment Brochure

8. Other Equipment Quotes for Items to be placed in CMC Room 1

   8A. Omnicell Items

   8B. Accriva Item

   8C. Surgical Light

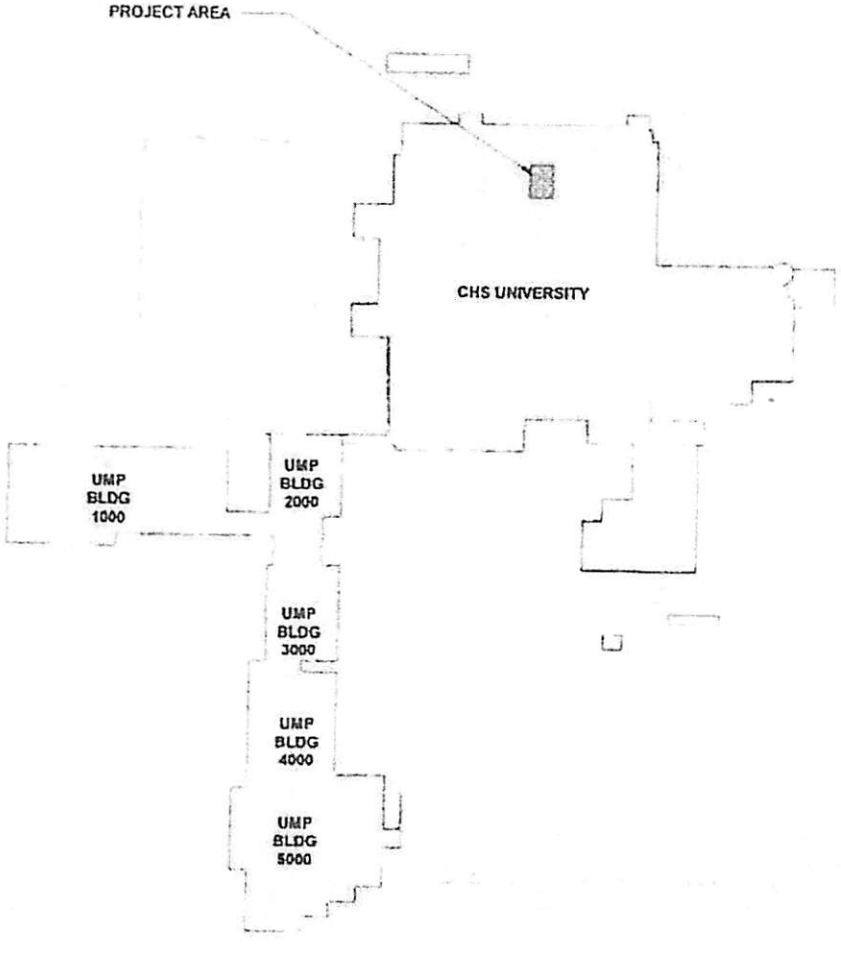
   8D. Stryker Items

9. Equipment Comparison Chart

COLOR KEY

EXISTING BUILDING

RENOVATION



CHS UNIVERSITY

SITE PLAN

Carolinas HealthCare System

08/18/2017

Cardiac Cath Lab

EXHIBIT

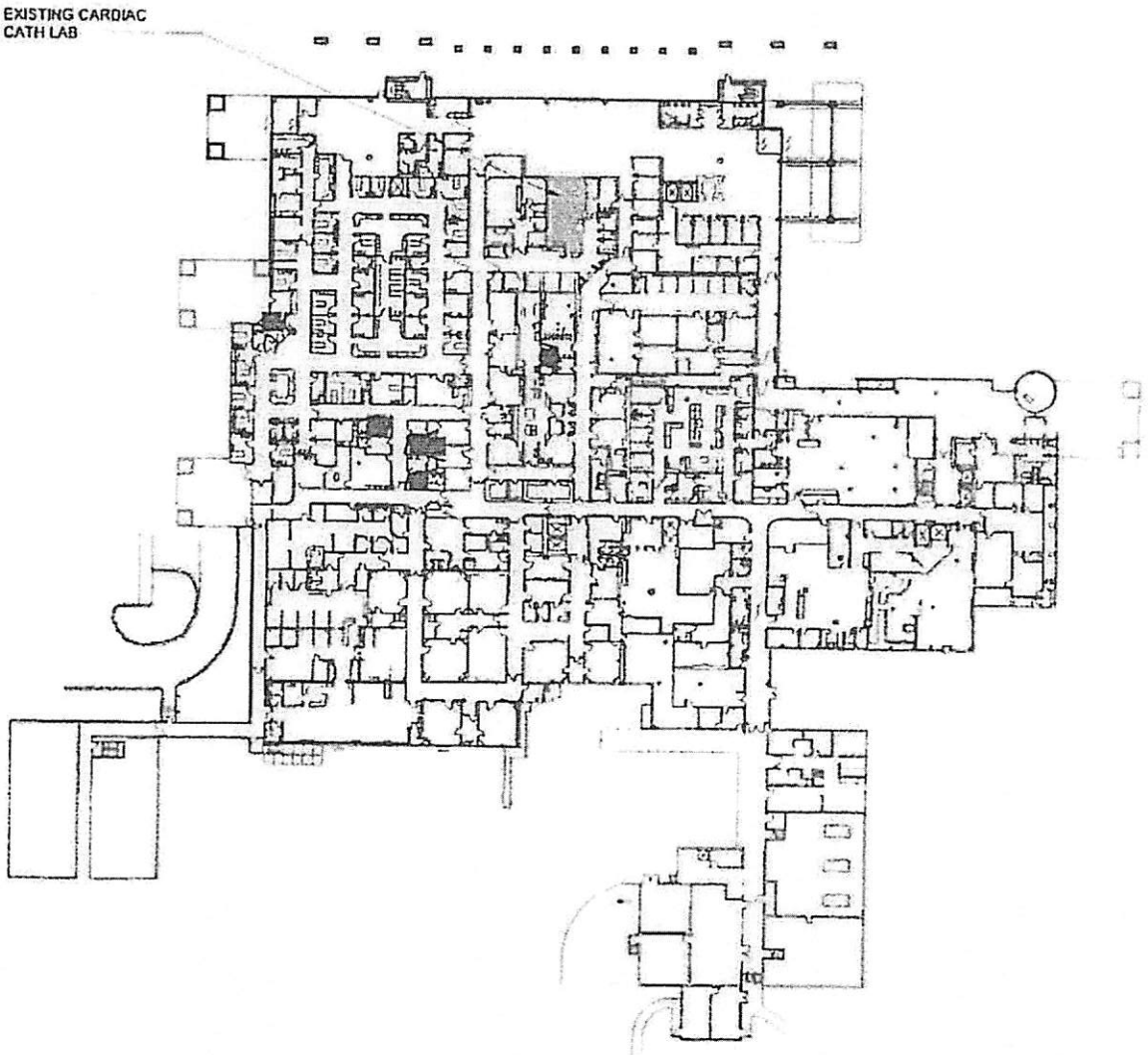
tabbies

1A

COLOR KEY

EXISTING BUILDING

RENOVATION



CHS UNIVERSITY

EXISTING PLAN - LEVEL 01

Carolinas HealthCare System

08/18/2017

Cardiac Cath Lab

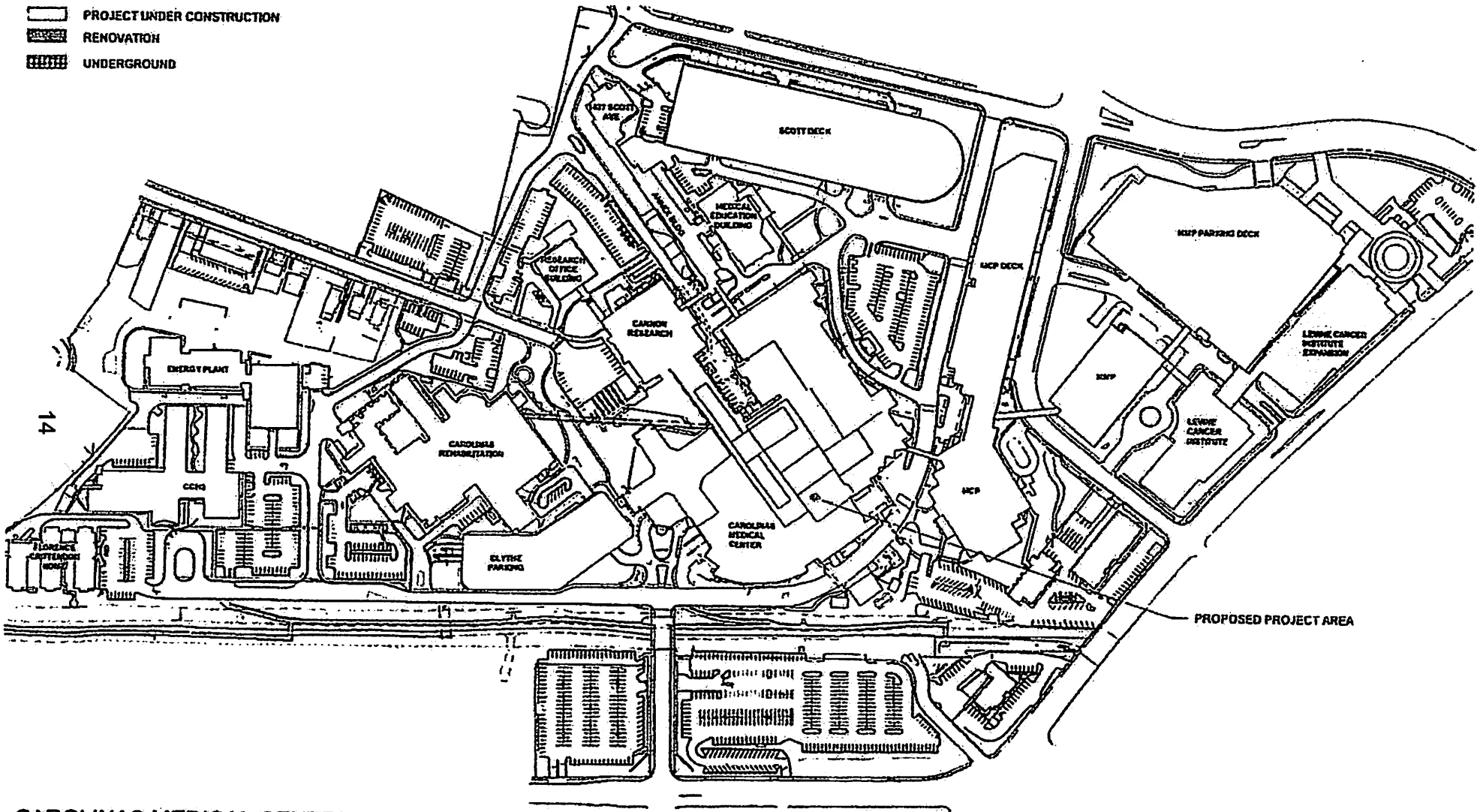
EXHIBIT

tabbies

1B

COLOR KEY.

- EXISTING BUILDING
- PROJECT UNDER CONSTRUCTION
- RENOVATION
- UNDERGROUND



14

CAROLINAS MEDICAL CENTER

SITE PLAN

Carolinas HealthCare System

08/18/2017

Cardiac Cath Lab

EXHIBIT

2A

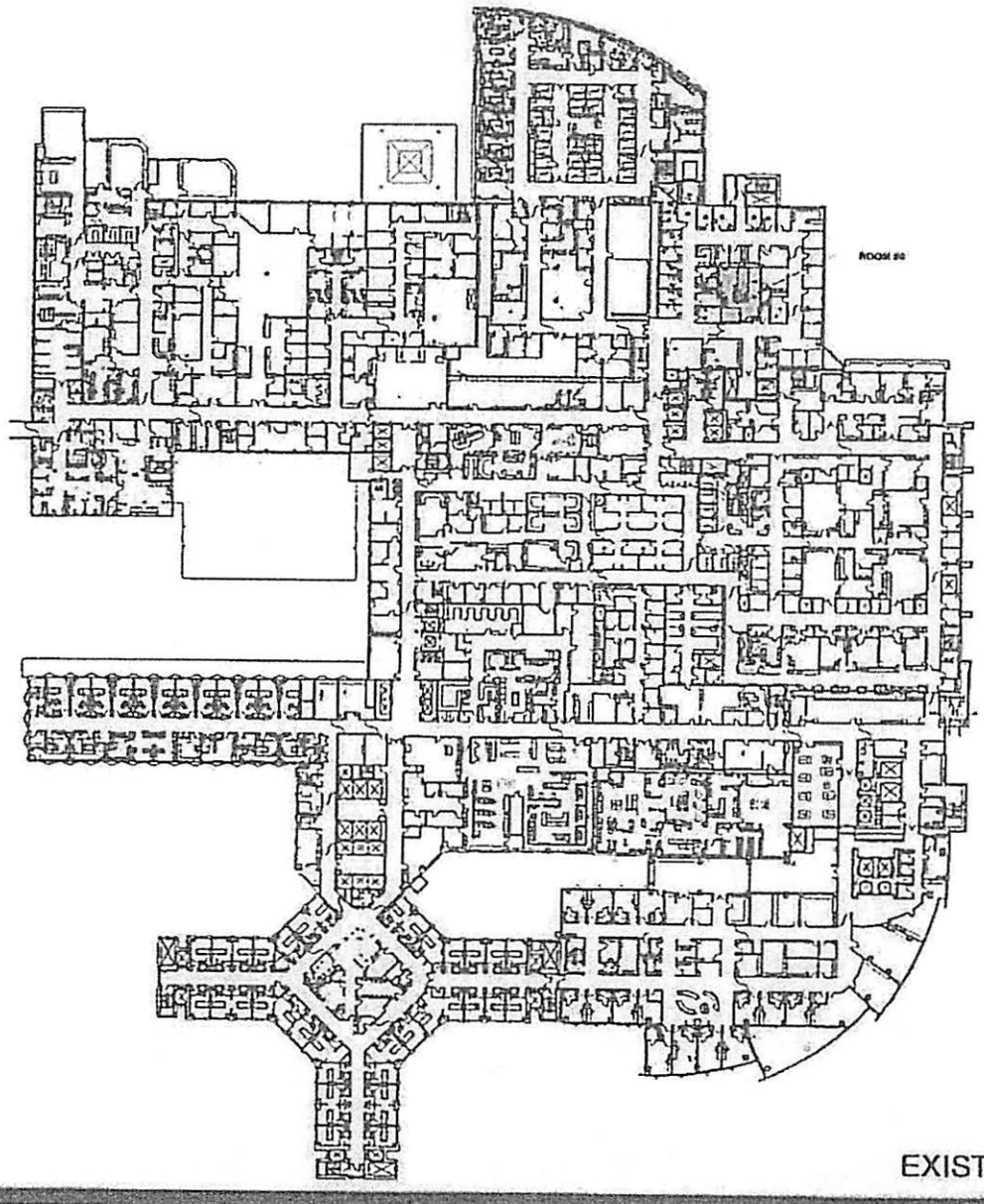
COLOR KEY

EXISTING BUILDING

RENOVATION

Current

Room #	Specialty	Licensed
2	Treatment Room	No
2	EP/PV/Cath	Yes
3	Cath	Yes
4	Cath	Yes
5	Cath	Yes
6	PV	No
7	EP	Yes
8	EP/SH	No



CAROLINAS MEDICAL CENTER

EXISTING PLAN- LEVEL 04

Carolinas HealthCare System

08/18/2017

Cardiac Cath Lab

EXHIBIT

2B

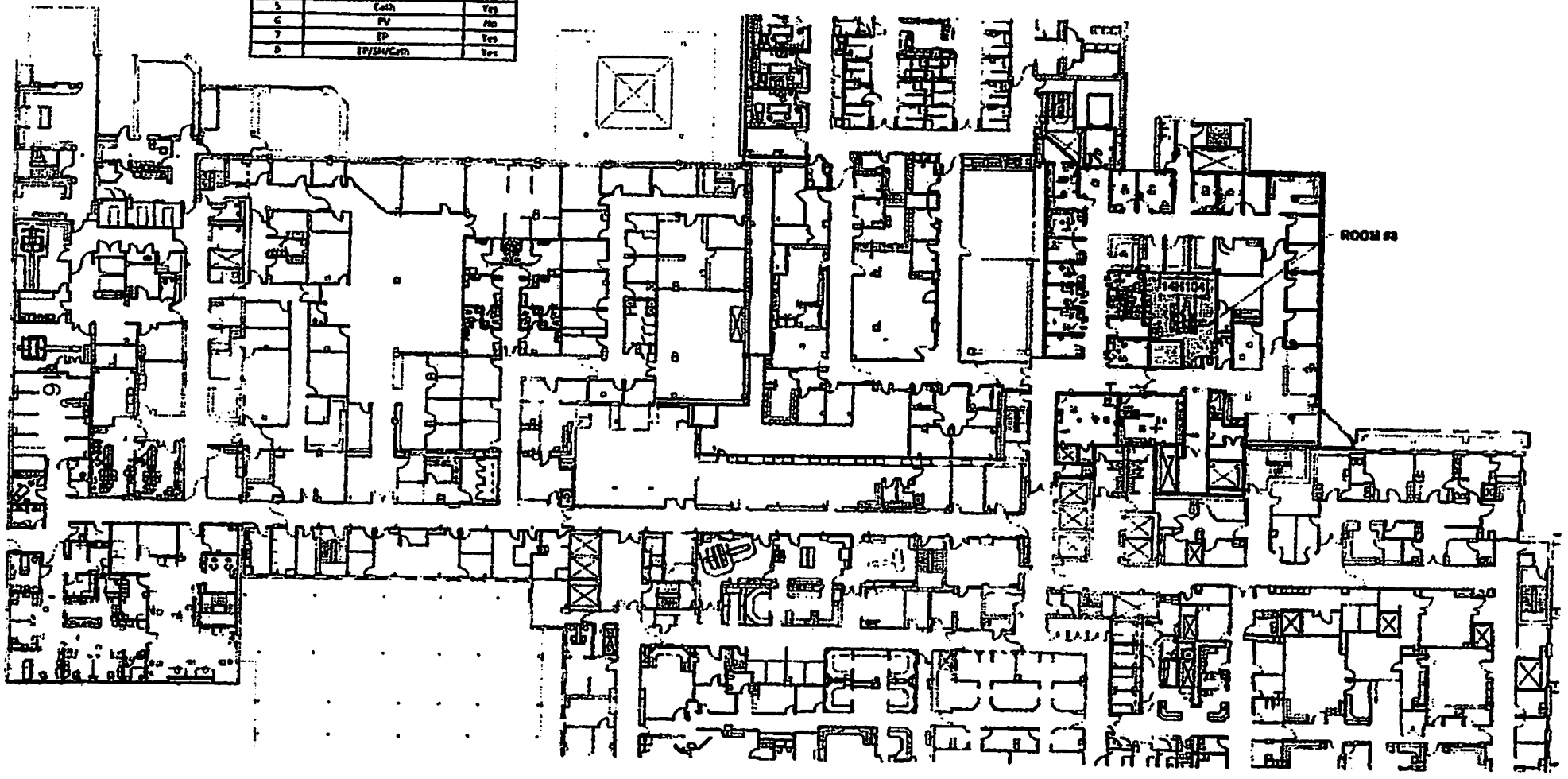
COLOR KEY

EXISTING BUILDING

RENOVATION

FUTURE

Room #	Specialty	Ultrasound
1	EP	No
2	PV/Cath	Yes
3	Cath	Yes
4	Cath	Yes
5	Cath	Yes
6	PV	No
7	EP	Yes
8	EP/SH/Cath	Yes



CAROLINAS MEDICAL CENTER

ENLARGED PROPOSED PLAN - LEVEL 04

Carolinas HealthCare System

03/18/2017

Cardiac Cath Lab

EXHIBIT

2C

EXHIBIT 3

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

August 5, 2015

Barbara L. Freedy
Certificate of Need
Novant Health, Inc.
2085 Frontis Plaza Drive
Winston-Salem, North Carolina 27103

Material Compliance Approval

Project ID #:	F-001810-83
Facility:	Novant Health Presbyterian Medical Center (NHPMC)
Project Description:	Locate replacement cardiac catheterization equipment at Novant Health Matthews Medical Center (NHMMC)
County:	Mecklenburg
FID #:	943501

Dear Ms. Freedy:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) has determined that the change proposed in your letter of July 9, 2015 is in material compliance with representations made in the application. This change includes relocating a cardiac catheterization lab from NHPMC's cardiac catheterization lab #1 to NHMMC. Both facilities are in the Mecklenburg County service area. However, you should contact the Agency's Construction Section to determine if they have any requirements pertinent to the proposed change.

It should be noted that the Agency's position is based solely on the facts represented by you, including supplemental information provided to the Agency in an additional letter, dated July 9, 2015, regarding NHMMC's ability to safely perform interventional cardiac catheterization procedures, 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. Please refer to the Project ID # and Facility ID # (FID) in all correspondence.

Sincerely,

Gloria C. Hale

Gloria C. Hale
Project Analyst

Martha J. Frisone

Martha J. Frisone,
Assistant Chief, Certificate of Need

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

EXHIBIT
4

Nelson Mullins

Nelson Mullins Riley & Scarborough LLP
Attorneys and Counselors at Law
380 Knollwood Street / Suite 530 / Winston-Salem, NC 27103
Tel: 336.774.3300 Fax: 336.774.3372
www.nelsonmullins.com

Denise M. Gunter
Tel: 336.774.3322
Fax: 336.774.3372
denise.gunter@nelsonmullins.com

July 16, 2015

RECEIVED
JUL 16 2015
By S. Even

Hand Delivered

Martha J. Frisone, Assistant Chief
North Carolina Department of Health and Human Services
Division of Health Service Regulation
Certificate of Need and Health Planning Section
809 Ruggles Drive
Raleigh, North Carolina 27603

Re: No Review Request for Novant Health, Inc., The Presbyterian Hospital d/b/a Novant Health Presbyterian Medical Center and Presbyterian Medical Care Corp. d/b/a Novant Health Matthews Medical Center
Mecklenburg County
Health Service Area III

Dear Ms. Frisone:

On behalf Novant Health, Inc. ("Novant"), The Presbyterian Hospital d/b/a Novant Health Presbyterian Medical Center ("NHPMC") and Presbyterian Medical Care Corp. d/b/a Novant Health Matthews Medical Center ("NHMMC"), I am writing to request written confirmation that the CON Law does not apply to the following transaction (the "Transaction").

Factual Background

Novant is a nonprofit health care system that owns fourteen hospitals. Two of these hospitals are NHPMC and NHMMC. NHPMC and NHMMC are acute care hospitals located in Mecklenburg County, North Carolina. NHPMC and NHMMC are wholly-owned subsidiaries of Novant Health Southern Piedmont Region, LLC, a member-managed limited liability company whose sole member is Novant. *See* Exhibit A. Novant is therefore the ultimate parent entity of both NHPMC and NHMMC. NHPMC and NHMMC are affiliates within the Novant corporate family. *See* Exhibit B, 2014 audited financials for Novant, p. 6, note 1.

Ex were disposed of

NHPMC owns four units of fixed cardiac catheterization equipment. NHMMC presently provides both diagnostic and interventional cardiac catheterization services using equipment owned by a third party. *See* Tables 9S, 9V and 9W of the 2015 SMFP, attached hereto as Exhibit C.

The Transaction

The contract with the third party ends in December 2015. Rather than continue to incur the cost of the contract, NHPMC proposes to move one of its four existing and operational cardiac catheterization units ("Cath Lab #1") to NHMMC. In separate correspondence to the CON Section, NHPMC and NHMMC request that the CON Section determine that the replacement of Cath Lab #1 qualifies for the replacement equipment exemption under N.C. Gen. Stat. § 131E-184(a)(7)(the "Replacement Cath Lab"). NHMMC has also submitted separate correspondence to the CON Section demonstrating that NHMMC can safely perform interventional cardiac catheterization procedures without open heart surgery services on site.[1] If the Transaction is approved, the Replacement Cath Lab would then be reported on NHMMC's annual Hospital License Renewal Application.

Analysis

The CON Law applies to "new institutional health services." N.C. Gen. Stat. § 131E-178(a). N.C. Gen. Stat. § 131-176(16)f1. defines "new institutional health service" to include "the acquisition by purchase, donation, lease, transfer, or comparable arrangement" of certain types of medical equipment, including cardiac catheterization equipment. *See* N.C. Gen. Stat. § 131E-176(16)f1.3. For the reasons set forth below, this provision of the CON Law should not apply to the Transaction.

The Transaction involves a move between and among entities that are entirely within the Novant corporate family. Novant ultimately controls both NHPMC and NHMMC. No one outside of Novant is acquiring anything in this Transaction. Ultimately, all assets at NHPMC (including Cath Lab #1) and NHMMC are owned by Novant. As has been demonstrated through dozens of CONs applications filed throughout the years, the financials for these hospitals and all other Novant-controlled facilities are consolidated, and only one set of audited financials is produced for the entire Novant family, including NHPMC and NHMMC. *See, e.g.*, Exhibit B, which are Novant's 2014 audited financials. As stated on page 6, note 2 of the 2014 audited financials: "[t]he consolidated financial statements include the accounts of all affiliates controlled by Novant Health." These affiliates include NHPMC and NHMMC. *See id.*, note 1. Further, when Novant issues bonds through the North Carolina Medical Care Commission, the proceeds are used to pay for projects at various

[1] These additional letters are incorporated by reference in this letter.

Novant-owned facilities, including NHPMC and NHMMC. Regarding bonds issued in 2013, page 32 of the 2014 audited financials reports:

> [t]he remaining proceeds [of the 2013 issue] were used to finance and reimburse Novant Health for expenditures primarily related to the construction of the following. . . . the vertical expansion of Novant Health Matthews Medical Center; . . . and the G-wing renovation at Novant Health Presbyterian Medical Center.

Exhibit B, p. 32

There will be no increase in the inventory of cardiac catheterization equipment in Mecklenburg County beyond those units which have already been approved. No new health service facilities or services are being added beyond those already approved. Rather, the Transaction should be regarded merely as a reorganization similar to those which the CON Section and the Department have previously determined are not subject to CON review.

For example, in 2011, CSA Medical Services, LLC ("CSA") proposed to transfer its interest in eight existing heart lung bypass machines to two wholly-owned subsidiary limited liability companies, CSAMS New Bern Avenue, LLC and CSAMS Lake Boone Trail, LLC. *See* Exhibit D. Five of the machines were located at WakeMed, and three of the machines were located at Rex.

In its no review request, CSA pointed out that 10A NCAC 14C.0502(b) allows for the transfer of *undeveloped* CONs in cases of corporate reorganizations. *See* Exhibit D, page 4. CSA further stated that ". . . [i]f the CON law permits the transfer of a CON for an undeveloped project to a subsidiary of the applicant without a new CON or other sanction, then it would make no sense to interpret the law to prevent an existing provider from transferring a service to a wholly-owned subsidiary after the project has been developed." *Id.* CSA also relied upon N.C. Gen. Stat. § 131E-189(c):

> [m]oreover, N.C. Gen. Stat. § 131E-189(c) acknowledges that completed projects may be transferred without CON review. It states that '[a]ny transfer after [the project is completed or becomes operational] will be subject to the requirement that the service be provided consistent with the representations made in the application and any applicable conditions.' That statute does not require that a CON first be acquired before such a transfer takes place. Clearly, the reorganization of CSA's assets and CON exemption into two wholly owned subsidiaries would not constitute the 'offering or development of a new institutional

> health service' within the definition of N.C. Gen. Stat. § 131E-178(a).

Id., p. 4. The CON Section determined that the CON Law did not govern CSA's proposal. *See* Exhibit E.[2]

The CSA decision applies here. Cath Lab #1 is an existing and operational cath lab. While NHMMC is not a subsidiary of NHPMC, these two hospitals are corporate affiliates within the Novant corporate family, and are subsidiaries of the same entity (Novant Health Southern Piedmont Region) which is in turn wholly owed by Novant. Ultimately, Novant owns and controls Cath Lab #1, and that will not change as a result of this Transaction. It would not serve the purposes of the CON Law to require regulatory review of an existing cath lab that is being moved from one corporate affiliate to another in Mecklenburg County. Further, both diagnostic and interventional cardiac catheterization services have been provided for years at NHMMC; thus, the need for the service has already been established. It would not make sense for NHMMC to have to reprove the need for a service it already offers.

The CSA no review also included the 2011 Radiation Oncology Centers of the Carolinas, Inc. ("ROCC") declaratory ruling (included in Exhibit D), which permitted ROCC to transfer its interests in two radiation oncology facilities owning linear accelerators to two wholly-owned subsidiaries of ROCC. In a more recent, analogous declaratory ruling, the Department permitted Caldwell Memorial Hospital, a subsidiary of UNC Health Care, to "redesignate" its cancer center space, including a linear accelerator, to unlicensed space of its sister hospital, UNC Hospitals. *See* Exhibit G, a March 12, 2015 declaratory ruling issued to UNC Healthcare System, UNC Hospitals and Caldwell Memorial. In the UNC/Caldwell declaratory ruling, the Department stated:

> Nor does the Redesignation of the Cancer Center Space trigger any of the 'acquisition-related' new institutional health service definitions in N.C. Gen. Stat. § 131E-176(16). The Cancer Center Space, the Radiation Oncology Equipment, and the Medical Oncology Equipment are not being acquired, because no legal entity outside of the UNC Health Care controlled affiliates is acquiring anything. Rather, this Redesignation is purely an intra-organizational Redesignation within UNC Health Care controlled affiliates. See 10A NCAC 14C.0502.

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[2] Subsequently, Rex was permitted to acquire the membership interests in CSAMS Lake Boone Trail, and WakeMed was permitted to acquire the membership interests in CSAMS New Bern Avenue. *See* Exhibit F. No third party outside the Novant corporate family is involved in the Transaction.

***

> This Redesignation does not involve the offering or expansion of any new facility, service or equipment, and the inventory of linear accelerators and CT scanners in Caldwell County and the State overall will not change. No new radiation oncology equipment or services will be placed in operation in Caldwell County or the State as a result of this Project.

Exhibit G, p. 7.

The UNC/Caldwell ruling applies here. No legal entity outside of Novant will be acquiring anything in the Transaction. The Transaction is purely intra-organizational. The Transaction does not involve the offering or expansion of any new facility, service or equipment, and neither the inventory of cardiac catheterization labs in Mecklenburg County nor the State overall will change as a result of the Transaction. No new cardiac catheterization equipment or services will be placed in operation in Mecklenburg County or the State as a result of this Transaction.[3]

As the UNC/Caldwell ruling aptly recognized,

> [i]t is a well-established principle of statutory construction that the intent of the Legislature controls the interpretation of the statute. *See State v. Fulcher*, 294 N.C. 503, 520, 2432 S.E.2d 338, 350 (1978). Prohibiting this simple intra-organizational Redesignation of existing services would not advance the goal of avoiding costly duplication because the Radiation Oncology Equipment and the Cancer Center Space already exist and are used to provide the same services they will provide after the Redesignation. Construing the statute otherwise would lead to absurd results that the General Assembly could not have intended. *King v. Baldwin*, 276 N.C. 316, 325, 172 S.E.2d 12, 18 (1970)('It is presumed that the legislature acted in accordance with reason and common sense and that it did not intend an unjust or absurd result.').

Exhibit G, p. 7.

[3] As discussed in separate correspondence filed with the CON Section, NHMMC intends to replace the nineteen-year old Cath Lab #1 with the Replacement Cath Lab. The proposed replacement, which is exempt under N.C. Gen. Stat. § 131E-184(a)(7), does not increase the inventory of cath labs in Mecklenburg County or the State overall.

The same is true here. The Transaction is not the sort of acquisition the CON Law seeks to regulate. Cath Lab #1 is existing equipment owned by a common parent. It will be used to provide the same services at NHMMC that it provides at NHPMC. Under these circumstances, the Transaction should not be deemed subject to CON review under N.C. Gen. Stat. § 131E-176(16)f1.3. *See also Cape Fear Memorial Hospital v. N.C. Dep't of Human Resources*, 121 N.C. App. 492, 494, 466 S.E.2d 299, 301 (1996) (holding that the legislature clearly did not intend to impose unreasonable limitations on maintaining, or expanding, presently offered health services).

Similarly, the Transaction does not implicate N.C. Gen. Stat. § 131E-176(16)b., requiring CON review for a capital expenditure greater than $2 million "to develop or expand a health service or a health service facility, or which relates to the provision of a health service." As discussed in the companion Replacement Equipment Exemption Request, the total cost to replace Cath Lab #1, including disposal of Cath Lab #1, is $922,524.

Finally, the relocation of Cath Lab #1 from Charlotte to Matthews is not reviewable under the CON Law. Both hospitals are in Mecklenburg County. They are approximately 11 miles and 16 minutes apart from each other. *See* Exhibit H, a Mapquest map. The Department has previously approved relocations of equipment within Mecklenburg County that involved similar or greater distances. *See, e.g.*, Exhibit I (November 13, 2006 ruling allowing Presbyterian to transfer an MRI scanner from Charlotte to Huntersville, a distance of approximately 15.44 miles); Exhibit J (March 3, 2008 ruling allowing Carolinas Imaging Services, LLC to relocate an MRI scanner from Huntersville to the Ballantyne area of Charlotte, a distance of approximately 31 miles); and Exhibit K (February 7, 2014 ruling allowing Presbyterian to change the location of an undeveloped linear accelerator from Matthews to Huntersville, a distance of approximately 25 miles).

Accordingly, Novant, NHPMC and NHMMC respectfully request that the CON Section determine that the Transaction described in this letter does not require CON review.

Thank you for your time and consideration.

Sincerely,

Denise M. Gunter

Enclosures

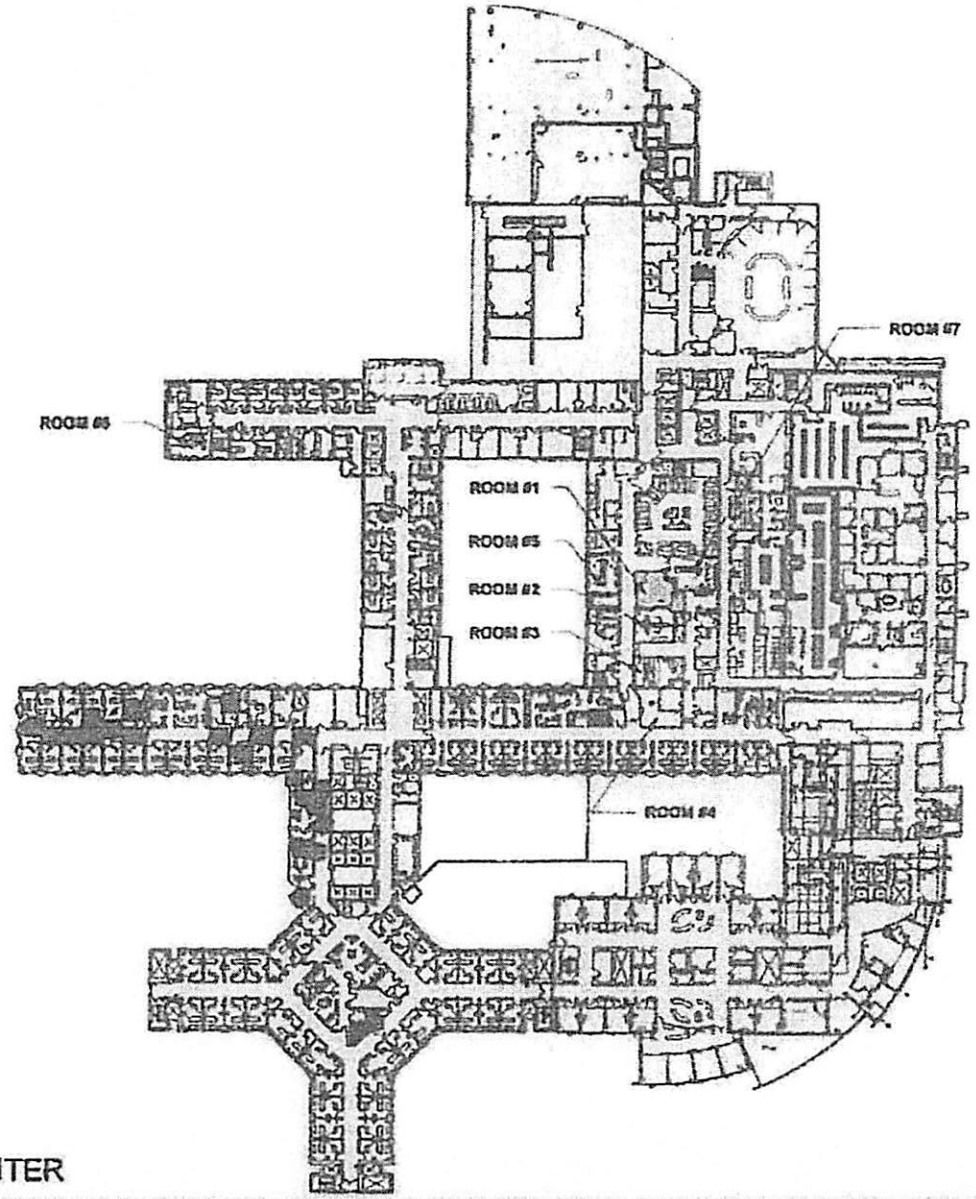
COLOR KEY

EXISTING BUILDING

RENOVATION

Current

Room #	Specialty	Upgraded
1	Treatment Room	No
2	EP/PV/Cath	Yes
3	Cath	Yes
4	Cath	Yes
5	Cath	Yes
6	PV	No
7	EP	Yes
8	EP/SH	No



CAROLINAS MEDICAL CENTER

EXISTING PLAN- LEVEL 06

Carolinas HealthCare System

08/18/2017

EXHIBIT

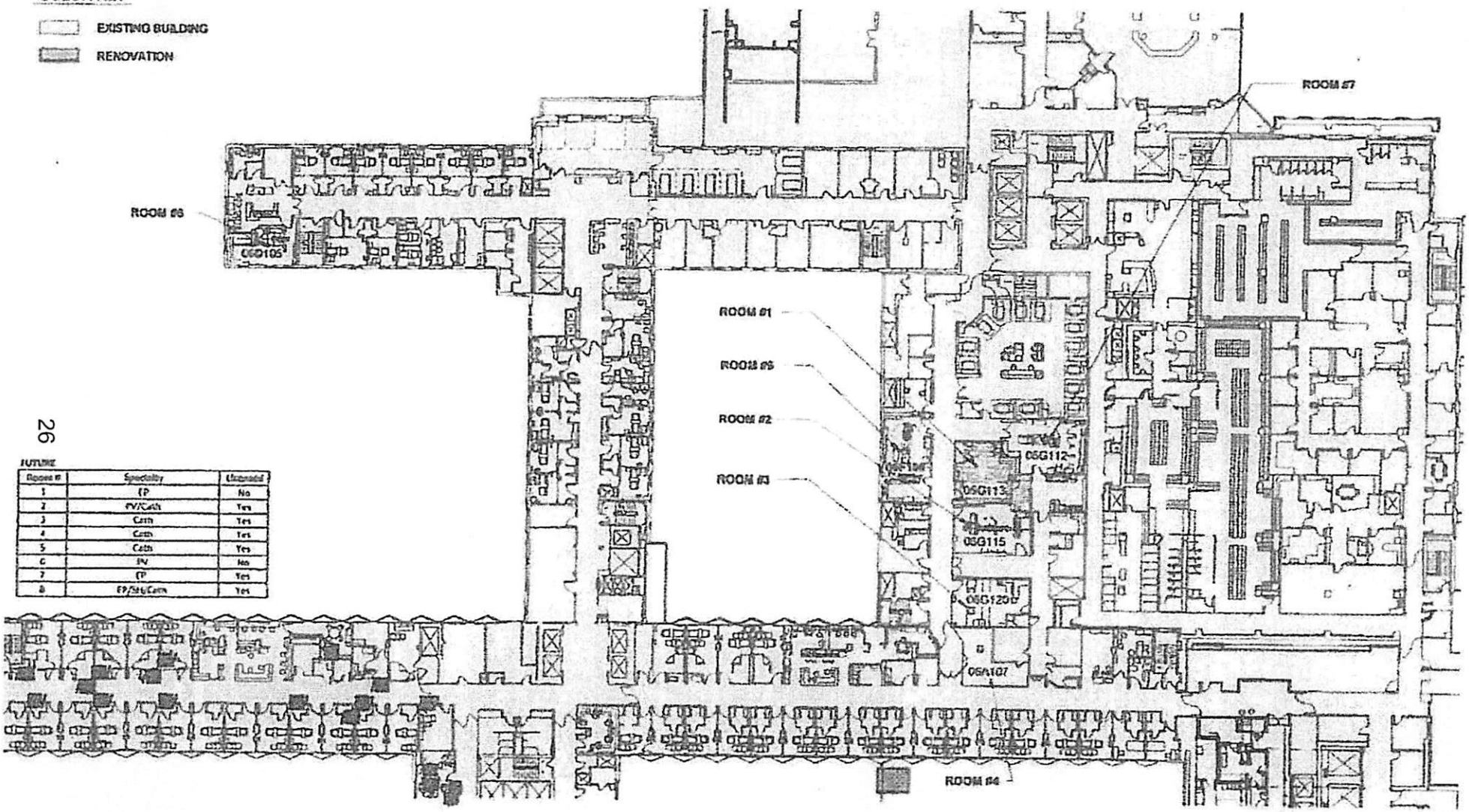
tabbies

5A

COLOR KEY

EXISTING BUILDING

RENOVATION



26

FUTURE

Room #	Specialty	Utilized
1	EP	No
2	PV/Cath	Yes
3	Cath	Yes
4	Cath	Yes
5	Cath	Yes
6	PV	No
7	EP	Yes
8	EP/Sth/Cath	Yes

CAROLINAS MEDICAL CENTER

ENLARGED PROPOSED PLAN- LEVEL 06

Carolinas HealthCare System

08/16/2017

EXHIBIT

tabbies

5B

EXHIBIT 6

PROPOSED TOTAL CAPITAL COST OF PROJECT

Project name: Cardiac Cath Lab

Provider/Company: Carolinas Healthcare System

(1)	Purchase price of land	NA
(2)	Closing costs	NA
(3)	Site Preparation	NA
(4)	Construction/Renovation Contract	$522,917.00
(5)	Landscaping	NA
(6)	Architect/Engineering Fees	$48,500.00
(7)	Medical Equipment	$1,235,707.84
(8)	Non Medical Equipment	NA
(9)	Furniture	$5,760.00
(10)	Consultant Fees (CON Fees, Legal Fees, Design Fees)	NA
(11)	Financing Costs	NA
(12)	Interest During Construction	NA
(13)	Other (IS, Security, Internal Allocation)	$149,231.75
(14)	**Total Capital Cost**	$1,962,116.59

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

9/04/17

(Signature of Licensed Architect or Engineer) *DATE*

Sales taxes have been included in these equipment costs. However, because CHS is entitled to a sales tax refund under N.C. Gen. Stat. § 105-164.14(b) and 105-467, the sales tax that CHS initially incurs for this medical equipment purchase will be refunded to CHS, and thus will reduce the capital costs that CHS actually incurs for the equipment by $83,129.93.

PHILIPS HEALTHCARE
A division of Philips North America LLC
22100 Bothell Everett Highway
P.O. Box 3003
Bothell, Washington 98041-3003

PHILIPS

Quotation #: 1-103XHZ1	Rev: 16	Effective From: 25-Jul-17	To: 15-Sep-17

Presented To:
CAROLINA MEDICAL CENTER
1000 BLYTHE BLVD
CHARLOTTE, NC 28203-5871

Tel:

Alternate Address:

Presented By:
Brett Kimball
Account Manager
Tel:
Fax:

John Hill
Regional Manager
Tel: (800) 722-7900 x6806
Fax:

Date Printed: 18-Aug-17

Submit Orders To:
22100 BOTHELL EVERETT HWY
BOTHELL WA 98021

Tel: (888) 564-8643 Fax:(425) 458-0390

IMPORTANT NOTICE: Health care providers are reminded that if the transactions herein include or involve a loan or discount (including a rebate or other price reduction), they must fully and accurately report such loan or discount on cost reports or other applicable reports or claims for payment submitted under any federal or state health care program, including but not limited to Medicare and Medicaid, such as may be required by state or federal law, including but not limited to 42 CFR 1001.952(h).

EXHIBIT
tabbies 7A

Quote Solution Summary

Line #	Product	Qty	Price
	100241 Allura Xper FD10	1	$862,279.98
		Equipment Total:	$862,279.98

Solution Summary Detail

Product	Qty	Each	Monthly	Price
100241 Allura Xper FD10	1	$862,279.98		$862,279.98

Buying Group: CAROLINAS HEALTHCARE SYSTEM SCA **Contract #:** CAA0013200

Addt'l Terms:

Each Quotation solution will reference a specific Buying Group/Contract Number representing an agreement containing discounts, fees and any specific terms and conditions which will apply to that single quoted solution. If no Buying Group/Contract Number is shown, Philips' Terms and Conditions of Sale will apply to the quoted solution.

Each equipment system listed on purchase order/orders represents a separate and distinct financial transaction. We understand and agree that each transaction is to be individually billed and paid.

Payment Terms: 0% Down, 80% Upon Delivery, 20% Due When the Product is Available for First Patient Use, Net due 30 days from date of invoice