



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

April 22, 2024

Elizabeth Kirkman  
Elizabeth.Kirkman@atriumhealth.org

**Exempt from Review – Replacement Equipment**

**Record #:** 4428  
**Date of Request:** April 10, 2024  
**Facility Name:** Carolinas Medical Center  
**FID #:** 943070  
**Business Name:** The Charlotte-Mecklenburg Hospital Authority  
**Business #:** 1770  
**Project Description:** Replace four heart-lung bypass machines  
**County:** Mecklenburg

Dear Ms. Kirkman:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that the above referenced project is exempt from certificate of need review in accordance with G.S. 131E-184(a)(7). Therefore, you may proceed to acquire without certificates of need four heart-lung bypass machines. Please see Attachment A. This determination is based on your representations that the existing units will be sold or otherwise disposed of and will not be used again in the State without first obtaining a certificate of need if one is required.

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  
Team Leader

Micheala Mitchell  
Chief

cc: Acute and Home Care Licensure and Certification Section, DHSR

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603  
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AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

ATTACHMENT A

<b>Carolinas Medical Center</b>	
<b>Existing Heart-Lung Bypass Machines</b>	<b>Replacement Heart-Lung Bypass Machines</b>
LivaNova S5 Heart Lung Perfusion System, serial # 48E01761	LivaNova S5 Heart Lung Perfusion System
LivaNova S5 Heart Lung Perfusion System, serial # 48E01769	LivaNova S5 Heart Lung Perfusion System
LivaNova S5 Heart Lung Perfusion System, serial # 48E02854	LivaNova S5 Heart Lung Perfusion System
LivaNova S5 Heart Lung Perfusion System, serial # 48E02856	LivaNova S5 Heart Lung Perfusion System

April 10, 2024

Ms. Micheala Mitchell, Chief  
Healthcare Planning and Certificate of Need Section  
Division of Health Service Regulation  
N.C. Department of Health & Human Services  
809 Ruggles Drive  
Raleigh, NC 27603

RE: Exemption Request for The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center to Replace Four Existing Heart-Lung Bypass Machines

Dear Ms. Mitchell:

The Charlotte-Mecklenburg Hospital Authority (“CMHA”) d/b/a Carolinas Medical Center (“CMC”) seeks to acquire four LivaNova S5 Heart Lung Perfusion Systems (“Replacement Heart-Lung Bypass Machines”) to replace four existing LivaNova S5 Heart Lung Perfusion Systems (“Existing Heart-Lung Bypass Machines”). Two of the Existing Heart-Lung Bypass Machines were acquired in 2011 and two were acquired in 2013. All four of the Existing Heart-Lung Bypass Machines are at the end of their useful life. The four Existing Heart-Lung Bypass Machines are currently housed in the surgical suite on the main campus of CMC at 1000 Blythe Boulevard, Charlotte, NC 28203.

The purpose of this letter is to provide the Agency with notice and to request a determination that CMC’s purchase of the Replacement Equipment is exempt from Certificate of Need (“CON”) review under the replacement equipment exemption provisions contained in NCGS § 131E-184(a)(7).

The General Assembly has chosen to exempt certain, otherwise reviewable events from CON review. Among those exemptions is the acquisition of “replacement equipment,” defined in NCGS § 131E-176(22a) as follows in the CON law:

“Replacement equipment” means equipment that costs less than three million dollars (\$3,000,000) 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. In determining whether the replacement equipment costs less than three million dollars (\$3,000,000), the costs of equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the replacement equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater. Beginning September 30, 2023, and on September 30 each year thereafter, the cost threshold amount in this subdivision shall be adjusted using the Medical Care Index component of the Consumer Price Index published by the U.S. Department of Labor for the 12-month period preceding the previous September 1.<sup>1</sup>

CMC’s proposal qualifies for this exemption.

**A. Cost of the Replacement Equipment**

The projected total capital cost of each Replacement Heart-Lung Bypass Machine is \$191,676 which is based on the purchase price of the Replacement Heart-Lung Bypass Machine (including freight) \$178,821 + \$12,855 tax. There are no renovation costs or other costs

<sup>1</sup>The current monetary threshold for replacement equipment is \$2,971,200.

associated with replacing each of the four Existing Heart-Lung Bypass Machines. The quote for the Replacement Heart-Lung Bypass Machines is provided in Attachment A.

## **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.

CMC intends to use the four Replacement Heart-Lung Bypass Machines for substantially the same cardiovascular surgical procedures for which it currently uses the four Existing Heart-Lung Bypass Machines. The four Existing Heart-Lung Bypass Machines are all LivaNova S5 Heart Lung Perfusion Systems that have been in use since they were acquired.

The four Replacement Heart-Lung Bypass Machines can and will perform all procedures currently performed on the four Existing Heart-Lung Bypass Machines, although they possess some expanded capabilities due to technological improvements (see Attachment B for the Equipment Brochure). The Replacement Heart-Lung Bypass Machines are therefore “comparable medical equipment” as defined in Subsection (c).

For further equipment comparison, please refer to Attachment C, which contains the Equipment Comparison Charts.

The heart-lung bypass machines in operation at CMC, including the four Existing Heart-Lung Bypass Machines, were used in over 900 procedures in 2023.

## **C. Disposition of Equipment**

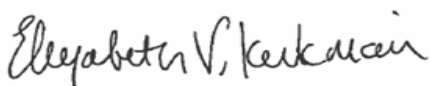
The four Existing Heart-Lung Bypass Machines will be taken out of service and will not be re-sold or re-installed in North Carolina without appropriate Certificate of Need approval.

### **CONCLUSION:**

Based on the foregoing information, CMC hereby requests that the Agency provide a written response confirming that the acquisition of the four Replacement Heart-Lung Bypass Machines described herein is exempt from CON review. If the Agency needs additional information to assist in its consideration of this request, please let us know.

Thank you for your consideration of this notice.

Sincerely,



Elizabeth V. Kirkman  
Assistant Vice President  
Core Market Growth Business Development

# **Attachment A**



Health innovation that matters

**OUTRIGHT PURCHASE PROPOSAL**

**Date:** February 23, 2024

**Deal Number:** DL-50472

**Account Name:** Atrium Health (“Customer”)

**Account Number:** 16489

**Account Address:** 1000 Blythe Boulevard, Charlotte, NC 28203

Catalog No.	Description	Quantity Per System
48-40-00Z	SRD S5 CONSOLE FOR 4 PUMP	1
45-09-11	S5 CABLE HOLDING SYS 25MM MAST	1
45-95-14USA	S5 PRO SYS. IFU USA	1
45-09-10	SRD S5 CABLE HOLDING SYS	1
43-42-61	CAP FOR QUICK CLAMP	1
10-80-00Z	SRD S5 SINGLE ROLLER PUMP 150	3
10-81-30	S5 VARIOLOCK TUB CLAMP RP150	3
10-85-00Z	S5 DOUBLE ROLLER PUMP 85	1
10-86-55	S5 TUBING CLAMP 1/8 X 1/16	2
10-84-64	S5 DRIP TRAY DOUBLE PUMP	1
10-84-60	SRD S5 DRIP TRAY ROLLER PUMP	1
50-80-99	S5 COLOR CODE SET	1
28-95-00	SRD S5 4-SLOT SYSTEM PANEL	1
28-95-10Z	SRD S5 CONTROL DISPLAY MODULE	4
20-30-20Z	SRD S5 TEMP SENSOR MODULE	1
22-20-20Z	SRD S5 PRESSURE SENSOR MODULE	1
27-80-20Z	S5 CARDIOPLEGIA SENSOR MODULE	1
23-41-00	LEVEL-3 SET COMPLETE S5	1
23-45-10Z	S5 3/8" BUBBLE MODULE W/620MM	1
10-07-48	METAL INSERTS BLUE	1
48-41-10	SRD S5 CROSSTRAY FOR 4 PUMP	1
050350000	PAS SECHRIST 3500 CP-G	1
050350100	SECHRIST IV308 HOSE AIR 14 FT	1
050350200	SECHRIST IV309 HOSE OXY 14 FT	1
10-07-49	METAL INSERTS PLAIN	1
10-86-59	S5 TUBING CLAMP 3/16 X 1/16	1
10-86-55	S5 TUBING CLAMP 1/8 X 1/16	1
10-86-56	S5 TUBING CLAMP 1/4 X 1/16	1
0395-2049	SPD TRUWAVE XDUCER CABLE	2
23-41-51	100PC ADHESIVE PAD LV-3 SENSOR	1
45-90-75USA	OPS MANUAL, CP5	1
60-00-60Z	CP5 CENTRIFUGAL PUMP	1
45-90-75USA	OPS MANUAL, CP5	1
<b>Net Price Per System</b>		<b>\$177,305.58</b>
<b>Freight Charges Per System</b>		<b>\$1,515.00</b>
<b>Extended Amount for Each System with Freight</b>		<b>\$178,820.58</b>
<b>Extended Amount for FOUR (4) System with Freight</b>		<b>\$715,282.32</b>

This proposal constitutes an offer for the listed products at the prices stated herein, and is subject to LivaNova USA, Inc.’s standard terms and conditions of sale, located at [LivaNova Standard Terms and Conditions-May2023](#). Customer’s submission of a purchase order for the listed products constitutes acceptance of this proposal and the standard terms and conditions of sale

# **Attachment B**

## S5<sup>®</sup>

### The world-leading perfusion system



Cardiac surgery solutions





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## READY TO MEET ANY CHALLENGE

### THE CONCEPT

- High quality design.
- Functional and easy to use.
- Fully configurable modular concept.
- S5 can be configured according to the clinical need by adapting pump numbers and modules.



## CONSOLE

### S5 console

The console housing accommodates 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.

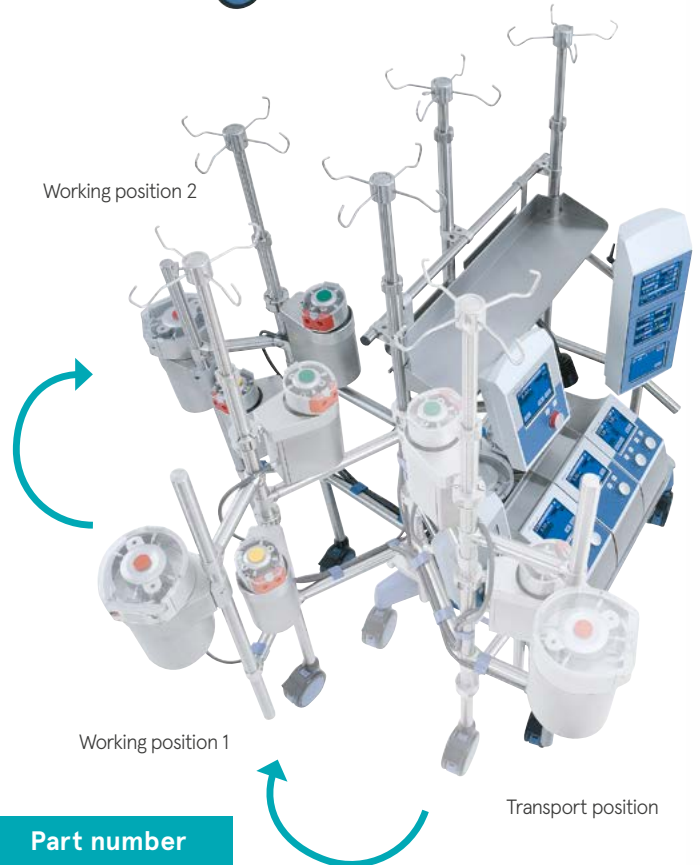


Product designation	Part number		
	3-position	4-position	5-position
<b>Consoles with E/P pack and standard mast system</b>			
S5 console	48-30-00Z	48-40-00Z	48-50-00Z
<b>Mast systems</b>	Size 3	Size 4	Size 5
Telescope mast with infusion rack	all sizes: 48-30-50		
Telescope mast, movable with infusion 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 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.



Product designation	Part number
<b>S5 mast system extension</b>	50-45-00
consisting of:	
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

Roller pumps can rotate in 15° increments; total rotation 180° for RP150 and 240° for DRP85.



### Product designation

### Part number

#### Mast roller pump system 85

50-80-70Z

consisting of:

1x mast roller pump 85  
(connection cable supplied)

10-88-60

Control panel for mast roller pump 150/85  
(connection cable supplied)

28-95-80Z



### Product designation

### Part number

#### Mast roller pump system 150

50-80-00Z

consisting of:

Mast roller pump 150  
(connection cable supplied)

10-88-00

Control panel for mast roller pump 150/85  
(connection cable supplied)

28-95-80Z



### Product designation

### Part number

#### Mast roller pump system 85

50-80-60Z

consisting of:

2x mast roller pumps 85  
(connection cable supplied)

10-88-60

Control panel for mast roller pump 85  
(connection cable supplied)

28-95-85Z



### Product designation

### Part number

#### Mast roller pump system with 2 MRP 85

50-80-62Z

consisting of:

2x mast roller pumps 85  
(connection cable supplied)

10-88-60

Control panel for 2 mast roller pumps 85  
(connection cable supplied)

28-95-85Z

Double holder (fixed)



S5°

## ROLLER PUMPS

### S5 roller pump

Roller pumps can rotate in 15° increments; total rotation 180° for RP150 and 240° for DRP85.

### 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.

Each pump can be operated in continuous or pulse mode.



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.

A 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.



#### Product designation

S5 roller pump 150 / S5 RP 150

#### Part number

10-80-00Z

S5 double roller pump 85 / S5 DRP 85

10-85-00Z

## CP5 CENTRIFUGAL PUMP

### CP5 centrifugal pump

The easy to use "all in one" centrifugal pump system, including centrifugal driver, panel control module, flowmeter, emergency driver and optional arterial clamp.

CP5 is designed with a maximum degree of programming flexibility and customization.

- CP5 can be flexibly positioned via the rotating arm articulations.
- CP5 can be easily mounted on the masts with the fast clamp.
- CP5 can be easily configured via the control panel.
- The geometry of the CP5 makes it easy to clean: smooth plain surfaces without sharp edges.

CP5 sophisticated flow control mode is like an extra set of hands during the case.

As pressure fluctuations occur with the patient and the circuit, it automatically maintains set flow for the perfusionist.

CP5 can be linked to level, bubble and pressure alarms that can completely occlude the arterial line via the ERC.

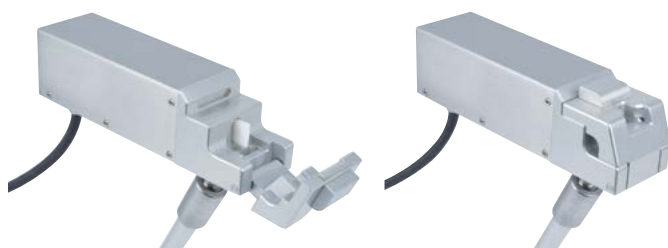


### Electrical Remote-Controlled Tubing Clamp (ERC)

The Electrical Remote-Controlled Tubing Clamp (ERC) is designed for operation with the CP5 system to improve for the safety of centrifugal perfusion.

When certain conditions are detected (low level, bubble or retrograde flow), the ERC occludes the arterial line immediately to minimize the danger of air delivery.

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



S5 allow simultaneous use of up to 2 centrifugal pump drivers: one for arterial and one for venous kinetic drainage applications.





## CP5 CENTRIFUGAL PUMP

Product designation	Part number
<b>CP5</b> (only for S5 C5) consisting of:	60-00-60Z
CP5 drive unit (with cable)	60-01-04
Pump control panel (with holder)	60-02-60Z
Emergency system (complete)	60-01-35
Flow sensor (3/8")	96-414-140
Flow measurement sensor module	25-60-70Z
<b>CP5 console</b>	48-20-00



## Electrical Remote-Controlled Tubing Clamp (ERC)

Product designation	Part number
<b>Electrical remote-controlled tubing clamp</b> consisting of: tubing clamp, 3-joint mast holder with fast clamp connector, 500 mm	60-05-60
<b>Electrical remote-controlled tubing clamp</b> 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.

Cardioplegia tubing clamp inserts allow two tubes with different diameters to be simultaneously connected to the roller pump heads. They are available for flow ratios from 1:1 to 8:1.



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

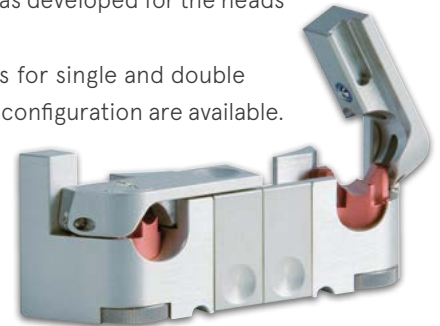
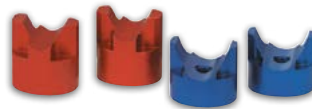
## TUBING CLAMPS

### Variolock tubing clamp module

Self-locking mechanism keeps tubing in place on the pump housing.

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

### 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
<b>Tubing clamp block DRP 85</b> (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

S5 panels are configured according to the customer's needs.

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.



## SYSTEM PANEL

### S5 display and control module

All display and control modules are physically identical but each one is controlled by its own separate microprocessor.

Panel displays are fully inter-changeable. Interchangeability of the control panel displays during ECC allows an immediate takeover of the dedicated configuration.

Information on the panel displays is retained even in case of replacement.

The high-contrast TFT display has a restrained colour scheme. 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.

Touch screen display enables a fast and easy panel navigation.



#### Product designation

#### Part number

#### S5 system components

3-position S5 system panel for 3 display and control modules	28-95-03
4-position S5 system panel for 4 display and control modules	28-95-00
5-position S5 system panel for 5 display and control modules	28-95-01
6-position S5 system panel for 6 display and control modules	28-95-04
1 display and control module	28-95-10Z
Blank module	28-95-30

## TIMERS

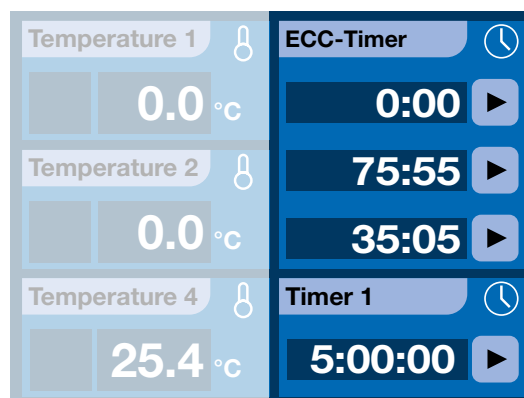
Three timers that work independently of each other can measure the duration of three simultaneous separate processes, for example the complete bypass time or the aortic cross-clamping time.

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 Pressure Control Module measures and displays the pressure in the cardiopulmonary bypass circuit.

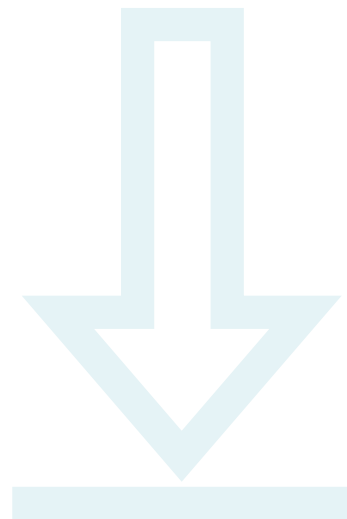
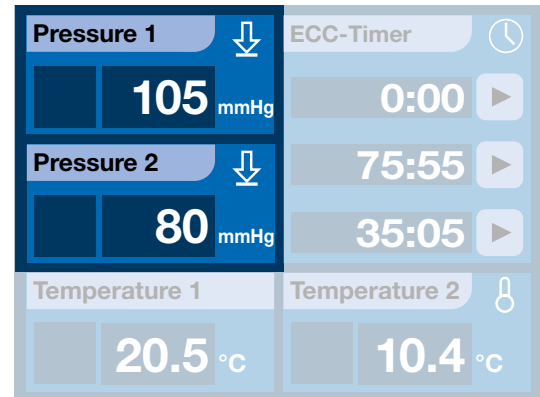
The Pressure Control Module controls perfusion with constant adjustable pressure (set value) through automatic variation of the pump speed (control mode).

The Pressure Control Module limits the pressure to values set by the clinician by stopping the pump (monitoring mode) when the preset pressure (stop limit) has been reached.

The display range extends from -300 mmHg to +800 mmHg.

The values can be displayed in either mmHg or kPa.

The Pressure Control Module allows the operator to control two pumps independently of one another.



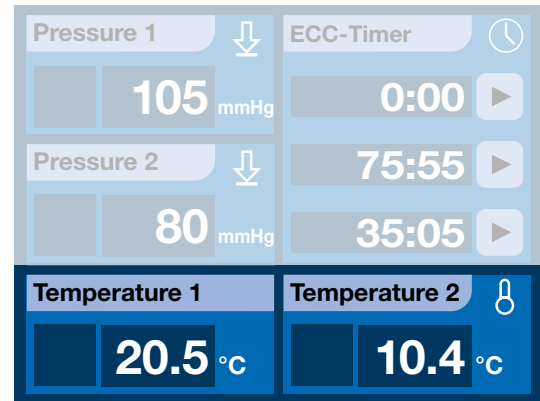
Product designation	Part number
Sensor module 2-channel pressure monitor	22-20-20Z
Sensors and accessories (optional)	Part number
Medex transducer (MX 960)	45-04-03
Cable for Medex transducer	45-04-15
Holder for one Medex transducer	45-04-16
Holder for 2 Medex transducers	45-04-17

## TEMPERATURE MONITOR

The temperature monitor simultaneously measures and displays up to four temperatures.

One temperature sensor module channel is reserved to 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. If the temperature limit is reached, visual and acoustic alarms are triggered.



Product designation	Part number
Sensor module 4-channel temperature monitor	20-30-20Z
Accessories (optional)	Part number
Temperature probes for direct measurement in the oxygenator (optional)	
Inspire™ temperature probe	45-03-10 04222900
Kids temperature probe	45-03-11 09026

## LEVEL CONTROL

New Level Sensor technology continues to enable a fast response for patient safety and includes a new transparent adhesive pad for a complete & clear blood level visibility.

A yellow line at the outside of the sensor probe indicates the stop level and triggers alarm or pump stop based on the set up.

### Level Sensor

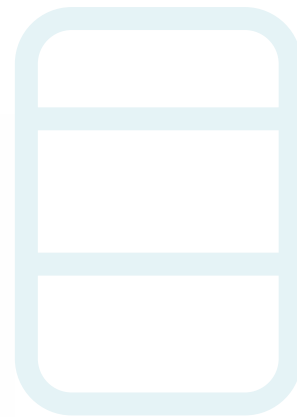
- Regulate and stop the arterial pump flow when the blood level in the reservoir reach the target volume.

### Level Sensor Module

- Fast recognition of the stop level in the reservoir.
- Design and performances in compliance with latest EMC regulation.

### Level Sensor Pad

- Easy to peel off protection foil of the Adhesive tape of the Pad. Symmetric pad to be mounted in both directions for an easy pad management.
- Small and flexible pad to fit and stick on every reservoir, including the pediatric ones.
- Transparent pad to offer a clear view of the blood level.



### Product designation

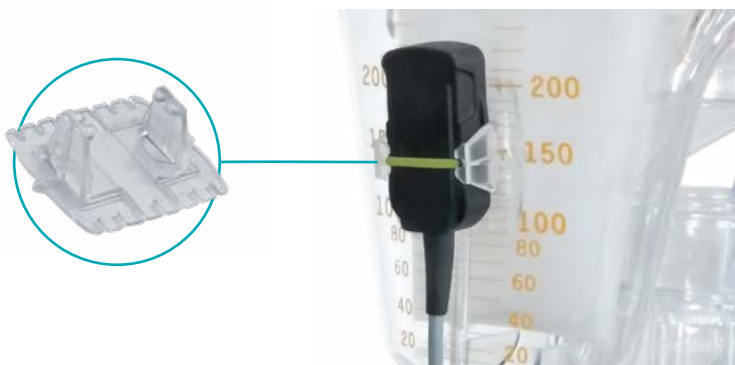
### Part number

**S5 New level sensor module**

23-41-00

Adhesive level sensor pads 100 units

23-41-51





## BUBBLE DETECTOR

S5 allows optimized air management supported by a bubble sensor that can recognize air bubbles of different sizes.

This monitoring device detects air 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.

Three different bubble detection alarm thresholds can be set up (4 mm, 5 mm and 6.5 mm Ø).

The bubble sensor positioned in the arterial line 1 meter from the patient allows effective and fast protection from air bubbles.

The micro-bubble detection function can also be activated.



Product designation	Part number
<b>Sensor module bubble detector</b> consists of: One bubble sensor <b>3/8"</b> (9.56 mm) (23-07-50) and one 3-joint mast holder, <b>420 mm</b> (23-26-96)	23-45-00Z
<b>Sensor module bubble detector</b> consists of: One bubble sensor <b>1/4"</b> (6.35 mm) (23-07-40) and one 3-joint mast holder, <b>420 mm</b> (23-26-96)	23-45-01Z
<b>Sensor module bubble detector</b> consists of: One bubble sensor <b>1/2"</b> (12.7 mm) (23-07-45) and one 3-joint mast holder, <b>420 mm</b> (23-26-96)	23-45-02Z
<b>Sensor module bubble detector</b> consists of: One bubble sensor <b>3/8"</b> (9.56 mm) (23-07-50) and one 3-joint mast holder, <b>620 mm</b> (23-26-91)	23-45-10Z
<b>Sensor module bubble detector</b> consists of: One bubble sensor <b>1/4"</b> (6.35 mm) (23-07-40) and one 3-joint mast holder, <b>620 mm</b> (23-26-91)	23-45-11Z
<b>Sensor module bubble detector</b> consists of: One bubble sensor <b>1/2"</b> (12.7 mm) (23-07-45) and one 3-joint mast holder, <b>620 mm</b> (23-26-91)	23-45-12Z

## CARDIOPLEGIA CONTROL

The Cardioplegia delivery system on the S5 offers a choice of different settings per cardioplegia technique.

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.

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.

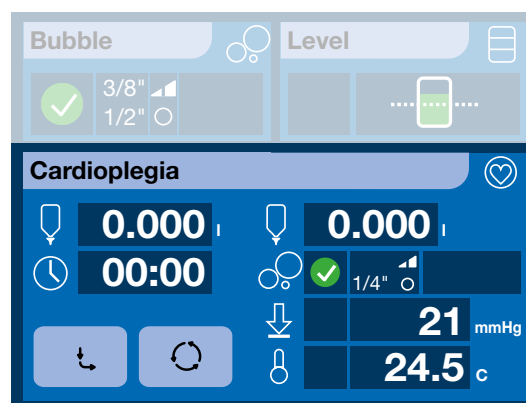
When the preset pressure (stop limit) has been exceeded, the cardioplegia pump stops and cardioplegia delivery is interrupted. At the same time, the visual and acoustic alarms are triggered (monitoring mode).

The control mode can also be set.

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.

The cardioplegia sensor module has its own connectors for a bubble sensor and a pressure transducer.



Product designation	Part number
<b>Sensor module cardioplegia control</b>	27-80-20Z
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
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-CAPTA

B-Capta is fully integrated in the world leading S5 Heart-Lung Machine.

B-Capta provides an in-line continuous monitoring of the patient's parameters during the entire duration of pediatric and adult procedures and provides visual and audible indicators when parameters fall outside user-specified thresholds. B-Capta is based on an accurate and reliable optical based technology improved to guarantee a high level of accuracy and reliability when measuring the patient blood gas parameters, even in long and complex cardiopulmonary bypass procedures.

### Venous and Arterial Sensor

B-Capta includes a venous sensor and an arterial sensor.

Both sensors must be used in conjunction with a disposable cuvette in the blood line for optical reading. By means of their cables, they are connected to the B-Capta sensor module installed in the S5 HLM.

The venous and arterial sensors can be identified by the **blue** (venous) or **red** (arterial) marker on the housing. The sensors are suitable for all available cuvette sizes.

### Sensor Module

The B-Capta sensor module is mounted in the electronics and power pack (E/P pack) of the S5.

The ports for the venous and the arterial sensors are colour-coded.

The sensor module is the interface between the sensors and the display on the S5 system panel and transfers all measured values.

**Blue connector** = venous sensor

**Red connector** = arterial sensor

### Mast-mountable holders with venous and arterial reference element

B-Capta is equipped with two reference elements respectively:

- one for the venous sensor
- one for the arterial sensor

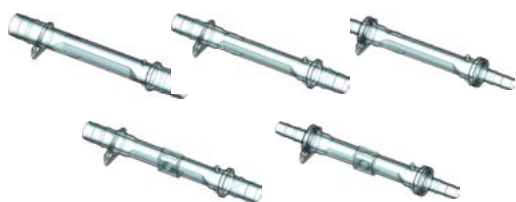
The reference elements are installed on mast-mountable holders and consist of a specific reference cuvette. Before the actual measurement, the sensors are subjected to a self-test by mounting them onto the reference elements.



## B-CAPTA

### Disposable Venous and Arterial cuvettes

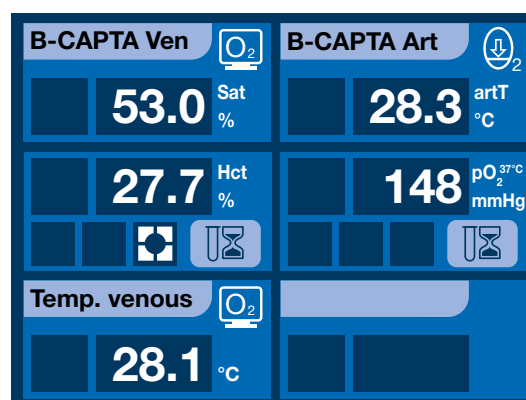
The cuvettes are available in different sizes for both venous and arterial lines. The disposable cuvettes are available as sterile stand-alone disposable and may be supplied as preconnected or non preconnected in the Perfusion Tubing Sets (PTS).



### The user interacts with the device through the display of the S5 HLM

The Graphical User Interface supports the user to:

- **Display values measured** by the sensors:
  - **Venous:**
    - Oxygen Saturation (Sat)
    - Hematocrit (Hct) or Hemoglobin (Hb)
    - Temperature (venT)
  - **Arterial:**
    - Partial pressure of oxygen ( $pO_2^{ACT}$  or  $pO_2^{37°C}$ )
    - Temperature (artT)
- **Select the value to be shown** on the main display:
  - Hct or Hb
  - $pO_2^{ACT}$  or  $pO_2^{37°C}$
- **Change measurement unit** (for Hb and  $pO_2$ )
- **Adjust the measured values** with laboratory values (not applicable for the temperature)
- **Set the warning limits** for each parameter: These are intended to inform the operator if the sensor is measuring values outside the set thresholds.



### B-Capta article numbers – Equipment & Disposable

	P/N	Sensor module venous & arterial	Venous sensor & ref. element	Venous ref. element holder	Arterial sensor & ref. element	Arterial ref. element holder
<b>FULL SYSTEM</b>	25-95-00	YES	YES	YES	YES	YES
<b>SYSTEM VENOUS ONLY</b>	25-95-05	YES	YES	YES	/	/

Venous cuvettes	Part number
1/2"	05184
3/8"	05183
1/4"	05182

Arterial cuvettes	Part number
3/8"	05191
1/4"	05190

## ELECTRONIC GAS BLENDER

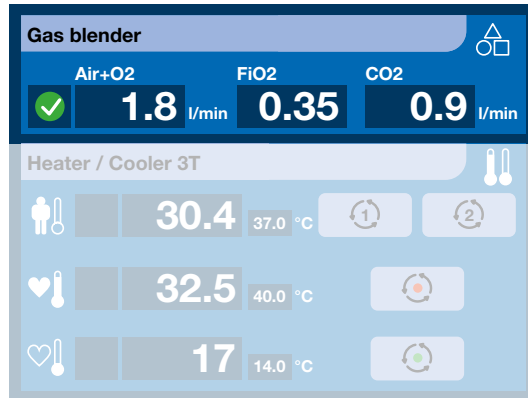
The electronic gas blender allows to set, monitor and display the gas flows required for extracorporeal circulation. The preset values (i.e. the total flow including Air + O<sub>2</sub>, FiO<sub>2</sub> and CO<sub>2</sub>) can be set independently and are displayed on both the gas blender and the display and control panel.

In the Electronic Gas Blender, 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 of the Electronic Gas Blender on the display and control module can be used to change the set values for Air + O<sub>2</sub>, FiO<sub>2</sub> and CO<sub>2</sub> 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



Product designation	Part number
<b>Electronic gas blender</b> (10 l/min)	25-28-67
<b>Electronic gas blender</b> (5 l/min)	25-28-68
<b>Electronic gas blender</b> (2 l/min)	25-28-69
Standard holder (straight, with fast clamp connector)	55-91-50
Accessories (optional)	Part number
Holder (U-shaped with plate, only compatible with 4- and 5-position consoles)	25-40-70

## VENOUS LINE CLAMP

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.



Product designation	Part number
<b>Venous line clamp remote control</b>	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
Tubing Inserts in sets with 4 pcs. each (incl.)	Part number
∅ 1/4" x 1/16"      red	10-07-20
∅ 3/8" x 3/32"      blue	10-07-23
∅ 1/2" x 3/32"      green	10-07-25
Tubing Inserts in sets with 4 pcs. each (opt.)	Part number
∅ 1/4" x 3/32"      yellow	10-07-21
∅ 3/8" x 1/16"      black	10-07-22
∅ 1/2" x 1/16"      grey	10-07-24
∅ 5/8" x 3/32"      brown	10-07-26
∅ 1/8" x 1/16"      violet	10-07-27
∅ 3/16" x 1/16"      turquoise	10-07-28

## EVO – ELECTRICAL VENOUS OCCLUDER

The Electrical Venous Occluder (EVO) provides precise, controlled and ergonomic operation when initiating and ending CPB.

The EVO is able to apply an occlusion of perfusion tubing that varies between fully unoccluded to fully occluded.

When the pump is stopped manually, EVO helps achieve controlled regulation of the venous return flow.

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.

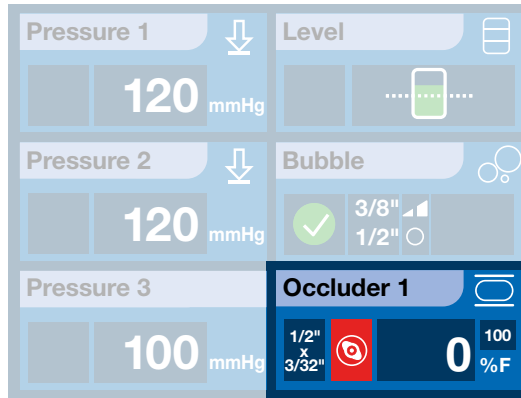
Use the relevant keys or the setting knob on the EVO operating unit to open and close. When the setting knob is turned, there is audible clicking and locking into place. Different ranges can be selected for a fine adjustment.

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
<b>Electrical venous occluder</b>	12-80-00Z
consists of:	
Occluder (with mast holder)	12-80-10Z
Control unit	28-95-70Z

## ACCESSORIES

### Colour coding set

To identify the role of each pump according to customer requirement.



### Cable holders

To ensure the desired routing of cables and tubing on the mast system. The holders can be installed anywhere on the mast system.

Available in sets of 6.

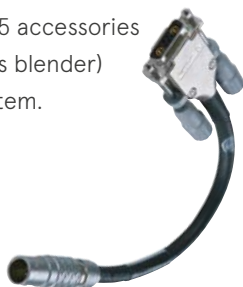


### Perfusionist's chair



### S5 adapter cable

To connect S5 accessories (SCP, ERC, gas blender) to the S5 System.



### LED console lamp



### Cover for fast clamp connectors



### Writing desk DIN A4



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
LED console lamp	35-05-80
Cover for fast clamp connectors (set of 6 pieces)	43-42-61
Writing desk DIN A4	48-04-00



S5°

## ACCESSORIES

### S5 shelf

The 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.



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: 10-84-64		

## ACCESSORIES



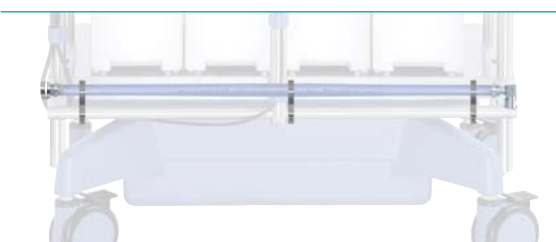
### S5 drawer module

The stainless steel drawer module can be used for storing utensils. It has a 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

Product designation	Part number
S5 drawer module	48-41-70
S5 tubing guide holder incl. connectors and a 6-m length of PVC tubing	16-05-60
LED console lamp	35-05-80
Writing desk DIN A4	48-04-00
Cover for fast clamp connectors (set of 6 pieces)	43-42-61

## HEATER-COOLER 3T

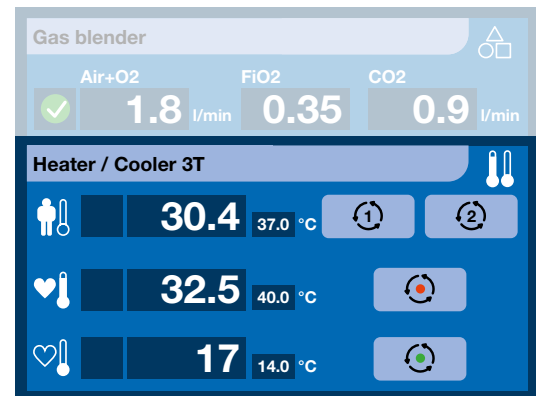
The Heater-Cooler System 3T / 3T plus is intended to provide temperature-controlled water to heat exchanger devices (cardiopulmonary bypass heat exchangers, cardioplegia heat exchangers, and thermal regulating blankets) to warm or cool a patient during cardiopulmonary bypass procedures.

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).



- 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.
- 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
Connection cable (6 m) between S5 and Heater-Cooler 3T	45-12-16
Connectors	Part number
Hansen connector (female) for oxy straight 3/8"	73-300-089
Hansen connector (female) for oxy 90° 3/8"	73-300-090
Disposable	Part number
3T Aerosol Collection Set	050900100
¼" ID vacuum extension line with connector, 366 cm (12 ft)	050900111

\*The product may not be available in all countries. Make sure to choose the model that corresponds to your area's electricity voltage.

## CONNECT®

The LivaNova intuitive perfusion data management system designed to improve clinical efficiency and enable Goal-Directed Perfusion Therapy.



### Main Connect features:

- Connect allows trending while centralizing all patient data on one screen.
- Connect permits automatic transfer of information from LivaNova disposables and the creation of electronic patient records.
- Provides customizable online quality indicators and post-op electronic quality reports.
- Connect enables Goal-Directed Perfusion (GDP) Therapy through the monitoring of critical metabolic patient parameters with the GDP Monitor.

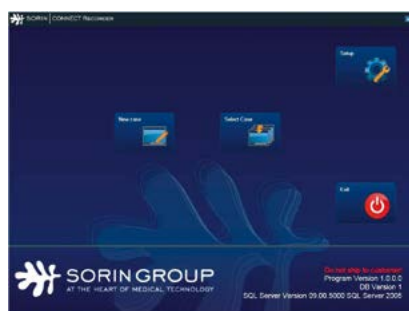
Connect is an electronic charting system that allows continuous data recording and trends visualization aimed to support clinicians and institutions in their perfusion management and documentation goals, before, during and after cardiac surgery.

### Connect supports the Perfusionist during the entire Perfusion journey:

- Prior to surgery, a case is created for each patient, either manually or automatically, through the hospital EMR system. This import contains all relevant demographic and other surgery-related information.
- During surgery, a 15" medical-grade computer, attached to the LivaNova Heart-Lung Machine (HLM) collects patient data from the HLM and other external patient monitoring devices.
- During the operation, the perfusionist can continuously view data and events as charts or tables, according to the user preference.
- The perfusionist may also enter data as well as comments and event entries in order to have complete documentation of the case.
- Connect may also be configured to collect data electronically from a variety of patient monitors, blood gas devices, ACT meters, cerebral oximetry devices, etc.
- Post-operatively, the perfusionist can create a complete electronic medical record of the patient, which can then be uploaded to various destinations, such as patient's EMR record.

### The Connect workflow system<sup>1</sup>:

- Minimize transcription errors, bias and all the drawbacks associated with manual operations
- Restrict Inefficiencies of manually entering product data
- Simplify data record analysis



1. Ottens J, Baker RA, Newland RF, Mazzone A. The Future of the Perfusion Record: Automated Data Collection vs. Manual Recording. JECT 2005;37:355-359.

## CONNECT®

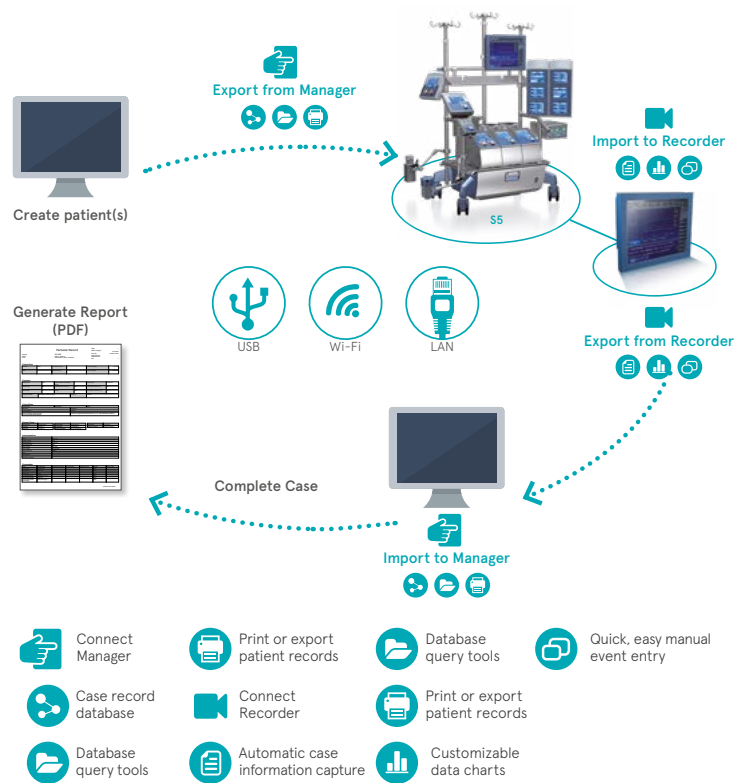
The Connect System consists of two core components:

### The Connect Manager:

- Manages all case data in one central SQL database
- Provides retrospective data analysis with included statistics tool
- Generates and exports electronic perfusion case reports
- Allows full customization of the Connect Recorder according to user preferences
- Can be installed on any hospital computer

### The Connect Recorder:

- Collects and visualizes data from the HLM and other external devices
- Offers a high level of customization to optimize viewing preferences
- Offers quick single-touch event entries at any time
- Enables Goal-Directed Perfusion parameters via the GDP Monitor



Connect system setups may be tailored to suit hospital requirements. The LivaNova technical support team works together with relevant hospital I.T. departments to identify the most appropriate Connect system setup.

Connect may be installed with a variety of connectivity options:

1. Basic, local installation
2. Full network installations with one Manager
3. Full network with multiple Manager installations
4. Direct network transfer between Manager and Recorder
5. HL7 integration with hospital EMR systems

## CONNECT™ HL7

Connect with HL7 integration simplifies data exchange between the Connect components and the Hospital EMR System (HIS). It is the keystone for the exchange, integration, sharing and retrieval of electronic health information.

The flexible and customizable optionally available HL7 interface is an integrate, bidirectional communication system between Connect and the Electronic Medical Record (EMR). It allows the perfusionist to retrieve and share patient information from and to an EMR system to simplify workflow and improve clinical practice<sup>1</sup>.

### Main clinical benefits of CONNECT HL7 interface/CONNECT HL7 interface<sup>1</sup>:

- Simplification of the clinical data workflow
- Improved data integrity
- Enhanced legibility
- Reduction in manual processes

### Main features of CONNECT HL7 interface/CONNECT HL7 interface:

- New graphical user interface with a powerful HL7 search engine to search for patient data in the EMR system and seamlessly import it into either Connect Manager or Connect Recorder
- Automatic upload of the post-operative PDF patient record into the EMR system
- Post-operative export of recorded patient data during Extra Corporeal Circulation (ECC) directly into the graphical user interface of the EMR system
- Full customization options to reflect hospital specific EMR and emergency workflows.

1. Newland et al. Integration of Electronic Perfusion Data for Perfusion Registries. J Extra Corpor Technol. 2018;50:102-12.

## CONNECT®



## Order Guide

ITEM CODE	IDENTIFICATION	DESCRIPTION	QUANTITY / BOX
24-90-80	Connect Recorder	for S5	1
24-90-45	Connect Manager		1

Please contact your local Representative for more details.

ITEM CODE	IDENTIFICATION
24-11-10	Connect HL7 Interface Package
24-11-20	Connect HL7 Datapoints
24-11-50	Connect HL7 1 Year Extension
24-11-60	Connect HL7 2 Years Extension
24-11-70	Connect HL7 3 Years Extension
24-11-80	Connect HL7 5 Years Extension
24-11-30	Additional Customization and Services (10h)
24-11-40	Additional Customization and Services (20h)

## SPECIFICATIONS:

**Connect Manager**

Operating system: Microsoft® Windows 10, commercial versions  
Database: Microsoft® SQL Server 2017.

**DataPad for Connect Recorder**

Operating system: Windows 10 Enterprise LTSC 2018 64-bit  
CPU: Intel® Celeron® 2002E 1.5GHz  
RAM: 4GB DDR3L 1600  
1x COM Port RS232  
4x USB Port (2.0, EHCI)  
1x DVI Port  
1x IEEE 802.3u 100 Base-Tx Fast Ethernet compatible port  
HDD: 64GB SSD  
Removable HDD: 16GB CFAST  
Database: Microsoft® SQL Express 2017  
15" Resistive touch screen

**WLAN Module Specifications**

Frequency Range: 2.4 GHz to 5 GHz  
Wireless network standard: IEEE 802.11a/b/g/n

## 1.0 DIMENSIONS, WEIGHTS, OPERATING CONDITIONS

### TECHNICAL SPECIFICATIONS

#### 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 <sup>(1)</sup>

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 <sup>(3)</sup>	200 mm <sup>(5)</sup>
Weight	15 kg	12 kg	11.9 kg <sup>(2)</sup>	5 kg <sup>(2)</sup>	11 kg <sup>(4)</sup>

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

<sup>(1)</sup> max. swivel arm 200 mm; <sup>(2)</sup> with fast clamp connector; <sup>(3)</sup> without fast clamp connector;

<sup>(4)</sup> with double holder; <sup>(5)</sup> without double holder

## TECHNICAL SPECIFICATIONS

### 1.3 PUMPS

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

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 <sup>(6)</sup>

## 2. ELECTRICAL SPECIFICATIONS

### 2.1 ELECTRONICS AND POWER PACK

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

<sup>(6)</sup> with holder



## TECHNICAL SPECIFICATIONS

### 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 1 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

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 $\pm 10$ 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)

## TECHNICAL SPECIFICATIONS

### 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 $\pm 10$ mm

Sensor module for bubble detector	
Alarm limit (bubble sensor) at $\geq 15$ rpm 1/2" and 3/8"	Air volume: 0.144 cm <sup>3</sup> ( $\varnothing$ 6.5 mm) Air volume: 0.065 cm <sup>3</sup> ( $\varnothing$ 5.0 mm) Air volume: 0.034 cm <sup>3</sup> ( $\varnothing$ 4.0 mm)

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

Cardioplegia sensor module	
Volume control	
Setting range	0 to 2 liter
Accuracy of dosage	$\pm 10\%$ , min. $\pm 20$ 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 $\pm 0.2$ °C 25.0 °C - 45.0 °C $\pm 0.1$ °C 45.0 °C - 50.0 °C $\pm 0.2$ °C

# LivaNova

Health innovation that matters

Manufacturer:

**Sorin Group Italia S.r.l.**

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info.cardiacsurgery@livanova.com

Manufacturer:


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[www.livanova.com](http://www.livanova.com)



LivaNova Deutschland Quality System complies with:  
EN ISO 13485:2012

 <sup>0123</sup> According to Annex II (Full Quality System) of  
MDD 93/42/EEC as amended by directive 2007/47/EEC

For professional use. Please contact us through our website to receive instructions for use containing full prescribing information, including indications, contraindications, warnings, precautions and adverse events. Not approved in all geographies. Consult your labeling.

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# **Attachment C**

## EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type (e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotripter, MRI, PET, Simulator, CT Scanner, etc.)	Heart-Lung Bypass Machine	Heart-Lung Bypass Machine
Manufacturer	LivaNova	LivaNova
Model name/number	S5 Heart Lung Perfusion System	S5 Heart Lung Perfusion System
Other method of identifying the equipment (e.g., Serial Number, VIN #)	48E01761	Not Available Until Installed
Is the equipment mobile or fixed?	Mobile	Mobile
Date of acquisition	2011	2024
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	\$191,676
Total cost of the equipment	Not available due to system transition	\$178,821
Location of the equipment	Carolinas Medical Center	Carolinas Medical Center
Document that the existing equipment is currently in use	Heart-lung bypass machines were used in over 900 procedures performed at CMC during CY2023	NA
Will the replacement equipment result in any increase in the <b>average charge per procedure</b> ?	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 <b>average operating expense per procedure</b> ?	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

## EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type (e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotripter, MRI, PET, Simulator, CT Scanner, etc.)	Heart-Lung Bypass Machine	Heart-Lung Bypass Machine
Manufacturer	LivaNova	LivaNova
Model name/number	S5 Heart Lung Perfusion System	S5 Heart Lung Perfusion System
Other method of identifying the equipment (e.g., Serial Number, VIN #)	48E01769	Not Available Until Installed
Is the equipment mobile or fixed?	Mobile	Mobile
Date of acquisition	2011	2024
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	\$191,676
Total cost of the equipment	Not available due to system transition	\$178,821
Location of the equipment	Carolinas Medical Center	Carolinas Medical Center
Document that the existing equipment is currently in use	Heart-lung bypass machines were used in over 900 procedures performed at CMC during CY2023	NA
Will the replacement equipment result in any increase in the <b>average charge per procedure</b> ?	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 <b>average operating expense per procedure</b> ?	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

## EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type (e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotripter, MRI, PET, Simulator, CT Scanner, etc.)	Heart-Lung Bypass Machine	Heart-Lung Bypass Machine
Manufacturer	LivaNova	LivaNova
Model name/number	S5 Heart Lung Perfusion System	S5 Heart Lung Perfusion System
Other method of identifying the equipment (e.g., Serial Number, VIN #)	48E02854	Not Available Until Installed
Is the equipment mobile or fixed?	Mobile	Mobile
Date of acquisition	2013	2024
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	\$191,676
Total cost of the equipment	Not available due to system transition	\$178,821
Location of the equipment	Carolinas Medical Center	Carolinas Medical Center
Document that the existing equipment is currently in use	Heart-lung bypass machines were used in over 900 procedures performed at CMC during CY2023	NA
Will the replacement equipment result in any increase in the <b>average charge per procedure</b> ?	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 <b>average operating expense per procedure</b> ?	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

## EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type (e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotripter, MRI, PET, Simulator, CT Scanner, etc.)	Heart-Lung Bypass Machine	Heart-Lung Bypass Machine
Manufacturer	LivaNova	LivaNova
Model name/number	S5 Heart Lung Perfusion System	S5 Heart Lung Perfusion System
Other method of identifying the equipment (e.g., Serial Number, VIN #)	48E02856	Not Available Until Installed
Is the equipment mobile or fixed?	Mobile	Mobile
Date of acquisition	2013	2024
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	\$191,676
Total cost of the equipment	Not available due to system transition	\$178,821
Location of the equipment	Carolinas Medical Center	Carolinas Medical Center
Document that the existing equipment is currently in use	Heart-lung bypass machines were used in over 900 procedures performed at CMC during CY2023	NA
Will the replacement equipment result in any increase in the <b>average charge per procedure</b> ?	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 <b>average operating expense per procedure</b> ?	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



**From:** [Huber, Brigid K](#)  
**To:** [Hale, Gloria](#); [Stancil, Tiffany C](#)  
**Subject:** [External] Exemption Request for The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center  
**Date:** Thursday, April 11, 2024 10:02:02 AM  
**Attachments:** [2024 CMHA dba CMC Exemption Request to Replace Existing Heart-Lung Bypass Machines.pdf](#)

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**CAUTION:** External email. Do not click links or open attachments unless verified. Report suspicious emails with the Report Message button located on your Outlook menu bar on the Home tab.

Good morning,

Please find attached an exemption request submitted by The Charlotte-Mecklenburg Hospital Authority (“CMHA”) d/b/a Carolinas Medical Center to replace four existing heart-lung bypass machines.

Thank you, and please let me know if you have any questions.

Best,

Brigid

**Brigid Knoll Huber, MHA, ATC**

*Core Market Growth Business Development*  
Mobile: 724-986-6214

**Atrium Health**

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