



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

October 6, 2022

Elizabeth V. Kirkman
Elizabeth.Kirkman@atriumhealth.org

Exempt from Review – Replacement Equipment

Record #: 4053
Date of Request: September 30, 2022
Facility Name: Atrium Health Pineville
FID #: 110878
Business Name: The Charlotte-Mecklenburg Hospital Authority
Business #: 1770
Project Description: Replace existing heart-lung bypass machine
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 a certificate of need the new LivaNova SRD S5 Heart Lung Perfusion System to replace the existing LivaNova SRD S5 Heart Lung Perfusion System (ID# 48E00247). This determination is based on your representations that the existing unit 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,

Handwritten signature of Julie M. Faenza

Julie M. Faenza
Project Analyst

Handwritten signature of Micheala Mitchell

for

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
MAILING ADDRESS: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704
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AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

September 30, 2022

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 Atrium Health Pineville to Replace a Heart-lung Bypass Machine

Dear Ms. Mitchell:

The Charlotte-Mecklenburg Hospital Authority (“CMHA”) d/b/a Atrium Health Pineville (“AH Pineville”) seeks to acquire a LivaNova S5 Heart Lung Perfusion System (“Replacement Equipment”) to replace an existing LivaNova S5 Heart Lung Perfusion System (“Existing Equipment”) that was acquired in 2011 and is at the end of its useful life. The Existing Equipment is currently housed in a storage room in the surgical suite on the campus of AH Pineville at 10628 Park Road, Charlotte, NC 28203.

The purpose of this letter is to provide the Agency with notice and to request a determination that AH Pineville’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 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.

In addition to the foregoing, to qualify for this exemption, the replacement equipment must be “comparable” to the equipment it replaces, and the equipment being replaced must be “sold or otherwise disposed of when replaced.” AH Pineville’s proposal qualifies for this exemption.

A. Cost of the Replacement Equipment

The projected total capital cost of the project is \$205,443 which is based on the purchase price of the Replacement Equipment \$190,037 + \$1,515 freight + \$13,888 Tax. There is no renovation cost or disposal cost, or any other cost associated with replacing the equipment. The quote for the Replacement Equipment 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.

AH Pineville intends to use the Replacement Equipment for substantially the same cardiovascular surgical procedures for which it currently uses the Existing Equipment. The Existing Equipment is a LivaNova S5 Heart Lung Perfusion System that has been used since its acquisition in 2011.

The Replacement Equipment can and will perform all procedures currently performed on the Existing Equipment, although it possesses some expanded capabilities due to technological improvements (see Attachment B for the Equipment Brochure). The Replacement Equipment is therefore “comparable medical equipment” as defined in Subsection (c).

For further equipment comparison, please refer to Attachment C, the Equipment Comparison Chart.

The existing equipment along with the other two heart-lung bypass machines in operation at AH Pineville have performed over 150 procedures year to date in 2022.

C. Disposition of Equipment

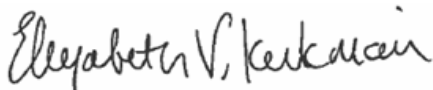
The Existing Equipment will be taken out of service and will not be re-sold or re-installed in North Carolina without appropriate certificate of need approval.

CONCLUSION:

Based on the foregoing information, AH Pineville hereby requests that the Agency provide a written response confirming that the acquisition of the Replacement Equipment 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
Atrium Health Strategic Services Group

Attachments

Attachment A



Health innovation that matters

August 25, 2022

**S5 HEART LUNG PERFUSION SYSTEM
 OUTRIGHT PURCHASE PROPOSAL INCLUDES TRADE IN
 For
 Atrium Health
 In
 Charlotte, NC**

S5 HEART LUNG PERFUSION SYSTEM:

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
23-41-51	100PC ADHESIVE PAD LV-3 SENSOR	1	\$656.00
Net Price Per System			\$190,037.42
Freight Per Each System			\$1,515.00
Net Price for One (1) System with Freight			\$191,552.42

Trade-in amount of the equipment listed below:

Quantity	Description	Serial Number	Make	Model	Trade-in Credit**
1	HLM System	TBD	LivaNova	S5	\$20,000.00

**Each \$20,000.00 credit requires the trade in of an S5 HLM system and the purchase of an S5 system.

TRADE-IN EQUIPMENT TERMS AND CONDITIONS:

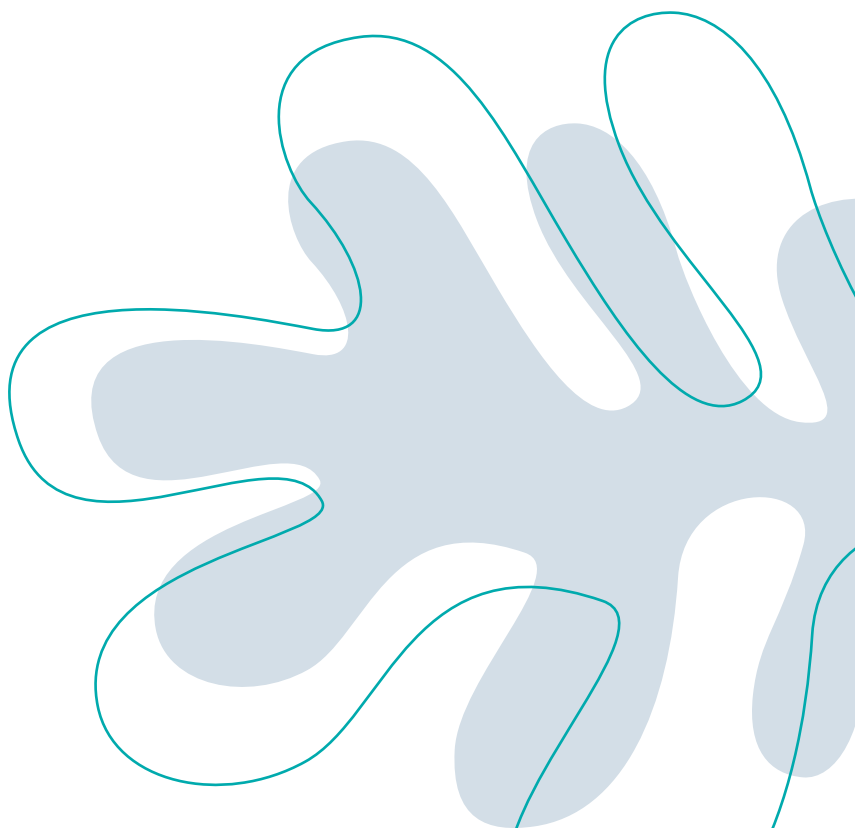
As part of this equipment purchase, LivaNova has agreed to the trade-in of the equipment listed above. LivaNova will make the necessary arrangements to return the equipment to our facilities for final disposition. By acceptance of this proposal, Customer confirms and guarantees that they have clear and unencumbered title to the equipment allowing for the trade-in arrangement and agrees to transfer title to LivaNova and will not be unreasonably withheld.

The LivaNova S5 trade-in credit outlined in this agreement will be issued to the customer's account upon receipt of the equipment at LivaNova USA's Arvada, Colorado facility. The LivaNova S5 trade-in must be received by LivaNova within ninety (90) days after the installation of the purchased equipment to receive the credit.

Attachment B



READY TO MEET ANY CHALLENGE



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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 designation	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

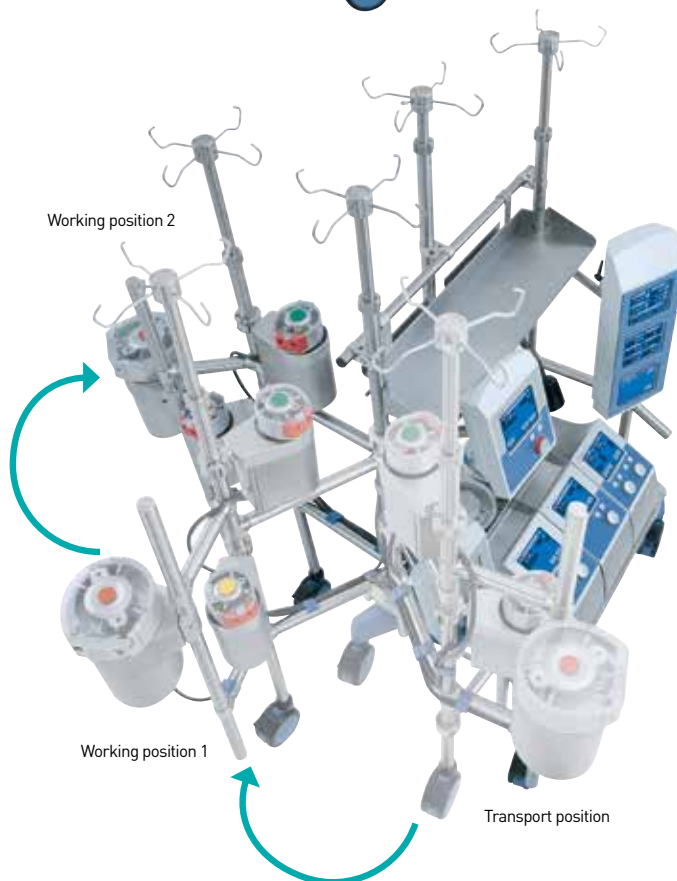


S5 Mast System Extension

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.

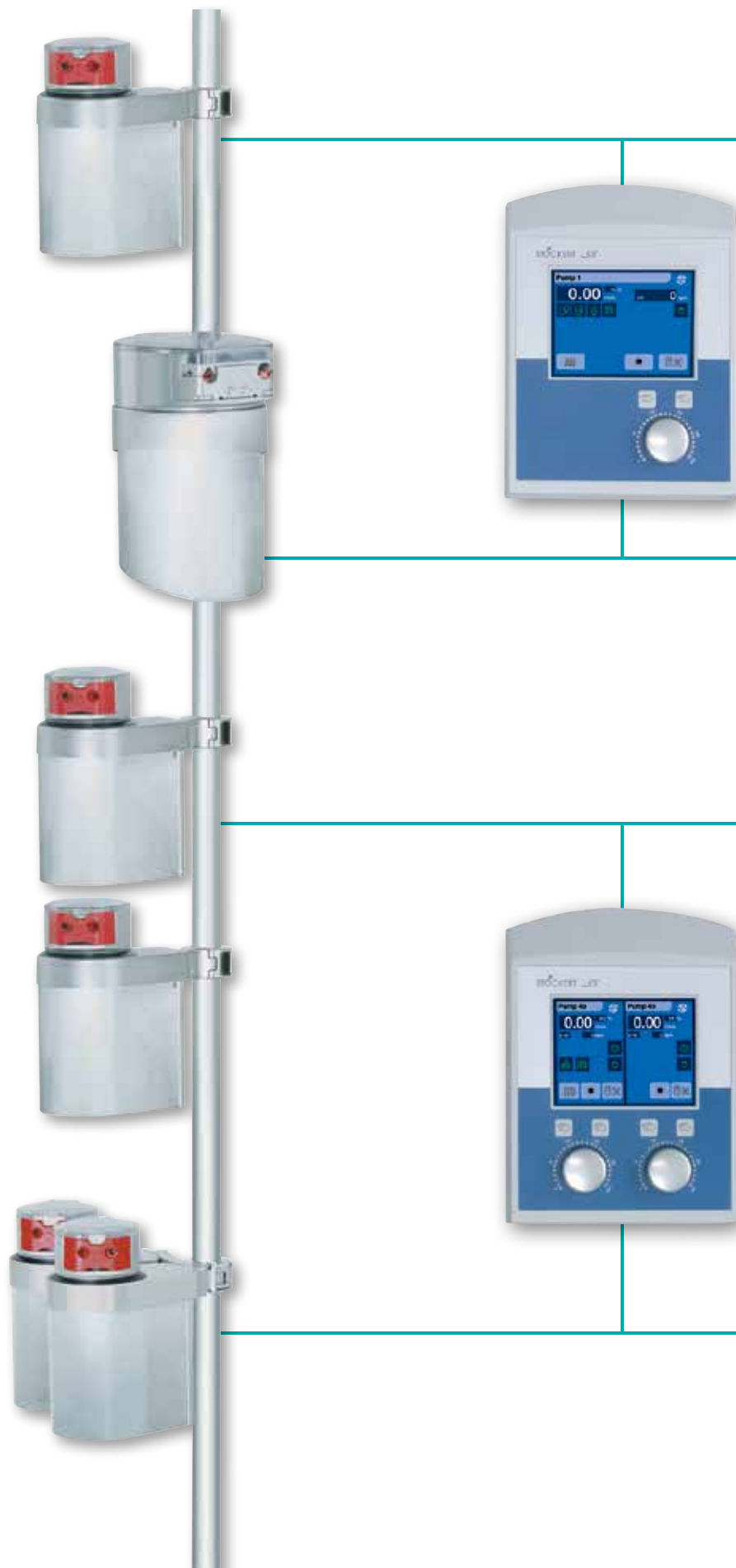
The mast system extension

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



Product designation	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 cardiomy 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 cardiomy 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 (horse-shoe shaped) keeps pressure peaks during operation to a minimum.



ROLLER PUMPS

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.



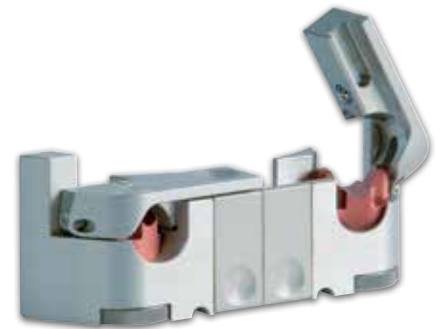
Product designation				Part number
Tubing clamp block RP 150 (included in RP 150, 10-80-00)				10-81-35
Tubing clamp inserts for tubing clamp block RP 150				
	1/4" x 1/16"	red		10-64-15
	1/4" x 3/32"	yellow		10-64-25
	5/16" x 1/16"			
	3/8" x 1/16"	black		10-64-40
	5/16" x 3/32"			
	3/8" x 3/32"	blue		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
Tubing clamp inserts 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

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"	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"		
	3/8" x 3/32"	blue (large)	10-61-72
	1/2" x 1/16"		
	1/2" x 3/32"		
Tubing clamp inserts 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
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.

SYSTEM PANEL



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.

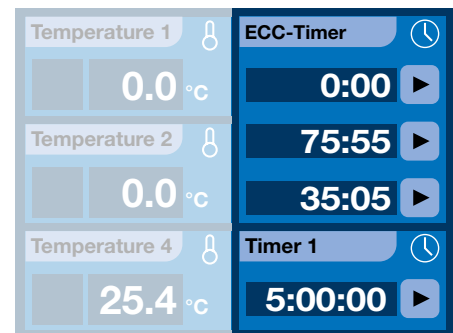
Product designation	Part number
S5 system components	
3-position S5 system panel 3 display and control modules	28-95-03
4-position S5 system panel 4 display and control modules	28-95-00
5-position S5 system panel 5 display and control modules	28-95-01
6-position S5 system panel 6 display and control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

TIMER

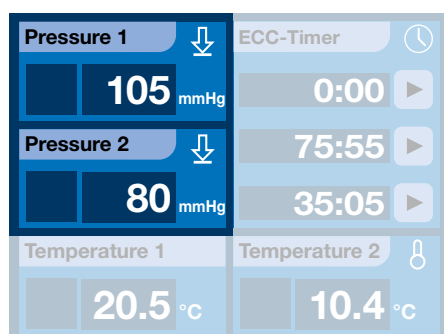
Three timers that work independently of each other can measure the duration of three simultaneous separate processes, for example the complete bypass time or the aortic cross-clamping time.

- 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



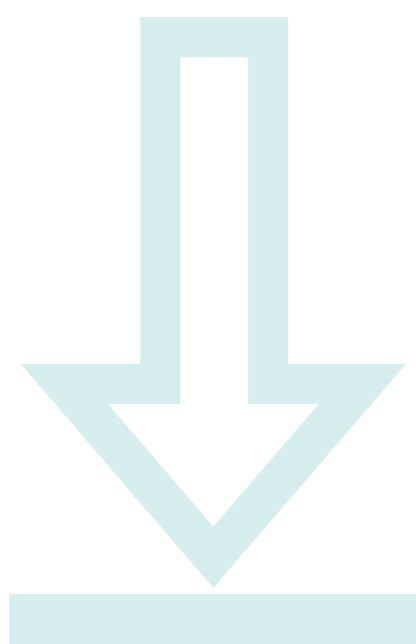
The double pressure sensor module is used for:

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.

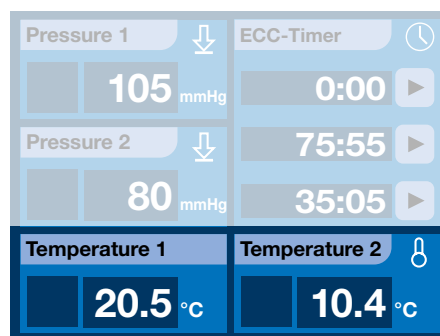


Product designation	Part number
Sensor module 2-channel pressure monitor	22-20-20
Sensors and accessories (optional)	Part number
Medex transducer (MX 960)	45-04-03
Cable for Medex transducer	45-04-15
Holder for one Medex transducer	45-04-16
Holder for 2 Medex transducers	45-04-17



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.

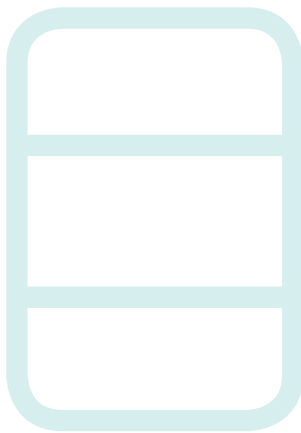


Product designation	Part number
Sensor module 4-channel temperature monitor	20-30-20

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

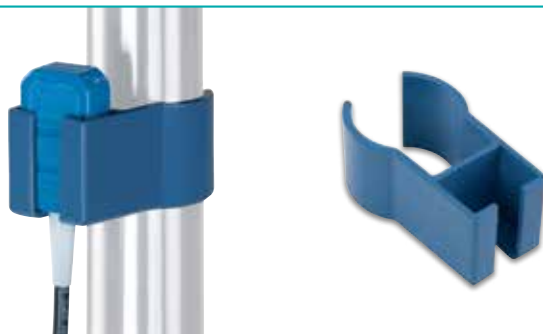


- The level monitor controls the blood level in the oxygenator/reservoir.
- The level sensor is mounted on special disposable, adhesive mounting strips which are attached to the reservoir or oxygenator. The sensor can be used with most hardshell oxygenators and reservoirs.
- The sensor is based on the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

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



BUBBLE DETECTOR

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

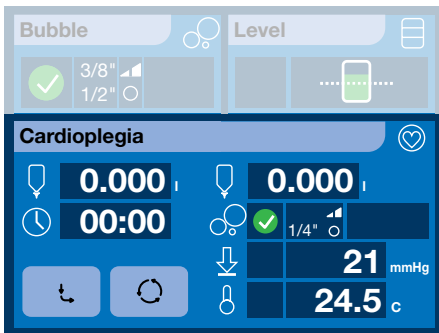
This function requires a sensor module and the corresponding sensor. The scope of delivery includes a bubble detector that can be used for 3/8" tubing. Alternatively, 1/2" and 1/4" sensors are available.

- 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-CARE₅

The In-Line Monitoring System for 3 vital parameters

Sorin B-Care₅ is the first in-line monitor fully integrated into a heart-lung machine.

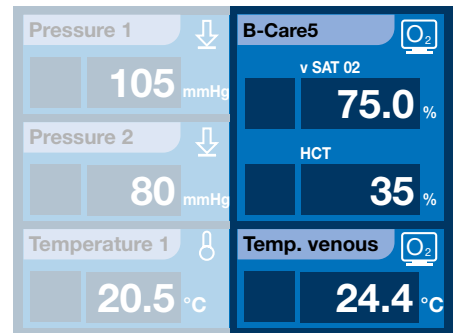
Vital parameters, i.e., venous saturation, haematocrit and venous temperature are measured and shown on a display and control module (DCM) of the S5 system panel. This new S5 sensor module is plugged into the E/P pack of the S5 perfusion system, eliminating the need of an external blood monitor. Moreover, 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.

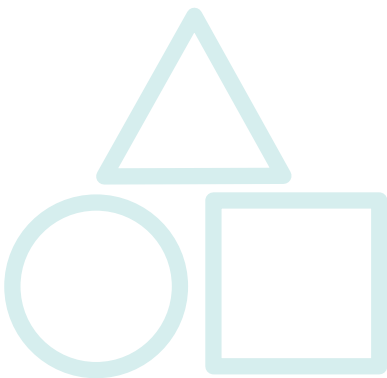
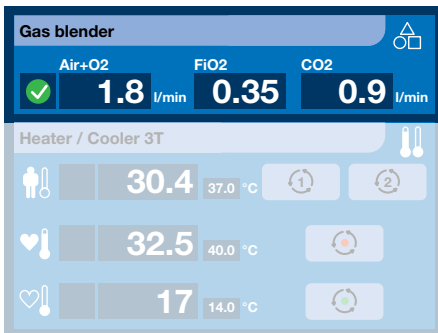
Venous Sensor

Sorin B-Care₅ 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



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)

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

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.

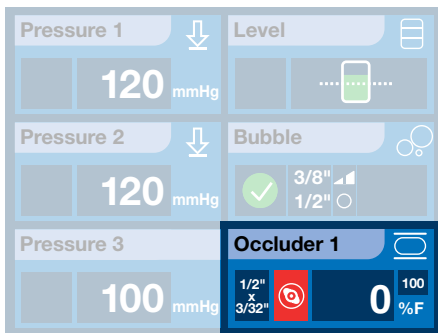


An overview of the remote-controlled venous line clamp's advantages:

- 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
∅ 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 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



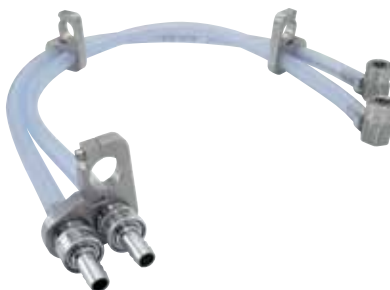
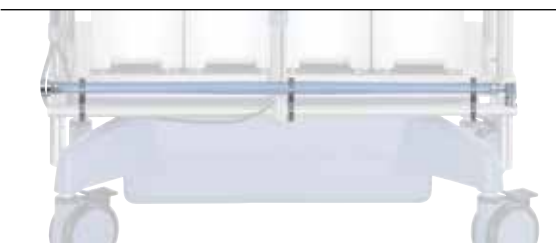
S5 drawer module

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).

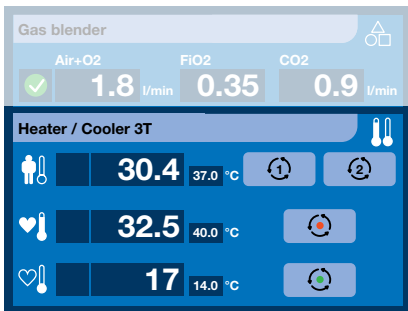
Product advantages:

- 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.

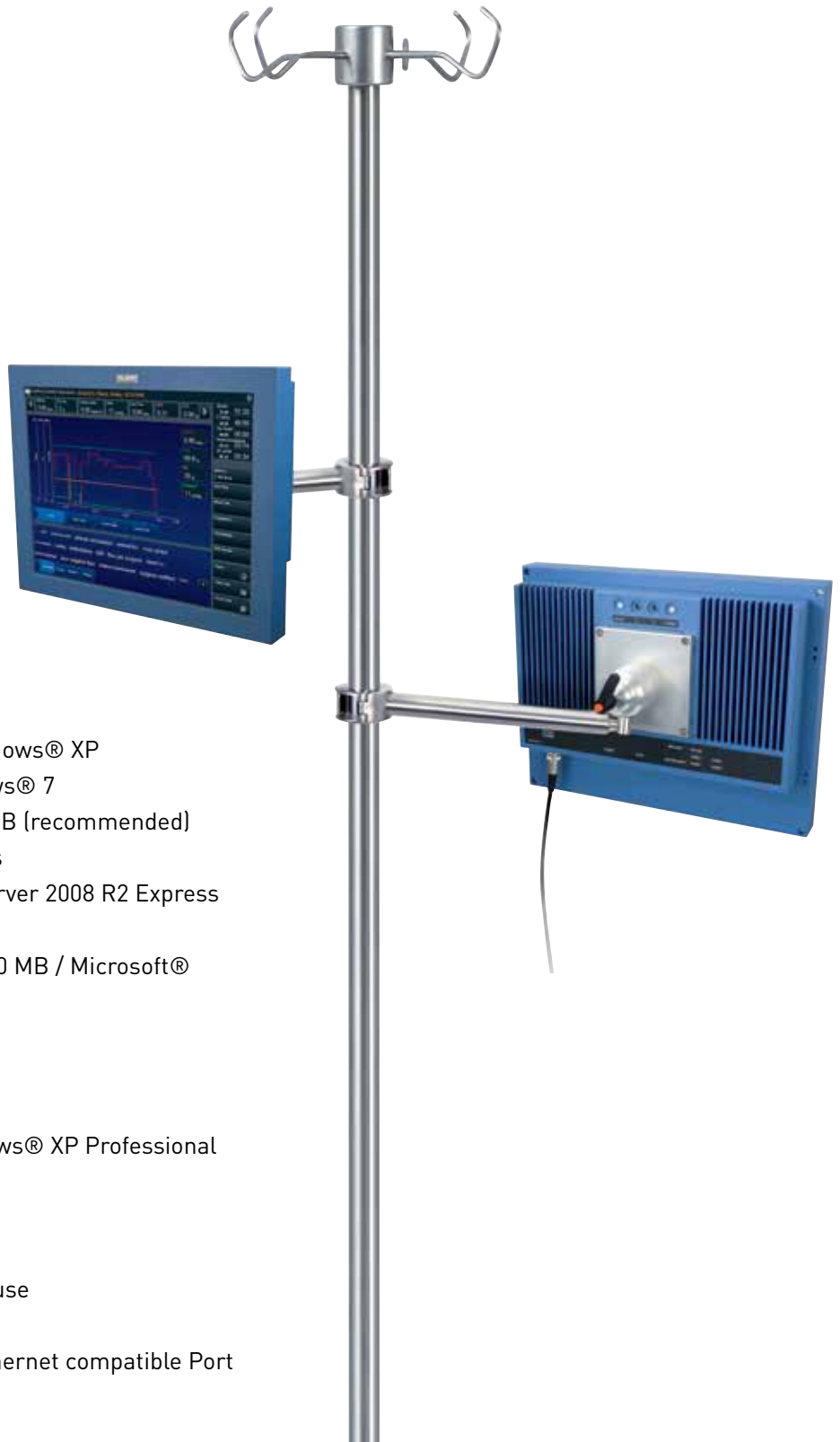
CONNECT Recorder operates on a touch screen datapad, custom designed as a drip proof, medical grade tablet PC that mounts onto the Sorin heart lung machine. The touch screen interface enables fast and easy case event entries and patient specific documentation via on screen virtual keyboards, pull down 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 VC_{O2} 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.

I. DIMENSIONS, WEIGHTS, OPERATING CONDITIONS

TECHNICAL SPECIFICATIONS

I.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%

I.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

I.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 \emptyset	150 mm	85 mm
Diameter of occlusion roller \emptyset	30.5 mm	15 mm

Speed range	0 to 250 rpm (clockwise, counterclockwise)	
Deviation in speed accuracy	$\pm 1\%$ of the terminal value 250 rpm plus $\pm 0.5\%$ 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
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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 (\varnothing 6.5 mm) Air volume: 0.065 cm ³ (\varnothing 5.0 mm) Air volume: 0.034 cm ³ (\varnothing 4.0 mm)

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

Cardioplegia sensor module	
Volume control	
Setting range	0 to 2 liter
Accuracy of dosage	$\pm 10\%$, 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



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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	SRD S5 Heart Lung Perfusion System	SRD S5 Heart Lung Perfusion System
Other method of identifying the equipment (e.g., Serial Number, VIN #)	48E00247	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	Atrium Health Pineville	Atrium Health Pineville
Document that the existing equipment is currently in use	Over 150 open heart surgery procedures utilizing a heart-lung bypass machine were performed at AH Pineville during 2022	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

From: [Huber, Brigid K](#)
To: [Faenza, Julie M](#); [Hunt, Tiffany C](#); [Waller, Martha K](#)
Cc: [Kirkman, Elizabeth](#)
Subject: [External] Exemption Request for The Charlotte-Mecklenburg Hospital Authority d/b/a Atrium Health Pineville
Date: Friday, September 30, 2022 7:11:24 PM
Attachments: [2022 AH Pineville HL Bypass Machine Replacement Exemption Letter.pdf](#)

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to [Report Spam](#).

Good evening,

I hope this email finds you well. Please find attached an exemption request submitted by The Charlotte-Mecklenburg Hospital Authority (“CMHA”) d/b/a Atrium Health Pineville to replace an existing heart lung bypass machine.

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

Best,

Brigid

Brigid Knoll Huber, MHA, ATC

Strategic Services Group

Mobile: 724-986-6214

Atrium Health

Carolinas HealthCare System is Atrium Health

2709 Water Ridge Parkway, Suite 200, Charlotte, NC 28217

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