

Attachment A
Product Descriptions and Salient Characteristics

Product Description and Definitions:

CLIN	MFG	P/N	Description	Definition
0001	Sorin/Liva Nova	48-40-00 4	Perfusion System (Heart-Lung Bypass Unit) 4 Pump S5 console (includes: control desk, display modules, timer, power supply, cross tray, emergency power supply, electronic and power supply pack and mast system, hand crank, hand crack bracket, poles, console holders, uninterruptable power supply/battery backup, LED Lamp, vacuum regulator)	A heart lung bypass unit provides temporary external circulatory support to the cardio-pulmonary functions, by oxygenating the body's venous supply of blood and pumping it back into the arterial system. Heart lung bypass units perform circulation oxygenation, and filtration of the blood. These units are usually assembled in a console, which main components consist of an arterial pump, a backup arterial pump, one or two suction pumps, an arterial vent pump, a cardioplegia pump, and a backup unit. The pumps (known as extracorporeal perfusion or arterial pumps) typically receive blood from the vena cava and deliver it back through the aorta by means of a plastic cannula after processing the blood in an oxygenator/heat exchanger, bypassing the heart and lungs completely. The console includes disposable components such as an oxygenator/heat exchanger, a cardiotomy reservoir, blood filters, and tubing. The system removes relatively oxygen-depleted blood from a patient's body and replaces it with oxygen-rich blood through a series of tubes (hoses). Warming/Cooling Units used in heart-lung bypass are designed to warm or cool the patient by extracorporeal heat exchange with the patient's perfused blood during heart-lung bypass procedures. These units consist of a central device including temperature control via a cooling system, heating element, and pumps for circulating liquid to a heat exchanger. The heat exchanger controls the blood and/or cardioplegic solution temperature during the entire cardiovascular procedure (e.g., induces hypothermia, warms the blood). Some heart-lung bypass units incorporate both the heat exchanger (which may be disposable) and the heating/cooling unit (i.e., the mixer) as integral parts. Some heart lung bypass units include data management software that allows automatic data collection, server storage and database analytics. Heart-lung bypass units are mostly used during open heart surgery,
0002	Sorin/Liva Nova	45-09-10	Cable holding and organizing system 1	Cable holder is a clamp intended to keep cabling and tubing organized, safe and secure
0003	Sorin/Liva Nova	45-09-11	Cable holding and organizing system	Cable holder is a clamp intended to keep cabling and tubing organized, safe and secure
0004	Sorin/Liva Nova	43-42-61	Cap for fast clamp (6 pcs.)	Cap that covers fast clamp used for clamping items to heart-lung bypass unit
0005	Sorin/Liva Nova	45-95-11	USA S5 Console Operators Manual	The operator's manual (also called an instruction manual, user guide or owner's manual) is an instructional book or booklet (hard copy of electronic) that is supplied with almost all technologically advanced consumer products such as medical devices, vehicles, home

				<p>appliances and computer peripherals. Information contained in the owner's manual typically includes:</p> <ul style="list-style-type: none"> •Safety instructions; for liability reasons these can be extensive, often including warnings against performing operations that are ill-advised for product longevity or overall user safety reasons. •Assembly instructions; for products that arrive in pieces for easier shipping. •Installation instructions; for products that need to be installed in a home or workplace. •Setup instructions; for devices that keep track of time or which maintain user accessible state. •Instructions for use. •Programming instructions; for microprocessor controlled products such as VCRs, programmable calculators, and synthesizers. •Maintenance instructions. •Troubleshooting instructions; for when the product does not work as expected. •Service locations; for when the product requires repair by a factory authorized technician. •Regulatory code compliance information; for example with respect to safety or electromagnetic interference. •Product technical specifications. •Warranty information; sometimes provided as a separate sheet. <p>With the increasing complexity of modern devices, many owner's manuals have become so large that a separate quick start guide is provided. Some owner's manuals are supplied on CD-ROM or on the web. Many businesses offer PDF copies of manuals that can be accessed or downloaded free of charge from their websites.</p>
0006	Sorin/Liva Nova	SM-48-40-00	USA S5 System Service Manual	The service manual (also called a technical manual, maintenance manual, or technical guide) is an instructional book or booklet (hard copy or electronic) that is supplied with almost all technologically advanced consumer products such as medical devices, vehicles, home appliances and computer peripherals. Information contained in the service manual typically includes: instructions for installation, theory of operation, use, preventive maintenance, troubleshooting and repair, parts list, system diagrams, support information and training requirements for the effective deployment of an equipment, machine, process, or system.
0007	Sorin/Liva Nova	10-80-00	S5 Pump Module, Single Roller Pump	Pump mechanism that includes a pump housing, head, cover, controls, blocks and clamps
0008	Sorin/Liva Nova	10-85-00	S5 Pump Module, Double Roller Pump	Pump mechanism that includes two independently operating pumps including housing, head, cover, controls, blocks and clamps
0009	Sorin/Liva Nova	10-84-60	S5 Pump Module, Pump Tray for RP150	Tray for single roller pump

0010	Sorin/Liva Nova	10-84-64	S5 Pump Module, Double Pump Tray	Tray for double roller pump
0011	Sorin/Liva Nova	60-01-50	Hand Crank	Crank that is turned by hand which enables the pump to be operated by hand in emergency situations
0012	Sorin/Liva Nova	60-01-00	Manual Drive	Enables the pump to be operated manually in emergency situations
0013	Sorin/Liva Nova	12-80-00	Venous Occluder	Occludes (blocks) the deoxygenated blood flow during its passage through the body and heart lung unit by clamping down on the venous line via the venous occluder
0014	Sorin/Liva Nova	12-80-10	Occluder Module	Module mechanism that occludes (blocks) flow
0015	Sorin/Liva Nova	12-80-70	Occluder Head	Head mechanism that occludes (blocks) flow
0016	Sorin/Liva Nova	10-81-30	Variolock Tubing Gate	The Variolock tubing clamp enables clamping of tubing in the heads of roller pumps. A large range of tubing clamp inserts allow for various tubing sizes. They are inserted into the tubing clamp block of the pump heads.
0017	Sorin/Liva Nova	10-61-72	Variolock Tubing Inserts for 3/8" X 3/32" and larger, Blue	Tubing clamp inserts allow for clamping 3/8" X 3/32" tubing size
0018	Sorin/Liva Nova	10-61-73	Variolock Tubing Inserts for 3/8" X 1/16" and smaller, Red	Tubing clamp inserts allow for clamping 3/8" X 1/16" tubing size
0019	Sorin/Liva Nova	10-61-91	Variolock CP Tubing Inserts (2) 1:1 Silver with ration engraved	Cardioplegia tubing clamp insert 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.
0020	Sorin/Liva Nova	28-95-00	S5 Control Desk, 4-slot system Panel	Desk like surface area
0021	Sorin/Liva Nova	28-95-10	Display Module	Display for displaying system data
0022	Sorin/Liva Nova	22-20-20	Pressure sensor module (2 channel)	Measures and displays pressure in the extracorporeal circuit
0023	Sorin/Liva Nova	20-30-20	Temperature sensor module (4 channels) for YSI probes	Measures simultaneous measurement and display of up to 4 temperatures
0024	Sorin/Liva Nova	23-40-00	Level Sensor (incl. 23-27-40, 23-27-	Measures blood levels

			41)	
0025	Sorin/Liva Nova	75-521-548	Holder (required for Level Sensor II 23-27-40)	Holder that holds level sensors
0026	Sorin/Liva Nova	23-27-60	Mounting pads, Level sensor II	Mounting pads for level sensors
0027	Sorin/Liva Nova	23-45-00	3/8" Bubble sensor module w/420 mm holder, incl. (23-07-50, 23-26-96, 23-45-20 and 96-06-10)	Detects bubbles in the tubing system providing protecting the system against air delivery
0028	Sorin/Liva Nova	10-07-48	Tubing insert, metal, 3/8 X 3/32, BLUE	Tubing inserts allow for 3/8" X 3/32" tubing size
0029	Sorin/Liva Nova	48-41-19	Cross tray 4 position W/Power Outlet	Tray with power outlet
0030	Sorin/Liva Nova	35-05-70	Led Lamp 24V	Lamp that provide light
0031	Sorin/Liva Nova	45-41-50	Adapter Plate	Plate for mounting accessories
0032	Sorin/Liva Nova	60-00-60	Centrifugal Pump S5 System	Uses centrifugal forces to transport blood instead of tubing compressions
0033	Sorin/Liva Nova	45-90-75	USA Operator Manual for the CP5 60-00-60	<p>The operator's manual (also called an instruction manual, user guide or owner's manual) is an instructional book or booklet (hard copy of electronic) that is supplied with almost all technologically advanced consumer products such as medical devices, vehicles, home appliances and computer peripherals. Information contained in the owner's manual typically includes:</p> <ul style="list-style-type: none"> •Safety instructions; for liability reasons these can be extensive, often including warnings against performing operations that are ill-advised for product longevity or overall user safety reasons. •Assembly instructions; for products that arrive in pieces for easier shipping. •Installation instructions; for products that need to be installed in a home or workplace. •Setup instructions; for devices that keep track of time or which maintain user accessible state. •Instructions for use. •Programming instructions; for microprocessor controlled products such as VCRs, programmable calculators, and synthesizers.

				<ul style="list-style-type: none"> •Maintenance instructions. •Troubleshooting instructions; for when the product does not work as expected. •Service locations; for when the product requires repair by a factory authorized technician. •Regulatory code compliance information; for example with respect to safety or electromagnetic interference. •Product technical specifications. •Warranty information; sometimes provided as a separate sheet. <p>With the increasing complexity of modern devices, many owner's manuals have become so large that a separate quick start guide is provided. Some owner's manuals are supplied on CD-ROM or on the web. Many businesses offer PDF copies of manuals that can be accessed or downloaded free of charge from their websites.</p>
0034	Sorin/Liva Nova	60-05-65	ERC Clamp (620 mm)	Electrical Remote-Controlled Tubing Clamp (ERC) is designed for operation with SCP (Stockert Centrifugal Pump) to improve the safety of centrifugal perfusion by adding a safeguard against air delivery during the centrifugal blood perfusion. When low level or retrograde flow is detected, the ERC obstructs the arterial line immediately to minimize danger of air delivery.
0035	Sorin/Liva Nova	60-05-60	ERC Clamp (500mm)	Electrical Remote-Controlled Tubing Clamp (ERC) is designed for operation with SCP (Stockert Centrifugal Pump) to improve the safety of centrifugal perfusion by adding a safeguard against air delivery during the centrifugal blood perfusion. When low level or retrograde flow is detected, the ERC obstructs the arterial line immediately to minimize danger of air delivery.
0036	Sorin/Liva Nova	45-91-71	USA Operator Manual for the ERC Clamp	<p>The operator's manual (also called an instruction manual, user guide or owner's manual) is an instructional book or booklet (hard copy or electronic) that is supplied with almost all technologically advanced consumer products such as medical devices, vehicles, home appliances and computer peripherals. Information contained in the owner's manual typically includes:</p> <ul style="list-style-type: none"> •Safety instructions; for liability reasons these can be extensive, often including warnings against performing operations that are ill-advised for product longevity or overall user safety reasons. •Assembly instructions; for products that arrive in pieces for easier shipping. •Installation instructions; for products that need to be installed in a home or workplace. •Setup instructions; for devices that keep track of time or which maintain user accessible state. •Instructions for use. •Programming instructions; for microprocessor controlled products such as VCRs, programmable calculators, and synthesizers. •Maintenance instructions. •Troubleshooting instructions; for when the product does not work as expected.

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0037	Sorin/Liva Nova	0264-2049	IV Pressure Transducer Cable	Cable that connects the pressure transducer to the medical device
0038	Sorin/Liva Nova	06-03-75	SCPC System (level/bubble/pressure configuration)	Stockert Centrifugal Pump Console (SCPC) controls and monitors level, bubble and pressure control
0039	Sorin/Liva Nova	45-04-16	Holder for one pressure transducer	Holder that holds the pressure transducer
0040	Sorin/Liva Nova	48-51-10	Shelf 5 Position	Shelf for storing small parts
0041	Sorin/Liva Nova	25-28-67	Electronic Gas Blender (incl. 55-91-50 & 45-12-02)	Electronic gas blender is used to set, monitor and display the gas flows required for extracorporeal circulation.
0042	Sorin/Liva Nova	050-350-000	Electronic Gas Blender (incl. 050-350-100 & 050-350-200)	Electronic gas blender is used to set, monitor and display the gas flows required for extracorporeal circulation.
0043	Sorin/Liva Nova	25-30-50	Accessories Kit for plugging into Mechanical Blender	Accessory that allows use of mechanical blender
0044	Sorin/Liva Nova	45-90-20	USA Operator Manual for Electronic Gas Blender 25-28-67	<p>The operator's manual (also called an instruction manual, user guide or owner's manual) is an instructional book or booklet (hard copy of electronic) that is supplied with almost all technologically advanced consumer products such as medical devices, vehicles, home appliances and computer peripherals. Information contained in the owner's manual typically includes:</p> <ul style="list-style-type: none"> •Safety instructions; for liability reasons these can be extensive, often including warnings against performing operations that are ill-advised for product longevity or overall user safety reasons. •Assembly instructions; for products that arrive in pieces for easier shipping.

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0045	Sorin/Liva Nova	25-40-70	Console Holder	Holder mechanism for the console
0046	Sorin/Liva Nova	25-60-00	SAT/HCT Monitors and Accessories B-Care 5 Complete	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 hematocrit (Hct %). An integrated thermistor reads the actual venous blood temperature.
0047	Sorin/Liva Nova	45-95-25	USA Operator Manual for SAT/HCT Monitors and Accessories B-Care 5 25-60-00	<p>The operator's manual (also called an instruction manual, user guide or owner's manual) is an instructional book or booklet (hard copy or electronic) that is supplied with almost all technologically advanced consumer products such as medical devices, vehicles, home appliances and computer peripherals. Information contained in the owner's manual typically includes:</p> <ul style="list-style-type: none"> •Safety instructions; for liability reasons these can be extensive, often including warnings against performing operations that are ill-advised for product longevity or overall user safety reasons. •Assembly instructions; for products that arrive in pieces for easier shipping. •Installation instructions; for products that need to be installed in a home or workplace. •Setup instructions; for devices that keep track of time or which maintain user accessible state. •Instructions for use. •Programming instructions; for microprocessor controlled products such as VCRs, programmable calculators, and synthesizers.

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0048	Sorin/Liva Nova	10-86-55	Tubing Clamp, 1/8" x 1/16", VIOLET for small roller pump	Tubing clamp allow for clamping 1/8" x 1/16" tubing size
0049	Sorin/Liva Nova	10-86-56	Tubing Clamp, 1/4" x 1/16", RED	Tubing clamp allow for clamping 1/4" x 1/16" tubing size
0050	Sorin/Liva Nova	45-90-75	USA Operator Manual for the CP5 60-00-60	<p>The operator's manual (also called an instruction manual, user guide or owner's manual) is an instructional book or booklet (hard copy or electronic) that is supplied with almost all technologically advanced consumer products such as medical devices, vehicles, home appliances and computer peripherals. Information contained in the owner's manual typically includes:</p> <ul style="list-style-type: none"> •Safety instructions; for liability reasons these can be extensive, often including warnings against performing operations that are ill-advised for product longevity or overall user safety reasons. •Assembly instructions; for products that arrive in pieces for easier shipping. •Installation instructions; for products that need to be installed in a home or workplace. •Setup instructions; for devices that keep track of time or which maintain user accessible state. •Instructions for use. •Programming instructions; for microprocessor controlled products such as VCRs, programmable calculators, and synthesizers. •Maintenance instructions. •Troubleshooting instructions; for when the product does not work as expected. •Service locations; for when the product requires repair by a factory authorized technician. •Regulatory code compliance information; for example with respect to safety or electromagnetic interference. •Product technical specifications. •Warranty information; sometimes provided as a separate sheet.

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0051	Sorin/Liva Nova	96-414-120	Stockert 3/8" flow probe	Probe that detects flow rate, i.e., blood flow, gas flow.
0052	Sorin/Liva Nova	10-86-55	Tubing insert, 1/8" x 1/16", VIOLET	Tubing clamp inserts allow for clamping 1/8" x 1/16" tubing size
0053	Sorin/Liva Nova	10-81-75	Pump Cover for RP150	Cover that provides protection of the roller pump
0054	Sorin/Liva Nova	48-51-30	5 Position Plexiglass Pump Cover	Cover that provides protection of the roller pump
0055	Sorin/Liva Nova	50-70-57	C-shaped Mast	Mount system for mounting heart-lung bypass unit accessories on an elevated pole or mast comprising a pole mount assembly and clamp members to secure the mounting of items to the pole(s) or mast
0056	Sorin/Liva Nova	50-80-99	Color Knob Set	Colored knobs
0057	Sorin/Liva Nova	27-80-20	Cardioplegia Sensor Module	Provide connection for bubble sensor and pressure transducer for cardioplegia control
0058	Sorin/Liva Nova	24-90-30	Data Management System, Connect Recorder for S5 & C5 Customers, with Dongle (24-90-45)	Perfusion automated electronic charting system capable of real time and retrospective analysis, data management consisting of software and hardware which manages case data in a central database for storing, retrieving displaying, printing or exporting case reports. Provides chart and table formats and allows easy entry of comments, drugs and volumes.
0059	Sorin/Liva Nova	24-90-45	Data Management System, Connect Manager with Dongle	Enables connection to and used with a computer to allow use of protected software and wireless access
0060	Sorin/Liva Nova	24-90-40	Data pad	Touch screen data pad, 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.
0061	Sorin/Liva Nova	29-02-50	Interface Data Management System module for	Computer interface between the heart-lung machine system and external devices

			connection of 4 external device connections via RS-232-order	
0062	Sorin/Liva Nova	29-02-xx	Interface Data Management System module for connection of VA EMR	Computer interface between the heart-lung machine system and VA's EMR
0063	Sorin/Liva Nova	45-90-14	USA User manual Sorin Connect	<p>The operator's manual (also called an instruction manual, user guide or owner's manual) is an instructional book or booklet (hard copy or electronic) that is supplied with almost all technologically advanced consumer products such as medical devices, vehicles, home appliances and computer peripherals. Information contained in the owner's manual typically includes:</p> <ul style="list-style-type: none"> •Safety instructions; for liability reasons these can be extensive, often including warnings against performing operations that are ill-advised for product longevity or overall user safety reasons. •Assembly instructions; for products that arrive in pieces for easier shipping. •Installation instructions; for products that need to be installed in a home or workplace. •Setup instructions; for devices that keep track of time or which maintain user accessible state. •Instructions for use. •Programming instructions; for microprocessor controlled products such as VCRs, programmable calculators, and synthesizers. •Maintenance instructions. •Troubleshooting instructions; for when the product does not work as expected. •Service locations; for when the product requires repair by a factory authorized technician. •Regulatory code compliance information; for example with respect to safety or electromagnetic interference. •Product technical specifications. •Warranty information; sometimes provided as a separate sheet. <p>With the increasing complexity of modern devices, many owner's manuals have become so large that a separate quick start guide is provided. Some owner's manuals are supplied on CD-ROM or on the web. Many businesses offer PDF copies of manuals that can be accessed or downloaded free of charge from their websites.</p>
0064	Sorin/Liva Nova	45-90-74	USA User Manual Data pad II	<p>The operator's manual (also called an instruction manual, user guide or owner's manual) is an instructional book or booklet (hard copy or electronic) that is supplied with almost all technologically advanced consumer products such as medical devices, vehicles, home appliances and computer peripherals. Information contained in the owner's manual typically</p>

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0065	Sorin/Liva Nova	080276011	Data Management Connection to S5 Medical Device	Computer interface between the heart-lung machine system and external devices
0066	Sorin/Liva Nova	45-12-68	Data Management CONN CABLE, S5 to Medical Device	Computer interface between the heart-lung machine system and VA's EMR
0067	Sorin/Liva Nova	45-12-46	Data Management Cable, 3M Extension	Cable for connecting data management system
0068	Sorin/Liva Nova	16-02-80	Warming/Cooling Unit for Heart-Lung Bypass Surgery (includes: standard unit, ice based unit with remote, wheel set, tubing with connectors / 16-02-	Warming/Cooling Units: Heart-Lung Bypass warm or cool the patient by extracorporeal heat exchange with the patient's perfused blood during heart-lung bypass procedures. These units consist of a central device including a cooling system, a heating element, and pumps for heating and circulating liquid to a heat exchanger; the heat exchanger controls the blood and/or cardioplegic solution temperature during the entire cardiovascular procedure (e.g., induces hypothermia, warms the blood).

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0069	Sorin/Liva Nova	45-12-16	Warming/Cooling Interface cable to Heart-Lung Bypass Unit	Cable for connecting warming/cooling unit to heart-lung bypass unit
0070	Sorin/Liva Nova	16-09-20	Warming/Cooling Telescope Mast for Warming/Cooling Unit	Mount system for mounting warming/cooling unit accessories on an elevated pole or mast comprising a pole mount assembly and clamp members to secure the mounting of items to the pole(s), or mast
0071	Sorin/Liva Nova	16-02-60	Warming/Cooling Ice Container	Container for containing ice
0072	Sorin/Liva Nova	16-10-50	Warming/Cooling Blanket for Adults	An adult size material used as a blanket for which warming/cooling fluid circulates through to provide warmth or cooling of the patient
0073	Sorin/Liva Nova	16-10-51	Warming/Cooling Blanket for Children	A child size material used as a blanket for which warming/cooling fluid circulates through to provide warmth or cooling of the patient
0074	Sorin/Liva Nova	16-10-55	Warming/Cooling Tubing Set	Tubing that connects the warming/cooling unit to a warming/cooling blanket or heat-lung bypass unit.
0075	Sorin/Liva Nova	16-10-10	Warming/Cooling Adapter connector set for blanket	Connector that adapts tubing to the warming/cooling blanket to allow proper connection between the tubing and the warming/cooling unit.
0076	Sorin/Liva Nova	CP_IFU_1 6-XX- XX_USA_0 14	USA Operator Manual for the Warming/Cooling Unit	<p>The operator's manual (also called an instruction manual, user guide or owner's manual) is an instructional book or booklet (hard copy of electronic) that is supplied with almost all technologically advanced consumer products such as medical devices, vehicles, home appliances and computer peripherals. Information contained in the owner's manual typically includes:</p> <ul style="list-style-type: none"> •Safety instructions; for liability reasons these can be extensive, often including warnings against performing operations that are ill-advised for product longevity or overall user safety reasons. •Assembly instructions; for products that arrive in pieces for easier shipping. •Installation instructions; for products that need to be installed in a home or workplace. •Setup instructions; for devices that keep track of time or which maintain user accessible state. •Instructions for use. •Programming instructions; for microprocessor controlled products such as VCRs, programmable calculators, and synthesizers. •Maintenance instructions. •Troubleshooting instructions; for when the product does not work as expected. •Service locations; for when the product requires repair by a factory authorized technician. •Regulatory code compliance information; for example with respect to safety or

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0077	Sorin/Liva Nova	SM-16-XX-XX.03 ENG	USA Service Manual for the Warming/Cooling Unit	The service manual (also called a technical manual, maintenance manual, or technical guide) is an instructional book or booklet (hard copy or electronic) that is supplied with almost all technologically advanced consumer products such as medical devices, vehicles, home appliances and computer peripherals. Information contained in the service manual typically includes: instructions for installation, theory of operation, use, preventive maintenance, troubleshooting and repair, parts list, system diagrams, support information and training requirements for the effective deployment of an equipment, machine, process, or system.
0078	Sorin/Liva Nova	Clinical User Training	Clinical User Training for the Heart-Lung Bypass Unit and Warming/Cooling Unit	The action of teaching a person, in this case a VAMC clinician (specifically a Perfusionist) a particular skill or type of behavior, in this case the proper use of the heart lung machine, data management system , warming/cooling units and all related accessories
0079	Sorin/Liva Nova	Technical Training	Biomedical Technical Training for the Heart-Lung Bypass Unit and Warming/Cooling Unit	The action of teaching a person, in this case a VAMC technical staff (specifically a Biomedical technician or engineer) a particular skill or type of behavior, in this case the proper scheduled and unscheduled maintenance, troubleshooting, parts and service support procedures, interfaces and other technical aspects, related to the maintenance of the heart lung machine, data management system , warming/cooling units and all related accessories

Heart-Lung Bypass Units

SC 1 Heart-Lung Bypass Units must provide safe and effective cardiac perfusion treatment, be state-of-the-art technology and provide universal compatibility with cardiac perfusion accessories.

SC 2 Heart-Lung Bypass Units must demonstrate compliance with requirements of widely accepted product safety standards, as determined through independent testing by organizations such as the American National Standards Institute (ANSI), Underwriters Laboratories (UL2601), American Section of the International Association for Testing Materials, International Electrotechnical Commission (IEC 60601-1). Must be FDA approved.

SC 3 Heart-Lung Bypass Units base cart console must be durable, non-absorbing, corrosion-resistant, modular design and allow for various configurations of pumps, upright masts, poles, cross bars, work trays, IV solution hangers and module lamps.

SC 4 Heart-Lung Bypass Units must be able to be cleaned using hospital grade cleaning solutions. Surfaces must be nonabsorbent. Surface material must be able to tolerate a very high frequency of intense cleaning. Vendor must provide training instructions, procedures, and documentation necessary to properly and safely clean and disinfect the equipment and accessories between patient uses.

SC 1 through SC 4 are associated with the following CLINS: 0001 to 0067.

CLIN	MFG	P/N	Description
0001	Sorin/LivaNova	48-40-00 4	Perfusion System (Heart-Lung Bypass Unit) 4 Pump S5 console (includes: control desk, display modules, timer, power supply, cross tray, emergency power supply, electronic and power supply pack and mast system, hand crank, hand crack bracket, poles, console holders, uninterruptable power supply/battery backup, LED Lamp, vacuum regulator)
0002	Sorin/LivaNova	45-09-10	Cable holding and organizing system 1
0003	Sorin/LivaNova	45-09-11	Cable holding and organizing system
0004	Sorin/LivaNova	43-42-61	Cap for fast clamp (6 pcs.)
0007	Sorin/LivaNova	10-80-00	S5 Pump Module, Single Roller Pump
0008	Sorin/LivaNova	10-85-00	S5 Pump Module, Double Roller Pump
0009	Sorin/LivaNova	10-84-60	S5 Pump Module, Pump Tray for RP150
0010	Sorin/LivaNova	10-84-64	S5 Pump Module, Double Pump Tray
0011	Sorin/LivaNova	60-01-50	Hand Crank
0012	Sorin/LivaNova	60-01-00	Manual Drive
0013	Sorin/LivaNova	12-80-00	Venous Occluder
0014	Sorin/LivaNova	12-80-10	Occluder Module
0015	Sorin/LivaNova	12-80-70	Occluder Head
0016	Sorin/LivaNova	10-81-30	Variolock Tubing Gate
0017	Sorin/LivaNova	10-61-72	Variolock Tubing Inserts for 3/8" X 3/32" and larger, Blue

0018	Sorin/LivaNova	10-61-73	Variolock Tubing Inserts for 3/8" X 1/16" and smaller, Red
0019	Sorin/LivaNova	10-61-91	Variolock CP Tubing Inserts (2) 1:1 Silver with ration engraved
0020	Sorin/LivaNova	28-95-00	S5 Control Desk, 4-slot system Panel
0021	Sorin/LivaNova	28-95-10	Display Module
0022	Sorin/LivaNova	22-20-20	Pressure sensor module (2 channel)
0023	Sorin/LivaNova	20-30-20	Temperature sensor module (4 channels) for YSI probes
0024	Sorin/LivaNova	23-40-00	Level Sensor (incl. 23-27-40, 23-27-41)
0025	Sorin/LivaNova	75-521-548	Holder (required for Level Sensor II 23-27-40)
0026	Sorin/LivaNova	23-27-60	Mounting pads, Level sensor II
0027	Sorin/LivaNova	23-45-00	3/8" Bubble sensor module w/420 mm holder, incl. (23-07-50, 23-26-96, 23-45-20 and 96-06-10)
0028	Sorin/LivaNova	10-07-48	Tubing insert, metal, 3/8 X 3/32, BLUE
0029	Sorin/LivaNova	48-41-19	Crosstray 4 position W/Power Outlet
0030	Sorin/LivaNova	35-05-70	Led Lamp 24V
0031	Sorin/LivaNova	45-41-50	Adapter Plate
0032	Sorin/LivaNova	60-00-60	Centrifugal Pump S5 System
0034	Sorin/LivaNova	60-05-65	ERC Clamp (620 mm)
0035	Sorin/LivaNova	60-05-60	ERC Clamp (500mm)
0037	Sorin/LivaNova	0264-2049	IV Pressure Transducer Cable
0038	Sorin/LivaNova	06-03-75	SCPC System (level/bubble/pressure configuration)
0039	Sorin/LivaNova	45-04-16	Holder for one pressure transducer
0040	Sorin/LivaNova	48-51-10	Shelf 5 Position
0041	Sorin/LivaNova	25-28-67	Electronic Gas Blender (incl. 55-91-50 & 45-12-02)
0042	Sorin/LivaNova	050-350-000	Electronic Gas Blender (incl. 050-350-100 & 050-350-200)
0043	Sorin/LivaNova	25-30-50	Accessories Kit for plugging into Mechanical Blender
0045	Sorin/LivaNova	25-40-70	Console Holder
0046	Sorin/LivaNova	25-60-00	SAT/HCT Monitors and Accessories B-Care 5 Complete
0048	Sorin/LivaNova	10-86-55	Tubing Clamp, 1/8" x 1/16", VIOLET for small roller pump
0049	Sorin/LivaNova	10-86-56	Tubing Clamp, 1/4" x 1/16", RED
0051	Sorin/LivaNova	96-414-120	Stockert 3/8" flow probe
0052	Sorin/LivaNova	10-86-55	Tubing insert, 1/8" x 1/16", VIOLET
0053	Sorin/LivaNova	10-81-75	Pump Cover for RP150
0054	Sorin/LivaNova	48-51-30	5 Position Plexiglass Pump Cover
0055	Sorin/LivaNova	50-70-57	C-shaped Mast
0056	Sorin/LivaNova	50-80-99	Color Knob Set
0057	Sorin/LivaNova	27-80-20	Cardioplegia Sensor Module
0058	Sorin/LivaNova	24-90-30	Data Management System, Connect Recorder for S5 & C5 Customers, with Dongle (24-90-45)

0059	Sorin/LivaNova	24-90-45	Data Management System, Connect Manager with Dongle
0060	Sorin/LivaNova	24-90-40	Data pad
0061	Sorin/LivaNova	29-02-50	Interface Data Management System module for connection of 4 external device connections via RS 232 order
0062	Sorin/LivaNova	29-02-xx	Interface Data Management System module for connection of VA EMR
0065	Sorin/LivaNova	080276011	Data Management Connection to S5 Medical Device
0066	Sorin/LivaNova	45-12-68	Data Management CONN CABLE, S5 to Medical Device
0067	Sorin/LivaNova	45-12-46	Data Management Cable, 3M Extension

SC 5 Heart-Lung Bypass Units and accessories must operate on 100-110 VAC, 60Hz and must not exceed 15 amps. The power cord must be no shorter than 10 feet in length, capable of being coiled or retracted, and must connect to existing power receptacles. The power cord must be durable and able to withstand the force of being pulled from the wall receptacle while still charging a unit as it's rolled away for use.

SC 6 Heart-Lung Bypass Units must include an integrated uninterruptable power supply (UPS) or backup battery that provides complete heart-lung bypass unit operation for a minimum of 1 hour. Battery recharge time must achieve full-charge state within 2 hours.

SC 5 and SC 6 are associated with the CLIN 0001.

CLIN	MFG	P/N	Description
0001	Sorin/LivaNova	48-40-00 4	Perfusion System (Heart-Lung Bypass Unit) 4 Pump S5 console (includes: control desk, display modules, timer, power supply, cross tray, emergency power supply, electronic and power supply pack and mast system, hand crank, hand crack bracket, poles, console holders, uninterruptable power supply/battery backup, LED Lamp, vacuum regulator)

~~SC 7 Heart-Lung Bypass Units must have a user-friendly and intuitive user interface and a cardiac perfusion electronic data management record keeping system including the capability to support an electronic perfusion record for each cardio-pulmonary bypass case. The system must be capable of interfacing with CPRS (or whatever electronic record the organization is using e.g. Corner) as part of the patient's permanent medical record and must interface with associated perfusion devices. The system must be capable of functioning on VA computers in compliance with all VA security policies. The system must provide creation of custom forms, charts, checklists, reports, equipment id, communication, scheduling and file uploads.~~

~~***SC 7 is associated with the following CLINS: 0001, 0058 to 0067.***~~

CLIN	MFG	P/N	Description
0001	Sorin/LivaNova	48-40-00 4	Perfusion System (Heart-Lung Bypass Unit) 4 Pump S5 console (includes: control desk, display modules, timer, power supply, cross tray, emergency power supply, electronic and power supply pack and mast system, hand crank, hand crack bracket, poles, console holders, uninterruptable power supply/battery backup, LED Lamp, vacuum regulator)

0058	Sorin/LivaNova	24-90-30	Data Management System, Connect Recorder for S5 & C5 Customers, with Dongle (24-90-45)
0059	Sorin/LivaNova	24-90-45	Data Management System, Connect Manager with Dongle
0060	Sorin/LivaNova	24-90-40	Data pad
0061	Sorin/LivaNova	29-02-50	Interface Data Management System module for connection of 4 external device connections via RS-232-order
0062	Sorin/LivaNova	29-02-xx	Interface Data Management System module for connection of VA EMR
0063	Sorin/LivaNova	45-90-14	USA User manual Sorin Connect
0064	Sorin/LivaNova	45-90-74	USA User Manual Data pad II
0065	Sorin/LivaNova	080276011	Data Management Connection to S5 Medical Device
0066	Sorin/LivaNova	45-12-68	Data Management CONN CABLE, S5 to Medical Device
0067	Sorin/LivaNova	45-12-46	Data Management Cable, 3M Extension

SC 8 Heart-Lung Bypass Units roller pump types must provide single or double roller pumps with rotating raceways. Centrifugal pump must provide method for retrograde flow avoidance when used for systemic circulation. All pumps must display flow rates and provide emergency manual drivers and continually monitor blood flow using flow rate probe/transducers to accurately reflect the flow delivered to the patient.

SC 8 is associated with the following CLINS: 0001, 0007 to 0010, 0032 and 0038.

CLIN	MFG	P/N	Description
0001	Sorin/LivaNova	48-40-00 4	Perfusion System (Heart-Lung Bypass Unit) 4 Pump S5 console (includes: control desk, display modules, timer, power supply, cross tray, emergency power supply, electronic and power supply pack and mast system, hand crank, hand crack bracket, poles, console holders, uninterruptable power supply/battery backup, LED Lamp, vacuum regulator)
0007	Sorin/LivaNova	10-80-00	S5 Pump Module, Single Roller Pump
0008	Sorin/LivaNova	10-85-00	S5 Pump Module, Double Roller Pump
0009	Sorin/LivaNova	10-84-60	S5 Pump Module, Pump Tray for RP150
0010	Sorin/LivaNova	10-84-64	S5 Pump Module, Double Pump Tray
0032	Sorin/LivaNova	60-00-60	Centrifugal Pump S5 System
0038	Sorin/LivaNova	06-03-75	SCPC System (level/bubble/pressure configuration)

SC 9 Heart-Lung Bypass Units must provide a touch screen central control display monitor and user interface for monitoring and controlling pumps, alarms, alerts, timers, temperatures (patient and device arterial, venous, myocardial, cardioplegia (including cardioplegia dose, delivery method, flow, line pressure (antegrade), coronary sinus pressure (retrograde) and ischemic intervals, blenders, Venous saturation /hematocrit (or hemoglobin) and/or blood gas monitoring and warming/cooling water temperature). The display must include flow rate (minimum of 1 per module), temperature (minimum of 4), pressure (minimum of 2), timers (minimum of 3) and Cardioplegia flow and pressure. Audible and visual alarms must allow user to define pump responses to the alarms including each level detector, bubble detector, temperature detector, pressures detector and retrograde flow detector as well as monitoring of the arterial line, cardioplegia delivery system and venous reservoir. Must be capable of servo

regulated control of the arterial/cardioplegia pumps and allow for interruption to the arterial/cardioplegia flow and must be positioned to enable timely identification and action.

SC 9 is associated with the following CLINS: 0001, 0020 to 0027, 0037 to 0043.

CLIN	MFG	P/N	Description
0001	Sorin/LivaNova	48-40-00 4	Perfusion System (Heart-Lung Bypass Unit) 4 Pump S5 console (includes: control desk, display modules, timer, power supply, cross tray, emergency power supply, electronic and power supply pack and mast system, hand crank, hand crack bracket, poles, console holders, uninterruptable power supply/battery backup, LED Lamp, vacuum regulator)
0020	Sorin/LivaNova	28-95-00	S5 Control Desk, 4-slot system Panel
0021	Sorin/LivaNova	28-95-10	Display Module
0022	Sorin/LivaNova	22-20-20	Pressure sensor module (2 channel)
0023	Sorin/LivaNova	20-30-20	Temperature sensor module (4 channels) for YSI probes
0024	Sorin/LivaNova	23-40-00	Level Sensor (incl. 23-27-40, 23-27-41)
0025	Sorin/LivaNova	75-521-548	Holder (required for Level Sensor II 23-27-40)
0026	Sorin/LivaNova	23-27-60	Mounting pads, Level sensor II
0027	Sorin/LivaNova	23-45-00	3/8" Bubble sensor module w/420 mm holder, incl. (23-07-50, 23-26-96, 23-45-20 and 96-06-10)
0037	Sorin/LivaNova	0264-2049	IV Pressure Transducer Cable
0038	Sorin/LivaNova	06-03-75	SCPC System (level/bubble/pressure configuration)
0039	Sorin/LivaNova	45-04-16	Holder for one pressure transducer
0041	Sorin/LivaNova	25-28-67	Electronic Gas Blender (incl. 55-91-50 & 45-12-02)
0042	Sorin/LivaNova	050-350-000	Electronic Gas Blender (incl. 050-350-100 & 050-350-200)
0043	Sorin/LivaNova	25-30-50	Accessories Kit for plugging into Mechanical Blender

Heart-Lung Bypass Units Biomedical Training

SC 1 Vendor must provide Biomedical technical training for overall maintenance and service by facilities technical staff to include factory service training courses that provide complete information on maintenance and repair of the system.

SC 2 Vendor shall provide any special service tools and/or test equipment comparable with that provided to the OEM's service personnel.

SC 3 Vendor must incur all transportation, tuition and lodging costs for service and maintenance technicians for 3 days of training for up to two Biomedical Engineer(s) per facility.

SC 1 through SC 3 are associated with the CLIN 0079.

CLIN	MFG	P/N	Description
0079	Sorin/LivaNova	Technical Training	Biomedical Technical Training for the Heart-Lung Bypass Unit and Warming/Cooling Unit

SC 4 Two (2) Service and Two (2) Operator manuals/CDs must be provided for each heart-lung bypass unit. Service manuals must include troubleshooting guides, necessary diagnostic software and equipment, schematic diagrams, and parts lists.

SC 4 is associated with the CLINS listed below.

CLIN	MFG	P/N	Description
0005	Sorin/LivaNova	45-95-11	USA S5 Console Operators Manual
0006	Sorin/LivaNova	SM-48-40-00	USA S5 System Service Manual
0033	Sorin/LivaNova	45-90-75	USA Operator Manual for the CP5 60-00-60
0036	Sorin/LivaNova	45-91-71	USA Operator Manual for the ERC Clamp
0044	Sorin/LivaNova	45-90-20	USA Operator Manual for Electronic Gas Blender 25-28-67
0047	Sorin/LivaNova	45-95-25	USA Operator Manual for SAT/HCT Monitors and Accessories B-Care 5 25-60-00
0050	Sorin/LivaNova	45-90-75	USA Operator Manual for the CP5 60-00-60
0063	Sorin/LivaNova	45-90-14	USA User manual Sorin Connect
0064	Sorin/LivaNova	45-90-74	USA User Manual Data pad II

Heart-Lung Bypass Units Clinical User Training

SC 1 Initial On-site User Training (40 hours), provided by a qualified cardiac perfusion clinical specialist instructor, must include information on how to operate and clean/disinfect the equipment safely and effectively and must include on-site Go-Live training.

SC 2 Vendor must provide DVD and/or web based training.

SC 1 and SC 2 are associated with the CLIN 0078.

CLIN	MFG	P/N	Description
0078	Sorin/LivaNova	Clinical User Training	Clinical User Training for the Heart-Lung Bypass Unit and Warming/Cooling Unit

SC 3 Vendor must provide an extended warranty that covers all accessories and parts.

SC 4 Vendor must provide assembly and installation services required to prepare the units and accessories for clinical use.

SC 3 and SC 4 are associated with the following CLINS: 0001 to 0067.

CLIN	MFG	P/N	Description
0001	Sorin/LivaNova	48-40-00 4	Perfusion System (Heart-Lung Bypass Unit) 4 Pump S5 console (includes: control desk, display modules, timer, power supply, cross tray, emergency power supply, electronic and power supply pack and mast system, hand crank, hand crack bracket, poles, console holders, uninterruptable power supply/battery backup, LED Lamp, vacuum regulator)
0002	Sorin/LivaNova	45-09-10	Cable holding and organizing system 1
0003	Sorin/LivaNova	45-09-11	Cable holding and organizing system
0004	Sorin/LivaNova	43-42-61	Cap for fast clamp (6 pcs.)
0007	Sorin/LivaNova	10-80-00	S5 Pump Module, Single Roller Pump
0008	Sorin/LivaNova	10-85-00	S5 Pump Module, Double Roller Pump
0009	Sorin/LivaNova	10-84-60	S5 Pump Module, Pump Tray for RP150
0010	Sorin/LivaNova	10-84-64	S5 Pump Module, Double Pump Tray
0011	Sorin/LivaNova	60-01-50	Hand Crank
0012	Sorin/LivaNova	60-01-00	Manual Drive
0013	Sorin/LivaNova	12-80-00	Venous Occluder
0014	Sorin/LivaNova	12-80-10	Occluder Module
0015	Sorin/LivaNova	12-80-70	Occluder Head
0016	Sorin/LivaNova	10-81-30	Variolock Tubing Gate
0017	Sorin/LivaNova	10-61-72	Variolock Tubing Inserts for 3/8" X 3/32" and larger, Blue
0018	Sorin/LivaNova	10-61-73	Variolock Tubing Inserts for 3/8" X 1/16" and smaller, Red
0019	Sorin/LivaNova	10-61-91	Variolock CP Tubing Inserts (2) 1:1 Silver with ration engraved
0020	Sorin/LivaNova	28-95-00	S5 Control Desk, 4-slot system Panel
0021	Sorin/LivaNova	28-95-10	Display Module
0022	Sorin/LivaNova	22-20-20	Pressure sensor module (2 channel)
0023	Sorin/LivaNova	20-30-20	Temperature sensor module (4 channels) for YSI probes
0024	Sorin/LivaNova	23-40-00	Level Sensor (incl. 23-27-40, 23-27-41)
0025	Sorin/LivaNova	75-521-548	Holder (required for Level Sensor II 23-27-40)
0026	Sorin/LivaNova	23-27-60	Mounting pads, Level sensor II
0027	Sorin/LivaNova	23-45-00	3/8" Bubble sensor module w/420 mm holder, incl. (23-07-50, 23-26-96, 23-45-20 and 96-06-10)
0028	Sorin/LivaNova	10-07-48	Tubing insert, metal, 3/8 X 3/32, BLUE
0029	Sorin/LivaNova	48-41-19	Crosstray 4 position W/Power Outlet
0030	Sorin/LivaNova	35-05-70	Led Lamp 24V
0031	Sorin/LivaNova	45-41-50	Adapter Plate
0032	Sorin/LivaNova	60-00-60	Centrifugal Pump S5 System

0034	Sorin/LivaNova	60-05-65	ERC Clamp (620 mm)
0035	Sorin/LivaNova	60-05-60	ERC Clamp (500mm)
0037	Sorin/LivaNova	0264-2049	IV Pressure Transducer Cable
0038	Sorin/LivaNova	06-03-75	SCPC System (level/bubble/pressure configuration)
0039	Sorin/LivaNova	45-04-16	Holder for one pressure transducer
0040	Sorin/LivaNova	48-51-10	Shelf 5 Position
0041	Sorin/LivaNova	25-28-67	Electronic Gas Blender (incl. 55-91-50 & 45-12-02)
0042	Sorin/LivaNova	050-350-000	Electronic Gas Blender (incl. 050-350-100 & 050-350-200)
0043	Sorin/LivaNova	25-30-50	Accessories Kit for plugging into Mechanical Blender
0045	Sorin/LivaNova	25-40-70	Console Holder
0046	Sorin/LivaNova	25-60-00	SAT/HCT Monitors and Accessories B-Care 5 Complete
0048	Sorin/LivaNova	10-86-55	Tubing Clamp, 1/8" x 1/16", VIOLET for small roller pump
0049	Sorin/LivaNova	10-86-56	Tubing Clamp, 1/4" x 1/16", RED
0051	Sorin/LivaNova	96-414-120	Stockert 3/8" flow probe
0052	Sorin/LivaNova	10-86-55	Tubing insert, 1/8" x 1/16", VIOLET
0053	Sorin/LivaNova	10-81-75	Pump Cover for RP150
0054	Sorin/LivaNova	48-51-30	5 Position Plexiglass Pump Cover
0055	Sorin/LivaNova	50-70-57	C-shaped Mast
0056	Sorin/LivaNova	50-80-99	Color Knob Set
0057	Sorin/LivaNova	27-80-20	Cardioplegia Sensor Module
0058	Sorin/LivaNova	24-90-30	Data Management System, Connect Recorder for S5 & C5 Customers, with Dongle (24-90-45)
0059	Sorin/LivaNova	24-90-45	Data Management System, Connect Manager with Dongle
0060	Sorin/LivaNova	24-90-40	Data pad
0061	Sorin/LivaNova	29-02-50	Interface Data Management System module for connection of 4 external device connections via RS-232-order
0062	Sorin/LivaNova	29-02-xx	Interface Data Management System module for connection of VA EMR
0065	Sorin/LivaNova	080276011	Data Management Connection to S5 Medical Device
0066	Sorin/LivaNova	45-12-68	Data Management CONN CABLE, S5 to Medical Device
0067	Sorin/LivaNova	45-12-46	Data Management Cable, 3M Extension

Warming/Cooling Units (For Use with Heart-Lung Bypass Units)

SC 1 Warming/Cooling Units must be state-of-the-art and provide adaptive temperature control technology with efficient pumps that produce a high flow rate and rapidly control and deliver accurate temperature-controlled water for heat exchange during cardiopulmonary bypass procedures including:

- flow rates (4.5 L to 20 L, LPM)
- temperature-controls; warm/cool ranges for patient/oxygenator (2 C to 41 C)
- cool range for Cardioplegia (2 C to 10 C)
- warm range for Cardioplegia (15 C to 41 C)
- warming/cooling ranges for patient/blanket (2 C to 41 C)

SC 2 Warming/Cooling Units must demonstrate compliance with requirements of widely accepted product safety standards, as determined through independent testing by organizations such as the American National Standards Institute (ANSI), Underwriters Laboratories (UL2601), American Section of the International Association for Testing Materials, International Electrotechnical Commission (IEC 60601-1-1. Must be FDA approved.

SC 3 Warming/Cooling Units must be corrosion-resistant and must be able to be cleaned using hospital grade cleaning solutions. Surfaces must be durable and nonabsorbent. Surface material must be able to tolerate a very high frequency of intense cleaning. Vendor must provide training instructions, procedures, and documentation necessary to properly and safely clean and disinfect the equipment and accessories between patient uses.

SC 1 through SC 3 are associated with the following CLINS: 0068 to 0075.

CLIN	MFG	P/N	Description
0068	Sorin/LivaNova	16-02-80	Warming/Cooling Unit for Heart-Lung Bypass Surgery (includes: standard unit, ice based unit with remote, wheel set, tubing with connectors / 16-02-80
0069	Sorin/LivaNova	45-12-16	Warming/Cooling Interface cable to Heart-Lung Bypass Unit
0070	Sorin/LivaNova	16-09-20	Warming/Cooling Telescope Mast for Warming/Cooling Unit
0071	Sorin/LivaNova	16-02-60	Warming/Cooling Ice Container
0072	Sorin/LivaNova	16-10-50	Warming/Cooling Blanket for Adults
0073	Sorin/LivaNova	16-10-51	Warming/Cooling Blanket for Children
0074	Sorin/LivaNova	16-10-55	Warming/Cooling Tubing Set
0075	Sorin/LivaNova	16-10-10	Warming/Cooling Adapter connector set for blanket

~~SC 4 Warming/Cooling Units must have separate dual reservoirs to permit instant changeover from warming to cooling. Each reservoir must have its own control mechanism for starting/stopping, temperature and alarm control; two independent heating and cooling systems including: two separate circuits for the patient/oxygenator, patient/cardioplegia, and patient/blanket.~~

SC 5 Warming/Cooling Units must operate on 100-120 VAC or 210/250VAC (220/240VAC nominal), 60Hz and must not exceed 16 amps. The power cord must be no shorter than 10 feet in length, capable of being coiled or retracted, and must connect to existing power receptacles. The power cord must be durable and able to withstand the force of being pulled from the wall receptacle while still charging a unit as it's rolled away for use.

SC 6 Warming/Cooling Units must have a user-friendly and intuitive user interface and touch screen for controlling and monitoring a display of temperatures (separate settings/displays for patient/oxygenator, warm cardioplegia, cold cardioplegia, patient/blanket). Audible and visual alarms must allow user to define responses to the alarms including each temperature detector.

SC 7 Warming/cooling unit air flow (internal fan(s), intake and exhaust ports) must be designed to minimize risk of nontuberculous mycobacterial infections.

SC 4 through SC 7 are associated with the CLIN 0068.

CLIN	MFG	P/N	Description
0068	Sorin/LivaNova	16-02-80	Warming/Cooling Unit for Heart-Lung Bypass Surgery (includes: standard unit, ice based unit with remote, wheel set, tubing with connectors / 16-02-80

SC 8 Warming/cooling unit disposables must be universally compatible

SC 8 is associated with the following CLINS: 0072 to 0075.

CLIN	MFG	P/N	Description
0072	Sorin/LivaNova	16-10-50	Warming/Cooling Blanket for Adults
0073	Sorin/LivaNova	16-10-51	Warming/Cooling Blanket for Children
0074	Sorin/LivaNova	16-10-55	Warming/Cooling Tubing Set
0075	Sorin/LivaNova	16-10-10	Warming/Cooling Adapter connector set for blanket

Warming/Cooling Units Biomedical Training

SC 1 Vendor must provide Biomedical technical training for overall maintenance and service to facilities technical staff to include factory service training courses that provide complete information on maintenance and repair of the system.

SC 2 Vendor shall provide any special service tools and/or test equipment comparable with that provided to the OEM's service personnel.

SC 3 Vendor must incur all transportation, tuition and lodging costs for service and maintenance technical for 3 days of training for up to

two Biomedical Engineer staff per facility.

SC 1 through SC 3 are associated with the CLIN 0079.

CLIN	MFG	P/N	Description
0079	Sorin/LivaNova	Technical Training	Biomedical Technical Training for the Heart-Lung Bypass Unit and Warming/Cooling Unit

SC 4 (2) Service and (2) Operator manuals/CDs must be provided for each heart-lung bypass unit. Service manuals must include troubleshooting guides, necessary diagnostic software and equipment, schematic diagrams, and parts lists.

SC 4 associated with the following CLINS: 0076 and 0077.

CLIN	MFG	P/N	Description
0076	Sorin/LivaNova	CP_IFU_16-XX-XX_USA_014	USA Operator Manual for the Warming/Cooling Unit
0077	Sorin/LivaNova	SM-16-XX-XX.03 ENG	USA Service Manual for the Warming/Cooling Unit

Warming/Cooling Units User Training

SC 1 Initial On-site User Training provided by a qualified cardiac perfusion clinical specialist instructor, must include information on how to operate and clean/disinfect the equipment safely and effectively and must include on-site Go-Live training.

SC 2 Vendor must provide DVD and/or web based training.

SC 1 and SC 2 are associated with the CLIN 0078.

CLIN	MFG	P/N	Description
0078	Sorin/LivaNova	Clinical User Training	Clinical User Training for the Heart-Lung Bypass Unit and Warming/Cooling Unit

SC 3 Vendor must provide an extended warranty that covers all accessories and parts.

SC 4 Vendor must provide assembly and installation services required to prepare the units and accessories for clinical use.

SC 3 and SC 4 are associated with the following CLINS: 0068 and 0075.

CLIN	MFG	P/N	Description
0068	Sorin/LivaNova	16-02-80	Warming/Cooling Unit for Heart-Lung Bypass Surgery (includes: standard unit, ice based unit with remote,

			wheel set, tubing with connectors / 16-02-80
0069	Sorin/LivaNova	45-12-16	Warming/Cooling Interface cable to Heart-Lung Bypass Unit
0070	Sorin/LivaNova	16-09-20	Warming/Cooling Telescope Mast for Warming/Cooling Unit
0071	Sorin/LivaNova	16-02-60	Warming/Cooling Ice Container
0072	Sorin/LivaNova	16-10-50	Warming/Cooling Blanket for Adults
0073	Sorin/LivaNova	16-10-51	Warming/Cooling Blanket for Children
0074	Sorin/LivaNova	16-10-55	Warming/Cooling Tubing Set
0075	Sorin/LivaNova	16-10-10	Warming/Cooling Adapter connector set for blanket

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