BC "MOLDINDCONBANK" S.A.
Filiala "Invest"

Filiala „Invest" BC „Moldindconbank" SA confirmă existenţa contului curent in moneda nationala al **"BIOSISTEM MLD" S.R.L. (c/f 1010600028048)**, cu **IBAN   MD95ML000000002251429243**.

Codul băncii MOLDMD2X329.

Director   **Nina Ţurcan**

Director financiar   **Nina Balmuş**

REPUBLICA MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

Societatea cu Răspundere Limitată "BIOSISTEM MLD"

ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

Numărul de identificare de stat - codul fiscal

1010600028048

Data înregistrării   **12.08.2010**

Data eliberării   **12.08.2010**

Svirepova Ludmila, registrator

*Funcția, numele, prenumele persoanei
care a eliberat certificatul*

semnătura

MD 0101250

AGENŢIA SERVICII PUBLICE

Departamentul înregistrare şi licenţiere a unităţilor de drept

EXTRAS

din Registrul de stat al persoanelor juridice

Nr. **531522** data **15.09.2023**

Denumirea completă: **Societatea cu Răspundere Limitată "BIOSISTEM MLD"**
Denumirea prescurtată: **"BIOSISTEM MLD" S.R.L.**
Forma juridică de organizare: **Societate cu răspundere limitată,**
Numărul de identificare de stat şi codul fiscal (IDNO): **1010600028048**
Data înregistrării de stat: **12.08.2010**
Sediul: **MD-2001, str. Albişoara, 16/1, ap. 7, mun. Chişinău, Republica Moldova.**
Obiectul principal de activitate:
1. Activitatea farmaceutică; importul şi (sau) producerea articolelor de parfumerie şi cosmetică
2. Fabricarea, comercializarea, asistenţa tehnică, repararea şi verificarea articolelor de tehnică şi optică medicală
3. Acordarea asistenţei medicale de către instituţiile medico-sanitare private
4. Comerţul cu ridicata al calculatoarelor, echipamentelor periferice şi software-ului
5. Întreţinerea şi repararea maşinilor de birou şi a tehnicii de calcul
6. Consultaţii în domeniul sistemelor de calcul

Capitalul social: **5400** lei.

Administrator: **POIATA VITALIE, IDNP 0983103892591,**

Asociaţii:
1. POIATA VITALIE, IDNP 0983103892591, cota 1803,60 lei, ce constituie 33,4%
Beneficiar efectiv:
1.1. POIATA VITALIE, IDNP 0983103892591,

2. NASEDCHIN ALEXANDR, IDNP 2002001070747, cota 1798,20 lei, ce constituie 33,3%
Beneficiar efectiv:
2.1. NASEDCHIN ALEXANDR, IDNP 2002001070747,

3. KOJEVNIKOV DMITRII, IDNP 0972305012362, cota 1798,20 lei, ce constituie 33,3%
Beneficiar efectiv:
3.1. KOJEVNIKOV DMITRII, IDNP 0972305012362

Prezentul extras este eliberat în temeiul art.34 al Legii nr.220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice şi a întreprinzătorilor individuali şi confirmă datele din Registrul de stat la data de: **15.09.2023.**

Registrator în domeniul
înregistrării de stat

Rusu Diana

EB 0461494

Date cu caracter personal

Lista fondatorilor Biosistem-mld SRL

Nr.	Nume, Prenume	IDNP
1.	Vitalie Poiata	0983103892591
2.	Alexandr Nasedchin	2002001070747
3.	Dmitrii Kojevnikov	0972305012362

S5®

The world-leading perfusion system

Cardiac surgery solutions

INDEX

READY TO MEET ANY CHALLENGE

THE CONCEPT

- High quality design.

- Functional and easy to use.

- Fully configurable modular concept.

- S5 can be configured according to the clinical need by adapting pump numbers and modules.

CONSOLE

S5 console

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

S5 pump table

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

S5 standard mast system

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

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

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

A horizontal mast stabilises the mast system.

Product designation	Part number		
Consoles with E/P pack and standard mast system	3-position	4-position	5-position
S5 console	48-30-00Z	48-40-00Z	48-50-00Z
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 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.

Working position 2

Working position 1

Transport position

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

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

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

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

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

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

ROLLER PUMPS

S5 roller pump

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

S5 double roller pump

The S5 double roller pump combines two roller pumps with a diameter of 85 mm in a single housing. Both roller pumps can be operated and controlled independently.

Each pump can be operated in continuous or pulse mode.

Every pump has an independent control system and its own pump control panel that is operated using a high-contrast colour touch screen.

The pumps can be individually configured, i.e. the monitoring functions can be individually assigned to each pump and displayed on the touch screen.

A knob (incremental shaft encoder) is used to adjust the set speed electronically.

A maximum of five roller pumps can be placed on the console pump table and connected to the E/P pack.

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

Technical claims supported by LivaNova data on file

CP5 CENTRIFUGAL PUMP

CP5 centrifugal pump

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

CP5 is designed with a maximum degree of programming flexibility and customization.
- CP5 can be flexibly positioned via the rotating arm articulations.
- CP5 can be easly mounted on the masts with the fast clamp.
- CP5 can be easly configured via the control panel.
- The geometry of the CP5 makes it easy to clean: smooth plain surfaces without sharp edges.

CP5 sophisticated flow control mode is like an extra set of hands during the case. As pressure fluctuations occur with the patient and the circuit, it automatically maintains set flow for the perfusionist.
CP5 can be linked to level, bubble and pressure alarms that can completely occlude the arterial line via the ERC.

Electrical Remote-Controlled Tubing Clamp (ERC)

The Electrical Remote-Controlled Tubing Clamp (ERC) is designed for operation with the CP5 system to improve for the safety of centrifugal perfusion.
When certain conditions are detected (low level, bubble or retrograde flow), the ERC occludes the arterial line immedi-ately to minImize the danger of air delivery.
If an alarm is triggered, the ERC closes the arterial line in a fraction of a second (e.g. retrograde flow, level or bubble alarm), keeping the danger of air delivery to a minimum.
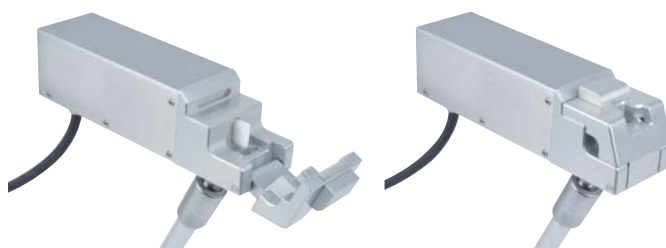
S5 allow simultaneous use of up to 2 centrifugal pump drivers:
on for arterial and one for venous kinetic drainage applications.

CP5 CENTRIFUGAL PUMP

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

Electrical Remote-Controlled Tubing Clamp (ERC)

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.

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

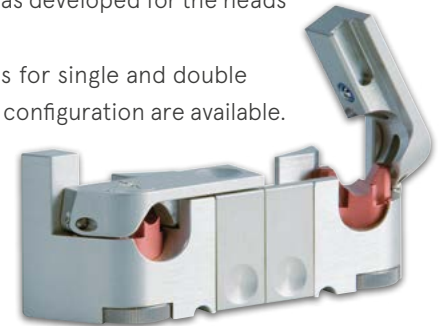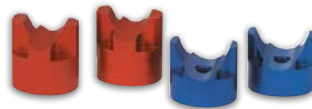| Product designation				Part number
Tubing clamp block RP 150 (included in RP 150, 10-80-00)				10-81-35
Tubing clamp inserts for tubing clamp block RP 150				
	1/4" x 1/16"	red		10-64-15
	1/4" x 3/32" 5/16" x 1/16"	yellow		10-64-25
	3/8" x 1/16" 5/16" x 3/32"	black		10-64-40
	3/8" x 3/32"	blue		10-64-50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

TUBING CLAMPS

Variiolock tubing clamp module

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

The Variolock tubing clamp module was developed for the heads of roller pumps.

A large range of tubing clamp inserts for single and double (e.g. for cardioplegia delivery) tubing configuration are available.

Product d 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

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

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

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

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

SYSTEM PANEL

S5 display and control module

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

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

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

The high-contrast TFT display has a restrained colour scheme. The display layout is determined by the chosen control and monitoring function. All pump control and monitoring function settings - with a few exceptions - are entered using the control module touch screens.

Touch screen display enables a fast and easy panel navigation.

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

TIMERS

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

The timers can be started and stopped individually.

It is possible to carry out cumulative measurements with each timer.

The measurement range for each timer is 999 min 59 sec.

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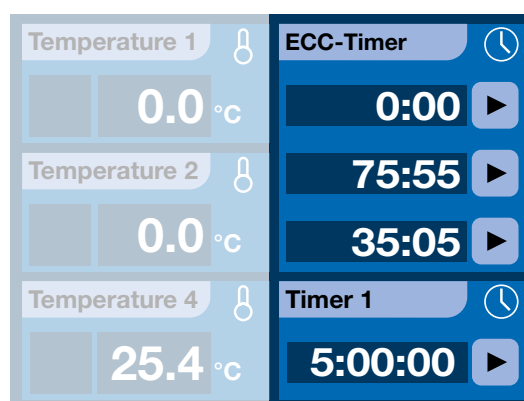
PRESSURE CONTROL

The Pressure Control Module measures and displays the pressure in the cardiopulmonary bypass circuit.
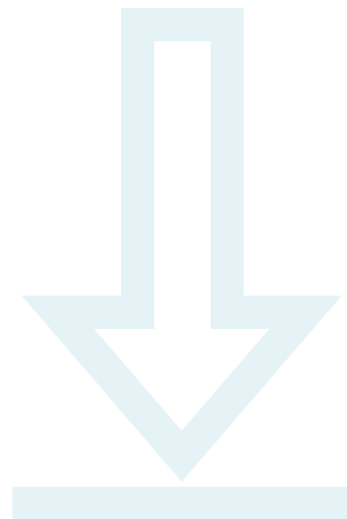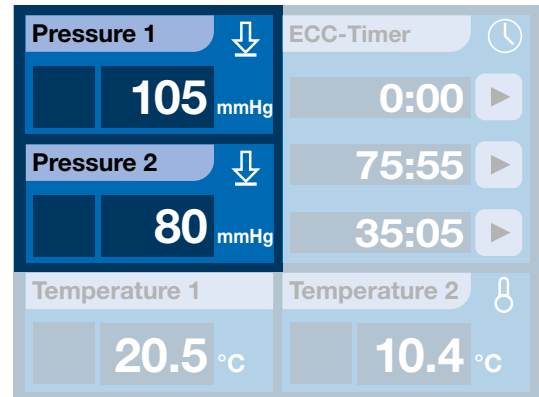
The Pressure Control Module controls perfusion with constant adjustable pressure (set value) through automatic variation of the pump speed (control mode).

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

The display range extends from -300 mmHg to +800 mmHg.
The values can be displayed in either mmHg or kPa.

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

Pressure 1 ⬇		ECC-Timer 🕐	
105 mmHg		0:00 ▶	
Pressure 2 ⬇		75:55 ▶	
80 mmHg		35:05 ▶	
Temperature 1		Temperature 2 🌡	
20.5 °C		**10.4** °C	

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

TEMPERATURE MONITOR

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

One temperature sensor module channel is reserved to cardioplegia control.

An upper and a lower temperature limit can be set. The values are set on the control and display module on the system panel. If the temperature limit is reached, visual and acoustic alarms are triggered.

Pressure 1	⬇	ECC-Timer	🕐
105 mmHg		**0:00** ▶	
Pressure 2	⬇	**75:55** ▶	
80 mmHg		**35:05** ▶	
Temperature 1		**Temperature 2**	🌡
20.5 °C		**10.4** °C	
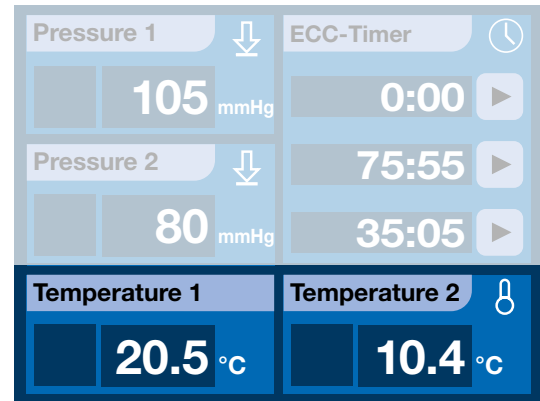
Product designation	Part number
Sensor module 4-channel temperature monitor	20-30-20Z

Accessories (optional)	Part number
Temperature probes for direct measurement in the oxygenator (optional)	
Inspire™ temperature probe	45-03-10 04222900
Kids temperature probe	45-03-11 09026

LEVEL CONTROL

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

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

Level Sensor

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

Level Sensor Module

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

Level Sensor Pad

- Easy to peel off protection foil of the Adhesive tape of the Pad. Symmetric pad to be mounted in both directions for an easy pad management.
- Small and flexible pad to fit and stick on every reservoir, including the pediatric ones.
- Transparent pad to offer a clear view of the blood level.
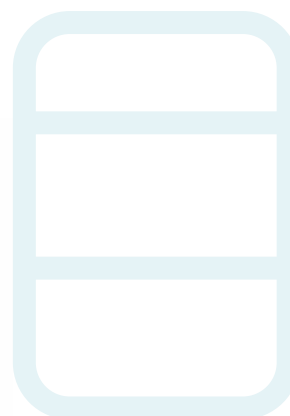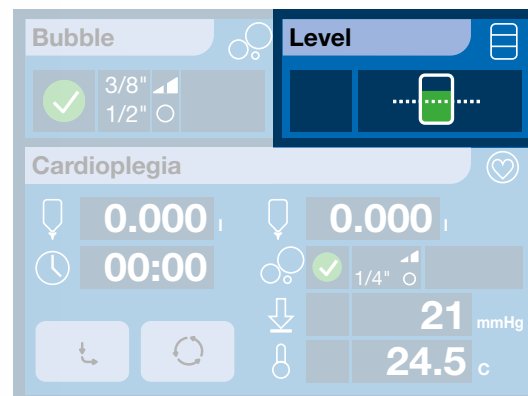
Product designation	Part number
S5 New level lensor module	23-41-00
Adhesive level sensor pads 100 units	23-41-51

BUBBLE DETECTOR

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

This monitoring device detects air bubbles in the extracorporeal circuit.

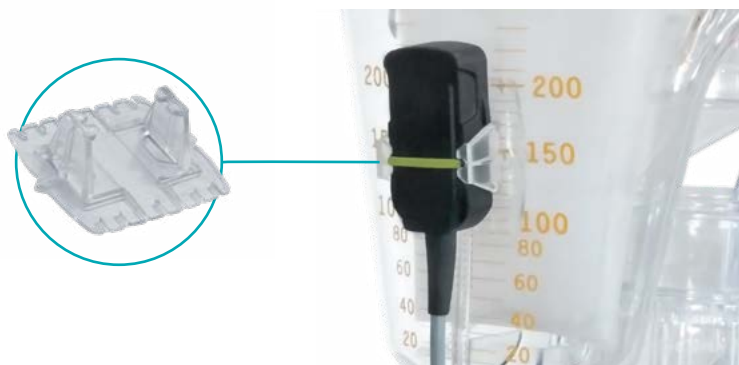This function requires a sensor module and the corresponding sensor. The scope of delivery includes a bubble detector that can be used for 3/8" tubing. Alternatively, 1/2" and 1/4" sensors are available.

The 3-joint mast holder with a fast clamp connector allows the bubble sensor to be positioned at the tubing system.

If air bubbles are detected, a visual and acoustic alarm is triggered and the connected pump stops.

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

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

The micro-bubble detection function can also be activated.

Product designation	Part number
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)	23-45-00Z
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)	23-45-01Z
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)	23-45-02Z
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)	23-45-10Z
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)	23-45-11Z
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)	23-45-12Z

CARDIOPLEGIA CONTROL

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

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

Manual operation

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

Automatic operation

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

As soon as the sensor detects bubbles, the cardioplegia pump stops automatically and the cardioplegia delivery is interrupted.
At the same time, the visual and acoustic alarms are triggered.

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

The integrated timer automatically starts during a pump stop regardless of operational mode and records the ischaemia time.

The (total) volume delivered since the start of cardioplegia is accumulated and displayed.

The cardioplegia sensor module has its own connectors for a bubble sensor and a pressure transducer.
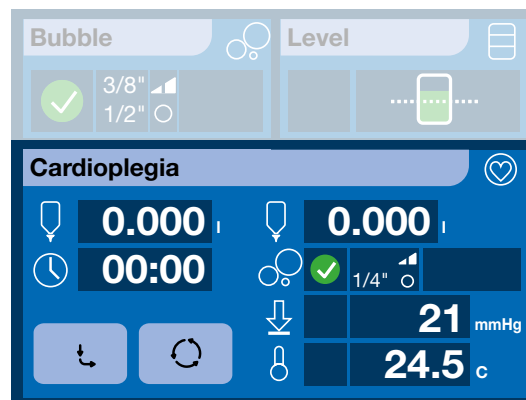
Product designation	Part number
Sensor module cardioplegia control	27-80-20Z
Sensors and accessories (optional)	**Part number**
Medex transducer (MX 960)	45-04-03
Cable for Medex transducer	45-04-15
Holder for one Medex transducer	45-04-16
Holder for 2 Medex transducers	45-04-17
Bubble sensor	
1/4" (6.35 mm)	23-07-40
1/2" (12.7 mm)	23-07-45
3/8" (9.56 mm)	23-07-50
3-joint mast holder with fast clamp connectors for 2 sensors, 620 mm	23-26-91
3-joint mast holder with fast clamp connectors for 2 sensors, 420 mm	23-26-96

Technical claims supported by LivaNova data on file

B-CAPTA

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

B-Capta provides an in-line continuous monitoring of the patient's parameters during the entire duration of pediatric and adult procedures and provides visual and audible indicators when parameters fall outside user-specified thresholds.

B-Capta is based on an accurate and reliable optical based technology improved to guarantee a high level of accuracy and reliability when measuring the patient blood gas parameters, even in long and complex cardiopulmonary bypass procedures.

Venous and Arterial Sensor

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

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

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

Sensor Module

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

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

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

Blue connector = venous senor

Red connector = arterial sensor

Mast-mountable holders with venous and arterial reference element

B-Capta is equipped with two reference elements respectively:
  - one for the venous sensor
  - one the arterial sensor

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

B-CAPTA

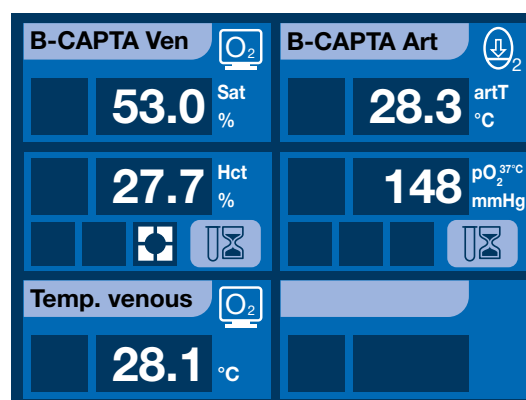## Disposable Venous and Arterial cuvettes

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

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

The Graphical User Interface supports the user to:

- **Display values measured**
  by the sensors:
  - **Venous:**
    - Oxygen Saturation (Sat)
    - Hematocrit (Hct) or Hemoglobin (Hb)
    - Temperature (venT)
  - **Arterial:**
    - Partial pressure of oxygen (pO_2^{ACT} or $pO_2^{37°C}$)
    - Temperature (artT)

- **Select**
  the value to be shown
  on the main display:
  - Hct or Hb
  - pO_2^{ACT} or $pO_2^{37°C}$

- **Change**
  measurement unit
  (for Hb and pO_2)

- **Adjust the measured values**
  with laboratory values
  (not applicable for the temperature)

- **Set the warning limits**
  for each parameter:
  These are intended to inform the operator if the sensor is measuring values outside the set thresholds.

B-CAPTA Ven O₂	**B-CAPTA Art**
53.0 Sat %	**28.3** artT °C
27.7 Hct %	**148** pO₂ 37°C mmHg
Temp. venous O₂	
28.1 °C	

B-Capta article numbers – Equipment & Disposable

		Sensor module venous & arterial	Venous sensor & ref. element	Venous ref. element holder	Arterial sensor & ref. element	Arterial ref. element holder
	P/N	25-95-20	96-414-170	25-95-70	96-414-180	25-95-80
FULL SYSTEM	25-95-00	YES	YES	YES	YES	YES
SYSTEM VENOUS ONLY	25-95-05	YES	YES	YES	/	/

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

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

Technical claims supported by LivaNova data on file
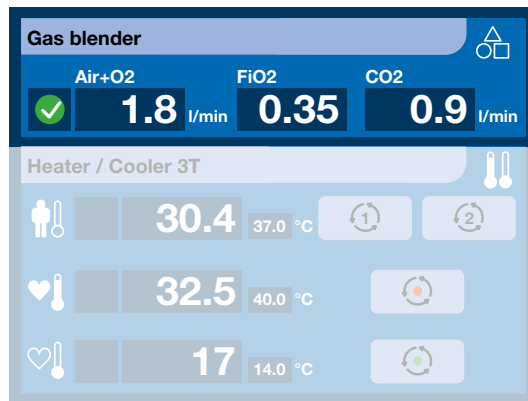
ELECTRONIC GAS BLENDER

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.

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

The remote control of the Electronic Gas Blender on the display and control module can be used to change the set values for Air + O_2, FiO_2 and CO_2 from gas flow to blood flow. The operator is made aware of the actual values exceeding or dropping below the set values by acoustic and visual signals.

The electronic gas blender is available in three different versions:

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

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

VENOUS LINE CLAMP

The venous line clamp has a mechanical remote control.

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

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

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

EVO – ELECTRICAL VENOUS OCCLUDER

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

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

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

The clamp closes automatically when the stop link function to the arterial pump is activated, if the latter has been stopped by monitoring functions in case of an alarm or is stopped manually.

When the arterial pump starts up, the EVO opens to the most recently specified set value. An override of the stop link function is possible at any time, directly at the EVO operating unit.

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

The set value can be preset when the occluder is closed and the stop link function is activated.

Audible clicking and locking into place make you doubly aware of setting knob adjustments.
A choice of fine adjustment from < 40% in 10% steps.

The stop link delay for a level alarm is adjustable from 0 to 60 seconds.

Pressure 1	Level
120 mmHg	
Pressure 2	Bubble
120 mmHg	✓ 3/8" 1/2"
Pressure 3	Occluder 1
100 mmHg	1/2" x 3/32" 0 100 %F
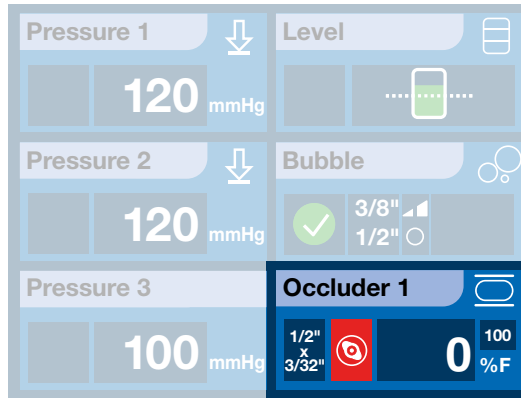
Product designation	Part number
Electrical venous occluder consists of:	12–80–00Z
Occluder (with mast holder)	12–80–10Z
Control unit	28–95–70Z

ACCESSORIES

Colour coding set

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

LED console lamp

Cover for fast clamp connectors

Cable holders

To ensure the desired routing of cables and tubing on the mast system. The holders can be installed anywhere on the mast system.
Available in sets of 6.

Perfusionist`s chair

Writing desk DIN A4

S5 adapter cable

To connect S5 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
LED console lamp	35-05-80
Cover for fast clamp connectors (set of 6 pieces)	43-42-61
Writing desk DIN A4	48-04-00

Technical claims supported by LivaNova data on file

ACCESSORIES

S5 shelf

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

S5 pump spacer

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

S5 plexiglas display protector

This cover protects the roller pump displays against falling objects.

S5 shelf for roller pump 150

A stainless steel shelf for storing small parts is available for every roller pump. A longer version for 2 roller pumps is also available.
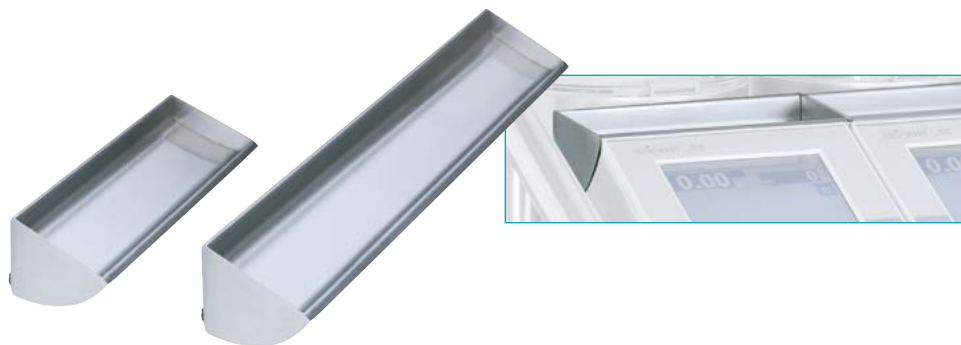
Product designation	Part number		
	3-position	4-position	5-position
S5 shelf with AC outlet strip	48-31-19	48-41-19	48-51-19
S5 shelf without AC outlet strip	48-31-10	48-41-10	48-51-10
S5 pump spacer	48-31-20	48-41-20	48-51-20
S5 plexiglas display protector	48-31-30	48-41-30	48-51-30
S5 shelf for roller pump 150	all sizes: 10-84-60		
S5 shelf for 2 roller pumps 150	all sizes: 10-84-64		

Technical claims supported by LivaNova data on file

ACCESSORIES

S5 drawer module

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

S5 ice container

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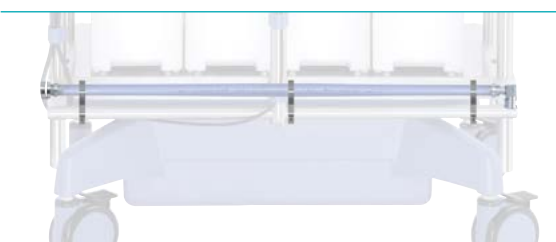
S5 tubing guide holder

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

Technical claims supported by LivaNova data on file

HEATER-COOLER 3T

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

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

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

Heating-cooling blankets connected to the heater-cooler provide an additional support for regulating the patient`s blood temperature.
The device is operated and monitored from its own control panel or, alternatively, from the display and control modules on the system panel (see illustration).
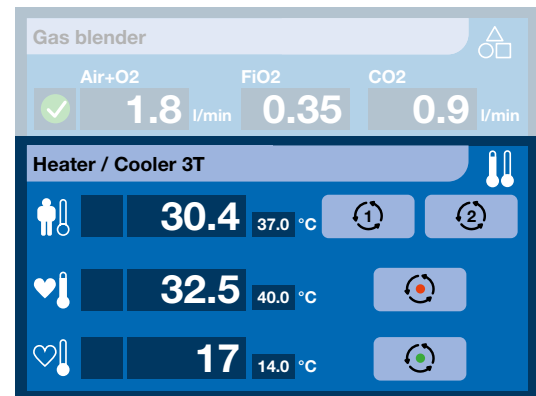
- Separate cold and warm water tanks allow the operator to switch between warm and cold cardioplegia spontaneously.

- The patient and cardioplegia circuits can be switched off separately when not in use.

- An independent safety system stops the water temperature reaching critical values.

- The pump suction stage ensures that the heat exchanger and tubing are purged.

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

Accessories (included)	Part number
Connection cable (6 m) between S5 and Heater-Cooler 3T	45-12-16

Connectors	Part number
Hansen connector (female) for oxy straight 3/8"	73-300-089
Hansen connector (female) for oxy 90° 3/8"	73-300-090

Disposable	Part number
3T Aerosol Collection Set	050900100
¼" ID vacuum extension line with connector, 366 cm (12 ft)	050900111

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

Technical claims supported by LivaNova data on file

CONNECT®

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

Main Connect features:

- Connect allows trending while centralizing all patient data on one screen.

- Connect permits automatic transfer of information from LivaNova disposables and the creation of electronic patient records.

- Provides customizable online quality indicators and post-op electronic quality reports.

- Connect enables Goal-Directed Perfusion (GDP) Therapy through the monitoring of critical metabolic patient parameters with the GDP Monitor.

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

Connect supports the Perfusionist during the entire Perfusion journey:

- Prior to surgery, a case is created for each patient, either manually or automatically, through the hospital EMR system. This import contains all relevant demographic and other surgery-related information.

- During surgery, a 15" medical-grade computer, attached to the LivaNova Heart-Lung Machine (HLM) collects patient data from the HLM and other external patient monitoring devices.

- During the operation, the perfusionist can continuously view data and events as charts or tables, according to the user preference.

- The perfusionist may also enter data as well as comments and event entries in order to have complete documentation of of the case.

- Connect may also be configured to collect data electronically from a variety of patient monitors, blood gas devices, ACT meters, cerebral oximetry devices, etc.

- Post-operatively, the perfusionist can create a complete electronic medical record of the patient, which can then be uploaded to various destinations, such as patient's EMR record.

The Connect workflow system[1]:

- Minimize transcription errors, bias and all the drawbacks associated with manual operations

- Restrict Inefficiencies of manually entering product data

- Simplify data record analysis

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

Technical claims supported by LivaNova data on file

CONNECT®

The Connect System consists of two core components:

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

The Connect Recorder:
- Collects and visualizes data from the HLM and other external devices
- Offers a high level of customization to optimize viewing preferences
- Offers quick single-touch event entries at any time
- Enables Goal-Directed Perfusion parameters via the GDP Monitor
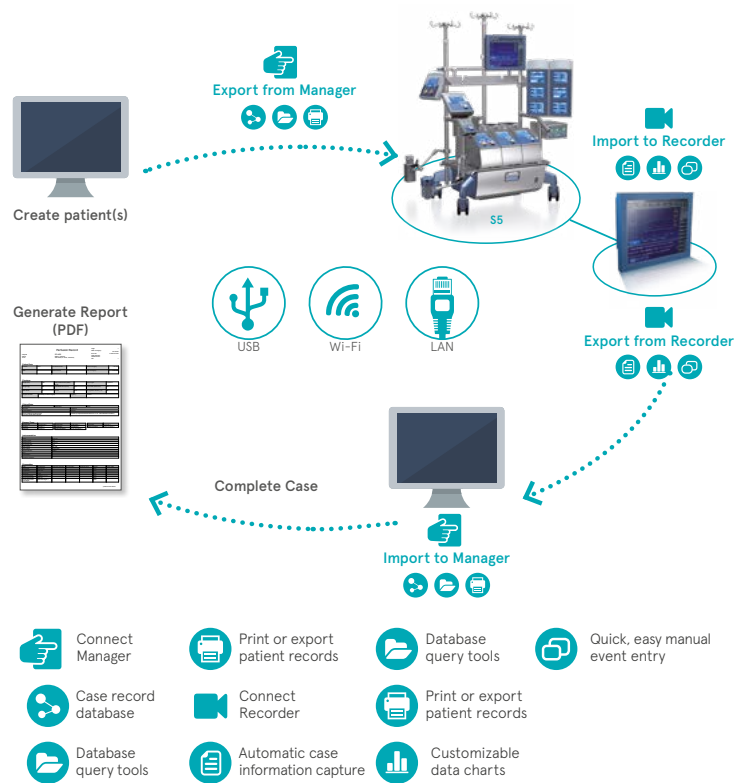
Connect system setups may be tailored to suit hospital requirements. The LivaNova technical support team works together with relevant hospital I.T. departments to identify the most appropriate Connect system setup.

Connect may be installed with a variety of connectivity options:

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

CONNECT™ HL7

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

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

Main clinical benefits of CONNECT HL7 interface/CONNECT HL7 interface[1]:
- Simplification of the clinical data workflow
- Improved data integrity
- Enhanced legibility
- Reduction in manual processes

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

---

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

CONNECT®

Order Guide

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

Please contact your local Representative for more details.

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

SPECIFICATIONS:

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

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

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

Technical claims supported by LivaNova data on file

1.0 DIMENSIONS, WEIGHTS, OPERATING CONDITIONS

TECHNICAL SPECIFICATIONS

1.1 CONSOLE

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

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

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

1.2 MASTS

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

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

1.3 PUMPS

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

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

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

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

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

Technical claims supported by LivaNova data on file

TECHNICAL SPECIFICATIONS

1.3 PUMPS

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

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

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

1.4 SYSTEM PANEL

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

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

2. ELECTRICAL SPECIFICATIONS
2.1 ELECTRONICS AND POWER PACK

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

[6] with holder

TECHNICAL SPECIFICATIONS

2.2 UPS and Batteries

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

2.3 System Panel

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

2.4 Shelf with AC Outlet

	3-/4-/5-position
Weight – shelf	approx. 6.5 kg
Maximum load – shelf	8 kg
Number of sockets	4
Protection	at 230/240 V: Circuit breaker 1 A at 110/115 V: Circuit breaker 2 A
Load rating	2 A maximum in total
Sum of leakage currents	500 µA max. in total

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

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

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

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

Timer	
Counting range	0 - 999 min 59 sec

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

TECHNICAL SPECIFICATIONS

2.5 Modules and Sensors

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

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

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

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

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

LivaNova

Health innovation that matters

Manufacturer:

Sorin Group Italia S.r.l.
A wholly-owned subsidiary of LivaNova PLC
Via Statale 12 Nord, 86
41037 Mirandola (MO) Italia
Tel.: +39.0535.29811 - Fax: +39 0535 25229
info.cardiacsurgery@livanova.com

Manufacturer:

LivaNova Deutschland GmbH
Lindbergstrasse 25
D-80939 München Germany
Tel: +49.(0)89.32301.0
Fax: +49.(0)89.32301.555

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

Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 098560 0001 Rev. 01

Manufacturer:	**LivaNova Deutschland GmbH** Lindberghstr. 25 80939 München GERMANY
Facility(ies):	LivaNova Deutschland GmbH Lindberghstr. 25, 80939 München, GERMANY
Product Category(ies):	**Heart Lung Machine Systems, Hypothermic Devices, Data Management Systems for Cardiopulmonary Perfusion, Gas and Bloodgas Management Systems, Blood Processing and Autotransfusion Systems**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713153940

Valid from: 2019-05-20
Valid until: 2024-05-19

Date, 2019-05-20

Stefan Preiß

Page 1 of 1
TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

LivaNova
Health innovation that matters

EG-Konformitätserklärung für Medizinprodukte
Declaration of Conformity for Medical Devices
(nach Anhang II der EG-Richtlinie über Medizinprodukte 93/42/EWG)
(*according to annex II of the Council Directive 93/42/EEC concerning Medical Devices*)

Name des Herstellers: LivaNova Deutschland GmbH
Name of Manufacturer:
Adresse des Herstellers: Lindberghstraße 25
Address of Manufacturer: 80939 München
    Germany
Telefon/*Phone:*   ++49 89 / 32301-0
Fax: ++49 89 / 32301-100

Wir erklären hiermit, dass das/die folgende(n) Medizinprodukt (e)
We herewith declare, that the following medical device(s)

Artikelnummer: *code number:*	Artikelbezeichnung: *designation:*	Klasse: *class:*
45-95-02	STÖCKERT S5	IIb
58-00-00	SORIN C5	IIb

den einschlägigen Bestimmungen der nachstehenden Richtlinie entspricht/entsprechen:
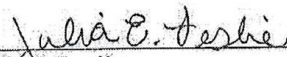*is/are in conformance with the Directive mentioned below:*

Richtlinie 93/42/EWG über Medizinprodukte
Council Directive 93/42/EEC concerning Medical Devices

Für das/die o.g. Medizinprodukte wurde von unserer Benannten Stelle TÜV Product Service das EC Zertifikat G1 098560 0001 Rev. 01 ausgestellt.
For the above mentioned medical device(s) our Notified Body has issued the EC Certificate G1 098560 0001 Rev. 01
Adresse/*address:* TÜV SÜD Product Service GmbH, Ridlerstrasse 65, D-80339 München
Kennnummer/*identification no.:* 0123

Das/die o.g. Medizinprodukt(e) ist/sind ein modulares System, das aus optionalen Komponenten bestehen kann, wie in der beigefügten Liste („Detachable Parts") aufgeführt.
The above mentioned medical device(s) is/are a modular system that can be composed of optional components, as mentioned in the attached list of "Detachable Parts".

Diese Konformitätserklärung gilt über die Laufzeit des o.g. EC Zertifikats.
This declaration of conformity is valid until the above mentioned EC certificate expires.
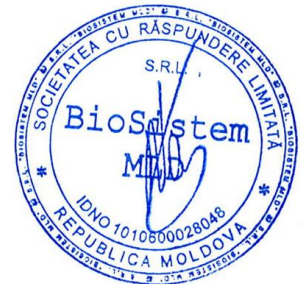
München, den 20. Mai 2019
Munich,

Julia E. Leslie
Julia E. Leslie
Director Regulatory Affairs / Cardiac Surgery
LivaNova Deutschland GmbH
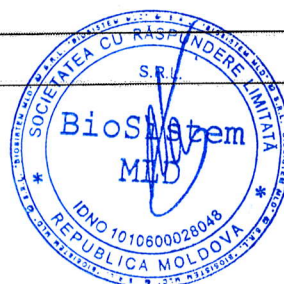
LivaNova
Health innovation that matters

Attachment to the Declaration of Conformity for S5 / C5 Heart Lung Machine Systems

List of detachable parts:

The item numbers listed below are optional components and detachable components of the S5 / C5 devices. Within the meaning of article 17 93/42/EEC, the CE mark may not be applied to each individual component for practicality reasons.

Rev: 051

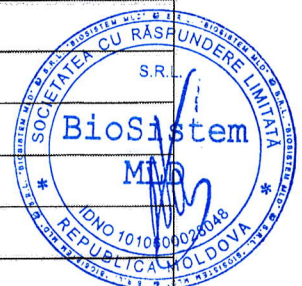| Item Number	Description
16-05-40	S5 ice container
23-07-40	Bubble sensor 1/4" (6,35 mm)
23-07-45	Bubble sensor 1/2" (12,7 mm)
23-07-50	Bubble sensor 3/8" (9.56 mm)
24-10-51	Notebook shelf
16-05-60	S5 tubing guide holder
12-05-80	Mast adapter
24-10-90	Datapad II, DMS software and S5 interface module
12-05-00	Venous line clamp mast mounted
24-10-10	Holder for Datapad II
10-07-20	Tubing inserts 1/4" x 1/16", red
10-07-21	Tubing inserts 1/4" x 3/32" yellow
10-07-22	Tubing inserts 3/8" x 1/16" black
10-07-23	Tubing inserts 3/8" x 3/32", blue
10-07-24	Tubing inserts 1/2" x 1/16" silver
10-07-25	Tubing inserts 1/2" x 3/32", green
10-07-26	Tubing inserts 5/8" x 3/32" brown
10-07-27	Tubing inserts 1/8" x 1/16" violet
10-07-28	Tubing inserts 3/16" x 1/16" turquoise

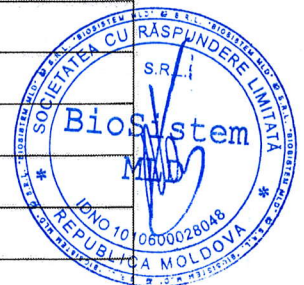| Item Number	Description
10-61-72	Tubing clamp inserts for variolock (Large) blue
10-61-73	Tubing clamp inserts for variolock (small) red
10-61-91	clamp insert variolock cardioplegia (1:1)
10-61-92	clamp insert variolock cardioplegia (2:1)
10-61-93	clamp insert variolock cardioplegia (4:1)
10-64-05	Clamp insert 1/8" x 1/16" violet
10-64-10	Clamp insert 3/16" x 1/16" mint green
10-64-15	Clamp insert 1/4" x 1/16" red
10-64-25	Clamp insert 1/4" x 3/32" or 5/ 16" x 1/16" yellow
10-64-40	Clamp insert 3/8" x 1/16" or 5/16" x 3/32" black
10-64-50	Clamp insert 3/8" x 3/32" blue
10-64-55	Clamp insert 1/2" x 1/16" grey
10-64-65	Clamp insert 1/2" x 3/32" green
10-64-69	Clamp insert 1/2" x 1/8" orange
10-64-70	Cardioplegia clamp insert 3/16"x 1/16" (1:1)
10-64-71	Cardioplegia clamp insert 1/4" x 1/16" (1:1)
10-64-72	Cardioplegia clamp insert 3/16"x 1/16" (2:1)
10-64-74	Cardioplegia clamp insert 1/4" x 1/16" (2:1)
10-64-76	Cardioplegia clamp insert 1/4" x 1/16" (4:1)
10-64-78	Cardioplegia clamp insert 17/64" x 1/16" (8:1)
10-80-00	S5 rollerpump 150 /S5 RP150
10-81-30	Variolock tubing clamp module RP 150
10-81-35	Tubing clamp block RP 150
10-84-60	S5 shelf for roller pump 150
10-84-64	S5 shelf for 2 roller pumps 150
10-85-00	S5 double roller pump 85 /S5 DRP 85
10-86-55	clamp insert DRP 85 (tubing clamp block) 1/8" x 1/16" violet
10-86-56	clamp insert DRP 85 (tubing clamp block) 1/4" x 1/16" red
10-86-57	clamp insert DRP 85 (tubing clamp block) 1/4" x 3/32" yellow
10-86-58	clamp insert DRP 85 (tubing clamp block) 5/16" x 3/32" black
10-86-59	clamp insert DRP 85 (tubing clamp block) 3/16"x 1/16" mint green

LivaNova

Health innovation that matters
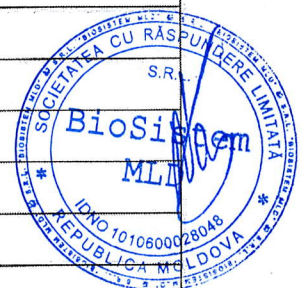
Item Number	Description
10-86-60	S5 Tubing clamp RP85 3/32x1/16", grey
10-88-00	1 x mast roller pump 150
10-88-60	1 x mast roller pump 85
12-30-90/95	3-joint mast holder for venous line clamp
12-40-00	Venous line clamp remote control
12-80-00	Electrical venous occluder
12-80-10	Occluder (with mast holder)
13-30-95	3-joint mast holder for venous line clamp
19-03-00	holder for gas bottles and heat exchanger
20-30-20	Sensor module 4-channels temperature monitor
21-15-00	3 channel timer
22-20-20	Sensor module 2-channel pressure monitor
23-26-91	3 joint mast holder with fast clamp connectors for 2 sensors Length: 620 mm
23-26-96	3 joint mast holder with fast clamp connectors for 2 sensors Length: 420 mm
23-27-40	Level sensor
23-27-41	Adhesive sensor holder
23-27-60	Adhesive sensor holder
23-40-00	Sensor module level monitor
23-45-05	APC
23-45-20	Bubble detector sensor module consisting of bubble sensors with holders of different sizes: 23-45-00, 23-45-01, 23-45-02, 23-45-03, 23-45-10, 23-45-11, 23-45-12, 23-45-13
23-45-22	S5 Sensor module APC
24-00-82	Datapad II complete without Software
24-90-15	Holder card reader complete
24-90-40	Datapad II without Software
25-40-45	Gas blender system (10 l/min)
25-40-46	Gas blender system (5 l/min)
25-40-47	Gas blender system (2 l/min)
25-40-70	Console holder for gas blender
25-60-00	B-Care$_5$

![LivaNova — Health innovation that matters]

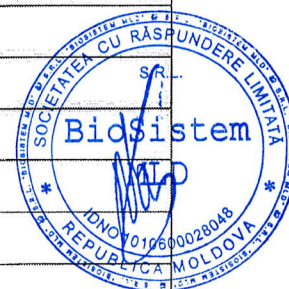| Item Number	Description
25-60-20	B-Care$_5$ sensor module
25-60-30	Holder for measuring head
25-60-70	Flow measurement sensor module
27-80-20	Sensor module cardioplegia control
28-95-00	4 position S5 system panel with 4 display and control modules
28-95-01	5 position S5 system panel with 5 display and control modules
28-95-03	3 position S5 system panel with 3 display and control modules
28-95-04	6 position S5 system panel with 6 display and control modules
28-95-10	Display and control module
28-95-30	Blank module
28-95-70	Control unit
28-95-80	Control panel for mast roller pump 150/85
28-95-85	Control panel for 2 mast roller pump 85
28-98-xx	E/P pack
29-02-50	S5 interface module
31-15-01	Temperature probe
31-15-02	Temperature probe
31-15-03	Temperature probe
35-05-50	Halogen console lamp
35-05-70	LED console lamp
43-42-61	Cover for fast clamp connectors
43-70-00	AC outlet without shelf for S5/C5 EU plug 230 V
43-70-05	AC outlet without shelf for S5/C5 French plug 230 V
43-70-10	AC outlet without shelf for S5/C5 Swiss plug 230 V
43-70-50	mechanical adapter
45-11-03	cable external device
45-12-00	S3 to S5 adapter cable
45-12-02	connection cable
45-12-03	cable for connection to the S5/C5 System (including blocking ferrite)
45-12-08	cable external pumps
45-12-12	cable patient monitor

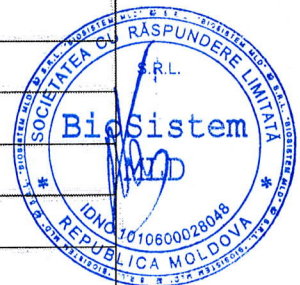| Item Number	Description
45-12-57	cable online analyzer
45-12-58	cable coagulation analyzer
45-12-61	cable online analyzer
45-12-62	cable online analyzer
45-12-63	cable online analyzer
45-12-64	cable patient monitor
45-12-65	cable patient monitor
45-12-66	cable patient monitor
45-12-67	cable coagulation analyzer
45-12-68	cable coagulation analyzer
45-12-69	cable patient monitor
45-12-70	cable external device
45-12-72	cable patient monitor
45-12-74	cable patient monitor
45-12-81	Cable for 24V connection to the S5/C5 System
48-04-00	Writing desk DIN A4
48-30-00	S5 console 3 position
48-30-50	Telescope mast with infusion rack
48-30-51	Telescope mast movable with infusion rack
48-30-57	Push bar (horizontal)
48-30-67	Push bar mast (vertical)
48-30-77	Horizontal mast 3 position
48-30-78	Horizontal mast 4 position
48-30-79	Horizontal mast 5 position
48-30-81	Crossbar for movable mast (horizontal) 3 position
48-30-82	Crossbar for movable mast (horizontal) 4 position
48-30-83	Crossbar for movable mast (horizontal) 5 position
48-31-10	S5 shelf without AC outlet strip
48-31-19	AC outlet with shelf for S5 (3 size Console)
48-31-20/25	S5 pump spacer
48-31-30	S5 plexiglass display protector
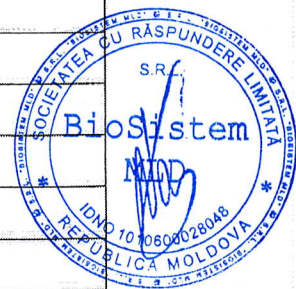
![LivaNova - Health innovation that matters]

Item Number	Description
48-40-00	S5 console 4 position
48-41-10	S5 shelf without AC outlet strip
48-41-19	AC outlet with shelf for S5 (4 size Console)
48-41-20	S5 pump spacer
48-41-30	S5 plexiglass display protector
48-41-70	S5 drawer holder
48-50-00	S5 console 5 position
48-51-10	S5 shelf without AC outlet strip
48-51-19	AC outlet with shelf for S5 (5 size Console)
48-51-20	S5 pump spacer
48-51-30	S5 plexiglass display protector
50-45-00	S5 mast system extension
50-45-05	Swivel telescope mast with infusion rack and castor
50-45-10	Two swivel arms
50-45-15	Vertical mast (including 2 horizontal masts)
50-45-20	Transport locking arm
50-70-57	Holder for mast pump module
50-80-00	Mast roller pump system 150
50-80-60	Mast roller pump system 85
50-80-62	Mast roller pump system with 2 MRP 85 S5
50-80-63	Mast roller pump system with 2 MRP 85 C5
50-80-70	Mast roller pump system 85
50-80-99	Colour coding set
55-91-50	Mast holder with fast clamp connector
58-42-30	Side mast (left and/or right oriented)
59312/1	holder for thermo box (SA 13/19)
59312/3	EVO holder (SA 13/19)
60-00-50	SCP system
60-00-55 60-00-10	SCP Plus
60-00-60	CP5 centrifugal driver

LivaNova
Health innovation that matters

Item Number	Description
60-01-00	SCP drive unit
60-01-04	CP5 drive unit
60-01-35	Emergency system
60-01-50	Emergency system
60-02-50	Pump control panel
60-02-60	Pump control panel
60-05-60	Electrical remote controlled tubing clamp
60-05-65	Electrical remote controlled tubing clamp
75-521-548	mast holder for level sensor
96-414-120	Flow sensor
96-415-126	Datapad II
97-231-059	Venous sensor
S20787/1	holder for mast (SA15/02)
S22940/1	special mast (SA15/02)
S24392/56	special cable (SA14/33)
S2549/25	additional mast (SA15/02)
S7265/3	special cable (SA13/25)
SA 47240-51	special holder
SA 47240-60	special holder
SA 64-896	AC outlet with special shelf for S5
SA 69379-1	special cable SCP panel EN block
SA 82303-01	special cable for SCPC (SA15/06)
SA14946/18	special cable (SA 13/24)
SA29001/1	S5 pump spacer(SA14/28)
SA42619-45	adapter plate (SA14/12) corresponds to SM000025 (SOR 2017-06)
SA47240-30	drawer special version (SA14/12)
SA47240-40	mast system special version (SA14/12)
SA47240-50	special mast (SA14/12)
SA47240-60	special holder pump unit (SA14/12)
SA47240-61	special holder corresponds to SM000029 (SOR 2017-04)
SA47240-70	panel special version (SA14/12)

LivaNova

Health innovation that matters

Item Number	Description
SA47240-80	panel special version (SA14/12) corresponds to SM000030 (SOR2017-06)
SA47240-81	panel special version (SA14/12) corresponds to SM000015 (SOR2017-06)
SA49320	adapter (SA15/08)
SA49468-12	special holder length (SA15/20)
SA54992-10 special desk	special desk (SA14/12)
SA54992-14	special EVO clamp (SA14/12)
SA54992-67 special mast	special mast (SA14/12) corresponds to SM000013 (SOR2016-07)
SA55169-10	holder kit for mast double pump 85 (SA14/11) corresponds to SM000017 (SOR2017-06)
SA70764-10	special panel (SA14/11) corresponds to SM000016 (SOR2017-06)
SA70764-30	special adapter (SA14/14)
SA70872	special holder (SA72915/SA14/15)
SA73367	special mast (SA 14/20)
SA76547-1	special cable(SA14/25)
SA76547-2	special cable(SA14/25)
SA76758-10	special desk (SA14/26, 14/27)
SA76758-80	panel special version (SA14/26, 14/27)
SA76758-81	panel special version (SA14/26, 14/27)
SA77737-10	special Datapad holder (SA14/30)
SA85167-04	special holder length S5 MRP (SA15/14)
SA86817-10	special cable Heater Cooler (SA15/19) corresponds to 2017-11 SE-000003 + 2017-01
SA28582	special mast system (SA16/03)
SA89947-10	special cable for Flextherm (SA16/01)
SE000001	special cable DHZ S5 (SOR 2016-06)
SM000017 SM000016 SM000015 SM000009 SM000001	twin holder kit for MRP 85 (SOR 2016-07 Giessen) panel complete (SOR 2016-07 Giessen) panel DRP (SOR 2016-07 Giessen) drawer module (SOR 2016-07 Giessen) Bedienpult (SOR 2016-07 Giessen)
96-415-130	Datapad III
25-02-10	VAMOS Holder
SE000004	special cable Datex 4m (SOR2017-02)
SE000005	S5 special connection cable XTRA 6m (SOR2017-08)
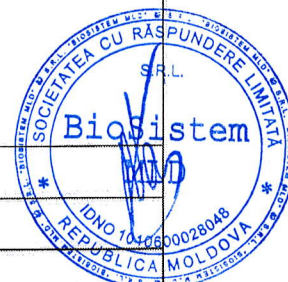
LivaNova

Health innovation that matters

Item Number	Description
35-05-80	LED console lamp
SM000020 SM000021 SM000027 SM000028	special cable guides for SOR 2017-18
48-35-00	S5 Min.I. (specific configuration of S5)
SE000008 SE000009	interface connection cable with special length 8,0 m (SOR2017-20)
SE000010	Special cable, length 8m (SOR 2017-22)
SE000011	Special cable, length 4m (SOR2017-24
SE000007	Special connector with 3 serial lines (2017-15)
SM000035-46	Special components for S5 (SOR2017-12)
SM000047-48	S5 Mastsystem (SOR2018-02)
SE000003	Special cable for Heater Cooler 3T (SOR2018-05)
SM000031-34	S5 Special mast (SOR 2017-19)
SM000049-51	Special S5 telescope masts (SOR 2018-06)
SM000054 SM000055	CP5 panel in shelf (SOR 2018-11) nur 1 panel