LivaNova
Cardiopulmonary

XTRA®

The eXtraordinary flexible, intuitive and powerful Autotransfusion System (ATS)

Autotransfusion (ATS)

Blood transfusion in cardiac surgery is a risk factor for increased hospital length of stay in adult patients.[1,2] ATS plays a key role as part of an effective blood management strategy.[3]

The procedure involves the collection of a patient's own blood from surgical sites and transfer back into the same patient during or after surgery, as required.[4]

ATS has two main advantages:[5]

Mitigate the risk of transfusion-transmitted infections from allogenic blood

Mitigate the risk of alloimmunisation (reaction to antigens on allogenic blood)

ATS lowers the transfusion rates during and after Cardiac Surgery.[6,7] Outside of cardiac surgery, ATS reduces the number of packed RBCs by -1.1 units and the length of stay by -1.0 day.[8]

Examples of indications for ATS[9]

Specialty	Surgical procedure
Cardiac	• Valve replacement • Redo bypass grafting • CABG[10] • Aortic dissection
Orthopedics	• Hip or knee replacement surgery • Major spine surgery • Bilateral knee replacement • Revision of hip replacement
Obstetrics	• Uncontrollable hemorrhage during/after childbirth • C sections[11] • Pregnancies at risk of high bleeding
Urology	• Radical retropubic prostatectomy • Cystectomy • Nephrectomy
Neurosurgery	• Giant basilar aneurysm
Vascular	• Thoraco-abdominal/abdominal aortic aneurysm repair
Other	• Liver transplant • Unexpected massive blood loss

Autotransfusion improves outcomes, reduces the need for homologous blood and lowers costs.[7,12]

Technical claims supported by LivaNova data on file. **1.** Galas F, *et al.* Blood transfusion in cardiac surgery is a risk factor for increased hospital length of stay in adult patients. *J Cardiothorac Surg.* 2013;8:54 DOI: https://doi.org/10.1186/1749-8090-8-54. **2.** Zelinka ES, *et al.* The Perfusionist's Role in a Collaborative Multidisciplinary Approach to Blood Transfusion Reduction in Cardiac Surgery. *J Extra Corpor Technol.* 2010;42:45–51. **3.** Eybohm *et al.* Washed cell salvage in surgical patients A review and meta-analysis of prospective randomized trials under PRISMA. *Medicine* (Baltimore). 2016 Aug;95(31):e4490. **4.** Carless PA, *et al.* Cell salvage for minimising perioperative allogeneic blood transfusion. *Cochrane Database Syst Rev.* 2010:CD001888 **5.** Rossi U. Medicine today. Available at: http://www.ztm.si/uploads/publication/1090/1094.pdf. Accessed December 2020. **6.** Vonk *et al.* Intraoperative cell salvage is associated with reduced postoperative blood loss and transfusion requirements in cardiac surgery: a cohort study. *Transfusion.* 2013 Nov;53(11):2782-9. **7.** Côté *et al.* Efficacy of intraoperative cell salvage in decreasing perioperative blood transfusion rates in first-time cardiac surgery patients: a retrospective study. *Can J Surg.* 2016 Sep;59(5):330-6. **8.** Waters *et al.* Clinical Efficacy of Washed Autotransfusion in Non-cardiac Settings Such as Vascular, Orthopedic and Obstetric Surgery: Subgroup Analysis of a Systematic Review and Meta-analysis of Randomized Control Trials. The Anesthesiology Annual Meeting A2296 October 22, 2017 http://www.asaabstracts.com/strands/asaabstracts/abstract.htm?year=2017&index=4&absnum=3584 **9.** Esper AS, Waters JH. Intra-operative cell salvage: a fresh look at the indications and contraindications. *Blood Transfus.* 2011;9:139–47. **10.** Schmidt, *et al.* Autotransfusion After Coronary Artery Bypass Grafting Halves the Number of Patients Needing Blood Transfusion. *Ann Thorac Surg.* 1996; 61:1177–81. **11.** Ashworth A, Klein AA. Cell salvage as part of a blood conservation strategy in anaesthesia. *Br J Anaesth.* 2010;105:401–16. **12.** Huseyin *et al.* Comparison of early period results of blood use in open heart surgery. *J Res Med Sci.* 2016; 21: 28.

XTRA® ATS System:
The complete solution for blood management

Excellent Performance from Small to Massive Bleeding[1,2]

LivaNova offers a long legacy in developing, producing and servicing our heart-lung machines (HLM), we are recognized as the world's #1 cardiopulmonary bypass company with perfusionists worldwide are benefiting from the reliability of our machines.

XTRA® leverages the HLM legacy but also brings together three decades of experience and improvements in cell salvage procedures, treating more than 0.5 million patients per year.

With its refined ergonomics and reduced footprint for manageable procedures, XTRA® brings you:

Flexibility **Intuitiveness** **Performance**

With Touch Screen user interface

The full-colour LCD, TFT (8.4") with a large view area (172x130 mm) and the touch screen technology allow optimal visibility of the information displayed and total control at your fingertips.

Taking inspiration from our world leading HLM machines, the XTRA® user interface displays all the information you need by means of modular displays that can be opened or closed at your desire and offers complete control of the system throughout intuitive and easy-to-navigate menu pages.

Technical claims supported by LivaNova data on file. **1.** Bauman, *et al*. Evaluation of the minimum volume of salvaged blood required for the successful use of two different autotransfusion device. *Pediatric Anesthesia*. 2015. 25:258–264. **2.** Seyfried, *et al*. The impact of bowl size, program setup, and blood hematocrit on the performance of a discontinuous autotransfusion system. *Transfusion*. 2017 Mar;57(3):589-598.

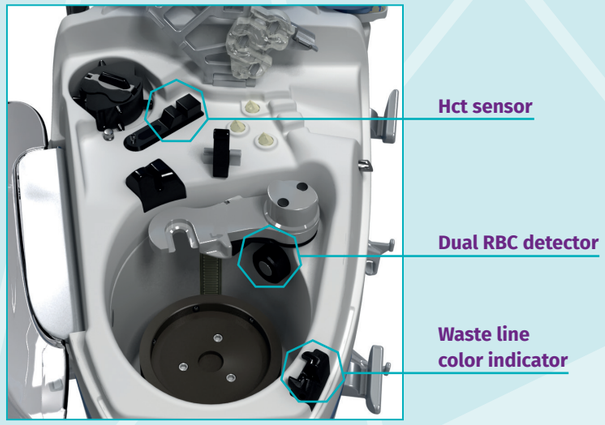
Advanced Data Management

Experience complete control over your data. From the tally screen you will be able to visualize case information at anytime, print a report, or download multiple cases on a USB memory stick.

- Internal memory capable of storing thousands of past cases
- Integrated ink printer, producing permanent case printouts, ensuring complete traceability
- Functional integration with the S5® HLM thanks to CONNECT™

Dual sensor technology

- The Dual RBC detector technology in XTRA® is composed of two optical sensors allowing a high filling of the bowl and thus an excellent supernatant washout and high outlet haematocrit
- The Hct sensor is an integrated, non-invasive, optical sensor providing information on RBC concentration of the inlet blood during Fill phase and outlet blood during the Empty phase providing on-screen information at-a-glance on the wash quality by a visual indicator



Technical claims supported by LivaNova data on file.

XTRA® Flexibility[1]

- **Flexible choice** of intra, post-op and sequestration protocols
- **Wide range of bowl sizes** and disposables to choose from
- **Low** minimum required Red Blood Cell mass to process
- **Fast Processing** to manage high volume blood loss
- **Complete control** over your data, printed or stored

INTRA-OPERATIVE FACTORY PROTOCOLS

Popt

Designed to obtain:
- Very high Hct[2]
- Excellent supernatant removal[3]
- Good processing speed[3]

Achieved by:
- Two step filling at different flow rates and automated stand-by
- Dual RBC detector technology for optimal bowl filling (active for XTRA® BOWL 55 and XTRA® BOWL 225)

Pstd

Designed to obtain:
- High processing speed (with XTRA® BOWL 225)[3]
- Good hematocrit[3]
- Good wash quality[3]

Achieved by:
- One-step automatic filling
- Possibility to adjust flows (filling, washing, emptying)
- High wash and empty flows

Pfat

Designed to obtain:
- Removal of fat particles
- Excellent supernatant removal
- Good Hematocrit

Achieved by:
- Newly designed fat removal phase
- High wash flows

POST-OPERATIVE FACTORY PROTOCOL

Post-op

Designed to obtain:
- A configuration suitable for post-op applications

Achieved by:
- Activating the same settings of the Popt protocol
- Automatically switching to gentle aspiration with the XVAC post-op mode

PREOPERATIVE SEQUESTRATION FACTORY PROTOCOL

The preoperative sequestration protocols enable the recovery of plasma and platelets from the patient whole blood into bags

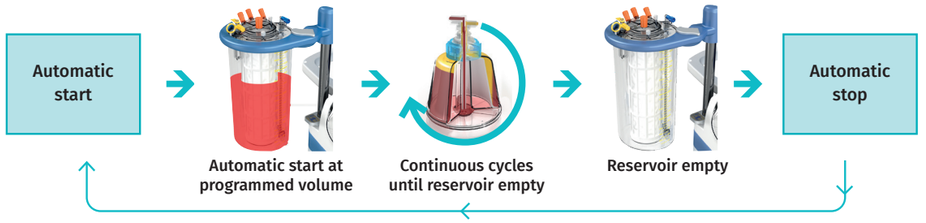
Technical claims supported by LivaNova data on file. **1.** Bauman, *et al*, (2015) Evaluation of the minimum volume of salvaged blood required for the successful use of two different autotransfusion device. *Ped Anesth*. 25:258–264. **2.** Overdevest, *et al*. Clinical evaluation of the Sorin Xtra® autotransfusion system. *Perfusion* 2012, 27(4) 278–283 **3.** Seyfried, *et al*. The impact of bowl size, program setup, and blood hematocrit on the performance of a discontinuous autotransfusion system. *Transfusion*. 2017 Mar;57(3):589-598.

XTRA® Intuitiveness

- **Fast and intuitive** setup
- **Fully automated operation** from the start to the end of the case
- **Intuitive User Interface** with colour touch screen, mimicking the S5® Heart-Lung Machine controls
- **Refined ergonomics** and reduced footprint for manageable procedures

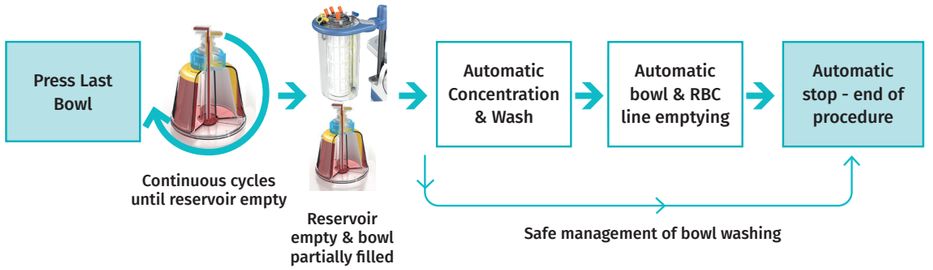
1-Touch

- **Automatic start** at target volume in the reservoir
- **Continuous processing** of bowls in sequence
- **Automatic stop** when reservoir is empty



Last Bowl

- Continuous processing of bowls in sequence
- **Automatic concentration,** wash and empty
- **Automatic** RBC line emptying



XTRA® Performance[1]

- **Multiple sensors and indicators** for enhanced patient safety
- **Consistently high RBC hematocrit and wash quality** with Popt protocol
- **Excellent** heparin and protein removal
- **High** RBC recovery rate
- **Quiet and powerful** vacuum pump

Popt

High RBC Hct and wash quality with Popt

The innovative RBC detector technology, combined with the Popt factory protocol and disposable design.

Hct[1]
60-65%

Time[2]
≈5 minutes

Heparin
Protein
Albumin
FPH

Removal Rate[2]
> 95%

Pfat

Complete fat removal with the new Pfat

The newly developed Pfat protocol will effectively remove fat particles.

Fat Particles Removal[3]
> 99%*

Hct[3]
≈50%*

Heparin
Protein
Albumin
FPH

Removal Rate[3]
> 95%**

* Using 225 ml Bowl, averaging both inlet HCT of 10% and 25%.
** Using 225 ml Bowl with inlet HCT of 10% and 25%.

Pstd

Fast high volume processing with Pstd

Ready to meet your high volume challenges: fast processing with the Pstd standard protocol, turning into emergency protocol with only one touch.

Hct[4]
≈50%

Time[4]
- Less than 4 minutes
- Emergency ≈3 minutes

Heparin
Protein
Albumin
FPH

Removal Rate[2]
> 92%

1. Overdevest, *et al*, Clinical evaluation of the Sorin XTRA® autotransfusion system. *Perfusion*. 2012. 27(4) 278–283. **2.** In vitro performance evaluation study with human blood 25% Hct with XTRA® BOWL 225. Data on file at LivaNova Italia. **3.** Seyfried TF, Gruber M, Breu A, Aumeier C, Zech N, Hansen E. - Fat removal during cell salvage: an optimized program for a discontinuous autotransfusion device. - *Transfusion*. 2015 AUG - Epub ahead of print. **4.** In-vitro performance evaluation with bovine blood 25% Hct on a modified version of Pstd with 225ml bowl introduced with SW 1.02. Data on file.

XVAC

- **XVAC** is a modular vacuum pump, designed to be extremely quiet and to deliver performance and maximum flexibility by working as a standalone unit or fully integrated into the **XTRA®** system.

  When seated in its housing and connected to the system, **XVAC can be activated and operated from a dedicated displet on the XTRA® user interface.** When used standalone, the vacuum pump can be controlled from the **XVAC** panel.

- **XVAC** guarantees flexibility functioning in two operative modes, **Intra** and **Post** delivering an optimized solution for perioperative blood recovery. Moreover, **XVAC** can be activated right after power-on, reacting promptly to critical emergency situations.

  The vacuum power ranges from:
  -50 to -300 mmHg (Intra-operative mode - High vacuum capacity)
  -10 to -100 mmHg (Post-operative mode - Gentle aspiration for wound drainage connection)

Technical Information

XTRA®	
Unit dimensions * = with cart.	Height = 660 mm (1055 mm*) - pole lowered Height = 1585 mm (1980 mm*) - pole completely lifted Height = 835 mm (1230 mm*) - display lifted Width = 375 mm - (including the side hangers) Width = 800 mm - with poles completely open Depth = 500 mm - 680 mm including the front and rear handles
Cart dimensions	Height = 500 mm Width = 480 mm Depth = 595 mm
Unit Weight	37 kg (81.4 LBS)
Cart Weight	22.5 kg (49.5 LBS)
Display Type	Graphic color LCD TFT 8.4” 172 mm x 130 mm (screen)
Main Voltage (Power Supply)	230 V~ or 100-120 V~
Frequency	50 - 60 Hz
Fuse Ratings	2 x T6.3 H
Centrifuge Speed	1500 ÷ 5600 rpm (steps of 100 rpm)
Pump Speed	25 - 1000 ml/min (adjustable)

XVAC	
Unit Weight	15 kg (33 lbs)
Functioning Range	-50 to -300 mmHg (-6.6 kPa to -40 kPa) (steps of 10 mmHg [1.3 kPa]) – intra and pre-operatively -10 to -100 mmHg (-1.3 to -13.3 kPa) (steps of 10 mmHg [1.3 kPa]) – post-operatively

XTRA® Disposable Offering

XRES Blood collection reservoir

The reservoir which sets the standards of blood **collection** to the highest levels

High capacity and filtration quality

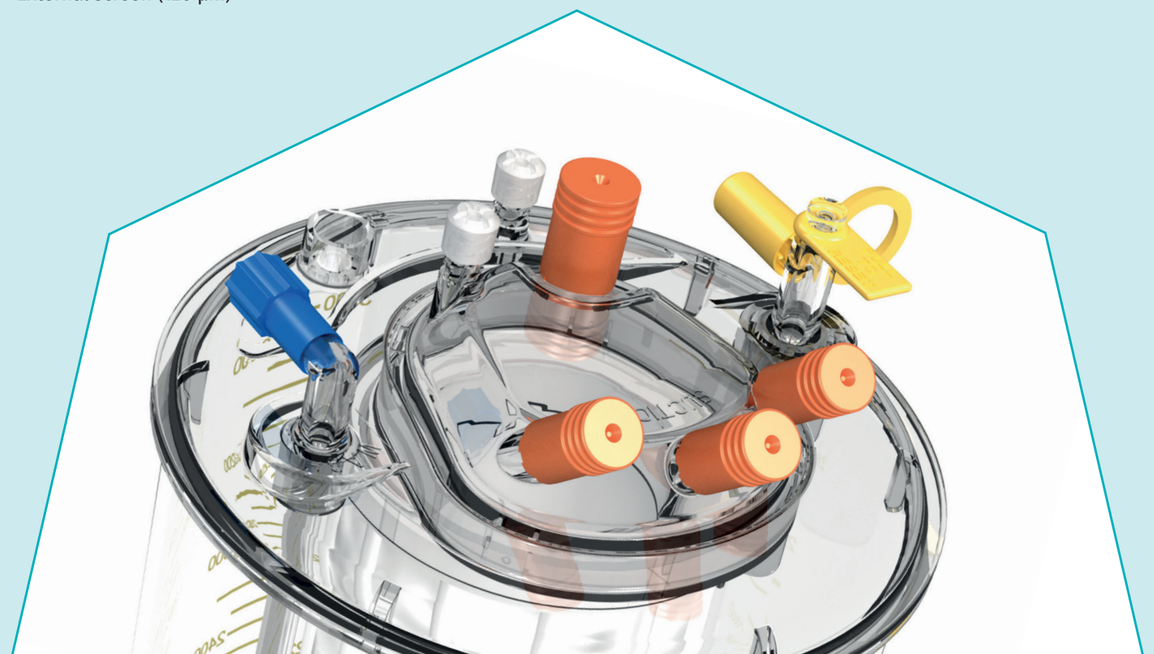
- 4-liter capacity
- Advanced, multi-layer filtration system, with:
  - Internal defoaming polyurethane layer (30 ppi)
  - Intermediate woven, non-woven filter (40 µm)
  - External screen (120 µm)

Easy and safe setup

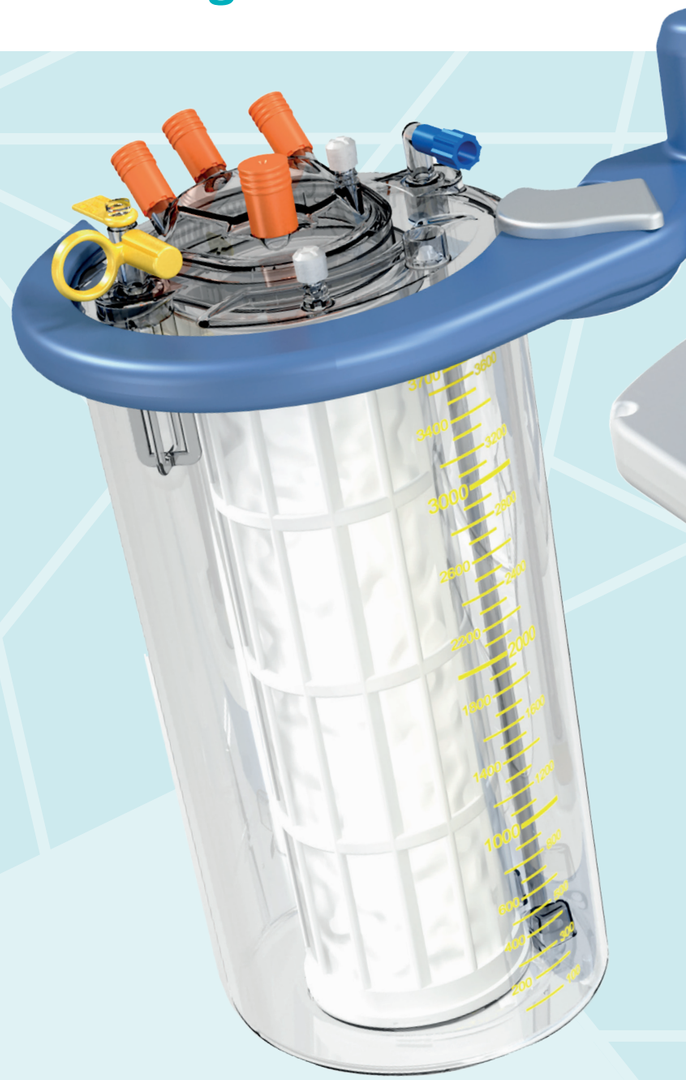
- New locking mechanism to firmly secure the reservoir to the holder
- 360° reservoir rotation capability within the holder
- Separate holder available for use with IV pole and vacuum regulator

Clear all-around visibility

- Transparent, flat body to allow constant monitoring of the collected blood
- Transparent, flat lid to allow visibility inside the inner filter



XTRA® - Collection & Processing



Broad Flexibility

- Three 1/4” suction ports, for the collection of blood both intra-operatively and post-operatively: 45° angled, to prevent occlusion from debris produced during surgery
- One 3/8” suction port, for intra-operative procedures where a 3/8” aspiration and anticoagulation line is used
- One filtered and one non-filtered luer lock port, for blood transfer or drugs administration

Safety Features

- Self regulated pressure relief valve
- Safe overflow level valve

TOP-outlet

BOTTOM-outlet

Two configurations available

- XRES T Blood Collection Reservoir
  - Top outlet connection to the bowl
  - Quick reinfusion port for immediate transfusion of non-processed blood in case of extreme emergency
- XRES B Blood Collection Reservoir
  - Bottom outlet connection to the bowl
  - Pre-connected outlet clamp
  - Also Available with 120µm gross filter

Xtra® Bowl

The most complete range of processing bowl sizes to face all operational situations

Broad Flexibility

Xtra® Bowl 55 ml The smallest bowl for minimal bleeding	Minimal Bleeding Orthopedic Surgery Small Size Patients Pre-operative Sequestration (PPP/PRP)
Xtra® Bowl 125 ml The standard bowl for low bleeding	Orthopedic Surgery (Total Joint Replacement) Obstetric Surgery Pre-Operative Sequestration (PPP/PRP)
Xtra® Bowl 175 ml The intermediate bowl for medium bleeding	High Bleeding Orthopedic Surgery (Revisions) Low Bleeding Cardiac Surgery (Mini-Bypass) Cardiovascular Surgery
Xtra® Bowl 225 ml The largest bowl for high bleeding	Cardiovascular Surgery (Bypass, Abdominal Aortic Aneurysm) Emergency & Trauma Transplant

Easy, fast and safe setup

- Innovative disposable design:
  - Xtra® Bowl design for quick 360° snap-in mounting onto the centrifuge plate
  - One-hand mechanism for locking/unlocking the bowl to/from the centrifuge arm
  - Cartridge and tubing design, to ensure straightforward setup
  - Lid-guided tubing positioning into seat when closing the clamp lid
  - Automatic pump loading/unloading at the beginning/end of case

High quality with the optimized protocol

- Optimized protocol (Popt), to achieve high hematocrit, red blood cell recovery rate and waste contaminants removal rate with the Xtra® Bowl 55 or Xtra® Bowl 225

Fast processing with the standard protocol

- Standard protocol (Pstd), to achieve the fastest processing times (comparable to the Baylor Bowl 250 ml) with the Xtra® Bowl 225

Collection Set (TX, TX Cardio, BX or BX Cardio)

Provides XRES reservoir and related items to collect blood recovered from intra-operative field or post-operative drains.

Content

- XRES T Blood Collection Reservoir (or XRES B Blood Collection Reservoir)
- AAL Aspiration and Anti-coagulation Line
- VEL Vacuum Extension Line
- Cardio Kit (only in Cardio configuration)

Advantages

- Modular solution where each item is packed and sterilized separately, allowing a cost effective stand-by strategy: collect first and process later
- Separate holder available to use XRES on IV pole and with vacuum regulator
- Available in standard and Cardio configurations (with Cardio Kit)

Indications

- Standard configuration: ortho-pedic surgery, spinal surgery, other non-cardiac applications (e.g. cardiovascular, obstetrics, urology)
- Cardio configuration: cardiac applications

Procedure Set (TX Cardio or BX) (55, 125, 175 or 225)

Provides XRES reservoir, XTRA® BOWL and all the necessary components to collect and process the blood recovered from the intra-operative field or post-operative drains.

Content

- Collection Set (TX Cardio or BX)
- Bowl Set X (55, 125, 175 or 225)

Advantages

- All-in-one solution for blood collection and processing
- Suitable for all surgical conditions with 4-liter reservoir and 4 bowl sizes
- Integrated solution to connect the oxygenator to the XRES reservoir with Cardio Kit (only available in Procedure Set TX)

Indications

- Cardiac surgery
- Abdominal/aortic aneurysm
- Emergency and trauma
- Transplant

Bowl Set X (55, 125, 175 or 225)

Provides XTRA® BOWL and related items to process the blood recovered from the intra-operative field and post-operative drains or separate hemocomponents in pre-operative sequestration procedures.

Content

- XTRA® BOWL with pre-connected color-coded tubing and cartridge
- Pre-connected BRB1 Blood Reinfusion Bag (1 liter)
- Waste Bag X (10 liters)

Advantages

- Flexibility with 4 bowl sizes suitable for minimal, small, medium and high bleeding
- New bowl, tubing and cartridge design for easy, fast and safe setup

Indications

- Intra-operative and post-operative processing
- Pre-operative sequestration

Cardiovascular Surgery

Cardio Kit

Includes all the adaptors, components and lines to connect the oxygenator to the autotransfusion system to recover and process the blood during and post bypass.

Tandem Reservoir “Y”

Allows the connection of two Xres reservoirs to the Xtra® system in procedures where large volumes of blood need to be recovered and processed.

Orthopedic Surgery

Fluid Collection Bag for Orthopedics

Designed to collect the blood lost during orthopedic operations, such as hip replacement/revision, and transfer it to the Xres reservoir through a preconnected aspiration and anticoagulation line. The 45 cm long adhesive strip suits any kind of wound size.

4-Way Adapters*

Connect patient drain tubes of various diameters to the aspiration & anticoagulation line during post-operative blood collection. Available with luer-locks or with multidiameter adapters.

Pre-operative Sequestration

Sequestration Set X

Intended for pre-operative sequestration (PPP and PRP) with transfer bag technique. To be used in combination with a Bowl Set X.

Miscellaneous

AAL Aspiration and Anticoagulation Line

Allows aspiration and anticoagulation of the blood coming from the operative site, collecting it into the Xres reservoir. A double woven non-woven layer protects the sterility when passing the line into the sterile field. Various diameters available: 1/4”, 1/4” – 3/8”, 3/8”.

BRB1 Blood Reinfusion Bag

Designed to collect 1 liter of concentrated RBCs during blood salvage procedures.

Waste Bag X

Used in connection with the Bowl Set X, it collects up to 10 liters of waste fluids during processing.

Goccia Filters*

Designed to remove microaggregates and protect the patient pulmonary micro-circulation.

*not available in US and Japan.

XTRA® Clinical Applications

Cardiac Surgery

Interventions

- Concentration of residual extra-corporeal circulation volume during/after bypass
- Mini Bypass
- Off-Pump
- Valve Replacement
- Surgical Repair of Great Vessels
- Suction Blood Washing

What you need

- Procedure Set or Collection Set (TX Cardio or BX Cardio) + Bowl Set X
- 20/40µm Microaggregate Goccia Filter*

*not for US and Japan

XTRA® Advantages

- S5® - like touch screen user interface, ensuring a straigthforward learning curve for all operators already familiar with LivaNova's heart-lung machine
- Functional integration with S5® through LivaNova CONNECT™ perfusion data management
- High quality or fast processing by simply selecting the appropriate protocol, either the optimized protocol (Popt) or the standard protocol (Pstd)
- Cardio Kit, for direct access to the oxygenator during and after bypass
- Broad spectrum of bowl sizes, to address different levels of bleeding

High Bleeding Surgery

Interventions

- Cardiovascular Surgery
- Organ Transplant
- Trauma Surgery
- Obstetric Surgery

What you need

- Procedure Set or Collection Set (TX or BX) + Bowl Set X
- 20/40µm Microaggregate Goccia Filter*
- Additional Components:
  - Tandem Reservoir “Y”
  - BRB1 Blood Reinfusion Bag
  - Waste Bag X

*not for US and Japan

XTRA® Advantages

- Live on-screen indication of critical data: volume and hematocrit of the fluid collected from the field, as well as of the red blood cells recovered after processing
- Powerful and silent blood aspiration with the integrated XVAC vacuum pump
- Immediate aspiration, independent from the XTRA® system boot-up time, by powering XVAC on from the control panel
- Fast processing with the standard protocol (Pstd)
- Dedicated Emergency button available in all screens to face critical situations
- Bowl Set X/225, to meet high volume challenges

Orthopedic Surgery

Interventions:

- Primary Hip and Knee Replacement
- Hip and Knee Revision
- Spine Surgery

What you need:

- Procedure Set or Collection Set (TX or BX) + Bowl Set X
- 20/40µm Microaggregate Goccia Filter*
- Additional Components:
  - Intra-operatively: Fluid Collection Bag for Orthopedic
  - Post-operatively: 4-Way Adapter* or Wound Drainage “Y” Connector

*not for US and Japan

XTRA® Advantages

- Option to mount the XRES reservoir on an IV pole by means of the separate holder, and connect it to the XVAC vacuum pump used in stand-alone mode, to easily move between ICU beds when collecting blood from post-operative wound drains
- Reduced footprint, to allow processing of the blood collected post-operatively from wound drains also in the narrow spaces of the ICU
- Dedicated post-operative protocol (Post-Op), assuring the same high quality setting of Popt protocol and turning the XVAC into a gentle mode to be safely connected to wound drains
- Dedicated fat protocol (PFat) assuring complete removal of lipid particles
- Modular disposable solutions, to allow collection first and process when enough blood has been shed
- Small to intermediate bowl sizes, to face minimal bleeding orthopedic surgery as well as joint replacements and revisions

Pre-operative Sequestration

Interventions:

- All cases where bleeding may occur during the post-operative course

What you need:

- Bowl Set X
- 20/40µm Microaggregate Goccia Filter*
- Additional Components:
  - Sequestration Set X

*not for US and Japan

XTRA® Advantages

- Full on-screen description of the actions to be performed, to guide the operator throughout the entire procedure
- Broad spectrum of pre-operative sequestration protocols:
  - PPP (for collection of platelet poor plasma in a single bag)
  - PRP1 (for collection of both platelets and plasma in a single bag)
  - PRP2 (for collection of platelet poor plasma in one bag and platelet rich plasma in a separate bag)
- Easy and quick conversion from pre-operative sequestration to intra-operative collection and processing by using the same Bowl Set X

Order Guide

Identification	Code	Description	Quantity / Box
Xtra®	75220	Xtra® Equipment 230V 50Hz Version	1
	75221	Xtra® Equipment 110V 50Hz Version	1
Xvac	75306	Xvac Vacuum Pump 220V Version	1
	75307	Xvac Vacuum Pump 110V Version	1
Xtra® Accessories	65151	Thermal Printer Paper Roll Kit	4
	65696	Centrifuge Well Fluid Container	1
	65666	Vinyl Cover For Xtra®	1
	65714	Xvac Trap	1
	63056	Xtra® USB Memory Stick	1

Disposables, Miscellaneous Processing Components and Adapters

Type	Item	Description	Quantity / Box
Procedure Sets	04254	Procedure Set Tx/55	3
	04255	Procedure Set Tx/125	3
	04256	Procedure Set Tx/175	3
	04257	Procedure Set Tx/225	3
	04261	Procedure Set Bx/55	3
	04262	Procedure Set Bx/125	3
	04263	Procedure Set Bx/175	3
	04264	Procedure Set Bx/225	3
	04259	Xres B Blood Collection Reservoir	6
	04260	Collection Set Tx	6
	04266	Collection Set Tx Cardio	6
	04265	Collection Set Bx	6
	04267	Collection Set Bx Cardio	6
	04268	BRB1 Blood Reinfusion Bag X, 1 Liter	50
	04272	Xres Blood Collection Reservoir Holder	1
Bowl Sets	04250	Bowl Set X/55	6
	04251	Bowl Set X/125	6
	04252	Bowl Set X/175	6
	04253	Bowl Set X/225	6
Sequestration Sets	04015	Sequestration Set X	40
Blood Sampling Kits For Quality Assurance	04270	Reservoir Outlet Clamp Xres B	12
	04271	Reservoir Outlet "Y" Xres B	12
	007016000	Blood access sampling adapter	25
Wound Drainage Kits	04128*	4-Way Multidiameter Adapter	20
	04059*	4-Way Adapter with Luer Lock	20
	007115000	Wound Drainage "Y" Connector	25
	007116000	Wound Drainage "Y" Connector with Dual Lumen Suction Line	10
Suction Assemblies	04273	Xtra® AAL Aspiration and Anticoagulation Line 1/4"	10
	04196	AAL Aspiration and Anticoagulation Line 1/4" - 3/8"	10
	04197	AAL Aspiration and Anticoagulation Line 3/8"	15
Miscellaneous Processing Components & Adapters	04269	Waste Bag X	10
	04133	Cardio Kit	60
	04028	VEL Vacuum Extension Line	50
	04129	Bag Adapter	80
	04152	Fluid Collection Bag For Orthopedics	12
	04058	Tandem Reservoir "Y"	20
Microaggregate Filters*	09085	40Um Goccia Filter	12
	09086	20Um Goccia Filter	12
	09087	20Um Goccia Filter with Infusion Line	6
	09088	40Um Goccia Filter with Infusion Line	6

*Not available in US and Japan.

Please always refer to the Instructions For Use (IFU) manual provided with each product for detailed information, warnings, precautions and possible adverse side effects. Not all products available in all countries, please consult local label.

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

The Sorin Group Italia Quality System complies with: **EN ISO 13485:2012**

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

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LivaNova

Health innovation that matters

Connect™

Get connected to optimal data management practices

The first innovative and intuitive perfusion data management system designed to improve clinical efficiency[1] and enable Goal-Directed Perfusion Therapy

Connect to clinical efficiency with greater confidence

Minimize
Transcription errors and bias.[1]

Connect™
Allows trending while centralizing all patient data on one screen.

Restrict
Inefficiencies of manually entering product traceability data.

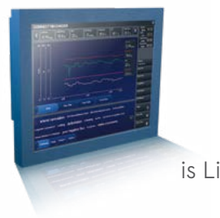
Connect
Permits automatic transfer of information from LivaNova disposables and creation of electronic patient records.

Decrease
Limitations of analyzing manually recorded data.

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

Enable
Application of GDP, which aims to reduce occurrence of Acute Kidney Injury.[2, 3, 4, 6, 7, 8, 9]

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



Connect

is LivaNova's innovative and intuitive perfusion data management system **designed by perfusionists, for perfusionists.**

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 Perfusion Case Reports
- Allows full customization of Connect Recorder according to preferences

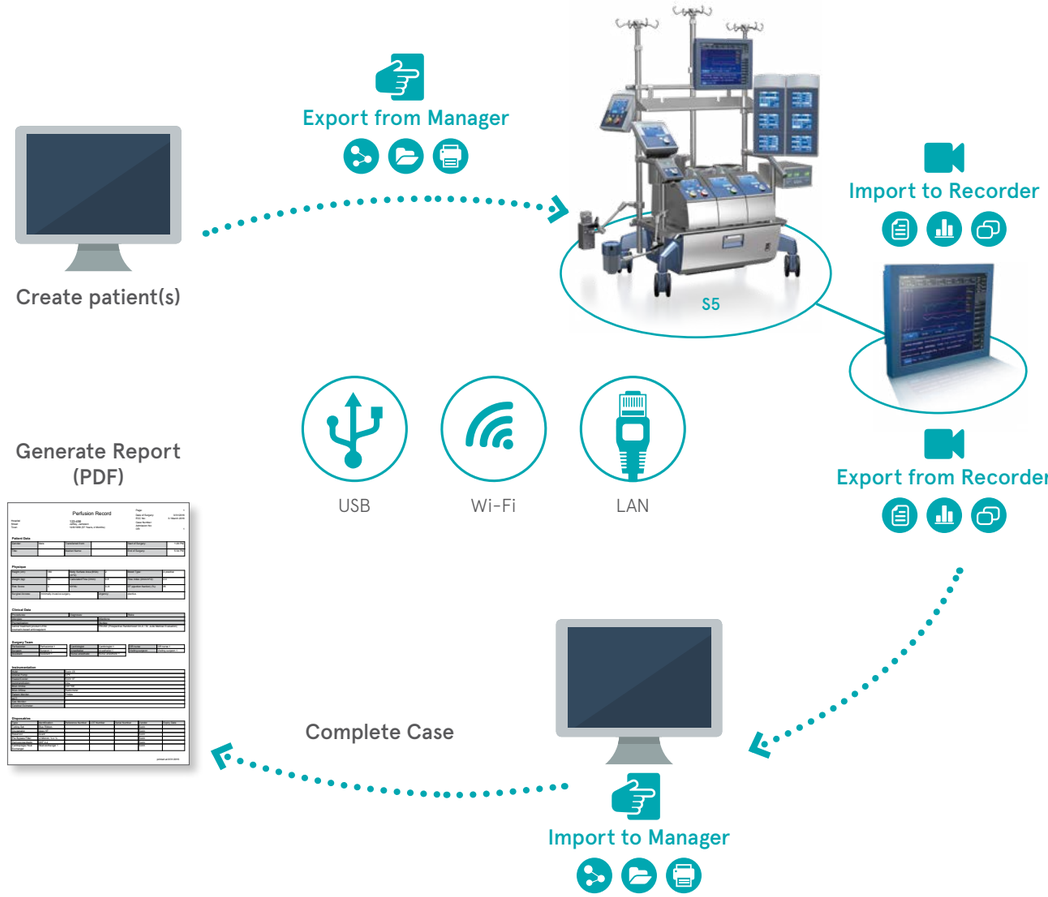
The **Connect Recorder®**:

- 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
- Displays Goal Directed Perfusion parameters via GDP Monitor

Improved clinical practice

The **Connect** workflow system minimizes transcription errors, bias and all the drawbacks associated with manual operations.[1] Connect allows trending and electronic transfer of data from LivaNova disposables.

The perfusionist accesses all perfusion data on one screen allowing more time to concentrate on the patient and circuit facilitating optimal patient management.[1] All data is then exported back to the Manager database where the clinician may consult case per case for statistical and inventory analysis, generate and export or print complete electronic medical records.



- Connect Manager
- Case record database
- Database query tools
- Print or export patient records
- Connect Recorder
- Automatic case information capture
- Customizable data charts
- Quick, easy manual event entry

All the information you need on one screen

Easy, intuitive and complete Graphical User Interface (GUI).

During the operation, the perfusionist can view, in near real-time, data and patient parameters in the form of graphs or charts according to personal preference. The perfusionist may also enter any data as well as comments and event entries in order to have complete documentation during the case.
The Connect System may also be configured to collect data electronically from a variety of patient monitors, blood gas devices, ACT meters, cerebral oximetry devices, etc.


Fluid balance overview screen


Events shown as chart


Gas flow chart

Powerful HL7 interface upgrade

CONNECT UPGRADE OPTION

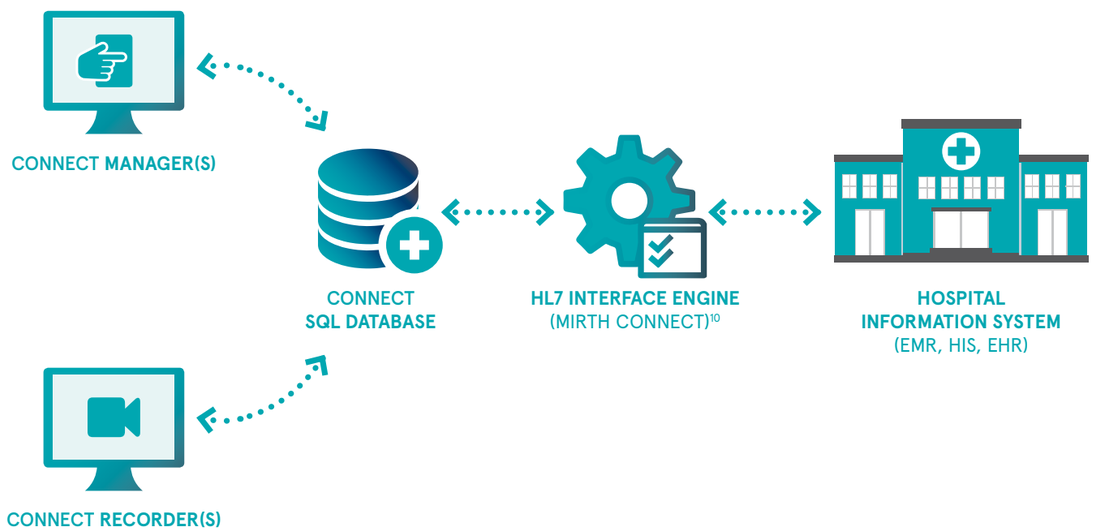
The new, powerful, optionally available **HL7 interface** is an integrated, bidirectional communication system between **Connect** and the **Electronic Medical Record** (EMR). It allows the perfusionist to retrieve and share patient information from and to an EMR system to **simplify workflow and improve clinical practice.**

Main clinical benefits of Connect HL7:

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

Main features of Connect HL7:

- 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



CONNECT
UPGRADE OPTION

GDP Monitor

Critical patient parameters at your fingertips

Implement Goal-Directed Perfusion Therapy with the optional GDP Monitor feature

Goal-Directed Perfusion is a perfusion therapy aimed at reducing the occurrence of Acute Kidney Injury (AKI), shortening ICU and hospital length of stay, and potentially decreasing Red Blood Cell (RBC) transfusions by respecting the metabolic needs of each patient during cardiac procedures.

5 GUIDING RULES TO IMPLEMENT GOAL-DIRECTED PERFUSION [2, 3, 4, 6, 7, 8, 9]

1. Limit hemodilution on CPB (Hct management)*
2. Oxygen Delivery index **DO_2i** to be kept **> 270 ml / min / m²**
3. Increase the DO_2 by acting on pump flow, PaO_2
4. Oxygen Delivery to Carbon Dioxide production radio (**DO_2i / VCO_2i**), to be kept **>5**
5. Transfuse RBC based on SvO_2 and **O_2ER****** rather than HCT

LivaNova, together with leading clinicians that have studied the clinical benefits and improved patient outcomes associated with Goal-Directed Perfusion, is at the forefront of creating global awareness of the advantages of this therapy. Furthermore, LivaNova implements and transparently provides the GDP formulas patented by Dr Marco Ranucci.

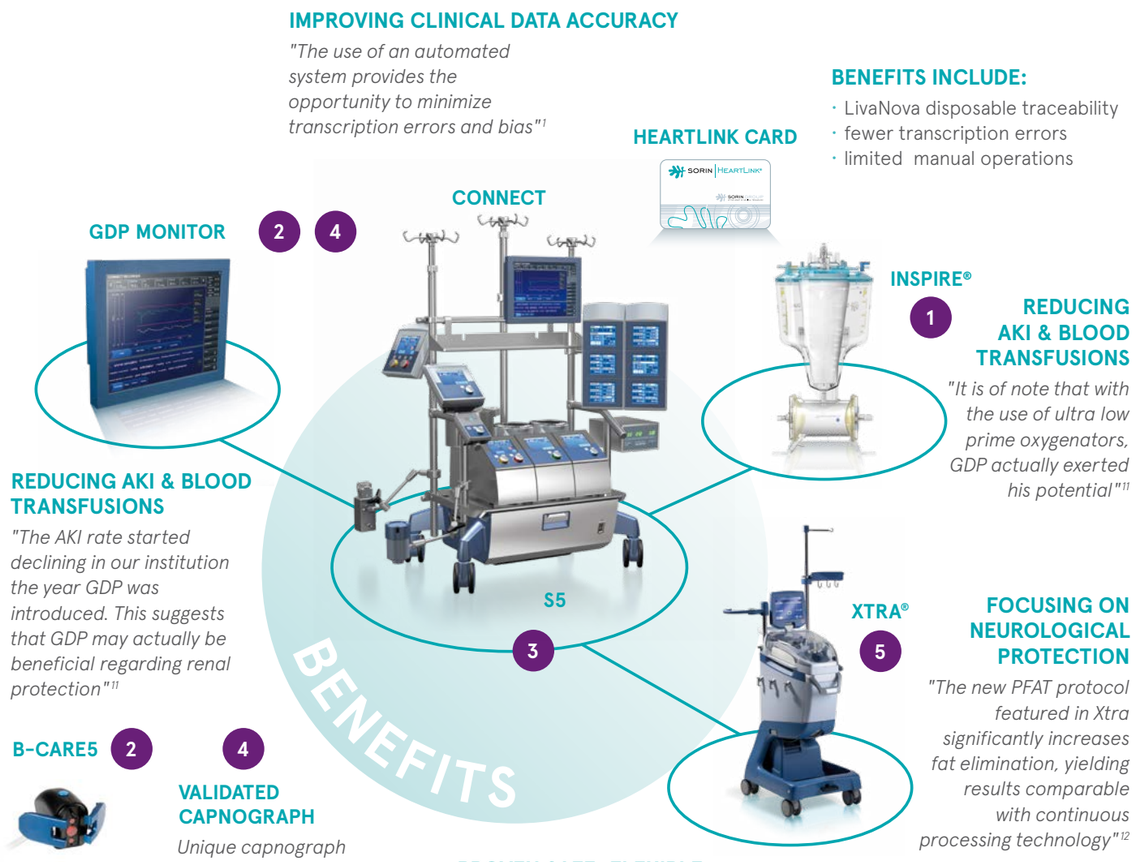
With the **GDP Monitor** the perfusionist may view advanced parameters such as **VCO_2i, O_2ER** and the metabolic ratio **DO_2i/VCO_2i**. Such parameters are relevant for optimal perfusion management where the metabolic needs of each patient during cardiac procedures is effectively respected.[2, 3, 4, 6, 7, 8, 9]

* ~1% point of Nadir Hct → +7% AKI (Ranucci et al., "Acute Kidney Injury and Hemodilution During Cardiopulmonary Bypass: A changing Scenario"; Ann Thoracic Surg. 2015 Jul;100(1):95-100

** VO_2i / DO_2i: fraction of DO_2 that diffuses from capillaries into tissues: goal <35-39% (VO_2= Oxygen Consumption)

Heartlink® System

The first integrated **Perfusion Management System** designed to **help clinicians to improve patient outcomes, increase clinical efficacy and apply Goal-Directed Perfusion therapy.**



PROVEN SAFE, FLEXIBLE AND MODULAR

"I am using the S5 in various configurations according to the different weight of my patients. This helps me to achieve an optimum relation between the priming and blood volume of the patient. The flexible mast mounted pumps allow a very close positioning of the whole system to the patient"

Frank Münch, Chief perfusionist, University hospital Erlangen, Germany

* Refer to LivaNova for more information

References:

1. The future of the perfusion record: Automated data collection vs. manual recording.
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2. O_2 delivery and CO_2 production during cardiopulmonary bypass as determinants of acute kidney injury: Time for a Goal-Directed Perfusion management?
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   Ranucci M, Romitti F, Isgró G, Cotza M, Brozzi S, Boncilli A, Ditta A; Ann Thorac Surg. 2005 Dec;80(6):2213-20
4. Anaerobic metabolism during cardiopulmonary bypass: Predictive value of carbon dioxide derived parameters.
   Ranucci M, Isgró G, Romitti F, Mele S, Biagioli B, Giomarelli P, Ann Thorac Surg. 2006 Jun;81(6):2189-95
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10. https://www.mirth.com/
11. Acute kidney injury and hemodilution during cardiopulmonary bypass: a changing scenario.
    Ranucci M, MD, FESC, Aloisio T, MD, Carboni G, CCP, Ballotta A, MD, FESC, Pistuddi V, Menicanti L, MD, and Frigiola A, MD; Surgical and Clinical Outcome REsearch (SCORE) Group. Departments of Cardiothoracic and Vascular Anesthesia and Intensive Care and Department of Cardiac Surgery, IRCCS Policlinico San Donato, Milan, Italy
12. The impact of bowl size, program setup, and blood hematocrit on the performance of a discontinuous autotransfusion system.
    Seyfried T F et al., doi:10.1111/trf.13954; Transfusion 2017

Order Guide

ITEM CODE	IDENTIFICATION	DESCRIPTION	QUANTITY / BOX
24-90-80	Connect Recorder	for S5	1
24-90-81	Connect Recorder	for S3	1
24-90-45	Connect Manager		1

Additional packages for upgrades from DMS are available, 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® XP service pack 3 / Microsoft® Windows® 7 / Windows 10 Enterprise LTSC 2018 64-bit
.NET used: 3.5 SP1
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

LivaNova
Health innovation that matters

www.livanova.com

ETHICAL COLLABORATION IN HEALTHCARE CERTIFIED
Licensed by Eucomed

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

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

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