

XTRA® The eXtraordinarily innovative, intuitive and powerful ATS system



Autotransfusion

A key role in an effective blood management strategy

The risks and costs related to homologous blood transfusion and its constantly decreasing worldwide availability have been widely documented.

Many health care providers and hospitals are now developing a **Blood Management Strategy**, a multidisciplinary approach to optimize the use of blood products, aiming to reduce the need for homologous blood, improve patient outcome and contain costs.

One of the key elements for a complete blood management strategy is **autotransfusion**, involving the collection, processing, and reinfusion of the patient's own blood that is lost during the peri-operative period at the surgical site.

Autotransfusion drives:

Maximum safety

It significantly reduces the demand for homologous blood and prevents the risks involved in its transfusion:

- Mistransfusion
- Transfusion Related Acute Lung Injury (TRALI)
- Systemic Inflammatory Response Syndrome (SIRS)
- Transfusion Related Immunomodulation (TRIM)
- Immunosuppression

Significant cost reduction for the hospital

It provides fresh, autologous, vital RBCs to the patient eliminating the costs related to bank blood tranfusion:

- The average total cost of transfusing a unit of homologous RBCs is \$1,158*
- No direct costs related to blood screening
- Indirect long-term costs reduction: several studies show that the reinfusion of RBC's recovered with autotransfusion improves post-operative outcome, and decreases hospital stay and additional medical treatments

^{*} Shander, Aryeh, Hofmann Axel Et al. The true cost of red blood cell transfusions in surgical patients. 2008: Presented at the 50th Annual American Society of Hematology Meeting, The Moscone Center Poster Board III-127

XTRA[®]

The complete solution for blood salvage

For over 30 years, LivaNova has treated more than 6.5 million patients with its ATS products. The experience and dedication towards research of innovative solutions allows LivaNova to be recognized as a world leader in autotransfusion.

XTRA[®] is the latest extraordinarily innovative, intuitive and powerful ATS system.

It is a compact, ergonomic and robust **ATS device** with an attractive design, developed by the same designers of LivaNova S5 and C5 heart lung machines. It inspires to BRAT 2 and Electa, combining and improving their best features, and introducing further innovation, through S5 and C5-like design, **graphic color touch screen user interface** and advanced **data management** capabilities.



XTRA® is the eXtraordinarily **innovative**, **intuitive** and **powerful** ATS system at your fingertips



Follow the symbol to discover the eXtraordinary features

XTRA® - INNOVATIVE



INNOVATIVE

LivaNova Family Design

With design characteristics similar to the world-leading heart lung machines S5 and C5, XTRA perfectly blends into the LivaNova product portfolio assuring high reliability and durability.



The first Graphic Color Touch Screen user interface

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

Taking inspiration from our world leading HLM machines S5 and C5, the XTRA user interface displays all the information you need by means of modular displets that can be opened or closed at your desire and offers complete control of the system throughout extremely intuitive and easy-to-navigate menu pages.



XTRA® - INNOVATIVE

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.

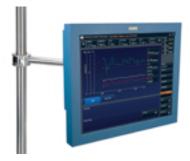
- Internal memory capable of storing thousands of past cases
- USB ports for simultaneous download of multiple cases to be imported in ATS Data Board
- Integrated ink printer, producing a permanent case printouts, ensuring complete traceability
- RS232 ports for external PC connection
- Functional integration with S5 and C5 thanks to CONNECT[™]



CONNECT[™]

CONNECT[™] is an innovative and intuitive **Perfusion charting system** focused on real time and retrospective calculations and trending tools to assist with CPB data management.

XTRA can electronically link to CONNECT[™] to integrate all Perfusion data into one case report.



ATS Data Board

ATS Data Board is the new PC based data management software that allows to store case files downloaded from XTRA autotransfusion system, easily consult and track case data and create user defined reports.

ATS Data Board offers a series of easy and intuitive software solutions to trace autotransfusion patient's case data, measure performance and use of autologous blood products, and help monitor the implementation of your blood management strategy.

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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
- The waste line color indicator is an optical sensor providing on-screen information at-a-glance on the wash quality by a visual indicator









XTRA® – INTUITIVE

INTUITIVE





Ergonomics

Special care was put in the **design** of the system ergonomics in order to improve interaction throughout all working phases and situations.

- XTRA has a small footprint that allows the machine to fit in narrow spaces
- The four pivoting wheels coupled with the front and rear handles ensure high maneuverability of the system
- The robust and transparent centrifuge lid protects the machine from any fluid spillage, helps reduce noise and allows complete visibility into the centrifuge
- The huge storage capacity of the machine allows transportation for all the necessary disposable to start the procedure. The cart was designed to transport more than 6 liters of fluids and maintain stability*

Eg: 5 | of saline bags + 1 | of anticoagulant bags + 1 Bowl Set (or Reservoir)

The IV poles offer several hooks for bags and also a compartment for storage of caps or pens

(*= with Xvac mounted)





Fast and intuitive setup

Experience the easy, fast and safe disposable setup. The newly designed XTRA top panel and disposables allow error proof setup, in a blink of an eye.

- The XTRA BOWL and the patented centrifuge plate ensure easy 360° mounting
- The new centrifuge arm allow one-hand arm locking/unlocking
- The new cartridge and tubing design guarantees a straightforward setup, with lid-driven tubing positioning into the air sensor seat



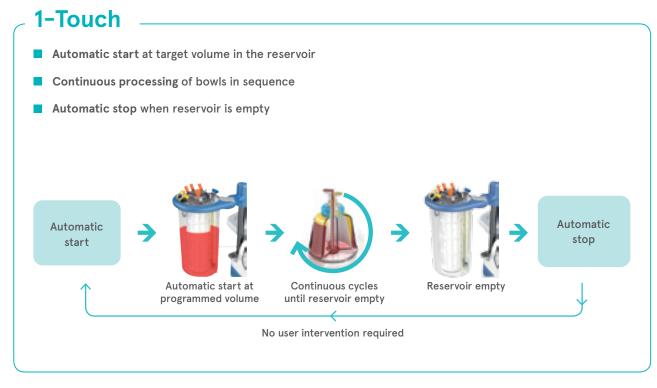




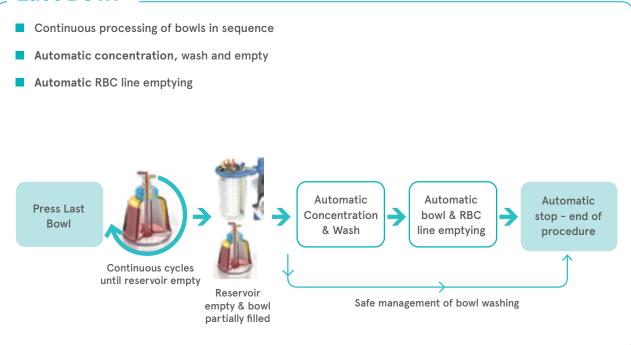


Fully automated processing

1-Touch mode and Last Bowl function provide complete automation from the beginning to the end of the procedure







Operating Protocols



2 In vitro performance evaluation study with human blood 25% Hct with XTRA Bowl 225. The result are consistent also with the other bowl sizes. Data on file at LivaNova.

XTRA® - POWERFUL



EXTRAORDINARILY POWERFUL

Popt

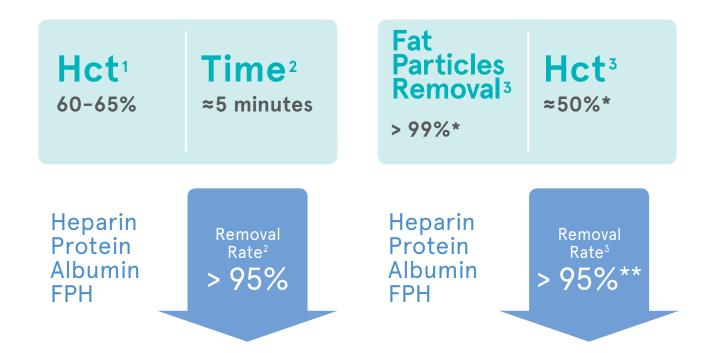
High RBC Hct and wash quality with Popt

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

Pfat

Complete fat removal with the new Pfat

The newly developed Pfat protocol will effectively remove fat particles.



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

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

XTRA® - POWERFUL



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.



Hct₄

≈50%



• Emergency ≈3 minutes

Removal Rate² > 92%



Sources:

- 1 "Clinical evaluation of the new LivaNova XTRA® Autotransfusion System" E.P. Overdevest, H.Feron, J.W.H. van Hees, P.Lanen, M.Sahin 10th ECOPEAT Geneve Switzerland, 2010.
- 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 at LivaNova Italia.

Quiet, Powerful Vacuum Xvac is a modular vacuum pump, designed to be

XvAC is a modular vacuum pump, designed to be extremely quiet and to deliver top 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

XvAC guarantees uncomparable 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	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				
* = with cart.					
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	230 V~ or 100-120 V~				
(Power Supply)					
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

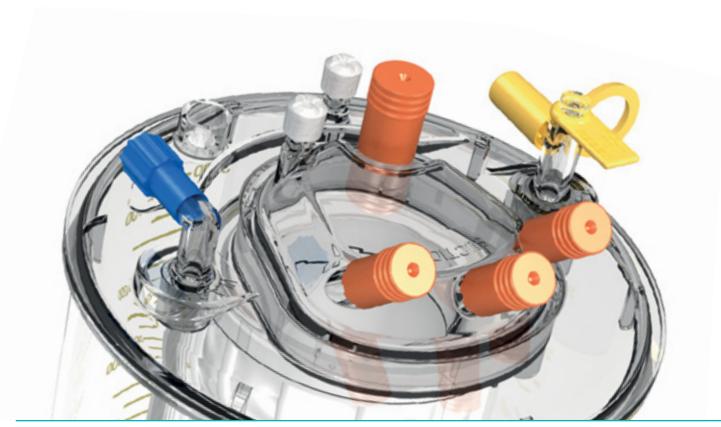
- 4-liter capacity
- Advanced, multi-layer filtration system, with:
 - Internal defoaming polyurethane layer (30 ppi)
 - Intermediate woven, non-woven filter (40 µm)
 - External screen (120 μm)

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



Broad Flexibility

- Three 1/4" suction ports, for the collection of blood both intra-operatively and postoperatively: 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



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 The smallest bowl for minimal bleeding	Minimal Bleeding Orthopedic Surgery Small Size Patients Pre-operative Sequestration (PPP/PRP)
XTRA BOWL 125 The standard bowl for low bleeding	Orthopedic Surgery (Total Joint Replacement) Obstetric Surgery Pre-Operative Sequestration (PPP/PRP)
XTRA BOWL 175 The intermediate bowl for medium bleeding	High Bleeding Orthopedic Surgery (Revisions) Low Bleeding Cardiac Surgery (Mini-Bypass) Cardiovascular Surgery
XTRA BOWL 225 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 Anticoagulation 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: orthopedic 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 postoperative 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.









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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

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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 -and C5- like touch screen user interface, ensuring a straigthforward learning curve for all operators already familiar with LivaNova heart-lung machines
- Functional integration with S5 and C5 through LivaNova Connect Perfusion Charting System
- 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

Interventions O

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

High Bleeding Surgery

/ Emergency

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 bootup 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

Interventions:

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

Orthopedic Surgery

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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

Interventions:

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

Pre-operative Sequestration

What you need:

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

*not for US and Japan

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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

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Code	Description	Quantity / Box
75220	XTRA Equipment 230V 50Hz Version	1
75221	XTRA Equipment 110V 50Hz Version	1
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28021	Country Box "F"	1
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28023	Country Box "D – A"	1
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Item	Description	Quantity / Box
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
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09086 09087	200m Goccia Filter with Infusion Line	6
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*Not available in US and Japan.

www.livanova.com



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