

Connect™

Get connected to optimal data management practices



The first innovative and intuitive perfusion data management system designed to improve clinical efficiency¹ and enable Goal-Directed Perfusion Therapy

Connect to clinical efficiency with greater confidence

Minimize

Transcription errors and bias.¹

Restrict

Inefficiencies of manually entering product traceability data.

Decrease

Limitations of analyzing manually recorded data.

Enable

Application of GDP, which aims to reduce occurrence of Acute Kidney Injury.^{2, 3, 4, 6, 7, 8, 9}

Connect™

Allows trending while centralizing all patient data on one screen.

Connect

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

Connect

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

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

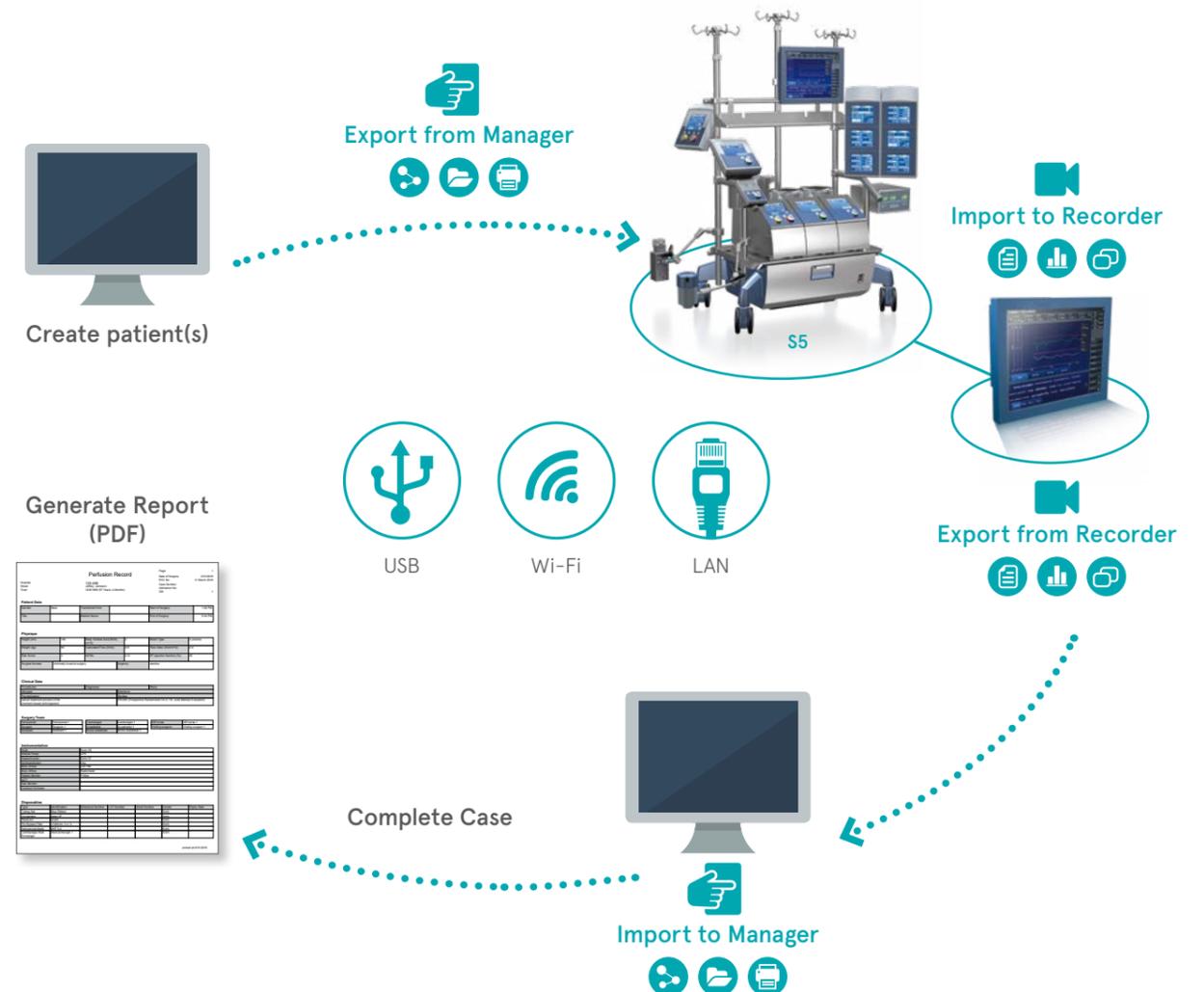
The **Connect Recorder**®:

- 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.

Setup any numerical parameters to be recorded

Define up to 5 parameters for graphical charting

Change charting views according to preferences

Single-touch event entry

Create up to 6 timers triggered by HLM or tag cloud

Toggle between 5 additional detail screens

Touch "Balance" in order to get a full overview of the fluid balance

Touch "Blood Gas" in order to get a full overview of blood withdrawals and lab results

Touch "Coagulation" to document blood withdrawals and lab results

Touch "Cardioplegia" to view electronically collected data or to enter cpl data manually

Activate GDP Monitor with a HeartLink or GDP Card



Fluid balance overview screen



Events shown as chart



Gas flow chart



Powerful HL7 interface upgrade



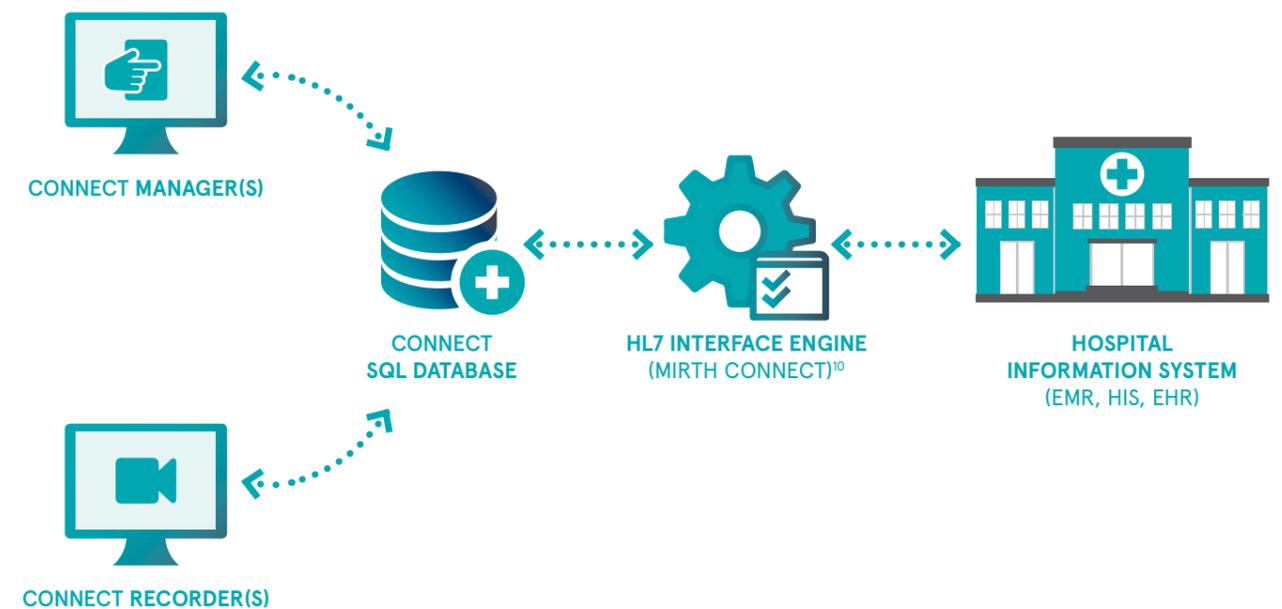
The new, powerful, optionally available **HL7 interface** is an integrated, bidirectional communication system between **Connect** and the **Electronic Medical Record (EMR)**. It allows the perfusionist to retrieve and share patient information from and to an EMR system to **simplify workflow and improve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



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 $> 270 \text{ ml} / \text{min} / \text{m}^2$
- 3 Increase the DO_2 by acting on pump flow, PaO_2
- 4 Oxygen Delivery to Carbon Dioxide production ratio (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.

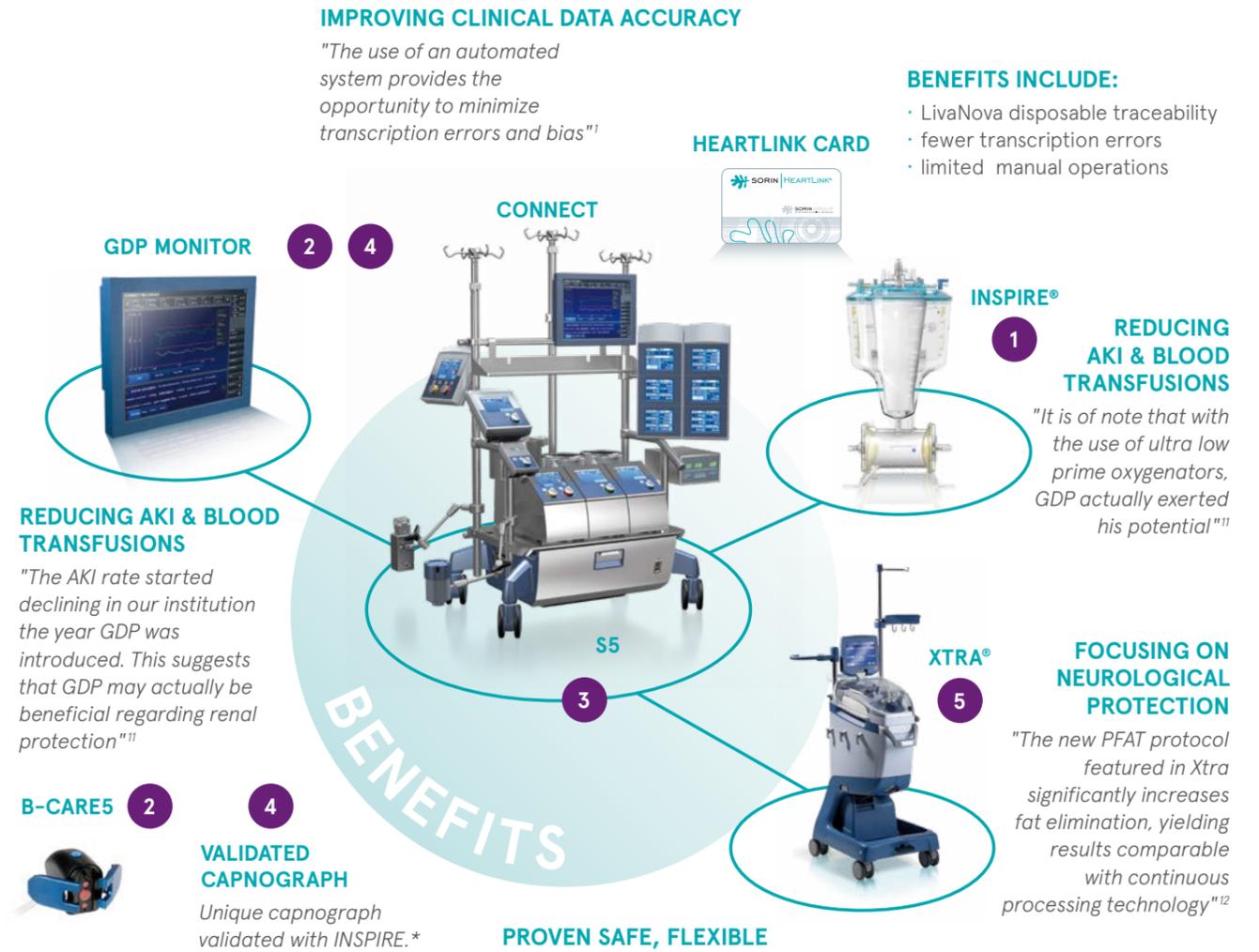
With the **GDP Monitor** the perfusionist may view advanced parameters such as VCO_{2i} , O_2ER and the metabolic ratio DO_{2i}/VCO_{2i} . Such parameters are relevant for optimal perfusion management where the metabolic needs of each patient during cardiac procedures is effectively respected.^{2, 3, 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.



* Refer to LivaNova for more information

References:

1. The future of the perfusion record: Automated data collection vs. manual recording. Ottens J et al., JECT 2005;37:355-359J Extra Corpor Technol. 2005 Dec;37(4):355-9.
2. O₂ delivery and CO₂ production during cardiopulmonary bypass as determinants of acute kidney injury: Time for a Goal-Directed Perfusion management? De Somer F, Mulholland JW, Bryan MR, Aloisio T, Van Nooten GJ, Ranucci M, Crit Care, 2011 Aug 10;15(4):R192
3. Oxygen delivery during cardiopulmonary bypass and acute renal failure after coronary operations. Ranucci M, Romitti F, Isgrò 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, Isgrò G, Romitti F, Mele S, Biagioli B, Giomarelli P, Ann Thorac Surg. 2006 Jun;81(6):2189-95
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6. Outcome with high blood lactate levels during cardiopulmonary bypass in adult cardiac operation. Demers P, Elkouri S, Martineau R, Couturier A, Cartier R. Department of Surgery, Montreal Heart Institute, Quebec, Canada
7. Frequency, risk factors, and outcome of hyperlactatemia after cardiac surgery. Maillet JM, Le Besnerais P, Cantoni M, Nataf P, Ruffenach A, Lessana A, Brodaty D. Cardiovascular and Thoracic Surgery Intensive Care Unit, Centre Cardiologique du Nord, Saint-Denis, France
8. Anaerobic metabolism during cardiopulmonary bypass: predictive value of carbon dioxide derived parameters. Ranucci M, Isgrò G, Romitti F, Mele S, Biagioli B, Giomarelli P. Department of Cardiothoracic Anesthesia, Policlinico San Donato, Milan, Italy
9. Hyperlactatemia during cardiopulmonary bypass: determinants and impact on postoperative outcome. Ranucci M, De Toffol B, Isgrò G, Romitti F, Conti D, Vicentini M. Department of Cardiovascular Anesthesia and Intensive Care, IRCCS Policlinico S. Donato, Via Morandi 30, 20097 San Donato Milanese, Milan, Italy
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

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 Health innovation that matters

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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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Please always refer to the Instructions For Use (IFU) manual provided with each product for detailed information, warnings, precautions and possible adverse side effects.

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