LivaNova

Health innovation that matters

INSPIRE™ 8 PH.I.S.I.O.

Powerful perfusion

Powerful perfusion

Without exception, clinicians demand safety and confidence from their perfusion devices.

LivaNova, using its 40 year experience in oxygenator systems design, has created the all new INSPIRE 8 LPM oxygenators with performance and patient protection in mind. The INSPIRE 8 has a newly designed polyurethane heat exchanger that is capable of a powerful heat transfer. The remarkably efficient longitudinal flow design oxygenator module maximizes gas exchange performance up to 8 LPM with efficient use of surface area.

INSPIRE 8 LPM oxygenator systems provide superior performance up to 8 LPM, allowing clinicians to safely and comfortably treat all adult patients, while reducing hemodilution and effectively controlling gaseous micro emboli (GME), thanks to a unique design approach focusing the entire oxygenator system.

INSPIRE 8 LPM oxygenator systems offer the ideal solution for **powerful perfusion** and have been designed to help clinicians standardize perfusion practice at the highest performance levels.

They are available with and without an integrated arterial filter, with traditional single chamber reservoir or unique DUAL chamber reservoir for enhanced biocompatibility.

INSPIRE™ 8
PH.I.S.I.O.

INSPIRE™ 8F
PH.I.S.I.O.

INSPIRE™ 8 DUAL
PH.I.S.I.O.

INSPIRE™ 8F DUAL
PH.I.S.I.O.

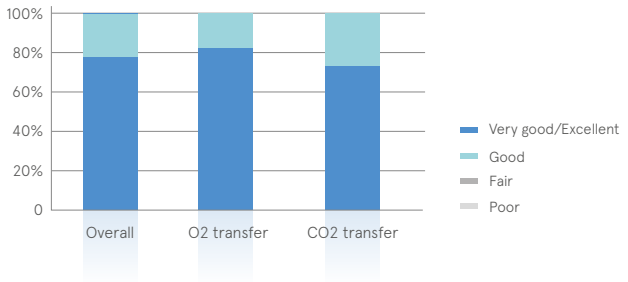
- Outstanding feedback from clinicians
- Powerful and consistent performance up to 8 LPM
- Low impact on hemodilution
- Superior GME handling*
- Dual chamber reservoir for enhanced biocompatibility (INSPIRE 8 DUAL and 8F DUAL)

** vs. competitive design*

OUTSTANDING FEEDBACK FROM CLINICIANS

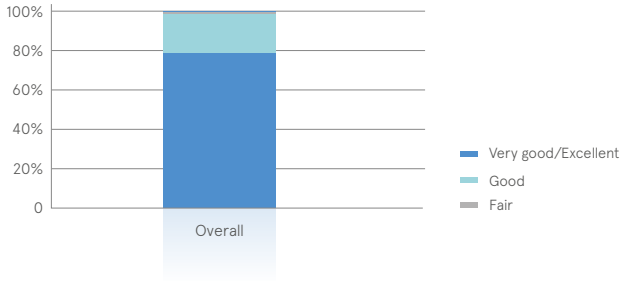
The powerful gas exchange capability of INSPIRE 8 and 8F has been rated as good, very good or excellent by 100% of clinicians during the Market Assessment Study.

Gas Exchange



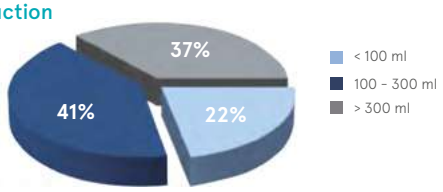
The INSPIRE newly designed polyurethane heat exchanger is capable of superior** performance providing highly efficient heat transfer.
The INSPIRE Heat Exchanger performance has been rated as good, very good or excellent by almost 100% of clinicians during the Market Assessment Study.

Heat Exchange



About 80% of clinicians answering reported that they perceived additional clinical benefits when using INSPIRE 8 LPM vs. their current oxygenator. Over 30% indicated this being a reduction in priming volume, while others experienced an increased hematorcrit during the case or reduced transfusions.
Among clinicians using INSPIRE 8 LPM clinically during the Market Assessment Study, who reported a reduction in priming volume, 78% quantified it as more than 100 ml less and almost 40% reduced prime by 300 ml.

Overall Priming Volume Reduction



Clinicians using INSPIRE 8 LPM oxygenators systems during the Market Assessment Study (MAS) commented that:

*"INSPIRE 8 looks like **a strong alternative** to improve outcomes by reducing prime volumes in a wide range of patients."*
*"Overall I would highly recommend this product to any other perfusionist and institute. **I've seen much better Hct's on CPB and the performance of the oxygenator is superior compared with the Synthesis.**"*
"INSPIRE 8 is a very efficient, low prime, low surface area oxygenator."
***"The Inspire is a very good system. Much improved** upon the older model with the ability setup and change the oxygenator (if need be) by a simple snap and drop."*

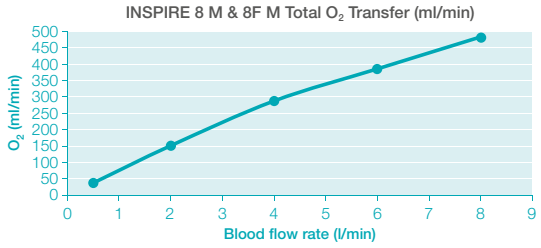
LOW PRIME OXYGENATORS WITH POWERFUL AND CONSISTENT PERFORMANCE UP TO 8 LPM

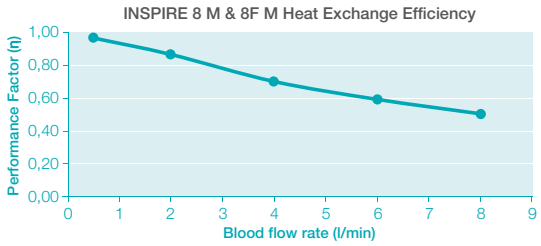
INSPIRE 8 LPM oxygenator systems are the only low prime oxygenators rated up to 8 LPM maximum blood flow. They are capable of delivering powerful and consistent performance throughout the entire blood flow range.

Thanks to the longitudinal flow path, the highly efficient design allows to significantly reduce prime volume:

- Only 219 ml oxygenator priming volume for the standard version, which contributes to make INSPIRE 8 the oxygenator system with the lowest dynamic operating volume (DOV) compared to other full size oxygenators.
- Only 351 ml oxygenator priming volume for the version with integrated arterial filter.

When an integrated arterial filter is added, the combined volume is only 351 ml.



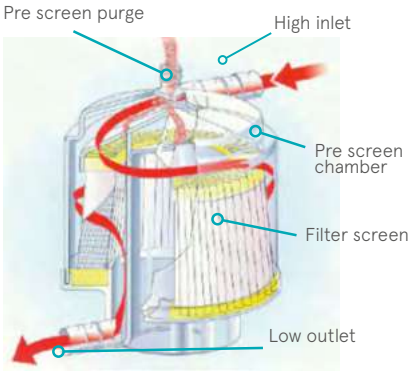


INTEGRATED ARTERIAL FILTER WITH SUPERIOR GME HANDLING*

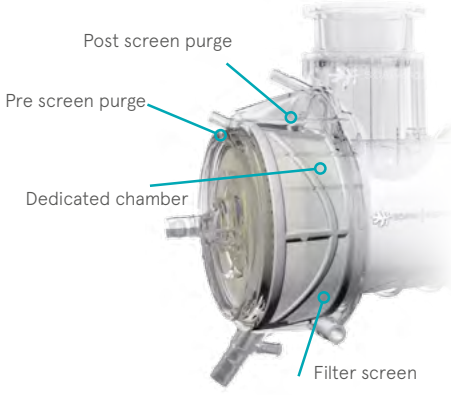
From its conception, the arterial filter has given confidence to the perfusionists by providing additional protection for the patient, hence adoption rate in recent years has consistently increased. Integration of arterial filter and oxygenator improves safety by reducing connections, reduces hemodilution and makes setup easier. **The INSPIRE integrated arterial filter design, thanks to its dedicated compartment, offers superior GME handling compared to competitive designs, while ensuring minimized impact on hemodilution.**

The INSPIRE Integrated Arterial Filter was designed for safety and ease of use, integrating the essential features of separate arterial filters. Studies have shown arterial filters with a pre-screen chamber and purge capability provide better protection from air and GME[1], by allowing a reduction of blood velocity before the screen. To facilitate air removal, INSPIRE includes purge ports on both sides of the 38 µ screen. This unique design allows for the first time to have full visibility on the filter outer side.

Common Filter Elements:



Inspire Integrated Arterial Filter:



** vs. competitive design*

[1] Evaluation of Integrated and Non-Integrated Oxygenator/Arterial Filters for Gaseous Microemboli Removal
Larry Petree, MS; Bob Eke, BA; Rob Haynes, BA; Cheri Voorhees, BAH(ASCP)SH
Sorin Group, Arvada, Colorado, USA

SAFE, EASY AND FLEXIBLE

The INSPIRE oxygenator systems are flexible and versatile. **INSPIRE is the most vertically compact oxygenator system on the market today. It allows optimal handling during the case and minimal storage on the shelf.** A single, newly designed bracket fits the entire family for maximum convenience. Ergonomics, port orientation and system priming have been optimized to offer easy set-up and operational flexibility.

FLEXIBILITY AND EASY HANDLING

- Most vertically compact design on market (< 500 mm)
  - Better venous drainage
  - Less storage volume
- 4.5 liter max. reservoir capacity volume
  - 4 liter maximum operating volume
  - Easy reading of graduated scales
- Maximal system rotational freedom
- Safe and easy set-up
  - Single sided sterile and unsterile ports on oxygenator module to avoid mis-connections
- Quick priming and easy de-bubbling
  - Fast priming with membrane fluid-dynamics designed to optimize air removal during priming

ONE BRACKET FITS ALL FAMILY MODELS

- Quick priming and easy de-bubbling
- Robust and durable
- Easy to clean
- Available with "Fast Clamp" for C5/S5 HLM

PH.I.S.I.O. COATING

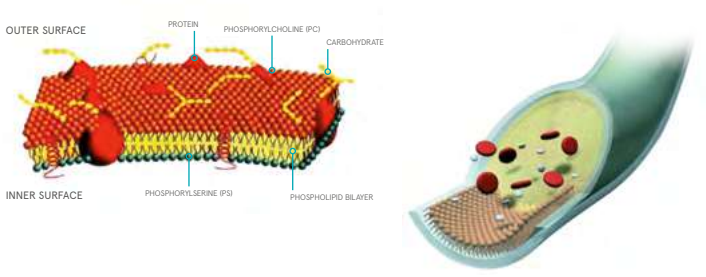
PH.I.S.I.O PC coating has proven to be extremely effective in reducing platelet activation and cell adhesion to foreign surface.

"The interaction of blood with foreign artificial surfaces during cardiopulmonary bypass (CPB) has been recognized as a major stimulus in evoking a systemic inflammatory and metabolic response. ***Phosphorylcholine (PC) is a new-generation coating material designed to ameliorate biocompatibility*** *and thereby to reduce the detrimental interactions of CPB".**

PH.I.S.I.O PC coating is a physiological inert material mimicking the endothelium widely proven by clinical experience on more than two millions patients to date.

All INSPIRE oxygenators are PH.I.S.I.O PC coated and, PH.I.S.I.O PC coating is also applied to all INSPIRE HVR and HVR DUAL blood contact surfaces: HVR bucket and venous return collector, frame of venous return filter. both venous and cardiotomy filtering nets.

PH.I.S.I.O.



* J Card Surg. 2009 Jul-Aug;24(4):363-8. doi: 10.1111/j.1540-8191.2009.00895.x.
Phosphorylcholine-coated circuits improve preservation of platelet count and reduce expression of proinflammatory cytokines in CABG: a prospective randomized trial. Schulze CJ, Han L, Ghorpade N, Etches WS, Stang L, Koshal A, Wang SH.

MINIMIZED IMPACT ON HEMODILUTION

Minimizing hemodilution contributes to decreased blood transfusions and improved clinical outcomes during and after cardiopulmonary bypass (CPB). Until now, the impact on hemodilution was associated with oxygenator module static priming volume.

With INSPIRE we are introducing a new concept: the oxygenator system dynamic operating volume (DOV), which allows to evaluate the overall hemodilution impact of an oxygenator system.

The oxygenator system DOV is defined as the sum of four elements: the oxygenator module priming volume, the reservoir minimum operating level, the venous filter dynamic hold-up volume and the venous collector priming volume.

INSPIRE oxygenator systems minimize the impact on hemodilution at a system level by featuring low priming oxygenator modules, the lowest minimum operating level in the reservoir (150 ml), outstanding low venous filter dynamic hold-up volume and low venous collector priming volume.

DYNAMIC OPERATING VOLUME (DOV)

Venous collector priming volume

Venous filter hold-up volume

Minimum operating level

Oxy module priming volume

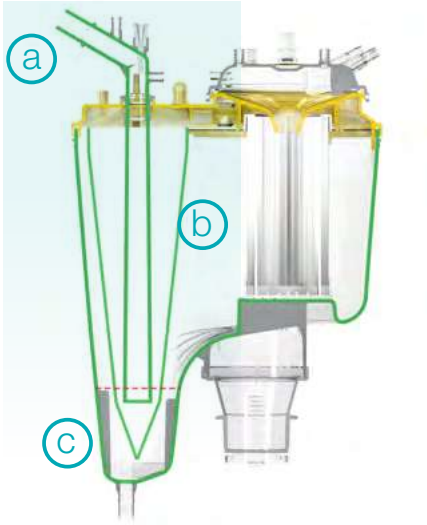
From Oxygenator Module to Oxygenator System

SUPERIOR GME HANDLING*

Gaseous microemboli are commonly indicated as potential sources of neurological damage after CPB. Dedicated design solutions within the INSPIRE HVR, HVR DUAL and in the INSPIRE oxygenator modules provide effective gaseous microemboli (GME) control, by approaching GME handling at a system level.

DESIGNED FOR EFFECTIVE AIR MANAGEMENT

It has been widely demonstrated by recent studies** that the reservoir plays a key role in controlling GME: *"The venous reservoir significantly influences embolic load delivered to the oxygenator (p < .001). [...] Venous reservoir design influenced the overall GME handling ability"*. INSPIRE HVR and HVR DUAL have been designed both on venous and cardiotomy side to maximize GME control through a mix of fluid-dynamics and filtration capabilities.

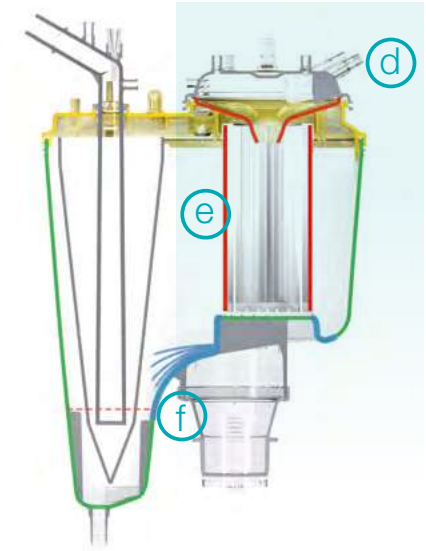


HVR VENOUS SIDE

a. Conical venous return tube to slow down blood speed and always submerged to avoids splashing

b. Dual filter screen on venous section (41µ + 120 µ)

c. Internal frame with specific design to slide air bubbles towards the top



HVR CARDIOTOMY SIDE

d. Suction blood is accompanied toward the filter floor or to the polyurethane sponge to minimize splashing

e. Pleated 41µ screen filter (vs. depth) designed for low GME and superior debris management

f. Diverging ribs on cardiotomy floor gently accompany blood to reduce blood speed

OXYGENATOR MODULE DESIGN

For GME, the longer path oxygenator design provides more blood side pressure and opportunity to remove air across the membrane fibers.

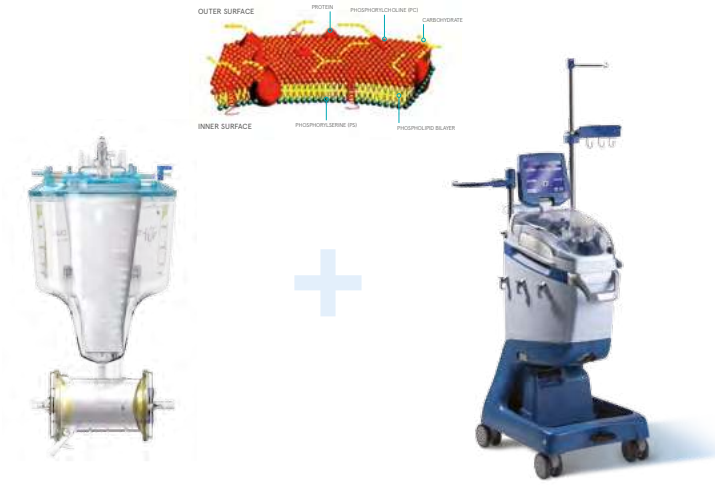
** vs. competitive design*

** J Extra Corpor Technol. 2011 Sep;43(3):107-14.
In vitro evaluation of gaseous microemboli handling of cardiopulmonary bypass circuits with and without integrated arterial line filters.
Liu S, Newland RF, Tully PJ, Tuble SC, Baker RA.

DUAL CHAMBER RESERVOIR FOR ENHANCED BIOCOMPATIBILITY

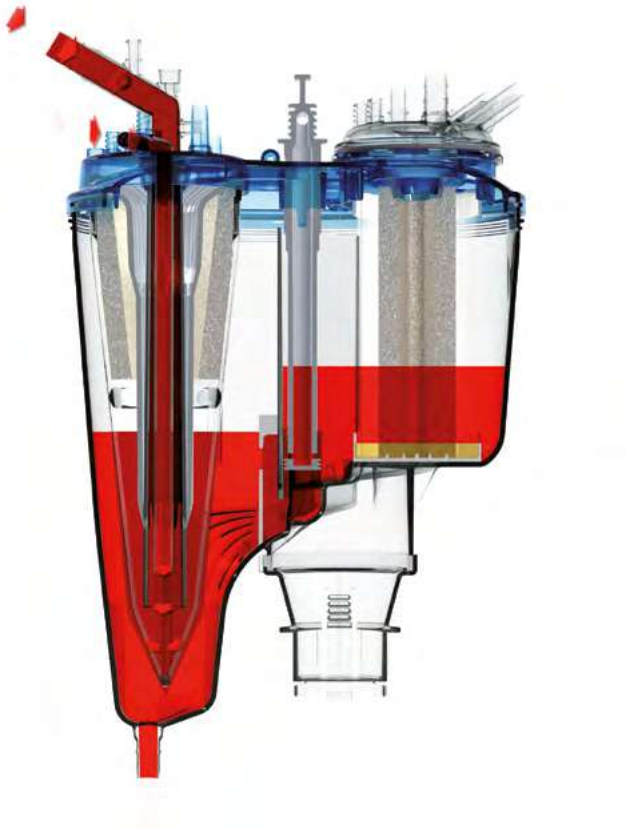
Full biocompatibilty includes reducing the multiple sources of cellular activation and inflammatory reaction. Surface coatings can reduce platelet and white blood cell adhesion to the circuit. But suction blood contains activated cells and stimulates additional activation. Combined, sequestering suction blood and using coated circuits offers maximum biocompatible benefit.

The INSPIRE DUAL Reservoir system provides clinicians new options for activated suction management.
The combination of the INSPIRE DUAL Reservoir system, PHISIO PC coating and LivaNova XTRA® autotransfusion system, offers clinicians a comprehensive solution to enhanced biocompatibility.



EASY PROCESSING AND FULL REVERSIBILITY

Separation of activated suction blood and washing with XTRA® autotransfusion system is made extremely easy by the chamber sequestration valve mechanism.
At the same time, clinicians have always at hand the choice to separate activated suction blood or the option to reverse INSPIRE DUAL to a single chamber venous reservoir.



LIVANOVA HEARTLINK™ SYSTEM

THE FIRST CARDIOPULMONARY BYPASS SYSTEM

LivaNova Heartlink™ is the first perfusion system to provide a unique link **between perfusion data, patient parameters and product information to assist with case management and Goal Directed Perfusion principles.** INSPIRE™ oxygenator family is the latest addition that, together with S5/C5 Heart-Lung machines, Connect Perfusion Charting System and XTRA® autotransfusion machine, completes the LivaNova Heartlink™ System.The LivaNova Heartlink™ card, available only with LivaNova INSPIRE, is the key to make system features available in Connect.

HEARTLINK™ CARD:

THE KEY TO CONTINUOUS PRACTICE IMPROVEMENT

HeartLink card, in conjunction with HeartLink reader and Connect, provides **automatic loading of data related to INSPIRE oxygenator systems and PTS** thus **reducing the number of manual operations** to collect this data and **potentially contributing to limit the number of human errors.** Connect is approved as a medical device and data transfer via HeartLink card has been validated to guarantee data integrity. Transferring data via the HeartLink card and including it in the database, together with patients' and procedures' data, allows clinicians to obtain a more complete perfusion record, **thus contributing to process standardization, a key to a continuous practice improvement.**

THE KEY TO INVENTORY TRACKING

Inventory management serves as an important and powerful tool to improve many key aspects of healthcare, tracking details such as quantities, usage rates and expiration dates so that items remain in stock and are used before they expire.

Thanks to HeartLink card and System, INSPIRE oxygenators and all the other components part of the INSPIRE Perfusion Tubing Set can be tracked in the perfusion report and the related information retained in Connect **for future statistical analysis and inventory reporting.**

THE KEY TO GOAL DIRECTED PERFUSION

HeartLink Card enables the GDP Monitor™ feature inside Connect™ allowing implementation of Goal Directed Perfusion principles in the operating room to **help in adapting adequacy of perfusion to patients while contributing to shorten ICU & hospital length of stay.**
With GDP Monitor™ it is possible to observe in real time and record parameters related to oxygen and carbon dioxide exchange and, in particular, **monitor DO_2 and DO_2/VCO_2 to ensure they are above their critical value** as this has been associated with a reduction in acute kidney injury (AKI) occurrence and reduced lactate peak level during CPB.

INSPIRE™ 8
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INSPIRE™ 8 DUAL
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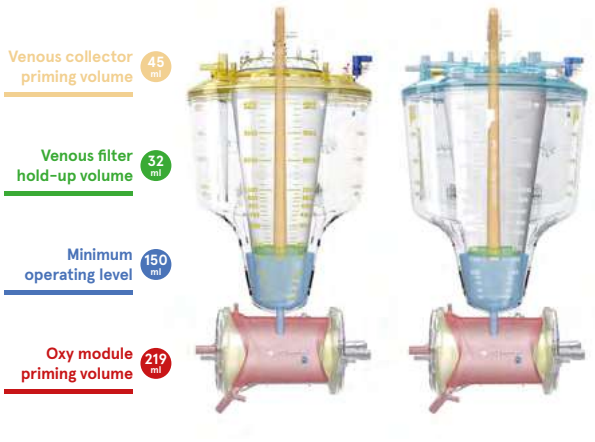
DYNAMIC OPERATING VOLUME (DOV)

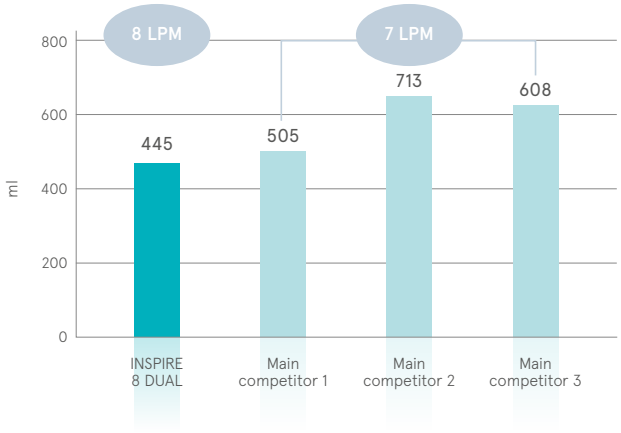


Overall impact on Hemodilution of the Oxygenator System at maximum blood flow

445 ml

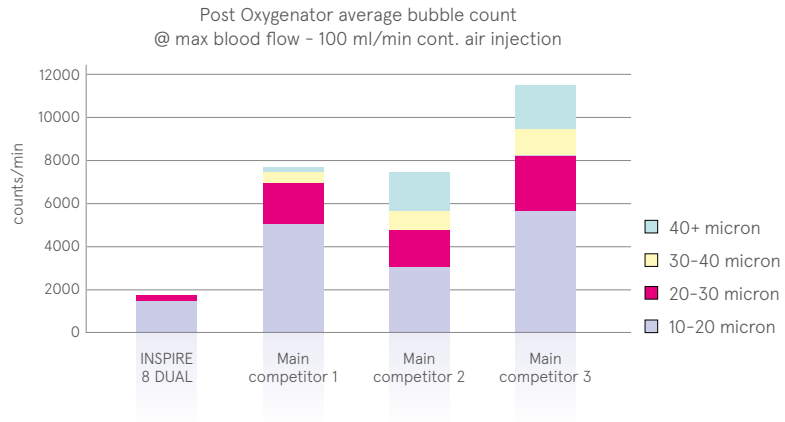
OXYGENATOR SYSTEM DOV
(at maximum blood flow)

INSPIRE 8 v. Small Adult Oxygenator Systems*



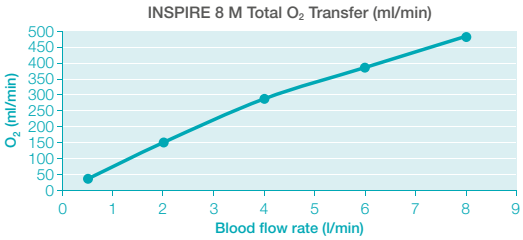
GME COMPARISON

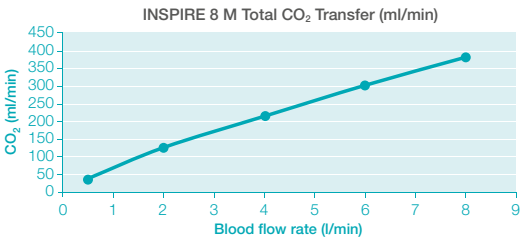
INSPIRE 8 v. Small Adult Oxygenator Systems*

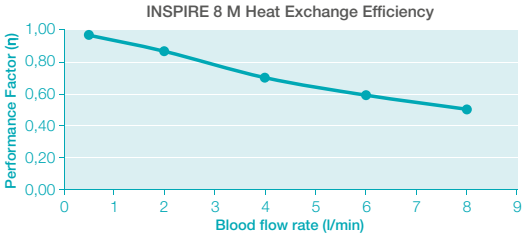


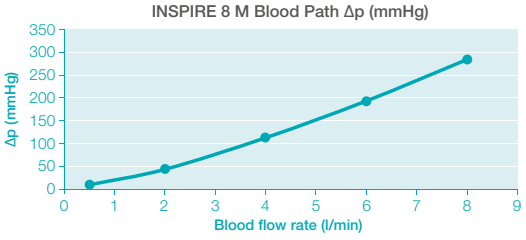
PERFORMANCE CHART

** TEST CONDITIONS*
(Bovine blood - Hb 12±0.2 gr/dl - B.E. 0±2mEq/l
- Venous pCO_2 45±5 mmHg - O_2 Venous Sat. 65±5%
- Blood Temp. 37±1 °C - Q_c/Q_B=1 - FiO_2 100% - Qw=11,5±0,2 l/min)









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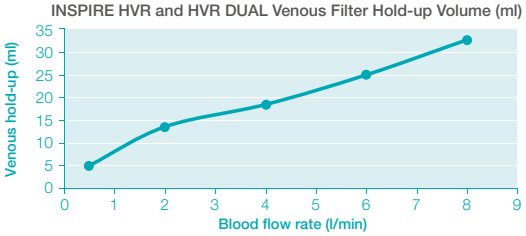

INSPIRE™ 8F
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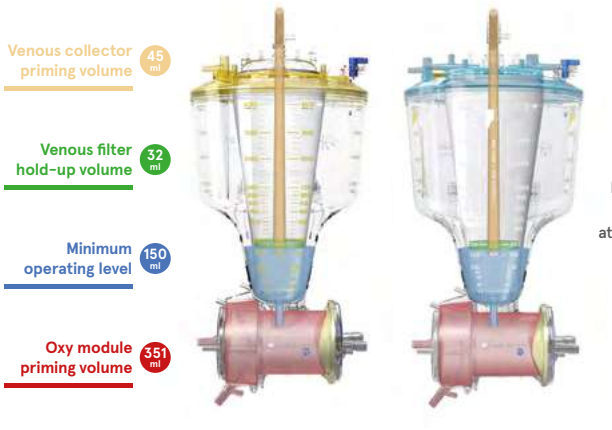
INSPIRE™ 8F DUAL
PH.I.S.I.O.

DYNAMIC OPERATING VOLUME (DOV)

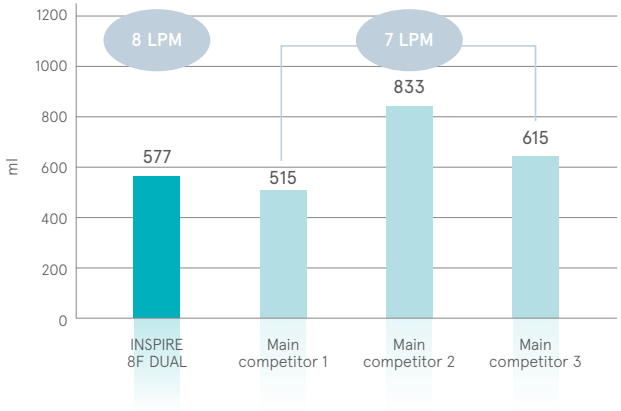


Overall impact on Hemodilution of the Oxygenator System at maximum blood flow

577 ml

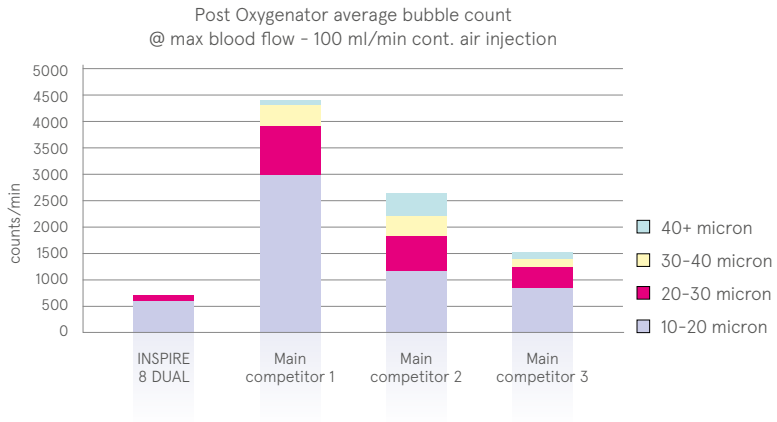
OXYGENATOR SYSTEM DOV
(at maximum blood flow)

INSPIRE 8F v. Small Adult Oxygenator Systems*



GME COMPARISON

INSPIRE 8F v. Small Adult Oxygenator Systems*



PERFORMANCE CHART

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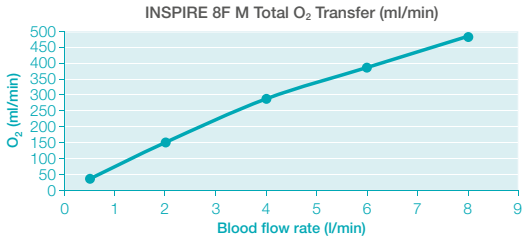

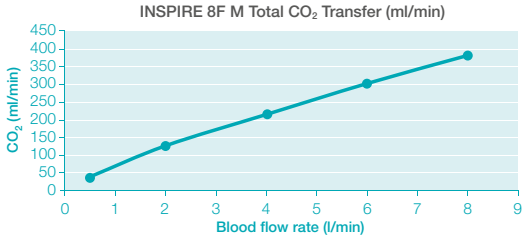

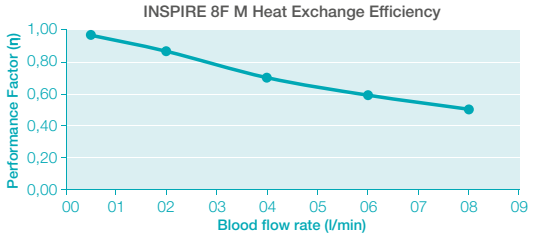

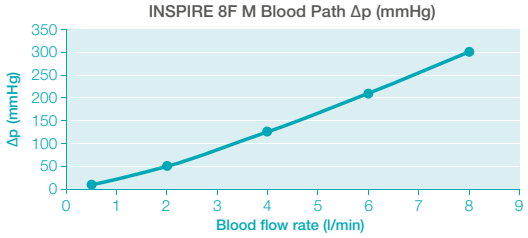

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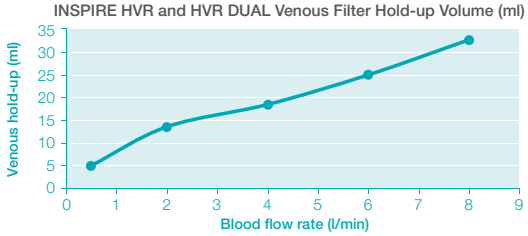

TECHNICAL SPECIFICATIONS

INSPIRE™ 8
PH.I.S.I.O.

OXYGENATOR SYSTEM	
- Oxygenator system DOV @ max flow	445 ml
- Biocompatible coating	Phosphorylcoline (PHISIO)
RESERVOIR	
MAX. VOLUME CAPACITY (approx.)	4500 ml
MAX. OPERATING LEVEL (approx.)	4000 ml
	150 ml
MIN. OPERATING LEVEL	
FILTRATION SECTIONS	
Venous reservoir section	
- Filtering media	41 µm polyester outer screen + 120 µm inner polyester net
Cardiotomy reservoir section	
- Filtering media	41 µm polyester screen
OXYGENATOR MODULE	
MAXIMUM BLOOD FLOW RATE	8 l/min
STATIC PRIMING VOLUME	
(oxy module + heat exchanger average value)	219 ml
MEMBRANE SECTION	
- Surface area (approx. value)	1,75 m²
HEAT EXCHANGER SECTION	
- Material type	Polyurethane
- Surface area (approx. value)	0,4 m²

INSPIRE™ 8 DUAL
PH.I.S.I.O.

OXYGENATOR SYSTEM	
- Oxygenator system DOV @ max flow	445 ml
- Biocompatible coating	Phosphorylcoline (PHISIO)
RESERVOIR	
MAX. VOLUME CAPACITY (approx.)	4500 ml
MAX. OPERATING LEVEL (approx.)	4000 ml
- Non activated blood section	2700 ml
- Activated blood section	1300 ml
MIN. OPERATING LEVEL	150 ml
FILTRATION SECTIONS	
Venous reservoir section	
- Filtering media	41 µm polyester outer screen + 120 µm inner polyester net
Cardiotomy reservoir section	
- Filtering media	41 µm polyester screen
OXYGENATOR MODULE	
MAXIMUM BLOOD FLOW RATE	8 l/min
STATIC PRIMING VOLUME	
(oxy module + heat exchanger average value)	219 ml
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INSPIRE™ 8F
PH.I.S.I.O.

OXYGENATOR SYSTEM	
- Oxygenator system DOV @ max flow	577 ml
- Biocompatible coating	Phosphorylcoline (PHISIO)
RESERVOIR	
MAX. VOLUME CAPACITY (approx.)	4500 ml
MAX. OPERATING LEVEL (approx.)	4000 ml
	150 ml
MIN. OPERATING LEVEL	
FILTRATION SECTIONS	
Venous reservoir section	
- Filtering media	41 µm Polyester outer screen + 120 µm inner Polyester net
Cardiotomy reservoir section	
- Filtering media	41 µm Polyester screen
OXYGENATOR MODULE	
MAXIMUM BLOOD FLOW RATE	8 l/min
STATIC PRIMING VOLUME	
(oxy module + heat exchanger average value)	351 ml
MEMBRANE SECTION	
- Surface area (approx. value)	1,75 m²
HEAT EXCHANGER SECTION	
- Material type	Polyurethane
- Surface area (approx. value)	0,4 m²
ARTERIAL FILTER SECTION	
- Material type	Polyester net
- Micron size	38 µ
- Surface area (approx. value)	97 cm²

INSPIRE™ 8F DUAL
PH.I.S.I.O.

OXYGENATOR SYSTEM	
- Oxygenator system DOV @ max flow	577 ml
- Biocompatible coating	Phosphorylcoline (PHISIO)
RESERVOIR	
MAX. VOLUME CAPACITY (approx.)	4500 ml
MAX. OPERATING LEVEL (approx.)	4000 ml
- Non activated blood section	2700 ml
- Activated blood section	1300 ml
MIN. OPERATING LEVEL	150 ml
FILTRATION SECTIONS	
Venous reservoir section	
- Filtering media	41 µm Polyester outer screen + 120 µm inner Polyester net
Cardiotomy reservoir section	
- Filtering media	41 µm Polyester screen
OXYGENATOR MODULE	
MAXIMUM BLOOD FLOW RATE	8 l/min
STATIC PRIMING VOLUME	
(oxy module + heat exchanger average value)	351 ml
MEMBRANE SECTION	
- Surface area (approx. value)	1,75 m²
HEAT EXCHANGER SECTION	
- Material type	Polyurethane
- Surface area (approx. value)	0,4 m²
ARTERIAL FILTER SECTION	
- Material type	Polyester net
- Micron size	38 µ
- Surface area (approx. value)	97 cm²

ORDER GUIDE

ITEM #	DEVICE	DESCRIPTION	UNITS PER CASE
INTEGRATED			
050714	INSPIRE 8	INSPIRE 8 LPM PHISIO OXY MODULE WITH INTEGRATED PHISIO HARD SHELL VENOUS RESERVOIR	2
050716	INSPIRE 8F	INSPIRE 8 LPM PHISIO OXY MODULE WITH INTEGRATED ARTERIAL FILTER AND PHISIO HARD SHELL VENOUS RESERVOIR	2
050718	INSPIRE 8 DUAL	INSPIRE 8 LPM PHISIO OXY MODULE WITH INTEGRATED PHISIO DUAL CHAMBER HARD SHELL VENOUS RESERVOIR	2
050720	INSPIRE 8F DUAL	INSPIRE 8 LPM PHISIO OXY MODULE WITH INTEGRATED ARTERIAL FILTER AND PHISIO DUAL CHAMBER HARD SHELL VENOUS RESERVOIR	2
OXY MODULES			
050701	INSPIRE 8 M	INSPIRE 8 LPM PHISIO OXY MODULE	2
050703	INSPIRE 8F M	INSPIRE 8 LPM PHISIO OXY MODULE WITH INTEGRATED ARTERIAL FILTER	2
OXY MODULES			
050704	INSPIRE HVR	INSPIRE PHISIO HARD SHELL VENOUS RESERVOIR	2
050705	INSPIRE HVR DUAL	INSPIRE PHISIO DUAL HARD SHELL VENOUS RESERVOIR	2
ACCESSORIES			
050640	INSPIRE BKT	BRACKET FOR INSPIRE OXY MODULES AND INTEGRATED OXYGENATOR SYSTEMS	1
48-42-10	INSPIRE BKT FAST*	BRACKET FOR INSPIRE OXY MODULES AND INTEGRATED OXYGENATOR SYSTEMS WITH FAST CLAMP	1
050641	INSPIRE BKTH	BRACKET FOR INSPIRE HVR AND DUAL HVR RESERVOIRS	1
042229000	TEMPERATURE PROBES	TEMPERATURE PROBES	2

* To be ordered as an accessory of LivaNova S5 and C5 HLMs

LivaNova's Green Leaf program

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

CE 0123 According to MDD 93/42/EEC emended by Directive 2007/47/EC

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LivaNova

Health innovation that matters

www.livanova.com

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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.