▲Perfusion System



Elevating Perfusion into a New Era

System catalog

Elevating Perfusion into a New Era

With technology advancements and an increased focus on patient outcomes, perfusion and the role of the perfusionist are changing and entering a New Era.

An era where data takes a central role in enabling truly patient-tailored care.

An era where, as a result, the spotlight can be placed on the true impact and value that perfusionists bring to clinical practice.

The Wisdom of Breath and Beat

Essenz™ is LivaNova's next generation perfusion system that bridges five decades of proven performance, an enduring commitment to the safety of the patient, and the data accuracy perfusionists need to bring more clinical wisdom to the OR.

Grounded upon four key pillars – safety, intuitiveness, efficiency, and patient-tailored care – Essenz is designed, validated, and tested with more than 300 perfusionists, to provide clinical wisdom and a value-added solution to thrive into the New Era of Perfusion.¹



Essenz Perfusion System catalog

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¹Preventive Strategies for Minimizing Hemodilution during Cardiopulmonary Bypass in the Cardiac Surgical Patient - August 2015 - Journal of Cardiothoracic and Vascular Anesthesia 29(6) DOI:10.1053/j.jvca.2015.08.002

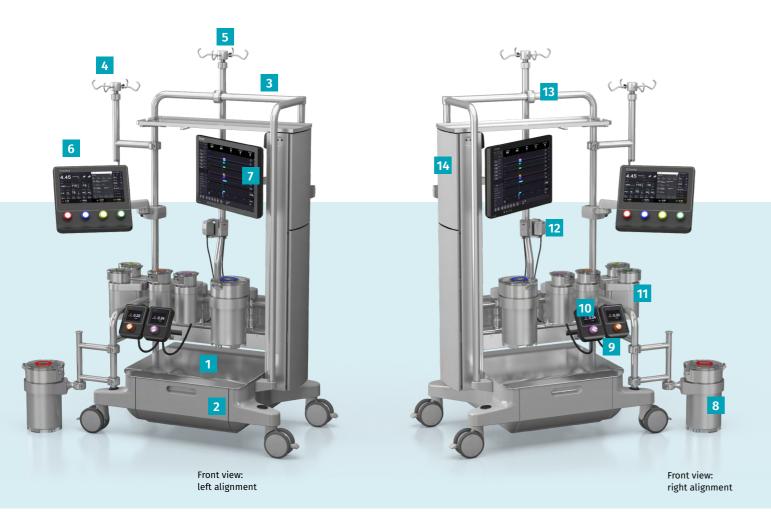
System overview

Essenz[™] Perfusion System includes state-of-the-art heart-lung-machine with embedded Patient Monitor for tailored patient care strategies and accurate sensing technology including the Essenz In-Line Blood Monitor (ILBM), for data-driven decision making.

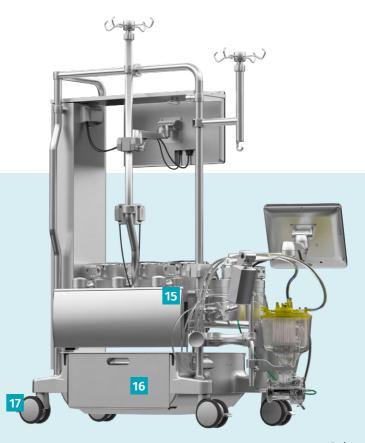
With the Essenz Perfusion System, it is possible to create a system layout that places devices and controls close to the perfusionists as well as the patient.

The advanced cable management and mast mounted design minimize clutter and make it easier to keep the space clean and hygienic.

Item	Name	Description
1	Console	Houses the power pack with the system electronics and the backup control unit
2	Front hatch	Allows access to the backup control panel
3	Mast system	For mounting pumps and other equipment
4	Table set mast	Telescoping mast with infusion rack for intermediate storage of the perfusion tubing set

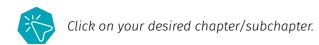


Item	Name	Description
5	Infusion mast	Telescoping mast with infusion rack and AV loop hook
6	Cockpit	For operating and controlling the HLM
7	Essenz Patient Monitor	Panel PC which runs and displays the Essenz Patient Monitor software, including hub to send data to EMR and built-in RFID reader
8	Roller pump 150	Shown here: arterial pump near the oxygenator; controlled via the cockpit
9	Roller pump 150 with control unit	Shown here: e.g. suction or vent pumps; controlled via separate control units
10	Control unit	Can control a pump or venous clamp (VC)
11	Roller pump 85	Shown here: 2 separate RP 85
12	Essenz In-Line Blood Monitor	For accurate blood monitoring
13	Shelf	For storing items used during surgery
14	Cabinet	Subdivided into 2 compartments with the interface panel and the multiple socket outlet; houses the hand cranks
15	Cable box	Houses the system component cables
16	Rear hatch	Allows access to the power pack
17	Castors	For transporting and securing the HLM



Back view: left alignment

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Essenz Console

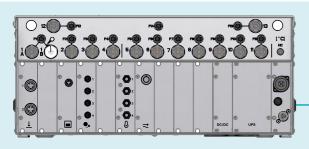


Power pack

The power pack comprises the power supply and UPS components, the sensor modules and the system connection panel.

The power pack is located behind the rear hatch of the console.

Essenz Perfusion System comes equipped with an emergency battery to ensure procedural continuity in the unlikely event of power loss. It is also equipped with an integrated battery discharger to maximise battery life.







Backup control panel

A backup control panel is available with every Essenz heart-lung machine.

In the unlikely event of cockpit failure, pumps can be managed via the spare control units at the bottom of the HLM.





Mast System

Standard mast system

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

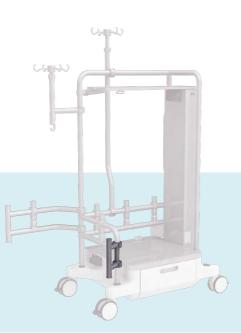
- One adjustable vertical telescope mast (1) with an infusion rack, and a table set mast (2) with an infusion rack and hook for holding Perfusion Tubing Set.
- The masts can be used for mounting the cockpit and additional accessories or disposables. The height of the telescope mast can be adjusted.
- Two vertical masts (3) on the side with the cabinet can be used for transporting Essenz.
 They can also be used to mount accessories
- A horizontal mast (4) stabilizes the system
- A hook for manual clamps (5) can be mounted anywhere on the mast system

The four casters (6) of the console can be locked in three different positions.

Mast system extension

Two extension arms are available:

 An arterial arm to place the arterial pump in a low position.





 An extension arm to mount either four small roller pumps or two large roller pumps at the side of the console.



Cabinet

The cabinet can be mounted on the left or the right side of the console, and integrates:

 the interface panel with the power switch, the connectors, for external devices and the Essenz Patient Monitor connector

· multiple socket outlet with six power sockets,

· the hand cranks.



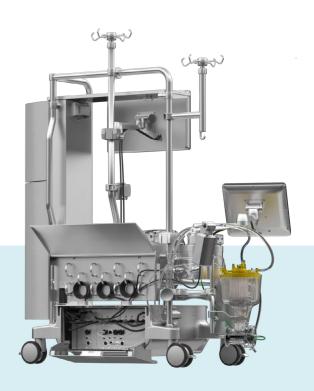


Console

The console housing accommodates the entire electronics of the power pack, including the central power supply and the uninterruptible emergency power supply.

All pump and sensor cables are placed at the back of the console, reducing cable length and improving cable management.





Cockpit



The innovative Essenz cockpit provides one central view to control the device and check all perfusion and patient parameters, minimizing distractions.

The cockpit can be mounted on multiple positions on the mast system, to allow flexibility and personalized ergonomics.

Each pump can be easily managed through color coded pump control knobs. The haptic difference in the arterial pump knob can add an extra layer of confidence by making it immediately identifiable, helping prioritize information even in challenging situations.

The intuitive user interface is developed according to the latest medical device standards, with a soothing background with white numbers to aid visibility. Colors are used only in case of alarms and "calls for action", to attract the user's attention towards the real priority areas.

The screen is divided into monitoring, dynamic navigation and control areas to facilitate the overall use of the system.

Thanks to the advanced profile management, up to 12 user profiles can be created and selected before each case.

All mandatory safety checks can be carried out according to the selected profile.

Perfusionists can temporarily change the selected profile and relevant configurations during the procedure, affording high levels of flexibility.



Control units

In addition to the four control knobs on the cockpit, individual pumps or the venous clamp can also be controlled by individual control units. Up to five control units can be added to the perfusion system. The user friendly display shows RPM and flow.

The control units can be mounted according to the perfusionist's preference:

- · on the large roller pump,
- · on the single mast holder,
- · on the double mast holder,
- · on the double flexible arm.

Pumps

It is possible to configure pumps on Essenz to meet all procedural needs:

- 1. Large roller pump
- 2. Small roller pump
- 3. Centrifugal pump

In case of emergency, it is possible to quickly install an additional pump to allow procedural continuity.

Each pump is controlled individually: one knob - one pump, for simple and straightforward operation.



Roller pumps

Roller pumps can rotate in 15° increments; total rotation is 270° (RPD85) to 360° (RPD150).

Each pump can be controlled either through the cockpit or via an individual control unit.

Design and technology

The compact pump design makes it easier to handle and replace it in case of emergency.

Pump motor direct drive technology secures years of problem-free performance, offering the advantages of very low noise and vibration, as well as reliable, maintenance-free pumps, free from belts and gearbox.

The self-locking mechanism designed to retain tubing on the pump housing simplifies tubing set up.



Redundant pump speed control (in the cockpit and in the backup control panel) are designed for procedural continuity in the unlikely event of failures occurring.

Excess cable length can be coiled inside the large roller pump housing to minimize visible cables.

Pump occlusion

The high degree of adjustment of the occlusion mechanism favors correct blood flow.

The roller pump occlusion mechnism allows steps of 0.015 mm per click.

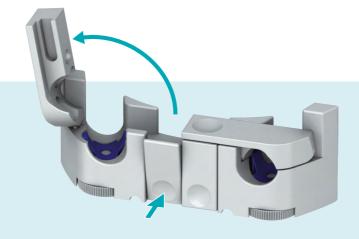


ltem	Name	Function
1	Tubing clamp inserts	Retain the installed tubing
2	Tubing guide rollers	Keep the tubing in position
3	Occlusion rollers	Occlude the installed tubing
4	Pump lid	Protects the inside of the pump head against contamination
5	Fast clamp connector	For mounting the roller pump on the mast system



Tubing clamps

- Tubing clamp inserts are available for all tubing sizes. They are inserted into the tubing clamp block of the pump heads.
- Variolock Tubing clamp module self-locking mechanism keeps tubing in place on the pump housing. The module was developed for the heads of roller pumps. A large range of tubing clamp inserts for single and double tubing configurations are available.
- For small roller pumps, tubing clamp blocks are available for tubing sizes up to 5/16" x 1/16".



Centrifugal pump

The centrifugal pump kit (1) consists of the pump drive, the emergency drive and the arterial clamp.

The position of the centrifugal pump can be rotated by the adjustable arm.

It can be easly mounted on the masts with the fast clamp.

Two centrifugal pumps can be used simultaneously.

The Essenz centrifugal pump is designed to improve outcomes for traditional bypass, mini-bypass and kinetic assist venous drainage. The centrifugal pump is linked to level, bubble and pressure alarms to control the pump speed and occlude the arterial line via the arterial clamp.

Arterial clamp

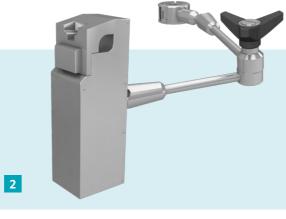
The arterial clamp (2) is designed to be used with the centrifugal pump, to provide safe centrifugal perfusion. The arterial clamp ensures a fast stop of the arterial flow and it helps to avoid negative flow.

When certain conditions are detected (low level, bubble or retrograde flow), the arterial clamp occludes the arterial line immediately to minimize the danger of air delivery.









Sensors

Bubble sensor

The bubble sensor in the Essenz Perfusion System enables optimized air management. It can be configured through the cockpit.

Sensors are available for 3/8" tubing, as well as 1/2", 3/16" and 1/4". One bubble module allows to operate up to four bubble sensors.

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

The small, lightweight bubbl e sensor makes it possible to keep the arterial lines under control.

Flow sensor

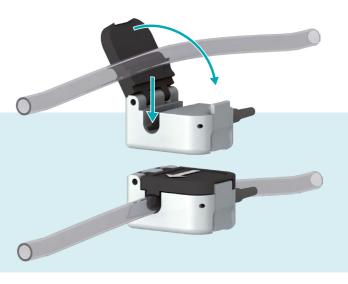
Flow sensors are available to provide accurate measurement of arterial and venous blood flow to and from the patient. They can be configured through the cockpit and can be used with centrifugal or roller head pumps.

The flow sensor is composed of a sensor module and the corresponding sensor. Sensors are available for 3/8" tubing, as well as 1/2", 3/16" and 1/4".

Up to three flows can be measured simultaneously.







¹⁻⁸ Resources at page 47

Pressure sensor

The pressure sensor measures and displays the pressure in the cardiopulmonary bypass circuit. The display range extends from -200 mmHg to +800 mmHg.

The values can be displayed in either mmHg or kPa. It can be configured through the cockpit.

The pressure module controls perfusion with constant adjustable pressure (set value) through automatic variation of the pump speed. It limits the pressure to values set by the clinician by stopping the pump when the preset pressure (stop limit) is reached.

The pressure module controls linked pumps. When the pressure value reaches the regulation limit, the pump will slow down and when it



reaches the alarm limit the pump will stop. In case of a centrifugal pump, also the arterial clamp will automatically close when the alarm limit is reached.

Up to 6 pressure values can be monitored.

Temperature sensor

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

Perfusionists can set an upper and a lower temperature limit. The values are set on the cockpit. If the temperature limit is reached, visual and acoustic alarms are triggered.



Level sensor

The level sensor is mounted directly on the reservoir by means of a self-adhesive level pad. A yellow line on the outside of the sensor probe indicates the stop level and triggers alarm or pump stop based on the set up.

Level sensor

- Regulates and stops the arterial pump flow when the blood level in the reservoir reaches the minimum volume.
- It is possible to utilize two level sensors: the first sensor will create an alarm, the second sensor controls the pump.

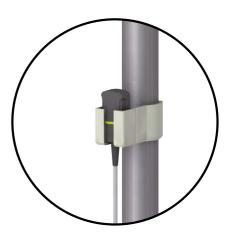
Level module

- Makes it possible to quickly recognize the stop level in the reservoir.
- Complies with latest EMC regulation

Level pad

- · Has an easy to peel off protective foil.
- Is symmetric, so it can be placed in either direction for quick and easy set-up.
- Adheres to every reservoir, including pediatric ones.
- The transparent pad improves the visibility of blood levels in the reservoir.







Essenz™ In-Line Blood Monitor (ILBM)

Essenz In-Line Blood Monitor (ILBM), powered by B-Capta sensing technology, is the ready-to-go blood monitoring system integrated into the Essenz Perfusion System and its cockpit.

The optical based technology provides high levels of reliability even in long and complex cardiopulmonary bypass procedures.

The system does not provide calculated parameters but only measured values for the accurate monitoring of Sat, HCT, pO2 and Temperature.

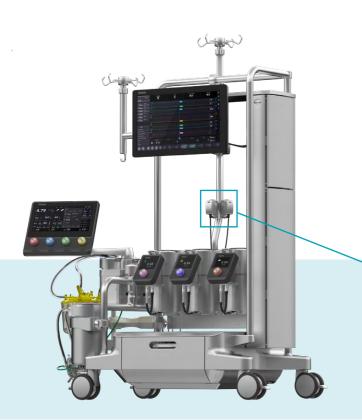
It also provides accurate sensing technology to support the delivery of patient-tailored care and the implementation of Goal-Directed Perfusion (GDP) therapy.

Venous and Arterial Sensors Sensor Module

Essenz ILBM includes a venous sensor and an arterial sensor.

Both sensors must be used in conjunction with a disposable cuvette in the blood line for optical reading. The sensors are suitable for all available cuvette sizes.

The venous and arterial sensors can be identified by the blue (venous) or red (arterial) marker on the housing.



The sensor module is the interface between the sensors and the cockpit and transfers all measured values.

Blue connector = venous sensor Red connector = arterial sensor

Mast-mounted holder with venous and arterial reference element

Essenz In-Line Blood Monitor is equipped with two reference elements respectively:

- · one for the venous sensor
- · one for the arterial sensor

The reference elements are needed to perform the self test of each sensor, to ensure measurement accuracy before blood measurement starts.

The reference elements are mounted on the mastmounted holders.



Disposable venous and arterial cuvettes

The venous and arterial disposable cuvettes are available as sterile stand-alone disposables or included in the Perfusion Tubing Systems.

Venous cuvettes sizes 1/2", 1/4", 3/8"

Arterial cuvettes sizes 3/8", 1/4"



Integration into the Essenz Perfusion System

Cockpit

The display of the Essenz In-Line Blood Monitor is integrated in the Essenz cockpit, avoiding the need for additional holders and monitors that may limit the workspace or obstruct the perfusionist's view during cardiopulmonary bypass.1

Through the cockpit it is possible to:

- View the real-time values measured by the
 - · Venous: Oxygen Saturation (Sat), Hematocrit (Hct) or Hemoglobin (Hb) and Temperature
 - Arterial: Partial pressure of oxygen (PaO₃ at ACT or PaO₃ at 37°) and Temperature (artT)
- · Change the measurement unit:
 - · Venous: Hct or Hb
 - Arterial: PaO, at ACT or PaO, at 37°
- · Align the measured values with laboratory values (not applicable to temperature values)
- · Set the warning limits for each parameter.

Essenz Patient Monitor

Arterial and venous parameters are automatically transferred to the Essenz Patient Monitor, supporting data-driven decision making.

The integration allows to:

- View the values measured by the sensors continuously in the timeline of the Chart and Table in the Essenz Patient Monitor
- Use the arterial and venous parameters for GDP
- Maintain accurate perfusion procedure records





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Cardioplegia control

Cardioplegia controls can be configured directly through the cockpit. The operator can start and stop the pump. The dose volume to be delivered shows on the volume display (beginning at 0).

As soon as the sensor detects bubbles, the pump automatically stops and the cardioplegia delivery is interrupted.

At the same time, the visual and acoustic alarms are triggered.



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

The integrated timer automatically starts during a pump stop to record the ischemia time. This happens regardless of which operational mode was selected

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

Venous clamp

The venous clamp can be configured through the cockpit.

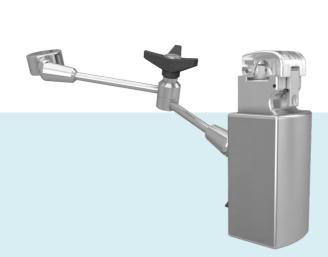
The venous clamp can apply an occlusion of perfuson tubing that varies between fully unoccluded to fully occluded.

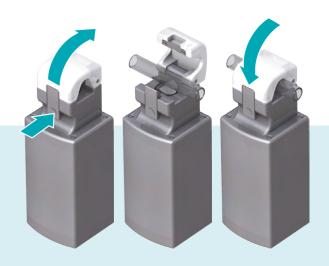
When the pump is stopped manually, the venous clamp helps achieve controlled regulation of the venous return flow.

The clamp closes automatically in case of a stopped arterial flow. The user can also control the venous flow manually.

When the arterial pump restarts, the venous clamp opens to the most recently specified set value. An override of the stop link function is possible at any time by simply turning the control knob of the venous clamp.







Mechanical venous clamp

The mechanical venous clamp has a remote control.

The 1 m Bowden cable connects the clamp head to the control unit and transfers settings entered on the control unit to the clamping lever in the clamp head.

The coarse and fine setting knobs are used to set the degree of occlusion and quickly regulate the venous return flow.



Electronic gas blender

The electronic gas blender allows to set, monitor and display the gas flows required for extracorporeal circulation. The preset values (i.e. the total flow including Air + O2, FiO2 and CO2) can be set independently and are displayed on both the gas blender and the cockpit.

In the electronic gas blender, actual and set values are continuously compared. Additionally, the actual value is measured by two independent sensors and an alarm is triggered if a deviation between the two values is detected.

The remote control of the electronic gas blender on the cockpit can be used to change the set values for Air + O2, FiO2 and CO2 from gas flow to blood flow. Acoustic and visual signals warn the operator if the actual values exceed or drop below the set values.

The electronic gas blender is available in three different versions:

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







▲ Patient Monitor

The Essenz Patient Monitor centralizes perfusion data on one screen, allowing the clinician to fully concentrate on the patient and CPB circuit management.

Essenz Patient Monitor is embedded in the Essenz Perfusion System. The dedicated perfusion software on Essenz Patient Monitor also works with S5 heart-lung machines.

"It is encouraging to clearly see that LivaNova has listened and responded to the needs of the perfusionist in the development of this system. This opens the way to further leverage the potential for clinical improvement that electronic data acquisition systems provide."

Richard Newland

Senior Perfusionist, Flinders Medical Centre

Ease of use and Intuitive interaction

- Intuitive and responsive Graphical User Interface (GUI). designed with over 100+ Perfusionists to ensure it supports the main clinical workflows
- The retrospective tool allows the perfusionist to view the parameter values at any point during the case

Facilitated procedure management

- The perfusion chart in one view centralizes live patient parameters and the integrated retrospective tool provides a view of the values at any time point throughout the case
- The pre-op checklists can be completed in advance of a patient being received in the OR for when the HLM is on standby, allowing quick deployment at the start of the case
- Time events and reminders are specifically designed to assist in case management
- The events bar allows quick entry of generic, drug, fluid and blood events during the case

Individualised Patient Care Strategies

- Quality indicators module allows the perfusionist to implement individualized patient care and safety strategies
- Essenz Patient Monitor enables Goal-Directed Perfusion (GDP) Therapy through the monitoring of critical **metabolic patient parameters** with the GDP Module



- 1. Date/Time/Patient Data Overview
- 2. Procedural Timers
- 3. Case Assist (access to products, priming and checklists)
- 4. Centralized view of online parameters (configurable)
- 5. Easily switch views, one-touch panel
- 6. Receive online notifications for Blood Gas results and Quality Indicator variance
- 7. Main Charting Area
- 8. View CPB Timer and Fluid Balance Summary
- 9. Timers/Reminders/Duration Events
- 10. Perfusion Events

Compliance and appropriate care

- Essenz Patient Monitor helps clinicians with **intra-op decision making** for an individualized patient care strategy based on the information provided by the Quality indicators tool
- The Quality Indicator report can be distributed postoperatively to support local compliance and variation targets

Integrated solution within the OR environment

- Connectivity with Hospital to meet Cyber and Patient Data security requirements, allowing integration with:
- OR external devices
- EMR systems
- Data can be exported as a .csv/json file for input into external statistical tool packages



Four types of installation options to connect your Essenz Patient Monitor to your hospital's systems.

Our Essenz Focus technical services team works with your hospital I.T. department to identify the most appropriate setup for your needs.

1. Baseline Installation Package

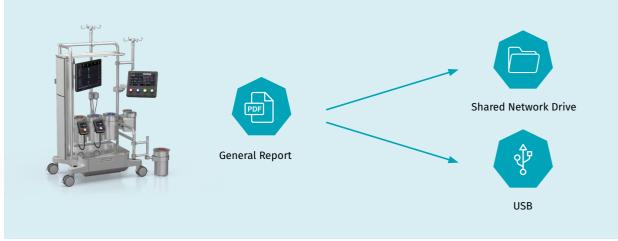
Basic Connectivity

This is the most basic installation for the Patient Monitor. Configuration settings and cases can be saved to USB and/or a shared network. There is no requirement for network integration. The Perfusion System monitor includes a Microsoft® SQL Server® 2019 Express database. A backup system is recommended to safeguard against any corruption.

- Microsoft® SQL Server® 2019 Express database is maintained locally on each PSM
- Import and export configuration settings and cases via a USB or a shared network drive
- Raw data (.csv/JSON) and PDF reports can be exported via a USB or saved to a shared network drive
- If the hospital has an active directory they can use this to install the users on the individual PSM's

Main Benefits

- · Eases installation, no complex IT integration
- Users can start using the product and choose to upgrade to the Connected Installation at anytime
- Standalone is suitable for hospitals where the IT infrastructure is less established



2. Connected Installation Package

Light Connectivity

The connected installation package offers installation to a centralized database. In this installation Microsoft® SQL Server® 2016 or 2019 needs to be installed within the hospital network. This option allows data to be stored centrally in the hospital. The case files and configuration settings can all be transferred seamlessly between all networked Perfusion system monitors.

- Import and export configuration settings, report templates and cases via the Central SQL Database
- Raw data (.csv/JSON) and PDF reports can be exported via a USB or a shared network drive

Main Benefits

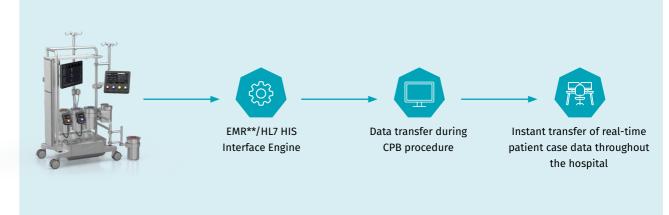
- Data integrity, as all data is preserved within the I.T. department and can be synchronized with other applications
- Automatic ECC number creation
- Role permissions can be connected to the active directory and distributed to all PSM systems
- · Centralised data storage for all cases and settings



3. Advanced Installation Package

Connectivity during the procedure

Instantly transfer real-time patient case data throughout the hospital to facilitate informed decisions across the entire continuum of care.



 $[\]hbox{* The installation, management and maintenance of the Central Database is under the hospital's responsibility.}$

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^{**} Electronic Medical Record or Hospital Information System

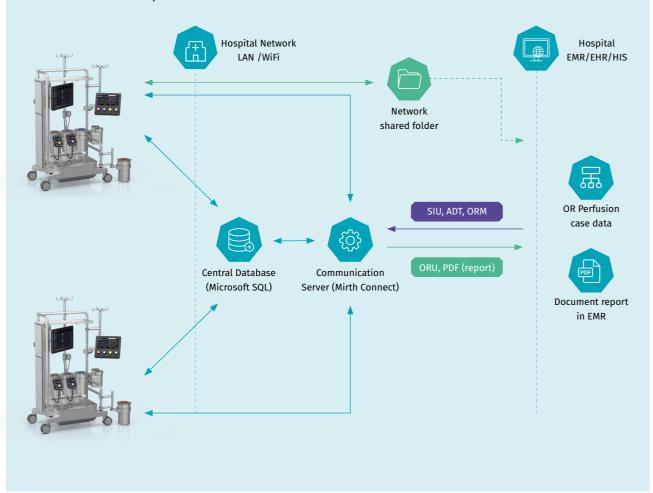


4. Advanced Plus Installation Package

Full connectivity during the procedure, as well as Pre- and Post-Op Integration

Perfusionist can manage and set up the case in advance of the procedure by reviewing the EMR case list directly in the Essenz Patient Monitor. Demographic data, Risks, Allergies, Pre-Op Hct/Hb, Blood Type, Procedure Type and Surgery Team data is integrated in to the Essenz Patient Monitor to ease case set up and to ensure continuity and traceability with the EMR patient record.

An embedded HL7 report can be automatically integrated in the EMR at the end of the case for review across the hospital.





Ordering information and Technical specifications

Ordering information

Please contact your local LivaNova sales representative to place your Essenz Perfusion System order.

Mandatory items to be ordered for your Essenz Perfusion System:

Component	Item name	Ordering code
	Console	
	Shelf	
HLM frame	Lamp	
num Italile	Mast system	
	Cable box	
	Main interface box	
	Cockpit	
Cockpit	Cockpit arm	
	Perfusion system monitor	
Patient Monitor	Connection cable Perfusion system monitor	
	Power cord Perfusion system monitor Mast holder with fast clamp connector	
	mast noticer with last clamp connector	
	Bubble module	Base unit
Mandatory sensors	Flow module	
	Pressure module	
	Arterial extension arm	
	Color knob rings & stickers	
	Cap for quick clamp	
	Pump support caps (6 pieces)	
	Cable clips (6 pieces)	
Accessories	Cable clip roof (3 pieces)	
	Cable holders (6 pieces)	
	Hook for clamps	
	Twin holder	
	Cable flags white	
	Color coding stickers	

Mandatory items to be selected to complete the minimal configuration:

Component	Item name	Ordering code
Power-Pack	Power pack blind cover	28-95-34
	Cabinet assembly left	49-10-99
HLM Frame	Cabinet assembly right	49-10-01
	Cabillet assembly right	45-10-01
	Power Cord HLM (Brazil)	97-102-221
	Power Cord HLM (China)	97-102-222
	Power Cord HLM (Switzerland)	97-102-223
Power cords	Power Cord HLM (Denmark)	97-102-224
rower colus	Power Cord HLM (Great Britain)	97-102-225
	Power Cord HLM (Europe - Schuko)	97-102-226
	Power Cord HLM (USA/Canada)	97-102-227
	Power Cord HLM (Australia/New Zealand)	97-102-228
	Power Cord EPM (2m, Europe - Schuko)	97-102-290
	Power Cord EPM (6m, Europe - Schuko)	97-102-291
	Power Cord EPM (2m, Great Britain)	97-102-292
	Power Cord EPM (6m, Great Britain)	97-102-293
	Power Cord EPM (2m, Switzerland)	97-102-294
	Power Cord EPM (6m, Switzerland)	97-102-295
D	Power Cord EPM (2m, Denmark)	97-102-296
Power cords	Power Cord EPM (6m, Denmark)	97-102-297
	Power Cord EPM (2m, Australia/New Zealand)	97-102-298
	Power Cord EPM (6m, Australia/New Zealand)	97-102-299
	Power Cord EPM (2m, Brazil)	97-102-300
	Power Cord EPM (6m, Brazil)	97-102-301
	Power Cord EPM (2m, USA/Canada)	97-102-302
	Power Cord EPM (6m, USA/Canada)	97-102-303
	Power plugs 230v	96-403-072
Power plugs	Power plugs 120v	96-403-073
	Bubble sensor 3/16"	96-414-320
	Bubble sensor 1/4"	96-414-330
	Bubble sensor 3/8"	96-414-340
Mandatory sensors	Bubble sensor 1/2"	96-414-350
	Flow sensor 3/16"	96-414-220
	Flow sensor 1/4"	96-414-230
	Flow sensor 3/8"	96-414-240
	Flow sensor 1/2"	96-414-250

Pumps selection:

Component	Item description	Ordering code
	Large roller pump	
Large Roller pump	Large roller pump support	RP150 large
	Large roller tube part short	
	Small roller pump	
Small Roller pump	Small roller pump support	
	Small roller tube part short	
	Tubing clamp block 1/8" x 1/16"	RP85 small
Small Roller pump -	Tubing clamp block 1/4" x 1/16"	
tubing clamps	Tubing clamp block 3/16" x 1/16"	
	Tubing clamp block 1/4" x 3/32"	10-96-13
Insert RP85	Tubing clamp block 5/16" x 1/16"	10-96-14
	Tubing clamp block 5/16" x 3/32"	10-96-15
	Variolock tubing clamp insert 1:1	10-61-91
w 'l len' ·	Variolock tubing clamp insert 2:1	10-61-92
Variolock CPL insert	Variolock tubing clamp insert 1:4	10-61-94
	Variolock tubing clamp insert 4:1 (USA only)	10-61-93
	Centrifugal pump drive	
	Pump support	
Centrifugal pump with	Centrifugal tube part - short	
Arterial Clamp -	Centrifugal pump emergency drive	CP short
short arm	Arterial Clamp - short arm	
	Pump support	
	Centrifugal tube part - short	
	Contributal numn drive	
	Centrifugal pump drive	
	Pump support Centrifugal tube part - short	
Centrifugal pump with Arterial Clamp -	Centrifugal pump emergency drive	CP long
long arm	Arterial Clamp - long arm	Cr tong
	Pump support	
	Centrifugal tube part - short	
	-	
Centrifugal for	Centrifugal pump drive	
kinetic assist	Pump support	CP kinetic assist
	Centrifugal tube part - short	

Console items selection:

Component	Item name	Ordering code
	Control Unit	Control unit
	Control Unit system cable	Control unit
Control unit	Control unit holder	28-96-40
	Control unit double holder	28-96-50
	Control unit arm	28-96-60
	Pump support	
	Centrifugal tube part - long	Long support
	Pump support	
	Centrifugal tube part - short	Short support
	Arterial extension arm	49-05-24
	Twin holder	10-95-80
	Cap for quick clamp	43-42-61
	Pump support caps (6 pieces)	49-05-80
Console accessories	Bracket for gas bottles	19-03-00
	Extension arm	49-05-29
	Tray - left side	49-05-39
	Tray - right side	49-05-35
	Perfusion Chair	41-02-98
	Table set mast	49-05-20
	Color knob rings & stickers	28-96-80
	Support plate	49-05-11

Sensors selection:

Component	Item name	Ordering code
	ILBM Module	
Essenz In-Line Blood Monitor Venous	Venous sensor & reference element	ILBM - V
Monitor Venous	Venous sensor holder	
	ILBM Module	
Essenz In-Line Blood	Venous sensor & reference element	ILBM - VA
Monitor Venous and	Arterial sensor & reference element	
Arterial	Arterial sensor holder	
	Venous sensor holder	
Flow sensor	Flow module	Flow

Component	Item name	Ordering code
	Level module	
Level sensor	Level sensor	Level
Level Selisui	Level sensor holder	
	Level pads - 100 pcs	
	Temperature module	20-30-10
Temperature sensor (4 channel)	Inspire oxygenator temp probe	042229000
	Kids oxygenator temp probe	09026
Pressure sensor	Pressure module	22-20-10

Additional accessories:

Component	Item name	Ordering code
	Electronic gas blender - 10L	EGB10L
	Electronic gas blender - 10L - cable	205102
	Electronic gas blender - 5L	EGB5L
	Electronic gas blender - 5L - cable	LOBSE
Electronic gas blender	Electronic gas blender - 2L	EGB2L
	Electronic gas blender - 2L - cable	EUDZL
	Air tubing set for Electronic gas blender	96-490-111
	O2 tubing set for Electronic gas blender	96-490-112
	CO2 tubing set for Electronic gas blender	96-490-113
	Mechanical gas blender, O2 & air	96-490-042
Mechanical gas	Air tubing set for mechanical gas blender	96-490-131
blender	O2 tubing set for mechanical gas blender	96-490-132
	Connection set for mechanical gas blender	25-30-50
	•	
	Mechanical venous line clamp	12-40-00
	Mechanical venous clamp holder	12-30-90
	MVC insert 1/4 x 3/32"	10-07-21
Mechanical venous	MVC insert 3/8 x 1/16"	10-07-22
clamp	MVC insert 1/2 x 1/16"	10-07-24
	MVC insert 5/8 x 3/32"	10-07-26
	MVC insert 1/8 x 1/16"	10-07-27
	MVC insert 3/16 x 1/16"	10-07-28
	Electronic venous clamp	
Electronic venous	Pump support	VC ven clamp
clamp	Centrifugal tube part - short	
	,	

Heater-cooler 3T heater-cooler (240V) 16-02-80 Heater-cooler (240V) 16-02-81 3T heater-cooler (208V) 16-02-82 3T heater-cooler (127V) 16-02-83 3T heater-cooler (120V) 16-02-85 3T heater-cooler (200V) 16-02-85 Adater-cooler (200V) 16-02-85 Mast Holder for power adapter with fast clamp connector 24-30-15 Cable clips (6 pieces) Clips + roofs Cable clip roof (3 pieces) Clips + roofs Adapter cable EU 97-102-305 Adapter cable US 97-102-306 Adapter cable UK 97-102-308 Extension cable 97-102-309 Adapter cable PSM power supply 97-102-307	Component	Item name	Ordering code
Heater-cooler Adapter power cords 3T heater-cooler (208V) 16-02-82 3T heater-cooler (127V) 16-02-83 3T heater-cooler (120V) 16-02-85 3T heater-cooler (200V) 16-02-95 Connection cable Essenz Patient Monitor 45-12-03 Mast Holder for power adapter with fast clamp connector 24-30-15 Cable clips (6 pieces) Clips + roofs Cable clip roof (3 pieces) 97-102-305 Adapter cable EU 97-102-306 Adapter cable UK 97-102-308 Extension cable 97-102-309		3T heater-cooler	16-02-80
Heater-cooler 3T heater-cooler (127V) 3T heater-cooler (120V) 3T heater-cooler (200V) 16-02-85 3T heater-cooler (200V) 16-02-95 Connection cable Essenz Patient Monitor 45-12-03 Mast Holder for power adapter with fast clamp connector Cable clips Cable clips (6 pieces) Cable clip roof (3 pieces) Adapter cable EU Adapter cable EU Adapter cable US Adapter cable US Adapter cable UK Extension cable 97-102-308 Extension cable		3T heater-cooler (240V)	16-02-81
3T heater-cooler (127V) 16-02-83 3T heater-cooler (120V) 16-02-85 3T heater-cooler (200V) 16-02-95 Connection cable Essenz Patient Monitor 45-12-03 Mast Holder for power adapter with fast clamp connector Cable clips Cable clips (6 pieces) Cable clip roof (3 pieces) Adapter cable EU 97-102-305 Adapter cable US 97-102-308 Extension cable 97-102-309	Hostor coolor	3T heater-cooler (208V)	16-02-82
Patient monitor accessories Connection cable Essenz Patient Monitor Mast Holder for power adapter with fast clamp connector Cable clips Cable clips (6 pieces) Cable clip roof (3 pieces) Adapter cable EU Adapter cable US Adapter cable US Adapter cable UK Extension cable 16-02-95 45-12-03 Clips + 700fs Clips + roofs 97-102-305 97-102-306 97-102-308	neater-cooler	3T heater-cooler (127V)	16-02-83
Patient monitor accessories Mast Holder for power adapter with fast clamp connector Cable clips Cable clips (6 pieces) Cable clip roof (3 pieces) Adapter cable EU Adapter cable US Adapter cable UK Extension cable Connection cable Essenz Patient Monitor 45-12-03 24-30-15 Clips + roofs Clips + roofs 97-102-305 97-102-306 97-102-308 97-102-309		3T heater-cooler (120V)	16-02-85
Patient monitor accessories Mast Holder for power adapter with fast clamp connector Cable clips (6 pieces) Cable clip roof (3 pieces) Cable clip roof (3 pieces) Adapter cable EU 97-102-305 Adapter cable US 97-102-306 Adapter cable UK 97-102-308 Extension cable 97-102-309		3T heater-cooler (200V)	16-02-95
Patient monitor accessories Mast Holder for power adapter with fast clamp connector Cable clips (6 pieces) Cable clip roof (3 pieces) Cable clip roof (3 pieces) Adapter cable EU 97-102-305 Adapter cable US 97-102-306 Adapter cable UK 97-102-308 Extension cable 97-102-309			
Adapter power cords Mast Holder for power adapter with fast clamp connector Cable clips (6 pieces) Cable clip roof (3 pieces) Adapter cable EU Adapter cable US Adapter cable UK Extension cable Mast Holder for power adapter with fast clamp connector 24-30-15 Clips + roofs Clips + roofs 97-102-305 97-102-306 97-102-308 Extension cable 97-102-309	Dationt monitor	Connection cable Essenz Patient Monitor	45-12-03
Cable clips (6 pieces) Cable clips (6 pieces) Cable clip roof (3 pieces) Adapter cable EU Adapter cable US Adapter power cords Adapter cable UK Extension cable Part of the clips (6 pieces) Clips + roofs Part of the clips (6 pieces) Clips + roofs Part of the clips (6 pieces) Clips + roofs 97-102-305 97-102-306 97-102-308	i discite intollico.	Mast Holder for power adapter with	2/-20-15
Cable clips Cable clip roof (3 pieces) Adapter cable EU Adapter cable US Adapter power cords Adapter cable UK Extension cable Clips + roofs Original Proofs Print Proofs Clips + roofs Print Proofs Since Print Proofs Clips + roofs Print Proofs Original Print Proofs Print Pr		fast clamp connector	24 30 13
Cable clips Cable clip roof (3 pieces) Adapter cable EU Adapter cable US Adapter power cords Adapter cable UK Extension cable Clips + roofs Original Proofs Print Proofs Clips + roofs Print Proofs Since Print Proofs Clips + roofs Print Proofs Original Print Proofs Print Pr			
Adapter cable EU 97-102-305 Adapter cable US 97-102-306 Adapter power cords Adapter cable UK 97-102-308 Extension cable 97-102-309	Cable clins	Cable clips (6 pieces)	Clips + roofs
Adapter cable US 97-102-306 Adapter power cords Adapter cable UK 97-102-308 Extension cable 97-102-309	caste cups	Cable clip roof (3 pieces)	
Adapter cable US 97-102-306 Adapter power cords Adapter cable UK 97-102-308 Extension cable 97-102-309		Adaptor cable EII	07-102-205
Adapter power cords Adapter cable UK 97-102-308 Extension cable 97-102-309		·	
Extension cable 97-102-309	Adapter power cords	Adapter cable US	97-102-306
		Adapter cable UK	97-102-308
Adapter cable PSM power supply 97-102-307		Extension cable	97-102-309
		Adapter cable PSM power supply	97-102-307

Technical Specifications

1.1 Operating, storage and transport conditions

Operating conditions

Operating conditions	
Operating temperature	+ 10 °C – + 30 °C
Relative humidity	30% – 75% (non-condensing)
Atmospheric pressure (operating altitude)	620 hPa - 1013 hPa (3,000 m max.)

Storage conditions	
Storage temperature	0 °C - + 40 °C
Relative humidity	15% – 75% (non-condensing)
Atmospheric pressure (operating altitude)	700 hPa – 1010 hPa

Transport conditions	
Transport temperature	- 20 °C - + 55 °C
Relative humidity	5% – 85% (non-condensing)
Atmospheric pressure (operating altitude)	700 hPa – 1010 hPa

1.2 HLM specifications

1.2.1 Dimensions and weights

Console		
Height (including castors)	319 mm	12.56 in.
Width	936 mm	36.85 in.
Depth	606 mm	23.86 in.
Weight (including power pack)	78 kg	172lb.

Cabinet		
Height	1210.5 mm	47.66 in.
Width	243 mm	9.57 in.
Depth	210 mm	8.27 in.
Depth including horizontal shelf	798 mm	31.42 in.

Cabinet		
Weight	29 kg	63.93lb

Mast system			
Measurements include cable box, infusion mast and table set mast			
Height 1431 mm 156.34 in.			
Width	794 mm	31.26 in.	
Depth	565 mm	22.24 in.	
Weight	40 kg	88.18lb.	

Extension arm		
Weight	4.1 kg	9.04lb.

Arterial extension arm		
Weight	1.9 kg	4.19lb.

Cockpit		
Height	326 mm	12.83 in.
Width	341 mm	13.43 in.
Depth	40 mm (58.6 mm including control knob)	1.57 in. (23.07 in.)
Weight without cockpit arm	4.5 kg	9.92lb.
Weight with cockpit arm	7.9 kg	17.42lb.

Control unit		
Height	151 mm	5.94 in.
Width	116.5 mm	45.87 in.
Depth	137.5 mm	5.41 in.
Weight (without cables)	1.5 kg	3.31lb.

1.2.2 Electrical specifications

Power pack	
Input voltages	100 – 240 V~; 50 – 60 Hz
Permissible mains voltage fluctuation	± 10%
Maximum power consumption (standard equipment)	1,000 W

Circuit breaker system slots

Power pack	
Mains power protection (implemented in mains power switch used	Circuit breaker E-T-A 3120
for isolation from the supply mains on all poles simultaneously)	10 A nominal trip current
Circuit breakers F1 – F13 (for pumps and devices)	One circuit breaker each, 10 A
Circuit breaker Module F14 (for modules and internal devices in power pack)	Automatic circuit breaker 10 A
Circuit breaker Module for spare connector CCU	Automatic circuit breaker 10 A

UPS and batteries

Output voltage	
Nominal voltage	24 V
Minimum voltage	19 V
Maximum voltage	32 V

Output power			
Nominal output power	400 W		
Capacity of new of batteries	17 Ah		
Fuse protection of batteries	40 A		

UPS operating time	
At 160 W output power	90 minutes
Charging time	12 – 15 hours

Discharger			
	Input voltage	24 V DC	
	Current	8 A	
	Fuse protection of the discharger	10 A slow (DIN 41662)	

Multiple socket outlet with isolation transformer (6 power sockets)				
Input voltage (country-specific)	200 – 250 V~; 50/60 Hz 100 – 130 V~; 50/60 Hz			
Number of outlets	6			
Output voltage (in accordance with permitted mains voltage fluctuation)	± 10%			
Maximum output power	200 W			
Input fuses (F1, F2)	200 – 250 V~: T1.60 A-H(L) 100 – 130 V~: T3.15A-H(L)			
Galvanically isolated potential/ isolation voltage	1,500 V			

Multiple socket outlet with isolation transformer (6 power sockets)			
Current consumption	Rated output current 200 – 250 V~: 1.50 – 1.20 A		
	100 – 130 V~: 3.00 – 2.30 A		
IP protection class	IP20		

1.2.3 Maximally allowed system configuration

HLM

The table lists the maximum attachable components and devices.

Component	Туре	Amount		Information/constraints	
		min.	max.		
	RP 85, RP 150, CPD	1	8 (9)*	 minimum: 1 arterial pump all pumps mounted on mast system 9 pumps can be mounted; 8 pumps can run simultaneously (Note: If 1 CPD and 1 RP are connected to connectors 1A and 1B, only one of the two connected pumps can be active at a time, i.e. either CPD or RP.) mix of different pump types possible 	
	CPD	0	2	1 CPD for arterial flow1 CPD for kinetic assist	
Pumps	RP 150	0	4 (5)*	 mast system can support the weight of 5 pumps max. 5 pumps can be connected to power pack with 2 RPs at connectors 1A and 1B, but only a maximum of 4 pumps can run simultaneously (power consumption limitation) 	
	RP 85	0	8	8 pumps can be mounted on the mast system and can run simultaneously	
	* The number in brackets (x) indicates the amount of pumps with 2 pump connected to the dual connector 1A/1B (these pumps are controlled by profiles so that only one of the pumps can be active at a time).				

Component	Туре	Amount		Information/constraints
		min.	max.	
	Venous clamp (VC)	0	1	mounted on mast system
Clamps	Arterial clamp (AC)	1	1	mandatory for CPD
	Mechanical venous clamp	0	1	mounted on mast system

Component	Туре	Amount		Information/constraints
		min.	max.	
Cockpit	Touch screen with control knobs	1	1	mounted on mast system

Component	Туре	Amount		Information/constraints
		min.	max.	
	Sensor modules	4	10	• total of 10 slots available in power pack
	Bubble module (4)*	1	1	 mandatory for arterial lines (for both RP and CPD)
	Pressure module (2)*	1	3	 mandatory for arterial lines (for both RP and CPD)
Power pack	Flow module	1	3	 mandatory for arterial lines (for both RP and CPD)
	Temperature module (4)*	0	1	
	Level module (1)*	1	2	 mandatory for open (hardshell) reservoirs second level sensor has no assigned
				function; does not trigger alarms
	* The number in b	rackets ((x) indica	tes the number of channels per sensor module.

Component	Туре	Amount		Amount		Information/constraints
		min.	max.			
	Bubble sensor	1	4	 mandatory for arterial lines (for both RP and CPD) 		
	Pressure sensor	1	6	 mandatory for arterial lines (for both RP and CPD) 		
Sensors	Flow sensor	1	3	 mandatory for arterial lines (for both RP and CPD) 		
Selisors	Temperature sensor	0	4			
	Level sensor	1	2	 mandatory for open (hardshell) reservoirs second level sensor has no assigned function; does not trigger alarms 		

Component	Туре	Amount		Information/constraints
		min.	max.	
Spare pump	RP or CPD, with control unit	0	1	 replacement in case of arterial pump failure to be connected to the backup connector on the backup control panel

Component	Туре	Amount		Information/constraints
		min.	max.	
	Essenz In-Line Blood Monitor	0	1	
	Essenz Patient Monitor	0	1	 mounted on mast system. See page 45 for tech specifications.
LivaNova devices	3T Heater-Cooler System	0	1	
	Electronic gas blender	0	1	
	Console lamp	0	1	

1.3 Pumps

1.3.1 Roller pumps

	RP 150		RP 85		
Height	319 mm	12.56 in.	237 mm	9.33 in.	
Width	188 mm	7.40 in.	116 mm	4.57 in.	
Depth	292 mm	11.50 in.	247 mm	9.72 in.	
Weight	12.2 kg	26.9lb.	4.6 kg	10.14lb.	
	RP 150		RP 85		
Pump raceway diameter	15.90 in.	150 mm	3.35 in.	85 mm	
Occlusion roller diameter	1.20 in.	30.5 mm	0.59 in.	15 mm	
Direction of rotation	clockwise, counterclockwise				
Speed range	0 to 250 rpm (clockwise, counterclockwise)				
Deviation in speed accuracy	±1% of the terminal value 250 rpm plus ±0.5% of set value				
Speed deviation in the event of a fault (detection of faulty speed from 30 rpm)	+15% max.; 2 revolutions max. until pump stops (during continuous operation)			uring	
	RP 150 RP 85				
Concentricity					
Pump raceway	0.03 mm	0.000118 in.	0.03 mm	0.000118 in.	
			0.00	0.000440;	
Occlusion symmetry	0.03 mm	0.000118 in.	0.03	0.000118 in.	

Power supply	RP 150	RP 85
Operating voltage	24 V DC	24 V DC
Power consumption	160 W	80 W
Degree of protection against liquid ingress and particulate matter	IPX1 (drip-proof)	

1.3.2 Centrifugal pump

Drive unit				
Dimensions and weights				
Diameter (without mast holder)	96 mm	3.78 in.		
Weight	3.0 kg	6.61lb.		
Height	135 mm	5.31 in.		
General specifications				
Drip-proof IPX2				
Pump specifications				
Speed range max.: 0 to 3500 rpm				
Minimum settable speed	Minimum settable speed 300 rpm			
Speed accuracy	±10 rpm			

1.4 Accessory specifications

Compatible tubing sizes (PVC tubing only)			
Inner diameter x wall thickness of tube	1/2" x 3/32" 3/8" x 3/32" 3/8" x 1/16" 1/4" x 3/32" 1/4" x 1/16" 3/16" x 1/16"		

1.5 Perfusion tubing system specifications

1.5.1 RP 150 - compatible single tubes

Tube size	Flow factor	Mat	erial
= inner diameter x wall thickness of tube	lpm/rpm	Silicone	PVC.
1/4" x 1/16"	0.01246	Υ	Υ
1/4" x 3/32"	0.01246	Υ	Υ
5/16" x 1/16"	0.01880	Υ	Υ
5/16" x 3/32"	0.01880	Υ	Υ
3/8" x 1/16"	0.02599	Υ	Υ
3/8" x 3/32"	0.02599	Υ	Υ
1/2" x 3/32"	0.04448	Υ	Υ
1/2" x 1/8"	0.04448	Υ	Υ

1.5.2 RP 150 - compatible double tubes

Ratio			Flow factor	Mate	erial
	Tube size = inner diameter x wall thickness of tube		lpm/rpm	Silicone	PVC.
1:1	1/4" x 1/16"	1/4" x 1/16"	0.02492	Υ	Υ
2:1	1/4" x 1/16"	3/16" x 1/16"	0.019625	Υ	Υ
4:1	1/4" x 1/16"	1/8" x 1/16"	0.015795	Υ	Υ
1:4	1/8" x 1/16"	1/4" x 1/16"	0.015795	Υ	Υ

1.5.3 RP 85 - compatible single tubes

Tube size	Flow factor	Mat	erial
= inner diameter x wall thickness of tube	lpm/rpm	Silicone	PVC.
1/8" x 1/16"	0.001748	Υ	Υ
3/16" x 1/16"	0.003715	Υ	Υ
1/4" x 1/16"	0.00625	Υ	Υ
1/4" x 3/32"	0.00625	Υ	Υ
5/16" x 1/16"	0.00930	Υ	Υ
5/16" x 3/32"	0.00930	Υ	Υ

1.6 Essenz Patient Monitor specifications

Operating system: Microsoft Windows 10 Enterprise LTSC 2019 64 bit, build 1809 Database Microsoft® SQL Express 2019

Flat Panel Display with LED retro-illumination

21.5", full-HD resolution (1920 x 1080 pixels)

Dimensions: (H) 325mm x (W) 533mm x (D) 59mm

Weight: 6.8 kg (including batteries), 1.49 kg (mast holder for power adapter), 0.7kg (power adapter without mast holder)

WiFi antenna: 2 x antennas integrated inside the device

Power input connector: 4 pin DIN connector

2 x RS232 ports with connector type DB9M with 4kV isolation

1 x Gigabit Ethernet port with RJ45 connector: Insulation of 4 kV and plastic connector

3 x USB 1.1 + 1 x USB 1.0 (those on back left and down) ports with 4kV isolation

1 x USB 3.0 port (covered)

1x HDMI port (covered)

CPU: Intel i5-6300U@ 2.4GHz, up to 3.0GHz, TDP 15W.

RAM: 16GB DDR4 SO-DIMM 2666Mbps

System drive: industrial SSD 2.5" form factor, 256GB

Removable drive: USB flash drive 32GB

RS232 interface able to drive at 2 external COM port

Unit Power Circuit: nominal input 19 VDC, operating range from 12 to 48 VDC, max input current <= 8 A

RTC/CMOS BIOS battery: +3V Li battery type CR2032 with expected shelf life >= 5 year

WLAN controller featuring WiFi dual band 802.11ac + Bluetooth 5. Certified for the use in Japan GITEKI MARK

(also FCC, IC, CE) compliant with ETSI EN 301 489-17

Gigabit Ethernet LAN controller

External Power Adapter: universal PSU 120W / 20VDC out switching power supply medical and isolated with lockable 4pin

DIN male connector for DC output and 3 pole AC inlet IEC320-C14, IEC CLASS I (gnd pole)

¹ Blood product use during routine open heart surgery: the impact of the centrifugal pump. Artif Organs 2001;25:300-5 - Klein M, Mahoney CB, Probst C, Schulte HD, Gams E.

² Comparison of the centrifugal and roller pump in elective coronary artery bypass surgery—a prospective, randomized study with special emphasis upon platelet activation. Scand Cardiovasc J 2003;37:356–62 - Andersen KS, Nygreen EL, Grong K, Leirvaag B, Holmsen H.

³ Use of minimal extracorporeal circulation improves outcome after heart surgery; a systematic review and meta[1]analysis of randomized controlled trials. Int J Cardiol 2013;164:158–69. - Anastasiadis K, Antonitsis P, Haidich AB, Argiriadou H, Deliopoulos A, Papakonstantinou C.

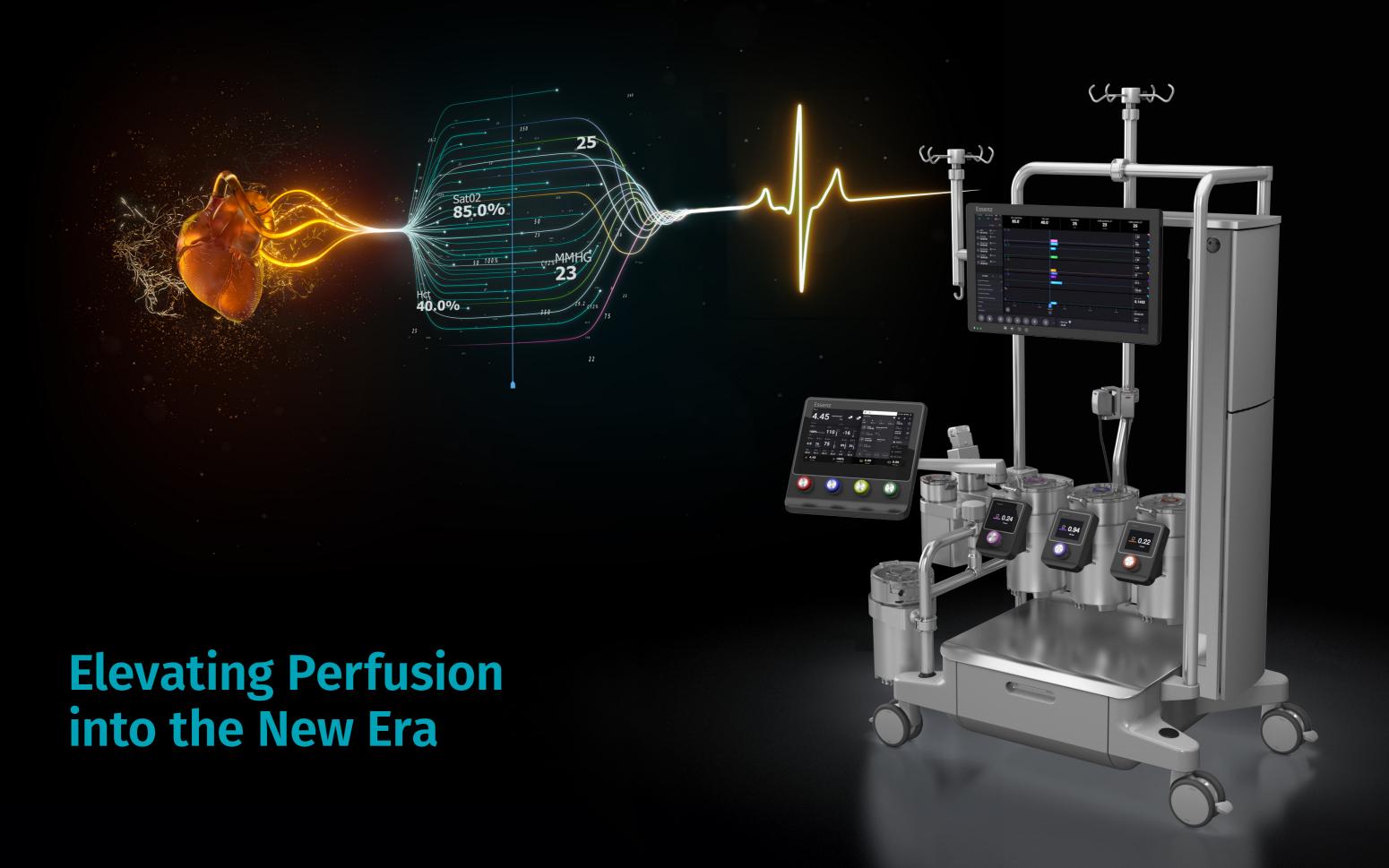
^{*} Do miniaturized extracorporeal circuits confer significant clinical benefit without compromising safety? A meta-analysis of randomized con[1]trolled trials. ASAIO J 2011;57:141–51.
- Harling L, Warren OJ, Martin A, Kemp PR, Evans PC, Darzi A et al.

⁵ 30-day mortality reduction with miniaturized extracorporeal circulation as compared to conventional cardio[1]pulmonary bypass for coronary revascularization. Meta-analysis of randomized controlled trials. Int J Cardiol 2015;198:63–5. - Kowalewski M, Pawliszak W, Kołodziejczak M, Navarese EP, Anisimowicz L. Anisimowicz L.

⁶ How firm is the evidence for miniaturized extracorporeal circulation versus conventional cardiopulmonary bypass for coronary revascularization? A trial sequential analysis. Int J Cardiol 2015;201:422-3. - Phan K, Phan S, Yan TD.

⁷ Vacuum-assisted venous drainage in extrathoracic cardiopulmonary bypass management during minimally invasive cardiac surgery. Perfusion 2006;21:361–5. - Colangelo N, Torracca L, Lapenna E, Moriggia S, Crescenzi G, Alfieri O.

⁸ Reduction of hemodilution in small adults undergoing open heart surgery: a prospective, randomized trial. Perfusion 2007;22:317–22. - Pappalardo F, Corno C, Franco A, Giardina G, Scandroglio AM, Landoni G et al



Essenz™ Perfusion System Important Safety Information

Heart-Lung Machine with Integrated Essenz In-Line Blood Monitor (ILBM)

The Essenz Heart-Lung Machine is intended to perform, control, monitor and support extracorporeal blood circulation replacing the mechanical pumping function of the heart, monitoring and regulating physiologic parameters during procedures requiring extracorporeal circulation.

US: Essenz HLM is intended to be used during cardiopulmonary bypass for procedures lasting six (6) hours or less.

Essenz ILBM is indicated for supplementary, in-line monitoring of the extracorporeal arterial oxygen partial pressure, venous oxygen saturation, venous hematocrit/hemoglobin, and arterial and venous temperature during cardiopulmonary bypass procedures up to six hours.

Essenz Patient Monitor

The Essenz Patient Monitor software is a modularly structured software program package that is exclusively used with LivaNova heartlung machines. The system allows detailed recording of perfusion data during cardiopulmonary bypass procedures as well as the processing and evaluation of this data. The data may be recorded automatically or entered manually. The LivaNova Perfusion System Monitor is a panel PC intended to be exclusively used with LivaNova heart lung machines as a base and user interface for the Essenz Patient Monitor software.

CONTRAINDICATIONS: No contraindications are known if the devices are used for the purpose described and in accordance with the stated operating conditions. Do not use the devices for any purpose other than indicated.

WARNINGS: The devices must be used in accordance with the instructions for use provided. For a complete listing of warnings please refer to the Instructions for Use. Medical intervention and therapeutic procedure must not be based solely on the Essenz Patient Monitor perfusion records (reports).

PRECAUTIONS: Federal law (U.S.A.) restricts these devices to sale by or on the order of a physician. For a complete listing of precautions/cautions please refer to the Instructions for Use. The devices should be used by qualified and skilled personnel, able to follow the indications and instructions for use contained in the information provided by the manufacturer.

Essenz In-Line Blood Monitor and B-Capta Blood Gas Monitor are clinically equivalent in terms of safety and performance as they have the same technology and intended use. Not approved in all geographies, consult your labeling. Please visit the LivaNova website to receive instructions for use containing full prescribing information including indications, contraindications, warnings, precautions and adverse events.

Gas Blender Important Safety Information

EU: The gas blender is designed and intended to be used, in accordance with the above listed standards and regulations, to precisely set, monitor and control gas flows (air/O2/CO2). The gas mixture serves to oxygenate the blood in an oxygenator.

USA: The Stöckert Gas Blenders are intended to enable qualified personnel to set, monitor and control gas flows of medical grade gases (air/O2/CO2) during cardiopulmonary bypass. The Stöckert Gas Blenders are used as a component part of or optional accessory to the Stöckert S5 System (or any compatible system using the S5 firmware versions of 3.0 or greater) for periods of six hours or less. CAN: The Stöckert Gas Blender is used with a Stöckert/Sorin S5/C5 heart-lung machine to set, monitor and control gas flow during extracorporeal perfusion.

CONTRAINDICATIONS: There are no known contraindications for the gas blender. The attending physician is solely responsible for the use of the system.

WARNINGS: The device must be used in accordance with the instructions for use provided in the Instructions for Use. For a complete listing of warnings, please refer to the Instructions for Use which accompany each product

PRECAUTIONS: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician. For a complete listing of precautions/ cautions please refer to the Instructions for Use which accompany each product. The devices should be used by qualified and skilled personnel, able to follow the indications and instructions for use contained in the information provided by the manufacturer. Please contact us through our website to receive instructions for use containing full prescribing information including indications, contraindications, warnings, precautions and adverse events.

Not approved in all geographies, consult your labeling. Please visit the LivaNova website to receive instructions for use containing full prescribing information including indications, contraindications, warnings, precautions and adverse events.

The information contained in this summary represents partial excerpts taken from the product labeling. The information is not intended to serve as a substitute for a complete and through understanding of the device nor does this information represent full disclosure of all pertinent information concerning the use of this product. Not approved in all geographies, consult your labeling.

Legal Manufacturer:

Distributed in the USA by: LivaNova Deutschland LivaNova USA Lindberghstrasse 25 14401 W 65th Way D-80939 Munich Arvada, CO 80004 Germany USA

Sorin Group Italia S.r.l. Via Statale 12 Nord, 86 41037 Mirandola (MO) Italy



www.essenzperfusion.com



