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## LivaNova Receives U.S. FDA 510(k) Clearance for Essenz Heart-Lung Machine for Cardiopulmonary Bypass Procedures

**London, March 9, 2023** – LivaNova PLC (Nasdaq: LIVN), a market-leading medical technology and innovation company, today announced it received U.S. Food and Drug Administration (FDA) 510(k) clearance for its Essenz™ Heart-Lung Machine (HLM). With FDA clearance, LivaNova initiates the commercial launch of Essenz in the U.S. The Company also recently received approval for the Essenz HLM from Health Canada and the Japanese Pharmaceuticals and Medical Devices Agency (PMDA). Additionally, LivaNova is initiating a broad commercial release in Europe, following a successful limited commercial release that supported more than 200 adult, pediatric and neonatal patients in Europe. The Essenz HLM and Essenz™ Patient Monitor comprise the Essenz™ Perfusion System, which enables a patient-tailored perfusion approach rooted in data-driven decisions that improve both clinical workflows and quality of patient care during cardiopulmonary bypass (CPB) procedures.

“The Essenz Perfusion System has tremendous potential to become a key addition to our clinical practice, fusing a new era of technology with the skill and expertise of the perfusionist,” said Larry Garrison, Chief Perfusionist at Franciscan Health Indianapolis in Indianapolis, Indiana. “Since we participated in the Essenz HLM validations and the early release of the Essenz Patient Monitor, we’ve witnessed the System’s immense ability to unlock the potential of individualized care throughout all phases of CPB procedures.”

Essenz is based on 50 years of trusted partnership with perfusionists. LivaNova worked hand in hand with more than 300 perfusionists around the world who participated during every step of design and development to address their evolving needs in the operating room (OR), with an emphasis on patient safety and risk management.

Key attributes of the Essenz Perfusion System include:

**Safe and Reliable:**

The system is built on the proven LivaNova S5™ HLM, which has supported millions of patients for safe CPB procedures. Each pump on Essenz is controlled individually for simple, straightforward operations. HLM sensor checks confirm readiness before the CPB procedure starts. The Essenz HLM cockpit and Essenz Patient Monitor are connected but operate separately to further ensure reliability.

**Patient-Tailored Care:**

Accurate sensing technology and an intuitive dashboard on the Essenz Patient Monitor provide critical data to support individualized, data-driven patient care during a case. Essenz Patient Monitor utilizes official formulas to support perfusionists in the implementation of goal-directed perfusion (GDP), a therapy effective in reducing the risk of acute kidney injury.<sup>1</sup> Mast-mounted pumps allow the user to optimize the position of the disposables (i.e., oxygenator and perfusion tubing set), which minimizes priming volumes and reduces hemodilution.

**Intuitive:**

The Essenz Patient Monitor offers an intuitive user interface and continuously records and displays data and events together to assist the perfusionist throughout a procedure. Data is automatically and seamlessly transferred, minimizing manual data entry and freeing up valuable time for the perfusionist in the OR. The technology platform is built to accommodate a stream of future software features and functionalities, making it a valuable long-term investment.

**Flexible and Efficient:**

The Essenz Perfusion System can be adapted to the individual needs of patients (adult and pediatric), workflows and users. It features an ergonomic design, including advanced cable management and a mast-mounted design that minimizes distractions and keeps the area clean and hygienic. The innovative cockpit provides one central view to control the device and check all perfusion and patient parameters. Also, Essenz has seamless integration with OR external devices and hospital information systems.

In addition, the Essenz Perfusion System is backed by a responsive service team of dedicated, local engineers in more than 100 countries, along with a global support center to address any needs.

“A perfusion system acts as a patient’s heart and lungs during an open-heart procedure, so having the highest-quality system backed by the expertise of a skilled perfusionist is paramount,” said Damien McDonald, Chief Executive Officer of LivaNova. “When we were designing Essenz, perfusionists told us they needed a system that gives them access to comprehensive data to drive more informed decision-making throughout the entire procedure. We’ve done that with Essenz. Through next-generation hardware and software, Essenz empowers perfusionists to better serve their patients with increasingly tailored care.”

Learn more about the entire [Essenz Perfusion System](#) on the LivaNova website.

*\*Note: The Essenz Heart-Lung Machine is not available for sale in all geographies. Visit the [LivaNova website](#) for important safety information.*

## References

- 1 *Goal-Directed Perfusion to reduce Acute Kidney Injury: A Randomized Trial* Ranucci M. et al. *J Thorac Cardiovasc Surg.* 2018 Nov; 156(5): 1918-1927.e2. doi.org/10.1016/j.jtcvs.2018.04.045

## About LivaNova

LivaNova PLC is a global medical technology and innovation company built on nearly five decades of experience and a relentless commitment to provide hope for patients and their families through innovative medical technologies, delivering life-changing improvements for both the Head and Heart. Headquartered in London, LivaNova employs approximately 2,900 employees and has a presence in more than 100 countries for the benefit of patients, healthcare professionals and healthcare systems worldwide. For more information, please visit [www.livanova.com](http://www.livanova.com).

## Safe Harbor Statement

This news release contains “forward-looking statements” concerning the Company’s goals, beliefs, expectations, strategies, objectives, plans and underlying assumptions and other statements that are not necessarily based on historical facts. These statements include, but are not limited to, statements regarding the Essenz Perfusion System, Essenz HLM and the Essenz Patient Monitor. Actual events may differ materially from those indicated in our forward-looking statements as a result of various factors, including those factors set forth in Item 1A of the Company’s most recent Annual Report on Form 10-K, as supplemented by any risk factors contained in Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. LivaNova undertakes no obligation to update the information contained in this press release to reflect subsequently occurring events or circumstances.

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