

Press Release

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Fresenius Medical Care is taking the next step in extracorporeal life support with Xenios 2.0

- Xenios 2.0 is Fresenius Medical Care's MDR-approved system for ECLS treatments applicable for all patients, from neonates to adults
- The system provides cutting-edge technical safety features and intelligent troubleshooting for physicians and caregivers
- Xenios 2.0 was developed according to the principles of safety, simplicity, and connectivity

Heilbronn (October 15, 2024) Fresenius Medical Care's heart & lung business unit, Xenios AG, introduces the all-new Xenios 2.0. This system enables healthcare professionals to take the next crucial step in extracorporeal life support (ECLS). It can be used for the full range of ECLS treatments, from neonatal to adult patients, and is approved according to the new Medical Device Regulation (MDR).

Xenios 2.0: Safety – simplicity – connectivity

The new device has been designed with innovative safety features, a simplified guided user interface, and advanced connectivity to support physicians and caregivers during ECLS treatment. Various new technical features were implemented during the development, including a redesigned graphical user interface (GUI). The new GUI supports all relevant handling steps and functions before and during treatment to make it as safe and trouble-free as possible.

Safety. The system includes features such as power consumption monitoring, which can help with circuit handling. The design of the integrated pressure sensors (IPS) eliminates the risk of air aspiration and measures the pressure directly at the tubing kit. Additionally, the intelligent alarm

functions offer recommendations for action in the event of certain physiological and technical alarms, ensuring prompt and appropriate responses.

Xenios 2.0 is equipped for various backup scenarios to maintain treatment even in the event of a system failure. Two backup battery packs supply the system with power during a power failure or interruption. A second pump drive can be used if the initial pump drive fails. In case of a technical failure of the operator unit itself, the pump drive and a battery pack can be connected directly to each other

Simplicity. Comprehensive step-by-step explanations and illustrations during the priming procedure help to avoid user errors, making the system user-friendly. This reduces potential sources of failure that can occur during an ECLS treatment in advance and thus can save time. In addition, Xenios 2.0 supports the learning effort for new personnel so that they are able to prepare a kit for ECLS treatment even in stressful situations.

The trend display allows users to visualize critical parameters and observe how they change over time, providing a clear and continuous overview of the system.

Connectivity. The system supports the simple implementation of standards-based medical data, allowing for flexible integration of machine data into various patient monitoring systems. Medical data is automatically sent to a Patient Data Management System (PDMS) or Electronic Medical Record (EMR), which can significantly reduce the workload for healthcare providers by streamlining documentation and data management processes.

An MDR-approved system available for the European CE market

An approval under the Medical Device Regulation (MDR) is a significantly higher bar than the previous Medical Device Directive (MDD) requirements, with an increased focus on safety, performance, and product lifecycle.

“Based on new regulatory requirements and the need for increased safety standards, the Xenios 2.0 offers enhanced safety features to support physicians and caregivers.”, says Dr. Benjamin Waldmann, CEO of Xenios AG, and adds: “With Xenios 2.0 we are taking the next step towards improved ECLS treatment.”

Fresenius Medical Care received approval from the notified body (CE 0123) at the end of August this year and will soon be able to make the first devices available.

For further information regarding Xenios 2.0 please contact: xenios-sales@freseniusmedicalcare.com.

A video about Xenios 2.0 can be found [here](#).

About Fresenius Medical Care:

Fresenius Medical Care is the world's leading provider of products and services for individuals with renal diseases of which around 4.1 million patients worldwide regularly undergo dialysis treatment. Through its network of 3,757 dialysis clinics, Fresenius Medical Care provides dialysis treatments for approx. 311,000 patients around the globe. Fresenius Medical Care is also the leading provider of dialysis products such as dialysis machines or dialyzers. Fresenius Medical Care is listed on the Frankfurt Stock Exchange (FME) and on the New York Stock Exchange (FMS).

For more information visit the Company's website at www.freseniusmedicalcare.com.

About Xenios:

At Xenios, a Fresenius Medical Care company, we offer extracorporeal membrane oxygenation (ECMO) solutions that combine cardiac and pulmonary support on one single technological platform. The ECMO device supports gas exchange in the lungs and the cardiovascular system to increase the chance of survival in critically ill patients. Physicians may gain vital treatment time during diagnosis and therapy.

Xenios AG is a part of Fresenius Medical Care, the world's leading provider of products and services for people with renal diseases. We are complementing Fresenius Medical Care's product portfolio in the field of intensive care and are continuing to shape the future of extracorporeal multi-organ support.

In our daily work, we share a passion for helping people. For patients. Worldwide. Every day.

For more information visit the Company's website at: www.xenios-ag.com

Disclaimer:

This release contains forward-looking statements that are subject to various risks and uncertainties. Actual results could differ materially from those described in these forward-looking statements due to various factors, including, but not limited to, changes in business, economic and competitive conditions, legal changes, regulatory approvals, impacts related to the COVID-19 pandemic results of clinical studies, foreign exchange rate fluctuations, uncertainties in litigation or investigative proceedings, and the availability of financing. These and other risks and uncertainties are detailed in Fresenius Medical Care's reports filed with the U.S. Securities and Exchange Commission. Fresenius Medical Care does not undertake any responsibility to update the forward-looking statements in this release.