
FDA Clearance For Edwards' Advanced Noninvasive Monitoring System



ClearSight system enables clinicians to reduce risk of post-surgical complications

Edwards Lifesciences Corporation, the global leader in the science of heart valves and hemodynamic monitoring, has announced it has received U.S. Food and Drug Administration (FDA) clearance for the ClearSight system.

The ClearSight system is a noninvasive monitor that provides clinicians access to valuable blood volume and blood flow information for patients at moderate or high risk of post-surgical complications, in whom invasive monitoring would not be used.

Using a cuff on the outside of the finger that is connected to the Edwards EV1000 clinical platform, the ClearSight system:

- utilises Edwards' proven, gold-standard monitoring technologies that are used in hospitals around the world, and incorporates a finger cuff and software elements that have been used for the noninvasive monitoring of the blood pressure of astronauts in space;
- automatically provides up-to-the-minute information without inserting anything into the body – as compared to the traditionally more invasive approach to monitoring, which today is only used in a fraction of those patients at risk of post-surgical complications; and thus
- provides an opportunity to extend the benefits of hemodynamic optimisation, or proper fluid administration and balance within a patient's organs and tissues, to a broader patient population that could benefit from close monitoring, but may not receive it without a noninvasive option.

"Proper intraoperative management of moderate and high-risk surgery patients is critical to help reduce the risk of post-surgical complications," said Julie K. Thacker, M.D., surgical oncologist at Duke University Hospital. "Studies have indicated that patient outcomes are improved through monitoring and management of vital hemodynamic information through hemodynamic optimisation protocols."

"The ClearSight system is the most advanced noninvasive monitor of its kind. This important development in the field of critical care medicine builds on Edwards' 40 years of experience in providing clinicians with tools to make more informed decisions that can advance patient care by helping to reduce complications, shorten hospital stays and lower associated costs," said Carlyn D. Solomon, Edwards' corporate vice president, critical care and vascular.

The ClearSight system is also available in CE Mark countries.

[Source: Edwards](#)

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