

PRESS RELEASE
FOR IMMEDIATE RELEASE

Nihon Kohden NKV-440 Ventilator System Receives US FDA 510(k) Clearance

SANTA ANA, California – June 1, 2023. Today, Nihon Kohden OrangeMed, Inc. received U.S. Food and Drug Administration (FDA) 510(k) clearance for its NKV-440 Ventilator System. The NKV-440, a turbine-based ventilator, is a “neonatal through adult” platform that provides independence from compressed air while providing high-quality ICU performance in a smaller, more mobile package. The NKV-440 ventilator leverages the same clinician-focused, app-based user interface as the NKV-550 Series Ventilator System.

Reinforcing our commitment to lung protection, the NKV-440 ventilator features our Gentle Lung® Suite of applications: Recruitability Assessment, Recruitment Maneuvers, and PEEP Titration. The NKV-440 ventilator also has a HEPA-filtered turbine and integrated pneumatic nebulization.

“The release of the NKV-440 ventilator, the third ventilator from Nihon Kohden in five years, exemplifies our solid commitment to respiratory solutions,” said Hong-Lin Du, M.D., President of Nihon Kohden OrangeMed. “The NKV-440 ventilator is an obvious choice for hospitals with limited infrastructure while requiring a feature-rich solution.”

“The release of the NKV-440 ventilator is an exciting step forward in advancing the ventilation portfolio for Nihon Kohden.” Eiichi Tanaka, Head of Nihon Kohden US Operations said. “This furthers our mission to improve the outcomes of our patients through innovative technologies and high-quality medical devices.”

For more information on the NKV-440 Ventilator System, please visit orange-med.com.

About Nihon Kohden OrangeMed, Inc.

Nihon Kohden OrangeMed, located in Orange County, California, focuses on design, development, and providing state-of-the-art innovative respiratory products distributed throughout the Nihon Kohden worldwide distribution network.

Nihon Kohden OrangeMed is part of Nihon Kohden Corporation headquartered in Tokyo, Japan. Nihon Kohden is one of the leaders in medical device design and manufacturing in the world. Listed on the Tokyo Stock Exchange, Nihon Kohden, with its 5,000 employees, tirelessly pursues to deliver medical technology innovations and high-quality medical products worldwide. Nihon Kohden's products range from bedside monitors, central monitors, defibrillators, AEDs, physiological measuring equipment, in vitro diagnostic equipment, and mechanical ventilators. Nihon Kohden has superior brand strength with over 70 years of advancing medical care through technological breakthroughs.