

PRESS RELEASE
FOR IMMEDIATE RELEASE

Nihon Kohden NKV-330 Ventilator System Receives US FDA 510(k) Clearance

SANTA ANA, California – July 1, 2022. Today, Nihon Kohden OrangeMed, Inc. received U.S. Food and Drug Administration (FDA) 510(k) clearance for its NKV-330 Ventilator System. The NKV-330 is a non-invasive ventilator that provides respiratory support to adult and pediatric patients. It offers not only non-invasive ventilation but also invasive ventilation as well as high flow oxygen therapy. In addition, it provides continuous monitoring of CO₂ when using our cap-ONE® NIV mask. The cap-ONE mask is an NIV interface that allows quality CO₂ monitoring directly from the ventilator.

“The NKV-330 ventilator can help hospitals who face a limited choice of new non-invasive ventilator platforms.” said Dr. Hong-Lin Du, CEO of Nihon Kohden OrangeMed. “The continuous monitoring of CO₂, the excellent portability, and many other features in the NKV-330 makes it a great choice for the hospitals and caregivers.”

The NKV-330 Ventilator System is distributed in the United States by Nihon Kohden America, Inc. and is expected to begin shipping in July 2022. It has been available outside of the United States since 2019.

For more information on the NKV-330 Ventilator System, please visit www.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.