

Vapotherm® Receives FDA 510(k) Clearance for Flowrest® Homecare Device

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Vapotherm, the global leader in High Flow Therapy (HFT™) products, has received 510(k) clearance from the Food and Drug Administration (FDA) for the Flowrest® homecare device. The device also recently received CE marking.

The Flowrest® delivers warmed, humidified high-flow breathing gases to patients via nasal cannula. Utilizing patent pending humidification and breathing circuit technology, the device is designed to maximize ease of use and patient comfort, both of which are critical in homecare and other low acuity settings.

"We are excited to expand our leadership position in HFT™ with the launch of this device intended specifically for homecare use," said Robert Storey, CEO of Vapotherm. "Our hospital customers have been asking us for a solution to enable earlier discharge of high flow therapy patients, and patients and families have consistently asked us to deliver a cost effective solution for comfortable, effective respiratory support in the home. We are pleased to answer this need with Flowrest®, which will address the broad population of patients who benefit from heated and humidified high flow breathing gases."

High Flow Therapy via nasal cannula is utilized in hospitals throughout the world to provide respiratory support for spontaneously breathing adult, pediatric and neonatal patients with a variety of acute or chronic conditions. Clinical practice and research has demonstrated that its use can help clinicians avoid more invasive respiratory therapies. Vapotherm's gas conditioning technology allows for high flows to be delivered via a simple nasal cannula, allowing patients to avoid the discomfort and confinement of mask therapy.

Vapotherm, Inc. is a privately held manufacturer of respiratory care devices for hospitals and homecare use based in Stevensville, Maryland. The Company is dedicated to the development of innovative, non-invasive technologies for respiratory therapy, especially for the treatment of chronic lung and acute breathing disorders. For more information, visit www.vtherm.com