



Voluntary Recall of Filled Oxygen Tanks Skilled Nursing Facility Letter

Dear Oxygen Customer,

September 2, 2022

NorCal Respiratory Inc. is voluntarily recalling all oxygen tanks that were provided to your facility. The reason for this recall is that the filling of these tanks at NorCal Respiratory's facility did not meet the established federal requirements for current good manufacturing practice (CGMP) regulations, which are the adopted regulations in California. The CGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The drug CGMP regulations help ensure that a product is safe for use, and that it has the ingredients and strength it claims to have. Additionally, the filling of the tanks with the Invacare Homefill® system was performed outside of the scope of the medical device manufacturer's specifications and beyond the approved use of the Homefill® system by the U.S. Food and Drug Administration (FDA). The filling of tanks using the Homefill® system is to be limited to the oxygen patient only, and the tanks must not be distributed to any other individual for any purpose, as per the warnings in the Invacare Homefill® Owner's and Operator Maintenance Manual.

As an Invacare Homefill® oxygen system customer, it is likely that you were provided filled oxygen tanks from NorCal Respiratory Inc. from time to time, and on an as-needed basis, in order to accommodate the temporary needs of your facility's patients. These filled Homefill® system tanks were provided to meet the urgent needs of your patients and only to supplement your facility's ability to fill sufficient Homefill® tanks to meet your patients' needs.

If you still have any tanks that were filled with the original oxygen provided to you by NorCal Respiratory Inc., you are to contact NorCal Respiratory Inc. immediately at the number below, whereupon we will coordinate an exchange of that tank, or tanks, with other empty tank(s) that you can refill with the Homefill systems you have at your facility.

NorCal Respiratory phone: 530-246-1200

To be clear, there have been no reported adverse events associated with the practice of NorCal Respiratory providing filled oxygen tanks to patients or facilities from the Homefill® system. Nor are we aware of any issues or concerns associated with the safety or efficacy of the Homefill® system when operating it according to manufacturer's guidelines in a patient's home or a regulated facility. NorCal Respiratory Inc. is only performing this voluntary recall out of an abundance of caution and to fall in compliance with the requirements of the California Department of Health and the US FDA. We appreciate your business and apologize for any inconvenience that may be caused by this recall.

Sincerely,

A handwritten signature in black ink that reads 'Scott Samuel'. The signature is fluid and cursive, with the first and last names clearly legible.

Scott Samuel

VP of Compliance