

URGENT NOTICE MEDICAL DEVICE CORRECTION

DEVILBISS HEALTHCARE 1025 SERIES OXYGEN CONCENTRATOR

March 9, 2023

Dear Oxygen Concentrator Customer/Distributor,

Purpose

The purpose of this Notice is to advise that DeVilbiss Healthcare is voluntarily initiating an instruction manual correction for the 1025 North America series oxygen concentrators, used to provide supplemental low flow oxygen therapy in the home, nursing homes, patient care facilities, etc. The voluntary instruction manual correction will apply to all 1025 North America series oxygen concentrators manufactured and distributed from May 23, 2017, through February 23, 2023. **This is the same action that was initiated for the 525 series to update the user manual to align the user manual with current standards. There is no additional risk to the user and no impact on product performance.**

Reason for Voluntary Correction

DeVilbiss Healthcare is voluntarily implementing this correction to replace the instruction manual with an updated version that is in alignment with labeling requirements specified in the IEC-60101-1 standard. There have been no specific complaints or adverse events related to this voluntary correction. DeVilbiss Healthcare decided to initiate this correction after reviewing the current standard and identifying clarifications needed.

The updated instruction manual (also referred to as “Instructions for Use, or “IFUs”) includes several updates, specifically:

- warnings related to applied parts that may come into contact with a patient that, when under single fault failure conditions while operating at maximum environmental temperatures, could cause the surface temperature of the part to exceed 41°C.
- clarifications regarding the expected service life for the unit; and
- additional instructions regarding wear components that may require maintenance during the expected service life of the product.

Risk to Health

This voluntary instruction manual correction should not affect patients, health care providers or other persons who are exposed to the device. The risk to an end user arises from the potential to touch an applied part that exceeds 41°C, which may result in a burn. However, a combination of extreme conditions must take place concurrently to create this potential hazard, and there is a low likelihood of this type of event occurring. The evidence from post-market surveillance of nearly 10 years of product in the field suggests that the risk of injury from a patient touching an applied part and receiving a burn is extremely low.

In cases related to wear components requiring maintenance during the service life of the product, the device contains visual and audible alarms that will advise the end user when such maintenance is required.

Actions to be Taken by Our Customers

Please immediately click on the hyperlinked Verification Code in the address block on the first page of this Notice to go to our dedicated instruction manual update website, www.recallrtr.com/1025series (or access the website manually), and follow the simple process set up to:

- Download electronic copies, or order hard copies, of the updated instruction manual.
- Download a spreadsheet containing the serial numbers of all affected units sold to your company.
- Replace the instruction manual for any units in your possession, and distribute the updated instruction manual to your customers, and
- Submit an Acknowledgement Form confirming the number of instruction manuals you replaced and distributed to customers to replace.

Should you need further assistance, we have also set up a dedicated call center, which can be reached at 1 (833) 820-0836, from 8:00 am to 7:00 pm EST Monday through Friday.

Product and Distribution Information

Product Name	Unique Identifier	Model Number	From	To	Mfg Dates
1025DS	00885304000846	1025DS	A175230001DS	A232160185DS	May 23, 2017 – February 23, 2023

The units have a five (5) year service life.

Other Information



100 DeVilbiss Drive, Somerset, PA 15501
800.338.1988 www.DeVilbissHealthcare.com

Once again, please access our dedicated website, www.recallrtr.com/1025series by clicking on your hyperlinked Verification Code in the address block on the first page of this Notice or accessing the website manually, or call our dedicated call center at 1 (833) 820-0836, from 8:00 am to 7:00 pm, EST Monday through Friday, to ensure compliance with this instruction manual update.

Very truly yours,

Yasily Ogando
Vice President, Quality and Regulatory Affairs
Drive DeVilbiss Healthcare