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

URGENT NOTICE
MEDICAL DEVICE CORRECTION

DEVILBISS HEALTHCARE 525 SERIES OXYGEN CONCENTRATOR

November 18, 2022

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 525 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 525 North America series oxygen concentrators manufactured and distributed from January 1, 2015, through October 31, 2022.

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/525series (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) 408-0512, from 8:00 am to 7:00 pm EST.

Product and Distribution Information

Product Name	Unique Identifier	Model Number	From	To	Mfg Dates
525DS	00885304000846	525DS, 525DS-BR, 525DS-MCK, 525DS-T	J708692DS	J798154DS	2015 to 2019
			N000001DS	N272201DS	2015 to 2019
			B191070001DS	B22B010212DS	2019 to October 31, 2022
525DS-Q	00885304009689	525DS-Q	J900001DS	J903501DS	2015 to 2019
			R000401DS	R013055DS	2015 to 2019
			B192270001DQ	B22A110255DQ	2019 to October 31, 2022

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

(continued)

Other Information

Once again, please access our dedicated website, www.recallrtr.com/525series 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) 408-0512, from 8:00 am to 7:00 pm, EST, to ensure compliance with this instruction manual update.

Very truly yours,

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