

MHRA Ref: 2022/012/005/601/007

23 Dec 2022

FSN 2022-02 – Safety information updated in the 525 Oxygen Concentrator IFU

Purpose

The purpose of this Field Safety Notice is to advise that DeVilbiss Healthcare Ltd has updated the IFU on the 525 series oxygen concentrators, used to provide supplemental low flow oxygen therapy in the home, nursing homes, patient care facilities, etc. The updated IFU will apply to all 525 series oxygen concentrators manufactured and distributed from 2017 onward.

Details of the affected devices:

Affects all 525KS, 525KS-LT and 525KS-UK Oxygen Concentrators. The units have a five (5) year service life.

The following Serial Numbers have been manufactured between Feb 2017 - Present:

B197030194KS to B197290228KS, B198080172KS to B198090053KS, B202030257KS to B202070400KS, B202120398KS to B202190095KS, B202200003KS to B202280504KS, B203020001KS to B203090359KS, B203100002KS to B203170091KS, B203230025KS to B203230055KS, B203310086KS to B203310200KS, B204010004KS to B204080236KS, B204130252KS to B204150178KS, B204200098KS to B204290262KS, B204300014KS to B204300100KS, B205010086KS to B205080028KS, B207020055KS to B207100136KS, B211270001KU to B211290036KU, B215250001KU to B215260126KU, B216160001KU to B216160432KU, B217180001KU to B217180255KU, B217200001KU to B217200255KU, B217210001KU to B217210060KU, B218090001KU to B218090432KU, B21C070001KU to B21C070432KU, B222170001KU to B222170432KU, B224110001KU to B224110218KU, B227050001KU to B227050432KU, B228150001KU to B228150432KU, B224093689KU, J789333KS to J797377KS, R000652KS to R090806KS

Description of the issue:

Following an update to the testing standard, Drive DeVilbiss Healthcare Ltd has issued an update on the safety information of the 525KS, 525KS-LT and 525KS-UK Oxygen Concentrators in accordance with the updated IEC-60601-1 Standard.

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

- fire protection close to the patient is now described in more detail within the warning
- 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.

Advice on the actions to be taken:

Drive DeVilbiss Healthcare Ltd will be contacting all affected distributor / dealers to issue the updated IFU. Hard copies can be made available free of charge or the updated IFU can be downloaded from the product page: <https://drivedevilbiss.co.uk/our-products/respiratory/oxygen-therapy/devilbiss-5-litre-oxygen-concentrator>.

Distributor / Dealers must replace the IFU for any devices in their possession and update IFU with their customers / users at the next service / maintenance interval. Complete and return the form on page 2 of this FSN to confirm that IFUs will be replaced.

This is not a product recall. The product has not been changed.

Transmission of this Field Safety Notice:

Please ensure that the information in this notice is made available to all relevant personnel within your organisation and/or customer base, and/or any organisation where the oxygen concentrators are used.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of this action.

e-mail feedback form:

As part of the MHRA vigilance and reporting structure, we are required to feedback that the Field Safety Notice has been acknowledged and the appropriate actions have taken place. Please confirm that the FSN has been received and that the IFUs will be replaced at the next service / maintenance interval.

The updated IFU ref **SE-525KS-1 Rev A** can be downloaded from our website at <https://drivedevilbiss.co.uk>
We also have printed versions available should they be needed.

PLEASE USE BLOCK CAPITALS

Name:	
Position:	
Organisation:	
Address:	
Signed:	
Date:	

Following completion, please sign, date and e-mail the completed form to quality@drivedevilbiss.co.uk