

Letter to healthcare professionals

Date April 24, 2020

DeVilbiss Oxygen concentrator 525KS

Preventive action to replace removable line cords

Information intended for healthcare providers providing a 525KS concentrator or in charge for maintenance of these devices.

Dear Sir / Madam Dear Partner

Drive DeVilbiss Healthcare has received reports of a thermal event on a very small number of power line cords. Per our vigilance process, some line cords that have been reported with an excessive internal wire crimping issue, resulting in weakened/damaged plug pins which can result in increased resistance. Increased internal resistance could cause an elevated thermal condition, followed by external deformation of the PVC plastic insulation at the line cord.

The material of the line cord is flame retardant and does prevent any fire from starting. However, an emission of smoke and a melting of the line cord is possible, which have been observed in a very small number of incidents.

There has been no serious injury or damage reported. The occurrence of this type of event remains extremely limited with less than 0.001%. However, in order to prevent any risk and resolve any concerns, Drive DeVilbiss Healthcare is initiating a campaign to replace potentially affected line cords.

The affected devices have been identified by manufacturing date and were sold only between April 2018 and April 2019.

Actions to be taken:

1. Drive DeVilbiss Healthcare will contact you in order to provide you with the appropriate number of replacement line cords.
2. Identify and replace line cords for device that are on the affected serial number list.
3. Due to the low risk and occurrence of the event, the line cords can be replaced during the routine visit to the patient's home or when the device is returned to the healthcare provider.

Please complete and return the acknowledgment below. Your response is essential to monitor the implementation of this preventive action.

Destroy the old line cords and communicate regularly to Drive DeVilbiss the quantities that have been replaced and destroyed.

Dissemination of this preventive action:

The BfArM has been informed of this preventive action. Drive DeVilbiss Healthcare thanks you for disseminating this information to all persons concerned.

We thank you for your trust and we apologize for any inconvenience this has caused. If you have any questions associated with this communication, please contact the Business Manager or Regulatory and Quality of Drive DeVilbiss Healthcare international:

md-vigilance@devilbisshc.com

Kind Regards

Dirk Kohl

Director Quality and Logistic

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Notice of receipt

Notice of receipt to be completed and returned to Drive DeVilbiss Healthcare international at:
md-vigilance@devilbisshc.com

Company	
Address	
Contact Name	
Position	
E-mail address	

I confirm that we undertake to carry out the required replacement actions

Done at _____ on ____ / ____ / 2020
 Signature