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

DeVilbiss 525KS Oxygen Concentrator – IEC Line Cord Evaluation Summary
20 May 2020

Dear customer,

Thank you for your attention in Drive DeVilbiss Healthcare's official reporting of complaints associated with the line cord used with the 525KS oxygen concentrator. The line cord is an IEC 220VAC/50Hz European style cord, Drive DeVilbiss part number 180-0006-001. Please note that all of the complaints to date are isolated to the line cord only; there have been no other related complaints associated with the use or performance of the 525KS concentrator. We provide herein a brief statement on the safety and risk associated with the reported line cord complaints.

Safety is Drive DeVilbiss's first priority, and we enacted our rigorous and thorough quality and regulatory processes in place to identify, investigate and resolve any potential safety issue. Immediately after receiving complaints related to the line cord, a comprehensive investigation was initiated to confirm and determine the root cause. The investigation identified a defect to the wires inside the PVC plug housing of certain line cords. The root cause is an internal failure of the wire/prong connection due to excessive crimping. The excessive crimping caused deformation or breakage of individual wire strands, which in some cases, may lead to an increased electrical resistance within the line cord/plug assembly. This may result in a thermal event that can be identified by an increased surface temperature and potential deformation of the male plug connector. Heating and degradation will continue until the wire/prong connection joint fails open or until the residential electrical circuit breaker is tripped. This condition was confirmed using electrical stress testing.

All complaint data and laboratory testing demonstrate the thermal energy generated by this failure mode is contained within the line cord/plug assembly. There is no evidence of exposed wire/conductors and no evidence to support the risk of electric shock during the failure mode. In each instance, the line cord demonstrated that it will fail safe.

There have been no complaints of adverse events associated with line cords, and specifically, no complaints / reports of any shock or injury to the user or caregiver associated with this fault condition. Additionally, other than minor smoke residue, there have been no complaints of any damage to property associated with this complaint and fault condition. In all cords received and tested, the PVC plug worked as intended, and the line cord and device failed safe. Our investigation demonstrates there have been no reported flames, injuries, electric shock, or serious property damage, and the probability of occurrence of a thermal event using a 525KS with an affected line cord is extremely low – 0.01%. In an abundance of caution, we are replacing the potentially affected line cords.

Drive DeVilbiss Healthcare is actively working with country regulatory agencies from all potentially affected regions to communicate this action to customers and to rapidly replace line cords from the affected period with a new, clearly distinguishable line cord.

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Thank you for your review. If you have questions or would like additional information about this issue, please contact us using the information below.

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SVP/GM, Clinical Care Business Unit
May 20, 2020

Dawn Rubel
SVP, Global Safety, Quality & Regulatory Compliance
May 20, 2020

INFORMATION TRANSMITTED UNDER THE AUTHORITY OF BfArM

Customer: 0 - Dr Pharma D.O.O.
Juncaril, parc. 303
HR - 10020 Zagreb, Croatia

Letter to healthcare professionals

Date July 14, 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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Gerichtsstand: Mannheim

Geschäftsführer
Oliver Niemann,
Timothy Walsh

Notice of receipt

Notice of receipt BfArM 02420/20 / DE-BfArM-2020-05-20-3253

To be completed and returned to Drive DeVilbiss Healthcare GmbH international at:
md-vigilance@devilbisshc.com

Company	Dr Pharma D.O.O. Customer-ID: 0
Address	Velika Cesta 33Odra HR - 10020 Zagreb, Croatia
Contact Name	
Position	
E-mail address	ljerka.rasan@drpharma.hr

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

Done at _____ on ____ / ____ / **2020**

Signature

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