Central Drugs Standard Control Organization

Directorate General of Health Services
Ministry of Health and Family Welfare
Government of India
(Medical Devices and Diagnostics Division)
Email: ddcimd-cdsco@nic.in
Food & Drugs Administration Bhawan,
Kotla Road, New Delhi.

F.No.29/Misc/03/2021-DC(185) **Date: 09th August 2021**

MEDICAL DEVICE ALERT

DEVICE

- **CPAP/BiPAP** – DreamStation, Dreamstation Go, ASV, ST AVAPS, SystemOne (Q-Series, Dorma 400, Dorma 500), SystemOne ASV4, C-Series ASV, C-Series S/T and AVAPS, A Series BiPAP Hybrid A30, A Series BiPAP V30 Auto, A Series BiPAP A40, A Series BiPAP A30, REMstar SE Auto
- **Mechanical ventilators** Trilogy 100, Trilogy 200, Garbein plus, Aeris, LifeVen, E 30.
- **OmniLab Advanced**

BACKGROUND

M/s Philips India Limited, Gurugram (the Company) is voluntarily issuing Field Safety Notice (FSN) for necessary rectification and continued usage of the above-mentioned affected devices. This FSN is issued due to operational issues relating to sound abatement foam, maintenance in high heat and humid environment and usage of unauthorized method of cleaning like ozone.

PROBLEM

1. The sound abatement foam used in the above-mentioned affected devices may degrade into particles which may enter the device air pathway. The foam degradation may be exacerbated by use of unapproved cleaning methods. High heat and high humidity environments may also contribute to foam degradation in certain regions.
2. The foam may emit certain chemicals and gases, which may occur during initial operation and May possibly, continue throughout the device's useful life.

IMMEDIATE ACTION TO BE TAKEN BY USER

- For patients using Bi level PAP and CPAP devices - discontinue use of affected units and consult with physician to determine the benefits of continuing therapy and potential risk.

- For patients using life sustaining mechanical ventilators devices – do not discontinue or alter prescribed therapy without consulting the physicians to determine appropriate next step.
- The company is deploying a permanent corrective action to address the two issues described in the recall notice.
- The company will replace the current sound abatement foam with a new material that is not affected by this issue and has already begun this process.
- Register your device on the recall website - https://www.philipssrcupdate.expertinquiry.com
- Firm request you to kindly fill up the form on the above stated website or contact us at 000800-852 1411 to get your device registered.

Important Note: CDSCO have not received any complaints from the market on this issue.

FURTHER DETAILS & CONTACTS

M/s Philips India Limited, Gurugram, Haryana had issued a Field Safety Notice which is attached herewith this alert.

M/s Philips India Limited,
Unit No. 402, 4th Floor, Tower 3,
World Mark 3, Maidawas Road
Sec-66, Gurugram, Haryana
Direct line: +91-124-4606000