香港特別行政區政府 衞生署 醫療儀器管制辦公室

香港灣仔皇后大道東 183 號 合和中心 31 樓 3101 室



DEPARTMENT OF HEALTH MEDICAL DEVICE CONTROL OFFICE

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本處檔號 OUR REF.: L/M (1202) to DH/MDCO/20-10/8

來函檔號 YOUR REF.:

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Dear Healthcare Professionals,

Risk of non-invasive ventilation devices being used as life-supporting ventilators

Your attention is drawn to a safety notice issued by Health Canada on the risk of non-invasive ventilation devices being used as life-supporting ventilators.

Non-invasive ventilation devices are used to provide non-invasive respiratory support to patients who experience respiratory insufficiency caused, for instance, by obstructive sleep apnea, chronic obstructive pulmonary disease and neuromuscular or chest wall disorders. Health Canada issued the notice in response to adverse events associated with these devices being used as life-supporting ventilators reported in Canada and internationally. One reported Canadian case resulted in the patient requiring resuscitation. So far, the Hong Kong Department of Health has not received any report of similar adverse events in Hong Kong.

Generally, non-invasive ventilation devices can be divided into continuous positive airway pressure (CPAP) and variable positive airway pressure (VPAP), also known as Bi-level positive airway pressure (BiPAP) ventilators. Unlike mechanical ventilators that provide life-sustaining ventilation, non-invasive ventilators may generally lack a power backup system, alarms, patient monitoring features and other safety mechanisms that are necessary to protect ventilator-dependent patients against device failure or warn healthcare providers in case of changes in patients' health condition. It is therefore recommended that non-invasive ventilators should not be used in patients with insufficient respiratory drive to tolerate brief interruptions in non-invasive ventilation therapy. For more details about the safety notice, please refer to the following link:

http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/ 2012/ventilation nth-aah-eng.php

Thank you for your attention.

Yours faithfully,

(Dr. LEUNG Yiu-hong) for Director of Health

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