

Medical Device Alarm Safety

Medical devices, such as ventilators, infusion pumps, pulse oximetry devices and patient monitors, are equipped with alarms as part of their safety features. These devices are essential for the monitoring of a patient's physiologic parameters and can be used at bedside or in critical care situations. When functioning effectively, a change in the patient's condition will trigger the device's in-built alarms to alert healthcare providers of changes in a patient's condition and situations that may require prompt attention for timely and appropriate clinical management.

A patient's health may be at risk when an alarm is not working appropriately. If it does not activate or display sufficient information as expected, it fails to communicate critical messages to healthcare providers for their necessary responses. On the other hand, inappropriate and excessive activation of alarms causes desensitisation and distracts healthcare providers from important health alerts.

Background information

Between 2005 and 2008, the US Food and Drug Administration (FDA) received 566 medical device adverse event (AE) reports concerning deaths arising from alarm-related issues. Common alarm system issues included devices not providing a critical alarm, which could be either due to alarms that were deactivated and not reset, or the lack of an alarm due to mistaken disconnections from a central station or inoperable speakers.^{1,2} In 2010, out of the estimated 2,500 AE reports that the US FDA received, about one third indicated an alarm-related issue.³

In Singapore, between 2012 to May 2014, HSA received two local reports of AEs arising from alarm issues related to locally registered medical devices. One AE involved the triggering of a false alarm in a patient monitoring system, while the other involved the failure of a negative pressure wound management system to trigger an alarm when it should. In the same period, 37 Field Safety Corrective Actions* (FSCAs) were conducted by local medical device dealers to address issues of false alarms and alarms not sounding when they should and these include a range of devices such as multi-parameter patient monitoring systems, ventilators, infusion pumps, incubators and fluid warmers.

Example of a recent FSCA related to a medical device alarm issue

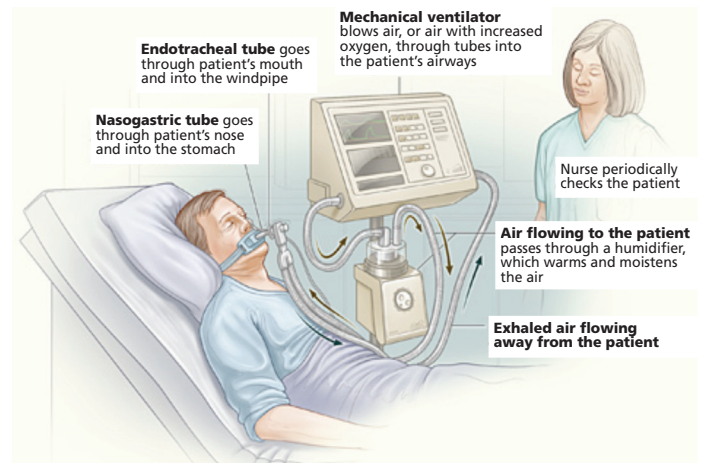
FSCA for Respironics V60 Ventilator

In June 2013, Philips Electronics (S) Pte Ltd ('Philips') reported that a component failure on the Power Management Board Assembly (PMBA) may cause a loss of ventilator support and backup alarm with potential consequence of no audible alarm. The Respironics V60 Ventilator is an assist ventilator and is intended to augment breathing in spontaneously breathing individuals who require mechanical ventilation. Should ventilator malfunction or shutdown occur simultaneously with a loss of alarm, patients could be at risk of hypoventilation as clinical personnel may not be alerted to provide timely interventions. To date, there have been no local complaints or incidents of AEs reported with this device.

Based on their investigation results, Philips identified that a PMBA component failure may cause excessive current flow, resulting in ventilator shutdown. Due to a software limitation, the alarm might not sound to indicate that ventilation had ceased. Affected healthcare institutions were informed through a Field Safety Notice of Philip's

*A Field Safety Corrective Action (FSCA) is an action undertaken by the product owner (also commonly referred to as legal manufacturer) with regard to a medical device to reduce the potential risk of serious deterioration in the state of health of a patient associated with continued use of the device. FSCAs can include, but are not limited to, recalls, software upgrades, device modification, and changes to instructions for use.

corrective actions to replace the PMBA and update the PMBA Software to enable the device alarm to annunciate in the event of a PMBA failure. Prior to the completion of these actions, the institutions were reminded to use the V60 ventilators in accordance with the directions for use. These include the use of an external oxygen monitor to verify the oxygen concentration in the delivered gas and to have available alternate mean of ventilation. To date, all corrective actions have been completed by Philips.



Standard Setup for a Ventilator in a Hospital Room

Source: National Heart, Lung, and Blood Institute, NIH, US Department of Health & Human Services
<http://www.nhlbi.nih.gov/health/health-topics/topics/vent/while.html>

Advisory to healthcare professionals and call for reporting

HSA would like to highlight the importance of medical device alarm safety as the effectiveness of an alarm can affect the clinical management of a patient. Healthcare providers are reminded to be familiar with the use of the medical devices and perform checks on their alarm and display functions before activating the devices, during patient transfers, as well as during shift changes between healthcare providers. When setting alarm parameters, it is advisable that checks are made to ensure that critical alarms are activated and appropriately audible. It is critical that all members of the clinical care team are comprehensively trained in safe alarm management and the responses required during an alarm situation. All devices should be used as indicated to ensure patient safety and should also be serviced periodically as recommended throughout their lifespan, to ensure optimal functionality and safety.

Healthcare professionals are encouraged to promptly report AEs related to medical device alarm safety issues to HSA as this allows timely investigations into the root cause of the AE, as well as implementation of corrective actions to the device as necessary. The AE reports can be emailed to HSA_productsafety@hsa.gov.sg

References

- <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm222022.htm>
- http://www.aami.org/publications/AlarmHorizons/articles/FDA_Response_Alarm_Systems_16.pdf
- <http://www.fda.gov/medicaldevices/safety/alertsandnotices/tipsandarticlesondevicesafety/ucm270894.htm>

All websites were last accessed on 25 July 2014.

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Editor-in-Chief:
A/Prof Chan Cheng Leng

Editorial team:
Chin Ching Siang, Joanna Koh,
Peck Li Fung, S Kumar Sanjay,
Tan Wei Chuen, Melody Tay

Please send your enquiries, comments and suggestions to:

Vigilance and Compliance Branch,
Health Products Regulation Group,
Health Sciences Authority
11 Biopolis Way, #11-01, Helios, Singapore 138667
Tel: (65) 6866 3538 Fax: (65) 6478 9069
Website: <http://www.hsa.gov.sg>
Email: HSA_productsafety@hsa.gov.sg