Safety Information Message

Reference: SIM2204 **Issued:** 01 April 2022 **Review Date:** 01 April 2023

National Procurement Incident Management Team (IMT) Supplementary Risk Assessment to *NatPSA/2022/002/MHRA: Philips Health Systems V60, V60 Plus and V680 ventilators – potential unexpected shutdown leading to complete loss of ventilation*

Summary

NatPSA/2022/002/MHRA: Philips Health Systems V60, V60 Plus and V680 ventilators – potential unexpected shutdown leading to complete loss of ventilation, issued on 29 March 2022, highlighted hardware faults affecting all V60, V60 Plus and V680 ventilators currently in use. The faults can result in an unexpected full shutdown, potentially without triggering a warning alarm or notification. Philips have confirmed that there is not currently a solution to resolve this issue.

National Procurement IMT produced a supplementary risk assessment with recommendations as affected devices are in use in Scotland (see annex).

Action

- Refer to the attached supplementary risk assessment produced by National Procurement IMT and follow the recommendations.

Enquiries

Enquiries and adverse incident reports should be addressed to:

Incident Reporting & Investigation Centre (IRIC)
NHS National Services Scotland
Tel: 0131 275 7575 Email: nss.iric@nhs.scot

IRIC remit: general information about adverse incidents, safety alerts and IRIC's role can be found in CEL 43 (2009), *Safety of Health, Social Care, Estates and Facilities Equipment: NHS Board and Local Authority Responsibilities,* issued 30 October 2009.

Report an incident: Information on how to report an adverse incident

NHS National Services Scotland is the common name for the Common Services Agency for the Scottish Health Service https://www.nss.nhs.scot/

Safety Issue Philips Respironics Ventilators

National Procurement IMT

Supplementary risk assessment to the National Patient Safety Alert (NatPSA) Issued by The MHRA in March 2022

Philips Health Systems have identified an issue affecting specific models of ventilators that are currently used in NHS Scotland. In March the MHRA were notified of hardware faults affecting all V60, V60 Plus and V680 ventilators currently in use. The faults can result in an unexpected full shutdown, potentially without triggering a warning alarm or notification. There are two ways in which this shutdown can occur: The first will sound a warning to alert the user that the machine is shutting down. This will let the user know they need to switch to an alternative source of ventilation. The second failure mode will cause the device to shut down with no warning to the user. Philips have confirmed that there is not currently a solution to resolve this issue.

Recommendations from the National Patient Safety Alert

Recommendations in response to the MHRA notification from Philips were set out in a National Patient safety alert:
https://www.gov.uk/drug-device-alerts/national-patient-safety-alert-philips-health-systems-v60-v60-plus-and-v680-ventilators-potential-unexpected-shutdown-leading-to-complete-loss-of-ventilation-natpsa-slash-2022-slash-002-slash-mhra

The recommendations include identifying and removing the affected devices where possible. A risk assessment is recommended where continued use of the ventilator is necessary due to the lack of alternative ventilator availability:

> 7.You may continue to use affected ventilators if there is a risk of severe patient harm due to lack of ventilator availability. A thorough risk assessment must be completed, and additional monitoring must be used (see notes section of the alert for advice on additional monitoring to be used). A backup form of ventilation must be available at all times.
>
> Where practical and appropriate independent capnography (CO2) monitoring should be used. Alarm limits on this monitoring should be set as appropriate for the patient. Appropriate physiological monitoring of the patient should be carried out at all times including blood oxygen saturation levels (SpO2), the patient's ECG and non-invasive blood pressure. All alarm limits on the measurements should be set as appropriate for the patient and alarms responded to promptly.

Outline of risk assessment from PCF IMT

Risk

There is a risk that the patient will be unventilated in the period required to identify that the ventilation has failed and for an alternative mechanism of external ventilation to be established.

Frequency and Impact

The frequency of failure is considered very low based on five cases of devices failure reported within the UK, and no cases causing patient harm identified in the UK. The impact of total device failure is tissue hypoxia and possible death over the course of several minutes, time to irreversible harm varying with patient comorbidity and effective gas transfer during prior ventilation.

Mitigation

Secondary physiological monitoring and alarms are described in the NatPSA as risk mitigations if no other suitable ventilator is available. Physiological monitoring such as CO2, SpO2, ECG, BP will only identify the consequences of ventilator failure once a physiological variable has breached alarm limits, rather than alerting at the time of device failure. Consequently, reliance on secondary physiological alarms will inevitable delay identification of device failure and generate alerts only once harm has initially occurred. Such patient harm may be reversible if alternative ventilation is rapidly initiated. Dependent on the indication for ventilation, the risk of permanent harm or death from hypoxia escalates rapidly.

Where the affected devices are used for CPAP or BiPAP without sedation or impairment of consciousness the risk of irreversible harm is reduced since the patient is expected to be able to maintain some capacity for breathing. This may however further delay the trigger of a physiological monitor alarm.

Secondary electronic alarms linked to the Philips Respironics devices are not recommended since the risk of secondary alarm failure cannot be established as any lower than that of the primary device, and may introduce additional risk of harm.

Recommendation

Following review of the NatPSA, the national procurement incident management team has recommended that:

- Secondary physiological monitoring for BiPAP and CPAP ventilation is only used where 24 hour staff monitoring of the **secondary monitoring alarm** is possible and where no other alternative suitable ventilator is available.
- Secondary physiological monitoring for ventilation with sedation or impairment of consciousness is only used where 24 hour staff **direct observation** of the individual patient is possible and where no other alternative suitable ventilator is available.
- Secondary electronic linking of the affected devices to ward alert systems is not recommended.
- That staff monitoring the use of the affected ventilators are made aware of the recommendations in the NatPSA and the requirement for monitoring.
- Proactive replacement of the affected devices and training for suitable alternatives is immediately prioritised.

31st March 2022
Dr Anna Lamont
Medical Director Procurement, Commissioning & Facilities. NSS.