National Patient Safety Alert

Philips Respironics V60 ventilator – actions to be taken to avoid potential unexpected shutdown leading to complete loss of ventilation.

Date of Issue:	23-Sep-20	Reference No:	NatPSA/2020/007/MHRA

This alert is for action by: All hospital trusts and other healthcare providers using the affected ventilators.

This is a safety critical and complex National Patient Safety Alert. Implementation should be coordinated by an executive leader (or equivalent role in organisations without executive boards). Supported by their clinical lead for critical care and heads of procurement.

Explanation of identified safety issue:

In March 2020 Philips Health Systems released an FSN concerning a number of V60 ventilators. This FSN concerned a hardware fault in the device, which can result in an unexpected shutdown.

There are 2 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. There is a risk that the patient will be unventilated while this second source of ventilation is prepared.

The second failure mode will cause the device to shut down with no warning to the user. If a device fails in use and does not alarm, the patient will not be adequately ventilated and there is a potential risk of brain damage or death, depending on how long it takes clinicians to become aware of the situation and respond.

There has been a significant delay of replacement parts arriving in the United Kingdom, resulting in an increased risk of this failure occurring. MHRA has decided to update the guidance issued in the Medical Device Alert published in June.

MHRA will continue to work with the manufacturer to improve the delivery time for replacement components.

See additional information for the complete list of affected device serial numbers.

Actions required

Primary actions (1-7) to be completed by 7 October 2020

1.Identify and locate affected devices in your organisation.

2.Identify alternative ventilators available on site.

3.If no suitable alternative is available, and capacity is an issue currently or expected imminently, follow protocol for resource shortage escalation set out by your local governance.

4.Train all relevant staff on alternative ventilators and ensure training records are up to date.

5.When actions 1–4 are complete, remove affected V60s from use and quarantine until repaired by the manufacturer.

6.Place the alternative devices into service in place of the affected V60s

7.You may continue to use affected V60s 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. A backup form of ventilation must be available at all times.

Secondary action to be completed by 23 December 2020

8. Review procurement and stock policies to ensure you are not reliant on one manufacturer or model of ventilator.

For NHS Trusts responding via the CAS website the response for this alert will be collected against actions 1-7 with a deadline of 07 October 2020.

Additional information:

Notes

List of affected device serial numbers. Note: some cells include a range of numbers so exercise caution when identifying affected devices:

100002908 to 100017733
100019389 to 100022246
100023220 to 100108298
100109211 to 100110991
100113082
100113271
100116388
100118560
100118889
100119580
100121701
100126907
201000040 to 201007766
201009257
201010952

The above ventilators must also have the Power Management PCBA part number 1055906 to be affected. Some of the ventilators listed above may have already had the Power Management PCBA replaced through the normal service process.

Manufacturer contact details:
Philips Respironics
Tel: 0870 532 9741, email: safetynoticeuki@philips.com

Protocol for resource shortage escalation

- **England** - Trusts in England can click here for guidance on resource shortage escalation.
- **Scotland** - Health Boards in Scotland should contact National Procurement to discuss Covid-19 pandemic ventilator supply (if required). National Procurement contact details are: Kate Henderson, kate.henderson@nhs.scot, tel: 0781 353 1487 or Laura Santi, laura.santi@nhs.scot, tel: 0797 046 2900.
- **Wales** - Please contact CriticalCare@gov.wales for guidance.
- **Northern Ireland** - There are no known affected devices in Northern Ireland. If you have one of these devices in Northern Ireland please contact niaic@health-ni.gov.uk.

Stakeholder engagement

- UK National Clinical Engineering Network
- Incident Reporting & Investigation Centre (IRIC) NHS National Services Scotland (NSS.iric@nhs.scot)
- Northern Ireland Adverse Incident Centre (NIAIC) (niaic@health-ni.gov.uk)
- Surgical Materials Testing Laboratory (SMTL)
- Department of Health and Social Care (MDCC-CCIM@dhsc.gov.uk)
- NHS England and NHS Improvement (https://www.england.nhs.uk/contact-us/)
- Welsh Government (Haz-Aic@gov.wales)

Advice for Central Alerting System (CAS) officers and risk managers

This is a safety critical and complex National Patient Safety Alert. In response to CHT/2019/001 your organisation should have developed new processes to ensure appropriate oversight and co-ordination of all National Patient Safety Alerts. CAS officers should send this Alert to the executive lead nominated in their new process to coordinate implementation of safety critical and complex National Patient Safety Alerts, copying in the leads identified on page 1.