National Patient Safety Alert

Medicines & Healthcare products Regulatory Agency

UPDATED 25/05/22 Philips Health Systems V60, V60 Plus and V680 ventilators – potential unexpected shutdown leading to complete loss of ventilation

Date of Issue:	29-Mar-22	Reference No:	NatPSA/2022/002/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 2022 Philips Health Systems informed the MHRA of an important safety issue due to potential unexpected shutdowns of **all of their V60 and V60 Plus non-invasive ventilators. All V680 invasive ventilators** used in critical care settings are also affected.

V60 and V60 Plus devices are designed for in-hospital use. They can be used to provide average volume-assured pressure support (AVAPS), pressure-controlled ventilation (PCV), continuous positive airway pressure (CPAP), and positive pressure ventilation (PPV) treatment to patients in critical care and high-dependency unit (HDU) settings.

The safety concern identified relates to a number of electrical faults in the devices, which can result in an unexpected shutdown, leading to loss of ventilation.

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. 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 alarm. If a ventilator fails in use and does not alarm, the patient will be unventilated until the clinician becomes aware and responds.

If unnoticed by healthcare professionals, ventilation failure can have a severe health impact on patients. This can include hypoxia, which can result in long-term cognitive impairment to the patient. There is also a risk of death if a patient is without ventilation for a sustained period of time

Philips has no permanent solution to correct this issue and as such we are issuing this alert to help hospitals manage the risk.

Note: This is a different alert to the one previously published on 23/09/2020 by the MHRA for a similar range of devices.
This alert should be acted on immediately.

Actions required

All actions to be completed by 12 July 2022

1. **Urgently** identify and locate affected devices in your organisation.

2. Identify alternative ventilators available on site.
   - **a.** If no alternatives are available, use local procurement procedures to acquire suitable alternative devices.
   - **b.** If no suitable alternative is available, and capacity is an issue currently (or expected imminently), additional devices are available for NHS organisations. Details for how to access these devices can be found in the 'Additional information' section of this alert.

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

4. If continued use of the device is required while actions 1–3 are implemented, extra patient monitoring should be enacted as detailed in the 'Additional information' section. A backup form of ventilation must be available at all times

5. When actions 1–3 are complete, remove affected ventilators from use and quarantine.

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

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 action 4).

Additional information:

UPDATED INFORMATION PUBLISHED 03/05/22

Manufacturers Field Safety Notice

The manufacturer has released a field safety notice (FSN) on this issue, published on the MHRA website 03/05/22. The MHRA would like to remind users that the advice in this National Patient Safety Alert supersedes the advice given by the manufacturer in their FSN. Failure to take the required actions detailed may lead to regulatory action. The MHRA has reconfirmed this advice as no long-term solution to this device problem has been implemented to date, therefore it is still felt that there is a significant risk to patients.

Information on adverse incidents

Since 2018 the manufacturer has received 5 reports of unexpected shutdowns occurring in the UK related to this issue. All of these incidents were accompanied by the appropriate alarms. There has been no patient harm reported in the UK to date.

Worldwide, there have been 340 reports of these failures occurring. This has included a number of serious injuries and some fatalities. None of the incidents involving patient death or injury have occurred in the UK.

Ordering of replacement devices if required

NHS organisations in the UK can request alternate ventilators free of charge from the DHSC National COVID ICU Equipment Reserve. This includes a limited quantity of Lowenstein Medical Prisma VENT50-C devices, which will be made available to facilitate withdrawal from use of the affected Phillips devices when there is an urgent clinical need.

Organisations in the NHS in England can order this equipment directly via their regional EPRR leads on the NHS Foundry system. Devolved Administrations can order equipment by emailing the DHSC Medical Technology Directorate Operations team at medtech.operations@dhsc.gov.uk.

Please contact medtech.operations@dhsc.gov.uk if you have any questions or would like to request a full list of available devices.

Devolved administrations additional contact points for supply issues

- **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 Josh Foggo, josh.foggo@nhs.scot, tel: 07855 060 653.
- **Wales** – Please contact haz-aic@gov.wales for guidance.
- **Northern Ireland** – please contact niaic@health-ni.gov.uk.

Risk assessment and additional patient monitoring requirements

If any of the affected devices need to be used while appropriate alternatives are sourced, then a through risk assessment must be carried out and recorded before the patient begins ventilation.

Patients using these ventilators should be positioned in the ward where direct observation by healthcare professional staff is most feasible. Consider whether the patient should be moved to a critical care setting, if they are on a respiratory or acute medical ward. A backup form of ventilation must be available at all times.

Independent capnography (CO2) monitoring should be used when practical and appropriate. Alarm limits on this monitoring should be set, as appropriate for the patient. The purpose of capnography is to provide reassure that the patient is breathing and that there is airflow through the machine. It should not be used as a substitute for blood sampling to monitor CO2 levels. Staff who are caring for the patient should be trained in capnography monitoring.

Appropriate physiological monitoring of the patient should be carried out at all times. This includes blood oxygen saturation levels (SpO2), electrocardiogram (ECG), and non-invasive blood pressure. All alarm limits on the measurements should be set as appropriate for the patient. All alarms should be responded to promptly.

The manufacturer has issued an FSN on this issue, containing advice on the implementation of additional monitoring to the ventilation system. If the affected devices need to be used, this advice should be followed where possible, in addition to the advice in this alert. Users should consider the availability and practicality of implementation of the remote alarm system advocated in the FSN when conducting their risk assessment.

Stakeholder engagement

An incident management team was consulted on the actions detailed in this alert. This team consisted of members of the Department of Health and Social Care, NHS England and NHS Improvement, and representatives from the Scottish, Welsh, and Northern Ireland Governments.

Report any suspected or actual adverse incidents involving these devices through your healthcare institution's local incident reporting system and/or your national incident reporting authority as appropriate: England, Scotland, Northern Ireland, Wales.

Department of Health www.health-ni.gov.uk

NHS National Services Scotland

Llywodraeth Cymru Welsh Government