National Patient Safety Alert

Medicines & Healthcare products Regulatory Agency

Removal of Philips Health Systems V60 and V60 Plus ventilators from service – potential unexpected shutdown leading to complete loss of ventilation

Date of Issue:	18-May-23	Reference No:	NatPSA/2023/005/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).

Explanation of identified safety issue:

PLEASE NOTE: this is a different alert to the one published on 29/03/2022 by the MHRA for this range of devices.
This alert should be acted on immediately.

This alert concerns **all Philips Respironics V60 and V60 Plus non-invasive ventilators.** The MHRA is issuing updated advice that these ventilators must be permanently removed from use.

This advice is issued following further in depth review of additional safety evidence and recent regulatory issues in consultation with a number of external stakeholders and the MHRA's independent Interim Devices Working Group. It has been concluded that the benefits of these devices no longer outweigh the potential risks.

V60 and V60 Plus devices are used in hospitals. Depending on the model these ventilators can provide non-invasive and continuous positive airway pressure treatment to patients in critical-care, respiratory support units and high-dependency units.

The safety concern relates to several electrical faults in the devices. These faults can result in an unexpected shutdown leading to loss of ventilation – in some instances without a warning alarm to alert users that the machine is shutting down.

If unnoticed by healthcare professionals, ventilation failure can have severe consequences for patients including hypoxia, which can result in long-term cognitive impairment. There is also a risk of death if a patient is without ventilation for a sustained period.

Philips previously proposed a corrective action to replace a printed circuit board within the device to address the loss of alarm function. However, this action will **not** address the potential for loss of ventilator function for which there is no permanent solution and, therefore, a significant and serious risk to patients remains.

On 30/08/22 Philips placed both devices in their "end-of-life" phase and the devices are no longer in production. As such Philips is reliant on its current stockpile of components to act as replacement parts while stocks last. The V680, an invasive ventilator also in the V60 range, has already been removed from service due to additional safety concerns.

Actions required

All actions to be completed by 30 September 2023

1. Identify all affected ventilators that remain in the hospital.
2. Evaluate and estimate the hospital's ventilation needs and initiate a procurement plan, using local procedures. Note that a limited number of replacement devices are available for NHS organisations from the national stockpile. Details of how to access these ventilators can be found in the 'Additional information' section of this alert.
3. Implement a training program for all relevant staff on the use of the replacement ventilators.
4. If continued use of affected Philips V60 and V60 Plus ventilators is unavoidable while suitable alternatives are sourced, additional monitoring must be put in place and a risk assessment documented (see additional information section for more information). These measures should be temporary and should not remain in place beyond 30 September 2023.
5. All V60 range ventilators must be removed from service with replacement devices in use by 30 September 2023.
6. Retain quarantined ventilators and await instructions for the disposal of the devices.

Additional information:

Reason for revised alert
The MHRA has issued this updated alert after conducting a further review which established that there is no satisfactory solution to the loss of ventilation fault affecting these devices. This represents an unacceptable risk of patient harm.

In addition, the manufacturer is treating these ventilators as 'end of life', which creates further significant risk. The limited supply of replacement components could mean that users are suddenly unable to safely maintain these ventilators. Additionally, Phillips has cancelled its contract with the notified body for these devices as part of the "end-of-life" process. Therefore, any supplementary changes required to address safety concerns will not have been assessed by a notified body. This is a requirement of the UK Medical Device Regulations 2002.

There has been substantial engagement with stakeholders throughout the review of this safety concern and the development of this advice, and the action is recommended by the MHRA's independent Interim Devices Expert Working Group.

Ordering of replacement devices if required
NHS organisations in the UK can request, if required, alternative ventilators free of charge from the DHSC National COVID ICU Equipment Reserve.

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 temporary use of affected devices cannot be avoided
These devices must be removed from use as soon as practicable but no later than 30 September 2023. If use of the affected ventilators is unavoidable until then because of lack of ventilator capacity 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.

End tidal capnography (CO_2) 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 reassurance 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 CO_2 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 (SpO_2), 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.

These measures should be temporary and should not be in place beyond the completion date of this alert. All affected ventilators should be removed from use by 30 September 2023.

Stakeholder engagement
This alert was published after consultation with a number of external stakeholders to advise on the benefit of continued use of the device over the risk of possible patient harm. These stakeholders include the MHRA Interim Devices Expert Working Group, the relevant clinical leads for NHS England and representatives from The British Thoracic Society and Faculty of Intensive Care Medicine.

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

NHS England

Please check website https://www.gov.uk/XXX for when actions should be ceased or advice to check for date restriction are lifted.