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Philips CPAP and Bi-Level PAP – National Patient Safety Alert

23 July 2021

Frequently asked questions

Is there a link to the affected device list?

Details are available here: https://www.philips.co.uk/healthcare/e/sleep/communications/src-update#section_2

Should we continue to use these devices?

Philips has issued field safety notices (FSNs) (for Ventilators and CPAP). The Medicines and Healthcare products Regulatory Agency (MHRA) has published information in relation to this issue. Both the FSN and the MHRA information advises that **patients should continue to use these products unless otherwise advised by their clinician** and seek clinical advice on where an alternative device would be appropriate.

How can we be assured that there isn't sound abatement foam in other CPAP and NIV devices?

As the regulator MHRA, has written to all manufacturers of such devices to seek clarification and confirmation that this issue is not present in their devices.

Should filters be used in the devices?

Philips has recommended that, if continuing to use some of the affected devices, patients should use an inline bacterial filter. A clinical assessment of each case should be made before inserting a filter, as for many patients there is a justification for not having a filter in the circuit, and it may impair triggering and alarm functions if it becomes waterlogged.

What are the alternative products and consumables?

NHS Supply Chain has issued an important customer notice in relation to these products. This includes list of alternative devices and their consumables.

Are these devices used on both adults and children? Are there any special considerations for children?

These devices are used on both adults and children and there are no special considerations for children.

The MHRA National Patient Safety Alert requires actions to be completed by 17 December 2021. Are there any guidelines by when organisations should have registered their devices? If Philips has not provided alternative devices by 17 December 2021, will organisations be penalised?

There is no timeline on when trusts need to have registered devices, however, trusts should register devices as soon as practical to help inform the allocation of new devices as part of Philips' replacement plan.

MHRA advised that the timeline for actions in the National Patient Safety Alert is 17 December 2021. By this date Philips will have to submit a return on what they have done. It is unlikely that organisations will have been able to complete actions 4 and 5 from the alert:

> "4. Source alternative devices where clinically appropriate. Guidance will be available through NHS Supply Chain in England (or national procurement services for Devolved Administrations).
>
> "5. Train staff and patients, and verify competency, in using the alternative devices. Ensure training records are updated."

MHRA recognises that they will need to support organisations to ensure that they are not performance managed for not achieving parts 4 and 5 of the safety notice that are out with their control.

Which organisation should register the device, the organisation who issued the device or the organisation who is now managing the patients care?

The device should be registered by the organisation currently treating the patient for the condition for which the device was issued.

Can Phillips support organisations in providing means to register serial numbers on mass?

Philips has changed the device registration form to enable organisations to register all their devices at once.

Philips has advised that their sales teams have been briefed and trained. Registering of serial numbers of devices now only requires trusts to download and complete one MS Excel document that asks for the serial number of the device and if it is active. The document is available on the registration page for hospitals to upload.

The registration process does not require any patient identifiable data to be sent to Philips.

How can procurement, safety officers and medical engineering be supported to register devices, seek alternative devices, and explore recompense?

Medical directors have also been encouraged to ensure local resource is in place to support the additional workload for teams managing the registration process. In addition to the above changes to the registration process, discussions with Philips around additional support are ongoing nationally.

Is there a standard letter/template for patients? Is there a script for verbal communication?

In its communication to the system NHS England and NHS Improvement provided a template letter for patients.

Royal Papworth Hospital NHS Trust developed a telephone script, which they are happy for other organisations to use. This has also been circulated directly to the NHS.