To: NHS England and NHS Improvement Regional Directors
NHS England and NHS Improvement Regional Medical Directors
NHS England and NHS Improvement Regional EPRR leads
NHS England and NHS Improvement Regional Directors of Nursing
NHS England and NHS Improvement Regional Comms Teams
NHS Trust Medical Directors
NHS Trust EPRR Leads
NHS Trust Directors of Nursing
NHS Trust Respiratory Leads
CCG EPRR Leads – For information
Independent providers of NHS services

NHS England and NHS Improvement
Skipton House
80 London Road
London
SE1 6LH

22 October 2021

Dear Colleague,

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

In June 2021 we wrote to advise you that Philips had identified potential health risks related to the polyester-based polyurethane (PE-PUR) sound abatement foam component in some of their CPAP and Bi-Level PAP devices. Following testing, it had been identified that there are possible risks to users related to this type of foam, including that it may degrade into particles which may enter the device's air pathway and be ingested / inhaled by the user, and the foam may release certain chemicals in gaseous form.

At the time, Philips issued two Field Safety Notices (FSNs) and MHRA published information in relation to this issue.

We now write to provide an update on this issue.

Following discussions with Philips, they have advised us that their repair and replace programme will begin in October 2021 and is likely to take a year to complete. Only devices registered with Philips will be repaired or replaced, so it is vital that any devices you are aware of are registered. Philips has indicated that they believe only 50% of the devices in the UK have been registered so far. Details of how to register the devices are in the FSNs, the link to the registration page is here.

Please note, the registration process has two parts, the first is acknowledging the FSN and listing the number of products your organisation is registering and the second part listing the devices by serial number and indicating whether the device is active or not.

The NHS England and Improvement clinical respiratory networks will help to coordinate the repair and replace programme at a regional level interfacing between Philips and local providers.

Philips has advised that once the repair and replace work has been completed, they will shift focus to the production of new stock. As a result of this, supply of these products is likely to be constrained until 2023.

NHS England and NHS Improvement are working closely with DHSC, NHS Supply Chain and MHRA along with alternative providers to source products that will alleviate these constraints. There is currently a limited supply of these products, however, we anticipate more becoming available in the coming months. Any alternative devices that become available will be clinically assessed to ensure it is an appropriate replacement for the Philips devices.

The British Thoracic society has published advice for clinicians on this matter, which clinicians should continue to use while supplies remain constrained.

In June we provided a template patient letter in relation to this issue. This letter has now been updated following further consultation with MHRA. You do not need to re-issue the letter to patients. However, if there are any patients that you have not yet contacted, please used the template letter in Annex A (a word version that can be edited is available on our website).

Yours sincerely,

Dr Mike Prentice
National Strategic Incident
Director, COVID-19

Annex A – Patient letter

We have been made aware of an issue with Philips Bi-Level Positive Airway Pressure (Bi-Level PAP), Continuous Positive Airway Pressure (CPAP), and mechanical ventilator devices. Philips, who make the machines, has issued a Field Safety Notice. There have been a small number of reports outside the UK of the issue causing minor, short-term effects.

We are writing to you as you have one of these devices.

For most patients the risk of stopping using these devices is far greater than the risk from the issue that Philips has reported. The Medicines & Healthcare products Regulatory Agency (MHRA), which advises on the safe use of medical equipment, has recommended that **patients should not stop using the devices unless a risk assessment, conducted by a suitably qualified clinician, has concluded that the risks outweigh the benefits.**

If you are not contacted by your clinician, you do not need to change devices and you can continue to use your device as normal.

Philips will be gradually replacing the devices. The notice that they have issued asks patients to register their devices. However, the NHS will do this on behalf of patients, so please contact us at XXX so we can arrange to register the device on your behalf.