Communication Ref: MHRA (Medicines and Healthcare Products Regulatory Authority)

Field Safety Notice - 2021-06-A (CPAP and BiLevel PAP devices)

Field Safety Notice - 2021-05-A (Trilogy 100 and BiPAP A40/A30 devices)

Following the release of the two (2) Field Safety Notices by medical device manufacturer Philips in relation to affected devices, we understand that this may generate concern for you.

Patients' safety being of the utmost concern for Air Liquide Healthcare Ireland, we are fully invested to address the situation. We are working closely with the NHS (National Health Service) and MHRA proactively informing them of any relevant updates, in conjunction with supplying them with the continued information requested.

We are already working on the following action plan:

1) Your prescribing centre will communicate with you proactively and as appropriate. This communication system will be specific in order to ensure the correct management of the FSN communicated by manufacturer Philips & Respironics. It will include a phone line for patients where we will explain the impacts of the FSN, while explaining our global action plan and address any questions or concerns.
2) After actively discussing with Philips and the local health regulatory authorities, Air Liquide Healthcare Ireland, as an authorized distributor and service provider, are allowed to register affected devices for patients. We will do this process in order to save time for you and avoid any unnecessary stress.
3) If you are using a device on FSN **2021-05-A (Trilogy 100 or BiPAP A40/A30)** and not already using a filter, then an inline filter will be provided as and you will be instructed to change this as per the manufacturer's instructions. The period of change is every 24 hours.
4) Sourcing of direct specification replacement devices. Once clarified we will liaise with the relevant authorities, and clinicians to introduce to the market as soon as possible.
5) Collaborating with Philips in coherence with their announced replacement plan in order to update you and manage the repair or replacement of the concerned devices.

As your healthcare provider, we are committed, once we have additional details, in relation to the above actions, to develop the individual action plans that will be required. We will work with you to provide solutions as soon as possible. We will coordinate the repair or the replacement of patients' devices, ensure the appropriate settings of the new equipment and assist you throughout the change.

The recommendations from the MHRA is that the patient DOES NOT discontinue treatment, without consulting with your physician to determine appropriate next steps.

Please note that the Philips field safety notice addresses the patient to consult with their physician, please do this immediately if you experience any visible dust particles whilst using your ventilator or CPAP or Bi Level PAP device. In addition if you are someone who suffers from Occupational Asthma related to isocyanates, then it is recommended that you contact your prescribing centre.

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