**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 and your patients.

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) Patients have been informed of the following:
    a) 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.
    b) 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.
2) If your patient is using a device (without inline humidification) on FSN **2021-05-A** then an inline bacterial viral filter compatible with their device will be provided once agreed with you.
3) 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.
4) 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 yourselves and your teams 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 physicians to determine appropriate next steps.

Please note that the Philips field safety notice addresses the patient to consult with their physician and while we deal with as many queries as possible there is always the chance that patients may try to contact you directly for that reason.

Air Liquide Healthcare Ireland, Customer Services Contact Details:

0800 3285875