TECHNICAL BULLETIN

Prepared by WG-10 TB 39/21 – July 2021

Impact on EIGA Members by the ongoing Field Safety Notice of Philips-Respironics (Sound Abatement Foam Degradation)

EIGA has been informed that a Field Safety Notice (FSN) is going to be, or has already been published in all European countries, following a Philips-Respironics press release of the 14th of June [1].

With this Technical Bulletin, EIGA wishes to contribute to creating realistic expectations for the practical execution of the FSN. Furthermore, it is EIGA members opinion that clear information is required to be provided to clinicians helping them to do a proper risk/benefit analysis.

EIGA's members as Homecare Service Providers (HSP) primary point of concern is patients' safety and to continue providing qualitative therapy services.

The Field Safety Notice relates to millions of devices worldwide, therefore affecting a huge number of homecare patients in Europe.

Philips-Respironics has issued a Field Safety Notice that requires the patient to consult their physician to assess the risk benefit ratio of continuing the therapy or finding an alternative solution. See also the European Respiratory Society Statement of 21st June'21[2]

EIGA's members, as distributors of these devices in their HSP capacities, will have to play an important role in the effective execution of this FSN.

EIGA draw the attention to the fact that the change-out and/or retrofit process of all devices, over a short time span is unrealistic and that, even with the cooperation of all actors involved (physicians and patients, HSP, equipment manufacturers), this FSN will take a long time to execute.

Moreover, it has also to be considered these additional difficulties:

- There is a high probability of shortage of devices on the world market because the same FSN was issued, in the form of an official recall in the US.
- There is currently no detailed change-out nor retrofit procedure available.
- It is doubtful that, on short notice, production by the other devices' manufacturers can be sufficiently upscaled.
- World-wide shortages of electronic components and the COVID-19 pandemic add to the complexity in this process.

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- Devices not already cleared for the union market cannot be used, unless product specific derogation are issued by national competent authorities, in the interest of public health or patient safety or health; this may also create a divergent approach throughout EU Member States.

The EIGA Home Care Service Providers will do all they can to support this FSN logistically, but it must not be lost sight of the fact that, to be able to handle such a massive action:

- Additional shipments of devices need to be organized;
- Call centers need to be re-organized to provide patients assistance and information;
- Additional technical staff needs to be hired to deliver the available alternatives to the patients, but first they need to be trained for the job and to deliver the right patient information;
- Additional logistic experts need to be hired to organise the installations at home;
- Additional patient training.

Other options that foresee an in-the-field retrofit are not an immediate solution either, considering that:

- Supply of parts for retrofit needs to be organized (orders, production time, shipment);
- Organising and planning retrofit at patients' home or at a maintenance centre.

Finally, intermediate or short terms solutions like the use of filters will also be a logistic challenge, as one can expect shortages and limited availability of adequate filter components. EIGA is also concerned about statements advising the use of a bacterial filter in combination with a humidifier, which may be not compatible and could create a risk for the patient.

[1] https://www.philips.com/a-w/about/news/archive/standard/news/press/2021/20210614-philips-issues-recall-notification-to-mitigate-potential-health-risks-related-to-the-sound-abatement-foam-component-in-certain-sleep-and-respiratory-care-devices.html?src=search

[2] European Respiratory Society Statement: *Recommendations for respiratory, sleep and critical care medicine professionals and patients regarding the Philips recall notice.*

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