Recommendations of the Swiss Society of Pulmonology (SSP), dated 12.07.2021, on the field safety notification by Philips Respironics on CPAP devices and ventilators (in collaboration with the Swiss Society for Sleep Medicine and Chronobiology (SSSSC) and Swissmedic), adapted on 20.9.21

On 22.06.2021 a safety communication on CPAP and ventilators from Philips Respironics[1,2], was published on the homepage of Swissmedic (last update 28.06.2021).

The **polyester-based polyurethane foam** used in **certain CPAP machines and ventilators** can pose two problems: First, particles can enter the respiratory tract, which may trigger acute adverse effects; second, gases (volatile organic compounds) may lead to toxic long-term effects.

A list of the devices concerned can be found on the following homepages:
https://www.philips.ch/healthcare/e/sleep/communications/src-update#section_2
In the meantime, the Swiss Society of Pneumology (SSP) has, in collaboration with the Swiss Lung League and in active exchange with Swissmedic, the Federal Office of Public Health and other authorities, actively sought more detailed information. The objective is to obtain a clearer picture on the risk assessment and toxicological data, repair/replacement plan of the affected devices by Philips, as well as clarification on the reimbursement of costs. The primary aim is to guarantee safety for our patients, competently advise our patients to establish the best possible treatment strategy until the repair or replacement of all affected devices in Switzerland.

Based on the currently available scarce information on risk assessment and therapeutic relevance of ventilation or CPAP therapy, the SSP and the SSSSC advise against interrupting or changing therapy without consulting the prescribing physicians or the CPAP provider who is in contact with the physicians. Although preliminary toxicological data did not identify evidence for an acutely increased and severe toxic risk, an additional carcinogenic risk cannot be excluded in during long-term use of the affected devices by children or patients with low body weight.

The course of action, i.e. immediate replacement, adjustment, interruption, or unchanged continuation until repair/exchange, must be assessed individually in each case. The decision should be based on the current state of information on risk assessment and individual patient characteristics (type and severity of respiratory insufficiency or sleep-associated respiratory disorder, age, comorbidities, symptoms, occupation, duration of therapy, etc.).

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[1] https://fsca.swissmedic.ch/mep/#/?q=Vk_20210610_14%20%7C%20Vk_20210610_16&onlyUpdates=false&sort=PUBLICATION_DATE&direction=DESC

[2] Philips Respironics: Worldwide safety notice for specific ventilators, sleep apnoea and respiratory care devices (swissmedic.ch)

Philips AG has to date failed to publish a clear and detailed action plan for the timing of repair or replacement of the affected devices for Switzerland, which is likely to last months to over a year. Likewise, the reimbursement of costs related to Philips' safety notification form remains unresolved. Our societies have contacted and informed the Federal Office of Public Health and requested support.

Specific recommendations for CPAP therapy and long-term ventilation with affected equipment (as of 12.07.2021)

Considering that Philips' plan to repair or replace the equipment is expected to take more than one year, treating physicians should prioritize patients for a possible earlier equipment change from a Philips' device to another device according to each patient's individual situation.

Under private law, Philips is liable for its devices. As reimbursement is currently still unclarified, the SSP and SSSSC recommends listing and documenting these cases as detailed as possible. It needs to be avoided that patients pay for costs or part thereof in the absence of reimbursement by a third party.

Proposed prioritization criteria to be considered:

- patients with chronic hypercapnic respiratory failure on home mechanical ventilation
- professional drivers
- older devices (possibly greater risk of foam degradation)
- patients who are dependent on their CPAP device (severe drowsiness...).
- apnea-hypopnea index > 30/h
- low body weight and children

CPAP: CPAP providers may be asked to replace CPAP equipment ahead of schedule based on the proposed prioritization, taking into account available equipment and resources. However, implementation depends on the availability of additional CPAP equipment. The usual stock of equipment that must be available for patients with new indications for CPAP therapy should continue to be ensured. Priority should be given to patients with severe sleep apnoea (according to the previously proposed criteria above). For patients with less severe sleep apnoea, alternative treatments (e.g. mandibular advancement splint or positional therapy) may be considered if possible. It should be kept in mind that also there are waiting times for such alternative treatment such as the fitting of a mandibular advancement splint and that a response to therapy is not guaranteed.

Home ventilation: Patients with an indication for home mechanical ventilation due to respiratory insufficiency, especially children, should have first priority when changing/repairing equipment. If possible, replacement of equipment should be planned promptly under medical supervision, ensuring adequate titration with monitoring and adherence to ventilation initiation standards.

In-line filters (for CPAP and home ventilation): The use of in-line bacterial filters on CPAP, ASV and NIV equipment affected by the Safety Note is generally not recommended due to insufficient risk

reduction prior to inhalation of potential emitted gases in the event of foam degradation (only larger, solid particles would be filtered), lack of validation of filters for this purpose, risk of interference with equipment algorithms and triggering, and incompatibility with commonly used humidifiers. Impairment of unit function may vary depending on settings and breathing patterns. Nevertheless, if in-line bacterial filters are used with CPAP therapy or non-invasive positive pressure ventilation, instruction and review should be performed by a qualified healthcare professional. Bacterial filters on the device outlet, on the other hand, are standard for invasive ventilation using Triology 100. The following points should be considered:

- The filters only protect the patient from solid particles and not from volatile gases.
- The filter must not be used together with a humidifier.
- The filter may interfere with the device algorithm (e.g. autoPAP adjustment) or the detection of residual apnoeas.
- A filter may make it difficult to trigger the ventilator, especially if there is respiratory muscle weakness.
- If an in-line bacterial filter is used, its characteristics must be those recommended by Philips (resistance: at a flow rate of 0.5 l/s max. 0.7 cmH2O). The filter is inserted between the device outlet and the tubing and should be changed regularly. Service life of the filters should depend on the type of machine and the duration of its use.
- For ventilators (not for CPAP), it is recommended that any filter insertion be done under medical supervision.

These recommendations are based on the SSP's knowledge as of 20.09.2021 and will be continuously updated as new relevant information becomes available. The SSP is neither responsible for analyzing health risks, nor for providing recommendations related to reimbursement.