

COMMENTS TO FMCSA MEDICAL REVIEW BOARD

9/29/21

PHILLIPS CPAP RECALL

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General Overview of Comments

**Sources of Reliable
information for Drivers and
CME on the Phillips Recall**

**Actions the MRB could take
in response to the recall to
ease current certification
problems for drivers.**

**Actions the MRB could take
in response to the recall
that may increase the
availability of sleep apnea
treatment for drivers during
the crisis.**

- **Phillips Medical Device Recall Notification**

<https://www.usa.philips.com/healthcare/e/sleep/communications/src-update>

- **AASM guidance in response to Phillips recall of PAP devices**

<https://aasm.org/clinical-resources/guidance-philips-recall-pap-devices>

**Sources of Reliable information for Drivers and CME on the
Phillips Recall**

- Contains link needed for drivers to register their Phillips machine for repair or replacement by Phillips.

<https://www.philipssrcupdate.expertinquiry.com/?ulang=en>

Phillips Device Recall Notification

- **Philips supplemental clinical information for the use of bacteria filters – August**

<https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/global-corporate/philips-global-bacteria-filter-document.pdf>

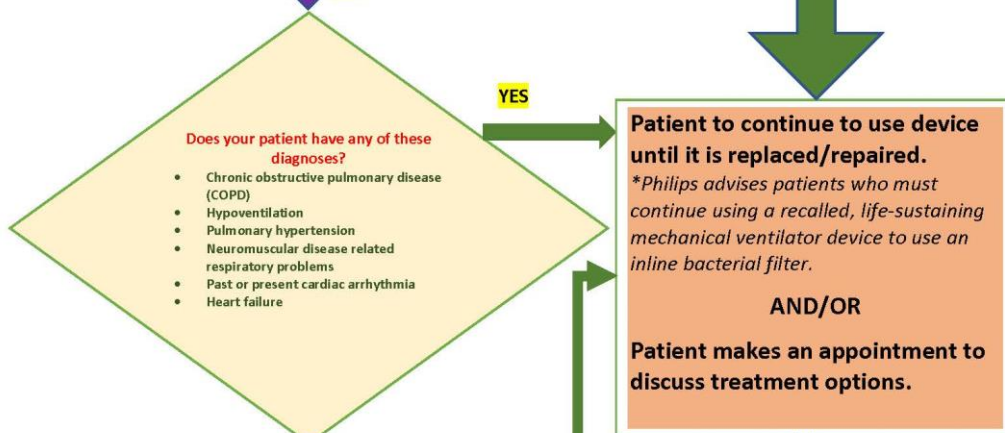
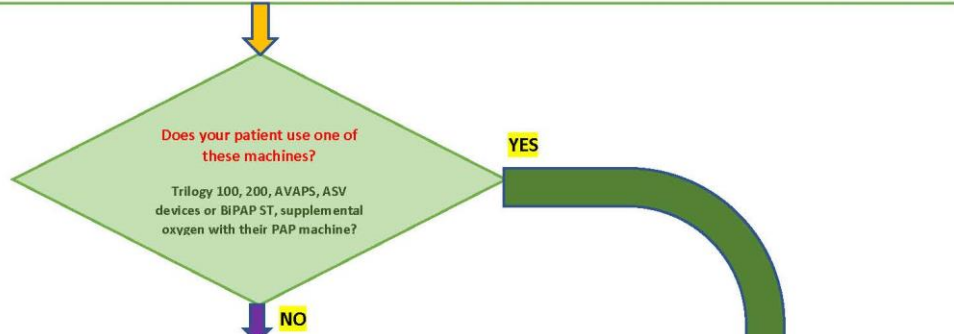
- **Philips PAP recall: Sample patient assessment for sleep medicine professionals (Draft 6/23/2021)**

AASM guidance in response to Philips recall of PAP devices

Philips PAP recall: Sample patient assessment for sleep medicine professionals (Draft 6/23/2021)

Device Registration & Cleaning

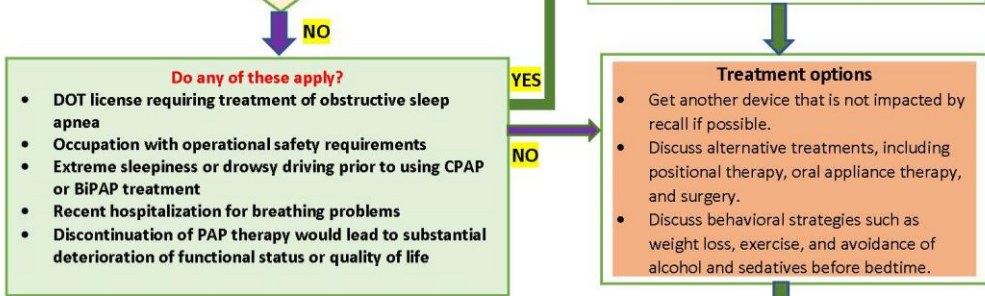
- Advise patient to register for repair or replacement on the [Philips website](#). Patient can call Philips at 877-907-7508 for additional support.
- Advise patient to avoid unapproved cleaning methods, such as ozone ([see FDA safety communication on use of ozone cleaners](#)), and certain environmental conditions involving high humidity and high temperature.



Patient to continue to use device until it is replaced/repaired.
**Philips advises patients who must continue using a recalled, life-sustaining mechanical ventilator device to use an inline bacterial filter.*

AND/OR

Patient makes an appointment to discuss treatment options.



Treatment options

- Get another device that is not impacted by recall if possible.
- Discuss alternative treatments, including positional therapy, oral appliance therapy, and surgery.
- Discuss behavioral strategies such as weight loss, exercise, and avoidance of alcohol and sedatives before bedtime.

Document patient's decision or stated intention in the EHR.



- **Issue interim emergency guidance to CME to issue temporary 30-day extensions on medical cards when:**

The driver is a newly diagnosed sleep apnea patient with an AHI>15 when the treating physician has recommended PAP therapy and when provided documentation from the DME or treating physician that they are unable to obtain PAP to dispense to the patient.

Actions the MRB could take in response to the recall to ease current certification problems for drivers.

- **Issue interim emergency guidance to medical examiners to issue 30-day extensions to existing medical cards for drivers who are using a recalled Phillips PAP who also:**

Have been evaluated using the AASM Sample patient assessment by their treating physician.

The treating physician recommends they discontinue using their affected PAP.

The treating physician and/or DME document that another device or alternative treatment options are not available.

Actions the MRB could take in response to the recall to ease current certification problems for drivers.

- **Modify the August 26, 2016 MRB recommendations related to MRB Task 16-1 .**

VI. Treatment: Oral appliance

- **A. MRB Recommendation: A driver with a diagnosis of moderate to severe OSA should try PAP therapy before oral appliance therapy,**

Remove “should try PAP therapy before oral appliance therapy” and allow OAT or MRD as a first line treatment option for drivers with AHI>15 but <than 25.

This would bring MRB recommendations in line with current AASM and AADSM clinical practice parameters.

Actions the MRB could take in response to the recall to ease current certification problems for drivers.

- **ResMed current order allocation process.**

Alternative ResMed order allocation process for CMV drivers with or seeking a DOT medical card with diagnosed OSA >15. Top priority for CMV drivers with AHI>25.

- **ResMed / DME policy on “releasing” 2nd user or “cadaver” CPAP.**

Actions the MRB could take in response to the recall that may increase the availability of sleep apnea treatment for drivers during the crisis.

Thank You

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Disclaimer. These opinions are the presenters only and do not represent any official position of Dedicated Sleep.