September 2021

**AAST Town Hall: Philips Recall Update with Dr. Teofilo Lee-Chiong:**

**A panel discussion with sleep technology leaders**

Tuesday, August 10, 2021
5:00 p.m. CT/6:00 p.m. ET

AAST compiled all questions submitted through Q&A throughout the Town Hall and via evaluation survey to develop a compressive FAQ document. Answers were formulated by panel members of the event including: Rita Brooks, MEd, RPSGT, REEG/EPT, FAAST, *Director of Cardiopulmonary, Neurodiagnostic and Vascular Services*, *Capital Health System;* Marietta Bibbs, RPSGT, *System Manager of Sleep Disorders and Clinical Research Coordinator*, *BayCare Health System*; Julie DeWitte, RCP, RPSGT, RST, FAAST, *Assistant Department Administrator*, *Kaiser Permanente, Sleep Disorders Center*

| Question: | Response: |
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| 1. ***Is it the AASM recommendation that all facilities using Respironics in-lab titration devices must have a waiver to offer all patients undergoing titration?*** | Our DME is utilizing ResMed products and we have always had ResMed surplus. (Marietta) |
| 2. ***I was wondering if they had a sample wavier from the first lab that choose to continue doing the titrations... This would be very helpful!*** | **Click here** for a SAMPLE PAP Titration Waiver. |
| 3. ***What was the name of the Philips machine that Marietta Bibbs was speaking about?*** | Philips Trilolgy EVO 300 (Marietta) |
| 4. ***Do the Triology units integrate with your software? Are the Techs able to view a flow signal, or are you having to put a p flow under the mask?*** | Yes, technologists can view a flow signal and yes. Trilogy can be are integrated with the Cadwell system. |
| 5. ***Is the lab that used the Trilogy EVO machines able to interface the vent with PSG software?*** | Trilogy cannot be titrated through the sleep center's software, but there is a flow signal from the mask. |
| 6. ***How are the panelist handling the delay in new patient's setups since there is a large backlog in obtaining CPAP units with the labs and HME Providers?*** | Our DME company had already ordered a surplus of ResMed machines prior to the Philip's recall; so this has not been problematic for new patient setups. The problem lies with getting patients changed to another device. (Marietta) |
| 7. ***Are there gases being released also from the foam break down? Or just particles?*** | The recall indicates there is a possibility of both gasses and particles related to the foam breakdown. (Rita) |

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| 8. ***I understand filter use on PAP devices isn't recommended by Philips. It seems as though filters to our high risk patients with co-morbidities are better than the option of not using the therapy. This being the case for CDL drivers required to demonstrate compliance as well. Thoughts?*** | We have used filters and have recommended them to our patients; however, Philips now indicated this is not recommended so we have revised our advice to patients and have stopped using filters in the sleep lab. Patients titrated in lab do sign a waiver. (Rita) |
| 9. ***Is it okay to just remove the sound abatement foam while waiting for the replacement?*** | Since the CPAP machines are FDA approved, this would not be advisable, as the FDA is recommending discontinued use of the product. (Marietta) |
| 10. ***Would you agree that the low rate of complaints may be also due to people not ever considering that their health failings would ever be caused by a health device? They did not perhaps connect the dots to that machine when they had respiratory issues etc.*** | The information provided by Philips indicates a very small percentage of these devices are affected; primarily those that have been cleaned using ozone. Many devices are probably not affected. (Rita) |
| 11. ***Has any clinic opted to get their Omnilabs Advanced+ machines serviced to remove the sound abatement foam?*** | We have not (All panelists). |
| 12. ***Are the Omni Lab CPAP machines we are using in the sleep lab for titrations part of the recall?*** | Yes (All panelists). |
| 13. ***Are you aware of any sleep centers removing the foam insulation in their lab machines used for titration purposes?*** | No (All panelists). |
| 14. ***Are any sleep labs using CPAPs from Asia that have been FDA approved?*** | No (All panelists). |

For additional questions for Philips or to learn more about the recall, determine if your device is impacted, or if you use one of the affected devices, the recall notification advises patients and customers refer to the recall update hub linked here, and review the FAQ section or the clinical resources section depending on the topic.

More frequently asked questions and answers are addressed in the recall update hub here.