U.S. FOOD & DRUG ADMINISTRATION

Thomas J. Fallon
Philips Respironics, Inc.
6400 Penn Avenue
Pittsburgh, PA 15206

Re: Philips Respironics Recall of DreamStation ASV; DreamStation ST, AVAPS; SystemOne ASV4; C-Series ASV; C-Series S/T and AVAPS; OmniLab Advanced+; SystemOne (Q-Series); DreamStation; DreamStation Go; Dorma 400; Dorma 50); REMstar SE Auto; E30 (Emergency Use Authorization); Trilogy 100; Trilogy 200; Garbin Plus, Aeris, LifeVent; A-Series BiPAP Hybrid A30 (not marketed in US); A-Series BiPAP V30 Auto; A-Series BiPAP A40; A-Series BiPAP A30

518(a) Notification Order

Dear Mr. Fallon:

On April 23, 2021, Philips Respironics (Philips) notified the United States Food and Drug Administration (FDA) of potential health risks related to the polyester-based polyurethane (PE-PUR) sound abatement foam used in specific Philips Continuous Positive Airway Pressure (CPAP), Bi-Level Positive Airway Pressure (BiLevel PAP, BiPAP, or BPAP) devices, and Mechanical Ventilators (collectively "Recalled Products"). The company also indicated that analysis of potential health risks was ongoing, and that further information would be provided when available. On June 14, 2021, Philips Respironics initiated a class I voluntary recall of the Recalled Products because the risks identified with respect to the PE-PUR sound abatement foam can result in serious injury which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment. Specifically, the PE-PUR sound abatement foam, which is used to reduce sound and vibration in the Recalled Products, may break down and potentially enter the device's air pathway. If this occurs, black debris from the foam or certain chemicals released into the device's air pathway may be inhaled or swallowed by the person using the device, which can cause irreversible harm to lung tissues, organ impairment and long lasting respiratory dysfunction.

Under section 518(a) of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C. 360h, if the FDA determines that (1) a device intended for human use, which is introduced or delivered for introduction into interstate commerce for commercial distribution, presents an unreasonable risk of substantial harm to the public health, and (2) notification under this subsection is necessary to eliminate the unreasonable risk of such harm and no more practicable means is available under the provisions of the Act, FDA may issue such order "as may be necessary to assure that adequate notification is provided in an appropriate form, by the persons and means best suited under the circumstances involved, to all health professionals who prescribe or use the device and to any other person (including manufacturers, importers, distributors, retailers, and device users) who should properly receive such notification in order to eliminate such risk."

FDA has determined that the degradation of the PE-PUR sound abatement foam and the potential for debris to be released into the device's air pathway has caused the Recalled Products to present an unreasonable risk of substantial harm to the public health. Particulate matter small enough to stay airborne can be inhaled through the nose (nasal route) or the mouth (oral route). Substantial deposition and encapsulation of fine particle debris may lead to irreversible harm to lung tissues and can cause organ impairment and long lasting respiratory dysfunction. Exposure to chemicals identified in testing revealed numerous compounds of concern that have known toxicology risks associated with exposures and possible adverse impact, including carcinogenicity, mutagenicity, and systemic toxicity. Furthermore, lung tissues are highly vascularized (tissue with many blood vessels), which enhances the risk from inhalation of compounds noted in testing of the degraded polyurethane foam. In addition, use of ozone cleaners to disinfect or sanitize the Recalled Products may exacerbate the breakdown of the foam.

Since the initiation of the recall in June 2021, FDA has been monitoring the effectiveness of Philips' communications with health professionals who prescribe or use the Recalled Products, and other persons (including consignees, distributors, retailers, and device users) who should be notified, of the recall and the health risks presented by the Recalled Products. FDA has received a number of calls from patients and consumers who contacted FDA to report problems and/or concerns regarding the Recalled Products, but were unaware of the recall and had not been informed of the health risks presented by the Recalled Products. FDA has also received many calls from patients and consumers who reported having heard of the recall through other sources than Philips. Using information provided by Philips, FDA calculations estimate that – even though the recall has been ongoing for over 9 months – approximately 50% of patients and consumers who have purchased or received the Recalled Products (excluding ventilators) within the last five years (the service life of the devices) have registered with Philips to obtain a replacement device. It is unclear whether the remaining patients and consumers have not registered because they are unaware of the need to register, or because they do not want or need a replacement device from Philips.

To assess the effectiveness of Philips' recall communications to consignees, FDA contacted a sample of 182 consignees to determine whether they had been notified of the recall. As suppliers of the Recalled Products and similar devices, consignees are uniquely positioned to inform their customers (which includes patients and other consumers) of the recall – if consignees are unaware of the recall and the health risks posed by the Recalled Products, it is likely that their customers are also unaware. On September 8 and October 29, 2021, FDA sent emails to Philips listing 28 consignees (of the 182 FDA contacted) who had reported to FDA that they were not aware of the recall. Philips did not respond to either email. On November 22, 2021, FDA had a call with Philips to discuss the ineffective recall audit checks. During that call, Philips stated that, as of November 22, 2021, 23 of the 28 consignees identified by FDA had received written notification of the recall and presented a spreadsheet identifying the consignees for which Philips had received "delivery confirmation." However, that spreadsheet did not include the date that each confirmation was received, nor did Philips indicate whether the consignees identified by FDA had been sent notification before, or only after, they had been identified by FDA as being unaware of the recall. FDA notes that delivery confirmation receipts generally do not confirm that a recall notification communication has been effective. That is, a delivery confirmation

receipt, by itself, does not confirm that the targeted entity or individual received the notice and is aware of the instructions therein. Typically, firms demonstrate the effectiveness of its recall communications through evidence more meaningful than a delivery confirmation receipt, such as a returned response form or a documented telephone conversation.

The fact that 23 consignees who purportedly received a recall notification reported to FDA that they were not aware of the recall, and that as of November 22, 2021 Philips could not confirm delivery of a notification to 4 of the 28 consignees, also raises concerns about the overall effectiveness of Philips' notification efforts.

Throughout the process of the recall, FDA has maintained regular communication with Philips, and on multiple occasions has informed Philips that FDA was concerned that Philips' efforts to notify patients and consumers, healthcare providers, and consignees regarding the recall have been insufficient, and that it is likely that a significant portion of patients and consumers using the Recalled Products are unaware of the health risks presented by those products. FDA has outlined its concerns to Philips both during meetings and in written communications. Despite FDA's efforts to encourage Philips to voluntarily expand its communications strategy regarding the recall, and to provide clearer information to the public regarding the health risks posed by the Recalled Products, FDA has continued to receive communications from patients and consumers who are unaware of the recall and to identify consignees who have not received notice of the recall from Philips.

Given the significant period of time that has transpired since the initiation of the recall, and Philips' failure to timely provide effective notice to health professionals who prescribe or use the Recalled Products and other persons (including consignees, distributors, retailers, and device users) who should be notified, of the recall and the health risks presented by the Recalled Products, FDA has determined that (1) notification under section 518(a) is necessary to eliminate the unreasonable risk of substantial harm to the public health presented by the Recalled Products; and (2) there exists no more practicable means available under the provisions of the Act to eliminate such risk. As a result, we are issuing this order under section 518(a) of the Act.

On March 8, 2022, FDA held a teleconference and informed Philips that, due to the serious risk posed by the Recalled Products, and lack of effectiveness of Philips' communications with the public regarding the risks presented by the Recalled Products, the Agency was considering issuing a notification order to Philips under section 518(a). At that teleconference, FDA described the reasons for, and the potential requirements of, a notification order and provided Philips 24 hours to provide feedback to FDA. On March 9, 2022, FDA held another teleconference at Philips' request to discuss whether an order under section 518(a) is necessary, given Philips' position that it is willing to voluntarily undertake the actions outlined in the March 8, 2022 teleconference that FDA was considering ordering Philips to complete. Philips also timely provided written feedback to FDA on the same day.

FDA has thoroughly considered the information Philips provided during the teleconferences on March 8 and 9, 2022 and in its written response of March 9, 2022 as part of the consultation under section 518(a) of the Act. FDA acknowledges that Philips expressed its willingness to work cooperatively with FDA and to take the actions FDA discussed during the March 8, 2022

teleconference; however, given the extensive time that has passed without effective notification to the public, FDA has determined that the standard for issuing this order under section 518(a) of the FD&C Act is met and taking action pursuant to section 518(a) is warranted.

Accordingly, pursuant to section 518(a) of the Act, Philips is ordered to notify all health professionals who prescribe or use the Recalled Products, and other persons (including consignees, distributors, retailers, and device users) who should be notified, of the recall and the health risks presented by the Recalled Products **within the next 45 days** as follows:

1. Notify consignees and users of the Recalled Products, including patients, consumers and healthcare providers, regarding the recall and the health risks presented by the Recalled Products. This will allow all end users to make informed decisions regarding the risks of continued use of the Recalled Products while awaiting a replacement device. Philips may implement the mandated notification to patients, healthcare providers and consumers in the following ways:
    - Request each consignee to provide you with contact information for each patient, consumer or healthcare provider who received a Recalled Product, and then contact those patients and consumers within 30 days of receiving their contact information to inform them of the recall, direct them to the Philips website, and provide instructions on how they can register their device.
    - In the alternative, obtain from each consignee documentation confirming that the consignee has provided, within 30 days of receiving Philips' notification, each patient, consumer or healthcare provider who received a Recalled Product with the Philips notification that informs them of the recall, directs them to Philips' website, and provides instruction on how they can register their device.
2. Maintain prominently displayed information on the risk of using ozone cleaners on the Recalled Products on the Philips Recall main landing page.
3. Provide a link for healthcare providers and registrants to access all available testing results and third party confirmed conclusions on results and findings from testing PUR-PE foam used in devices manufactured by Philips for VOCs and particulates, regardless of the Philips device that the foam may have been tested in. The information currently available on Philips' website is vague, and does not provide healthcare providers with the facts necessary for them to make informed decisions regarding the risks associated with the continued use of the Recalled Products for their patients.
4. Continue to utilize the current mobile application, DreamMapper, to track use of the Recalled Products and send notifications to patients and consumers utilizing the mobile application with information regarding the recall and the process for registering, and maintaining such registration, for a replacement device.

We acknowledge that Philips has begun to undertake some of these actions in response to the March 8, 2022 teleconference. To help FDA confirm that you are in compliance with this order, we recommend that you submit, within two weeks of this order's issuance, a plan describing how you will verify that you have completed the actions ordered above. FDA will review and provide feedback on any plan submitted.

You should email a copy of any plan to: Denise.Hampton@fda.hhs.gov

The failure or refusal to comply with any requirement prescribed under section 518(a) is a prohibited act under section 301(q) of the Act, 21 U.S.C. § 331(q).

FDA also has concerns that Philips has not, and is not, providing patients and consumers with sufficient information regarding the progress of the recall and the process for obtaining a replacement device. Since the initiation of the recall in June 2021, FDA has received, and continues to receive, complaints from patients and consumers expressing confusion regarding the recall and replacement process. Many patients and consumers that were informed of the recall and registered their device with Philips have reported to FDA that they have received no follow-up information or communications from Philips. Due to their health conditions, many patients and consumers are not able to cease using the Recalled Products they were prescribed, and have expressed to FDA fear about the extensive delay in receiving a replacement device given the health risks associated with use of the Recalled Products. As a result, FDA recommended, and Philips has agreed, to implement a prioritization approach that ensures patients who are most vulnerable to poor healthcare outcomes with continued use or ceasing use of the Recalled Products receive replacement devices as quickly as possible. Patients and consumers are frustrated due to the slow progress of the recall, and have resorted to frequently contacting FDA for answers and requesting that the Agency take action.

Therefore, FDA recommends that Philips take the following actions to keep health professionals and other persons (including consignees, distributors, retailers, and device users) better informed regarding the progress of the recall and process for obtaining a replacement device:

1. Develop a strategy to increase patient and consumer registration of Recalled Products on Philips' website and provide regular updates to FDA on the number of new registrants.
2. Improve communication with patients and consumers who register a Recalled Product on Philips' website by:
    a. Providing a specific estimate to each patient or consumer regarding the expected length of time to receive a replacement device. Please note that FDA believes that informing patients and consumers to expect a replacement "within a year" is too vague a timeframe to be meaningful to them.
    b. Providing monthly updates to patients and consumers that include information on expected time to receive a replacement device and current rate of replacement of Recalled Products.
    c. Developing a tracker or method for patients and consumers to look up the status of their replacement device and providing instructions to them on how to do so.
3. Respond to patients and consumers who contact Philips through the recall-assistance phone number provided on Philips' website within 24 hours of receipt.
4. Provide detailed information regarding the process for obtaining a replacement device including, but not limited to:
    a. Advising patients and consumers not to send their device to Philips until they have received a replacement device.
    b. Describing any cost associated with the replacement process or clearly stating in all communications regarding the replacement process that the process will be free of charge.

   c. If the replacement device to be received is different from the device returned by the patient or consumer, providing information regarding any of the accessories that will be sent to them with the replacement device as well as appropriate instructions for use.

5. Provide language on your website and to patients and consumers after registration that emphasizes the importance of keeping track of the registration number and confirmation number provided by Philips during the registration process so those numbers may be used to facilitate future inquiries into the status of their replacement device.

Please direct any inquiries to Denise Hampton, Denise.Hampton@fda.hhs.gov.

Sincerely yours,

Malvina Eydelman, M.D.
Director
OHT 1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health