IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

IN RE: PHILIPS RECALLED CPAP, BI-LEVEL PAP, AND MECHANICAL VENTILATOR PRODUCTS LITIGATION,	)	Master Docket: Misc. No. 21-1230
	)	MDL No. 3014
This Document Relates to: All Actions	)	

SECOND AMENDED INTERIM PRESERVATION ORDER
(APPLICABLE TO TRILOGY DEVICES)

Defendants Philips RS North America LLC f/k/a Respironics, Inc. ("Philips RS"); Koninklijke Philips N.V.; Philips North America LLC; Philips Holding USA, Inc.; and Philips RS North America Holding Corporation (collectively, "Defendants") and Plaintiffs, by and through Co-Lead Counsel (collectively, the "Parties"), jointly submit this Second Amended Interim Preservation Order (Applicable to Trilogy Devices) (the "Trilogy Order" or "Order") for approval and entry by the Court. This Trilogy Order sets forth the Parties' preservation obligations with respect to Trilogy Devices only.

WHEREAS, Philips RS has submitted to the FDA a proposal for rework and remediation of Trilogy Devices, as defined below, under which Trilogy Device users will have the PE-PUR foam, and if necessary the airpath components, of the Trilogy Devices removed and replaced, and the user's same Trilogy Device will then be returned to the user, and the FDA has allowed rework and remediation activities to proceed; and

WHEREAS, Philips' RS represents that new Trilogy Devices are not being manufactured, and the number of available Trilogy Devices makes it infeasible for Philips RS to preserve whole Trilogy Devices without interfering with the FDA-allowed rework and remediation plan or to allow Trilogy Device users to preserve their own Trilogy Device and also receive a replacement Trilogy Device.

The Parties now agree as follows:

I. DEFINITIONS

1. **DMEs**: Durable medical equipment distributors.

2. **FDA**: The U.S. Food and Drug Administration.

3. **Identifying Information**: Includes the following information for Trilogy Devices and/or Trilogy Device owners or users: (i) the individual's name, address, and date of birth; and (ii) the serial number of the Trilogy Device.

4. **Other Prospective Plaintiffs**: Non-Plaintiff owners or users of Trilogy Devices who have not retained counsel as of the date of this Order, or who have retained counsel that do not have notice of the entry of this Order through appearance in the MDL, but who may in the future assert claims based upon their purchase and/or use of a Trilogy Device, whether through counsel or *pro se*, whether their damages and/or injuries are currently known or unknown.

5. **Plaintiffs**: Persons who, in actions that are part of this MDL as of the date of this Order, are either (i) Plaintiffs in actions seeking individualized relief on behalf of themselves only, or injunctive relief (including through mass actions), and/or (ii) named class representatives in proposed class actions.

6. **Recall**: Philips RS's recall, announced on June 14, 2021, of certain prescription medical devices, including CPAP, BiPAP, and mechanical ventilator devices, due to potential health risks related to a PE-PUR sound abatement foam used in the devices. *See* Recall Notice, *available at*: https://www.usa.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.

7. **Recalled Device Claimants**: All Plaintiffs, Represented Prospective Plaintiffs, and Other Prospective Plaintiffs.

8. **Represented Prospective Plaintiffs**: Owners or users of Trilogy Devices who have retained counsel in anticipation of asserting claims against one or more of the Defendants based upon their purchase and/or use of a Trilogy Device and who are not currently Plaintiffs in actions that are part of this MDL as of the date of this Order, but who have notice of the entry of this Order through their counsel's appearance in the MDL.

9. **Trilogy Devices**: All configurations of Trilogy 100 and Trilogy 200 devices.

10. **Trilogy Foam**: The Removable Air Path PE-PUR Foam as well as the entire Airpath Inlet Assembly (including its PE-PUR foam).

11. **Trilogy Recall Remediation**: Philips RS's plan submitted to the FDA, and which the FDA has allowed to proceed, to rework and remediate Trilogy Devices by replacing the polyester-based polyurethane ("PE-PUR") sound abatement foam with silicone-based foam and, where applicable, replacing the airpath components.

II. PRESERVATION PROTOCOL FOR COMPONENTS OF TRILOGY DEVICES

A. Remediation Activities for Trilogy Devices

12. Philips RS may conduct rework and remediation activities under the Trilogy Recall Remediation on Trilogy Devices as allowed by the FDA. The following is a general overview of the process Philips RS will follow to perform rework activities pursuant to the Trilogy Recall Remediation.

13. Philips RS will provide written notice and instructions to Trilogy Device owners on how to return their affected Trilogy Device to Philips RS and include a pre-paid return shipping label for return of the recalled Trilogy Device. Philips RS will share proposed communications in advance and will meet and confer with respect to the content and recipients of such communications; however, Plaintiffs shall not be deemed to have approved of any communications sent by Philips RS.

14. Rework and remediation performed by Philips RS includes: (i) cleaning and disinfecting the exterior of the Trilogy Device prior to repair; (ii) conducting a check-in procedure by inspecting and evaluating the Trilogy Device to ensure it is operating properly, documenting observations, error codes, or alarms; (iii) removing the SD card, if an SD card is present; (iv) retrieving and storing the Trilogy Event Log information to a network drive; (v) accessing, photographing, and removing Trilogy Foam from the Trilogy Device and replacing it with a removable airpath foam and airpath inlet assembly containing silicone foam; (vi) if the PE-PUR foam shows signs of degradation upon visual inspection, and/or if particulate is visible in the blower bellows or air outlet of the Trilogy Device, removing and replacing the air path components with new airpath components; (vii) performing a checkout procedure on the remediated Trilogy Device by comparing error codes and alarms observed at check-in procedure; and (viii) sending the remediated Trilogy Device back to the owner.

15. Except for the preservation requirements set forth herein, Philips RS is not required to preserve any parts, components or accessories of Trilogy Devices, including internal airpath components, circuits, bacteria filters, tubing, water chambers, humidifiers, masks, or tracheotomy tubes (other than SD cards, as set forth in Section II.B.2), that are returned for remediation pursuant to the Trilogy Recall Remediation after the date of this Order.

B. Philips RS's Preservation of Foam and Airpath Components of Certain Trilogy Devices

1. Creation of a Trilogy Device Preservation Registry

16. To have the Trilogy Foam and airpath components of their Trilogy Device(s) preserved by Philips RS under this Trilogy Order, Recalled Device Claimants, individually or through counsel, shall submit Identifying Information to Philips RS in the format attached as

Exhibit A as an Excel document[1] and sent by email to MDL3014PreservationRegistry@morganlewis.com or by using a web entry form available at www.MDL3014PreservationRegistry.com. Philips RS will update the website and the web entry form to include information specific to Trilogy Devices. The content and format of the web entry form is subject to review and approval by Plaintiffs' Lead Counsel. The web entry form link will be available for use within three (3) business days after entry of this Trilogy Order. Plaintiffs and Represented Prospective Plaintiffs who elect to have their Trilogy Foam and airpath components preserved by Philips RS under Section II.B shall submit Identifying Information relating to this Trilogy Device within 60 days of the entry of this Order, or within 60 days of becoming a Represented Prospective Plaintiff.

17. Philips RS is maintaining a list of known Recalled Device Claimants (the "Preservation Registry"), which Preservation Registry includes all individuals for whom Identifying Information has been provided to Philips RS. Recalled Device Claimants who provide Identifying Information to Philips RS with respect to Trilogy Devices will be added to the Preservation Registry. Philips RS will update the Preservation Registry as soon as practicable when it receives Identifying Information from Recalled Device Claimants, but no less than weekly. All Trilogy Devices returned to Philips RS shall be checked against the Preservation Registry.

2. Preservation of Trilogy Foam and Airpath Components of Trilogy Devices of Persons on the Preservation Registry.

18. Pending negotiation by the Parties and entry of an examination protocol and Order, Philips RS will remove and preserve the Trilogy Foam, airpath components, and (if applicable) SD cards from Trilogy Devices that are on the Preservation Registry. The preservation obligation of Philips RS set forth herein does not apply where (i) a Trilogy Device was reworked after entry

[1] The Excel form can be downloaded at https://www.mdl3014preservationregistry.com/

of this Order and before the individual submitted Identifying Information to Philips RS; or (ii) the Identifying Information on the Preservation Registry does not include all of the following: name, address, and either the serial number of the Trilogy Device or, only if the serial number is not available to the Recalled Device Claimant, then the registration confirmation code provided to the Recalled Device Claimant by Philips RS via e-mail at the time the Recalled Device Claimant registered his or her Trilogy Device on Philips RS's recall website; provided, however, that Philips RS will undertake reasonable and good faith efforts to preserve the foam and airpath components of the Trilogy Devices of all Recalled Device Claimants on the Preservation Registry who return or have returned their Trilogy Devices but have not provided either the serial number of the Trilogy Device in their Identifying Information or the registration confirmation code, but only if the Recalled Device Claimant has provided his or her name, address, and date of birth. If Philips RS receives Identifying Information and has any questions about the Identifying Information provided, it shall direct those questions to the counsel who provided the Identifying Information, or to the claimant if *pro se.* The packaging and storage obligations in Exhibit B to this Trilogy Order shall apply to the Trilogy Foam and airpath components removed from Trilogy Devices on the Preservation Registry.

19. Except for Trilogy Foam, airpath components, and SD cards as described in the foregoing Paragraph, Philips RS is not obligated to preserve any other components of Trilogy Devices of persons on the Preservation Registry.

3. Trilogy Foam and Airpath Components from Trilogy Devices from Persons Other than those on the Preservation Registry

20. Philips RS will preserve the removed Trilogy Foam from all Trilogy Devices (as well as any SD cards returned with those devices) received for remediation after the date of this Trilogy Order. If Trilogy Foam removed from Trilogy Devices pursuant to this Paragraph shows

evidence of degradation upon visible inspection, and/or if particulate matter is observed in the blower bellows or air outlet of the device, Philips RS will also preserve the airpath components from that Trilogy Device. To ensure that a sufficient quantity of replaced Trilogy Foam and air path components are available for inspection, testing, and analysis, Philips RS will randomly select and segregate 7.5% of the Trilogy Foam removed from Trilogy Devices, along with any airpath components preserved for Trilogy Devices in the 7.5% sample. The Trilogy Foam and, if applicable, airpath components for this 7.5% sample will be selected under the procedure set forth in Exhibit C to this Trilogy Order. The removed Trilogy Foam, and if applicable, airpath components and/or any associated SD cards will be preserved will be packaged, labeled, and stored according to the requirements of Exhibit B to this Trilogy Order.

21. Subject to Paragraph 20, for all Trilogy Devices that are returned for the Trilogy Recall Remediation, Philips RS will preserve that Trilogy Device's SD card, if present, in the manner set forth in Exhibit B to this Order. Philips RS will also retrieve and store the Trilogy Event Log for all Trilogy Devices on a network drive.

22. In addition to the foam and airpath components set forth in Paragraphs 20-21, Philips RS will provide to Plaintiffs a reasonable quantity of new, unused Trilogy Device PE-PUR foam for examination, testing, and analysis within a reasonable time following Plaintiffs' Co-Lead Counsel's request. Philips RS may also retain the same reasonable quantity as provided to Plaintiffs of new, unused Trilogy Device PE-PUR foam for examination, testing, and analysis. Additionally, Philips RS will set aside 100 used Trilogy Devices, selected at random from all Trilogy Devices with a manufacturing date of 2013 or earlier that are in Philips RS's possession as of the date of this Order. These 100 devices will be split randomly but equally between Plaintiffs' Co-Lead Counsel and Philips. After the 100 Trilogy Devices are randomly selected and randomly split

evenly for the Parties, Philips RS will pull and provide all Event Log data for each of the 100 Trilogy Devices to Plaintiffs' Co-Lead Counsel in a usable format. The foam and Trilogy Devices described in this paragraph do not need to be preserved and may be examined, tested, and analyzed (including destructive testing, if necessary) by the Parties and their experts.

III. USER-PRESERVED TRILOGY FOAM AND AIRPATH COMPONENTS

23. Persons who have added a Trilogy Device to the Preservation Registry and who wish to have their Trilogy Device remediated, but do not want to send their device to Philips RS for such remediation, may elect to retain their Trilogy Device ("Self-Preserving Trilogy Users"). Users may elect to self-preserve by so indicating at the time they register for the Preservation Registry.

24. Philips RS will provide each Self-Preserving Trilogy User with a replacement ventilator device at no cost (the "Replacement Device"). Philips RS will provide a Self-Preserving Trilogy User with a Trilogy Device as a Replacement Device if a Trilogy Device is available in Philips RS's inventory. If a Trilogy Device is not available based on Philips RS's inventory, Philips RS will provide a different kind of appropriate Replacement Device. In advance of doing so, Philips RS will advise Plaintiffs' Co-Lead Counsel and counsel for the Trilogy user (if the Trilogy user has counsel and counsel information is available) or the Trilogy user (if the Trilogy user does not have counsel or counsel information is not available) if a different kind of Replacement Device will be provided.

25. Self-Preserving Trilogy Users may not resell or otherwise transfer their Replacement Device. The Replacement Device shall be returned to Philips RS, at the cost of Philips RS, at the conclusion of the Self-Preserving Trilogy User's use of the Replacement Device.

26. Trilogy Devices provided to Self-Preserving Trilogy Users as Replacement Devices will have been remediated according to the procedures and standards in the Trilogy Recall Remediation (as defined in Paragraph 11 of this Order).

27. To coordinate the provision of a Replacement Device, Self-Preserving Trilogy Users will need to register with their DME, which will verify with Philips RS that the individual is a Self-Preserving Trilogy User. Within 60 days of entry of this Order, Philips RS will send counsel for each Self-Preserving Trilogy User (if the Trilogy user has counsel and counsel information is available) or the Self-Preserving Trilogy User (if the Trilogy user does not have counsel or counsel information is not available) specific instructions on the process for the user to register with their DME and receive the Replacement Device. Pursuant to Paragraph 13, Philips RS agrees to provide Co-Lead Counsel a copy of this communication for review and agrees to do so within 30 days of entry of this Order. Philips RS will ship the Replacement Device to the Trilogy Device User's DME within 60 days of the user registering with their DME.

28. Self-Preserving Trilogy Users will store their existing Trilogy Device in the manner set forth in Exhibit B, which shall occur within 60 days of a Self-Preserving Trilogy Users' receipt of their Replacement Device.

29. Additionally, Persons who have added a Trilogy Device to the Preservation Registry may request that Philips RS return the removed Trilogy Foam and the removed airpath components (and if applicable the SD card), from their Trilogy Device to the address included in the Preservation Registry. Upon such request, Philips RS will return the foam and airpath components and any SD card within a reasonable time.

IV. STIPULATIONS

30. Provided that Philips RS has substantially and in good faith complied with the terms of this Trilogy Order, to the extent the removed Trilogy Foam or, if applicable, airpath components

from any Trilogy Device is unavailable because the Trilogy Device was returned to Philips RS after the date of this Trilogy Order and the removed Trilogy Foam and, if applicable, airpath components were not preserved by Philips RS pursuant to this Trilogy Order, then Defendants shall not be subject to a claim of spoliation or an adverse inference instruction regarding the removed Trilogy Foam and, if applicable, airpath components of that specific Trilogy Device.

31. For any Recalled Device Claimant for whom the removed Trilogy Foam and, if applicable, airpath components of the Recalled Device Claimant's Trilogy Device is unavailable because the Trilogy Device was returned to Philips RS after the date of this Trilogy Order and was not preserved by Philips RS pursuant to this Order, that Recalled Device Claimant will not be subject to any defense or claim of a failure of causation, or any failure of proof in that plaintiff's case, based on the argument that the foam and airpath components of that Recalled Device Claimant's Trilogy Device are unavailable to be tested; provided, however, that if the Recalled Device Claimant is a Plaintiff or Represented Prospective Plaintiff, the Plaintiff or Represented Prospective Plaintiff must have complied with his, her, or its obligations under the Preservation Registry for this stipulation to apply. In particular, for purposes of this Paragraph, the Plaintiff or Represented Prospective Plaintiff must have provided either (i) their name, address, and serial number; or (ii) if the serial number is not reasonably available, then (a) the registration confirmation code provided to the Recalled Device Claimant by Philips RS via e-mail at the time they registered their Trilogy Device on Philips RS's recall website; or (b) if neither the serial number nor the registration confirmation code is reasonably available, the date of birth of the Recalled Device Claimant.

32. For any Recalled Device Claimant who brings claims in this MDL or in any state court, and the removed Trilogy Foam and airpath components of that individual's Trilogy Device

are unavailable because they were not required to be preserved under the terms of this Order, the Parties stipulate and agree that removed Trilogy Foam and airpath components preserved under this Trilogy Order, or a subsequent Order, may be subject to analyses by the parties' experts to support the parties' claims and defenses in connection with the unavailable removed foam and airpath components of that individual's Trilogy Device. Under such circumstances, the parties stipulate and agree that an expert's conclusions may not be challenged based on the argument that the expert did not analyze the removed foam and airpath components from that particular individual's Trilogy Device specifically, but only other removed Trilogy Foam and airpath components preserved under this Trilogy Order. This provision applies to all Recalled Device Claimants for whom the removed Trilogy Foam and airpath components from their Trilogy Devices are unavailable because they did not need to be preserved under the terms of this Order, including those who have not yet retained counsel and who were unaware of any preservation requirements.

33. This Trilogy Order has been entered into before substantial discovery has occurred and is based on the parties' respective good faith understanding of the relevant facts and circumstances at this time. The parties stipulate and agree as follows:

a. The manner and method of bagging and storing the preserved devices as set forth in the Packaging and Storage Protocol in **Exhibit B** is intended, as best as reasonably possible, to preserve the Trilogy Foam and airpath components in substantially the same condition as they were in at the time of the bagging. If the Packaging and Storage Protocol in **Exhibit B** is followed substantially and in good faith, the Parties stipulate and agree (i) not to argue that the condition of the Trilogy Foam and/or airpath components at issue was affected in any way by the manner and/or method of bagging and storing the preserved Trilogy Foam and/or airpath

components, and (ii) not to challenge the reliability or admissibility of the opposing parties' expert opinions on the grounds that the condition of the stored Trilogy Foam and/or airpath components was affected by the manner and/or method of bagging and storing and/or the temperature and humidity of the storage location of the preserved Trilogy Foam and/or airpath components, but nothing in this paragraph precludes any Party from challenging the reliability or admissibility of an expert opinion on any other grounds, including, subject to Paragraph 28 below, as to the question of the extent (if any) of degradation or further degradation of the bagged and stored foam solely due to the passage of time.

b. Philips RS will set aside 100 percent of the removed Trilogy Foam (and where applicable, airpath components) from Trilogy Devices for the first 60 days after entry of this Trilogy Order, and for a minimum of Trilogy Foam (and where applicable, airpath components) from 10,000 Trilogy Devices, as well as setting aside a random sample as set forth in the Protocol in **Exhibit C** for purposes of later testing of a subset or subsets of that sample for purposes of analysis by the Parties' experts.

34. The Parties recognize the possibility that the Trilogy Foam may degrade or further degrade as time passes, despite the bagging and storage provided for in **Exhibit B**. Accordingly, Philips RS will set aside a number of Trilogy Foam separate from, and in addition to, all other preservation set aside obligations for the purpose of testing to determine the extent of foam degradation due to the passage of time after the Trilogy Foam has been bagged and stored pursuant to the Packaging and Storage Protocol in **Exhibit B**. The Parties shall meet and confer concerning the number of devices to be retained and the process of their selection, and, to the extent Plaintiffs or Defendants wish to inspect, evaluate, or test any of the devices retained pursuant to this paragraph, the protocol for doing so.

35. The stipulations and agreements contained herein shall apply to any case pending in this MDL as of the date of the entry of this Trilogy Order, and to any case subsequently filed in or transferred to this MDL or remanded to state court from this MDL, regardless of whether: (a) such action currently has been transferred to this MDL, (b) such case currently is filed or unfiled, and/or (c) any asserted injury is known or unknown. However, Other Prospective Plaintiffs shall not have any obligations under this Order unless or until they become a party in this MDL or have retained counsel that has made an appearance in this MDL (whether such appearance was made before or after the date of this Order), at which point the person will immediately become subject to this Order.

36. Except as otherwise agreed above, all parties reserve any and all claims, defenses, and arguments that they may have or make in any litigation related to the Recalled Devices.

37. The Parties reserve the right to request further modification or amendment of this Order, including (1) through the entry of a stipulated device examination protocol; (2) as agreed by the Parties; or (3) for other good cause shown.

IT IS SO ORDERED.

BY THE COURT:

s/Joy Flowers Conti

Joy Flowers Conti
Senior United States District Judge

DATED: June 15, 2023

This 14th day of June 2023,

STIPULATED AND AGREED TO BY:

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AMENDED EXHIBIT A to Amended Preservation Order

	Product User Information					**Product User Address**					**Product User Device Information** (If you have more than one device to register, please complete a separate entry for each device)		**Device Preservation**	**Lawsuit**	**Return Label Needed** (Select "Yes" only if you are having Philips preserve the Product User's Device AND the Product User already received their refurbished machine and did not retain the return information or if Product User is no longer using machine and not awaiting a refurbished one from Philips)		
Plaintiff Counsel Firm(s)	**Last Name**	**First Name**	**Middle Name**	**Suffix**	**Date of Birth** (If no Device Serial Number or Recall Confirmation Number Is Provided)	**Street Address**	**City**	**State**	**ZIP**	**Country**	**Device Serial Number**	**Recall Confirmation Number** (if no serial number is available)	**Indicate whether (a) the user is self-preserving the device or (b) the user is returning the device to Philips Respironics for preservation**	**Has a lawsuit been filed with respect to this user's use of the device in question?**	**If you still have the device in your possession, would you like to request that Philips RS email you a return authorization label so you can return your device to Philips RS for preservation?** (If, Yes, provide Telephone Number and Email for FedEx label)	**Telephone Number for FedEx label** (can be product user or attorney's number)	**Email Address for FedEx label** (can be product user or attorney's email)

Exhibit B

Packaging and Storage Protocol

I. *Philips RS's Obligations*

Upon entry of the Trilogy Order, the following sets forth Philips RS's obligations with respect to the handling, packaging, and storage of Trilogy Foam and airpath components removed from Trilogy Devices returned to Philips RS pursuant to Section II.B of the Trilogy Order.

A. Obligations for Removed Trilogy Foam and Airpath Components of Trilogy Devices of Individuals on the Preservation Registry.

1. After opening the packaging, a photograph will be taken of the device label on the bottom of the device. The image will be saved and used to create identifying labels that identify the serial number of the device ("Identifying Label"). The device's serial number, blower hours, and therapy hours will be recorded in SAP and this information will be retained by Philips RS.

2. The Trilogy Foam and airpath components will be removed from the Trilogy Device. The removed Trilogy Foam and airpath components will be placed in a 2 mil (.002) thickness, bottom-gusseted Polyethylene ("Poly") bag.

3. The Poly bag will be heat sealed (without vacuum or purging). Philips RS will use reasonable efforts to ensure that air is removed from the Poly bag prior to heat sealing. After heat sealing, an Identifying Label will be placed on the Poly bag.

4. The sealed bag containing the removed Trilogy Foam and the airpath components will be placed in a box. The box will be closed and sealed with tape. An Identifying Label will be placed on the outside of the box.

5. The sealed box will be palletized and the pallet will be wrapped in shrink wrap. A pallet log for the pallet will be created and will be kept with the completed pallet.

6. The sealed pallet will be stored in an environmentally-controlled setting equipped with ambient air temperature and humidity monitoring. The pallet's storage location will be recorded. The sealed pallets will be stored at a temperature range of 2-25 degrees Celsius (35-77 degrees Fahrenheit) with relative humidity of less than 50 percent.

7. If an SD card is provided with the returned device, the SD card will be placed in a plastic binder sleeve and an Identifying Label will be put on the binder sleeve. The binder containing SD cards will be stored in a secure location at the Philips RS facility.

8. Pursuant to Paragraph 21 of this Trilogy Order, persons who have added a Trilogy Device to the Preservation Registry may request that Philips RS return the removed Trilogy Foam and the removed airpath components (and if applicable the SD card), from their Trilogy Device to the address included in the Preservation Registry. Upon such request, Philips RS will return the foam and any airpath components and SD card within a reasonable time.

B. Obligations for Removed Trilogy Foam and Airpath Components of Trilogy Devices of Individuals Not on the Preservation Registry.

9. After opening the packaging, a photograph will be taken of the device label on the bottom of the device. The image will be saved and used to create an Identifying Label. A screenshot will be generated which includes the device serial number, therapy hours, and blower hours (as reflected on the device), and Philips RS will retain copies of the screenshot.

10. The Trilogy Foam will be removed from the Trilogy Device. If visual inspection of the Trilogy Foam shows evidence of degradation, and/or if particulate matter is visible in the blower bellows or air outlet of the Trilogy Device, the airpath components will be removed from the Trilogy Device as well. The removed Trilogy Foam and, if applicable, the airpath components will be placed in a Poly bag.

11. The Poly bag will be heat sealed (without vacuum or purging). Philips RS will use reasonable efforts to ensure that air is removed from the Poly bag prior to heat sealing. After heat sealing, an Identifying Label will be placed on the Poly bag.

12. The sealed bag containing the removed Trilogy Foam and, if applicable, the airpath components will be placed in a box. The box will be closed and sealed with tape. An Identifying Label will be placed on the outside of the box.

13. The sealed box will be palletized and the pallet will be wrapped in shrink wrap. A pallet log for the pallet will be created and will be kept with the completed pallet.

14. The sealed pallet will be stored in an environmentally-controlled setting equipped with ambient air temperature and humidity monitoring. The pallet's storage location will be recorded. The sealed pallets will be stored under the temperature and humidity parameters set forth in Paragraph I.A.6, above.

15. If an SD card is provided with the returned device, the SD card will be placed in a plastic binder sleeve and an Identifying Label will be put on the binder sleeve. The binder containing SD cards will be stored in a secure location at the Philips RS facility.

16. Other than the removed Trilogy Foam, the airpath components (if applicable), and any SD card provided with the returned device, Philips RS may reuse or discard other components of the returned Trilogy Device, such as masks or tubing.

II. ***Self-Preserving Trilogy User's Obligations***

Within 60 days of this Order or within 60 days of receiving a Replacement Device, Self-Preserving Trilogy User or their counsel will ensure the following steps are taken:

1. The Trilogy Device will be placed in a 2 mil (.002) thickness, bottom-gusseted Poly bag. Any mask and tubing will be removed before storing. The user does not need to preserve the

mask and tubing but may retain them, including for use with the Replacement Device. The SD card may either be used with the Replacement Device or preserved by Plaintiff or Plaintiff's counsel.

2. Poly bag will be heat sealed (without vacuum or purging). The person sealing the bag will use reasonable efforts to ensure that air is removed from the Poly bag prior to heat sealing.

3. The sealed Poly bag will be stored either (a) in an environmentally-controlled setting equipped with ambient air temperature and humidity monitoring at the temperature and humidity parameters set forth in Paragraph I.A.6, above or (b) in a temperature-controlled setting at a temperature range of 2-5.5 degrees Celsius (35-42 degrees Fahrenheit).

4. To the extent the above steps are completed by a Plaintiff or Represented Prospective Plaintiff and not by their counsel, confirmation will be provided to Plaintiff's or Represented Prospective Plaintiff's counsel that the foregoing steps have been completed (which communications are attorney-client privileged) and counsel shall document such communications in their file.

5. Self-Preserving Trilogy Users may choose to preserve their Trilogy Device via a third-party storage facility, if that entity is instructed to follow the above-specified preservation process.

Exhibit C

Protocol For Randomly Setting Aside Trilogy Foam from Trilogy Devices

This Protocol for Randomly Setting Aside Removed Trilogy Foam from Trilogy Devices ("Trilogy Protocol") shall be used with respect to Trilogy Devices that have been returned to Philips RS and sets forth the quantity of recalled Trilogy Foam and, if applicable, airpath components that Philips RS will preserve and retain, at least on an interim basis, after the date of entry of the Trilogy Order, and how they will be selected for preservation, in accordance with Paragraph 20 of the Trilogy Order.

1. Philips RS will preserve removed Trilogy Foam, and, if applicable, airpath components from all Trilogy Devices returned by Recalled Device Users who are not included on the Preservation Registry, as described in Paragraph 19 of the Trilogy Order. From this population, Philips RS shall segregate the removed Trilogy Foam from at least seven and 1/2 percent (7.5%) of the Trilogy Devices, pursuant to a random sampling procedure whereby Philips RS will set aside and preserve the removed foam and SD card (if present), for devices in the sample. For each Trilogy Device in this 7.5% sample, if there is evidence of foam degradation, and/or evidence of particulate matter in the blower bellows or air outlet of the Trilogy Device, Philips RS will preserve the airpath components for such Trilogy Devices. Each business day, Philips RS will preserve removed foam from 7.5% of the volume of Trilogy Devices received on the preceding business day (e.g., if Philips RS receives 200 Trilogy Devices on Monday, Philips RS will preserve removed foam for the first 15 of the Trilogy Devices received on Tuesday). Philips RS will conduct preservation in this matter at each location where remediation work is being conducted. Philips RS will document and maintain a record of the individuals involved in the preservation of removed foam.

2. Philips RS will provide an accounting of the set aside Trilogy Foam and, if applicable, airpath components under this Trilogy Order and Exhibit C. Such reports shall be provided to Plaintiffs' Lead Counsel on a monthly basis beginning August 1, 2022. Philips RS will also report to Plaintiffs' Lead Counsel if the number of returned Trilogy Devices drops below Philips RS's estimate of 120,000 thousand by a degree of 10% or more.

3. As discovery proceeds in this MDL, the Parties agree to periodically discuss whether modification of the preservation and retention of materials required under this Protocol is appropriate.