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	)	

AMENDED PRESERVATION ORDER APPLICABLE TO DREAMSTATION 1 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 Lead Counsel (collectively, the "Parties"), jointly submit this [Proposed] Amended Preservation Order Applicable to DreamStation 1 Devices pursuant to Pretrial Order Nos. 2 and 4 for approval and entry by the Court. This [Proposed] Amended Preservation Order (the "Order" or "Amended Preservation Order") amends the Interim Preservation Order entered by the Court on January 11, 2022 (Doc. 332) (the "Interim Preservation Order").

I. DEFINITIONS

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

2. **DreamStation 1 Devices**: All models of recalled continuous positive airway pressure ("CPAP") and bilevel positive airway pressure ("BiPAP") devices that are being reworked and returned to customers in accordance with the DS1 Recall Remediation. The DreamStation 1 Devices include all configurations of the following: DreamStation CPAP: Pro, Auto; DreamStation BiPAP Pro, Auto; and DreamStation SV, ASV, AVAPS.

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

4. **DS1 Recall Remediation**: Philips RS's plan to rework and remediate DreamStation 1 Devices by replacing the blower boxes of the DreamStation 1 Devices that contain polyester-based polyurethane ("PE-PUR") sound abatement foam with blower boxes that contain silicone-based foam, as submitted by Philips RS to the FDA and as to which the FDA allowed rework activities to proceed on August 16, 2021.

5. **Identifying Information**: Includes the following information for DreamStation 1 Devices: (i) the individual's name, address, and date of birth; and (ii) the serial number of the DreamStation 1 Device.

6. **Other Recalled Devices**: CPAP machines, BiPAP machines, and/or mechanical ventilator devices that are subject to the Recall, other than the DreamStation 1 Devices.

7. **Plaintiffs**: Individuals 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.

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

9. **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.

10. **Recalled Devices**: All devices subject to the Recall, including both the DreamStation 1 Devices and the Other Recalled Devices. *See* **Appendix 1**.

11. **Represented Prospective Plaintiffs**: Owners or users of DreamStation 1 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 DreamStation 1 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.

12. **Other Prospective Plaintiffs**: Non-Plaintiff owners or users of DreamStation 1 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 DreamStation 1 Device, whether through counsel or *pro se*, whether their damages and/or injuries are currently known or unknown.

13. **User-Preserve(d Devices)**: Recalled DreamStation 1 Devices that are retained by Plaintiffs or Represented Prospective Plaintiffs, or by counsel or third parties on their behalf, and are not returned to Philips RS.

II. FORMATION OF MDL AND ISSUANCE OF PRESERVATION ORDERS

14. On October 8, 2021, the Judicial Panel on Multidistrict Litigation established this MDL, finding that the actions "share factual questions arising from Philips' recall" of the Recalled Devices.

15. On January 11, 2022, the Court entered the Interim Preservation Order applicable to DreamStation 1 Devices. (Doc. 332.). On March 7, 2022, the Court entered an Order Modifying Deadline to Submit Identifying Information to the Preservation Registry Under Paragraph 24 of the Interim Preservation Order. (Doc. 434).

16. Following extensive meet and confer negotiations, the Parties submit this Proposed Amended Preservation Order Applicable to DreamStation 1 Devices pursuant to Pretrial Order Nos. 2 and 4. This Order supersedes and replaces the preservation provisions of Pretrial Orders Nos. 1 and 2 to the extent they are contrary to this Order and amends the Interim Preservation Order, as modified. The Interim Preservation Order defines the Parties' respective obligations with respect to the preservation of Dream Station 1 Devices from the date it was entered to the date this Order is entered, and nothing in this Order is intended to alter the Parties' obligations under the Interim Preservation Order as of the time the Interim Preservation Order was in effect, or to affect any deadlines set forth in the Interim Preservation Order, as modified by the Order Modifying Deadline to Submit Identifying Information to the Preservation Registry Under Paragraph 24 of the Interim Preservation Order. This Order defines the Parties' respective obligations with respect to the preservation of DreamStation 1 Devices as of the date this Order is entered.[1]

17. As of the date of this Order, the FDA has allowed rework activities to proceed for Trilogy devices. The Parties' obligations with respect to Trilogy devices are set forth in the Interim Preservation Order (Applicable to Trilogy Devices) (Doc. 578), and nothing in this Order changes, or is intended to change, the parties' obligations or requirements with respect to Trilogy devices. The Parties agree that if the FDA allows rework activities to proceed for any Other Recalled Devices, the Parties will promptly meet and confer and submit a proposed preservation order for such Other Recalled Devices.

[1] The Parties agree that they will not use the existence of the Interim Preservation Order or this Order to argue that the preservation steps set forth therein or in their accompanying Exhibits were required to be taken or implemented prior to entry of the respective Order.

III. PRESERVATION PROTOCOL FOR DREAMSTATION 1 DEVICES

A. Remediation Activities for DreamStation 1 Devices

18. Philips RS may continue to conduct rework and remediation activities under the DS1 Recall Remediation on DreamStation 1 Devices.

19. The following is a general overview of the process Philips RS states it uses to perform rework activities pursuant to the DS1 Recall Remediation: Philips RS provides written notice and instructions to DreamStation 1 Device users with their replacement device when shipped on how to return their affected DreamStation 1 Device to Philips RS and includes a pre-paid return shipping label for return of the recalled DreamStation 1 Device.[2] Philips RS instructs users to remove and retain the SD card from their device, and not to return the SD card, tubing, mask, or humidifier. When Philips RS receives a DreamStation 1 Device for remediation, Philips RS may: (i) clean and disinfect the exterior of the DreamStation 1 Device prior to repair; (ii) evaluate the DreamStation 1 Device to ensure it is operating properly, documenting observations and error codes; (iii) remove the SD card, if an SD card is present; (iv) generate a screenshot or data file that documents the device serial number, blower hours, therapy hours and/or machine hours (as those hours are reflected in the device); (v) access, photograph, and remove from the DreamStation 1 Device the blower box assembly that contains the PE-PUR sound abatement foam; (vi) photograph the model label of the DreamStation 1 Device; (vii) assemble a blower box containing a silicone-based sound abatement foam, and replace the old blower box in the DreamStation 1 Device with the new blower box; (viii) test the remediated device to ensure it is operating properly; and (ix) send the remediated DreamStation 1 Device to a Recalled Device Claimant.

[2] Return instructions are addressed in Section III.B.2.

B. Philips RS's Preservation of Certain DreamStation 1 Devices

20. Subject to the stipulations set forth below, and except for the preservation requirements set forth herein (including **Amended Exhibit C**), Philips RS is not required to preserve DreamStation 1 Devices, or components or accessories of DreamStation 1 Devices (other than SD cards, as set forth in Paragraph 34), that are returned for remediation pursuant to the DS1 Recall Remediation after the date of this Order.

1. Creation of a DreamStation 1 Preservation Registry

21. To have their DreamStation 1 Device(s) preserved by Philips RS under this Order, Recalled Device Claimants, individually or through counsel, shall submit Identifying Information to Philips RS in the format attached as **Amended Exhibit A** as an Excel document[3] and sent by email to MDL3014PreservationRegistry@morganlewis.com or by using a web entry form available at www.MDL3014PreservationRegistry.com. The web entry form link will be available for use within three (3) business days after entry of this Order. A Plaintiff or Represented Prospective Plaintiff who has already submitted Identifying Information pursuant to the Interim Preservation Order should not register again, but if such Plaintiff or Represented Prospective Plaintiff wishes to return their DreamStation 1 Device to Philips RS, they may request to do so using the process set forth in Section II.B.2. Plaintiffs or Represented Prospective Plaintiffs who have not submitted Identifying Information as of the date this Order is entered, and who elect to have their DreamStation 1 Devices preserved by Philips RS under Section III.B.3, shall submit Identifying Information within 60 days of the entry of this Amended Preservation Order (including **Amended Exhibit B**), or within 60 days of becoming a Represented Prospective Plaintiff.

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

22. Philips RS shall maintain a list of known Recalled Device Claimants (the "Preservation Registry"), which Preservation Registry shall include all individuals for whom Identifying Information has been provided to Philips RS pursuant to Paragraph 21. 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 DreamStation 1 Devices returned to Philips RS shall be checked against the Preservation Registry.

2. User-Initiated Returns for Preservation

23. Recalled Device Claimants on the Preservation Registry who both (1) elect to have Philips RS preserve their DreamStation 1 Device and (2) have requested remediation of their DreamStation 1 Device, but have not yet received their refurbished replacement DreamStation 1 Device should wait to for Philips RS to contact them as part of the DreamStation 1 Remediation process to arrange return of their DreamStation 1 Device and should not utilize the below user-initiated return process.

24. Recalled Device Claimants on the Preservation Registry who elect to have Philips RS preserve their DreamStation 1 Device, do not fall within Paragraph 23, and need to return their DreamStation 1 Device to Philisp RS (*e.g.*, if they have already obtained a replacement CPAP device from another CPAP manufacturer or if they did not return their DreamStation 1 Device after receiving their refurbished replacement and no longer have the return label), they may initiate return of their DreamStation 1 Device to Philips RS using the process described in this Section.

25. If the Recalled Device Claimant wishes to initiate a request to return his or her DreamStation 1 Device to Philips RS, and the Recalled Device Claimant is **not** on the Preservation Registry as of the date this Order is entered, the Recalled Device Claimant may do so as part of the process of being added to the Preservation Registry. The Recalled Device Claimant must request a return authorization label by responding "Yes" in the return authorization label request

column in **Amended Exhibit A**. For shipping purposes, the Recalled Device Claimant must provide a telephone number and e-mail address in the relevant columns in **Amended Exhibit A**.

26. If the Recalled Device Claimant wishes to initiate a request to return his or her DreamStation 1 Device to Philips RS, and the Recalled Device Claimant **is already** on the Preservation Registry as of the date this Order is entered, the Recalled Device Claimant may make the request by providing the information listed in **Exhibit D**[4] to this Order.

27. To receive a return authorization label, a Recalled Device Claimant must provide sufficient Identifying Information, as set forth in Paragraph 21, and must also request a return authorization label and provide a telephone number and e-mail address, either for themselves or their counsel, provided for shipping purposes (if not on the Preservation Registry as of the date this Order is entered) or must provide the information listed in **Exhibit D** (if already on the Preservation Registry as of the date this Order is entered).

28. For Recalled Device Claimants who validly request a return authorization label, Philips RS shall, within a reasonable time of receiving the request, e-mail the e-mail address provided for the Recalled Device Claimant or their counsel a QR code and instructions for returning the DreamStation 1 Device to Philips RS. The instructions will direct the Recalled Device User to bring their DreamStation 1 Device and the QR code to a FedEx location for packaging and shipment to Philips RS. The FedEx shipping label will indicate that the DreamStation 1 Device should be preserved. Philips RS will preserve and store DreamStation 1 Devices received as a result of user-initiated returns under the process set forth in Section III.B.3 and in **Amended Exhibit B**.

[4] **Exhibit D** in Excel form can be downloaded at https://www.mdl3014preservationregistry.com/

29. If Philips RS need to follow up with the Recalled Device Claimant regarding any issue with the user-initiated return, Philips RS shall contact counsel for the Recalled Device Claimant unless the Recalled Device Claimant is *pro se*, then Philips RS may contact the *pro se* Recalled Device Claimant using the telephones number or e-mail address provided for the return.

3. Preservation of DreamStation 1 Devices of Persons on the Preservation Registry

30. Pending negotiation by the Parties and entry of an examination protocol and Order, Philips RS shall preserve and not remediate the DreamStation 1 Devices of all Recalled Device Claimants on the Preservation Registry who return or have returned their DreamStation 1 Devices to Philips RS. The preservation obligation of Philips RS set forth herein does not apply where (i) a DreamStation 1 Device was reworked after entry 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 DreamStation 1 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 DreamStation 1 Device on Philips RS's recall website; provided, however, that Philips RS will undertake reasonable and good faith efforts to preserve and not remediate DreamStation 1 Devices of all Recalled Device Claimants on the Preservation Registry who return or have returned their DreamStation 1 Devices but have not provided either the serial number of the DreamStation 1 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*.

31. When Philips RS identifies a DreamStation 1 Device received, directly or indirectly, from a Recalled Device Claimant listed on the Preservation Registry, Philips RS will package, label, and store the device according to Section I.A of the Packaging and Storage Protocol attached hereto as **Amended Exhibit B**. If the Recalled Device Claimant returns an SD card or humidifier along with the DreamStation 1 Device, Philips RS will also preserve the SD card and humidifier according to Section I.A of the Packaging and Storage Protocol as **Amended Exhibit B**. If returned to Philips RS by a Recalled Device Claimant, Philips RS is not required to preserve and may discard any other accessories that are returned, such as masks or tubing.

4. DreamStation 1 Devices from Persons Other than those on the Preservation Registry

32. To ensure that a sufficient quantity of devices is available for inspection, testing, and analysis, Philips RS will preserve an additional quantity of blower box assemblies from DreamStation 1 Devices (as well as any SD cards or humidifiers returned with those devices), at least on an interim basis, received for remediation after the date of this Order and which are not DreamStation 1 Devices subject to the requirements of Section III.B.3. The devices for which blower box assemblies and any associated SD cards and humidifiers will be preserved will be identified and retained according to the Protocol attached hereto as **Amended Exhibit C**, and will be packaged, labeled, and stored according to Section I.B of the Packaging and Storage Protocol attached hereto as **Amended Exhibit B**. Philips RS need not preserve any other components or accessories, such as masks or tubing, that are returned with the DreamStation 1 Device.

33. In addition to the DreamStation 1 Devices described in Paragraph 35 Philips RS will identify and set aside an additional 400 DreamStation 1 Devices received for remediation after

the date of the Interim Preservation Order and which are not DreamStation 1 Devices subject to the requirements of Section III.B.3 or III.B.4. The DreamStation 1 Devices identified under this Paragraph will be divided equally between Philips RS and the Plaintiffs' lead counsel, and may be examined, tested, and analyzed (including destructive testing, if necessary) by the Parties and their experts. The DreamStation 1 Devices preserved under this Paragraph will be identified and retained according to the random selection process in Paragraph 1 of **Amended Exhibit C** to this Order.

34. For all DreamStation 1 Devices that are returned for the DS1 Recall Remediation and not subject to Section III.B.3 or III.B.4 (both of which already provide for preservation of SD cards), if any returned DreamStation 1 Device has an SD card included in it, Philips RS will preserve that DreamStation 1 Device's SD card in the manner set forth in Paragraph 13 of **Amended Exhibit B**.

5. Preservation of New, Unused DreamStation 1 Devices

35. Philips RS shall preserve and provide upon request to Plaintiffs' lead counsel 35 new, unused versions of each model of DreamStation 1 Device (280 DreamStation 1 Devices total), and may be examined, tested, and analyzed (including destructive testing, if necessary) by Plaintiffs' counsel or their experts. The new, unused devices will be maintained securely and segregated from any other stored DreamStation 1 Devices until requested by Plaintiffs' lead counsel.

IV. PHILIPS RS'S PRESERVATION OF OTHER RECALLED DEVICES

36. Philips RS represents that, as of the date of this Order, other than for Trilogy Devices, Philips RS has not instructed users of Other Recalled Devices to return Other Recalled Devices to Philips RS or to any DME. In certain limited instances, however, users of such Other Recalled Devices have returned them to Philips RS. When users of such Other Recalled Devices

return such Other Recalled Devices to Philips RS, Philips RS will preserve such Other Recalled Devices consistent with Section I.A of the Packaging and Storage Protocol at **Amended Exhibit B** or, at Philips RS's option, may return such Other Recalled Device to the user.

37. Except as otherwise provided in the preceding Paragraph, nothing in this section is intended to modify the preservation obligations of any Party under Pretrial Order No. 1 with respect to such Other Recalled Devices.

V. USER-PRESERVED DEVICES

38. All Parties acknowledge and agree that for medical reasons, any person may choose to continue to use their DreamStation 1 Device prior to its replacement, in which case, Section V of this Order shall not apply to them until they stop using their DreamStation 1 Device.

39. Any Plaintiff or Represented Prospective Plaintiff may choose to retain his or her DreamStation 1 Device or have their counsel or a third party retain his or her DreamStation 1 Device. The Plaintiff or Represented Prospective Plaintiff shall not be required to return the DreamStation 1 Device to receive a replacement device from Philips RS; however, the Plaintiff or Represented Prospective Plaintiff must still submit Identifying Information for inclusion on the Preservation Registry in order for Philips RS to track what DreamStation 1 Devices are not being returned under the DS1 Recall Remediation.

40. User-Preserved Devices shall be preserved according to Section II of the Packaging and Storage Protocol attached hereto as **Amended Exhibit B** pending negotiation by the Parties and entry of an examination protocol and Order. Plaintiff or Represented Prospective Plaintiffs will also be instructed by their counsel to preserve the SD card and any humidifier from their DreamStation 1 Device, but that they do not need not preserve any other components or accessories, such as masks or tubing, with the DreamStation 1 Device, although they may choose to do so; however, any Plaintiff or Represented Prospective Plaintiff who participates in the DS1

Recall Remediation and receives a replacement DreamStation 1 Device may use the humidifier from their DreamStation 1 Device with the replacement DreamStation 1 Device. The Packaging and Storage Protocol in **Amended Exhibit B** must be followed substantially and in good faith within 90 days of entry of this Order.

41. If a Plaintiff or Represented Prospective Plaintiff who chooses to User-Preserve their DreamStation 1 Device personally or through their counsel, instead of returning their Recalled Device to Philips RS, does not comply substantially and in good faith with their preservation obligations under this Order and **Amended Exhibit B**, that Recalled Device Claimant may not rely upon the Stipulations in Paragraph 43 and Paragraph 45(a). In such a case, the Plaintiff or Represented Prospective Plaintiff shall not be deemed to have failed to adequately preserve their User-Preserved Device, but Defendants are not precluded from arguing that the Plaintiff or Represented Prospective Plaintiff's manner of preservation was inadequate and was a failure of preservation.

VI. STIPULATIONS

42. Provided that Philips RS has substantially and in good faith complied with the terms of this Order, to the extent any DreamStation 1 Device is unavailable because it was returned to Philips RS after the date of the Interim Preservation Order or this Order and was not preserved by Philips RS pursuant to the applicable Order, then Defendants shall not be subject to a claim of spoliation or an adverse inference instruction regarding that specific DreamStation 1 Device.

43. For any Recalled Device Claimant whose DreamStation 1 Device (or any component) is unavailable because it was returned to Philips RS after the date of the Interim Preservation Order or this Order and was not preserved by Philips RS pursuant to the applicable 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 his or her

particular DreamStation 1 Device (or components of that DreamStation 1 Device) is 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 DreamStation 1 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.

44. For any Recalled Device Claimant who brings claims in this MDL or in any state court, and that individual's DreamStation 1 Device is unavailable because it was not required to be preserved under the terms of this Order, the Parties stipulate and agree that DreamStation 1 Devices preserved under the Interim Preservation Order or this Order may be subject to analysis by the parties' experts to support the parties' claims and defenses in connection with that individual's unavailable DreamStation 1 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 that particular individual's DreamStation 1 Device specifically, but only other devices preserved under the Interim Preservation Order or this Order. This provision applies to all Recalled Device Claimants whose DreamStation 1 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.

45. This 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 **Amended Exhibit B** is intended, as best as reasonably possible, to preserve the DreamStation 1 Devices in substantially the same condition as they were in at the time of the bagging. If the Packaging and Storage Protocol in **Amended Exhibit B** is followed substantially and in good faith, the Parties stipulate and agree (i) not to argue that the condition of the Recalled Device at issue was affected in any way by the manner and/or method of bagging and storing the preserved Recalled Device, and (ii) not to challenge the reliability or admissibility of the opposing parties' expert opinions on the grounds that the condition of the stored Recalled Device (including but not limited to the foam and other 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 Recalled Device, 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 46 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. The Protocol for Preservation of Additional Devices in **Amended Exhibit C** will preserve a sufficient sample of the entire population of recalled DreamStation 1 Devices for purposes of later testing of a subset or subsets of that sample for purposes of analysis by the Parties' experts.

46. The Parties recognize the possibility that the foam in the DreamStation 1 Devices may degrade or further degrade as time passes, despite the bagging and storage provided for in **Amended Exhibit B**. Accordingly, Philips RS will set aside a number of devices separate from, and in addition to, all other preservation obligations before and after the entry of this Order for the purpose of testing to determine the extent of foam degradation due to the passage of time after a DreamStation 1 Device has been bagged and stored pursuant to the Packaging and Storage Protocol in **Amended 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.

47. The stipulations and agreements contained herein shall apply to any case pending in this MDL as of the entry of this 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.

48. 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.

VII. OTHER PROVISIONS

49. To the extent Philips RS uses third-party contractors for any preservation or rework for any Recalled Device, or for any packaging or storing of preserved devices, Philips RS is

responsible for ensuring its third-party contractors have notice of this Order and agree to comply with the provisions of this Order.

50. To the extent not already done, Philips RS will send a written communication to all of its DMEs advising them that if a customer returned any DreamStation 1 Device to the DME, the DreamStation 1 Device should be returned to Philips RS. Philips RS will then treat the device as if it was returned directly to Philips RS under the terms of this Order.

51. This Order applies to all cases in the MDL as of the date of entry of this Order, and to all cases later filed in, removed to, or transferred to this Court and made part of the MDL.

52. Nothing in this Protocol shall be interpreted or construed in a manner inconsistent with, or contravening, any federal law, rule, or regulation, in effect at the time of the execution of this Protocol by Defendants and Plaintiffs and approval by this Court and any subsequent amendment.

53. The Parties reserve the right to request further modification or amendment of this Order: (1) through the entry of a stipulated DreamStation 1 and/or Recalled Device examination protocol; (2) in the event that the FDA allows rework activities to proceed with respect to additional Other Recalled Devices; (3) in the event the random sampling selection process provided for in **Amended Exhibit C** does not result in the collection of a sufficient number of DreamStation 1 devices produced of any single model; (4) as agreed by the Parties; or (5) for other good cause shown.

IT IS SO ORDERED.

BY THE COURT:

Dated: September 21, 2022

/s/ JOY FLOWERS CONTI
Joy Flowers Conti
Senior United States District Judge

STIPULATED AND AGREED TO this 20th day of September, 2022:

/s/ John P. Lavelle, Jr
John P. Lavelle, Jr., Esquire
MORGAN, LEWIS & BOCKIUS LLP
1701 Market Street
Philadelphia, PA 19103-2921
T 215.963.5000
john.lavelle@morganlewis.com

Wendy West Feinstein, Esquire
MORGAN, LEWIS & BOCKIUS LLP
One Oxford Center, 32nd Floor
Pittsburgh, PA 15219-6401
T 412.560.3300
wendy.feinstein@morganlewis.com

Lisa C. Dykstra, Esquire
MORGAN, LEWIS & BOCKIUS LLP
1701 Market Street
Philadelphia, PA 19103-2921
T 215.963.5000
lisa.dykstra@morganlewis.com

Counsel for Defendant Philips RS North America, LLC

/s/ Michael H. Steinberg
Michael H. Steinberg, Esquire
SULLIVAN & CROMWELL LLP
1888 Century Park East
Los Angeles, CA 90067
T (310) 712-6670
steinbergm@sullcrom.com

William B. Monahan, Esquire
SULLIVAN & CROMWELL LLP
125 Broad Street
New York, NY 10004
T (212) 558-7375
monahanw@sullcrom.com

/s/ Kelly K. Iverson
Kelly K. Iverson, Esquire
LYNCH CARPENTER, LLP
1133 Penn Avenue, 5th Floor
Pittsburgh, PA 152222
T (412) 322-9243
kelly@lcllp.com

/s/ Christopher A. Seeger
Christopher A. Seeger, Esquire
SEEGER WEISS LLP
55 Challenger Road 6th Floor
Ridgefield Park, NJ 07660 212-584-0700
cseeger@seegerweiss.com

/s/ Sandra L. Duggan
Sandra L. Duggan, Esquire
LEVIN SEDRAN & BERMAN
510 Walnut Street
Ste 500
Philadelphia, PA 19106
215-592-1500
215-592-4663 (fax)
sduggan@lfsblaw.com

/s/ Steven A. Schwartz
Steven A. Schwartz, Esquire
Chimicles Schwartz Kriner & Donaldson-Smith LLP
361 West Lancaster Avenue
One Haverford Centre
Haverford, PA 19041
(610) 642-8500
steveschwartz@chimicles.com

Plaintiffs' Co-Lead Counsel

Counsel for Defendants Koninklijke Philips NV, Philips North America LLC, Philips Holding USA Inc., and Philips RS North America Holding Corporation

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)

Amended Exhibit B

Packaging and Storage Protocol

I. *Philips RS's Obligations*

Upon entry of the Amended Preservation Order, the following sets forth Philips RS's obligations with respect to the handling, packaging, and storage of DreamStation 1 Devices, or components thereof, returned to Philips RS pursuant to Sections III.B or IV of the Amended Preservation Order.

A. Obligations for DreamStation 1 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"). 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.

2. The DreamStation 1 Device (or Other Recalled Device under Section IV, if applicable) will be placed in a 2 mil (.002) thickness, bottom-gusseted Polyethylene ("Poly") bag. If an SD card is provided with the returned device, the SD card will be left in the SD card slot in the device.

3. If a humidifier is provided with the returned device, an Identifying Label will be placed on the humidifier, and the humidifier will be placed in the Poly bag along with the returned device.

4. 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.

5. The sealed bag containing the device (and, if present, the humidifier and/or the SD card) 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.

6. 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.

7. 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.

B. Obligations for Components of DreamStation 1 Devices of Individuals Not on the Preservation Registry.

8. 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.

9. The blower box assembly (which contains the foam), SD card (if provided), and humidifier (if provided) will be removed.

10. 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.

11. The blower box assembly will be placed in a Poly bag.

12. 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.

13. 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.

14. The sealed bag containing the blower box assembly 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.

15. 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.

16. 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 7, above.

17. If a humidifier is provided with the returned device, an Identifying Label will be placed on the humidifier, and the humidifier will be placed on a pallet along with other returned humidifiers. The storage location will be recorded.

18. Other than the blower box assembly and any SD card or humidifier provided with the returned device, Philips RS may reuse or discard other components of the returned DreamStation 1 Device, such as masks or tubing.

19. Philips RS may choose to preserve Recalled Devices subject to this **Amended Exhibit B** via a third-party storage facility, if that entity is instructed to follow the preservation process specified above in Part I(A) and Part I(B), as applicable.

II. *Plaintiffs' and Represented Prospective Plaintiffs' Obligations for User-Preserved DreamStation 1 Devices.*

Upon entry of this Amended Preservation Order, the following sets forth Plaintiffs' and Represented Prospective Plaintiffs' obligations with respect to User-Preserved Devices in accordance with Section V of the Interim Preservation Order. This section applies only to Plaintiffs and Represented Prospective Plaintiffs who elect to User-Preserve their Devices.

With respect to DreamStation 1 Devices, Plaintiffs and Represented Prospective Plaintiffs shall take these actions in order to receive the Parties' stipulations in Paragraphs 43 and 45(a) of the Amended Preservation Order and if they (i) have received or obtained a replacement device; or (ii) have not received or obtained a replacement device but are no longer using the DreamStation 1 Device. If the Plaintiff or Represented Prospective Plaintiff has not received or obtained a replacement device and is using the DreamStation 1 Device, then upon receiving or obtaining a replacement device, they shall preserve the DreamStation 1 Device pursuant to the steps below:

1. The DreamStation 1 Device will be placed in a 2 mil (.002) thickness, bottom-gusseted Poly bag. The 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 replacement device or preserved by Plaintiff or Plaintiff's Counsel. With respect to humidifiers, the user shall preserve them unless the user elects to use the humidifier with their replacement DreamStation 1 Device. The humidifier will be preserved by placing it in the Poly bag with the DreamStation 1 Device or in its own Poly bag.

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.7, 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 the 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. Plaintiffs and Represented Prospective Plaintiffs may choose to preserve their DreamStation 1 Device via a third-party storage facility, if that entity is instructed to follow the above-specified preservation process.

III. ***Deadline for Compliance***

1. For 90 days after entry of the Amended Preservation Order, the Parties may comply with the original **Exhibit B** to the Interim Preservation Order or with this **Amended Exhibit B** to this Amended Preservation Order. All Parties shall comply with the provisions of this **Amended Exhibit B** no later than 90 days after entry of the Amended Preservation Order.

2. For any Plaintiff or Represented Prospective Plaintiff that (a) elects to User-Preserve their DreamStation 1 Device, (b) has not received or obtained a replacement device upon the entry of this Amended Preservation Order, **and** (c) is using the DreamStation 1 Device, then the Plaintiff or Represented Prospective Plaintiff shall comply with the provisions of Section II of this **Amended Exhibit B** no later than 60 days after they either (a) receive or obtain a replacement device, or (b) discontinue use of their DreamStation 1 Device, whichever is sooner.

Amended Exhibit C

Amended Protocol For Preservation of Additional DreamStation 1 Blower Boxes and Certain Components

This Protocol for Preservation of Additional DreamStation 1 Blower Boxes and Certain Components ("Protocol") shall be used with respect to DreamStation 1 Devices that have been returned to Philips RS and sets forth the quantity of recalled blower boxes and certain other components that Philips RS will preserve and retain, at least on an interim basis, after the date of entry of the Amended Preservation Order, and how they will be selected for preservation, in accordance with Paragraph 32 of the Amended Preservation Order.

1. Philips RS shall preserve the blower box assemblies removed from at least seven and 1/2 percent (7.5%) of the DreamStation 1 Devices returned by Recalled Device Users who are not included in the Preservation Registry, pursuant to a random sampling procedure whereby Philips RS will set aside and preserve the blower box assembly, SD card (if present), and humidifier (if present), for devices in the sample. Each business day, Philips RS will preserve blower box assemblies representing 7.5% of the volume of the DreamStation 1 Devices received on the preceding business day (e.g., if Philips RS receives 1,000 DreamStation 1 devices on Monday, Philips RS will preserve blower box assemblies for the first 75 of the DreamStation 1 Devices received on Tuesday). Philips RS will conduct preservation in this matter at each location (Mt. Pleasant, Pennsylvania and Guadalajara, Mexico) where remediation work is being conducted.[1] Philips RS will document and maintain a record of the individuals involved in the preservation of blower box assemblies.

[1] Consistent with Pretrial Order No. 2, if a blower box assembly selected as part of the random sample shows evidence of insect infestation, that blower box assembly may be discarded and the next blower box assembly that does not show evidence of insect infestation will be preserved. Philips RS shall comply with Pretrial Order No. 2 as to such device and, additionally, shall notify Plaintiffs' Lead Counsel of any device selected as part of the random sample and not preserved based on this footnote.

2. The blower box assemblies and any associated SD cards or humidifiers preserved in this process will be packaged and stored in the manner provided for in Part I.B of **Amended Exhibit B** to the Preservation Order.

3. Philips RS will provide an accounting of the randomly selected devices that are preserved pursuant to Paragraph 1 of this **Amended Exhibit C**, and the number of devices preserved pursuant to Section III.B.3 of the Amended Preservation Order (*i.e.*, those that are on the Preservation Registry). Such reports shall be provided to Plaintiffs' Lead Counsel on a monthly basis beginning with the first day of the month following the date this Order is entered. Philips RS will also report to Plaintiffs' Lead Counsel if, at any point, the estimated number of DreamStation 1 Devices returned for remediation drops below Philips RS's initial estimate of 1.8 million by a degree of 10% or more.

4. 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.

EXHIBIT D to Amended Preservation Order Applicable to DreamStation 1 Devices

****For use to request return label - only use if you are having Philips preserve the Product User's device AND 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****

	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)	**Information for Return Label**	
Plaintiff Counsel Firm(s)	**Last Name**	**First Name**	**Middle Name**	**Suffix**	**Date of Birth**	**Street Address**	**City**	**State**	**ZIP**	**Country**	**Device Serial Number**	**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)

Appendix 1: Recalled Devices

The following is a list of the Recalled Devices as defined in the Order.

CPAP and BiPAP Devices

All Devices Manufactured Before 26 April 2021 All Serial Numbers	
Continuous Ventilator, Minimum Ventilatory Support, Facility Use	∆ E30
Continuous Ventilator, Non-life Supporting	∆ DreamStation ASV ∆ DreamStation ST, AVAPS ∆ SystemOne ASV4 ∆ C-Series ASV ∆ C-Series S/T and AVAPS ∆ OmniLab Advanced+
Noncontinuous Ventilator	∆ SystemOne (Q-Series) ∆ DreamStation ∆ DreamStation Go ∆ Dorma 400 ∆ Dorma 500 ∆ REMstar SE Auto

Ventilators

Device Type	Model Name and Number (All Serial Numbers)
Continuous Ventilator	∆ Trilogy 100 ∆ Trilogy 200 ∆ Garbin Plus, Aeris, LifeVent
Continuous Ventilator, Minimum Ventilatory Support, Facility Use	∆ A-Series BiPAP Hybrid A30 (not marketed in US) ∆ A-Series BiPAP V30 Auto
Continuous Ventilator, Non-life Supporting	∆ A-Series BiPAP A40 ∆ A-Series BiPAP A30

Trilogy Evo Ventilator
Repair Kits for Trilogy Evo muffler assembly

Device Type	**Model Name and Number**
Trilogy Evo Ventilator Repair kits for Trilogy Evo muffler assembly	• Trilogy Evo ventilator model numbers with certain serial numbers as listed in the recall database: DS2110X11B KR2110X15B (not distributed in the U.S.) • Repair kits for Trilogy Evo muffler assembly model and lot numbers as listed in the recall database: Part number 1135257 Lot numbers between 210414 and 210524 • Manufacturing Dates: April 15, 2021 to May 24, 2021 • Distribution Dates: April 15, 2021 to May 24, 2021