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	)	

INTERIM PRESERVATION ORDER

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 Interim Lead Counsel (collectively, the "Parties"), jointly submit this Interim Preservation Order pursuant to Pretrial Order Nos. 2 and 4 for approval and entry by the Court.

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. As of the date of this Order, the DreamStation 1 Devices are the only devices Philips RS has recalled for which the FDA has reviewed Philips RS's remediation proposal and allowed rework activities to proceed.

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 November 10, 2021, the Court entered Pretrial Order No. 1, which imposed certain preservation obligations on the Parties, including to preserve evidence that "may be relevant to this action." Pretrial Order No. 1 ¶ 13.

16. On November 12, 2021, Philips RS filed a motion requesting relief from Pretrial Order No. 1 to (a) permit Philips RS to resume its rework of DreamStation 1 Devices under the DS1 Recall Remediation, and (b) permit users to return their DreamStation 1 Devices to Philips

RS to be reworked under the DS1 Recall Remediation. Certain Plaintiffs opposed the motion. In its reply, Philips RS agreed—on an interim basis—to preserve the blower boxes (including the PE-PUR foam contained therein) and the Secure Data ("SD") cards (if present) for all returned devices that had not yet been remediated, subject to negotiation of an interim preservation protocol. As an exception, Philips RS stated that for safety reasons it did not intend to preserve devices with evidence of insect infestation.

17. On November 19, 2021, the Court entered Pretrial Order No. 2, granting in part and denying in part Philips RS's motion. Pretrial Order No. 2 set forth Philips RS's preservation obligations with respect to the DreamStation 1 Devices, applicable until further order of the Court. Pretrial Order No. 2 provides that: (i) consistent with the DS1 Recall Remediation, users may submit their recalled DreamStation 1 Devices to Philips RS for replacement or repair pursuant to the DS1 Recall Remediation; (ii) Philips RS may continue to replace or remediate the DreamStation 1 Devices under the DS1 Recall Remediation, subject to the preservation requirements set forth in Pretrial Order No. 1, as amended by Pretrial Order No. 2; (iii) with respect to insect-infested devices, Philips RS must retain a record of all insect-infested DreamStation 1 Devices of which it disposes, record and retain a list of the senders, and if reasonably possible the users, of the insect-infested DreamStation 1 Devices, and take a photograph of each insect-infested DreamStation 1 device, but Philips RS is not required to retain insect-infested devices; (iv) with respect to all DreamStation 1 Devices that will not be repaired, Philips RS must preserve, store, and catalogue all such devices so that each device can, if possible, be traced back to the specific individual who used the device; and (v) with respect to all DreamStation 1 Devices that will be remediated and returned to the sender, Philips RS must preserve, store, and catalogue with the original serial number the blower box, PE-PUR foam, and SD card removed from all such devices.

18. Pretrial Order No. 2, as subsequently amended by Pretrial Order No. 6, also appointed Interim Lead Counsel for Plaintiffs for purposes of negotiating a proposed preservation order with Defendants' counsel.

19. Following extensive meet and confer negotiations, the Parties submit this Interim Preservation Order 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. This Order is intended to be prospective, and nothing in this Order addresses the Parties' duties to preserve evidence prior to the entry of this Order.[1]

20. The Parties agree that if the FDA allows rework activities to proceed for Other Recalled Devices, the Parties will promptly meet and confer and submit a proposed interim preservation order (or an amendment to this Interim Preservation Order) for such Other Recalled Devices.

III. PRESERVATION PROTOCOL FOR DREAMSTATION 1 DEVICES

A. Remediation Activities for DreamStation 1 Devices

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

22. 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-

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

paid return shipping label for return of the recalled DreamStation 1 Device.[2,3] 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.

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

23. Subject to the stipulations set forth below, and except for the preservation requirements set forth herein (including Exhibit C), Philips RS is not required to preserve DreamStation 1 Devices, or components or accessories of DreamStation 1 Devices (other than SD

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[2] Plaintiffs have requested that communications about matters relevant to this litigation between Philips RS and any Recalled Device Claimants, and/or DMEs, and documentation thereof, be the subject of a separate agreement and Order. The Parties are scheduled to meet and confer on this issue.

[3] In the event that a Recalled Device Claimant has received a replacement device and has discarded or misplaced the return instructions for his or her DreamStation 1 Device, the Recalled Device Claimant or his or her counsel may contact Interim Lead Counsel, or Liaison Counsel following their appointment, to obtain return instructions.

cards, as set forth in Section III.B.3), 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

24. 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 **Exhibit A** and sent by email to MDL3014PreservationRegistry@morganlewis.com or by using a web entry form available at www.MDL3014PreservationRegistry.com. The content and format of the web entry form is subject to review and approval by Interim Lead Counsel. The web entry form link will be available for use within three (3) business days after entry of this Order. Plaintiffs and Represented Prospective Plaintiffs who elect to have their DreamStation 1 Devices preserved by Philips RS under Section III.B (if the device has not been reworked in the interim) shall submit Identifying Information within 60 days of the entry of this Order, or within 60 days of becoming a Represented Prospective Plaintiff.

25. 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 24. 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. Preservation of DreamStation 1 Devices of Persons on the Preservation Registry

26. 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 serial number of the DreamStation 1 Device; 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 the serial number of the DreamStation 1 Device in their Identifying Information, if at least all of the following Identifying Information is provided: 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*.

27. 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 **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 **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.

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

28. 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.2. 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 **Exhibit C**, and will be packaged, labeled, and stored according to Section I.B of the Packaging and Storage Protocol attached hereto as **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.

29. For all DreamStation 1 Devices that are returned for the DS1 Recall Remediation and not subject to Section III.B.2 or Paragraph 28 (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 **Exhibit B**.

4. Preservation of New, Unused DreamStation 1 Devices

30. Philips RS shall preserve an agreed-upon number of new, unused versions of each model of DreamStation 1 Device for potential examination and testing. The Parties will continue to meet and confer to determine the number of each model to be preserved under this paragraph and will notify the Court when such agreement is reached. The new, unused devices will be maintained securely and segregated from any DreamStation 1 Devices that were returned to Philips

RS for DS1 Recall Remediation. The new devices will be subject to testing by the Parties pursuant to a testing protocol order to be negotiated by the Parties.

IV. PHILIPS RS'S PRESERVATION OF OTHER RECALLED DEVICES

31. Philips RS represents that, as of the date of this Order, Philips RS has not instructed users of Other Recalled Devices to return them to Philips RS or to any DME. If users of Other Recalled Devices nonetheless return such Other Recalled Devices to Philips RS despite not being instructed to do so, Philips RS will preserve such Other Recalled Devices consistent with Section I.A of the Packaging and Storage Protocol at **Exhibit B** or, at Philips RS's option, may return the Other Recalled Device to the user.

32. 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 Other Recalled Devices.

V. USER-PRESERVED DEVICES

33. 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.

34. 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.

35. User-Preserved Devices shall be preserved according to Section II of the Packaging and Storage Protocol attached hereto as **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 **Exhibit B** must be followed substantially and in good faith within 90 days of the Parties finalizing their agreement on the specifics that remain subject to agreement under Exhibit B, and it is entered as an Order.

36. 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 Exhibit B, that Recalled Device Claimant may not rely upon the Stipulations in Paragraph 38 and Paragraph 40(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

37. Provided that Philips RS has substantially and in good faith complied with the terms of this Preservation Order, to the extent any DreamStation 1 Device is unavailable because it was

returned to Philips RS after the date of this Order and was not preserved by Philips RS pursuant to this Order, then Defendants shall not be subject to a claim of spoliation or an adverse inference instruction regarding that specific DreamStation 1 Device.

38. For any Recalled Device Claimant whose DreamStation 1 Device (or any component) is unavailable because, after it was returned to Philips RS after the date of this Order, it 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 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, their name, address, and date of birth.

39. 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 this Preservation Order, or a subsequent Preservation Order, may be subject to analyses 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 this Preservation 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.

40. This Preservation 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 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 **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 41 below, as to the question of the extent (if any) of degradation or further degradation of the bagged and stored foam as time passes.

b. The Protocol for Preservation of Additional Devices in **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.

41. 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 **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 after a DreamStation 1 Device has been bagged and stored pursuant to the Packaging and Storage Protocol in **Exhibit B**. The number of devices to be retained, the process of their selection, and the protocol for conducting testing on these devices will be the subject of a separate Order to be negotiated by the Parties.

42. The stipulations and agreements contained herein shall apply to any case pending in this MDL as of the date of entry of this Stipulation by the Court 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.

43. 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

44. 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.

45. 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.

46. This Protocol 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.

47. 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.

48. The Parties reserve the right to request 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 Other Recalled Devices; (3) in the event the random sampling selection process provided for in 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: January 11, 2022

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

This 7th day of January, 2022,

STIPULATED AND AGREED TO BY:

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EXHIBIT A

	Product User					Product User Address					Device Serial Number	Device Preserved by User?	Lawsuit
Plaintiff Counsel Firm(s)	Last Name	First Name	Middle Name	Suffix	Date of Birth	Street Address	City	State	ZIP	Country	Device Serial Number	Indicate whether user is preserving the device or 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?

Exhibit B

Packaging and Storage Protocol

I. *Philips RS's Obligations*

Upon entry of the 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 Interim 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 name of the returnee and the serial number of the device ("Identifying Label").

2. The DreamStation 1 Device (or Other Recalled Device under Section IV, if applicable) will be placed in a Polyethylene ("Poly") bag. The specifications of the Poly bag are to be provided to Interim Lead Counsel, and the Parties will meet and confer on those specifications.

3. The Poly bag will be heat sealed (without vacuum or purging). After heat sealing, an Identifying Label will be placed on the Poly bag.

4. The sealed bag containing the device 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-monitored setting equipped with ambient air temperature and humidity monitoring. The Parties will meet and confer regarding

appropriate temperature and humidity ranges for storage. The pallet's storage location will be recorded.

7. 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 a box along with other returned humidifiers. The storage location will be recorded.

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). 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-monitored setting equipped with ambient air temperature and humidity monitoring. The Parties will meet and confer regarding appropriate temperature and humidity ranges for storage. The pallet's storage location will be recorded.

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 in a box 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 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 the 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.

With respect to DreamStation 1 Devices, Plaintiffs and Represented Prospective Plaintiffs shall take these actions in order to receive the Parties' stipulations in Paragraphs 38 and 40(a) of the 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 (including the SD card) will be placed in a Poly bag, the specifications of which are to be provided to Interim Lead Counsel and subject to meet and confer. 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. With respect to humidifiers, the user shall preserve them in the sealed box (see below at Paragraph 3), unless the user elects to use the humidifier with their replacement DreamStation 1 Device.

2. The Poly bag will be heat sealed (without vacuum or purging).

3. The sealed bag containing the DreamStation 1 Device will be placed in a box, and the box will be closed and sealed with tape.

4. The sealed box will be stored in an environmentally-monitored setting equipped with ambient air temperature and humidity monitoring. The Parties will meet and confer regarding appropriate temperature and humidity ranges for storage.

5. 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.

6. 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. ***Further Agreement By the Parties***

1. Pending further discussions by the parties as to the specifics of the Poly bag to be used and the appropriate temperature and humidity ranges for storage, Philips RS shall continue to use the Poly bags and the temperature and humidity ranges for storage that it was using prior to entry of this Order, but otherwise will comply with Section I, above.

2. As set forth above, Defendants and Interim Lead Counsel shall meet and confer and determine the exact specifications to be used for the Poly bags and for temperature and humidity ranges for storage for Sections I and II of this Exhibit B. Upon agreement, the parties shall submit an Amended Exhibit B to be entered as an Order of the Court.

3. Section II, for User-Preserved Devices, shall not take effect until the Amended Exhibit B contemplated by the preceding paragraph is entered as an Order.

4. The Parties shall have 90 days after entry of the Order set forth in Paragraph 2 to comply with the provisions of that Order.

Exhibit C

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 Preservation Order, and how they will be selected for preservation, in accordance with Section III.B.3 of the 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.

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 Exhibit B to the Preservation Order.

3. Philips RS will provide an accounting of the randomly selected devices preserved pursuant to Paragraph 1. The specifics of such accounting are being negotiated by Philips RS and Interim Lead Counsel. Such reports shall be provided to Plaintiffs' Lead Counsel on a monthly basis beginning with April 1, 2022. Philips RS will also report to Plaintiffs' Lead Counsel if the number of returned DreamStation 1 Devices drops below Philips RS's estimates to a material degree, the threshold for which reporting will be discussed and agreed to by the Parties. Philips RS will confirm the estimates it provided to Interim Lead Counsel by written letter or email to Interim Lead Counsel on or before January 14, 2022.

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.

[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.

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