

- System One 50 series;
 - System One 60 series;
 - DreamStation GO CPAP, APAP, Auto CPAP;
 - Dorma 400, 500 CPAP, Auto CPAP;
 - Garbin Plus, Aeris, LifeVent Ventilator;
 - A-Series BiPAP Hybrid A30 (also known as BiPAP Hybrid A30 Ventilator (A-Series));
 - A-Series BiPAP V30 Auto Ventilator (also known as BiPAP V30 Auto Ventilator (A-Series));
 - A-Series BiPAP A40 (also known as BiPAP A40 Ventilator (A-Series));
 - A-Series BiPAP A30 (also known as BiPAP A30 Ventilator (A-Series)).
- For avoidance of doubt, Other Recalled Devices does not include DreamStation 1 Devices as defined by and subject to the Amended Preservation Order Applicable to DreamStation 1 Devices entered on September 23, 2022 (Doc. 773) and Trilogy Devices as defined by and subject to the Second Amended Interim Preservation Order Applicable to Trilogy Devices entered on June 15, 2023 (Doc. 2049). A list all Recalled Devices can be found at https://www.usa.philips.com/healthcare/e/sleep/communications/src-update/information-for-patients-and-caregivers#affected_devices.

4. **Recalled Device Claimants**: All Plaintiffs, Represented Prospective Plaintiffs, and Other Prospective Plaintiffs, as defined below:

- a. **Plaintiffs**: Persons who, in actions that are part of this MDL as of the date of this Order, are either (i) Plaintiffs in actions seeking individualized relief on behalf of

themselves only, or injunctive relief (including through mass actions), and/or (ii) named class representatives in proposed class actions.

b. **Represented Prospective Plaintiffs**: Owners or users of Other Recalled 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 an Other Recalled 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.

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

5. **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>.

6. **Recalled Devices**: All devices subject to the Recall.

7. **Settlement**: The Parties' Amended Class Settlement Agreement and Release of Economic Loss Claims (ECF 2279-1), which the Court preliminarily approved on October 10,

2023 (ECF 2289), and information on which is available at the Settlement Website available at <https://www.respironicscpap-elsettlement.com/>.

8. This Order defines the Parties' respective obligations with respect to the preservation of Other Recalled Devices as of the date this Order is entered.¹

II. PRESERVATION PROTOCOL FOR OTHER RECALLED DEVICES

A. Philips RS's Preservation of Certain Other Recalled Devices

1. Preservation Registry

9. To have their Other Recalled Device(s) preserved by Philips RS under this Order, Recalled Device Claimants, individually or through counsel, shall submit Identifying Information to Philips RS within 60 days of the entry of this Order, or within 60 days of becoming a Represented Prospective Plaintiff, in the format attached as **Exhibit A** as an Excel document² and sent by email to MDL3014PreservationRegistry@morganlewis.com or by using a web entry form available at www.MDL3014PreservationRegistry.com. A Plaintiff or Represented Prospective Plaintiff who has already submitted Identifying Information to the Preservation Registry for their Other Recalled Device need not register again. 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 Other Recalled Devices preserved by Philips RS under Section II.A.2, shall submit Identifying Information within 60 days of the entry of this Order, or within 60 days of becoming a Represented Prospective Plaintiff.

10. Philips RS shall maintain a list of known Recalled Device Claimants (the "Preservation Registry"), which Preservation Registry shall include all individuals for whom

¹ The Parties agree that they will not use the existence of 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.

² The Excel form can be downloaded at <https://www.mdl3014preservationregistry.com/>

Identifying Information has been provided to Philips RS pursuant to the prior paragraph. 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 Recalled Devices returned to Philips RS shall be checked against the Preservation Registry.

11. Recalled Device Claimants on the Preservation Registry who elect to have Philips RS preserve their Other Recalled Device and need to return their Other Recalled Device to Philip RS may initiate return of their Other Recalled Device to Philips RS using the process described in the Settlement for receipt of a pre-paid return label.³

2. Preservation of Other Recalled Devices of Persons on the Preservation Registry

12. Pending negotiation by the Parties and entry of an examination protocol and Order specific to each Other Recalled Device, Philips RS shall preserve the Other Recalled Devices of all Recalled Device Claimants on the Preservation Registry who return or have returned their Other Recalled Devices to Philips RS. The preservation obligation of Philips RS set forth herein does not apply where the Identifying Information on the Preservation Registry does not include all of the following: name, address, and either the serial number of the Other Recalled 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 Other Recalled Device on Philips RS's recall website; provided, however, that Philips RS will undertake reasonable and good faith efforts to preserve Other Recalled Devices of all Recalled Device Claimants on the Preservation Registry who return or have returned their Other Recalled Devices but have not provided either the serial

³ An interactive tool setting forth the Settlement process to obtain a pre-paid label is available on the Settlement Website—<https://www.respironicscpap-elsettlement.com/>.

number of the Other Recalled 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*.

13. When Philips RS identifies an Other Recalled 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 the Packaging and Storage Protocol attached hereto as **Exhibit B**. To the extent that the model of Other Recalled Device can be used with a humidifier and/or an SD Card, and if the Recalled Device Claimant returns an SD card or humidifier along with the Other Recalled Device, Philips RS will also preserve the SD card and humidifier according to 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. Other Recalled Devices from Persons Other than those on the Preservation Registry

14. To ensure that a sufficient quantity of devices is available for inspection, testing, and analysis, Philips RS will preserve an additional quantity of the Other Recalled Devices (as well as any SD cards or humidifiers returned with those devices), at least on an interim basis, which are not Other Recalled Devices subject to the requirements of Section II.A.2. The Other Recalled Devices which will be preserved pursuant to this Section, the amount of such Other Recalled Devices Philips RS will preserve, and the manner of selection are identified **Exhibit C**, and such Other Recalled Devices will be packaged, labeled, and stored according to the Packaging

and Storage Protocol attached hereto as **Exhibit B**. Philips RS need not preserve other components or accessories, such as masks or tubing, that are returned with the Other Recalled Device.

15. Philips RS will identify by random selection and set aside 200 of each type of Other Recalled Devices received after the date of this Order and that are not subject to preservation under Section II.A.2 for those on the Preservation Registry. The Other Recalled Devices identified under this Paragraph shall be divided equally between Philips RS and Plaintiffs' lead counsel and the Other Recalled Devices distributed pursuant to this paragraph do not need to be preserved and may be examined, tested, and analyzed (including destructive testing, if necessary) by the Parties and their experts.

4. Preservation of New, Unused Other Recalled Devices

16. Philips RS shall preserve and provide upon request to Plaintiffs' Co-Lead counsel new, unused Other Recalled Devices, which may be examined, tested, and analyzed (including destructive testing, if necessary) by Plaintiffs' counsel or their experts. The foregoing sentence is subject to availability for each model of Other Recalled Device, given that some models of Other Recalled Devices are no longer manufactured. The quantity of each type of Other Recalled Device to be preserved under this paragraph will be subject to negotiation among counsel for the Parties. Philips RS may also retain the same quantity as provided to Plaintiffs of new, unused Other Recalled Devices for examination, testing, and analysis (including destructive testing, if necessary). The new, unused devices will be maintained securely and segregated from any other stored Other Recalled Devices until requested by Plaintiffs' Co-Lead counsel.

III. USER-PRESERVED DEVICES

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

18. Any Plaintiff or Represented Prospective Plaintiff may choose to retain his or her Other Recalled Device or have their counsel or a third party retain his or her Other Recalled Device. 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 Other Recalled Devices are not being returned under the Recall.

19. 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 Other Recalled Device, but that they do not need to preserve any other components or accessories, such as masks or tubing, with the Other Recalled Device, although they may choose to do so.

20. If a Plaintiff or Represented Prospective Plaintiff who chooses to User-Preserve their Other Recalled Device personally or through their counsel, instead of returning their Other 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 22 and Paragraph 24(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.

IV. STIPULATIONS

21. Provided that Philips RS has substantially and in good faith complied with the terms of this Order, to the extent any Other Recalled 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 Other Recalled Device.

22. For any Recalled Device Claimant whose Other Recalled Device (or any component) is unavailable because it was returned to Philips RS after the date of this Order and was not preserved by Philips RS pursuant to the 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 Other Recalled Device (or components of that Other Recalled 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 Other Recalled 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.

23. For any Recalled Device Claimant who brings claims in this MDL or in any state court, and that individual's Other Recalled Device is unavailable because it was not required to be preserved under the terms of this Order, the Parties stipulate and agree that Recalled Devices preserved under 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 Other Recalled 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 Other Recalled Device specifically, but only other devices preserved under this Order. This provision applies to all Recalled Device Claimants whose Other Recalled 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.

24. This Order 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 Other Recalled 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 25 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 **Exhibit C** will preserve a sufficient sample of the entire population of recalled Other Recalled Devices for

purposes of later testing of a subset or subsets of that sample for purposes of analysis by the Parties' experts.

25. The Parties recognize the possibility that the foam in the Other Recalled 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 due to the passage of time after an Other Recalled Device has been bagged and stored pursuant to the Packaging and Storage Protocol in **Exhibit B**. The Parties shall meet and confer concerning the number of devices to be retained and the process of their selection, and, to the extent Plaintiffs or Defendants wish to inspect, evaluate, or test any of the devices retained pursuant to this paragraph, the protocol for doing so.

26. 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.

27. 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.

V. OTHER PROVISIONS

28. 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.

29. 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 Other Recalled Device to the DME, the Other Recalled 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 and/or the Settlement.

30. 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.

31. 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.

32. The Parties reserve the right to request further modification or amendment of this Order: (1) through the entry of a Recalled Device examination protocol; (2) as agreed by the Parties; or (3) for other good cause shown.

IT IS SO ORDERED.

Dated: February 26, 2024

BY THE COURT:

s/Joy Flowers Conti
Joy Flowers Conti
Senior United States District Judge

STIPULATED AND AGREED TO this 20th day of February, 2024

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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 Other Recalled Devices, or components thereof, returned to Philips RS pursuant to Sections II.A. of this Order.

1. After opening the packaging, an identifying label that identifies 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 Other Recalled Device 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 removed and stored in a binder with the serial number of the associated Device included.

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.

II. *Plaintiffs' and Represented Prospective Plaintiffs' Obligations for User-Preserved Other Recalled Devices.*

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

With respect to Other Recalled Devices, Plaintiffs and Represented Prospective Plaintiffs shall take these actions in order to receive the Parties' stipulations in Paragraphs 22 and 24(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 Other Recalled Device. If the Plaintiff or Represented Prospective Plaintiff has not received or obtained a replacement device and is using the Other Recalled Device, then upon receiving or obtaining a replacement device, they shall preserve the Other Recalled Device pursuant to the steps below:

1. The Other Recalled 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 Device. The humidifier will be preserved by placing it in the Poly bag with the Other Recalled 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.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 Other Recalled Device via a third-party storage facility, if that entity is instructed to follow the above-specified preservation process.

III. *Deadline for Compliance*

1. Philips RS shall comply with the provisions the Order and this Exhibit B upon entry of the Order. All Plaintiffs and Represented Prospective Plaintiffs shall comply with the provisions of this **Exhibit B** no later than 90 days after entry of this Order.

2. For any Plaintiff or Represented Prospective Plaintiff that (a) elects to User-Preserve their Other Recalled Device, (b) has not received or obtained a replacement device upon the entry of this Order, **and** (c) is using the Other Recalled Device, then the Plaintiff or Represented Prospective Plaintiff shall comply with the provisions of Section II of this **Exhibit B** no later than

60 days after they either (a) receive or obtain a replacement device, or (b) discontinue use of their Other Recalled Device, whichever is sooner.

Exhibit C

Protocol For Preservation of Additional Other Recalled Devices

This Protocol for Preservation of Additional Other Recalled Devices (“Protocol”) shall be used with respect to Other Recalled Devices that have been returned to Philips RS and sets forth the quantity of recalled devices and certain other components that Philips RS will preserve and retain, at least on an interim basis, after the date of entry of the Order, and how they will be selected for preservation, in accordance with Paragraph 30 of this Order.

1. Philips RS will preserve 100% of the System One Series 50 and System One Series 60 devices that are currently in Philips RS’s possession and being stored in at Philips RS’s facility in Cleveland, Ohio, representing approximately 33,000 devices. For all other System One Series 50 and System One Series 60 devices that are not on the Preservation Registry and either (i) are in Philips RS’s possession but not being stored at Philips RS’s facility in Cleveland, Ohio as of the date this Order is entered; or (ii) are returned to Philips RS after the date of this Order, Philips RS shall preserve at least seven and 1/2 percent (7.5%) of the System One Series 50 and System One Series 60 devices. The 7.5% sample will be obtained pursuant to a random sampling procedure whereby Philips RS will set aside and preserve the device, SD card (if present), and humidifier (if present), for devices in the sample.

2. Philips RS shall preserve 100% of all other models of Other Recalled Devices (*i.e.* devices other than the System One Series 50 and System One Series 60 devices addressed in the preceding paragraph) in Philips RS’s possession as of the date of the Preservation Order, or received after the date the Preservation Order is entered, returned by Recalled Device Users who are not included in the Preservation Registry.

3. The Other Recalled Devices preserved in this process will be packaged and stored in the manner provided for in Part I of **Exhibit B** to this Preservation Order.

4. Philips RS will provide an accounting of the randomly selected devices that are preserved pursuant to this **Exhibit C**, and the number of devices preserved pursuant to Section II.A.2. of the 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.

5. As discovery proceeds in this MDL, the Parties agree to periodically discuss whether modification of the preservation and retention of devices required under this Protocol is appropriate, including but not limited to the percentage of Other Recalled Devices required to be preserved pursuant to this Exhibit C.