NIGH GOLDENBERG RASO & VAUGHN

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

IN RE: PHILIPS RECALLED CPAP, BI-LEVEL PAP, AND MECHANICAL VENTILATOR LITIGATION This Document Relates to: Potential Claimants	Master Docket No. 2:21-mc-1230 MDL No. 3014

PRETRIAL ORDER NO. 25(a)

MODIFYING CENSUS REGISTRY PROGRAM

The Court, upon consideration of the Joint Motion by Plaintiffs and Defendants to, *inter alia*, Modify Pretrial Order No. 25 Approving Census Registry Program as Pretrial Order No. 25(a), it is hereby ORDERED that the Motion is GRANTED.

The Census Registry Program Agreement (attaching the former Census Registry Form) that is currently made available for download from the Court's website at https://www.pawd.uscourts.gov/mdl-3014-re-philips-recalled-cpap-bi-level-pap-and-mechanical-ventilator-products-litigation shall be removed and replaced with the new Census Registry Program Agreement (with attachments, including the modified Census Registry Form), attached hereto as Exhibit A.

Dated: 11/16/2022

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

EXHIBIT A

EXHIBIT A

CENSUS REGISTRY PROGRAM AGREEMENT

Subject to the terms and conditions below, this agreement (the "Agreement") is by and between participating Potential Claimants and Philips RS North America LLC ("Philips RS"), Philips North America LLC, Philips Holding USA, Inc., Philips RS North America Holding Corporation, and Koninklijke Philips N.V. (collectively, "Philips").

This Agreement provides for the creation of a new and voluntary Court-approved Census Registry, and associated tolling, for Potential Claimants[1] who have not filed claims, but may file claims in the future, relating to the CPAP, BiPAP, and ventilator devices Philips RS has recalled (the "Recalled Devices").

Termination of Prior Tolling Agreement

1. Upon entry of an Order by the Court approving this Census Registry Program, Philips will provide notice that it is terminating the Tolling Agreement, dated February 4, 2022 (ECF No. 383) (the "Prior Tolling Agreement"), for all individuals who had previously participated in the Prior Tolling Agreement (the "Termination Notice"). Tolling benefits under the Prior Tolling Agreement shall end upon completion of the notice periods set forth in Paragraph 5 of the Prior Tolling Agreement.

2. As of the date of the entry of the Order approving this Census Registry Program, Philips hereby terminates any availability to participate in the Prior Tolling Agreement with respect to any individuals who have not yet entered into the Prior Tolling Agreement. No

[1] The term "Potential Claimant" refers to individuals who state that they are investigating potential claims related to the Recalled Devices but have neither filed, nor made a decision on whether to file, a lawsuit relating to any such potential claims in any court.

additional individuals may be added to the Prior Tolling Agreement following entry of the Order approving this Census Registry Program.

Census Registry Agreement Tolling

3. No Potential Claimant is obligated to participate in the Census Registry. Nor is there any obligation to bring a lawsuit by any individual on the Census Registry. In order to obtain the tolling provided for herein, however, participation in the Census Registry through compliance with this Agreement is required.

4. Philips agrees to the tolling of Limitations[2] with respect to any Claim(s)[3] held by a Potential Claimant as of the Effective Date for that Potential Claimant solely in accordance with the terms of this Census Registry Program Agreement. The "Effective Date" shall mean the date that a Census Registry Form ("CRF") is submitted on behalf of the Potential Claimant pursuant to Paragraph 8 below.

5. The "Tolling Period" for any particular Potential Claimant shall begin on the Effective Date for that Potential Claimant and shall end on the earlier of: (i) the date on which the Potential Claimant files or otherwise commences a tolled Claim against one or more of the Philips entities; or (ii) 90 days after any Philips entity provides written notice that it is withdrawing from this Agreement—either in its entirety as to all Potential Claimants, or with respect to a particular Potential Claimant or Claimants—with respect to tolling as to that particular Philips entity;

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[2] The term "Limitations" shall refer to any and all time limitations for filing or pursuing Claims, including statutes of limitation, statutes of repose, prescription, laches, and any other time bars, including, but not limited to, those based in equity, to the extent permitted by applicable law.

[3] The term "Claim(s)" shall refer to any claim(s) or cause(s) of action alleging personal injury (including for wrongful death) allegedly caused by a Recalled Device. The term "Claim" as defined herein specifically includes any punitive damages claims that may exist and wrongful death and/or survivorship, loss of consortium claims or other claims of representative or derivative claimants of the user of the Recalled Device, if any.

provided, however, that in the case of (ii), no such notice shall be served during the 18-month period after entry of the Order approving this Census Registry Program.

6. If any Philips entity gives notice of their intent to terminate this Agreement as to all Potential Claimants, that Philips entity, or those Philips entities, will work cooperatively to provide notice to all Potential Claimants, including by filing notice with the Court and distributing a notice to persons who have registered on the Census Registry.

7. The tolling of Limitations is not intended to, and shall not for any purposes be deemed to, limit or adversely affect any defense, other than a Limitations defense, that Philips has, may have, or would have had in the absence of Census Registry Tolling. Nor does the tolling of Limitations hereunder limit or adversely affect any Potential Claimant from asserting any argument against any Limitations defense that Philips may assert, or other tolling to any Limitations period based upon any discovery rule or on any other legal or equitable basis. Further, Census Registry Tolling does not have any impact on any tolling provided to a Potential Claimant under the Prior Tolling Agreement for those individuals who previously entered into the Prior Tolling Agreement. For the avoidance of doubt, for those Potential Claimants who avail themselves of both the Prior Tolling Agreement and Census Registry Tolling, the Tolling Period afforded Potential Claimants by Census Registry Tolling is addition to, and not in lieu of, tolling afforded by the Prior Tolling Agreement.

Census Registry Form

8. Within 5 days of entry of the Order approving this Census Registry Program, Philips will make available through MDL Centrality the CRF attached to this Agreement. Submission through MDL Centrality of a completed and signed CRF, including a signed Limited Authorization To Disclose Health Information for certain data on Care Orchestrator,

DreamMapper and/or EncoreAnywhere relating to Recalled Device usage and ambient temperature and ambient humidity ("Data Release Form"), will provide a Potential Claimant with Census Registry Tolling, as described above. Potential Claimants shall not bear any expenses in association with collection of the data subject of the Data Release Form.

9. CRFs must be substantially complete, which means a Potential Claimant must:

i. Answer all applicable questions (Potential Claimants may answer questions by indicating "not applicable," "I don't know," or "I don't recall," or "unknown" where such response is made in good faith in accordance with the signed counsel certification); and

ii. Include a completed and signed Data Release Form.

10. If a Potential Claimant serves a CRF that is not substantially complete, Philips shall notify the Potential Claimant's counsel. The Potential Claimant will then have one 30-day period to serve a substantially complete CRF to Philips (the "Cure Period") in order to obtain the tolling benefits set forth herein. Provided the Potential Claimant serves a substantially complete CRF within the Cure Period, the Effective Date for tolling will relate back to the date the Potential Claimant originally served his or her CRF.

Confidentiality of Census Registry Forms & Related Data; Use of Information

11. CRFs, the information and data reflected therein, and information and data produced in response to Data Release Forms shall be deemed "Confidential" information of Third Parties, and accorded treatment as such by Receiving Parties, as provided by the applicable Protective Order. Such treatment shall be afforded the CRFs and associated information and data regardless of the presence or absence of any formal confidentiality designation on the CRFs, information, or data themselves. Such information shall be made available to the parties and their counsel in MDL 3014 for use in the litigation.

12. Recognizing that the Census Registry is drawn from the potential claims of Potential Claimants that are unfiled and in many cases not yet vetted by counsel, Philips and Plaintiffs' leadership agree that information obtained through the Census Registry, including data and information contained on CRFs, or obtained from Data Release Forms, shall not be employed by any party in connection with or in opposition to the bellwether selection process, including to support or oppose (a) the selection of any case for any discovery or bellwether pool, (b) the selection of any case as representative of some broader segment of cases, or (c) the selection of a case for any trial or consolidation of cases. In the event that a Potential Claimant files suit against one or more of the Philips entities, then information obtained by Philips pursuant to that Potential Claimant's CRF, subject to the reservations of Paragraph 14, may be used in the MDL litigation in any lawsuit asserting claims by that Potential Claimant.

13. Given the anticipated composition of the Potential Claimant pool on the Census Registry, Plaintiffs' leadership specifically objects to any disclosure of information obtained through the Census Registry for purposes other than (i) the vetting of Potential Claimants' potential claims by counsel for those Potential Claimants, and (ii) understanding the composition of unfiled and unvetted claims by Plaintiffs' leadership and by Philips. Philips disagrees that the information obtained through the Census Registry should be limited in the ways set forth in this Paragraph 13, but the parties agree to preserve all their arguments should any party seek to use such information for other purposes.

Additional Terms

14. Nothing in this Agreement or the parties' participation in the Census Registry shall impact any party's rights or positions, including with respect to the admissibility of the data or information obtained through the CRF or Data Release Form, as well as which evidence constitutes

sufficient proof of usage or injury and with respect to any future discovery, or the scope of such discovery.

AGREED TO THIS 23rd DAY OF AUGUST, 2022:

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IN RE: PHILIPS RECALLED CPAP, BI-LEVEL PAP, AND MECHANICAL VENTILATOR PRODUCTS LIABILITY LITIGATION

CENSUS FORM FOR POTENTIAL CLAIMANTS

*If you have already filed a lawsuit relating to a Philips Respironics Device, please do **not** complete this form. Instead, you are or will be required to complete a Plaintiff Fact Sheet.*

I. POTENTIAL CLAIMANT/COUNSEL INFORMATION

(If you are filling this out on behalf of someone else, please list the user of the Philips Respironics Device as the Potential Claimant)

1. Potential Claimant's Name:

2. Potential Claimant's Date of Birth:

3. Potential Claimant's Address:

4. Potential Claimant's Registering Counsel (including firm name):

II. PHILIPS RESPIRONICS DEVICE AND USAGE INFORMATION

5. List each Model of Philips Respironics Device Used:
(If you used more than one Philips Respironics Device, complete the questions in this Section II for each Device used.)

☐ *E30 (Emergency Use Authorization)* ☐ *DreamStation ASV* ☐ *DreamStation ST, AVAPS* ☐ *SystemOne ASV4* ☐ *C-Series ASV* ☐ *C-Series S/T and AVAPS* ☐ *OmniLab Advanced +* ☐ *SystemOne (Q-Series)* ☐ *DreamStation* ☐ *DreamStation Go* ☐ *Dorma 400*	☐ *Dorma 500* ☐ *REMstar SE Auto* ☐ *Trilogy 100* ☐ *Trilogy 200* ☐ *Garbin Plus, Aeris, LifeVent* ☐ *A-Series BiPAP Hybrid A30 (not marketed in U.S.)* ☐ *A-Series BiPAP V30 Auto* ☐ *A-Series BiPAP A40* ☐ *A-Series BiPAP A30* ☐ *Other Philips Respironics Device*; if other, identify the model or indicate if you do not recall:

Model	***Serial Number***	***Approximate Date Began Using***	***Approximate Date Stopped Using (if Applicable)***

6. For what reason or condition was the Philips Respironics Device prescribed by the Potential Claimant's physician?

7. Did Potential Claimant ever use an ozone-based cleaning device (*e.g.*, SoClean, Respify, Sleep8, VirtuOx, etc.) with Potential Claimant's Philips Respironics Device?

☐ *Yes* ☐ *No*

If yes, please identify manufacturer of cleaning device: _____

III. REPLACEMENT DEVICE INFORMATION

8. Has Potential Claimant registered his or her Philips Respironics Device for repair or replacement on the Philips Respironics website [https://www.usa.philips.com/healthcare/e/sleep/communications/src-update]?

☐ *Yes* ☐ *No*

If yes, please provide registration code: _____.

9. Has Potential Claimant received a repaired or replacement device from Philips Respironics?

☐ *Yes* ☐ *No*

IV. INFORMATION CONCERNING ALLEGED INJURY OR INJURIES

10. Has Potential Claimant experienced any physical injury in connection with the Potential Claimant's use of the Philips Respironics Device?

☐ *Yes* ☐ *No*

If yes, please select the injury or injuries below:

- ☐ Eye Irritation
- ☐ Nose Irritation
- ☐ Skin Irritation
- ☐ Respiratory Tract Irritation
- ☐ Dizziness and/or Headache
- ☐ Hypersensitivity
- ☐ Nausea / Vomiting
- ☐ Asthma (new or worsening)
- ☐ Inflammatory Response
- ☐ Kidney Disease/Toxicity
- ☐ Liver Disease/Toxicity
- ☐ Lung Disease
- ☐ Reduced Cardiopulmonary Reserve
- ☐ Cancer: _____ [specify type]
- ☐ Death (if you are completing this form for the Device user)
- ☐ Other: _____

RELEASE FORM FOR CARE ORCHESTRATOR, DREAMMAPPER AND ENCOREANYWHERE DATA

Potential Claimant must complete, sign and return the enclosed Limited Authorization To Disclose Health Information for data maintained by Philips RS North America LLC on Care Orchestrator, DreamMapper and/or EncoreAnywhere relating to Recalled Device usage and ambient temperature and ambient humidity.

* * * * *

Either Potential Claimant or their counsel, but not both, must sign below:

By signing this Census Form, counsel confirms that they or their agent have discussed with the Potential Claimant and the Potential Claimant has confirmed the accuracy of the information provided herein.

Date: _____ _____

Counsel Signature

By signing this Census Form, Potential Claimant confirms the accuracy of the information provided herein.

Date: _____ _____

Potential Claimant Signature

LIMITED AUTHORIZATION TO DISCLOSE HEALTH INFORMATION
(Pursuant to the Health Insurance Portability and Accountability Act "HIPAA" of 4/14/03)

TO: Philips RS North America LLC

Patient Name: _____

DOB: _____

SSN: _____

City/State: _____

I, _____, hereby authorize you to release and furnish to: Litigation Management Inc., PO Box 241370, Cleveland, OH 44124 COPIES ONLY of the following information:

* Usage, temperature and humidity data from Care Orchestrator, DreamMapper and/or EncoreAnywhere.

1. I am a potential claimant in connection with MDL 3014 and provide this authorization in connection with my participation in the Census Registry.
2. To my medical provider: this authorization is being forwarded by, or on behalf of, attorneys for the defendants. This authorization is for the sole purpose of allowing copies of the above-mentioned medical records to be provided to the named parties and their counsel in MDL 3014. I understand and consent to the disclosure of this information to the named parties and their counsel in MDL 3014 for use in the litigation. It does not allow discussions of my medical history, care, treatment, diagnosis, prognosis, information revealed by or in the medical records, or any other matter bearing on my medical or physical condition.
3. I understand that I have the right to revoke this authorization at any time. I understand that if I revoke this authorization I must do so in writing and present my written revocation to the health information management department. I understand the revocation will not apply to information that has already been released in response to this authorization. I understand the revocation will not apply to my insurance company when the law provides my insurer with the right to contest a claim under my policy. Unless otherwise revoked, this authorization will expire in one year.
4. I understand that authorizing the disclosure of this health information is voluntary. I can refuse to sign this authorization. I need not sign this form in order to assure treatment. I understand I may inspect or copy the information to be used or disclosed as provided in CFR 164.524. I understand that any disclosure of information carries with it the potential for an unauthorized re-disclosure and the information may not be protected by federal confidentiality rules. If I have questions about disclosure of my health information, I can contact the releaser indicated above.
5. A notarized signature is not required. CFR 164.508. A copy of this authorization may be used in place of an original.

Print Name: _____(Potential Claimant/Representative)

Signature: _____(Potential Claimant/Representative)

Date: _____