

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

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

Master Docket: Misc. No. 21-01230

This Document Relates To:
All Actions

MDL NO. 3014

STIPULATED PROTECTIVE ORDER

WHEREAS, existing and future cases involving claims related to certain recalled Continuous Positive Airway Pressure (CPAP), Bi-Level Positive Airway Pressure (Bi-Level PAP), and mechanical ventilator devices have been centralized for coordinated or consolidated pretrial proceedings into MDL 3014 (the “Action”¹);

WHEREAS, the Plaintiffs and Defendants in this Action (collectively, the “Parties”), by and through their respective counsel,² stipulate, pursuant to Federal Rule Civil Procedure 26(c), to the entry of the following Stipulated Protective Order (“Protective Order”) to govern the use, production, storage, handling, and disclosure of documents, information, things, and testimony in this Action;

WHEREAS, the Parties have further moved this Court to order the adoption of this Protective Order; and

¹ As used in this Protective Order, “Action” means the above-captioned Multi-District Litigation pending in the Western District of Pennsylvania, Master Docket No. 21-mc-01230, MDL 3014, any individual cases filed in or transferred to the MDL, any cases remanded from the MDL, and any appeals arising from any such cases.

² This Protective Order was negotiated on behalf of Plaintiffs by Interim Lead Plaintiffs’ Counsel appointed by the Court in Pretrial Order #2 to facilitate the early, informal exchange of documents and information to help the Parties reach an informed agreement on a stipulated preservation protocol. Consistent with the provisions of paragraph X(B) herein, the terms of the Protective Order shall remain in full force and effect until modified, superseded, or terminated on the record by agreement of the Parties or by Order of the Court.

WHEREAS, the Court has reviewed the terms of the Protective Order.

ACCORDINGLY, to expedite the flow of discovery material, facilitate the prompt resolution of disputes over confidentiality, protect material entitled to be kept confidential, and ensure that protection is afforded only to material entitled to such treatment, it is ORDERED pursuant to this Court's authority under Fed. R. Civ. P. 26(c) and 28 U.S.C. § 1407(b):

I. PURPOSES AND SCOPE OF PROTECTIVE ORDER

A. Discovery in this Action, including any appeal, may involve the production of information containing personal identifying information, personal health information, financial information, proprietary commercial or business information, trade secret information, information subject to one or more U.S. or foreign data privacy laws or regulations, and/or other sensitive or confidential information for which protection from public disclosure and use for any purpose other than this Action is warranted.

B. This Protective Order is necessary to protect hard copy and electronic materials, devices, and other products of discovery, as well as all of the information and data contained therein and/or derived therefrom, including but not limited to Document(s), data, information, devices and other things, electronically stored information, responses to discovery requests and subpoenas under the Federal Rules of Civil Procedure, deposition testimony, transcripts of non-public hearings, affidavits, certifications, declarations, expert reports and supporting data, and other information—including all copies, excerpts, and summaries thereof (“Discovery Material”) produced and/or received in this Action; to establish a procedure for disclosing such Discovery Material to the parties in this Action; to impose obligations on persons receiving such documents and other information to protect it from unauthorized use or disclosure; and to establish a procedure for objecting to confidentiality designations.

C. This Protective Order governs the use, production, storage, handling, and disclosure of Discovery Material produced, submitted, or otherwise supplied by any Party or any other individual or entity in connection with this Action by any Party or any Third Party (the “Producing Party”) to any other Party (the “Receiving Party”).

D. The protections conferred by this Protective Order cover Protected Information produced in discovery in this Action as well as (1) any information copied or extracted from Protected Information; (2) all copies, excerpts, summaries, or compilations of Protected Information; and (3) any testimony, conversations, or presentations by Parties or their counsel that reveal Protected Information. However, the protections conferred by this Protective Order do not cover the following information: (a) any information that is in the public domain at the time of disclosure to a Receiving Party or becomes part of the public domain after its disclosure to a Receiving Party as a result of publication not involving a violation of this Protective Order, including becoming part of the public record through trial or otherwise; and (b) any information obtained by the Receiving Party from a source who obtained the information lawfully and under no obligation of confidentiality to the Designating Party.

E. This Order does not restrict or limit the use of Protected Information that is admissible under the Federal Rules of Evidence at any trial in this MDL, any trial in any individual case coordinated in this MDL, or at any trial in a remanded action. Nothing in this Order, however, shall prevent any Party from seeking an appropriate protective order to govern the use of such Protected Information at trial.

F. This Protective Order is binding upon the Parties in this Action, as well as their respective attorneys (including associates, assistants, paralegals, and employees), experts (both testifying and consulting) including persons employed by such experts, consultants, agents,

representatives, officers, directors, employees, any individual or entity who becomes a Party to this Action, and others as set forth in this Protective Order.

G. Third Parties may avail themselves of, and agree to be bound by, the terms and conditions of this Protective Order, and thereby become a Designating Party and/or Receiving Party for purposes of this Protective Order. The ability of any such Third Party to become a Receiving Party is contingent on the Third Party signing a copy of the Declaration attached as Exhibit A to this Protective Order or a Court Order binding that Third Party to this Protective Order, or in the case of a deposition of a Third Party deponent, compliance with Section IV(H) of this Protective Order.

H. If additional Parties are added to this Action, they shall be bound by this Protective Order.

I. The entry of this Protective Order does not prevent any Party from seeking a further Order of this Court pursuant to Federal Rules of Civil Procedure 26(c) or 37(a).

J. Nothing in this Protective Order shall affect any right of a Party or witness to make any otherwise proper objection, claim, or response to discovery requests (including, without limitation, interrogatories, requests for admission, requests for production, or questions at deposition).

K. This Protective Order shall not be construed as a waiver by any Party of any applicable privilege to withhold production of Discovery Material, or of any right which any Party may have to assert such privilege at any stage of the litigation of this Action.

L. Nothing in this Protective Order shall preclude any Party or its representatives from inspecting, reviewing, using, or disclosing its own Protected Information in this Action or in matters unrelated to this Action.

M. This Protective Order is HIPAA-compliant pursuant to 45 C.F.R. § 164.512(e)(1)(v). The Parties agree that a Receiving Party (or any other person who receives Protected Information from a Receiving Party) may use Protected Information only for the purposes of this Action, including documents that contain Protected Health Information and individually identifiable health information that is protected from unauthorized disclosure by the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), codified in 45 C.F.R. §§ 160, 164. The Receiving Party must destroy or return all documents containing Protected Health Information to the Producing Party (including all copies made) at the end of this Action pursuant to Section VIII of this Protective Order.

N. Nothing in this Protective Order shall prevent disclosure of Protected Information beyond the terms and conditions of this Protective Order if the Designating Party consents in writing to such disclosure.

O. This Protective Order does not relieve any Party of its obligations to respond to discovery in this Action, and nothing in this Protective Order shall prevent a Party from using or disclosing Discovery Material, including Protected Information, obtained through discovery as necessary to meet reporting obligations to U.S. or foreign governmental agencies, including but not limited to the FDA.

II. ADDITIONAL DEFINITIONS

A. “Confidential” means information of any type, kind or character that a Party believes in good faith constitutes, reflects, discloses, or contains: (1) information that the Designating Party reasonably believes constitutes a trade secret under applicable statutory and case law; (2) information that the Designating Party reasonably believes constitutes sensitive technical or proprietary business information that, if disclosed, may result in an unfair competitive, financial,

or commercial advantage to others or disadvantage to the Designating Party; (3) Protected Health Information, as defined herein; (4) personal identifying information, personal data, sensitive personal data, or other data the Designating Party believes in good faith to be subject to federal, state, or foreign Data Protection Laws; or (5) any other sensitive information or tangible things (regardless of how they are generated, stored or maintained) that requires protection under Federal Rule of Civil Procedure 26(c).³ A designation as Confidential can apply to information contained within a document, revealed during a deposition or other testimony, revealed in a written discovery response, or otherwise revealed. This Protective Order shall be understood to encompass not only those items or things that are expressly designated as Confidential, but also Confidential information contained in copies, excerpts, and summaries thereof, testimony, oral communications, and other work product.

B. “Copies” means any photocopies, reproductions, duplicates, extracts, summaries, notes, or descriptions of Discovery Material and/or Protected Information.

C. “Competitor” means any person or entity who is in the same business or commercial stream as the Designating Party, including but not limited to any other person or entity involved in the design, development, manufacture, distribution, sale, or marketing of positive airway pressure machines (including Continuous Positive Airway Pressure, Bi-Level Positive Airway Pressure machines), and mechanical ventilator prescription medical devices.

D. “Data Management Service” means a person or entity that manages, stores, and/or analyzes the data generated by the Devices at issue in this Action.

³ Nothing in this Protective Order shall be construed to limit the definition of Confidential as it is defined by Federal Rule of Civil Procedure 26(c) and applicable caselaw.

E. “Data Protection Laws” means any federal, state, or foreign laws governing data protection or other privacy obligations. Examples of such Data Protection Laws include, without limitation, The Gramm-Leach-Bliley Act, 15 U.S.C. § 6801 et seq. (financial information); The Health Insurance Portability and Accountability Act and the regulations thereunder (HIPAA), 45 CFR Part 160 and Subparts A and E of Part 164 (medical information); Fair Credit Reporting Act (FCRA), 15 USC § 1681 et seq. (financial information); Electronic Communications Privacy Act of 1986, 18 U.S.C. § 2511 (private communication); Genetic Information Non-discrimination Act of 2008 (GINA) (biometric information); the California Consumer Privacy Act (CCPA); Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the Protection of Natural Persons with Regard to the Processing of Personal Data and on the Free Movement of Such Data (General Data Protection Regulation or GDPR); the UK General Data Protection Regulation (UK GDPR); Data Protection Act 2018 (c. 12) (United Kingdom personal information); the Swiss Federal Act on Data Protection of 19 June 1992 (FADP) and the Swiss Revised Federal Act on Data Protection of 25 September 2020 (Revised FADP); Personal Information Protection and Electronic Documents Act (PIPEDA), S.C. 2000, c. 5 (Canada personal information); The Federal Law on Protection of Personal Data held by Private Parties (published July 5, 2010) (Mexico personal information); and The Act on the Protection of Personal Information (Law No. 57 of 2003) (APPI) (Japan personal information); The Information Security Technology Personal Information Security Specification GB/T 35273-2017 (China Data Protection Law); and China’s 2021 Personal Information Protection Law (PIPL).

F. “Designating Party” means any Party or Third Party who has designated the Discovery Material at issue as Confidential or Highly Confidential – Attorney’s Eyes Only.

G. “Devices” means those Continuous Positive Airway Pressure, Bi-Level Positive Airway Pressure, and mechanical ventilator prescription medical devices that are at issue in this Action.

H. “Document(s)” shall be defined as they are in the Federal Rules of Civil Procedure and Federal Rules of Evidence, whether produced or created by a Party or another person or entity, and whether produced pursuant to the Federal Rules of Civil Procedure, the Local Rules of this Court, subpoena, agreement of the Parties, or otherwise. “Document(s)” encompasses hard-copy and electronically stored information, and shall include, but not be limited to: writings, drawings, graphs, charts, photographs, sound recordings, images, other data and data compilations, interrogatory answers, responses to request for production, responses to requests for admission, deposition testimony, deposition exhibits, hearing testimony, hearing exhibits, trial testimony, and trial exhibits, as well as all Copies of any of these materials.

I. “DME” means a supplier of durable medical equipment, including suppliers of the Devices at issue in this Action.

J. “Expert” means a person with specialized knowledge or experience in a matter pertinent to the Action who has been retained by a Party or its counsel to serve as an expert witness or expert consultant in the Action. No Party or employee of a Party shall qualify as an expert for purposes of this Protective Order.

K. “Highly Confidential – Attorney’s Eyes Only” means information of any type, kind, or character that the Designating Party believes in good faith constitutes, reflects, discloses, or contains highly confidential commercial, business, financial, or competitive information including proprietary research, development, manufacturing, and/or production information; business and prospective marketing plans; trade secrets; customer lists; pricing, market share, cost, and

projected sales data; data relating to mergers and acquisitions; non-public dealings with or internal deliberations concerning any regulatory body, including but not limited to the FDA; and other information of a highly sensitive nature, which is not publicly available, the disclosure of which may cause the Designating Party competitive harm.

L. “Party” means a party to this Action, as well as any officers, directors, and employees of such Party.

M. “Privacy Information” means any documents containing an individual's social security number or taxpayer identification number (other than only the last four digits thereof), an individual's birth date (other than only the year of the individual's birth), the name of an individual known to be a minor (other than only the minor's initials), a financial account number (other than only the last four digits thereof), "Personal Data," "Personally Identifiable Information," "Sensitive Private Data," or "Nonpublic Personal Information" as these terms are defined under federal, state or foreign data protection laws, including without limitation the GDPR, or any information that a party or non-party believes in good faith to be subject to non-US data protection laws, regardless of whether such information has been designated as "Confidential” or “Highly Confidential – Attorney’s Eyes Only” (collectively “Privacy Information”).

N. “Protected Health Information,” as used herein, shall have the same definition as set forth in 45 CFR § 160.103.

O. “Protected Information” means information that has been designated Confidential and/or Highly Confidential – Attorney’s Eyes Only, as those terms are defined in this Protective Order.

P. “Third Party” means any individuals or entities which are not parties to the Action.

III. DESIGNATION OF CONFIDENTIALITY

A. All Discovery Material produced or generated in this action pursuant to the discovery provisions of the Federal Rules of Civil Procedure, the Local Rules for the District of Western District of Pennsylvania, by order of this Court, or otherwise, and which contain, describe, identify, or refer to Protected Information shall be subject to the provisions of this Protective Order. Any Party shall have the right to designate, prior to production, any Discovery Material or portion thereof, as Confidential or Highly Confidential – Attorney’s Eyes Only using the procedures set forth in Section III(B).

B. Method of Designation

Any Discovery Material that is eligible for designation as Confidential or Highly Confidential – Attorney’s Eyes Only as defined in this Protective Order above may be so designated in the following ways:

i. ***Hardcopy Discovery Material:*** Discovery Material in hardcopy form that includes Protected Information shall be marked with the words “Confidential – Subject to Protective Order” or “Highly Confidential – Attorney’s Eyes Only – Subject to Protective Order,” as appropriate, in such a way so as not to obscure any part of the text or content, so that the designation is communicated to the Receiving Party.

ii. ***Electronically Stored Information:*** ESI Discovery Material in a modifiable format shall be designated in accordance with the procedure outlined in Section III(B)(i). ESI Discovery Material not in a modifiable form shall be designated by (1) referring to the Confidential or Highly Confidential – Attorney’s Eyes Only Discovery Material in a cover letter accompanying the Discovery Material; (2) incorporating the appropriate designation into the file or directory name; or (3) affixing the appropriate designation to the media (*i.e.*, disc, hard drive, thumb drive,

etc.) containing the Discovery Material so that the designation is communicated to the Receiving Party. Whenever a Receiving Party reduces any such information to hard copy form, that Party shall mark the hard copy in accordance with the procedure outlined in Section III(B)(i).

iii. *Responses to Discovery Requests:* Any Protected Information contained in answers to interrogatories, responses to requests for production, or responses to requests for admission shall be designated as such by means of a statement within each of the answers or responses specifying that it is designated as Confidential or Highly Confidential – Attorney’s Eyes Only, as appropriate.

iv. *Transcripts and Exhibits:* All portions of any deposition or hearing transcript taken in the Action in which Protected Information is identified, discussed, or disclosed shall also be designated as Protected Information and shall be subject to the terms of this Protective Order. Within thirty (30) days after receiving a transcript, a Party may designate pages of the transcript and/or exhibits, or parts thereof as reasonable, as Protected Information by giving notice to all parties of same. Until expiration of the 30-day period, the entire transcript and any exhibits will be treated as Highly Confidential – Attorney’s Eyes Only subject to protection against disclosure under this Protective Order. Designation of a hearing transcript is subject to approval by the Court.

Protected Information within the transcript may be designated by indicating the portions of the pages that are Confidential or Highly Confidential – Attorney’s Eyes Only and marking such pages with the appropriate legend pursuant to the procedures set forth in Section III(B)(i). If portions of a deposition transcript or deposition exhibits have been so designated, the front page of the original transcript and each copy thereof shall be marked Confidential or Highly Confidential – Attorney’s Eyes Only, as appropriate. If all or part of a videotaped or otherwise

recorded deposition is designated as Confidential or Highly Confidential – Attorney’s Eyes Only, the physical recording media, such as videotape, DVD, removable computer drive, or audio recording shall be labeled with the appropriate designation. To the extent possible, the court reporter shall segregate into a separate transcript (the “Segregated Transcript”) all information that has been designated as Confidential or Highly Confidential pursuant to the procedures outlined in this Protective Order. The Segregated Transcript shall have page numbers that correspond to blank or redacted pages in the main transcript, and each such page will be marked Confidential or Highly Confidential – Attorney’s Eyes Only, as appropriate.

An exhibit to a deposition shall be treated in accordance with any confidentiality designation or redaction previously given to it, and if not previously designated as Protected Information, then according to the designation later applied under this section.

If a timely designation is made, the portions and exhibits designated shall be filed only under provisional seal, separate from the portions and exhibits not so designated, and all Copies of the portions and exhibits so designated shall be treated as Protected Information pursuant to the terms of this Protective Order. If any Party in good faith disagrees with a designation of any portion of a transcript or of any exhibit thereto as containing Protected Information, the procedures regarding objections to designations set forth in Section V of this Protective Order will govern.

v. *All other information or tangible items:* The Designating Party shall affix to the other information or tangible item itself, or in a prominent place on the exterior of the container or containers in which the information or item is stored, the designation Confidential or Highly Confidential – Attorney’s Eyes Only, as appropriate. If only a portion or portions of the information or item warrant protection, the Designating Party, to the extent practicable, shall identify the protected portion(s) and specify the level of protection being asserted.

C. Inspection of Discovery Material

If Discovery Material is produced for inspection at a Designating Party's facilities or other location agreed to by the Parties, such Discovery Material may be produced for inspection before being marked for designation, but all such Discovery Material shall be presumed to be Highly Confidential – Attorney's Eyes Only, and any copies or other reproductions made at that time shall be treated as so designated by all Parties, and shall remain as designated for thirty (30) days after inspection or receipt, during which time any Party or Third Party may designate such Discovery Material as Protected Information. If specific Discovery Materials are designated for copying during such inspection, the Discovery Material containing Protected Information may be marked as Confidential or Highly Confidential – Attorney's Eyes Only after copying but before delivery to the Party who inspected the Discovery Material. There will be no waiver of confidentiality by the inspection of Discovery Material before it is copied and marked as Confidential or Highly Confidential – Attorney's Eyes Only pursuant to this procedure.

D. Notice of Designation of Third Party Produced Discovery Material

i. Discovery Material produced by a Third Party must be treated by the Receiving Party as Protected Information for a period of thirty (30) days from the date the Discovery Material is produced to all of the Parties. In the event any Third Party produces Discovery Material containing a Party's Protected Information, that Party may designate such Discovery Material, or portions thereof, as Protected Information pursuant to the provisions in Section III(B)(i), by providing notice of such designation on all Parties within thirty (30) days of receipt.

E. Inadvertent Production and Correction of Designations

i. Inadvertent production of any Discovery Material without a designation of Confidential or Highly Confidential – Attorney’s Eyes Only will not be deemed to waive a later claim to its protected nature or preclude a Party from designating said Discovery Material as Confidential or Highly Confidential – Attorney’s Eyes Only pursuant to this Protective Order at a later date.

ii. A Designating Party that fails to designate Discovery Material as Confidential or Highly Confidential – Attorney’s Eyes Only, or fails to designate Discovery Material with the appropriate level of protection at the time of its production shall be entitled to make a correction to its designation. A correction shall be accomplished by serving written notice (“Notice of Correction”) to the Receiving Party within thirty (30) days following the discovery of the inadvertent production with incorrect designation or without designation. The Designating Party shall produce corrected versions of the Discovery Material with the appropriate designation within fourteen (14) business days of the date of service of the Notice of Correction. Upon receipt of the Notice of Correction, the Receiving Party shall (1) treat such Discovery Material with the level of protection specified in the Notice of Correction in accordance with the terms of this Protective Order from the date the Notice of Correction is received; (2) take reasonable steps to notify any person or entity known to have possession of any Discovery Material that was incorrectly designated; (3) promptly endeavor to procure all Copies of such incorrectly designated Discovery Material from persons or entities known to have possession of such Discovery Material who are not entitled to receipt of such Discovery Material under the terms of this Protective Order; and (4) promptly destroy or return all of the inadvertently produced Discovery Material with incorrect designation or without designation to the Designating Party. Within twenty-one (21) days

of (or for voluminous impacted productions, a reasonable agreed or ordered period of time) following receipt of the Notice of Correction, the Receiving Party of inadvertently produced Discovery Material with incorrect designation or without designation shall provide the Designating Party with written confirmation that the inadvertently produced Discovery Material with incorrect designation or without designation was destroyed or returned, or of the Receiving Party's failure to procure any inadvertently produced Discovery Material with incorrect designation or without designation, including the identification of that Discovery Material and the person or entity known to be in possession thereof. Any objection to a correction shall follow the procedures set forth in Section V of this Protective Order.

iii. The production of Discovery Material in an unredacted form that would otherwise be subject to redaction under this Protective Order shall not be deemed a waiver, in whole or in part, of a Party's claim that such Discovery Material contains Protected Information. To the extent a Party discovers the inadvertent production of such Discovery Material subject to redaction, the provisions of this Section shall apply.

F. Redaction of Third-Party Personal Information

i. Prior to producing Discovery Material that contain the names of patients other than Plaintiffs, the Designating Party may redact or delete the names, addresses, telephone numbers, social security numbers, and other information that would identify patients/research subjects, if such information is required to be withheld from disclosure by 21 C.F.R. § 20.63, the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 ("HIPAA") and related regulations, applicable federal and state privacy laws, and other applicable laws and regulations.

ii. The Designating Party may redact the following information contained in adverse event reports, consumer complaints, product experience reports, clinical studies, and other similar documents: names and any information that would identify the person (other than a Plaintiff or a Plaintiff's decedent) who used the Device. If the Designating Party produces copies of documents containing the names or other personal information of patients other than Plaintiffs or their physicians that is protected from disclosure pursuant to HIPAA or other governmental statute, rule, or regulation, neither the Parties nor their counsel shall disclose the names or other personal information or contact any such patient identified through the production of such documents. The prohibition does not apply, however, to information that was lawfully obtained through sources independent from the Designating Party's discovery productions.

iii. Nothing in this Section shall be construed to permit a Party to redact the names of any patients, healthcare providers, DMEs, or any individuals or entities that have serviced Devices at issue in this Action.

iv. Nothing in this Section shall be construed to affect a Party's ability to redact information pursuant to applicable law, such as information that is subject to the attorney-client privilege, work-product doctrine, legal prohibition against disclosure, or any other privilege or immunity. To the extent a Party seeks to redact material that it deems irrelevant or non-responsive in documents that also contain responsive material, the Parties agree to promptly meet and confer and negotiate in good faith regarding such redactions.

G. A Designating Party's designation of Protected Information under this Protective Order shall not be construed as an admission or an agreement by any other Party that the Discovery Material actually constitutes or contains Protected Information.

H. Any designation of Protected Information under this Protective Order shall not be construed as an admission or agreement by any Party that any Discovery Material, or portions thereof, constitutes competent, material, relevant, or admissible evidence in this Action.

IV. DISCLOSURE OF DISCOVERY MATERIAL AND PROTECTED INFORMATION

A. Any Discovery Material produced in this Action, including but not limited to any Discovery Material designated as Confidential or Highly Confidential – Attorney’s Eyes Only pursuant to the terms of this Protective Order, shall be used or disclosed only for purposes of this Action. Such Discovery Material shall not be used or disclosed for any other purpose, including but not limited to any business, competitive, personal, private, or public purpose. No Discovery Material designated as Protected Information, including but not limited to summaries of such Discovery Material, shall be produced or disseminated orally, or by any other means, except as permitted by this Protective Order. Notwithstanding the foregoing, nothing in this Protective Order shall be deemed to limit or restrict any Designating Party from using or disclosing its own Discovery Material for any purpose. The Designating Party may withdraw or modify any designation.

B. Discovery Material designated as Confidential shall not, without leave of this Court, be disclosed to any person or entity other than the following categories of persons:

- i. Counsel for the Parties (including members, partners, of-counsel, associates, or paralegals of such counsel's firm), and the employees of such counsel to whom it is reasonably necessary to disclose the information in this Action;
- ii. The Court (and any appellate court), including court personnel and any court-appointed special master;

- iii. Mediators, Arbitrators, and/or Early Neutral Evaluators, and the employees of such counsel to whom it is reasonably necessary to disclose the information to assist the mediator in connection with this Action;
- iv. Employees of outside copying, document imaging, litigation and trial support, and facsimile services to the extent reasonably necessary to render professional services in this Action, provided such persons first execute a copy of the Declaration attached as Exhibit A to this Protective Order;
- v. The persons who authored, created, or contributed to the preparation of the Discovery Material containing the Confidential information, or who are shown on the face of the Discovery Material, or through other documentary or testimonial evidence, to be an original author or recipient of the Discovery Material;
- vi. Experts or consultants who are retained by a Party or their counsel for to assist in the preparation and trial of this litigation, provided the expert or consultant first (i) execute a copy of the Declaration attached as Exhibit A to this Protective Order, and (ii) certify in writing that they are not Competitors or employed by Competitors. The Party shall maintain copies of all such Declaration(s) and certification(s), and shall serve copies of such Declaration(s) and certification(s) for testifying experts contemporaneously with its expert disclosures.;⁴

⁴ In no event shall a Receiving Party make disclosure to experts or consultants who are serving or have served as consultants, employees, officers, or directors of any Competitors of Defendants, or anyone who at the time of disclosure is anticipated to become a consultant, employee, officer, or director of any Competitor of Defendants, except pursuant to the terms of this provision. In the event a Receiving Party wishes to make a disclosure of Discovery Material designated as

- vii.** The Designating Party;
- viii.** Witnesses or deponents, provided they first execute a copy of the Declaration attached as Exhibit A to this Protective Order or otherwise comply with Section IV(H) of this Protective Order;
- ix.** Court reporters, videographers, and their support personnel to whom disclosure is reasonably necessary in this Action, provided they first execute a copy of the Declaration attached as Exhibit A to this Protective Order;
- x.** The Parties, their current and former officers, directors, and employees (including in-house counsel) to whom disclosure is reasonably necessary in this Action, except that former officers, directors, and employees must first execute a copy of the Declaration attached as Exhibit A to this Protective Order;
- xi.** Any other person to whom the Designating Party agrees in advance of the disclosure, in writing or on the record, to disclose it.
- xii.** Notwithstanding the foregoing, a Receiving Party shall provide written notice to the Designating Party of any Confidential Discovery Material at least fourteen (14) business days prior to any disclosure of Confidential

Confidential to any such experts or consultants, or to anyone who at the time of disclosure is anticipated to become such experts or consultants, the Parties shall meet and confer to determine a method to address such proposed disclosure. If the Parties are unable to agree on a method to address such proposed disclosure, the Party seeking to make the disclosure may file a motion with the Court requesting determination as to whether and under what circumstances such disclosure by the Receiving Party will be permitted. Prior to a determination by the Court on these issues, the Receiving Party may not disclose any Confidential Discovery Material to the proposed experts or consultants.

Discovery Material to any person known or reasonably believed to be a current or former employee, agent, consultant, officer, director of any Competitor of the Party whose Discovery Material is sought to be disclosed. Such written notice shall provide (1) a reasonable description of the person, including but not limited to their identity and their affiliation with the Competitor, to whom disclosure is to be made, sufficient to permit objections to be made, and (2) specify the Confidential Discovery Material the Receiving Party seeks to disclose. If a Party objects in writing to such disclosures within fourteen (14) business days of receipt of the written notice, no disclosure shall be made until the Party seeking to make the disclosure obtains prior approval of the Court or the objecting Party.

C. Discovery Material designated as Highly Confidential – Attorney’s Eyes Only shall not, without leave of this Court, be disclosed to any person or entity other than the categories of persons set forth in IV(B)(i)-(vii), (ix), and (xi). Counsel for a Receiving Party may give advice and opinions to his or her client solely related to this Action based on his or her evaluation of the Highly Confidential – Attorney’s Eyes Only Discovery Material, provided that such advice and opinions shall not reveal the content of the Highly Confidential – Attorney’s Eyes Only Discovery Material except by prior written agreement of counsel for the Parties or by Order of the Court.

D. Protected Information may not be disclosed to any persons or entities not identified in the categories specified in Sections 4(B) and 4(C), except if counsel for the Designating Party provides written consent prior to such disclosure. If counsel for the Designating Party refuses to give consent, the Protected Information shall not be disclosed. The Party requesting disclosure may request relief from the Court using the procedure set forth in Section V.

E. All persons or entities subject to this Protective Order who receive Discovery Material, as well as any other individuals permitted to receive Protected Information under any provision of this Protective Order, shall take all steps reasonably necessary to prevent disclosure of Protected Information other than in accordance with the terms of this Protective Order.

F. Third Party Requests for Protected Information

If any Receiving Party receives from any Third Party (including natural persons, corporations, partnerships, firms, governmental agencies, departments or bodies, boards, or associations) a subpoena or other process that seeks production or disclosure of Protected Information, the following provisions shall apply:

- i. The subpoenaed Party shall promptly, and in any case within seven (7) calendar days, give written notice by email to counsel for the Designating Party so that the Designating Party may have adequate time before the Discovery Material is to be produced to act pursuant to this Protective Order to guard against the disclosure of Protected Information. The written email notice shall identify the Discovery Material sought and the return date of the subpoena or other process, and include a copy of the subpoena or other process.
- ii. The subpoenaed Party shall also promptly inform the person or entity seeking the Protected Information that such information is subject to this Protective Order.
- iii. Within ten (10) business days of receipt of such notice, the Designating Party shall inform the subpoenaed Party or person either that it does not

object to production of the Discovery Material, or that it will seek Court protection to prevent such production.

- iv. If the Designating Party responds that it will seek court protection, then the subpoenaed Party or person may not produce the Discovery Material unless (1) the court denies such protection, or (2) the Designating Party fails to move the Court for such protection within thirty (30) days of its response.
- v. If the Designating Party responds that it will not seek court protection, then the subpoenaed Party or person may produce the Discovery Material.
- vi. If the Designating Party fails to respond to the written notice within fourteen (14) business days, the subpoenaed Party or person may produce the Discovery Material.

G. Use of Protected Information in Court Submissions

i. Any Party seeking to file any pleading, brief, memorandum, motion, letter, affidavit, exhibit, or other document with the Court that discloses, summarizes, describes, characterizes, or otherwise communicates Protected Information must seek approval from the Court to file under seal, in accordance with the Local Rules for the Western District of Pennsylvania, including Local Rule 5.2(H). If any Party fails to file Protected Information under seal, any Party may request that the Court place such filing under seal. A Party may submit a redacted filing contemporaneously with a motion to file under seal, provided the Party: (1) identifies only by Bates number any Discovery Materials constituting or containing Protected Information that would have been attached to the filing; and (2) completely redacts all Protected Information, as well as anything that contains, reflects, mentions, or in any way reveals the contents of Protected Information. If the Party filing the motion to seal is not the Designating Party,

the Designating Party shall file any additional information required to support a request to keep information under seal within ten (10) business days of the filing of the initial motion to seal.

ii. Any pleading, brief, memorandum, motion, letter, affidavit, exhibit, or other document to be filed under seal shall be filed using a procedure authorized in the Court's order granting leave to file under seal. First, the filing Party shall electronically file a redacted version of the document(s) using the Redacted Document event in the ECF system, unless otherwise ordered by the Court. Next after obtaining an order granting leave to file under seal, the filing Party shall deliver the unredacted version of the document(s) to the Clerk of Court. Assuming the Court issues its standard form order granting leave to seal, the filing Party may deliver the unredacted version of the document(s) to the Clerk by either: (1) making arrangements with the Intake Section to deliver the filing via email (if the filing is small enough for the Intake Section of the Clerk's Office to permit this method), or (2) delivering a disk containing the files, and a paper copy in a sealed envelope, to the Clerk's Office. Under either method, the filing Party must clearly mark the email or sealed envelope and disk with the case number, the docket number(s) corresponding to the previously filed redacted version of the document(s), and a notation that the documents are to be filed under seal and are subject to a protective order. All such material so filed shall be maintained by the Clerk's Office separate from the public records of this Action and shall be released only upon further Order of the Court, with the exception that the Clerk's Office may release such materials to Court personnel and to counsel of record for the Parties without further Order.

H. Use of Protected Information at Depositions & Hearings

i. A Party who seeks to introduce Discovery Material containing Protected Information at a hearing shall advise the Designating Party prior to publishing the Discovery

Material in Court. If the Designating Party requests that the protection be continued, the Court may review the Discovery Material *in camera* to determine if the Discovery Material is entitled to continued protection.

ii. If a Party, the current employee of a Party, or anyone represented by counsel for a Party, is noticed for deposition or to testify at a hearing, that Party's counsel is responsible for providing a copy of this Protective Order to the witness and obtaining the witness's signature on the Declaration attached as Exhibit A to this Protective Order prior to the deposition. If a Third Party is subpoenaed for deposition or hearing, prior to the examination of a Third Party witness at a deposition or non-public hearing, a Party proposing to disclose Protected Information to the witness shall obtain from the witness an executed copy of the Declaration attached as Exhibit A to this Protective Order. If a Third Party witness has refused to sign the Declaration, no Protected Information shall be disclosed to the witness unless (1) the issuing counsel provides the witness with a copy of the Protective Order; (2) the issuing counsel advises the witness on the record as to the purpose and effects of the Protective Order, and (3) the witness agrees on the record to be bound by the Protective Order.

iii. Provided that a deponent is subject to the provisions of this Protective Order, Discovery Material designated as Protected Information may be shown to the deponent during a deposition, but the deponent may not retain a copy of that Discovery Material.

iv. In the event that any question is asked at a deposition or non-public hearing, which a Party asserts calls for Protected Information, or Discovery Material containing Protected Information are identified as an exhibit or in testimony, such question shall nevertheless be answered by the witness fully and completely to the extent required by law. While a witness is being examined about any Protected Information, persons to whom disclosure is not authorized

under this Protective Order may be excluded from being present by the Designating Party, unless there is a legal basis to preclude exclusion.

v. In the case of deposition or a non-public hearing in which testimony may be heard or an exhibit introduced, the transcript, video, or exhibit, or portions thereof, as applicable, may be designated as Protected Information in accordance with the procedure set forth in Section III(B)(iv) this Protective Order. Pursuant to that section, the transcript shall be deemed Highly Confidential – Attorney’s Eyes Only during the thirty (30) days after receipt of the transcript.

vi. Any court reporter or transcriber in this case shall be informed before the beginning of the deposition or non-public hearing about this Protective Order and shall be asked to take appropriate steps to preserve Protected Information. Transcripts and exhibits generated in connection with any depositions or non-public hearings shall be handled in accordance with the provisions of Section III(B)(iv).

I. Improper Disclosure of Protected Information

If Discovery Material designated as Confidential or Highly Confidential – Attorney’s Eyes Only is disclosed to any person or entity other than in accordance with this Protective Order, regardless as to whether any such disclosure is inadvertent or otherwise, the Party responsible for the disclosure shall (1) immediately notify the Designating Party, including bringing all pertinent facts relating to such disclosure to the attention of the Designating Party; (2) use reasonable efforts to bind the recipient to the terms of this Protective Order; (3) make every effort to retrieve any Protected Information, confirm the destruction of all work product and other materials reflecting the Protected Information, and otherwise prevent further unauthorized disclosure on its own part or on the part of the recipient of such Discovery Material; and (4) request that the recipient of the

Discovery Material sign the Declaration attached as Exhibit A to this Protective Order. All such efforts shall be without prejudice to the rights and remedies of the Designating Party.

J. All persons receiving or given access to Protected Information in accordance with the terms of this Protective Order consent to the continuing jurisdiction of this Court for the purposes of enforcing this Protective Order and determining a remedy for a breach of this Protective Order.

K. Disclosure of Protected Information other than in accordance with the terms of this Protective Order may subject the disclosing person or entity to such sanctions and remedies as this Court deems appropriate. In the event a Designating Party reasonably anticipates that its Protected Information may be improperly disclosed, it may apply to the Court to obtain appropriate relief, including injunctive relief. In the event the aggrieved Designating Party seeks injunctive relief, it may petition the Court for such relief, which may be granted at the discretion of the Court. Any intentional violation of this Protective Order shall constitute contempt of Court, shall be punishable as such, and shall subject the offending Party and/or persons to such sanctions and remedies as the Court may deem appropriate. All rights at law are reserved for any violation of this Protective Order.

V. OBJECTIONS TO DESIGNATION

A. No Party is required to object to the propriety of designating Discovery Material as Confidential or Highly Confidential – Attorney’s Eyes Only at the time such designation is made. A failure to make an objection at the time of designation shall not preclude a subsequent objection thereto. In the event a Party objects to the designation of any Discovery Material as Confidential

or Highly Confidential – Attorney’s Eyes Only, the procedure set forth below in Section V(B) shall apply.

B. Counsel for the objecting Party shall serve on the Designating Party, and on all other Parties, a written objection to such designation which shall describe with particularity the Discovery Material in question and shall state the grounds for objection. Counsel for the Designating Party shall respond in writing to such objection within twenty-one (21) days of receiving the written objection, and shall state with particularity the grounds for asserting that the Discovery Material constitutes Protected Information. If no timely written response is made to the objection, the designation against which the objection was made will be deemed to be void. If the Designating Party makes a timely response to such objection asserting the propriety of the designation, counsel shall then meet and confer in good faith within fourteen (14) days of the date when the Designating Party's written response is dated in an effort to resolve the dispute. If the Parties are unable to resolve the dispute regarding the designation:

- i. The objecting Party may move the Court (or Special Master, if appropriate) for a ruling that the designation is improper. The objecting Party shall make its best efforts to consolidate any such objections into a few motions as practicable to save resources for both the Parties and the Court.
- ii. Within fourteen (14) days of an objecting Party’s motion, the Designating Party must file a response articulating its position as to each objection, and which Discovery Material, if any, is no longer being maintained as Protected Information.

iii. Within seven (7) days of the Designating Party's response, the objecting Party must file a reply articulating its position as to each remaining objection.

C. If such a motion is made by the objecting Party, the Designating Party shall bear the burden of establishing the propriety of the designation.

D. Any Discovery Material that is the subject of such a dispute shall be treated as originally designated until the dispute is resolved.

E. If the Designating Party agrees to change or remove the designation, the Designating Party shall send a written notice of the change in designation to all other Parties.

F. This Section shall also govern any objections related to whether Discovery Material designated as Highly Confidential – Attorney's Eyes Only should be designated as Confidential.

VI. CLAWBACK OF PRIVILEGED DISCOVERY MATERIAL

Inadvertent production of Discovery Material (hereinafter "Inadvertently Produced Discovery Material") claimed to be subject to the attorney-client privilege, the work-product privilege, or other legal privilege or doctrine protecting information from discovery shall not constitute a waiver of the privilege or doctrine. Procedures governing treatment of the inadvertent production of Discovery Material claimed to be subject to the attorney-client privilege, the work-product privilege, or other legal privilege or doctrine protecting information from discovery is set forth in the parties' proposed Rule 502(d) and Privilege Logging Protocol.

VII. STORAGE OF PROTECTED INFORMATION

A. The recipient of any Protected Information that is provided under this Protective Order shall maintain such Protected Information in a reasonably secure and safe manner, including reasonable administrative, technical, and physical safeguards designed to protect the security and

confidentiality of such information against unauthorized access and any other reasonably anticipated threats or hazards, and that ensures that access is limited to the persons authorized under this Protective Order, and shall further exercise the same or greater standard of due and proper care with respect to the storage, custody, use, and/or dissemination of such information as is exercised by the recipient with respect to its own proprietary information, but no less than the reasonable precautions set forth in this Protective Order.

B. Protected Information in electronic form shall be maintained in a secure litigation support site that applies standard industry practices regarding data security, including but not limited to, application of access control rights to those persons entitled to access the information under this Protective Order. A list of current and former authorized users of the Receiving Party's litigation support site shall be maintained while this Action, including any appeal, is pending.

C. Protected Information downloaded from the litigation support site in electronic format shall be stored or shipped only on devices or media (*e.g.*, laptop, tablet, smartphone, USB drive) that are encrypted with access limited to persons entitled to access Protected Information under this Protective Order.

D. Protected Information in hard copy format shall be maintained in the Receiving Party's counsel's law offices or comparably secure location, with access reasonably limited to persons entitled to access Protected Information under this Protective Order.

E. Electronic delivery of Protected Information shall be by secure File Transfer Protocol or encrypted email addressed only to persons entitled to access Protected Information under this Protective Order.

F. Physical shipments of Protected Information shall be securely sealed and addressed only to persons entitled to access Protected Information under this Protective Order.

G. If a Receiving Party or authorized recipient discovers any loss of Protected Information or a breach of security, including any actual or suspected unauthorized access, relating to another Party's Protected Information, the Receiving Party or authorized recipient shall: (1) promptly provide written notice to Designating Party of such breach within twenty-four (24) hours of the breach discovery; (2) investigate and make reasonable efforts to remediate the effects of the breach, and provide Designating Party with assurances reasonably satisfactory to Designating Party that such breach shall not recur; and (3) provide sufficient information about the breach that the Designating Party can reasonably ascertain the size and scope of the breach. The Receiving Party or authorized recipient agrees to cooperate with the Designating Party or law enforcement in investigating any such security incident. In any event, the Receiving Party or authorized recipient shall promptly take all necessary and appropriate corrective action to terminate the unauthorized access.

VIII. PROCEDURE FOLLOWING FINAL ADJUDICATION

A. Subject to Section VIII(B) below, within thirty (30) days of the final resolution of this Action (which final resolution includes expiration of any time for appeal), the Parties and counsel having possession, custody, or control of any Discovery Material designated as Confidential or Highly Confidential – Attorney's Eyes Only, shall be returned to counsel for the Designating Party or, alternatively, shall be destroyed. In addition, the Parties shall destroy the portions of any Discovery Material that contains, reflects, or mentions Protected Information. The Parties shall also obtain or destroy, at the election of the Designating Party, all such Protected Information previously provided to any experts, consultants, and any other individuals who executed a copy of the Declaration attached as Exhibit A to this Protective Order. At the conclusion of the 30-day period, each Receiving Party shall certify, in writing, that all Discovery Material that

contains, reflects, or mentions Protected Information has been returned to counsel for the Designating Party or has been destroyed.

B. Outside counsel for the Parties shall not, however, be required to return or destroy any pleadings, pretrial, or trial records as are regularly maintained by that counsel in the ordinary course of business. All such records shall continue to be maintained as Protected Information governed by this Protective Order.

C. The Clerk of Court shall maintain or dispose of all Discovery Material filed under seal and/or designated as Confidential or Highly Confidential – Attorney’s Eyes Only including, without limitation, all transcripts or other things which were subject to the provisions of this Protective Order, in accordance with the Federal Rules of Civil Procedure, the Local Rules of the Western District of Pennsylvania, and any applicable orders regarding the maintenance or disposal of sealed documents.

IX. AMENDMENT OF THIS PROTECTIVE ORDER

This Protective Order may be amended with leave of Court for good cause shown, or by the agreement of counsel for the Parties in the form of a stipulation submitted to the Court for approval.

X. MISCELLANEOUS PROVISIONS

A. Effective Date – This Protective Order shall become effective and binding on all Parties and their counsel on the date the Court approves and enters this Protective Order.

B. Duration – This Protective Order is intended to regulate the handling of Protected Information during this Action, but shall remain in full force and effect until modified, superseded, or terminated on the record by agreement of the Parties thereto or by Order of the Court. The obligations of this Protective Order shall survive any termination or resolution of this Action. This

Court shall retain jurisdiction to enforce the provisions of this Protective Order after final resolution of this Action, including but not limited to final adjudication of any appeals and petitions for extraordinary writs. After Final Disposition, all Protected Information shall be maintained and or destroyed pursuant to normal business practice and/or local Data Protection Laws.

C. Waiver – Any Party may expressly waive in writing the applicability of any provision of this Protective Order to any Discovery Material or portions thereof that the Party produces, or may effectuate a waiver pursuant to the terms of this Protective Order. Such waiver shall only apply to the Discovery Material or portions thereof to which the applicability of the specific provision of this Order is expressly waived.

D. Applicability to Future Parties – The terms of this Protective Order shall be binding on all current and future Parties to this Action and their counsel.

E. Inadmissibility of Protective Order – This Protective Order, including any discussion of the procedures and provisions herein, shall not be admissible in evidence. Counsel for a Party shall not, in the presence of the jury, comment on the Protective Order nor comment on the reasons or motivation for designating any Discovery Material as Confidential or Highly Confidential – Attorney’s Eyes Only without first having obtained leave of Court to do so.

F. Right to Supplement or Request Deletion – If during the course of litigation, a data subject with privacy rights pursuant to the Data Protection Laws identified herein exercises his or her right to erasure of personal data contained within the previously produced Protected Information, the Producing Party shall furnish newly redacted versions of the Protected Information within a reasonable time. The Requesting Party will promptly destroy the original version of the Protected Information and replace it with the redacted version. The Producing Party

may also require the entire document destroyed and replaced with a slip-sheet indicating the Protected Information is subject to erasure pursuant to the applicable Data Protection Law.

G. Personally Identifiable Information – Personally identifiable information that a party has designated as Protected Information as defined herein, based on its good faith belief that the information is subject to federal, state, or foreign Data Protection Laws, data privacy laws, or other privacy obligations, or any of the information contained therein, shall be handled by Counsel for the Receiving Party with the highest care.

AGREED TO AND STIPULATED TO BY:

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Dated: December 10, 2021

SO ORDERED.

/s/ JOY FLOWERS CONTI

Joy Flowers Conti

Senior United States District Court Judge

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

In Re: PHILIPS RECALLED CPAP, BI-LEVEL
PAP, AND MECHANICAL VENTILATOR
PRODS. LITIG.

Master Docket: Misc. No. 21-1230

MDL No. 3014

EXHIBIT A
ACKNOWLEDGMENT AND AGREEMENT TO BE BOUND

I, _____ [name], of _____ [address],
declare under penalty of perjury that I have been provided the opportunity to read in its entirety, the
Stipulated Protective Order (“Protective Order”) that was issued by the United States District Court
for the Western District of Pennsylvania, in the case of *In Re: Philips Recalled CPAP, Bi-Level
Pap, And Mechanical Ventilator Prods. Litig.*, and that I have either read the Protective Order, or I
have knowingly and voluntarily waived the reading of the entire Protective Order. I further declare
that I understand I am not permitted to disclose any Discovery Material designated as Confidential
and/or Highly Confidential – Attorney’s Eyes Only, or use any Discovery Material constituting or
containing Confidential and/or Highly Confidential – Attorney’s Eyes Only information for any
purpose other than as permitted in the Protective Order. I agree to comply with, and to be bound by
the terms of the Protective Order, and I understand and acknowledge that I will be subject to such
sanctions and remedies as the Court deems appropriate for violations of this Protective Order.

I further agree to submit to the jurisdiction of the United States District Court for the
Western District of Pennsylvania for the purpose of enforcing the terms of the Protective Order,
even if such enforcement proceedings occur after termination of this lawsuit.

Date: _____

Signature: _____