

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION							
DISTRICT ADDRESS AND PHONE NUMBER US Customhouse Rm900 200 Chestnut St Philadelphia, PA 19106 (215) 597-4390 Ext:4200 Fax: (215) 597-0875		DATE(S) OF INSPECTION 8/26/2021-11/9/2021* FEI NUMBER 2518422					
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Rodney D. Mell, Head of Quality							
FIRM NAME Philips Respironics, Inc.		STREET ADDRESS 1001 Murry Ridge Ln					
CITY, STATE, ZIP CODE, COUNTRY Murrysville, PA 15668-8517		TYPE ESTABLISHMENT INSPECTED Medical Device Manufacturer					
<p>This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.</p> <p><i>The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.</i></p>							
<p>DURING AN INSPECTION OF YOUR FIRM I OBSERVED: OBSERVATION 1 Risk analysis is inadequate.</p> <p>Specifically,</p> <p>a) There is no documented investigation, risk analysis, or design failure mode effect analysis to support your firm's rationale for which polyester polyurethane foam-containing products were affected, included, or not included in your firm's ongoing recalls. Your firm is currently conducting on-going, Class 1 medical device recalls of various models of Philips Respironics ventilator, CPAP, and BiPAP devices, due to polyester polyurethane foam degradation and volatile organic compound emission, which was publicly announced on 06/14/2021.</p> <p>The provided justification document titled, "REQ 310 - Rationale for Concluding which Devices are Impacted by the Recall" does not document the performance or results of an investigation, risk analysis, or design failure mode effect analysis, therefore you have not sufficiently demonstrated that other devices, also containing polyester polyurethane foam, should not be included in your ongoing recalls, as well.</p>							
SEE REVERSE OF THIS PAGE		<table border="0" style="width: 100%;"> <tr> <td style="width: 60%;"> EMPLOYEE(S) SIGNATURE Katelyn A Staub-Zamperini, Investigator </td> <td style="width: 40%; text-align: center; vertical-align: bottom;"> <div style="border: 1px solid black; padding: 5px; margin: 0 auto; width: 80%;"> Katelyn A Staub-Zamperini Investigator Signed By: Katelyn A. Staub-Zamperini -s Date Signed: 11-09-2021 DE: 1:23 </div> </td> </tr> <tr> <td></td> <td style="text-align: center;"> <div style="border-top: 1px solid black; width: 100%;"></div> </td> </tr> </table>		EMPLOYEE(S) SIGNATURE Katelyn A Staub-Zamperini, Investigator	<div style="border: 1px solid black; padding: 5px; margin: 0 auto; width: 80%;"> Katelyn A Staub-Zamperini Investigator Signed By: Katelyn A. Staub-Zamperini -s Date Signed: 11-09-2021 DE: 1:23 </div>		<div style="border-top: 1px solid black; width: 100%;"></div>
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- b) No investigation, health hazard evaluation, risk analysis, or design review was performed or documented when your firm was made aware that a preventative maintenance procedure for Trilogy ventilator devices was being implemented by another Philips entity in (b) (4) due to potential foam degradation, and related complaints, on Trilogy ventilator devices in the field.

On or around 11/25/2015, your firm was aware and knowledgeable of a preventative maintenance servicing procedure implemented by another Philips entity in (b) (4) on Trilogy ventilator products, and no further investigation, health hazard evaluation, risk analysis, or design review was performed, or documented by your firm. This preventative maintenance was implemented by Philips (b) (4) LTD., in (b) (4) only, in response to foam degradation issues and complaints in the field related to Trilogy ventilator products.

Your firm provided the email, dated 11/25/2015, sent from the other Philips entity to applicable servicing technicians/departments within their organization, detailing this new preventative maintenance procedure and timeline. This email was provided in response to an inspection request for any applicable documentation, communication, investigation, or follow-up that your firm has or did, in response to these polyester polyurethane foam degradation complaints/issues received in or prior to 2015, and this resulting preventative maintenance, implemented by another Philips entity in (b) (4)

No further investigation, health hazard evaluation, risk analysis, or design review was performed or documented by your firm regarding potential polyester polyurethane foam degradation on any Philips

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Sleep and Respiratory Care products. Additionally, no further preventative maintenance servicing procedures were implemented by your firm.

Your firm is currently conducting on-going, Class 1 medical device recalls of over 15 million Philips Respironics ventilator, CPAP, and BiPAP devices, due to polyester polyurethane foam degradation and volatile organic compound emission, which was publicly announced on 06/14/2021.

- c) A risk analysis is inadequate or was not performed when appropriate or within an appropriate time frame of your firm becoming aware of potential polyester polyurethane foam degradation and/or Volatile Organic Compound (VOC) emission concerns regarding various CPAP, BiPAP, and ventilator devices. Specifically, there were at least fourteen instances, assessments, and/or test reports, dated from 04/01/2016 to 01/22/2021, where your firm was aware of issues and concerns related to potential foam degradation and/or Volatile Organic Compound (VOC) emissions, with various Sleep and Respiratory care devices, including:

- The (b) (4) ", dated 04/01/2016, which is documented in and utilized Trilogy 100 field samples from consumer complaint numbers 306210645 and 306220735, both received by your firm in October 2015, documents base polymer cleavage and embrittlement of the returned foam material of the related field samples.

As a result, a risk analysis was not performed and no further design change, corrective action, or field correction was conducted when appropriate or within an appropriate timeframe.

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2. Test Report AST282T-161438, dated 08/30/2016 and titled, "Degradation (b) (4) respironics Trilogy appliance", states in part, "The chemical analysis group was requested to analyze (b) (4) from the respironics Trilogy 200 series", "The samples which were received by the chemical analysis group are (b) (4) production samples from 2016, 2 customer complaints from 2015 with sample codes 10360957 and 10360958 and (b) (4) samples from 2001. The main focus of this report will be on polyester polyurethane (PUR) analysis and degradation". It further states, "At (b) (4) of the (b) (4) test de foam became (b) (4) even after (b) (4), and at (b) (4) it was a (b) (4). Also the color changes from (b) (4) to a (b) (4), (b) (4) and finally a (b) (4) is observed during visual inspection", "All foams are polyester based urethanes except (b) (4) Polyester urethanes show bad resistance against high humidity in combination with high temperature". This test report was conducted as a result of field reports/complaints regarding foam degradation in Trilogy 200 ventilator devices in 2015.

As a result, a risk analysis was not performed and no further design change, corrective action, or field correction was conducted when appropriate or within an appropriate timeframe.

3. Test Report AST 282T-161459, dated 11/25/2016 and titled, (b) (4) of (b) (4) (b) (4) foam", states in part, "Previously the degradation of polyester urethane foams, which are used in the air inlet path of the Respironics Trilogy 200 series, have been tested (see report AST 282T-161438). In this follow-up study (b) (4) different type of foams, made of (b) (4) (b) (4) (b) (4) "The focus of this research is on whether these foams (b) (4) It further states, "In contrary to polyester urethane foams, (b) (4) (b) (4) foams show a far better resistance against high humidity at high temperature. Some degradation is observed, as can be seen from (b) (4) (b) (4), but it happens only slowly and gradually". This test report was conducted as a result of field reports/complaints regarding foam degradation in Trilogy 200 ventilator devices in

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2015 and as a follow-up to AST282T-161438.

As a result, a risk analysis was not performed and no further design change, corrective action, or field correction was conducted when appropriate or within an appropriate timeframe.

4. Test Report AST 282T-182160, dated 12/12/2018 and titled (b) (4)", states in part, "There was a problem of degradation of the damping foam in Trilogy Respironics appliance in 2016. Investigation had done and the problem was found as (b) (4) polyester polyurethane. (refer to AST 282T-161438 attached below) Currently the project team is considering (b) (4)

(b) (4) Therefore, there are no data for polyester polyurethane (b) (4) . (b) (4) als (b) (4) This test report was conducted as a result of field reports/complaints regarding foam degradation in Trilogy ventilator devices in 2016 and is documented in CAPA 7211.

As a result, a risk analysis is inadequate and no further design change, corrective action, or field correction was conducted when appropriate or within an appropriate timeframe.

5. The test report identified as (b) (4)", dated 05/22/2019, states in part, "At your request the following samples were analyzed by (b) (4) for investigation of degradation of a polyurethane foam". It concludes, "The most significant evidence that the (b) (4) gives is of (b) (4) , "This chemical reaction can occur if the foam is constantly wet, i.e. exposier to high heat and humidity". The test samples are described

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as, "Degraded Polyurethane foam", "Polyurethane Foam", and "Current Production Foam". The test report identified as (b) (4) is documented in CAPA 7211.

As a result, a risk analysis is inadequate and no further design change, corrective action, or field correction was conducted when appropriate or within an appropriate timeframe.

6. (b) (4), dated 01/30/2020, documents that a DreamStation 1 device failed emissions testing for VOCs and Aldehydes, which was analyzed/tested from 01/18/2019 to 01/25/2019. Specifically, Table 3 documents that the tolerable limits of the Formaldehyde compound were exceeded during initial operation, as well as at the (b) (4). This Test Report was conducted to support FDA guidance and following the guidelines of ISO 18562-3, and the test subject was a DreamStation (1) CPAP device.

As a result, a risk analysis is inadequate and no further design change, corrective action, or field correction was conducted when appropriate or within an appropriate timeframe.

7. (b) (4), dated 01/30/2020, documents that a DreamStation 1 device failed emissions testing for VOCs and Aldehydes, which was analyzed/tested from 01/25/2019 to 02/01/2019. Specifically, Table 3 documents that the tolerable limits of the Formaldehyde compound were exceeded during initial operation, as well as at the (b) (4). This Test Report was conducted to support FDA guidance and following the guidelines of ISO 18562-3, and the test subject was a DreamStation (1) CPAP device.

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As a result, a risk analysis is inadequate and no further design change, corrective action, or field correction was conducted when appropriate or within an appropriate timeframe.

8. ER 2241475 v00 Biological Risk Assessment, dated 07/02/2020 and titled, "EXPOSURE TO POLYESTER-POLYURETHANE FOAM PARTICULATES FROM SYSTEM ONE FOAM DEGRADATION: BIOLOGICAL RISK ASSESSMENT", states in part, "Compounds of concern were identified as analytes with Margin of Safety (MOS) values (b) (4) of these compounds had MOS (b) (4) Based upon the exposure to (b) (4) with potential for carcinogenicity, mutagenicity, and systemic toxicity, the biological and toxicological risks from exposure to degraded PE-PUR foam are of concern and the severity of harm is crucial with respect to both the 30 kg and 70 kg patient populations of the System One medical device". This Biological Risk Assessment was conducted as a result of field reports/complaints regarding degraded sound abatement foam in various CPAP and ventilator products and states in part, "Philips Respironics Inc. (PRI) was made aware in May 2019 that four CPAP units were returned to a service center with degraded sound abatement foam". This Biological Risk Assessment is documented in CAPA 7211.

As a result, a risk analysis is inadequate and no further design change, corrective action, or field correction was conducted when appropriate or within an appropriate timeframe.

9. Biological Risk Assessment ER 2241475 Appendix C, dated 12/10/2020 and titled "DEGRADED POLYESTER-POLYURETHANE FOAM-BIOLOGICAL RISK ASSESSMENT", states in part, "The purpose of this report is to evaluate the potential biological risks posed by the degraded PE-PUR foam according to the risk management process outlined in FDA Guidance 2020 and ISO 10993-1:2018". It further states, "The cytotoxicity and positive genotoxicity results observed from degraded PE-PUR foam samples indicate a potential patient risk. Potential cytotoxicity and

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genotoxicity leading to carcinogenicity are possible outcomes from degraded PE-PUR foam exposure. Overall, based on an understanding of the toxicological significance of the foam degradants and the results of the ISO 10993 testing to include mutagenic responses in both a bacterial and mammalian system, the degraded PE-PUR foam is not considered biocompatible and presents a significant biological risk to those patient populations who are exposed to degraded PE-PUR foam”.

This Biological Risk Assessment was conducted as a result of field reports/complaints regarding degraded sound abatement foam in various CPAP and ventilator products and states in part, “Philips Respironics Inc. (PRI) has received field reports of CPAP and ventilator units returned to service centers with degraded sound abatement foam”. This Biological Risk Assessment is documented in CAPA 7211.

As a result, a risk analysis is inadequate and no further design change, corrective action, or field correction was conducted when appropriate or within an appropriate timeframe.

10. The “Biocompatibility Risk Assessment for Degraded Sound Abatement Foam in CPAP and Ventilator Units”, written by (b) (6) (b) (4) and dated 01/11/2021, states in part, “Based on an understanding of the toxicological significance of the foam degradants and the results of the biological testing to include mutagenic responses in both a bacterial and mammalian system, the degraded PE-PUR foam is not considered biocompatible and presents a significant biological risk to patients exposed to the degraded PE-PUR foam. Potential cytotoxicity and genotoxicity leading to carcinogenicity are possible outcomes from degraded PE-PUR foam exposure”, “I have read and concur with the findings in the Biological Risk Assessment noted above and I have no further comments”. This Biocompatibility Risk Assessment was conducted as a result of field reports/complaints regarding degraded sound

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abatement foam in various CPAP and ventilator products and is documented in CAPA 7211.

As a result, a risk analysis is inadequate and no further design change, corrective action, or field correction was conducted when appropriate or within an appropriate timeframe.

11. The (b) (4) report, "FINAL GLP REPORT: 20-03961-G2", dated 01/13/2021, states in part, "The purpose of the study is to determine the potential mutagenicity of the test article or its extract on various strains of (b) (4)) and (b) (4) via (b) (4)". The test article is polyester polyurethane foam (PE-PUR), and this test report concludes, "Based on the criteria of the study protocol, the test article is considered to be mutagenic". The (b) (4) report, "FINAL GLP REPORT: 20-03961-G2" is documented in CAPA 7211.

As a result, a risk analysis is inadequate and no further design change, corrective action, or field correction was conducted when appropriate or within an appropriate timeframe.

12. The (b) (4) report, "FINAL GLP REPORT: 20-03961-G5", dated 01/13/2021, states in part, "The purpose of the study was to determine the potential mutagenicity effect on (b) (4) in response to the test article extract". The test article is polyester polyurethane foam (PE-PUR), and this test report concludes, "Based on the criteria of the protocol, the test article does not meet the requirements of the test and is considered mutagenic". The test article, polyester polyurethane foam (PE-PUR) is used in various Sleep and Respiratory Care Products and the (b) (4) test report, "FINAL GLP REPORT: 20-03961-G5" is documented in CAPA 7211.

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13. The (b) (4) report, "FINAL GLP REPORT: 20-03961-G1", dated 01/13/2021, states in part, "The purpose of the study was to determine the potential biological reactivity of a mammalian cell culture (b) (4) in response to the test article extract". The test article is polyester polyurethane foam (PE-PUR), and this test report concludes, "Based on the criteria of the protocol and the ISO 10993-5 guidelines, the test article does not meet the requirements of the test and is considered to have a cytotoxic potential". The test article, polyester polyurethane foam (PE-PUR) is used in various Sleep and Respiratory Care Products and the (b) (4) test report, "FINAL GLP REPORT: 20-03961-G1" is documented in CAPA 7211.

As a result, a risk analysis is inadequate and no further design change, corrective action, or field correction was conducted when appropriate or within an appropriate timeframe.

14. ER 2241475 v00 Biological Risk Assessment, dated 01/22/2021, and titled, "DEGRADED POLYESTER POLYURETHANE SOUND ABATEMENT FOAM: BIOLOGICAL RISK ASSESSMENT", states in part, "Overall, based on an understanding of the toxicological significance of the foam degradants and the results of the ISO 10993 testing to include mutagenic responses in both a bacterial and mammalian system, the degraded PE-PUR foam is not considered biocompatible and presents a significant biological risk to those patient populations who are exposed to degraded PE-PUR foam". This Biological Risk Assessment was conducted as a result of field reports/complaints regarding degraded sound abatement foam in various CPAP and ventilator products and is documented in CAPA 7211.

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- d) No risk analysis, health hazard evaluation, or design review was documented as a result of an A Series CPAP device, containing silicone foam, failing Volatile Organic Compound (VOC) testing as part of ISO 18562-2 and 18562-3 testing.

Test Report Number 600253-RP-12 (Rev A), dated 08/24/2021, documents that an A Series CPAP device failed VOC testing as part of ISO 18562-2 and 18562-3 testing. Test Report Number 600253-RP-12 (Rev A) documents that (b) (4) compounds of concern (COCs) were identified, and (b) (4) compounds were confirmed, due to their carcinogenic/mutagenic properties. Additionally, Report Number 600253-RP-12 (Rev A) documents that pediatric patients would potentially be exposed to higher concentrations of compounds of concern, if they utilized an A Series CPAP device for sustained periods of time.

No health hazard evaluation, risk analysis, or design review was documented by your firm.

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<small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small> Rodney D. Mell, Head of Quality		<small>FEI NUMBER</small> 2518422			
<small>FIRM NAME</small> Philips Respironics, Inc.		<small>STREET ADDRESS</small> 1001 Murry Ridge Ln			
<small>CITY, STATE, ZIP CODE, COUNTRY</small> Murrysville, PA 15668-8517		<small>TYPE ESTABLISHMENT INSPECTED</small> Medical Device Manufacturer			
<p>The affected A Series device contains silicone foam and is not affected by the ongoing Class I recalls related to polyester polyurethane foam.</p> <p>e) The Biological Risk Assessment, dated 05/22/2018, and Health Hazard Evaluation ER2227646 V06, both related to CAPA INV 0988, are inadequate because they do not accurately reflect the known data at that time. CAPA INV 0988, the Biological Risk Assessment, dated 05/22/2018, and Health Hazard Evaluation ER2227646 V06 were all initiated to investigate potential polyester polyurethane foam degradation in Trilogy ventilator devices, as alleged in various field complaints and medical device reports.</p> <p>The Biological Risk Assessment, dated 05/22/2018, titled, "EXPOSURE TO POLYESTER-POLYURETHANE FOAM PARTICULATES FROM TRILOGY 100 INLET AIR PATH FOAM DEGRADATION: BIOLOGICAL RISK ASSESSMENT", states in part, "A total of 17 cases were reported pertaining to the degraded foam in the Trilogy ventilator device". The Health Hazard Evaluation ER2227646 V06, related to CAPA INV 0988, states in part, "Post market surveillance information revealed 17 instances allegedly related to degradation of air inlet path foam".</p> <p>Alternatively, a query of your firm's consumer complaints from 01/01/2008 to current, for the keywords contaminants, particles, foam, debris, airway, particulate, airpath, and black, resulted in over 222,000 complaints, and over 20,000 of which occurred between 2008 to 2017 and involved Trilogy devices. Additionally, your firm performed a foam related complaint data analysis in April 2021 on complaints confirmed to be related to or involve foam degradation issues. The raw complaint data documents that 30 Trilogy related complaints were received from 2014 to 2017, and 1,254 related complaints were received across all products containing the affected foam, from 2014 to 2021. Therefore, this Biological Risk Assessment and Health Hazard Evaluation are not adequate because they do not accurately reflect the known data at that time.</p>					
SEE REVERSE OF THIS PAGE		<table border="0" style="width: 100%;"> <tr> <td style="width: 60%; vertical-align: top;"> <small>EMPLOYEE(S) SIGNATURE</small> Katelyn A Staub-Zamperini, Investigator </td> <td style="width: 40%; vertical-align: top;"> <div style="text-align: right;"> <small>DATE ISSUED</small> 11/9/2021 </div> <div style="text-align: right; font-size: small;"> Katelyn A Staub-Zamperini Investigator Signed By: Katelyn A. Staub-Zamperini -s Date Signed: 11-09-2021 DE: 1:23 </div> </td> </tr> </table>		<small>EMPLOYEE(S) SIGNATURE</small> Katelyn A Staub-Zamperini, Investigator	<div style="text-align: right;"> <small>DATE ISSUED</small> 11/9/2021 </div> <div style="text-align: right; font-size: small;"> Katelyn A Staub-Zamperini Investigator Signed By: Katelyn A. Staub-Zamperini -s Date Signed: 11-09-2021 DE: 1:23 </div>
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FIRM NAME Philips Respironics, Inc.	STREET ADDRESS 1001 Murry Ridge Ln
CITY, STATE, ZIP CODE, COUNTRY Murrysville, PA 15668-8517	TYPE ESTABLISHMENT INSPECTED Medical Device Manufacturer

Your firm is currently conducting on-going, Class 1 medical device recalls of over 15 million Philips Respironics ventilator, CPAP, and BiPAP devices, due to polyester polyurethane foam degradation and volatile organic compound emission, which was publicly announced on 06/14/2021.

- f) Health Hazard Evaluation ER2227646 V06, approved and closed on 06/15/2018 and related to CAPA INV 0988 and foam degradation on Trilogy 100 and Trilogy 200 ventilator devices, is inadequate because it does not accurately reflect the probability and severity of harm related to such foam degradation. Health Hazard Evaluation ER2227646 V06 and CAPA INV 0988 were both initiated to investigate potential polyester polyurethane foam degradation in Trilogy ventilator devices, as alleged in various field complaints and medical device reports.

Specifically, Health Hazard Evaluation ER2227646 V06 documents a *probability of harm* score of (b) (4) or unlikely, which is defined as, "'Not likely' that use will cause harm*; possible but improbable". Health Hazard Evaluation ER2227646 V06 further states, "*Note: If harm has already occurred as a result of the issue under review, then:", "Probability level (b) (4) and (b) (4) can only be used if the investigation shows the harm was the result of an isolated incident and no other units are likely to be affected; a detailed rationale for why harm is not likely to occur again must be provided". Alternatively, this Health Hazard Evaluation also states in part, "Post market surveillance information revealed 17 instances allegedly related to degradation of air inlet path foam". Additionally, at least fourteen of these seventeen complaints have associated medical device reports filed by either your firm or another entity. Therefore, potential foam degradation in Trilogy ventilator devices is not an isolated incident, and you also have not documented a detailed rationale for why harm is not likely to occur again, as required by your Health Hazard Evaluation's instructions.

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OBSERVATION 2

Procedures for corrective and preventive action have not been adequately established.

Specifically,

- a) No formal CAPA was initiated or implemented, when appropriate, and no verification of effectiveness was performed. Specifically, CAPA INV 0988 was opened due to various complaints alleging foam degradation in Trilogy ventilator devices but was never made into a formal CAPA and was closed approximately (b) (4).

CAPA INV 0988 was opened on 04/12/2018, due to, "Units were returned from the field where the Trilogy Removable Air Path Foam (b) (4) and the foam in the Inlet Air Path Assembly (b) (4) was degrading, and getting into the motor/air path, causing at least 1 Trilogy unit to fail". At the time, your firm's process was to open CAPA requests, referred to as CAPA INVs, as a precursor to formal CAPAs, but would only be made into formal CAPAs, if approved by a CAPA Review

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Board, or delegate(s), as documented by your written procedure in place at that time, QSP 8.5-206 v 30 titled, "Manage Corrective and Preventive Actions (CAPA)". Alternatively, CAPA INV 0988 was closed on 06/20/2018 and no formal CAPA was initiated or implemented.

Additionally, CAPA INV 0988 documents your firm implemented Field Communication FC 16-700-403 v 00, as a correction to the potential foam degradation in Trilogy ventilator devices. FC 16-700-403 v 00 is a preventative maintenance procedure affecting, "All Trilogy models with Air Path Assembly", specifically all Trilogy 100 and 200 ventilator models, which requires that "At both the (b) (4) and (b) (4), the Inlet Air Path Assembly and Removable Air Path Foam are to be replaced". Alternatively, no verification of effectiveness was performed for this corrective and preventive action.

Your firm is currently conducting on-going, Class 1 medical device recalls of over 15 million Philips Respironics ventilator, CPAP, and BiPAP devices, due to polyester polyurethane foam degradation and volatile organic compound emission, which was publicly announced on 06/14/2021.

- b) CAPA INV 0988 involves Trilogy 100 and 200 ventilator devices only and does not include, investigate, or examine all of your firm's CPAP and BiPAP medical devices, which also include similar air path assemblies and/or the affected polyester polyurethane foam, which is susceptible to degradation.

CAPA INV 0988 included only Trilogy 100 and Trilogy 200 ventilators and states in part, "This issue impacts all Trilogy 100 and Trilogy 200 devices (All Trilogy Models with an Inlet Air Path Assembly). The related Biological Risk Assessment, dated 05/22/2018, also only included the Trilogy 100 and Trilogy 200 ventilator devices. Alternatively, your firm manufactures various CPAP and BiPAP devices, which also

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include similar air path assemblies and/or the affected polyester polyurethane foam. Furthermore, per a complaint analysis conducted by your firm on April 9, 2021, your firm received approximately eighty complaints related to foam degradation, on non-Trilogy ventilator devices, from 2014 to 2017.

Your firm is currently conducting on-going, Class 1 medical device recalls of over 15 million Philips Respironics ventilator, CPAP, and BiPAP devices, due to polyester polyurethane foam degradation and volatile organic compound emission, which was publicly announced on 06/14/2021.

c) Analysis of quality data, such as complaints and medical device reports, was not adequately performed to identify or detect quality problems.

1. No formal investigation, risk analysis, or CAPA were initiated, performed, or documented, in response to the at least 222,000 complaints that could potentially be related to foam degradation and received from 2008 to 2017, prior to the initiation of CAPA INV 0988 in 2018.

CAPA INV 0988 was initiated on 04/12/2018 in response to field complaints alleging foam degradation on Trilogy ventilator devices, and CAPA 7211 was initiated on 06/19/2019 in response to field complaints alleging foam degradation on ventilator, CPAP, and BiPAP devices. A query of your firm's consumer complaints from 01/01/2008 to current, for the keywords contaminants, particles, foam, debris, airway, particulate, airpath, and black, resulted in over 222,000 complaints, and over 175,000 of which occurred between 2008 to 2017. Alternatively, no formal investigation, risk analysis, or CAPA were initiated, performed, or documented, in response to the at least 175,000 complaints potentially related to degraded foam, prior to CAPA INV 0988, initiated on 04/12/2018.

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Furthermore, your firm performed a foam degradation-related complaint analysis, dated 04/09/2021, as part of CAPA 7211, and identified 1,254 complaints confirmed to be related to foam degradation from 2014 to April 2021. Your analysis also identified 110 foam degradation related complaints were received from 2014 to 2017, before the initiation of CAPA INV 0988 on 04/12/2018.

2. Your analysis of quality data related to medical device reports conducted in or around February 2021, was not adequately performed to identify, or detect quality problems because it did not include all the known data at that time. Specifically, your firm performed a search of the Maude database, as part of CAPA 7211 activities and investigations, which resulted in three MDRs associated with your firm and potential foam degradation on Trilogy ventilator devices from 01/01/2011 to 01/31/2021. Alternatively, CAPA INV 0988, opened and closed in 2018, documented seventeen complaints related to foam degradation in Trilogy 100 and Trilogy 200 Ventilator devices, and at least 14 of these 17 complaints had related medical device reports, filed by either your firm or another entity. Therefore, your analysis of quality data did not include all applicable medical device reports known at that time.
3. Your analysis of quality data related to complaints, was not adequately performed to identify, or detect quality problems because it did not include all the known data at that time. Specifically, your firm performed a foam degradation-related complaint analysis, dated 04/09/2021, as part of CAPA 7211, and identified 1,254 complaints confirmed to be related to foam degradation from 2014 to April 2021, across all affected product platforms.

Alternatively, the raw data listing of these 1,254-foam degradation-related complaints, does not include 7 of the 17 complaints documented in CAPA INV 0988, opened and closed in 2018, and that are confirmed to be related to foam degradation in Trilogy 100 and 200 ventilator devices. Your analysis of quality data did not include all applicable complaints known at that time and

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therefore, was not adequately performed to identify, or detect the severity or magnitude of potential quality issues/concerns.

Your firm is currently conducting on-going, Class 1 medical device recalls of over 15 million Philips Respironics ventilator, CPAP, and BiPAP devices, due to polyester polyurethane foam degradation and volatile organic compound emission, which was publicly announced on 06/14/2021.

- d) No formal CAPA was initiated or implemented, when appropriate. Specifically, email correspondence between your firm and your raw foam supplier beginning 10/30/2015 and forward, document that your firm was made aware of polyester polyurethane foam degradation issues in/around October 2015, which was later confirmed by your foam supplier on 08/05/2016, via email. Alternatively, no CAPA was initiated or implemented.

An email message from your firm to your supplier, dated 10/30/2015, implies that a customer made your firm aware of polyester polyurethane foam degradation issues. A subsequent response from your supplier to your firm, dated 08/05/2016, implies that degradation of polyester polyurethane foam is likely and could occur in as little (b) (4). Additionally, a later email message from your firm to your supplier, dated 04/20/2018, documents that your firm has received complaints related to foam degradation in Trilogy ventilator devices, and that disintegrated foam has been pulled into ventilator and patients' air pathways. A follow-up email amongst your firm's personnel, dated 08/24/2018, states that testing confirmed that the affected foam breaks down in high heat and high humidity environments, which concurred with Trilogy ventilator related complaints received from both Florida and (b) (4). It further states that your firm made the decision not to change the design, and continue to include polyester polyurethane foam, in the Trilogy ventilator platform of devices.

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OBSERVATION 3

Design validation did not ensure the device conforms to defined user needs and intended uses.

Specifically,

- a) Health Hazard Evaluation ER2227646 V06, approved and closed on 06/15/2018, related to CAPA INV 0988, and concerning Trilogy 100 and 200 ventilator devices, documents typical and healthy lung and bodily functions, and does not conform to or address the user needs of the intended patient population of these ventilatory medical devices. The intended patient population of Trilogy 100 and 200 ventilator devices are individuals requiring mechanical ventilation, that potentially lack typical and healthy lung and bodily functions considered in your HHE. Furthermore, Health Hazard Evaluation ER2227646 V06 does not consider patients with a tracheostomy, which are also part of the intended patient population of these Trilogy ventilator devices.

Health Hazard Evaluation ER2227646 V06 states in part, "If particulate was to reach the patient, the patient's upper airway filtering mechanisms would remove the particulate from the airway. The large particulate (greater than 5 microns) would be removed from the airway by the cilia and mucosal lining through inertial impaction. Impacted particles would then be expectorated by the patient. The increased velocity of the particulate due to the flow generated by the device would increase the probability of impacting in the upper airway. Medium particulate (1-5 microns) would be removed from the airway by the cilia and mucosal lining through sedimentation. Sedimentation occurs as particulates deposit into the mucosal layer of the airway as flow decreases. Small particles (less than 1 micron) not removed through impaction and sedimentation would be subjected to Alveolar Macrophages. Alveolar Macrophages, a type of white blood cell on the surface of alveoli, are another defense mechanism for the lungs. Alveolar Macrophages seek out deposited particles, bind to them, ingest them, kill any that are living, and digest them. When the lungs are exposed to serious threats, additional white blood cells in the circulation, especially neutrophils, can be recruited to help ingest and kill pathogens. For

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<p>example, when the person inhales a great deal of dust, more macrophages are produced and neutrophils are recruited”.</p> <p>The intended use for both the Trilogy 100 and 200 ventilator devices is for “continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation”, which also includes patients with a tracheostomy. Alternatively, this Health Hazard Evaluation ER2227646, documents typical and healthy lung and bodily functions, and does not conform to or address the user needs of the intended patient population of these ventilatory medical devices, including patients with a tracheostomy or that lack typical and healthy lung and bodily functions.</p> <p>b) Health Hazard Evaluation ER2227646 V06, approved and closed on 06/15/2018 and related to CAPA INV 0988, and the Biological Risk Assessment, dated 05/22/2018 and also related to CAPA INV 0988, titled, “EXPOSURE TO POLYESTER-POLYURETHANE FOAM PARTICULATES FROM TRILOGY 100 INLET AIR PATH FOAM DEGRADATION: BIOLOGICAL RISK ASSESSMENT”, do not ensure Trilogy 100 and 200 ventilator devices conform to defined user needs and intended uses. They document the risk and hazard evaluation based on the use of a humidifier and/or bacterial filter with the use of Trilogy 100 and 200 ventilator devices, but neither component nor attachment is required for proper use of these ventilators.</p> <p>Health Hazard Evaluation ER2227646 V06, states in part, “To reach the patient, particulate would have to pass through the device, through the humidifier and through the patient circuit. If a bacteria filter was in place, the particulate would not reach the patient”. Furthermore, the Biological Risk Assessment, dated 05/22/2018, states in part, “The Trilogy user manual recommends the use of a bacterial filter for invasively ventilated patients or if the device will be used on multiple patients. This filter would catch any particulates released into the Trilogy airpath”. Alternatively, neither the humidifier or bacterial filter are required for use of the Trilogy ventilator devices, and both the Trilogy 100 and Trilogy 200 ventilator</p>					
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devices will function properly without the use of the humidifier and/or bacterial filter accessories. Therefore, the design validation, Health Hazard Evaluation ER2227646 V06, and the Biological Risk Assessment, dated 05/22/2018, do not ensure Trilogy 100 and 200 devices conform to defined user needs and intended uses.

Your firm is currently conducting on-going, Class 1 medical device recalls of over 15 million Philips Respironics ventilator, CPAP, and BiPAP devices, due to polyester polyurethane foam degradation and volatile organic compound emission, which was publicly announced on 06/14/2021.

OBSERVATION 4

Procedures for design change have not been adequately established.

Specifically, design changes, including changes and updates to preventative maintenance schedules and servicing procedures, were not adequately verified, reviewed, or validated before implementation.

- a) A preventative maintenance procedure for Trilogy ventilator devices, the intended replacement component, or the (b) (4) time frame for this preventive maintenance were not verified, reviewed, or validated before implementation.

On or around 11/25/2015, your firm was aware and knowledgeable of a preventative maintenance servicing procedure implemented by another Philips entity in (b) (4) on Trilogy ventilator products, which was implemented in (b) (4) only, in response to issues/complaints in the field related to polyester polyurethane foam degradation. This preventative maintenance servicing procedure instructed service personnel of the other Philips entity in (b) (4) to "exchange the air inlet assembly at (b) (4)", which

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is a requirement to replace the air intake assembly component of Trilogy ventilator devices (b) (4) (b) (4) This preventative maintenance procedure, the intended replacement component, or the (b) (4) time frame were not verified, reviewed, or validated before implementation.

- b) A preventative maintenance procedure for Trilogy 100 and 200 devices, the intended replacement components, or the (b) (4) and time frame were not verified, reviewed, or validated before implementation.

As part of CAPA INV 0988 and in response to polyester polyurethane foam degradation complaints in the field, your firm implemented Field Communication 16-700-403, on/around 06/12/2018, which states in part, "At (b) (4)) and (b) (4) the Inlet Air Path Assembly and Removable Air Path Foam are to be replaced". This preventative maintenance procedure, the intended replacement components, or (b) (4) and time frame were not verified, reviewed, or validated before implementation.

Your firm is currently conducting on-going, Class 1 medical device recalls of over 15 million Philips Respironics ventilator, CPAP, and BiPAP devices, due to polyester polyurethane foam degradation and volatile organic compound emission, which was publicly announced on 06/14/2021.

OBSERVATION 5

A correction or removal, conducted to reduce a risk to health posed by a device, was not reported in writing to FDA.

Specifically, the corrective actions implemented as a result of CAPA INV 0988 included a field correction of Trilogy 100 and 200 ventilator devices to reduce a risk to health and was not reported to the FDA. The field

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER US Customhouse Rm900 200 Chestnut St Philadelphia, PA 19106 (215) 597-4390 Ext:4200 Fax: (215) 597-0875	DATE(S) OF INSPECTION 8/26/2021-11/9/2021* FEI NUMBER 2518422
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Rodney D. Mell, Head of Quality

FIRM NAME Philips Respironics, Inc.	STREET ADDRESS 1001 Murry Ridge Ln
CITY, STATE, ZIP CODE, COUNTRY Murrysville, PA 15668-8517	TYPE ESTABLISHMENT INSPECTED Medical Device Manufacturer

correction is documented in Field Communication 16-700-403 v 00, dated 06/12/2018, which affected (b) (4) Trilogy 100 ventilators and (b) (4) Trilogy 200 ventilators.

Field Communication 16-700-403 v 00 states in part, "At (b) (4), the Inlet Air Path Assembly and removable Air Path Foam are to be replaced". This field correction was implemented as a corrective action in response to CAPA INV 0988, which was initiated due to multiple field complaints and at least 1 Trilogy unit failure, caused by polyester polyurethane foam degradation. This affected foam was later found to be mutagenic, cytotoxic, carcinogenic, and non-biocompatible.

Additionally, per a complaint analysis performed by this firm on 04/09/2021, this firm received approximately 30 complaints related to foam degradation of Trilogy devices from 2014 to 2017, and approximately 80 complaints related to degraded foam on other CPAP and BiPAP devices from 2014 to 2017.

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OBSERVATION 6

Management with executive responsibility has not ensured that the quality policy is understood, implemented and maintained at all levels of the organization.

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Specifically, firm management, including management with executive responsibility, were aware of potential foam degradation issues concerning CPAPs, BiPAPs, and Trilogy ventilators since at least 01/31/2020, or earlier, and implemented no further corrective actions until April 2021.

Polyester polyurethane foam degradation issues concerning CPAPs, BiPAPs, and Trilogy Ventilators were discussed at all (b) (4) management review meetings, since the 2019 (b) (4), dated 01/31/2020. Alternatively, firm management implemented no further corrective actions until April 2021. Additionally, your firm became aware of this issue and related field complaints in at least 2015 or earlier.

Your Quality Manual QMS-0031 defines Sleep and Respiratory Care's (SRC) Management with Executive Responsibility as, "Top Management for the overall SRC Organization is the Business Leader/General Manager (Management with Executive Responsibility)", and both your Quality Manual and Management Review 5.1-079 written procedure document that your Business Leader (Management with Executive Responsibility) and Head of Quality (Management Representative) are required attendees of management review meetings. Both your Sleep and Respiratory Care Business Leader and Head of Quality, that held the position at the time, attended all (b) (4) management review meetings since the 2019 (b) (4), which were on the following dates:
(b) (4)

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OBSERVATION 7

Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been adequately established.

Specifically, you have no established data, documentation, or written agreement that clearly describes or references the quality requirements of your raw foam supplier, or the specified requirements of the raw material components they supply, including raw foam components/materials.

Furthermore, SCAR 1052449, initiated 06/28/2021, and HHE ER2227930 V16, approved and closed on 09/23/2021, document that an incorrect and non-specified polyester polyurethane, raw foam product, sourced from your raw foam supplier resulted in (b) (4) non-conforming Trilogy Evo ventilatory finished devices being approved, released, and distributed, which further resulted in the ongoing correction and removal, identified with # 2021-CC-SRC-018 and approved on 09/15/2021. SCAR 1052449 documents that the suspect lot of raw foam was moved to your production line for use on 04/15/2021. SCAR 1052449, HHE ER2227930 V16, and correction and removal # 2021-CC-SRC-018 were established as part of this firm's response to failed VOC and ISO 18562 testing of related Trilogy EVO ventilatory medical devices, documented in PSN Report Number 700018-RP-02 (Rev B), dated 08/09/2021, which resulted from the presence of the non-specified polyester polyurethane foam component, incorrectly supplied by your raw foam supplier. Alternatively, this firm's supplier performance monitoring of this supplier documents no issues or concerns were observed, which was documented on (b) (4).

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OBSERVATION 8

Potential consultants were not evaluated and selected based on their ability to meet specified requirements.

Specifically, (b) (4) consultants were not evaluated and selected based on their ability to meet specified requirements, including quality requirements. Additionally, this firm did not evaluate, select, and approve these consultants, as approved suppliers before utilizing their consulting services on the quality issue of polyester polyurethane foam degradation and CAPA 7211.

The Work Instruction titled, "Perform Supplier Qualification" with document number 16.2.18.1.2, states in part, "Service Supplier: A third party is contracted to deliver agreed services. Examples may include, but are not limited to; (b) (4)

" Additionally, no Supplier Qualification Forms, Form 5077, were completed for the (b) (4) consultants, as required per your supplier quality procedures and work instructions.

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***DATES OF INSPECTION**

8/26/2021(Thu), 8/27/2021(Fri), 8/30/2021(Mon), 8/31/2021(Tue), 9/01/2021(Wed), 9/02/2021(Thu), 9/03/2021(Fri), 9/07/2021(Tue), 9/08/2021(Wed), 9/10/2021(Fri), 9/14/2021(Tue), 9/15/2021(Wed), 9/22/2021(Wed), 9/23/2021(Thu), 9/27/2021(Mon), 9/29/2021(Wed), 10/07/2021(Thu), 10/14/2021(Thu), 10/22/2021(Fri), 11/01/2021(Mon), 11/09/2021(Tue)

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Annotations to Observations

Observation 1:

Observation 2:

Observation 3:

Observation 4:

Observation 5:

Observation 6:

Observation 7:

Observation 8:

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."