Managing Director
Philips Electronics Australia Ltd
ABN: 24 008 445 743
65 Epping Road
North Ryde, NSW 2113
Australia

By Express Post and By Email:
s22 [redacted] @philips.com

Infringement Notice Number:
TGAIN-DPMRR-2022-10

Date given: 31/05/2022

Penalty total: $13,320

Payment due: 28/06/2022

Enquiries:
Devices Post Market Reform and Review Section
Telephone: 1800 020 653

Email: postmarketdevices@health.gov.au

INFRINGEMENT NOTICE GIVEN TO
Philips Electronics Australia Ltd

PART A: Infringement Notice given by

s22 [redacted]
Delegate of the Secretary of the Australian Government Department of Health

PART B: Details of alleged contravention

I am a delegate of the Secretary of the Australian Government Department of Health under section 42YK of the *Therapeutic Goods Act 1989* (**the Act**). I have decided to give this Infringement Notice (**the notice**) to Philips Electronics Australia Ltd (**Philips Australia**) under Part 5A-2 of the Act on the basis that I reasonably believe that it has contravened subsection 41MPA(1) of the Act.

The details of the alleged contravention are that:

Philips Australia is the person in relation to whom a kind of device is included in the Australian Register of Therapeutic Goods (**ARTG**), namely the kind of device with ARTG number **133794** (**the Device**).

On or before 28 April 2021, Philips Australia became aware that the polyester-based polyurethane foam **(PE-PUR foam)** in the Device was known to degrade and present a significant biological risk to patients.

As of 31 May 2021, being 33 days after Philips Australia becomes aware, Philips Australia had not informed the Secretary that Philips Australia therefore contravened subsection 41MPA(1) of the Act.

The maximum penalty a court could impose on a company for a single contravention of subsection 41MPA(1) is 30,000 penalty units.[1] For the above-alleged contravention, this amounts to $6,660,000.

The amount payable under this notice is **$13,320**. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read ***Part D: Information about this Infringement Notice***.

PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.

CHEQUE

Return **this notice** to **Department of Health, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health. Please allow 5 business days for payment to be received

CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number TGAIN-DPMRR-2022-10 as reference to identify your payment

ELECTRONIC FUNDS TRANSFER

Account name: Department of Health
BSB: 092 009
Account: 114 071
Bank: Reserve Bank of Australia, London Circuit, Canberra ACT 2601
Swift: RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number TGAIN-DPMRR-2022-10 in the description of your transfer and allow two business days for payment to be received.

Note: The Department of Health accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment

[1] A penalty unit is currently $222 (section 4AA of the *Crimes Act 1914*).

PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (**TGA**) is not legally able to accept payment of the notice after it has lapsed.

How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health (the **Secretary**) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- postmarketdevices@health.gov.au or
- PO Box 100; WODEN ACT 2609

Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health will, from time to time, make public reference to infringement notices that have been given to companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

Effect of the lapsing of the compliance period for the notice

If the compliance period has passed and no payment has been received by the TGA, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay

the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this notice.

How this notice can be withdrawn

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- postmarketdevices@health.gov.au or
- PO Box 100; WODEN ACT 2609

Effect of withdrawal of this notice

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

Signed electronically

s22 [redacted]
A/g Assistant Secretary
Medical Devices Surveillance Branch
Therapeutic Goods Administration
E-mail: postmarketdevices@health.gov.au
PO Box 100 WODEN ACT 2609

Date: 31/05/2022

Managing Director
Philips Electronics Australia Ltd
ABN: 24 008 445 743
65 Epping Road
North Ryde, NSW 2113
Australia

By Express Post and By Email:
s22 [redacted] @philips.com

Infringement Notice Number:
TGAIN-DPMRR-2022-9

Date given: 31/05/2022

Penalty total: $13,320

Payment due: 28/06/2022

Enquiries:
Devices Post Market Reform and Review Section
Telephone: 1800 020 653

Email: postmarketdevices@health.gov.au

INFRINGEMENT NOTICE GIVEN TO
Philips Electronics Australia Ltd

PART A: Infringement Notice given by

s22 [redacted]
Delegate of the Secretary of the Australian Government Department of Health

PART B: Details of alleged contravention

I am a delegate of the Secretary of the Australian Government Department of Health under section 42YK of the *Therapeutic Goods Act 1989* (**the Act**). I have decided to give this Infringement Notice (**the notice**) to Philips Electronics Australia Ltd (**Philips Australia**) under Part 5A-2 of the Act on the basis that I reasonably believe that it has contravened subsection 41MPA(1) of the Act.

The details of the alleged contravention are that:

Philips Australia is the person in relation to whom a kind of device is included in the Australian Register of Therapeutic Goods (**ARTG**), namely the kind of device with ARTG number **159490** (**the Device**).

On or before 28 April 2021, Philips Australia became aware that the polyester-based polyurethane foam **(PE-PUR foam)** in the Device was known to degrade and present a significant biological risk to patients.

As of 31 May 2021, being 33 days after Philips Australia becomes aware, Philips Australia had not informed the Secretary that Philips Australia therefore contravened subsection 41MPA(1) of the Act.

The maximum penalty a court could impose on a company for a single contravention of subsection 41MPA(1) is 30,000 penalty units.[1] For the above-alleged contravention, this amounts to $6,660,000.

The amount payable under this notice is **$13,320**. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read ***Part D: Information about this Infringement Notice***.

PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.

CHEQUE

Return **this notice** to **Department of Health, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health. Please allow 5 business days for payment to be received

CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number TGAIN-DPMRR-2022-9 as reference to identify your payment

ELECTRONIC FUNDS TRANSFER

Account name: Department of Health
BSB: 092 009
Account: 114 071
Bank: Reserve Bank of Australia, London Circuit, Canberra ACT 2601
Swift: RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number TGAIN-DPMRR-2022-9 in the description of your transfer and allow two business days for payment to be received.

Note: The Department of Health accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment

[1] A penalty unit is currently $222 (section 4AA of the *Crimes Act 1914*).

PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (**TGA**) is not legally able to accept payment of the notice after it has lapsed.

How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health (the **Secretary**) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- postmarketdevices@health.gov.au or
- PO Box 100; WODEN ACT 2609

Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health will, from time to time, make public reference to infringement notices that have been given to companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

Effect of the lapsing of the compliance period for the notice

If the compliance period has passed and no payment has been received by the TGA, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay

the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this notice.

How this notice can be withdrawn

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- postmarketdevices@health.gov.au or
- PO Box 100; WODEN ACT 2609

Effect of withdrawal of this notice

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

signed electronically

s22 [redacted]
A/g Assistant Secretary
Medical Devices Surveillance Branch
Therapeutic Goods Administration
E-mail: postmarketdevices@health.gov.au
PO Box 100 WODEN ACT 2609

Date: 31/05/2022

Managing Director
Philips Electronics Australia Ltd
ABN: 24 008 445 743
65 Epping Road
North Ryde, NSW 2113
Australia

By Express Post and By Email:
s22 [redacted] @philips.com

Infringement Notice Number:
TGAIN-DPMRR-2022-8

Date given: 31/05/2022

Penalty total: $13,320

Payment due: 28/06/2022

Enquiries:
Devices Post Market Reform and Review Section
Telephone: 1800 020 653

Email: postmarketdevices@health.gov.au

INFRINGEMENT NOTICE GIVEN TO
Philips Electronics Australia Ltd

PART A: Infringement Notice given by

s22 [redacted]
Delegate of the Secretary of the Australian Government Department of Health

PART B: Details of alleged contravention

I am a delegate of the Secretary of the Australian Government Department of Health under section 42YK of the *Therapeutic Goods Act 1989* (**the Act**). I have decided to give this Infringement Notice (**the notice**) to Philips Electronics Australia Ltd (**Philips Australia**) under Part 5A-2 of the Act on the basis that I reasonably believe that it has contravened subsection 41MPA(1) of the Act.

The details of the alleged contravention are that:

Philips Australia is the person in relation to whom a kind of device is included in the Australian Register of Therapeutic Goods (**ARTG**), namely the kind of device with ARTG number **200289** (**the Device**).

On or before 28 April 2021, Philips Australia became aware that the polyester-based polyurethane foam **(PE-PUR foam)** in the Device was known to degrade and present a significant biological risk to patients.

As of 31 May 2021, being 33 days after Philips Australia becomes aware, Philips Australia had not informed the Secretary that Philips Australia therefore contravened subsection 41MPA(1) of the Act.

The maximum penalty a court could impose on a company for a single contravention of subsection 41MPA(1) is 30,000 penalty units.[1] For the above-alleged contravention, this amounts to $6,660,000.

The amount payable under this notice is **$13,320**. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read ***Part D: Information about this Infringement Notice***.

PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.

CHEQUE

Return **this notice** to **Department of Health, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health. Please allow 5 business days for payment to be received

CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number TGAIN-DPMRR-2022-8 as reference to identify your payment

ELECTRONIC FUNDS TRANSFER

Account name: Department of Health
BSB: 092 009
Account: 114 071
Bank: Reserve Bank of Australia, London Circuit, Canberra ACT 2601
Swift: RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number TGAIN-DPMRR-2022-8 in the description of your transfer and allow two business days for payment to be received.

Note: The Department of Health accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment

[1] A penalty unit is currently $222 (section 4AA of the *Crimes Act 1914*).

PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (**TGA**) is not legally able to accept payment of the notice after it has lapsed.

How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health (the **Secretary**) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- postmarketdevices@health.gov.au or
- PO Box 100; WODEN ACT 2609

Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health will, from time to time, make public reference to infringement notices that have been given to companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

Effect of the lapsing of the compliance period for the notice

If the compliance period has passed and no payment has been received by the TGA, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay

the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this notice.

How this notice can be withdrawn
The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- postmarketdevices@health.gov.au or
- PO Box 100; WODEN ACT 2609

Effect of withdrawal of this notice
If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

signed electronically

s22 [redacted]
Acting Assistant Secretary
Medical Devices Surveillance Branch
Therapeutic Goods Administration
E-mail: postmarketdevices@health.gov.au
PO Box 100 WODEN ACT 2609

Date: 31/05/2022

Managing Director
Philips Electronics Australia Ltd
ABN: 24 008 445 743
65 Epping Road
North Ryde, NSW 2113
Australia

By Express Post and By Email:
s22 [redacted] @philips.com

Infringement Notice Number:
TGAIN-DPMRR-2022-6

Date given: 31/05/2022

Penalty total: $13,320

Payment due: 28/06/2022

Enquiries:
Devices Post Market Reform and Review Section
Telephone: 1800 020 653

Email: postmarketdevices@health.gov.au

INFRINGEMENT NOTICE GIVEN TO
Philips Electronics Australia Ltd

PART A: Infringement Notice given by

s22 [redacted]
Delegate of the Secretary of the Australian Government Department of Health

PART B: Details of alleged contravention

I am a delegate of the Secretary of the Australian Government Department of Health under section 42YK of the *Therapeutic Goods Act 1989* (**the Act**). I have decided to give this Infringement Notice (**the notice**) to Philips Electronics Australia Ltd (**Philips Australia**) under Part 5A-2 of the Act on the basis that I reasonably believe that it has contravened subsection 41MPA(1) of the Act.

The details of the alleged contravention are that:

Philips Australia is the person in relation to whom a kind of device is included in the Australian Register of Therapeutic Goods (**ARTG**), namely the kind of device with ARTG number **235674** (**the Device**).

On or before 28 April 2021, Philips Australia became aware that the polyester-based polyurethane foam **(PE-PUR foam)** in the Device was known to degrade and present a significant biological risk to patients.

As of 31 May 2021, being 33 days after Philips Australia becomes aware, Philips Australia had not informed the Secretary that Philips Australia therefore contravened subsection 41MPA(1) of the Act.

The maximum penalty a court could impose on a company for a single contravention of subsection 41MPA(1) is 30,000 penalty units.[1] For the above-alleged contravention, this amounts to $6,660,000.

The amount payable under this notice is **$13,320**. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read ***Part D: Information about this Infringement Notice***.

PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.

CHEQUE

Return **this notice** to **Department of Health, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health. Please allow 5 business days for payment to be received

CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number TGAIN-DPMRR-2022-6 as reference to identify your payment

ELECTRONIC FUNDS TRANSFER

Account name: Department of Health
BSB: 092 009
Account: 114 071
Bank: Reserve Bank of Australia, London Circuit, Canberra ACT 2601
Swift: RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number TGAIN-DPMRR-2022-6 in the description of your transfer and allow two business days for payment to be received.

Note: The Department of Health accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment

[1] A penalty unit is currently $222 (section 4AA of the *Crimes Act 1914*).

PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (**TGA**) is not legally able to accept payment of the notice after it has lapsed.

How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health (the **Secretary**) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- postmarketdevices@health.gov.au or
- PO Box 100; WODEN ACT 2609

Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health will, from time to time, make public reference to infringement notices that have been given to companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

Effect of the lapsing of the compliance period for the notice

If the compliance period has passed and no payment has been received by the TGA, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay

the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this notice.

How this notice can be withdrawn

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- postmarketdevices@health.gov.au or
- PO Box 100; WODEN ACT 2609

Effect of withdrawal of this notice

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

signed electronically

s22 [redacted]
A/g Assistant Secretary
Medical Devices Surveillance Branch
Therapeutic Goods Administration
E-mail: postmarketdevices@health.gov.au
PO Box 100 WODEN ACT 2609

Date: 31/05/2022

Managing Director
Philips Electronics Australia Ltd
ABN: 24 008 445 743
65 Epping Road
North Ryde, NSW 2113
Australia

By Express Post and By Email:
s22 [redacted] @philips.com

Infringement Notice Number:
TGAIN-DPMRR-2022-5

Date given: 31/05/2022

Penalty total: $13,320

Payment due: 28/06/2022

Enquiries:
Devices Post Market Reform and Review Section
Telephone: 1800 020 653

Email: postmarketdevices@health.gov.au

INFRINGEMENT NOTICE GIVEN TO
Philips Electronics Australia Ltd

PART A: Infringement Notice given by

s22 [redacted]
Delegate of the Secretary of the Australian Government Department of Health

PART B: Details of alleged contravention

I am a delegate of the Secretary of the Australian Government Department of Health under section 42YK of the *Therapeutic Goods Act 1989* (**the Act**). I have decided to give this Infringement Notice (**the notice**) to Philips Electronics Australia Ltd (**Philips Australia**) under Part 5A-2 of the Act on the basis that I reasonably believe that it has contravened subsection 41MPA(1) of the Act.

The details of the alleged contravention are that:

Philips Australia is the person in relation to whom a kind of device is included in the Australian Register of Therapeutic Goods (**ARTG**), namely the kind of device with ARTG number **257012** (**the Device**).

On or before 28 April 2021, Philips Australia became aware that the polyester-based polyurethane foam **(PE-PUR foam)** in the Device was known to degrade and present a significant biological risk to patients.

As of 31 May 2021, being 33 days after Philips Australia becomes aware, Philips Australia had not informed the Secretary that Philips Australia therefore contravened subsection 41MPA(1) of the Act.

The maximum penalty a court could impose on a company for a single contravention of subsection 41MPA(1) is 30,000 penalty units.[1] For the above-alleged contravention, this amounts to $6,660,000.

The amount payable under this notice is **$13,320**. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read ***Part D: Information about this Infringement Notice***.

PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.

CHEQUE

Return **this notice** to **Department of Health, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health. Please allow 5 business days for payment to be received

CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number TGAIN-DPMRR-2022-5 as reference to identify your payment

ELECTRONIC FUNDS TRANSFER

Account name: Department of Health
BSB: 092 009
Account: 114 071
Bank: Reserve Bank of Australia, London Circuit, Canberra ACT 2601
Swift: RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number TGAIN-DPMRR-2022-5 in the description of your transfer and allow two business days for payment to be received.

Note: The Department of Health accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment

[1] A penalty unit is currently $222 (section 4AA of the *Crimes Act 1914*).

PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (**TGA**) is not legally able to accept payment of the notice after it has lapsed.

How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health (the **Secretary**) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- postmarketdevices@health.gov.au or
- PO Box 100; WODEN ACT 2609

Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health will, from time to time, make public reference to infringement notices that have been given to companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

Effect of the lapsing of the compliance period for the notice

If the compliance period has passed and no payment has been received by the TGA, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay

the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this notice.

How this notice can be withdrawn

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- postmarketdevices@health.gov.au or
- PO Box 100; WODEN ACT 2609

Effect of withdrawal of this notice

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

Signed electronically

s22 [redacted]
A/g Assistant Secretary
Medical Devices Surveillance Branch
Therapeutic Goods Administration
E-mail: postmarketdevices@health.gov.au
PO Box 100 WODEN ACT 2609

Date: 31/05/2022

Managing Director
Philips Electronics Australia Ltd
ABN: 24 008 445 743
65 Epping Road
North Ryde, NSW 2113
Australia

By Express Post and By Email:
s22 [redacted] @philips.com

Infringement Notice Number:
TGAIN-DPMRR-2022-7

Date given: 31/05/2022

Penalty total: $13,320

Payment due: 28/06/2022

Enquiries:
Devices Post Market Reform and Review Section
Telephone: 1800 020 653

Email: postmarketdevices@health.gov.au

INFRINGEMENT NOTICE GIVEN TO
Philips Electronics Australia Ltd

PART A: Infringement Notice given by

s22 [redacted]
Delegate of the Secretary of the Australian Government Department of Health

PART B: Details of alleged contravention

I am a delegate of the Secretary of the Australian Government Department of Health under section 42YK of the *Therapeutic Goods Act 1989* (**the Act**). I have decided to give this Infringement Notice (**the notice**) to Philips Electronics Australia Ltd (**Philips Australia**) under Part 5A-2 of the Act on the basis that I reasonably believe that it has contravened subsection 41MPA(1) of the Act.

The details of the alleged contravention are that:

Philips Australia is the person in relation to whom a kind of device is included in the Australian Register of Therapeutic Goods (**ARTG**), namely the kind of device with ARTG number **209934** (**the Device**).

On or before 28 April 2021, Philips Australia became aware that the polyester-based polyurethane foam **(PE-PUR foam)** in the Device was known to degrade and present a significant biological risk to patients.

As of 31 May 2021, being 33 days after Philips Australia becomes aware, Philips Australia had not informed the Secretary that Philips Australia therefore contravened subsection 41MPA(1) of the Act.

The maximum penalty a court could impose on a company for a single contravention of subsection 41MPA(1) is 30,000 penalty units.[1] For the above-alleged contravention, this amounts to $6,660,000.

The amount payable under this notice is **$13,320**. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read ***Part D: Information about this Infringement Notice***.

PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.

CHEQUE

Return **this notice** to **Department of Health, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health. Please allow 5 business days for payment to be received

CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number TGAIN-DPMRR-2022-7 as reference to identify your payment

ELECTRONIC FUNDS TRANSFER

Account name: Department of Health
BSB: 092 009
Account: 114 071
Bank: Reserve Bank of Australia, London Circuit, Canberra ACT 2601
Swift: RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number TGAIN-DPMRR-2022-7 in the description of your transfer and allow two business days for payment to be received.

Note: The Department of Health accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment

[1] A penalty unit is currently $222 (section 4AA of the *Crimes Act 1914*).

PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (**TGA**) is not legally able to accept payment of the notice after it has lapsed.

How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health (the **Secretary**) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- postmarketdevices@health.gov.au or
- PO Box 100; WODEN ACT 2609

Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health will, from time to time, make public reference to infringement notices that have been given to companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

Effect of the lapsing of the compliance period for the notice

If the compliance period has passed and no payment has been received by the TGA, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay

the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this notice.

How this notice can be withdrawn
The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- postmarketdevices@health.gov.au or
- PO Box 100; WODEN ACT 2609

Effect of withdrawal of this notice
If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

signed electronically

s22 [redacted]
A/g Assistant Secretary
Medical Devices Surveillance Branch
Therapeutic Goods Administration
E-mail: postmarketdevices@health.gov.au
PO Box 100 WODEN ACT 2609

Date: 31/05/2022

Managing Director
Philips Electronics Australia Ltd
ABN: 24 008 445 743
65 Epping Road
North Ryde, NSW 2113
Australia

By Express Post and By Email:
s22 [redacted] @philips.com

Infringement Notice Number:
TGAIN-DPMRR-2022-4

Date given: 31/05/2022

Penalty total: $13,320

Payment due: 28/06/2022

Enquiries:
Devices Post Market Reform and Review Section
Telephone: 1800 020 653

Email: postmarketdevices@health.gov.au

INFRINGEMENT NOTICE GIVEN TO
Philips Electronics Australia Ltd

PART A: Infringement Notice given by

s22 [redacted]
Delegate of the Secretary of the Australian Government Department of Health

PART B: Details of alleged contravention

I am a delegate of the Secretary of the Australian Government Department of Health under section 42YK of the *Therapeutic Goods Act 1989* (**the Act**). I have decided to give this Infringement Notice (**the notice**) to Philips Electronics Australia Ltd (**Philips Australia**) under Part 5A-2 of the Act on the basis that I reasonably believe that it has contravened subsection 41MPA(1) of the Act.

The details of the alleged contravention are that:

Philips Australia is the person in relation to whom a kind of device is included in the Australian Register of Therapeutic Goods (**ARTG**), namely the kind of device with ARTG number **257013** (**the Device**).

On or before 28 April 2021, Philips Australia became aware that the polyester-based polyurethane foam **(PE-PUR foam)** in the Device was known to degrade and present a significant biological risk to patients.

As of 31 May 2021, being 33 days after Philips Australia becomes aware, Philips Australia had not informed the Secretary that Philips Australia therefore contravened subsection 41MPA(1) of the Act.

The maximum penalty a court could impose on a company for a single contravention of subsection 41MPA(1) is 30,000 penalty units.[1] For the above-alleged contravention, this amounts to $6,660,000.

The amount payable under this notice is **$13,320**. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read ***Part D: Information about this Infringement Notice***.

PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.

CHEQUE

Return **this notice** to **Department of Health, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health. Please allow 5 business days for payment to be received

CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number TGAIN-DPMRR-2022-4 as reference to identify your payment

ELECTRONIC FUNDS TRANSFER

Account name: Department of Health
BSB: 092 009
Account: 114 071
Bank: Reserve Bank of Australia, London Circuit, Canberra ACT 2601
Swift: RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number TGAIN-DPMRR-2022-4 in the description of your transfer and allow two business days for payment to be received.

Note: The Department of Health accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment

[1] A penalty unit is currently $222 (section 4AA of the *Crimes Act 1914*).

PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (**TGA**) is not legally able to accept payment of the notice after it has lapsed.

How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health (the **Secretary**) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- postmarketdevices@health.gov.au or
- PO Box 100; WODEN ACT 2609

Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health will, from time to time, make public reference to infringement notices that have been given to companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

Effect of the lapsing of the compliance period for the notice

If the compliance period has passed and no payment has been received by the TGA, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay

the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this notice.

How this notice can be withdrawn
The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- postmarketdevices@health.gov.au or
- PO Box 100; WODEN ACT 2609

Effect of withdrawal of this notice
If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

Signed electronically

s22 [redacted]
A/g Assistant Secretary
Medical Devices Surveillance Branch
Therapeutic Goods Administration
E-mail: postmarketdevices@health.gov.au
PO Box 100 WODEN ACT 2609

Date: 31/05/2022

Managing Director
Philips Electronics Australia Ltd
ABN: 24 008 445 743
65 Epping Road
North Ryde, NSW 2113
Australia

By Express Post and By Email:
s22 [redacted] @philips.com

Infringement Notice Number:
TGAIN-DPMRR-2022-3

Date given: 31/05/2022

Penalty total: $13,320

Payment due: 28/06/2022

Enquiries:
Devices Post Market Reform and Review Section
Telephone: 1800 020 653

Email: postmarketdevices@health.gov.au

INFRINGEMENT NOTICE GIVEN TO
Philips Electronics Australia Ltd

PART A: Infringement Notice given by

s22 [redacted]
Delegate of the Secretary of the Australian Government Department of Health

PART B: Details of alleged contravention

I am a delegate of the Secretary of the Australian Government Department of Health under section 42YK of the *Therapeutic Goods Act 1989* (**the Act**). I have decided to give this Infringement Notice (**the notice**) to Philips Electronics Australia Ltd (**Philips Australia**) under Part 5A-2 of the Act on the basis that I reasonably believe that it has contravened subsection 41MPA(1) of the Act.

The details of the alleged contravention are that:

Philips Australia is the person in relation to whom a kind of device is included in the Australian Register of Therapeutic Goods (**ARTG**), namely the kind of device with ARTG number **285420** (**the Device**).

On or before 28 April 2021, Philips Australia became aware that the polyester-based polyurethane foam **(PE-PUR foam)** in the Device was known to degrade and present a significant biological risk to patients.

As of 31 May 2021, being 33 days after Philips Australia becomes aware, Philips Australia had not informed the Secretary that Philips Australia therefore contravened subsection 41MPA(1) of the Act.

The maximum penalty a court could impose on a company for a single contravention of subsection 41MPA(1) is 30,000 penalty units.[1] For the above-alleged contravention, this amounts to $6,660,000.

The amount payable under this notice is **$13,320**. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read ***Part D: Information about this Infringement Notice***.

PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.

CHEQUE

Return **this notice** to **Department of Health, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health. Please allow 5 business days for payment to be received

CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number TGAIN-DPMRR-2022-3 as reference to identify your payment

ELECTRONIC FUNDS TRANSFER

Account name: Department of Health
BSB: 092 009
Account: 114 071
Bank: Reserve Bank of Australia, London Circuit, Canberra ACT 2601
Swift: RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number TGAIN-DPMRR-2022-3 in the description of your transfer and allow two business days for payment to be received.

Note: The Department of Health accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment

[1] A penalty unit is currently $222 (section 4AA of the *Crimes Act 1914*).

PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (**TGA**) is not legally able to accept payment of the notice after it has lapsed.

How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health (the **Secretary**) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- postmarketdevices@health.gov.au or
- PO Box 100; WODEN ACT 2609

Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health will, from time to time, make public reference to infringement notices that have been given to companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

Effect of the lapsing of the compliance period for the notice

If the compliance period has passed and no payment has been received by the TGA, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay

the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this notice.

How this notice can be withdrawn

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- postmarketdevices@health.gov.au or
- PO Box 100; WODEN ACT 2609

Effect of withdrawal of this notice

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

Signed electronically

s22 [redacted]
A/g Assistant Secretary
Medical Devices Surveillance Branch
Therapeutic Goods Administration
E-mail: postmarketdevices@health.gov.au
PO Box 100 WODEN ACT 2609

Date: 31/05/2022

Managing Director
Philips Electronics Australia Ltd
ABN: 24 008 445 743
65 Epping Road
North Ryde, NSW 2113
Australia

By Express Post and By Email:
s22 [redacted] @philips.com

Infringement Notice Number:
TGAIN-DPMRR-2022-2

Date given: 31/05/2022

Penalty total: $13,320

Payment due: 28/06/2022

Enquiries:
Devices Post Market Reform and Review Section
Telephone: 1800 020 653

Email: postmarketdevices@health.gov.au

INFRINGEMENT NOTICE GIVEN TO
Philips Electronics Australia Ltd

PART A: Infringement Notice given by

s22 [redacted]
Delegate of the Secretary of the Australian Government Department of Health

PART B: Details of alleged contravention

I am a delegate of the Secretary of the Australian Government Department of Health under section 42YK of the *Therapeutic Goods Act 1989* (**the Act**). I have decided to give this Infringement Notice (**the notice**) to Philips Electronics Australia Ltd (**Philips Australia**) under Part 5A-2 of the Act on the basis that I reasonably believe that it has contravened subsection 41MPA(1) of the Act.

The details of the alleged contravention are that:

Philips Australia is the person in relation to whom a kind of device is included in the Australian Register of Therapeutic Goods (**ARTG**), namely the kind of device with ARTG number **295664** (**the Device**).

On or before 28 April 2021, Philips Australia became aware that the polyester-based polyurethane foam **(PE-PUR foam)** in the Device was known to degrade and present a significant biological risk to patients.

As of 31 May 2021, being 33 days after Philips Australia becomes aware, Philips Australia had not informed the Secretary that Philips Australia therefore contravened subsection 41MPA(1) of the Act.

The maximum penalty a court could impose on a company for a single contravention of subsection 41MPA(1) is 30,000 penalty units.[1] For the above-alleged contravention, this amounts to $6,660,000.

The amount payable under this notice is **$13,320**. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read ***Part D: Information about this Infringement Notice***.

PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.

CHEQUE

Return **this notice** to **Department of Health, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health. Please allow 5 business days for payment to be received

CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number TGAIN-DPMRR-2022-1 as reference to identify your payment

ELECTRONIC FUNDS TRANSFER

Account name: Department of Health
BSB: 092 009
Account: 114 071
Bank: Reserve Bank of Australia, London Circuit, Canberra ACT 2601
Swift: RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number TGAIN-DPMRR-2022-1 in the description of your transfer and allow two business days for payment to be received.

Note: The Department of Health accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment

[1] A penalty unit is currently $222 (section 4AA of the *Crimes Act 1914*).

PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (**TGA**) is not legally able to accept payment of the notice after it has lapsed.

How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health (the **Secretary**) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. Requests can be made by sending them directly to:

- postmarketdevices@health.gov.au or
- PO Box 100; WODEN ACT 2609

Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health will, from time to time, make public reference to infringement notices that have been given to companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

Effect of the lapsing of the compliance period for the notice

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How this notice can be withdrawn

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- postmarketdevices@health.gov.au or
- PO Box 100; WODEN ACT 2609

Effect of withdrawal of this notice

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

Signed electronically

s22 [redacted]
A/g Assistant Secretary
Medical Devices Surveillance Branch
Therapeutic Goods Administration
E-mail: postmarketdevices@health.gov.au
PO Box 100 WODEN ACT 2609

Date: 31/05/2022

Managing Director
Philips Electronics Australia Ltd
ABN: 24 008 445 743
65 Epping Road
North Ryde, NSW 2113
Australia

By Express Post and By Email:
s22 [redacted] @philips.com

Infringement Notice Number:
TGAIN-DPMRR-2022-1

Date given: 31/05/2022

Penalty total: $13,320

Payment due: 28/06/2022

Enquiries:
Devices Post Market Reform and Review Section
Telephone: 1800 020 653

Email: postmarketdevices@health.gov.au

INFRINGEMENT NOTICE GIVEN TO
Philips Electronics Australia Ltd

PART A: Infringement Notice given by

s22 [redacted]
Delegate of the Secretary of the Australian Government Department of Health

PART B: Details of alleged contravention

I am a delegate of the Secretary of the Australian Government Department of Health under section 42YK of the *Therapeutic Goods Act 1989* (**the Act**). I have decided to give this Infringement Notice (**the notice**) to Philips Electronics Australia Ltd (**Philips Australia**) under Part 5A-2 of the Act on the basis that I reasonably believe that it has contravened subsection 41MPA(1) of the Act.

The details of the alleged contravention are that:

Philips Australia is the person in relation to whom a kind of device is included in the Australian Register of Therapeutic Goods (**ARTG**), namely the kind of device with ARTG number **327227** (**the Device**).

On or before 28 April 2021, Philips Australia became aware that the polyester-based polyurethane foam **(PE-PUR foam)** in the Device was known to degrade and present a significant biological risk to patients.

As of 31 May 2021, being 33 days after Philips Australia becomes aware, Philips Australia had not informed the Secretary that Philips Australia therefore contravened subsection 41MPA(1) of the Act.

The maximum penalty a court could impose on a company for a single contravention of subsection 41MPA(1) is 30,000 penalty units.[1] For the above-alleged contravention, this amounts to $6,660,000.

The amount payable under this notice is **$13,320**. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read ***Part D: Information about this Infringement Notice***.

PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.

CHEQUE

Return **this notice** to **Department of Health, Accounts Receivable, GPO Box 9848, Canberra ACT 2601** with your cheque made payable to the Department of Health. Please allow 5 business days for payment to be received

CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number TGAIN-DPMRR-2022-1 as reference to identify your payment

ELECTRONIC FUNDS TRANSFER

Account name: Department of Health
BSB: 092 009
Account: 114 071
Bank: Reserve Bank of Australia, London Circuit, Canberra ACT 2601
Swift: RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number TGAIN-DPMRR-2022-1 in the description of your transfer and allow two business days for payment to be received.

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- PO Box 100; WODEN ACT 2609

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If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

signed electronically

s22 [redacted]
A/g Assistant Secretary
Medical Devices Surveillance Branch
Therapeutic Goods Administration
E-mail: postmarketdevices@health.gov.au
PO Box 100 WODEN ACT 2609

Date: 31/05/2022

HEALTH HAZARD EVALUATION FORM

ER 2242138 – DreamStation 1 Volatile Organic Compounds (VOC), Version 01

Step I – Identification of the Issue/Problem

CAPA Number:	858229	HHE Date Open:	19 May 2021	HHE Date Closed:	25 May 2021
- Product Data -					
Product Code:	BZD (noncontinuous ventilator (Intermittent positive pressure breathing - IPPB)) MNT (continuous ventilator, minimal ventilatory support, facility use) MNS (continuous ventilator, non-life supporting)				
Model:	All finished good part numbers under the devices listed below fall within the scope of this HHE. For a comprehensive list of all finished good numbers, refer to CAPA 858229.				
Device Name:	DreamStation 1 CPAP, Auto CPAP, BiPAP DreamStation 1 ASV DreamStation 1 ST, AVAPS Philips Respironics E30 ventilator (considered a part of the DreamStation 1 platform due to similar engineering/design)				
Lot/Serial Numbers:	All DreamStation 1 devices in the field and released in inventory currently using the polyester-based polyurethane foam (PE-PUR) could be subject to this potential failure mode.				
Marketing Status (Include 510(k) or PMA Number, Specify if Class I Exempt from 510(k)):	- DreamStation 1 - K131982 - DreamStation 1 ASV - K090539 - DreamStation 1 ST, AVAPS - K102465 - E30 Ventilator – cleared under Emergency Use Authorization (EUA)				
Manufacturing/Recall Firm Address:	Respironics Inc. 1010 Murry Ridge Ln Murrysville, PA 15668				
Product Description (Include Intended Use from Labeling):	***K131982*** **DreamStation Product Identification and Intended use:** **Regulation** : 21 CFR 868.5905 Identification : A noncontinuous ventilator (IPPB) is a device intended to deliver intermittently, an aerosol to patient's lungs or to				

	assist a patient's breathing. Classification: Class II (performance standards) **Intended Use**: The Philips Respironics DreamStation systems deliver positive airway pressure therapy for the treatment of Obstructive Sleep Apnea in spontaneously breathing patients weighing over 30 kg (66 lbs.). It is for use in the home or hospital/institutional environment. **Device Description:** The DreamStation is designed to provide CPAP, CPAP-Check, Auto CPAP, Bi-Level and Auto Bi-Level therapy. The optional heated humidifier offers Heated Tube (via optional 15mm heated tube, HT15), Adaptive or Fixed humidification. In addition to the ramp function, depending on the therapy selected, one or more of the following pressure relief features is available to increase patient comfort: C-Flex, A-Flex, P-Flex, Bi-Flex and Rise Time. DreamStation is intended for use with a patient circuit that is used to connect the device to the patient interface device (mask). A typical patient circuit consists of disposable or reusable smooth lumen tubing, (22mm, 15mm, Heated Tube15, or 12mm tubing). A typical patient interface device provides a method of venting exhaled gases. Bluetooth wireless technology gives a patient access to their compliance data in markets where the DreamMapper mobile application is available. Optional modem accessories, Cellular Modem or Wi-Fi Accessory, automatically upload patient compliance data to their provider. If included, a Secure Digital (SD) card will also store compliance data allowing a provider to collect a patient's data periodically. ***K090539*** **DreamStation ASV Product Identification and Intended use**: **Regulation**: 21 CFR 868.5905 Identification: A noncontinuous ventilator (Intermittent positive pressure breathing - IPPB) is a device intended to deliver intermittently, an aerosol to patient's lungs or to assist a patient's breathing. Classification: Class II (performance standards) **Intended Use**: The BiPAP autoSV device is intended to provide non-invasive ventilatory support to treat adult patients (>30 kg/66 lbs.) with Obstructive Sleep Apnea and Respiratory Insufficiency caused by central and/or mixed apneas and periodic breathing. This device may be used in the hospital or home. **Device Description:** The BiPAP autoSV device is intended to augment breathing by supplying pressurized air through a circuit. It senses breathing effort by monitoring airflow in the circuit and adjusts its output to assist with inhalation. This therapy is known as Bi-level ventilation. Bi-level ventilation provides a higher pressure, known as IPAP (Inspiratory Positive Airway Pressure), during inhalation and a lower pressure, known as EPAP (Expiratory Positive Airway Pressure), during

	exhalation. The higher pressure makes it easier to inhale, and the lower pressure makes it easier to exhale. A user interface displays clinical data and enables the operator to set and adjust certain clinical parameters. The devices are intended for use with a patient circuit that is used to connect the device to the patient interface device (mask). A typical patient circuit consists of a six-foot disposable or reusable tubing and a patient interface device. ***K102465*** **DreamStation S/T and AVAPS Product Identification and Intended use**: **Regulation**: 21 CFR 868.5905 Identification: A noncontinuous ventilator (IPPB) is a device intended to deliver intermittently, an aerosol to patient's lungs or to assist a patient's breathing. Classification: Class II (performance standards) **Intended Use**: The BiPAP S/T device is intended to provide non-invasive ventilatory support to treat adult and pediatric (> 7 years of age and > 40 lbs) patients with obstructive Sleep Apnea (OSA) and Respiratory Insufficiency. The device may be used in the hospital or home. The BiPAP AVAPS device is intended to provide non-invasive ventilatory support to treat adult and pediatric (> 7 years of age and > 40 lbs) patients with obstructive Sleep Apnea (OSA) and Respiratory Insufficiency. The device may be used in the hospital or home. **Device Description:** The DreamStation BiPAP S/T and DreamStation BIPAP AVAPS devices are a microprocessor controlled blower based positive pressure system with optional integrated heated humidifier. The BiPAP S/T and BiPAP AVAPS devices are intended to provide non-invasive ventilatory support to Obstructive Sleep Apnea (OSA) and Respiratory Insufficiency patients weighing over 18 kg. This device may be used in the hospital or home. A user interface displays clinical data and enables the operator to set and adjust certain clinical parameters. The DreamStation BiPAP AVAPS and BiPAP S/T is fitted with alarms to alert the user to changes that will affect the treatment. Some of the alarms are pre-set (fixed), others are user adjustable. The devices are intended for use with a patient circuit that is used to connect the device to the patient interface device (mask). A typical patient circuit consists of a six-foot disposable or reusable tubing and a patient interface device. **Philips Respironics E30 Ventilator Product Identification and Intended use**: **Regulation**: The Cardigan ventilator will be an Emergency Use Authorization ventilator approved by the FDA.

	Classification and Identification: It will be a Class II, Ventilator, Continuous, Minimal Ventilator Support, Facility Use (Product Code MNT). **Intended Use**: The Philips Respironics E30 ventilator is intended to provide invasive and non-invasive ventilatory support for individuals with Respiratory Insufficiency. It is specifically for the care of adult and pediatric patients >7 years of age and >18kgs. It is intended to be used in the hospital or other institutional healthcare environments, as well as spaces converted for the care of large numbers of COVID-19 patients (e.g. convention centers, university dormitories, motels). The Philips Respironics E30 ventilator is intended for use by qualified, trained personnel under the direction of a physician. **Device Description:** The Philips Respironics E30 Ventilator is intended to reduce the burden and need for mechanical ventilation in acute settings during high census periods of respiratory distress related to the COVID health crisis. The Philips Respironics E30 Ventilator t is a simplified invasive and non-invasive device for clinicians to provide CPAP, non-invasive and invasive pressure ventilation with up to 40 lpm supplemental oxygen therapy in all modalities and modes 40 lpm of supplemental O2 can be integrated into the air path or bled into a patient's passive circuit. This Philips Respironics E30 Ventilator is meant to treat patients in the hospital or other institutional healthcare facilities where there are not enough mechanical ventilators to provide adequate care/therapy/ventilation, The Philips Respironics E30 Ventilator is for patients with respiratory insufficiency that may also experience shortness of breath.
Brief description of the issue/problem and how it was identified:	Testing conducted by Philips (in conjunction with Third-party laboratories) indicates that DreamStation 1 (DS1) devices with PE-PUR sound abatement foam were found to exceed acceptable levels of Volatile Organic Compound (VOC) emissions that could potentially cause patient harm per ISO 18562 (a standard released in 2017 and recognized by FDA in 2018). A recent PSN Test report (700025-RP-01(Rev E), dated May 25, 2021) indicated that dimethyl diazene and alkylphenol are Chemicals Of Concern (COC). When calculated with the ICH M7 guideline of 1.5 µg/day for long-term (exceeding 30 days) exposure to a potential mutagenic or carcinogenic analyte, the margin of safety is below 1, indicating a potential hazard for both 30 and 70 kg patient populations. This confirms dimethyl diazine (and its oxidized derivative azoxymethane) and alkylphenol as COCs. The other devices in this HHE are included as they share the same engineering platform but lack VOC testing data.

Affected Patient/User Population:	All patient groups that fall within the intended use of the devices referenced in the Product Description are within the affected patient population. The intended patient population broadly includes the following: adult and pediatric patients weighing over 18 kg with Respiratory Insufficiency. Higher risk populations within the intended patient population include infants, elderly, pregnant women, critically ill patients, and patients with comorbidities such as heart failure, COPD, and obesity.
HHE Author (Name/Function):	s22 [redacted] – Design Quality Engineer/Safety Risk Management
HHE Contributors (Name/Function):	s22 [redacted] – Design Quality Engineer/Safety Risk Management s22 [redacted] – Head of Global Clinical and Scientific Affairs s22 [redacted] – Medical Leader, SRC s22 [redacted] – Medical Director, Connected Care s22 [redacted] – Head of Design Quality Engineering s22 [redacted] – Medical Safety Manager

Step II – Analyze Post Release Health Risk Associated with Affected Units

Note: Assess the risk as if no corrective action will be taken and all affected devices will remain in the marketplace.

A. Identification of the Individual Hazard(s)

Hazard Category:	**Hazard Category:** Biological and Chemical **Hazard**: Biocompatibility / Toxicity of chemical constituents
Hazard Cause:	Emission of VOC's for devices with PE-PUR sound abatement foam. Investigation into the root cause of the VOC's emission is ongoing.
Hazardous Situation:	While receiving therapy patients may be exposed to hazardous levels of VOCs that are unacceptable per ISO standards.

B. Estimation of Severity

Description of reported and/or potential harm:	Dimethyl diazene is also known as azomethane with no specific pre-clinical toxicological data available in scientific literature, nor a known daily permissible daily exposure limit. A Quantitative Structure Activity Relationship (QSAR) analysis reveals a genotoxic alert based on the azo chemistry. The data also suggest that it has high skin permeability. Finally, the literature suggest that azo compounds have mutagenic potential.[1,2,3] The oxide derivative of this surrogate azomethane compound, azoxymethane (CAS Number 25843-45-2) is a potent carcinogen. Phenol, 2,6-bis(1,1-dimethylethyl)-4-(1-methylpropyl)- (CAS Number 17540-75-9) has no specific pre-clinical toxicological data available in scientific literature, nor a known daily permissible daily exposure limit. QSAR analysis with the Derek Nexus predictive software revealed an open structural alert for chromosome damage (in vitro chromosome aberration test) due to it being an alkylphenol, a potential mutagen.

[1] Sweeney EA, Chipman JK, Forsythe SJ. Evidence for direct-acting oxidative genotoxicity by reduction products of azo dyes. Environ Health Perspect. 1994 Oct;102 Suppl 6(Suppl 6):119-22. doi: 10.1289/ehp.94102s6119. PMID: 7889833; PMCID: PMC1566849.

[2] Mori H, Mori Y, Sugie S, Yoshimi N, Takahashi M, Ni-i H, Yamazaki H, Toyoshi K, Williams GM. Genotoxicity of a variety of azobenzene and aminoazobenzene compounds in the hepatocyte/DNA repair test and the Salmonella/mutagenicity test. Cancer Res. 1986 Apr;46(4 Pt 1):1654-8. PMID: 3081253.

[3] Shuji Tsuda, Naonori Matsusaka, Hiroo Madarame, Shunji Ueno, Nobuyuki Susa, Kumiko Ishida, Noriko Kawamura, Kaoru Sekihashi, Yu F Sasaki, The comet assay in eight mouse organs: results with 24 azo compounds, Mutation Research/Genetic Toxicology and Environmental Mutagenesis, Volume 465, Issues 1–2, 2000, Pages 11-26, ISSN 1383-5718, https://doi.org/10.1016/S1383-5718(99)00199-0.

<table>
<tr><td></td><td>It is not known what duration of exposure is required for certain harms to develop.

Potential harms that can be exhibited as a result of exposure to VOCs as a class:
• Headache/dizziness
• Irritation (eyes, nose respiratory tract, skin)
• Hypersensitivity
• Nausea/emesis
• Toxicity: genotoxic, mutagenic, carcinogenic effects
• Hepatotoxicity, nephrotoxicity, neurotoxicity[4]</td></tr>
<tr><td>Estimation of Severity of Harm</td><td>3 (Crucial)

Results in serious injury: life-threatening, or permanent impairment or necessitates medical intervention to preclude permanent impairment

This is considering the reasonable worst-case scenario.</td></tr>
<tr><td>Comments:

(Severity of Harm Rationale)</td><td>Severity of harm was estimated based on the findings in various test reports, literature searches, and the experience of credentialed medical professionals.

Based on a foreseeable worst-case patient population being exposed to the harms identified above, it was determined that the Crucial severity of harm (level 3) recognizes the seriousness of any potential harm that may significantly impact the clinical status of patients and require additional medical intervention.</td></tr>
<tr><td>Reference Information:</td><td>
<table>
<tr><th>Check (X) Applicable Level*</th><th>Examples</th></tr>
<tr><td>___ 4 (Catastrophic)</td><td>Directly results in death</td></tr>
<tr><td>x 3 (Crucial)</td><td>Results in serious injury: life-threatening, or permanent impairment or necessitates medical intervention to preclude permanent impairment</td></tr>
<tr><td>___ 2 (Marginal)</td><td>Results in moderate injury: temporary impairment, or self-limiting illness</td></tr>
<tr><td>___ 1 (Negligible)</td><td>Results in less than moderate or no injury</td></tr>
</table>
* Severity Levels 4 and 3 are “serious adverse health consequences”
</td></tr>
</table>

[4] United States Environmental Protection Agency (EPA). Volatile Organic Compounds’ Impact on Indoor Air Quality. Retrieved online on 4/29/21 from Volatile Organic Compounds' Impact on Indoor Air Quality | Indoor Air Quality (IAQ) | US EPA.

	per FDA's CDRH Health Hazard Evaluation Form Version 3-1 01/12/2007. Severity Levels 2 and 1 are not serious adverse health consequences per FDA's HHE Form.

C. Estimation of Probability of Harm Resulting from Affected Units

Estimated quantity of affected devices (# in field, # in factory, # in distribution centers, etc.):	A total of 7,166,491 DreamStation 1 platform devices were shipped between 2015 and April 2021. This includes : • 6909399 shipments of DS1 CPAP devices • 137042 shipments of DS1 AVAPS/ST NIV devices • 98860 shipments of DS1 ASV NIV devices • 21,190 shipments of E30 ventilator
Number and type of injuries/number of deaths attributed to the problem with the device (if any):*	It should be noted that harm may not be immediately recognizable and may not be something that the customer would/could report. Serious adverse events = 0 Deaths = 0
Describe the factor(s) that need to occur to create the hazardous situation (reasonably foreseeable sequence or combination of events):	A hazardous situation is created when a patient uses a DreamStation 1 therapy device with PE-PUR foam. COCs at unacceptable levels per ISO standard are released from the device, expelled through the airpath and patient circuit and delivered to the patient.
Factors that might mitigate risk (e.g., safety mechanisms present in the design, instructions for use, current label warnings, etc.):	There are no safety mechanisms present that would aid in mitigating the risks associated with harmful chemicals being emitted from device materials for devices in the field.
Would a user detect the hazardous situation prior to occurrence of harm? If so, describe how:	It is unlikely that a user would detect VOC exposure while using the device.

Probability Estimate

Estimation of Probability that the Harm will occur:	**2 (Occasional)** 'Remote probability' that use will cause harm; expected to cause harm rarely/ from time to time (e.g., with no clear trend)

Comments:	Probability of Hazardous Situation Occurring (P1)
(Probability of Harm Rationale)	Hazardous situation: While receiving therapy, patients may be exposed to hazardous levels of VOCs that are unacceptable per ISO standards. **Probability that Hazardous Situation will Lead to Harm (P2)** There are no data to accurately estimate the probability of the hazardous situation leading to harm. **Probability of Occurrence of Harm (P)** Taking into consideration P1 and P2, it is challenging to accurately estimate the probability of harm quantitatively. A probability of 2 (Occasional) was chosen as the reasonable worst-case scenario for a Severity 3 harm.

Considering the factors above, assess the probability that use of, or exposure to, the affected devices will cause future harm during the product's lifetime. Consider segments of the population most at risk (e.g. infants, elderly, pregnant women, critically ill patients, etc.).

Check (X) applicable level*	***Example of probability of harm***
___ **4** **(Always)**	Occurs 'every time'*
___ **3** **(Likely)**	'Reasonable probability' that use will cause harm*; good chance/ considerable certainty to cause harm
X **2** **(Occasional)**	'Remote probability' that use will cause harm*; expected to cause harm rarely/ from time to time (e.g., with no clear trend)
___ **1** **(Unlikely)**	'Not likely' that use will cause harm*; possible but improbable
___ **0** **(Inconceivable)**	Inconceivable; not possible

*** Corresponds with probability levels set forth in FDA's CDRH HHE Form Version 3-1 01/12/2007.**

***Note: If harm has already occurred as a result of the issue under review, then:**

- Probability level zero (0) and one (1) 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.
- Probability level 0 rarely applies to post-market risk evaluation in cases where harm has occurred.

Step III – Health Hazard Evaluation Conclusion

Probability	Severity			
	1	2	3	4
4	Unacceptable	Unacceptable	Unacceptable	Unacceptable
3	Acceptable	Unacceptable	Unacceptable	Unacceptable
2	Acceptable	Further Analysis Required[1)]	**Unacceptable**	Unacceptable
1	Acceptable	Acceptable	Further Analysis Required[1)]	Unacceptable
0	Acceptable	Acceptable	Acceptable	Acceptable

[1)] If the results of a risk evaluation fall into one of these two cells (3x1 or 2x2), then a risk/benefit analysis and/or appropriate justification must be documented in section C below.

Note:

- The original premarket risk/benefit analysis may be reused if still applicable as the evaluation to justify an acceptable risk.
- The above Risk Table helps assess whether the risk is acceptable or not; however, reviewer/approvers of this document make the final determination.
- Even if a risk is deemed "acceptable", action to address the issue may still be warranted.

A. Document the results of the Health Hazard Evaluation for each hazardous situation under review:

Severity: **3** / Probability: **2** = UNACCEPTABLE (acceptable/unacceptable)

B. If the risk of the individual hazardous situation is acceptable, review the Risk Management File and consider combined impact of all the individual risks to evaluate whether overall residual risk of the device is still acceptable. Is the summary of all the risks acceptable or not acceptable?

UNACCEPTABLE (acceptable / unacceptable)

C. Any additional information (if applicable):	The risk management files associated with these products will be evaluated and updated per the information above. The Philips Respironics team is continuing to conduct additional investigational activities to better understand the root cause of the PE-PUR sound abatement foam to emit VOCs that exceed the acceptable limits provided in ISO 18562. Testing is currently underway to understand the nature of VOC emission in degraded foam.

	To ensure that we maintain our perspective and focus on our users, we have made conservative assumptions in identifying the severity and probability of the harms associated with this issue. This HHE will be updated (as required) when additional testing on degraded foam is completed.
Health Hazard Evaluation Conclusion:	**Medical Assessment** The Health Hazard Evaluation conducted by the Philips Respironics Team concluded that the Hazards described herein represent an unacceptable risk to users. **Severity 3; Probability 2** The severity of harm (level 3) recognizes the seriousness of any potential harm and the need for medical intervention to preclude permanent impairment. Probability of harm (level 2) indicates a remote probability that device use will cause harm; expected to cause harm rarely/ from time to time (i.e., with no clear trend).

Step IV – Outcome approved by the following individuals:

Prepared By:

Signature Date

See EDMS for e-signature and date

Print Name and Title

s22 – Design Quality Engineer / Safety Risk Management

Approved By Director of BIU QARA:

Signature Date

See attached signature sheet

Print Name and Title

s22 – Head of Design Quality Engineering

Approved By VP of Corporate QA – HHS Q&R (or delegate):

Signature Date

See attached signature sheet

Print Name and Title

s22 – Head of Quality SRC

Approved By Credentialed Medical Professional:

Signature Date

See attached signature sheet

Print Name and Title

s22 – Medical Leader SRC

Approved By Credentialed Medical Professional:

Signature Date

See attached signature sheet

Print Name and Title

s22 – Medical Director Connected Care

Approved By Clinical Affairs Representative:

Signature Date

See EDMS for e-signature and date

Print Name and Title

s22 – Head of Clinical Affairs

Note: This form may be emailed or faxed to the person(s) above. Signature (electronic or fax) is required for all HHEs.

HEALTH HAZARD EVALUATION FORM

ER 2241623 – Foam Degradation in Trilogy Devices, Version 00

Step I – Identification of the Issue/Problem

CAPA Number:	**7211**	**HHE Date Open:**	11/16/2020	**HHE Date Closed:**	04/26/2021
- Product Data -					
Product Code:	CBK (Ventilator, Continuous, Facility Use)				
Model:	All finished good part numbers under the devices listed below fall within the scope of this HHE. For a comprehensive list of all finished good numbers, refer to CAPA 7211.				
Device Name:	Trilogy Ventilator				
Lot/Serial Numbers:	All devices in the field and released in inventory currently using the polyester-based polyurethane foam (PE-PUR) could be subject to this potential failure mode.				
Marketing Status (Include 510(k) or PMA Number, Specify if Class I Exempt from 510(k)):	Trilogy 100: K083526 Trilogy 200: K093416				
Manufacturing/Recall Firm Address:	Respironics Inc. 1010 Murry Ridge Ln Murrysville, PA 15668				
Product Description (Include Intended Use from Labeling):	**Trilogy Product Identification and Intended use**: **Regulation**: 21 CFR 868.5895 Identification: A continuous ventilator (respirator) is a device intended to mechanically control or assist patient breathing by delivering a predetermined percentage of oxygen in the breathing gas. Adult, pediatric, and neonatal ventilators are included in this generic type of device. Classification: Class II (performance standards) **Intended Use for Trilogy 100** - The Philips Respironics Trilogy100 system provides continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. Trilogy100 is intended for pediatric through adult patients weighing at least 5 kg (11 lbs.). The device is intended to be used in home, institution/hospital, and portable applications such as wheelchairs and gurneys, and may be used for both invasive and non-invasive ventilation. It is not intended to be used as a transport ventilator. The system is recommended to be used only with various combinations of Philips Respironics-approved patient circuit accessories, such as patient interface devices, humidifiers, water				

	traps, and circuit tubing. **Intended Use for Trilogy 200** - The Philips Respironics Trilogy200 system provides continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. Trilogy200 is intended for pediatric through adult patients weighing at least 5 kg (11 lbs.). The device is intended to be used in home, institution/hospital, and portable applications such as wheelchairs and gurneys, and may be used for both invasive and non-invasive ventilation. It is not intended to be used as a transport ventilator. The system is recommended to be used only with various combinations of Philips Respironics-approved patient circuit accessories, such as patient interface devices, humidifiers, water traps, and circuit tubing. **Device Description (100 and 200):** The Trilogy ventilator provides invasive and non-invasive, positive pressure ventilation to pediatric through adult patients with a minimum weight of 2.5 kg. It is an electronically-controlled, pneumatic ventilation system that is compatible with a range of accessories to provide a variety of therapy modes. The subject devices provide different modes of ventilator support. Mode of ventilation refers to the method of inspiratory support provided by the ventilator. It is the specific combination of breathing pattern and control variables to deliver inspiration. Selection of the modes to be used will depend on the patient's condition and Clinician's decision.
Brief description of the issue/problem and how it was identified:	Philips Respironics received complaints in 2019 regarding SystemOne CPAP devices from Thailand (Complaint numbers RA 307829970 and 307806329) alleging the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask). In one of these complaints, the patient's family member expressed concerns that the black particulate was delivered to the patient's airway and could affect the user's health. The SystemOne devices for both complaints were returned and visual inspection showed signs of foam degradation. Chemical analysis of the foam confirmed degradation, triggering the initiation of CAPA 7211 and additional investigational activities. The sound abatement foam is an open-cell polyester-based polyurethane (PE-PUR) foam that is widely used for sound dampening purposes in many industries. The PE-PUR foam is also used in Philips Respironics Trilogy devices, the subject of this Health Hazard Evaluation (HHE). A complaint analysis performed as part of CAPA 7211 indicated that complaints for PE-PUR foam degradation were also identified for the Trilogy devices. Specifically, 66 complaints were identified suggesting the presence of degraded foam with Trilogy devices. In addition, the complaint analysis showed an overall increase in complaints related to alleged PE-PUR foam degradation across the PRI PAP devices, NIV, and ventilators. The majority of complaints were reported by Philips service personnel and were found subsequent to investigating the patients'

	primary complaints. As of the date of this HHE, 268,140 Trilogy devices have been shipped. Accordingly, Philips Respironics initiated this HHE to evaluate potential foam degradation in the context of Trilogy devices based on available data generated to date. Prior to the 2019 complaints, Philips Respironics received two complaints (RA # 307114335 and 307270215) alleging that a Trilogy device displayed a "vent INOP" error (a "Ventilator Inoperable" alarm). The investigation (INV0988) into the complaint identified that the alarm was triggered due to foam debris that had built up in the motor blower. Following these complaints, an HHE was conducted for the Trilogy platform (see ER 2227646, v06). Based on the data available at that time, the HHE concluded acceptable risk. Based on the results of the 2018 HHE, Philips added foam replacement as part of an existing preventive maintenance (PM) program. This Health Hazard Evaluation only assesses the risks associated with physical exposure to foam particulates. Emission of chemical compounds as a result of foam breakdown is recognized as a potential source of harm, however testing is ongoing to further investigate the potential harms associated with this. As additional information becomes available, this HHE will be updated to reflect any changes to the overall risk profile.
Affected Patient/User Population:	All patient groups that fall within the intended use of the devices referenced in the Product Description are within the affected patient population. The intended patient population across the Trilogy platforms broadly includes the following: adult and pediatric patients weighing over 11 lbs. (5 kg) who require mechanical ventilation. Higher risk populations within the intended patient population include pediatrics; the elderly; pregnant women; and patients with comorbidities such as heart failure, COPD, and obesity.
HHE Author (Name/Function):	s22 [redacted] – Design Quality Engineer/Safety Risk Management
HHE Contributors (Name/Function):	s22 [redacted] – Design Quality Engineer/Safety Risk Management s22 [redacted] – Design Quality, Sr. Manager s22 [redacted] –Quality Engineering, Manager s22 [redacted] – Head of Design Quality Engineering s22 [redacted] – Sustaining Engineering Manager s22 [redacted] – Sr. Quality Engineer s22 [redacted] – Sr. Bio Safety and Verification Engineer s22 [redacted] – Head of Global Clinical and Scientific Affairs s22 [redacted] – Medical Director, Connected Care s22 [redacted] – Director of Regulatory Affairs s22 [redacted] – Medical Leader, SRC s22 [redacted] – Medical Safety Manager, SRC

Step II – Analyze Post Release Health Risk Associated with Affected Units

Note: Assess the risk as if no corrective action will be taken and all affected devices will remain in the marketplace.

A. Identification of the Individual Hazard(s)

Hazard Category:	**Hazard Category:** Biological and Chemical **Hazard**: Biocompatibility / Toxicity of chemical constituents
Hazard Cause:	Polyester-based polyurethane foam (PE-PUR) is used as a sound abatement foam in the Trilogy device airpath. Based on all available data generated to date, Philips Respironics determined that the PE-PUR foam's reaction with moisture (hydrolysis) was a source of the foam degradation potentially caused and/or exacerbated by the following factors: • Device operation in higher heat and humidity environmental conditions; and/or • Use of unapproved cleaning and disinfection methods with the Trilogy device (e.g. ozone). *Environmental Conditions* The labeled environmental conditions for operating temperature are 5° to 40° C (41° to 104° F) with storage temperatures ranging from -20° to 60° C (-4° to 140° F). Preliminary test results conducted by Philips Respironics show that high temperature (90° C) contributes to significant degradation of the foam. Testing is ongoing to further refine the impact of various ambient temperatures and humidity on foam degradation including: (1) models that may better simulate real world device operation conditions; and (2) lower temperatures within the labeled range. Refer to Section III,C for additional information on planned testing. *Unapproved Cleaning and Disinfection Methods* The Trilogy user manual cleaning instructions do not include ozone disinfection; rather, the instructions recommend water and a mild liquid dishwashing detergent for cleaning and Hydrogen Peroxide, Isopropyl Alcohol or a Chlorine Bleach solution for disinfection. The manual states that any deviation from these instructions or agents not listed in this guide may impact the performance of the product. Ozone disinfection devices appear to have become more readily available around the same time as Philips Respironics received complaints of foam degradation, however further investigation is ongoing. Foam degradation has also been reported even when ozone disinfection was not reported.
Hazardous Situation:	**Exposure to particulate by-products of foam degradation during use.** If PE-PUR foam degrades, small particulates (estimated size range of 2.69 µm-724 µm) may be expelled from the device blower box, through the motor and patient circuit and could enter the patient respiratory tract and/or Gastrointestinal (GI) tract. Based on our analysis of the degraded foam, the particles may include compounds such as diethylene glycol (DEG), toluene diamine isomers (TDA), and toluene diisocyanate isomers (TDI). Due to an inability to obtain a sufficient quantity of representative field

	samples for biocompatibility lab testing, we created lab degraded foam used for such testing, including: cytotoxicity, genotoxicity, irritation, and sensitization tests.

B. Estimation of Severity

Description of reported and/or potential harm:	**Harm resulting from Short-Term and Intermediate-Term Exposure:** exacerbation or worsening of the underlying patient condition Potential Harms: • Irritation (skin, eye, and respiratory tract) • Inflammatory response • Headache • Asthma • Effects to reproductive system • Neoplasia While no harm was reported for Trilogy devices, 10 reported cases of harm were reported for PAP devices. These complaints are detailed in CAPA 7211 and generally included complaints of headache, upper airway irritation, cough, chest pressure, and sinus infection. Attributable harm may be confounded by the additional use of ozone (alleged to be used in 5 of the 10 complaints) or the use of PAP therapy in general. **Harm resulting from Long-Term Exposure:** cytotoxic, genotoxic, and potential carcinogenic effects Zero cases of harm have been directly or indirectly linked to this failure mode.
Estimation of Severity of Harm	**3 (Crucial) – Short/Intermediate Term Exposure** Results in serious injury: life-threatening, or permanent impairment or necessitates medical intervention to preclude permanent impairment This is considering the reasonable worst-case scenario, per the rationale in the comments section below. **3 (Crucial) – Long Term Exposure** Results in serious injury: life-threatening, or permanent impairment or necessitates medical intervention to preclude permanent impairment Philips Respironics identified no significant difference in the estimated severity of harm when considering the general and higher risk patient populations.
Comments: (Severity of Harm Rationale)	A Bio Endpoint Analysis and toxicological risk assessment was performed on the specific chemical constituents and their potential impact to patients. This analysis is included as part of CAPA 7211; the testing is summarized below. Due to the difficulty in obtaining a sufficient quantity of representative field

samples for biocompatibility lab testing, laboratory accelerated aged foam was used to conduct the cytotoxicity, genotoxicity, irritation, and sensitization tests. The following results were noted:

- Cytotoxicity was noted for all extraction concentrations.
- Two genotoxicity assays confirmed a positive mutagenic response.
- Irritation results for the non-polar extract returned a passing result.
- Sensitization results from both polar and non-polar extracts returned a passing result.

Daily chemical dosages and concentrations are unknown at this time. Philips is in the process of constructing a model that calculates the start and rate of foam degradation. Further investigations are ongoing and detailed in Step III, Section C. Additionally, the literature does describe tolerable intake (TI) references for some of the major degradative by-products of the polyester polyurethane foam: TDA, TDI and DEG. Specifically:

- **Toluene diamine isomers (TDA)**, such as toluene-2,4-diamine, are primarily used in the synthesis of polyurethane, various dyes, and heterocyclic compounds.[1,2]
    - A chronic reference dose (RfD) for 2, 6 toluene diamine has been listed by the IRIS EPA at 0.03 mg/kg per day.[3]
- **Toluene diisocyanate isomers (TDI)** such as 2,4-toluene diisocyanate are chemical intermediates utilized in the production of polyurethane products.[4]
    - A reference concentration of 0.00007 mg/m^3 (0.07 µg/m^3) has been recommended for toluene diisocyanates by the EPA IRIS risk assessment.[5]
    - The U.S. Office of Environmental Health Hazard Assessment (OEHHA) has listed the Safe Harbor Levels at 20 µg/day for the no significant risk level (NSRL) to toluene diisocyanates.
- **Diethylene glycol (DEG)** is a polyol building block utilized in the synthesis of polyurethane.
    - Literature suggests a proposed human oral ingestion reference dose of 0.3 mg/kg for DEG.[6]
    - A WEEL occupational level of 10 mg/m^3 has been proposed by TERA for inhalational limits of DEG[7]- but this is not adequate or protective for sensitive patient populations and only accounts for an occupational worker exposure.
    - Per prior informal feedback from the FDA, 1% of the WEEL occupational value (10 mg/m^3) would be an adjusted tolerable intake of 0.1 mg/m^3.

Philips Respironics is working to complete the additional investigatory activities described in Step III, Section C to assess whether the amount of

degraded PE-PUR form inhaled and/or ingested by the patient may potentially exceed the TI references provided above.

In order to evaluate the risks posed by the PE-PUR foam particulates, exposure time and patient airway physiology must be considered. Data generated to date suggests that the PE-PUR foam degrades into particulates of varying sizes. The location of collected particulates in the respiratory tract and the body's response to them is partially dictated by size.

- For this HHE, the PE-PUR foam particulates are assumed to reach the patient airway (the amount or concentration in µg/m^3 is unknown).

  The location of where aerosolized particulates collect in the respiratory tract and the body's response to them is partially dictated by size.[1] A multitude of tissues compose the respiratory tract which includes the conducting airways that consist of the nose and mouth, pharynx, larynx, leading into the trachea, main bronchi, lobar, segmental bronchi, and terminal bronchioles.[2] The terminal bronchioles then lead into the respiratory bronchioles, alveolar ducts, and lastly alveolar sacs.[2] There are defense mechanisms in the respiratory system which help prevent particulates from entering into the lung, these include cilia and mucous layers. Cilia are hair-like projections of the cells that line the airway and propel the liquid layer of mucous which can trap pathogens and particulates prior to reaching the lungs.[3]

- The nose and accompanying respiratory tract is capable of filtering foreign particles dependent on particle size and airflow rate with a filtration efficacy decreasing with particulate size.[4] Small particles (<1-3 µm) are capable of diffusing into deep lung tissue and deposit into the alveoli whereas larger particulates (> 8 µm) will be deposited throughout the nasal passages and larger bronchioles.[1]

- Macrophages: one of the three types of alveolar cells, also known as dust cells, can eliminate foreign particles and bacteria through the process of phagocytosis

Philips Respironics particle size analysis identified that the majority of particulate (> 8 µm) is of a size that is unable to penetrate into deep lung tissue and thus will remain in the patient upper airway. A smaller fraction of the particulate (<1-3 µm) may still penetrate into the lower respiratory tract.

Our conclusions are as follows:

- Based on the cytotoxicity and genotoxicity results and toxicological risk assessment, combined with our conclusion that particles are likely to reach the upper airway and potentially the lower respiratory track, a reasonable worst-case estimate for the **general** and **higher risk** (e.g., patient populations with preexisting conditions or comorbidities) patient populations is a severity level 3 (Crucial) for both short/intermediate and long term exposure.

Reference Information:

Check (X) Applicable Level*	Examples
___ 4 (Catastrophic)	Directly results in death
X 3 (Crucial)	Results in serious injury: life-threatening, or permanent impairment or necessitates medical intervention to preclude permanent impairment
___ 2 (Marginal)	Results in moderate injury: temporary impairment, or self-limiting illness
___ 1 (Negligible)	Results in less than moderate or no injury

*Severity Levels 4 and 3 are “serious adverse health consequences” per FDA’s CDRH Health Hazard Evaluation Form Version 3-1 01/12/2007. Severity Levels 2 and 1 are not serious adverse health consequences per FDA’s HHE Form.

References:

1. Thomas, R. J. Particle size and pathogenicity in the respiratory tract. Virulence 4, 847–858 (2013).

2. Patwa, A. & Shah, A. Anatomy and physiology of respiratory system relevant to anaesthesia. Indian J. Anaesth. 59, 533–541 (2015).

3. Defense Mechanisms of the Respiratory System - Lung and Airway Disorders. Merck Manuals Consumer Version Available at: https://www.merckmanuals.com/home/lung-andairway-disorders/biology-of-the-lungs-and-airways/defense-mechanisms-of- the-respiratorysystem. (Accessed: 23rd May 2018)

4. Imre Salma, Imre Balásházy, Renate Winkler-Heil, Werner Hofmann, Gyula Záray,. Effect of particle mass size distribution on the deposition of aerosols in the human respiratory system, Journal of Aerosol Science, Volume 33, Issue 1, 2002, Pages 119-132, ISSN 0021-8502, https://doi.org/10.1016/S0021-8502(01)00154-9. (https://www.sciencedirect.com/science/article/pii/S0021850201001549)

5. Knowles, M. R. & Boucher, R. C. Mucus clearance as a primary innate defense mechanism for mammalian airways. J. Clin. Invest. 109, 571–577 (2002)

C. Estimation of Probability of Harm Resulting from Affected Units

Estimated quantity of affected devices (# in field, # in factory, # in distribution centers, etc.):	Between 2008 through March 2021, a total of 268,140 shipments of Trilogy Devices.
Number and type of injuries/number of deaths attributed to the problem with the device (if any):*	No instances of harm have been reported in Trilogy devices where foam degradation was alleged. Injuries = 0 Deaths = 0 In the case of long-term exposure, it should be noted that harm may not be immediately recognizable and may not be something that the customer would/could report. A total of 66 complaints were filed for foam degradation with Trilogy devices. The reported complaint rate for this failure mode is 0.025%. While no harm was reported for Trilogy devices, 10 reported cases of harm were reported for PAP devices. These complaints are detailed in CAPA 7211 and generally included complaints of headache, upper airway irritation, cough, chest pressure, and sinus infection. Attributable harm may be confounded by the additional use of ozone (alleged to be used in 5 of the 10 complaints) or PAP therapy in general.
Describe the factor(s) that need to occur to create the hazardous situation (reasonably foreseeable sequence or combination of events):	A hazardous situation is created when a patient uses a Trilogy device where the PE-PUR foam exhibits degradation. As described in Step II, Section A under Hazard Cause, foam may degrade when exposed to specific conditions. Once the foam starts to degrade, airborne particulates from degraded foam material could potentially enter the Trilogy system air flow path. The particulate must travel through the path outlined below. Trilogy Air Flow Path: Air enters through the inlet filter and into the blower box that contains the PE-PUR foam. From the blower box, the air continues through the angled elbow of blower and through the blower impeller. Air then travels through the angled outlet port, continuing through the patient circuit. The patient circuit consists of a 6 ft tube, an angled connection interface, and mask, before reaching the patient airway.
Factors that might mitigate risk (e.g., safety mechanisms present in the design, instructions for use, current label warnings, etc.):	<u>Device inspection per device IFU</u>: Exposure to the hazard may be partially mitigated through device, tubing and mask inspection. Device User Manuals instruct patients to “Periodically inspect electrical cords, cables, tubing, and accessories for damage or signs of wear.” This same mitigation factor applies to care providers when used in a clinical setting, such as a hospital. However, patients or care providers may not detect the particles (e.g., because the particles are too small).

	Bacteria Filter: Labeling recommends that a main line outlet bacteria filter (Part Number 342077) be used whenever the device is used for invasive therapy or if the ventilator may be used on multiple patients. When a bacterial filter is used within the patient circuit, particulate is unable to reach the patient. According to the Ambu 20801 performance sheet, the filter tested 99.97% effective on an inert test particle of 0.3µm. Based on the particle size report (detailed in CAPA 7211), the bacteria filter will effectively filter out any foam particulate that could make its way up the patient circuit. Routine Maintenance: Periodic routine maintenance instructs service centers to replace blower foam every 10,000 blower hours or every 24 months (whichever may come first). After being implemented in June 2018, a total of 63,099 devices have undergone the routine maintenance. Zero complaints of foam degradation have been reported for these devices that received PM. However, complaints of foam degradation have been received for devices that did not receive the PM. Although there are factors that may mitigate the risk of exposure to foam particulates, e.g. using a filter and completion of prescribed PMs, we cannot ensure that these are followed by all end users / customers and thus we need to be cautious when estimating the actual protections afforded from these mitigations. References: • IFU > Replacing the Air Inlet Path Foam • IFU > Bacteria filter (Part Number 342077) • Service Manual 1002735 > Ch. 8 Maintenance • AARC Clinical Practice guideline 2007 revision & Update, Respiratory Care, August 2007 VOL 52 NO 1 – recommends "Humidification systems are essential for invasive mechanical ventilation"(sec 10.1.7.)
Would a user detect the hazardous situation prior to occurrence of harm? If so, describe how:	Detection of Foam Particulate: The particulate analysis (as detailed in CAPA 7211) demonstrates a variety of small and large particles that may or may not be detectable based on size and quantity. Small, black contaminants may become visible near the air outlet port or within the patient circuit. Particulate that is large enough to be seen with the naked eye, however, may have a greater chance of detection considering that many of these devices

	are used in a hospital setting and subject to mandatory cleaning and inspection by hospital staff. Because Trilogy devices follow a 2-year PM schedule, the chance of detecting foam degradation is greater.

Probability Estimate

Estimation of Probability that the Harm will occur:	Short/Intermediate-Term Hazard Exposure **2 (Occasional)** 'Remote probability' that use will cause harm; expected to cause harm rarely/ from time to time (e.g., with no clear trend) This Hazard has zero reports of harm from 2008 through March 2021 for Trilogy devices. While no harm was reported for Trilogy devices, 10 reported cases of harm were reported for PAP devices. These complaints are detailed in CAPA 7211 and generally included complaints of headache, upper airway irritation, cough, chest pressure, and sinus infection. Attributable harm may be confounded by the additional use of ozone (alleged to be used in 5 of the 10 complaints) or PAP therapy in general. Long-Term Exposure **2 (Occasional)** 'Remote probability' that use will cause harm; expected to cause harm rarely/ from time to time (e.g., with no clear trend) This Hazard has zero reports of harm from 2008 through March 2021
Comments: (Probability of Harm Rationale)	**Probability of Hazardous Situation Occurring (P1)** While Philips Respironics' testing and investigation to date indicates that the PE-PUR foam within the devices is degrading, and the degradation may be due to device exposure to certain conditions (e.g., environmental, disinfection using unauthorized cleaning agents) over a period of time, Philips Respironics is in the process of conducting additional studies to better understand: (1) the specific conditions that cause the foam to degrade; and (2) the rate of foam degradation when the device experiences such conditions. For example, if the device must experience certain environmental conditions for an extended period of time for the foam to degrade (e.g., high humidity, high temperature), not all users may subject their device to such conditions. Therefore, completion of these ongoing and planned studies will help Philips Respironics better estimate the reasonable worst-case probability of the foam degrading within the device population. See ongoing and planned investigational activities described in Step III, Section C. Although the observed complaint rate is 0.025%, as noted above, the complaint rate may not accurately reflect the probability of the failure because patients may not detect the particles and/or report

	the event to Philips Respironics. Time is a critical variable that must also be taken into account. Periodic routine maintenance may help to minimize the impact of this variable as much as possible by replacing blower foam every 10,000 blower hours or every 24 months (whichever may come first). Although complaint data may not accurately reflect the occurrence of the failure, there have been zero complaints of foam degradation for devices that have undergone the recommended routine maintenance. Additional factors to consider when assessing whether or not a patient could be exposed to foam particulate is the use of a bacteria filter in-line with the patient circuit. If used, the bacteria filter prevents particulate of 0.3µm or larger from reaching the patient. This would effectively filter out all particulate, based on the sizes observed in the foam particulate analysis performed as part of CAPA 7211. Nonetheless, based on the available information and test data collected to date, Philips Respironics estimates that the reasonable worst-case probability of the foam degrading in the device to be *occasional* over the device's useful life. **Probability that Hazardous Situation will Lead to Harm (P2)** The probability that the hazardous situation will lead to harm is dependent upon the amount of degraded foam a patient may inhale and/or ingest and may be exacerbated by the patient's underlying comorbidities. As noted in Step II, Section B, further investigations are ongoing and detailed in Step III, Section C. Short and long-term exposure to the hazard may cause generalized inflammation in patients that could facilitate clinical deterioration in certain patient populations as dictated by the underlying disease or associated comorbidities. As an inhalational therapy, it is possible that patients with low cardio-pulmonary reserve (e.g. COPD, CHF) may experience a meaningful deterioration in their function that requires medical intervention. Clinical events of this nature may not be easily linked to the hazardous situation or device use in general. Based on lab testing, exposure to the degraded foam and its components may lead to cellular DNA mutations. Such mutations may lead to uncontrolled cellular replication given a sufficient dose and duration of exposure that have not been determined. Patient related factors including bodily defenses, target tissue deposition, and immune function will also likely impact the development of the reasonable worst-case scenario harm. Additionally, a presumed lag time from exposure to harm development may make it difficult for patients to attribute their individual harm to the device usage. No severity 3 (Crucial) harm has been reported to date. It should be noted that harm in this case may not be immediately recognizable and may not be something that the patient would/could report. **Probability of Occurrence of Harm (P)** Taking into consideration P1 and P2, it is challenging to accurately estimate the probability of harm quantitatively. A probability of 2 (Occasional) was chosen as the reasonable worst-case scenario, despite taking into consideration existing risk mitigations and the

	information known at this time.

Considering the factors above, assess the probability that use of, or exposure to, the affected devices will cause future harm during the product's lifetime. Consider segments of the population most at risk (e.g. infants, elderly, pregnant women, critically ill patients, etc.).

Check (X) applicable level*	***Example of probability of harm***
___ **4** **(Always)**	Occurs 'every time'*
___ **3** **(Likely)**	'Reasonable probability' that use will cause harm*; good chance/ considerable certainty to cause harm
X **2** **(Occasional)**	'Remote probability' that use will cause harm*; expected to cause harm rarely/ from time to time (e.g., with no clear trend)
___ **1** **(Unlikely)**	'Not likely' that use will cause harm*; possible but improbable
___ **0** **(Inconceivable)**	Inconceivable; not possible

*** Corresponds with probability levels set forth in FDA's CDRH HHE Form Version 3-1 01/12/2007.**

***Note: If harm has already occurred as a result of the issue under review, then:**

- Probability level zero (0) and one (1) 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.
- Probability level 0 rarely applies to post-market risk evaluation in cases where harm has occurred.

Step III – Health Hazard Evaluation Conclusion

Probability	Severity			
	1	2	3	4
4	Unacceptable	Unacceptable	Unacceptable	Unacceptable
3	Acceptable	Unacceptable	Unacceptable	Unacceptable
2	Acceptable	Further Analysis Required[1)]	Unacceptable Short/Intermediate-Term Exposure Long-Term Exposure	Unacceptable
1	Acceptable	Acceptable	Further Analysis Required[1)]	Unacceptable
0	Acceptable	Acceptable	Acceptable	Acceptable

*These conclusions will be re-evaluated once the additional testing described in Section III.C is completed.

[1)] If the results of a risk evaluation fall into one of these two cells (3x1 or 2x2), then a risk/benefit analysis and/or appropriate justification must be documented in section C below.

Note:

- The original premarket risk/benefit analysis may be reused if still applicable as the evaluation to justify an acceptable risk.
- The above Risk Table helps assess whether the risk is acceptable or not; however, reviewer/approvers of this document make the final determination.
- Even if a risk is deemed "acceptable", action to address the issue may still be warranted.

A. Document the results of the Health Hazard Evaluation for each hazardous situation under review:

Short/Intermediate-Term Exposure

Severity: **3** / Probability: **2** = UNACCEPTABLE (acceptable/unacceptable)

Long-Term Exposure

Severity: **3** / Probability: **2** = UNACCEPTABLE (acceptable/unacceptable)

B. If the risk of the individual hazardous situation is acceptable, review the Risk Management File and consider combined impact of all the individual risks to evaluate whether overall residual risk of the device is still acceptable. Is the summary of all the risks acceptable or not acceptable?

UNACCEPTABLE (acceptable / unacceptable)

C. Any additional information (if applicable):	As noted above, the Philips Respironics team is continuing to conduct additional investigational activities to better understand the myriad of variables and considerations related to the reported foam degradation. To ensure that we maintain our perspective and focus on our users, we have made conservative assumptions in identifying the severity and probability of the harms associated with this issue. As we complete the testing listed below, we will update this HHE (as required). The risk management files associated with these products will be evaluated and updated per the information above. ADDITIONAL TESTING CONSIDERATIONS: Accelerated PE-PUR Foam Life Testing • The goal of this testing is to develop a model to help us understand the foam degradation behavior at ambient conditions within the specified operating temperature and humidity ranges, in the presence or absence of ozone. • Preliminary results, at the experiments' mid-point, show visual separation between the ozone and non-ozone groups, within the operating temperature ranges, indicating that ozone does accelerate degradation at lower temperatures. These results are not yet final; therefore, this potential impact has not been considered in the overall residual risk rating. Ozone Cycling on PE-PUR Foam • The purpose of this benchtop testing is to understand how ozone impacts the visual and chemical breakdown of PE-PUR foam at ambient conditions. The outcome of this test could provide further confirmation on the hypothesis that ozone has a direct connection to the premature breakdown of device sound abatement foam. • Preliminary results indicate that PE-PUR foam exposed to various cycles of ozone at ambient temperatures show significant accelerated foam degradation, even after only one cycle. As these results are also not yet final, this potential impact has not been considered in the overall residual risk rating. Dosage Test • The goal of this test is to estimate the daily and total dosage of particulate being delivered to a patient over the device's expected use life. Foam Volatile Organic Compounds(VOC) Testing • As more details become known, additional information will be added to this section.
Health Hazard	

Evaluation Conclusion:	**Health Hazard Evaluation Medical Assessment** The Health Hazard Evaluation conducted by the Philips Respironics Team concluded that the Hazards described herein represent an unacceptable risk to patients. **Short/Intermediate-Term Exposure to Hazard: Severity 3; Probability 2** The severity of harm (level 3) recognizes the seriousness of any potential harm that may significantly impact the clinical status of patients and require additional medical intervention. Probability of harm (level 2) indicates a remote probability that device use will cause harm; expected to cause harm rarely/ from time to time (e.g., with no clear trend). **Long Term Exposure to Hazard: Severity 3; probability 2** The severity of harm (level 3) recognizes the seriousness of any potential malignancy and the need for medical intervention to preclude permanent impairment. Probability of harm (level 2) indicates a remote probability that device use will cause harm; expected to cause harm rarely/ from time to time (e.g., with no clear trend).

Step IV – Outcome approved by the following individuals:

Prepared By:

Signature Date

See EDMS for e-signature and date

Print Name and Title

s22 – Design Quality Engineer / Safety Risk Management

Approved By Director of BIU QARA:

Signature Date

See EDMS for e-signature and date

Print Name and Title

s22 – Head of Design Quality Engineering

Approved By VP of Corporate QA – HHS Q&R (or delegate):

Signature Date

See attached signature sheet

Print Name and Title

s22 – Head of Quality SRC

Approved By Credentialed Medical Professional:

Signature Date

See attached signature sheet

Print Name and Title

s22 – Medical Leader SRC

Approved By Credentialed Medical Professional:

Signature Date

See attached signature sheet

Print Name and Title

s22 – Medical Director Connected Care

Approved By Clinical Affairs Representative:

Signature Date

See EDMS for e-signature and date

Print Name and Title

s22 – Head of Clinical Affairs

Note: This form may be emailed or faxed to the person(s) above. Signature (electronic or fax) is required for all HHEs.

HEALTH HAZARD EVALUATION FORM

ER 2241621 – Foam Degradation in PAP Devices, Version 00

Step I – Identification of the Issue/Problem

CAPA Number:	**7211**	**HHE Date Open:**	11/16/2020	**HHE Date Closed:**	04/26/2021
- Product Data -					
Product Code:	BZD (noncontinuous ventilator (Intermittent positive pressure breathing - IPPB))				
Model:	All finished good part numbers under the devices listed below fall within the scope of this HHE. For a comprehensive list of all finished good numbers, refer to CAPA 7211.				
Device Name:	SystemOne (Q-Series) DreamStation CPAP, Auto CPAP, BiPAP DreamStation Go CPAP, Auto CPAP Dorma				
Lot/Serial Numbers:	All devices in the field and released in inventory currently using the polyester-based polyurethane foam (PE-PUR) could be subject to this potential failure mode.				
Marketing Status (Include 510(k) or PMA Number, Specify if Class I Exempt from 510(k)):	K130077 • Dorma K131982 • SystemOne • DreamStation • DreamStation Go				
Manufacturing/Recall Firm Address:	Respironics Inc. 1010 Murry Ridge Ln Murrysville, PA 15668				
Product Description (Include Intended Use from Labeling):	***K130077*** **Dorma Product Identification and Intended use**: **Regulation**: 21 CFR 868.5905 Identification : A noncontinuous ventilator (IPPB) is a device intended to deliver intermittently, an aerosol to patient's lungs or to assist a patient's breathing.				

	Classification: Class II (performance standards) **Intended Use**: These devices are intended to deliver positive airway pressure therapy for the treatment of Obstructive Sleep Apnea in spontaneously breathing patients weighing over 30kg (66 lbs.). They are for use in the home or hospital/institutional environment. **Device Description:** This device delivers CPAP/Auto CPAP and incorporates a ramp function that allows the patient to start therapy at a lower pressure (e.g., 4 cm H2O) when trying to fall asleep and gradually increases the delivered pressure up to the prescription pressure over the time interval selected. For example, air pressure can be gradually increased in 0.5 cm H2O increments if ramp time is set to > 0 and therapy pressure is > 4 cm H2O, until the prescription pressure is reached. Depending on the therapy mode, therapy pressure setting could be any of the following: CPAP pressure, CPAP-Check pressure, or Auto minimum pressure. Also, a Flex comfort feature provides pressure relief during exhalation. ***K131982*** **SystemOne (Q-Series) Product Identification and Intended use:** **Regulation** : 21 CFR 868.5905 Identification : A noncontinuous ventilator (IPPB) is a device intended to deliver intermittently, an aerosol to patient's lungs or to assist a patient's breathing. Classification: Class II (performance standards) **Intended Use**: SystemOne devices deliver positive airway pressure therapy for the treatment of Obstructive Sleep Apnea in spontaneously breathing patients weighing over 30 kg. For use in the home or hospital/institutional environment. **Device Description:** This device delivers CPAP/Auto CPAP and incorporates a ramp function that allows the patient to start therapy at a lower pressure (e.g., 4 cm H2O) when trying to fall asleep and gradually increases the delivered pressure up to the prescription pressure over the time interval selected. For example, air pressure can be gradually increased in 0.5 cm H2O increments if ramp time is set to > 0 and therapy pressure is > 4 cm H2O, until the prescription pressure is reached. Depending on the therapy mode, therapy pressure setting could be any of the following: CPAP pressure, CPAP-Check pressure, or Auto minimum pressure. Also, a Flex comfort feature provides pressure relief during exhalation. In addition to these features, these devices incorporate additional features including BiPAP (one level of output pressure during the expiratory breath phase and a second higher level during the inspiratory breath phase), auto-BiPAP, and auto Bi-Level Split Night. A ramp function is also available, and depending on the therapy selected, one or more of the following pressure relief features is available to increase patient comfort: C-Flex, A-Flex, C-Flex+, P-Flex, and mask

	resistance compensation. **DreamStation Product Identification and Intended use:** **Regulation** : 21 CFR 868.5905 Identification : A noncontinuous ventilator (IPPB) is a device intended to deliver intermittently, an aerosol to patient's lungs or to assist a patient's breathing. Classification: Class II (performance standards) **Intended Use**: The Philips Respironics DreamStation systems deliver positive airway pressure therapy for the treatment of Obstructive Sleep Apnea in spontaneously breathing patients weighing over 30 kg (66 lbs.). It is for use in the home or hospital/institutional environment. **Device Description:** The DreamStation is designed to provide CPAP, CPAP-Check, Auto CPAP, Bi-Level and Auto Bi-Level therapy. The optional heated humidifier offers Heated Tube (via optional 15mm heated tube, HT15), Adaptive or Fixed humidification. In addition to the ramp function, depending on the therapy selected, one or more of the following pressure relief features is available to increase patient comfort: C-Flex, A-Flex, P-Flex, Bi-Flex and Rise Time. DreamStation is intended for use with a patient circuit that is used to connect the device to the patient interface device (mask). A typical patient circuit consists of disposable or reusable smooth lumen tubing, (22mm, 15mm, Heated Tube15, or 12mm tubing). A typical patient interface device provides a method of venting exhaled gases. Bluetooth wireless technology gives a patient access to their compliance data in markets where the DreamMapper mobile application is available. Optional modem accessories, Cellular Modem or Wi-Fi Accessory, automatically upload patient compliance data to their provider. If included, a Secure Digital (SD) card will also store compliance data allowing a provider to collect a patient's data periodically. **DreamStation Go Product Identification and Intended use:** **Regulation**: 21 CFR 868.5905 Identification : A noncontinuous ventilator (IPPB) is a device intended to deliver intermittently, an aerosol to patient's lungs or to assist a patient's breathing. Classification: Class II (performance standards) **Intended Use**: The Philips Respironics DreamStation Go systems deliver positive airway pressure therapy for the treatment of Obstructive Sleep Apnea in spontaneously breathing patients weighing over 30 kg (66 lbs.). It is for use in the home or hospital/institutional environment. **Device Description:** The DreamStation Go device targets a market segment of compliant

	PAP patients looking for smaller therapy solutions. DreamStation Go is designed to provide CPAP, CPAP-Check and Auto CPAP therapy by a smaller, lightweight portable device offering patients an alternative to packing and re-assembling their home CPAP system. The DreamStation Go system offers three configurations: CPAP only, CPAP and battery pack or CPAP and heated humidifier and comes standard with 12mm micro tubing. In addition to the ramp function, depending on the therapy selected, one or more of the following pressure relieve features is available to increase patient comfort: C-Flex, A-Flex, and P-Flex. DreamStation Go is intended for use with a patient circuit that is used to connect the device to the patient interface device (mask). A typical patient circuit consists of disposable or reusable smooth lumen tubing, (22mm, 15mm, or 12mm tubing). A typical patient interface device provides a method of venting exhaled gases.
Brief description of the issue/problem and how it was identified:	Philips Respironics received complaints in 2019 regarding SystemOne CPAP devices from Thailand (Complaint numbers RA 307829970 and 307806329) alleging the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask). The patient's nephew expressed concerns that the black particulate was delivered to the patient's airway and could affect her health. The SystemOne devices were returned and visual inspection showed signs of foam degradation. Chemical analysis of the foam confirmed degradation, triggering the initiation of CAPA 7211 and additional investigational activities. The sound abatement foam is an open-cell polyester-based polyurethane (PE-PUR) foam that is widely used for sound dampening purposes in many industries. A complaint analysis performed as part of CAPA 7211 indicated that complaints for PE-PUR foam degradation were identified across various PAP device platforms. Specifically, 1,105 complaints were identified suggesting the presence of degraded foam with PAP devices. In addition, the complaint analysis showed an overall increase in complaints related to alleged PE-PUR foam degradation across the PRI PAP devices, noninvasive ventilators (NIV), and ventilators. The majority of complaints were reported by Philips service personnel and were found subsequent to investigating the patients' primary complaints. As of the date of this HHE, 14,792,965 PAP devices have been shipped. Accordingly, Philips Respironics initiated this HHE to evaluate potential foam degradation in the context of PAP devices based on available data generated to date. This Health Hazard Evaluation (HHE) only assesses the risks associated with physical exposure to foam particulates. Emission of chemical compounds as a result of foam breakdown is recognized as a potential source of harm, however testing is ongoing to further investigate the potential harms associated with this. As additional information becomes available, this HHE will be updated to reflect any changes to the overall risk profile.

Affected Patient/User Population:	All patient groups that fall within the intended use of the devices referenced in the Product Description are within the affected patient population. The intended patient population across multiple PAP platforms broadly includes the following: adult and pediatric patients weighing over 66 lbs. with Obstructive Sleep Apnea. Higher risk populations within the intended patient population include pediatrics; the elderly; pregnant women; and patients with comorbidities such as heart failure, COPD, and obesity.
HHE Author (Name/Function):	s22 [redacted] – Design Quality Engineer/Safety Risk Management
HHE Contributors (Name/Function):	s22 [redacted] – Design Quality Engineer/Safety Risk Management s22 [redacted] – Design Quality, Sr. Manager s22 [redacted] –Quality Engineering, Manager s22 [redacted] – Head of Design Quality Engineering s22 [redacted] – Sustaining Engineering Manager s22 [redacted] – Sr. Quality Engineer s22 [redacted] – Sr. Bio Safety and Verification Engineer s22 [redacted] – Head of Global Clinical and Scientific Affairs s22 [redacted] – Medical Director, Connected Care s22 [redacted] – Director of Regulatory Affairs s22 [redacted] – Medical Leader, SRC s22 [redacted] – Medical Safety Manager, SRC

Step II – Analyze Post Release Health Risk Associated with Affected Units

Note: Assess the risk as if no corrective action will be taken and all affected devices will remain in the marketplace.

A. Identification of the Individual Hazard(s)

Hazard Category:	**Hazard Category:** Biological and Chemical **Hazard**: Biocompatibility / Toxicity of chemical constituents
Hazard Cause:	Polyester-based polyurethane foam (PE-PUR) is used as a sound abatement foam in the PAP device airpath. Based on all available data generated to date, Philips Respironics determined that the PE-PUR foam's reaction with water (hydrolysis) was a source of the foam degradation potentially caused and/or exacerbated by the following factors: • Device operation in higher heat and humidity environmental conditions; and/or • Use of unapproved cleaning and disinfection methods with the PAP device (e.g. ozone). *Environmental Conditions* The labeled environmental conditions for operating temperature are 5° to 35° C (41° to 95° F) with storage temperatures ranging from -20° to 60° C (-4° to 140° F). Preliminary test results conducted by Philips Respironics show that high temperature (90° C) contributes to significant degradation of the foam. Testing is ongoing to further investigate the impact of ambient temperature and humidity on foam degradation including: (1) models that may better simulate real world device operation conditions; and (2) lower temperatures within the labeled range. Refer to Section III,C for additional information on planned testing. *Unapproved Cleaning and Disinfection Methods* The PAP user and provider manual cleaning instructions do not include ozone disinfection; rather, the instructions recommend water and a mild liquid dishwashing detergent for cleaning and DisCide Ultra Towelettes or a Chlorine Bleach solution for disinfection. The manual states that any deviation from these instructions or agents not listed in this guide may impact the performance of the product. Ozone disinfection devices appear to have become more readily available around the same time as Philips Respironics received complaints of foam degradation, however further investigation is ongoing. Foam degradation has also been reported even when ozone disinfection was not reported.
Hazardous Situation:	**Exposure to particulate by-products of foam degradation during use.** If PE-PUR foam degrades, small particulates (estimated size range of 2.69 µm-724 µm) may be expelled from the device blower box, through the motor and patient circuit and could enter the patient respiratory tract and/or Gastrointestinal (GI) tract. Based on our analysis of the degraded foam, the particles may include compounds such as diethylene glycol (DEG), toluene diamine isomers (TDA), and toluene diisocyanate isomers (TDI). Due to an inability to obtain a sufficient quantity of representative field

	samples for biocompatibility lab testing, we created lab degraded foam used for such testing, including: cytotoxicity, genotoxicity, irritation, and sensitization tests.

B. Estimation of Severity

Description of reported and/or potential harm:	**Harm resulting from Short-Term and Intermediate-Term Exposure:** exacerbation or worsening of the underlying patient condition Potential Harms: • Irritation (skin, eye, and respiratory tract) • Inflammatory response • Headache • Asthma • Effects to reproductive system • Neoplasia A total of 10 reported cases of harm were reported for PAP devices. These complaints are detailed in CAPA 7211 and generally included complaints of headache, upper airway irritation, cough, chest pressure, and sinus infection. Attributable harm may be confounded by the additional use of ozone (alleged to be used in 5 of the 10 complaints) or the use of PAP therapy in general. **Harm resulting from Long-Term Exposure:** cytotoxic, genotoxic, and potential carcinogenic effects Zero cases of harm have been directly or indirectly linked to this failure mode.
Estimation of Severity of Harm	**3 (Crucial) – Short/Intermediate Term Exposure** Results in serious injury: life-threatening, or permanent impairment or necessitates medical intervention to preclude permanent impairment This is considering the reasonable worst-case scenario, per the rationale in the comments section below. **3 (Crucial) – Long Term Exposure** Results in serious injury: life-threatening, or permanent impairment or necessitates medical intervention to preclude permanent impairment Philips Respironics identified no significant difference in the estimated severity of harm when considering the general and higher risk patient populations.
Comments: (Severity of Harm Rationale)	A Bio Endpoint Analysis and toxicological risk assessment was performed on the specific chemical constituents and their potential impact to patients. This analysis is included as part of CAPA 7211; the testing is summarized below. Due to the difficulty in obtaining a sufficient quantity of representative field samples for biocompatibility lab testing, laboratory accelerated aged foam was used to conduct the cytotoxicity, genotoxicity, irritation, and sensitization tests. The following results were noted:

- Cytotoxicity was noted for all extraction concentrations.
- Two genotoxicity assays confirmed a positive mutagenic response.
- Irritation results for the non-polar extract returned a passing result.
- Sensitization results from both polar and non-polar extracts returned a passing result.

Daily chemical dosages and concentrations are unknown at this time. Philips is in the process of constructing a model that calculates the start and rate of foam degradation. Further investigations are ongoing and detailed in Step III, Section C. Additionally, the literature does describe tolerable intake (TI) references for some of the major degradative by-products of the polyester polyurethane foam: TDA, TDI and DEG. Specifically:

- **Toluene diamine isomers (TDA)**, such as toluene-2,4-diamine, are primarily used in the synthesis of polyurethane, various dyes, and heterocyclic compounds.[1,2]
    - A chronic reference dose (RfD) for 2, 6 toluene diamine has been listed by the IRIS EPA at 0.03 mg/kg per day.[3]
- **Toluene diisocyanate isomers (TDI)** such as 2,4-toluene diisocyanate are chemical intermediates utilized in the production of polyurethane products.[4]
    - A reference concentration of 0.00007 mg/m^3 (0.07 µg/m^3) has been recommended for toluene diisocyanates by the EPA IRIS risk assessment.[5]
    - The U.S. Office of Environmental Health Hazard Assessment (OEHHA) has listed the Safe Harbor Levels at 20 µg/day for the no significant risk level (NSRL) to toluene diisocyanates.
- **Diethylene glycol (DEG)** is a polyol building block utilized in the synthesis of polyurethane.
    - Literature suggests a proposed human oral ingestion reference dose of 0.3 mg/kg for DEG.[6]
    - A WEEL occupational level of 10 mg/m^3 has been proposed by TERA for inhalational limits of DEG[7]- but this is not adequate or protective for sensitive patient populations and only accounts for an occupational worker exposure.
    - Per prior informal feedback from the FDA, 1% of the WEEL occupational value (10 mg/m^3) would be an adjusted tolerable intake of 0.1 mg/m^3.

Philips Respironics is working to complete the additional investigatory activities described in Step III, Section C to assess whether the amount of degraded PE-PUR form inhaled and/or ingested by the patient may potentially exceed the TI references provided above.

In order to evaluate the risks posed by the PE-PUR foam particulates, exposure time and patient airway physiology must be considered. Data generated to date

	suggests that the PE-PUR foam degrades into particulates of varying sizes. The location of collected particulates in the respiratory tract and the body's response to them is partially dictated by size. • For this HHE, the PE-PUR foam particulates are assumed to reach the patient airway (the amount or concentration in µg/m^3 is unknown). The location of where aerosolized particulates collect in the respiratory tract and the body's response to them is partially dictated by size.[8] A multitude of tissues compose the respiratory tract which includes the conducting airways that consist of the nose and mouth, pharynx, larynx, leading into the trachea, main bronchi, lobar, segmental bronchi, and terminal bronchioles.[9] The terminal bronchioles then lead into the respiratory bronchioles, alveolar ducts, and lastly alveolar sacs.[9] There are defense mechanisms in the respiratory system which help prevent particulates from entering into the lung, these include cilia and mucous layers. Cilia are hair-like projections of the cells that line the airway and propel the liquid layer of mucous which can trap pathogens and particulates prior to reaching the lungs.[10] • The nose and accompanying respiratory tract is capable of filtering foreign particles dependent on particle size and airflow rate with a filtration efficacy decreasing with particulate size.[11] Small particles (<1-3 µm) are capable of diffusing into deep lung tissue and deposit into the alveoli whereas larger particulates (> 8 µm) will be deposited throughout the nasal passages and larger bronchioles.[8] • Macrophages: one of the three types of alveolar cells, also known as dust cells, can eliminate foreign particles and bacteria through the process of phagocytosis Philips Respironics particle size analysis identified that the majority of particulate (> 8 µm) is of a size that is unable to penetrate into deep lung tissue and thus will remain in the patient upper airway. A smaller fraction of the particulate (<1-3 µm) may still penetrate into the lower respiratory tract. Our conclusions are as follows: • Based on the cytotoxicity and genotoxicity results and toxicological risk assessment, combined with our conclusion that particles are likely to reach the upper airway and potentially the lower respiratory track, a reasonable worst-case estimate for the **general** and **higher risk** (e.g., patient populations with preexisting conditions or comorbidities) patient populations is a severity level 3 (Crucial) for both short/intermediate and long term exposure.

Reference Information:

Check (X) Applicable Level*	Examples
___ 4 (Catastrophic)	Directly results in death
_X_ 3 (Crucial)	Results in serious injury: life-threatening, or permanent impairment or necessitates medical intervention to preclude permanent impairment
___ 2 (Marginal)	Results in moderate injury: temporary impairment, or self-limiting illness
___ 1 (Negligible)	Results in less than moderate or no injury

*Severity Levels 4 and 3 are "serious adverse health consequences" per FDA's CDRH Health Hazard Evaluation Form Version 3-1 01/12/2007. Severity Levels 2 and 1 are not serious adverse health consequences per FDA's HHE Form.

References:

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2. Lewandowski, T. A., Hayes, A. W. & Beck, B. D. Risk evaluation of occupational exposure to methylene dianiline and toluene diamine in polyurethane foam. Hum Exp Toxicol 24, 655–662 (2005).

3. Provisional Peer Reviewed Toxicity Values for 2,6-Toluenediamine (CASRN 823-40-5). 15.

4. Pubchem. Toluene 2,4-diisocyanate. https://pubchem.ncbi.nlm.nih.gov/compound/11443.

5. US EPA, O. 2,4-/2,6-Toluene diisocyanate mixture (TDI) CASRN 26471-62-5 | IRIS | US EPA, ORD. https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=503.

6. Snellings, W. M., McMartin, K. E., Banton, M. I., Reitman, F. & Klapacz, J. Human health assessment for long-term oral ingestion of diethylene glycol. Regulatory Toxicology and Pharmacology 87, S1–S20 (2017).

7. OARS. DEG (111-46-6) WEEL.

8. Thomas, R. J. Particle size and pathogenicity in the respiratory tract. Virulence 4, 847–858 (2013).

9. Patwa, A. & Shah, A. Anatomy and physiology of respiratory system relevant to anaesthesia. Indian J. Anaesth. 59, 533–541 (2015).

10. Defense Mechanisms of the Respiratory System - Lung and Airway Disorders. Merck Manuals Consumer Version Available at: https://www.merckmanuals.com/home/lung-andairway-disorders/biology-of-

	the-lungs-and-airways/defense-mechanisms-of- the-respiratorysystem. (Accessed: 23rd May 2018) 11. Imre Salma, Imre Balásházy, Renate Winkler-Heil, Werner Hofmann, Gyula Záray,. Effect of particle mass size distribution on the deposition of aerosols in the human respiratory system, Journal of Aerosol Science, Volume 33, Issue 1, 2002, Pages 119-132, ISSN 0021-8502, https://doi.org/10.1016/S0021-8502(01)00154-9. (https://www.sciencedirect.com/science/article/pii/S0021850201001549) 12. Knowles, M. R. & Boucher, R. C. Mucus clearance as a primary innate defense mechanism for mammalian airways. J. Clin. Invest. 109, 571–577 (2002)

C. Estimation of Probability of Harm Resulting from Affected Units

Estimated quantity of affected devices (# in field, # in factory, # in distribution centers, etc.):	Between 2008 through March 2021, a total of 14,792,965 shipments of PAP Devices (see list of devices above).
Number and type of injuries/number of deaths attributed to the problem with the device (if any):*	10 cases of harm have been reported in PAP devices where foam degradation was suspected. Injuries (Severity 2) = 10 Injuries (Severity 3) = 0 Deaths = 0 In the case of long-term exposure, it should be noted that harm may not be immediately recognizable and may not be something that the customer would/could report. A total of 1,105 complaints were filed for foam degradation with PAP devices. The reported complaint rate for this failure mode is 0.007%. A total of 10 reported cases of harm were reported for PAP devices. These complaints are detailed in CAPA 7211 and generally included complaints of headache, upper airway irritation, cough, chest pressure, and sinus infection. Attributable harm may be confounded by the additional use of ozone (alleged to be used in 5 of the 10 complaints) or PAP therapy in general.
Describe the factor(s) that need to occur to create the hazardous situation (reasonably foreseeable sequence or combination of events):	A hazardous situation is created when a patient uses a PAP device where the PE-PUR foam exhibits degradation. As described in Step II, Section A under Hazard Cause, foam may degrade when exposed to specific conditions. Once the foam starts to degrade, airborne particulates from degraded foam material could potentially enter the PAP system air flow path. The particulate must travel through the path outlined below. PAP Air Flow Path: Air enters through the inlet filter and into the blower box that contains the PE-PUR foam. From the blower box, the air continues through the angled elbow of blower and through the blower impeller. Air then travels through the angled outlet port where it may interface with an optional humidifier, continuing through the patient circuit. The patient circuit consists of a 6 ft tube, an angled connection interface, and mask, before reaching the patient airway. Note that the air flow path referenced above is a broad generalization of each of the devices in scope of this report.
Factors that might mitigate risk (e.g., safety mechanisms present in the design, instructions for use, current label warnings, etc.):	Device inspection per device IFU: Exposure to the hazard may be partially mitigated through device, tubing and mask inspection. Device User Manuals instruct patients to “Periodically inspect electrical cords, cables, tubing, and accessories for damage or signs of wear.” Mask IFU’s instruct patients to “Inspect the mask parts

	regularly for damage or wear" and to clean the mask daily. However, patients may not detect the particles (e.g., because the particles are too small).
Would a user detect the hazardous situation prior to occurrence of harm? If so, describe how:	Detection of Foam Particulate: The particulate analysis (as detailed in CAPA 7211) demonstrates a variety of small and large particles that may or may not be detectable based on size and quantity. Small, black contaminants may become visible near the air outlet port or within the patient circuit. Daily cleaning of the mask and weekly cleaning of the tubing may remove trapped particles and increase the odds of detection.

Probability Estimate

Estimation of Probability that the Harm will occur:	Short/Intermediate-Term Hazard Exposure **2 (Occasional)** 'Remote probability' that use will cause harm; expected to cause harm rarely/ from time to time (e.g., with no clear trend) This Hazard has 10 reports of harm from 2008 through March 2021 for PAP devices. These complaints are detailed in CAPA 7211 and generally included complaints of headache, upper airway irritation, cough, chest pressure, and sinus infection. Attributable harm may be confounded by the additional use of ozone (alleged to be used in 5 of the 10 complaints) or PAP therapy in general. Long-Term Exposure **2 (Occasional)** 'Remote probability' that use will cause harm; expected to cause harm rarely/ from time to time (e.g., with no clear trend) This Hazard has zero reports of harm from 2008 through March 2021.

Comments:	Probability of Hazardous Situation Occurring (P1)
(Probability of Harm Rationale)	While Philips Respironics' testing and investigation to date indicates that the PE-PUR foam within the devices is degrading, and the degradation may be due to device exposure to certain conditions (e.g., environmental, disinfection using unauthorized cleaning agents) over a period of time, Philips Respironics is in the process of conducting additional studies to better understand: (1) the specific conditions that cause the foam to degrade; and (2) the rate of foam degradation when the device experiences such conditions. For example, if the device must experience certain environmental conditions for an extended period of time for the foam to degrade (e.g., high humidity, high temperature), not all users may subject their device to such conditions. Therefore, completion of these ongoing and planned studies will help Philips Respironics better estimate the reasonable worst-case probability of the foam degrading within the device population. See ongoing and planned investigational activities described in Step III, Section C. Although the observed complaint rate is 0.007%, as noted above, the complaint rate may not accurately reflect the probability of the failure because patients may not detect the particles and/or report the event to Philips Respironics. Nonetheless, based on the available information and test data collected to date, Philips Respironics estimates that the reasonable worst-case probability of the foam degrading in the device to be *occasional* over the device's useful life. **Probability that Hazardous Situation will Lead to Harm (P2)** The probability that the hazardous situation will lead to harm is dependent upon the amount of degraded foam a patient may inhale and/or ingest and may be exacerbated by the patient's underlying comorbidities. As noted in Step II, Section B, further investigations are ongoing and detailed in Step III, Section C. Short and long-term exposure to the hazard may cause generalized inflammation in patients that could facilitate clinical deterioration in certain patient populations as dictated by the underlying disease or associated comorbidities. As an inhalational therapy, it is possible that patients with low cardio-pulmonary reserve (e.g. COPD, CHF) may experience a meaningful deterioration in their function that requires medical intervention. Clinical events of this nature may not be easily linked to the hazardous situation or device use in general. Based on lab testing, exposure to the degraded foam and its components may lead to cellular DNA mutations. Such mutations may lead to uncontrolled cellular replication given a sufficient dose and duration of exposure that have not been determined. Patient related factors including bodily defenses, target tissue deposition, and immune function will also likely impact the development of the reasonable worst-case scenario harm. Additionally, a presumed lag time from exposure to harm development may make it difficult for patients to attribute their individual harm to the device usage. No severity 3 (Crucial) harm has been reported to date. It should be noted that harm in this case may not be immediately recognizable and may not be something that the patient would/could report.

	Probability of Occurrence of Harm (P) Taking into consideration P1 and P2, it is challenging to accurately estimate the probability of harm quantitatively. A probability of 2 (Occasional) was chosen as the reasonable worst-case scenario.

Considering the factors above, assess the probability that use of, or exposure to, the affected devices will cause future harm during the product's lifetime. Consider segments of the population most at risk (e.g. infants, elderly, pregnant women, critically ill patients, etc.).

Check (X) applicable level*	***Example of probability of harm***
___ **4** **(Always)**	Occurs 'every time'*
___ **3** **(Likely)**	'Reasonable probability' that use will cause harm*; good chance/ considerable certainty to cause harm
X **2** **(Occasional)**	'Remote probability' that use will cause harm*; expected to cause harm rarely/ from time to time (e.g., with no clear trend)
___ **1** **(Unlikely)**	'Not likely' that use will cause harm*; possible but improbable
___ **0** **(Inconceivable)**	Inconceivable; not possible

*** Corresponds with probability levels set forth in FDA's CDRH HHE Form Version 3-1 01/12/2007.**

***Note: If harm has already occurred as a result of the issue under review, then:**

- Probability level zero (0) and one (1) 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.
- Probability level 0 rarely applies to post-market risk evaluation in cases where harm has occurred.

Step III – Health Hazard Evaluation Conclusion

Probability	Severity			
	1	2	3	4
4	Unacceptable	Unacceptable	Unacceptable	Unacceptable
3	Acceptable	Unacceptable	Unacceptable	Unacceptable
2	Acceptable	Further Analysis Required[1)]	Unacceptable Short/Intermediate-Term Exposure Long-Term Exposure	Unacceptable
1	Acceptable	Acceptable	Further Analysis Required[1)]	Unacceptable
0	Acceptable	Acceptable	Acceptable	Acceptable

*These conclusions will be re-evaluated once the additional testing described in Section III.C is completed.

[1)] If the results of a risk evaluation fall into one of these two cells (3x1 or 2x2), then a risk/benefit analysis and/or appropriate justification must be documented in section C below.

Note:

- The original premarket risk/benefit analysis may be reused if still applicable as the evaluation to justify an acceptable risk.
- The above Risk Table helps assess whether the risk is acceptable or not; however, reviewer/approvers of this document make the final determination.
- Even if a risk is deemed "acceptable", action to address the issue may still be warranted.

A. Document the results of the Health Hazard Evaluation for each hazardous situation under review:

Short/Intermediate-Term Exposure

Severity: **3** / Probability: **2** = UNACCEPTABLE (acceptable/unacceptable)

Long-Term Exposure

Severity: **3** / Probability: **2** = UNACCEPTABLE (acceptable/unacceptable)

B. If the risk of the individual hazardous situation is acceptable, review the Risk Management File and consider combined impact of all the individual risks to evaluate whether overall residual risk of the device is still acceptable. Is the summary of all the risks acceptable or not acceptable?

UNACCEPTABLE (acceptable / unacceptable)

Dorma SystemOne DreamStation DreamStation Go	
C. Any additional information (if applicable):	The risk management files associated with these products will be evaluated and updated per the information above. As noted above, the Philips Respironics team is continuing to conduct additional investigational activities to better understand the myriad of variables and considerations related to the reported foam degradation. To ensure that we maintain our perspective and focus on our users, we have made conservative assumptions in identifying the severity and probability of the harms associated with this issue. As we complete the testing listed below, we will update this HHE (as required). ADDITIONAL TESTING CONSIDERATIONS: Accelerated PE-PUR Foam Life Testing • The goal of this testing is to develop a model to help us understand the foam degradation behavior at ambient conditions within the specified operating temperature and humidity ranges, in the presence or absence of ozone. • Preliminary results, at the experiments' mid-point, show visual separation between the ozone and non-ozone groups, within the operating temperature ranges, indicating that ozone does accelerate degradation at lower temperatures. These results are not yet final; therefore, this potential impact has not been considered in the overall residual risk rating. Ozone Cycling on PE-PUR Foam • The purpose of this benchtop testing is to understand how ozone impacts the visual and chemical breakdown of PE-PUR foam at ambient conditions. The outcome of this test could provide further confirmation on the hypothesis that ozone has a direct connection to the premature breakdown of device sound abatement foam. • Preliminary results indicate that PE-PUR foam exposed to various cycles of ozone at ambient temperatures show significant accelerated foam degradation, even after only one cycle. As these results are also not yet final, this potential impact has not been considered in the overall residual risk rating. Dosage Test • The goal of this test is to estimate the daily and total dosage of particulate being delivered to a patient over the device's expected use life.

	Foam Volatile Organic Compounds (VOC) Testing • As more details become known, additional information will be added to this section.
Health Hazard Evaluation Conclusion:	**Health Hazard Evaluation Medical Assessment** The Health Hazard Evaluation conducted by the Philips Respironics Team concluded that the Hazards described herein represent an unacceptable risk to patients. **Short/Intermediate-Term Exposure to Hazard: Severity 3; Probability 2** The severity of harm (level 3) recognizes the seriousness of any potential harm that may significantly impact the clinical status of patients and require additional medical intervention. Probability of harm (level 2) indicates a remote probability that device use will cause harm; expected to cause harm rarely/ from time to time (e.g., with no clear trend). **Long Term Exposure to Hazard: Severity 3; probability 2** The severity of harm (level 3) recognizes the seriousness of any potential malignancy and the need for medical intervention to preclude permanent impairment. Probability of harm (level 2) indicates a remote probability that device use will cause harm; expected to cause harm rarely/ from time to time (e.g., with no clear trend).

Step IV – Outcome approved by the following individuals:

Prepared By:

Signature Date

See EDMS for e-signature and date

Print Name and Title

s22 – Design Quality Engineer / Safety Risk Management

Approved By Director of BIU QARA:

Signature Date

See EDMS for e-signature and date

Print Name and Title

s22 – Head of Design Quality Engineering

Approved By VP of Corporate QA – HHS Q&R (or delegate):

Signature Date

See attached signature sheet

Print Name and Title

s22 – Head of Quality SRC

Approved By Credentialed Medical Professional:

Signature Date

See attached signature sheet

Print Name and Title

s22 – Medical Leader SRC

Approved By Credentialed Medical Professional:

Signature Date

See attached signature sheet

Print Name and Title

s22 [redacted] – Medical Director Connected Care

Approved By Clinical Affairs Representative:

Signature Date

See EDMS for e-signature and date

Print Name and Title

s22 [redacted] – Head of Clinical Affairs

Note: This form may be emailed or faxed to the person(s) above. Signature (electronic or fax) is required for all HHEs.

HEALTH HAZARD EVALUATION FORM

ER 2241622 – Foam Degradation in NIV Devices, Version 00

Step I – Identification of the Issue/Problem

CAPA Number:	**7211**	**HHE Date Open:**	11/16/2020	**HHE Date Closed:**	04/26/2021
- Product Data -					
Product Code:	MNT (continuous ventilator, minimal ventilatory support, facility use) MNS (continuous ventilator, non-life supporting)				
Model:	All finished good part numbers under the devices listed below fall within the scope of this HHE. For a comprehensive list of all finished good numbers, refer to CAPA 7211.				
Device Name:	DreamStation ASV DreamStation ST, AVAPS A-Series BiPAP A40 BiPAP A30 BiPAP Hybrid A30 BiPAP V30 Auto OmniLab Advanced+ SystemOne ASV4 C-Series ST/AVAPS				
Lot/Serial Numbers:	All devices in the field and released in inventory currently using the polyester-based polyurethane foam (PE-PUR) could be subject to this potential failure mode.				
Marketing Status (Include 510(k) or PMA Number, Specify if Class I Exempt from 510(k)):	K090248 • SystemOne ASV4 K090539 • SystemOne ASV4 • DreamStation ASV K092818 • C-Series ASV • C-Series ST, AVAPS K102465 • DreamStation ST, AVAPS K113053				

	• OmniLab Advanced+ • A-Series BiPAP A30 • A-Series BiPAP V30 Auto K121623 • A-Series BiPAP A40 Products Not Marketed in the US • A-Series BiPAP Hybrid A30 (Japan only)
Manufacturing/Recall Firm Address:	Respironics Inc. 1010 Murry Ridge Ln Murrysville, PA 15668
Product Description (Include Intended Use from Labeling):	***K090248 and K090539*** **SystemOne ASV4 Product Identification and Intended Use** **Regulation**: 21 CFR 868.5905 Identification: A noncontinuous ventilator (IPPB) is a device intended to deliver intermittently, an aerosol to patient's lungs or to assist a patient's breathing. Classification: Class II (performance standards) **Intended Use**: The BiPAP autoSV Advanced System One is intended to provide non-invasive ventilatory support to treat adult patients (>30 kg / 66 lbs) with Obstructive Sleep Apnea and Respiratory Insufficiency caused by central and/or mixed apneas and periodic breathing. This device may be used in the hospital or home. **Device Description:** The BiPAP autoSV device is intended to augment breathing by supplying pressurized air through a circuit. It senses breathing effort by monitoring airflow in the circuit and adjusts its output to assist with inhalation. This therapy is known as Bi-level ventilation. Bi-level ventilation provides a higher pressure, known as IPAP (Inspiratory Positive Airway Pressure), during inhalation and a lower pressure, known as EPAP (Expiratory Positive Airway Pressure), during exhalation. The higher pressure makes it easier to inhale, and the lower pressure makes it easier to exhale. A user interface displays clinical data and enables the operator to set and adjust certain clinical parameters. The devices are intended for use with a patient circuit that is used to connect the device to the patient interface device (mask). A typical patient circuit consists of a six-foot disposable or reusable tubing and a patient interface device. **DreamStation ASV Product Identification and Intended use**: **Regulation**: 21 CFR 868.5905 Identification: A noncontinuous ventilator (Intermittent positive pressure breathing - IPPB) is a device intended to deliver intermittently, an aerosol to patient's lungs or to assist a patient's

	breathing. Classification: Class II (performance standards) **Intended Use**: The BiPAP autoSV device is intended to provide non-invasive ventilatory support to treat adult patients (>30 kg/66 lbs) with Obstructive Sleep Apnea and Respiratory Insufficiency caused by central and/or mixed apneas and periodic breathing. This device may be used in the hospital or home. **Device Description:** The BiPAP autoSV device is intended to augment breathing by supplying pressurized air through a circuit. It senses breathing effort by monitoring airflow in the circuit and adjusts its output to assist with inhalation. This therapy is known as Bi-level ventilation. Bi-level ventilation provides a higher pressure, known as IPAP (Inspiratory Positive Airway Pressure), during inhalation and a lower pressure, known as EPAP (Expiratory Positive Airway Pressure), during exhalation. The higher pressure makes it easier to inhale, and the lower pressure makes it easier to exhale. A user interface displays clinical data and enables the operator to set and adjust certain clinical parameters. The devices are intended for use with a patient circuit that is used to connect the device to the patient interface device (mask). A typical patient circuit consists of a six-foot disposable or reusable tubing and a patient interface device. ***K092818*** **C-Series S/T and AVAPS Product Identification and Intended Use** **Regulation**: 21 CFR 868.5905 Identification: A noncontinuous ventilator (IPPB) is a device intended to deliver intermittently, an aerosol to patient's lungs or to assist a patient's breathing. Classification: Class II (performance standards) **Intended Use**: The BiPAP C Series device is intended to provide non-invasive ventilatory support to treat adult patients weighing over 30 kg (66 lbs) and pediatric patients 7 years or older and weighing over 18 kg (40 lbs) with Obstructive Sleep Apnea (OSA) and Respiratory Insufficiency. This device may be used in the hospital or home. **Device Description:** The C-Series is a microprocessor controlled blower based positive pressure system with integrated heated humidifier. The BiPAP S/T and BiPAP AVAPS devices are intended to provide non-invasive ventilatory support to Obstructive Sleep Apnea (OSA) and Respiratory Insufficiency patients weighing over 18 kg. This device may be used in the hospital or home. A user interface displays clinical data and enables the operator to set and adjust certain clinical parameters. The BiPAP AVAPS and

	BiPAP S/T is fitted with alarms to alert the user to changes that will affect the treatment. Some of the alarms are pre-set (fixed), others are user adjustable. The devices are intended for use with a patient circuit that is used to connect the device to the patient interface device (mask). A typical patient circuit consists of a six-foot disposable or reusable tubing and a patient interface device. ***K102465*** **DreamStation S/T and AVAPS Product Identification and Intended use**: **Regulation**: 21 CFR 868.5905 Identification: A noncontinuous ventilator (IPPB) is a device intended to deliver intermittently, an aerosol to patient's lungs or to assist a patient's breathing. Classification: Class II (performance standards) **Intended Use**: The BiPAP S/T device is intended to provide non-invasive ventilatory support to treat adult and pediatric (> 7 years of age and > 40 lbs) patients with obstructive Sleep Apnea (OSA) and Respiratory Insufficiency. The device may be used in the hospital or home. The BiPAP AVAPS device is intended to provide non-invasive ventilatory support to treat adult and pediatric (> 7 years of age and > 40 lbs) patients with obstructive Sleep Apnea (OSA) and Respiratory Insufficiency. The device may be used in the hospital or home. **Device Description:** The DreamStation BiPAP S/T and DreamStation BIPAP AVAPS devices are a microprocessor controlled blower based positive pressure system with optional integrated heated humidifier. The BiPAP S/T and BiPAP AVAPS devices are intended to provide non-invasive ventilatory support to Obstructive Sleep Apnea (OSA) and Respiratory Insufficiency patients weighing over 18 kg. This device may be used in the hospital or home. A user interface displays clinical data and enables the operator to set and adjust certain clinical parameters. The DreamStation BiPAP AVAPS and BiPAP S/T is fitted with alarms to alert the user to changes that will affect the treatment. Some of the alarms are pre-set (fixed), others are user adjustable. The devices are intended for use with a patient circuit that is used to connect the device to the patient interface device (mask). A typical patient circuit consists of a six-foot disposable or reusable tubing and a patient interface device. ***K113053*** **BiPAP A30 Product Identification and Intended use**:

	Regulation: 21 CFR 868.5895 Identification: A continuous ventilator (respirator) is a device intended to mechanically control or assist patient breathing by delivering a predetermined percentage of oxygen in the breathing gas. Adult, pediatric, and neonatal ventilators are included in this generic type of device. Classification: Class II (performance standards) **Intended Use**: The BiPAP A30 ventilator is intended to provide non-invasive ventilatory support to treat adult and pediatric patients weighing over 10 kg (22 lbs) with Obstructive Sleep Apnea (OSA) and Respiratory Insufficiency. It is intended to be used in both the home and clinical settings, such as hospitals, sleep laboratories, and sub-acute care institutions. **Device Description:** The ventilator augments patient breathing by supplying pressurized air through a patient circuit. The device senses the patient's breathing effort by monitoring airflow in the patient circuit and adjusts output to assist inhalation and exhalation. This therapy is known as Bi-level ventilation. Bi-level ventilation provides a higher pressure, known as Inspiratory Positive Airway Pressure (IPAP), when inhaling, and a lower pressure, known as Expiratory Positive Airway Pressure (EPAP), when exhaling. The device can also provide a single pressure level known as Continuous Positive Airway Pressure (CPAP). A user interface displays clinical data and enables the operator to set and adjust device parameters. These devices are fitted with alarms to alert the user to changes that will affect the treatment. Some of the alarms are pre-set (fixed), others are user adjustable. The devices are intended for use with a patient tubing circuit that connects the device to the patient interface (mask for non-invasive ventilation). A typical patient circuit consists of a six-foot disposable or reusable smooth lumen tubing, an exhalation device, and a mask. **V30 Product Identification and Intended use**: **Regulation**: 21 CFR 868.5895 Identification: A continuous ventilator (respirator) is a device intended to mechanically control or assist patient breathing by delivering a predetermined percentage of oxygen in the breathing gas. Adult, pediatric, and neonatal ventilators are included in this generic type of device. Classification: Class II (performance standards) **Intended Use**: The BiPAP V30 Auto ventilator is intended to provide non-invasive ventilatory support to treat adult and pediatric patients weighing over 10 kg (22 lbs.) with Obstructive Sleep Apnea (OSA) and Respiratory Insufficiency. The autoSV mode is intended for adult patients >30 kg (66 lbs.) with Respiratory Insufficiency and Obstructive Sleep Apnea caused by central and/or mixed apneas and periodic breathing.

	The device is intended to be used within an institution and/or hospital and is not intended for life support. It may be used during intra-facility transport. **Device Description:** The ventilator augments patient breathing by supplying pressurized air through a patient circuit. The device senses the patient's breathing effort by monitoring airflow in the patient circuit and adjusts output to assist inhalation and exhalation. This therapy is known as Bi-level ventilation. Bi-level ventilation provides a higher pressure, known as Inspiratory Positive Airway Pressure (IPAP), when inhaling, and a lower pressure, known as Expiratory Positive Airway Pressure (EPAP), when exhaling. The device can also provide a single pressure level known as Continuous Positive Airway Pressure (CPAP). A user interface displays clinical data and enables the operator to set and adjust device parameters. These devices are fitted with alarms to alert the user to changes that will affect the treatment. Some of the alarms are pre-set (fixed), others are user adjustable. The devices are intended for use with a patient tubing circuit that connects the device to the patient interface (mask for non-invasive ventilation). A typical patient circuit consists of a six-foot disposable or reusable smooth lumen tubing, an exhalation device, and a mask. **OmniLab Advanced + Product Identification and Intended Use** **Regulation**: 21 CFR 868.5895 Identification: A continuous ventilator (respirator) is a device intended to mechanically control or assist patient breathing by delivering a predetermined percentage of oxygen in the breathing gas. Adult, pediatric, and neonatal ventilators are included in this generic type of device. Classification: Class II (performance standards) **Intended Use**: The OmniLab Advanced + is intended to provide non-invasive ventilation for pediatric patients 7 years or older >18.2 kg (40 lbs) with Respiratory Insufficiency or Obstructive Sleep Apnea (OSA). It is also intended to treat adult patients >30 kg (66 lbs) with Respiratory Insufficiency or Obstructive Sleep Apnea caused by central and/or mixed apneas and periodic breathing. The OmniLab Advanced + is intended to provide non-invasive ventilation in a hospital or sleep lab setting. **Device Description:** This device augments patient breathing by supplying pressurized air through a patient circuit. It senses the patient's breathing effort by monitoring airflow in the patient circuit and adjusts its output to assist in inhalation and exhalation. This therapy is known as Bi-level therapy. Bi-level therapy provides a higher pressure, known as IPAP (Inspiratory Positive Airway Pressure), when the patient inhales, and a lower pressure, known as EPAP (Expiratory Positive Airway Pressure), when the patient exhales. The higher pressure makes it easier for the patient to inhale, and the lower pressure makes it

	easier for the patient to exhale. The device can also provide a single pressure level, known as CPAP (Continuous Positive Airway Pressure). ***K121623*** **BiPAP A40 Product Identification and Intended use**: **Regulation**: 21 CFR 868.5895 Identification: A continuous ventilator (respirator) is a device intended to mechanically control or assist patient breathing by delivering a predetermined percentage of oxygen in the breathing gas. Adult, pediatric, and neonatal ventilators are included in this generic type of device. Classification: Class II (performance standards) **Intended Use**: The BiPAP A40 ventilator is intended to provide invasive and non-invasive ventilatory support to treat adult and pediatric patients weighing over 22 lbs (10 kg) with Obstructive Sleep Apnea (OSA), Respiratory Insufficiency, or Respiratory Failure. It is intended to be used in home, institutional/hospital, and portable applications such as wheelchairs and gurneys. It is not intended to be used as a transport ventilator, and is not intended for life support. **Device Description:** The ventilator augments patient breathing by supplying pressurized air through a patient circuit. The device senses the patient's breathing effort by monitoring airflow in the patient circuit and adjusts output to assist inhalation and exhalation. This therapy is known as Bi-level ventilation. Bi-level ventilation provides a higher pressure, known as Inspiratory Positive Airway Pressure (IPAP), when inhaling, and a lower pressure, known as Expiratory Positive Airway Pressure (EPAP), when exhaling. The device can also provide a single pressure level known as Continuous Positive Airway Pressure (CPAP). A user interface displays clinical data and enables the operator to set and adjust device parameters. The BiPAP A40 Pro and BiPAP A40 EFL are fitted with alarms to alert the user to changes that will affect the treatment. Some of the alarms are pre-set (fixed), others are user adjustable. The devices are intended for use with a patient tubing circuit that connects the device to the patient interface (mask for non-invasive ventilation). A typical patient circuit consists of a six-foot disposable or reusable smooth lumen tubing, an exhalation device, and a mask. ***Products Not Marketed in the US*** **BiPAP Hybrid A30 Product Identification and Intended Use** **Regulation**: 21 CFR 868.5895 Identification: A continuous ventilator (respirator) is a device intended to mechanically control or assist patient breathing by delivering a predetermined percentage of oxygen in the breathing

	gas. Adult, pediatric, and neonatal ventilators are included in this generic type of device. Classification: Class II (performance standards) **Intended Use**: The BiPAP Hybrid A30 is intended to provide non-invasive ventilation for pediatric patients 7 years or older >18.2 kg (40 lbs) with Respiratory Insufficiency or Obstructive Sleep Apnea (OSA). It is also intended to treat adult patients >30 kg (66 lbs) with Respiratory Insufficiency or Obstructive Sleep Apnea caused by central and/or mixed apneas and periodic breathing. The device is intended for use in the hospital. **Device Description:** This device augments patient breathing by supplying pressurized air through a patient circuit. It senses the patient's breathing effort by monitoring airflow in the patient circuit and adjusts its output to assist in inhalation and exhalation. This therapy is known as Bi-level therapy. Bi-level therapy provides a higher pressure, known as IPAP (Inspiratory Positive Airway Pressure), when the patient inhales, and a lower pressure, known as EPAP (Expiratory Positive Airway Pressure), when the patient exhales. The higher pressure makes it easier for the patient to inhale, and the lower pressure makes it easier for the patient to exhale. The device can also provide a single pressure level, known as CPAP (Continuous Positive Airway Pressure).
Brief description of the issue/problem and how it was identified:	Philips Respironics received complaints in 2019 regarding SystemOne CPAP devices from Thailand (Complaint numbers RA 307829970 and 307806329) alleging the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask). The patient's nephew expressed concerns that the black particulate was delivered to the patient's airway and could affect her health. The SystemOne devices were returned and visual inspection showed signs of foam degradation. Chemical analysis of the foam confirmed degradation, triggering the initiation of CAPA 7211 and additional investigational activities. The sound abatement foam is an open-cell polyester-based polyurethane (PE-PUR) foam that is widely used for sound dampening purposes in many industries. The PE-PUR foam is also used in Philips Respironics noninvasive ventilator (NIV) devices, the subject of this Health Hazard Evaluation (HHE). A complaint analysis performed as part of CAPA 7211 indicated that complaints for PE-PUR foam degradation were also identified for the NIV devices. Specifically, 42 complaints were identified suggesting the presence of degraded foam with NIV devices. In addition, the complaint analysis showed an overall increase in complaints related to alleged PE-PUR foam degradation across the PRI PAP devices, NIV, and ventilators. The majority of complaints were reported by Philips service personnel and were found subsequent to investigating the patients' primary complaints. As of the date of this

	HHE, 766,587 NIV devices have been shipped. Accordingly, Philips Respironics initiated this HHE to evaluate potential foam degradation in the context of NIV devices based on available data generated to date. This Health Hazard Evaluation only assesses the risks associated with physical exposure to foam particulates. Emission of chemical compounds as a result of foam breakdown is recognized as a potential source of harm, however testing is ongoing to further investigate the potential harms associated with this. As additional information becomes available, this HHE will be updated to reflect any changes to the overall risk profile.
Affected Patient/User Population:	All patient groups that fall within the intended use of the devices referenced in the Product Description are within the affected patient population. The intended patient population across multiple NIV platforms broadly includes the following: adult and pediatric patients weighing over 22 lbs. (10 kg) with Obstructive Sleep Apnea, Respiratory Insufficiency, or Respiratory Failure. Higher risk populations within the intended patient population include pediatrics; the elderly; pregnant women; and patients with comorbidities such as heart failure, COPD, and obesity.
HHE Author (Name/Function):	s22 [redacted] – Design Quality Engineer/Safety Risk Management
HHE Contributors (Name/Function):	s22 [redacted] – Design Quality Engineer/Safety Risk Management s22 [redacted] – Design Quality, Sr. Manager s22 [redacted] –Quality Engineering, Manager s22 [redacted] – Head of Design Quality Engineering s22 [redacted] – Sustaining Engineering Manager s22 [redacted] – Sr. Quality Engineer s22 [redacted] – Sr. Bio Safety and Verification Engineer s22 [redacted] – Head of Global Clinical and Scientific Affairs s22 [redacted] – Medical Director, Connected Care s22 [redacted] – Director of Regulatory Affairs s22 [redacted] – Medical Leader, SRC s22 [redacted] – Medical Safety Manager, SRC

Step II – Analyze Post Release Health Risk Associated with Affected Units

Note: Assess the risk as if no corrective action will be taken and all affected devices will remain in the marketplace.

A. Identification of the Individual Hazard(s)

Hazard Category:	**Hazard Category:** Biological and Chemical **Hazard**: Biocompatibility / Toxicity of chemical constituents
Hazard Cause:	Polyester-based polyurethane foam (PE-PUR) is used as a sound abatement foam in the NIV device airpath. Based on all available data generated to date, Philips Respironics determined that the PE-PUR foam's reaction with water (hydrolysis) was a source of the foam degradation potentially caused and/or exacerbated by the following factors: • Device operation in higher heat and humidity environmental conditions; and/or • Use of unapproved cleaning and disinfection methods with the NIV device (e.g. ozone). *Environmental Conditions* The labeled environmental conditions for operating temperature are 5° to 35° C (41° to 95° F) with storage temperatures ranging from -20° to 60° C (-4° to 140° F). Preliminary test results conducted by Philips Respironics show that high temperature (90° C) contributes to significant degradation of the foam. Testing is ongoing to further investigate the impact of ambient temperature and humidity on foam degradation including: (1) models that may better simulate real world device operation conditions; and (2) lower temperatures within the labeled range. Refer to Section III,C for additional information on planned testing. *Unapproved Cleaning and Disinfection Methods* The NIV user manual cleaning instructions do not include ozone disinfection; rather, the instructions recommend water and a mild liquid dishwashing detergent for cleaning and DisCide Ultra Towelettes or a Chlorine Bleach solution for disinfection. The manual states that any deviation from these instructions or agents not listed in this guide may impact the performance of the product. Ozone disinfection devices appear to have become more readily available around the same time as Philips Respironics received complaints of foam degradation, however further investigation is ongoing. Foam degradation has also been reported even when ozone disinfection was not reported.
Hazardous Situation:	**Exposure to particulate by-products of foam degradation during use.** If PE-PUR foam degrades, small particulates (estimated size range of 2.69 µm-724 µm) may be expelled from the device blower box, through the motor and patient circuit and could enter the patient respiratory tract and/or Gastrointestinal (GI) tract. Based on our analysis of the degraded foam, the particles may include compounds such as diethylene glycol (DEG), toluene diamine isomers (TDA), and toluene diisocyanate isomers (TDI). Due to an inability to obtain a sufficient quantity of representative field

	samples for biocompatibility lab testing, we created lab degraded foam used for such testing, including: cytotoxicity, genotoxicity, irritation, and sensitization tests.

B. Estimation of Severity

Description of reported and/or potential harm:	**Harm resulting from Short-Term and Intermediate-Term Exposure:** exacerbation or worsening of the underlying patient condition Potential Harms: • Irritation (skin, eye, and respiratory tract) • Inflammatory response • Headache • Asthma • Effects to reproductive system • Neoplasia While no harm was reported for NIV devices, 10 reported cases of harm were reported for PAP devices. These complaints are detailed in CAPA 7211 and generally included complaints of headache, upper airway irritation, cough, chest pressure, and sinus infection. Attributable harm may be confounded by the additional use of ozone (alleged to be used in 5 of the 10 complaints) or the use of PAP therapy in general. **Harm resulting from Long-Term Exposure:** cytotoxic, genotoxic, and potential carcinogenic effects Zero cases of harm have been directly or indirectly linked to this failure mode.
Estimation of Severity of Harm	**3 (Crucial) – Short/Intermediate Term Exposure** Results in serious injury: life-threatening, or permanent impairment or necessitates medical intervention to preclude permanent impairment This is considering the reasonable worst-case scenario, per the rationale in the comments section below. **3 (Crucial) – Long Term Exposure** Results in serious injury: life-threatening, or permanent impairment or necessitates medical intervention to preclude permanent impairment Philips Respironics identified no significant difference in the estimated severity of harm when considering the general and higher risk patient populations.
Comments: (Severity of Harm Rationale)	A Bio Endpoint Analysis and toxicological risk assessment was performed on the specific chemical constituents and their potential impact to patients. This analysis is included as part of CAPA 7211; the testing is summarized below. Due to the difficulty in obtaining a sufficient quantity of representative field

samples for biocompatibility lab testing, laboratory accelerated aged foam was used to conduct the cytotoxicity, genotoxicity, irritation, and sensitization tests. The following results were noted:

- Cytotoxicity was noted for all extraction concentrations.
- Two genotoxicity assays confirmed a positive mutagenic response.
- Irritation results for the non-polar extract returned a passing result.
- Sensitization results from both polar and non-polar extracts returned a passing result.

Daily chemical dosages and concentrations are unknown at this time. Philips is in the process of constructing a model that calculates the start and rate of foam degradation. Further investigations are ongoing and detailed in Step III, Section C. Additionally, the literature does describe tolerable intake (TI) references for some of the major degradative by-products of the polyester polyurethane foam: TDA, TDI and DEG. Specifically:

- **Toluene diamine isomers (TDA)**, such as toluene-2,4-diamine, are primarily used in the synthesis of polyurethane, various dyes, and heterocyclic compounds.[1,2]
    - A chronic reference dose (RfD) for 2, 6 toluene diamine has been listed by the IRIS EPA at 0.03 mg/kg per day.[3]
- **Toluene diisocyanate isomers (TDI)** such as 2,4-toluene diisocyanate are chemical intermediates utilized in the production of polyurethane products.[4]
    - A reference concentration of 0.00007 mg/m^3 (0.07 µg/m^3) has been recommended for toluene diisocyanates by the EPA IRIS risk assessment.[5]
    - The U.S. Office of Environmental Health Hazard Assessment (OEHHA) has listed the Safe Harbor Levels at 20 µg/day for the no significant risk level (NSRL) to toluene diisocyanates.
- **Diethylene glycol (DEG)** is a polyol building block utilized in the synthesis of polyurethane.
    - Literature suggests a proposed human oral ingestion reference dose of 0.3 mg/kg for DEG.[6]
    - A WEEL occupational level of 10 mg/m^3 has been proposed by TERA for inhalational limits of DEG[7]- but this is not adequate or protective for sensitive patient populations and only accounts for an occupational worker exposure.
    - Per prior informal feedback from the FDA, 1% of the WEEL occupational value (10 mg/m^3) would be an adjusted tolerable intake of 0.1 mg/m^3.

Philips Respironics is working to complete the additional investigatory activities described in Step III, Section C to assess whether the amount of

degraded PE-PUR form inhaled and/or ingested by the patient may potentially exceed the TI references provided above.

In order to evaluate the risks posed by the PE-PUR foam particulates, exposure time and patient airway physiology must be considered. Data generated to date suggests that the PE-PUR foam degrades into particulates of varying sizes. The location of collected particulates in the respiratory tract and the body's response to them is partially dictated by size.

- For this HHE, the PE-PUR foam particulates are assumed to reach the patient airway (the amount or concentration in µg/m^3 is unknown).

  The location of where aerosolized particulates collect in the respiratory tract and the body's response to them is partially dictated by size.[1] A multitude of tissues compose the respiratory tract which includes the conducting airways that consist of the nose and mouth, pharynx, larynx, leading into the trachea, main bronchi, lobar, segmental bronchi, and terminal bronchioles.[2] The terminal bronchioles then lead into the respiratory bronchioles, alveolar ducts, and lastly alveolar sacs.[2] There are defense mechanisms in the respiratory system which help prevent particulates from entering into the lung, these include cilia and mucous layers. Cilia are hair-like projections of the cells that line the airway and propel the liquid layer of mucous which can trap pathogens and particulates prior to reaching the lungs.[3]

- The nose and accompanying respiratory tract is capable of filtering foreign particles dependent on particle size and airflow rate with a filtration efficacy decreasing with particulate size.[4] Small particles (<1-3 µm) are capable of diffusing into deep lung tissue and deposit into the alveoli whereas larger particulates (> 8 µm) will be deposited throughout the nasal passages and larger bronchioles.[1]

- Macrophages: one of the three types of alveolar cells, also known as dust cells, can eliminate foreign particles and bacteria through the process of phagocytosis

Philips Respironics particle size analysis identified that the majority of particulate (> 8 µm) is of a size that is unable to penetrate into deep lung tissue and thus will remain in the patient upper airway. A smaller fraction of the particulate (<1-3 µm) may still penetrate into the lower respiratory tract.

Our conclusions are as follows:

- Based on the cytotoxicity and genotoxicity results and toxicological risk assessment, combined with our conclusion that particles are likely to reach the upper airway and potentially the lower respiratory track, a reasonable worst-case estimate for the **general** and **higher risk** (e.g., patient populations with preexisting conditions or comorbidities) patient populations is a severity level 3 (Crucial) for both short/intermediate and long term exposure.

Reference Information:

Check (X) Applicable Level*	Examples

*	___ 4 **(Catastrophic)**	Directly results in death
	X 3 **(Crucial)**	Results in serious injury: life-threatening, or permanent impairment or necessitates medical intervention to preclude permanent impairment
	___ 2 **(Marginal)**	Results in moderate injury: temporary impairment, or self-limiting illness
	___ 1 **(Negligible)**	Results in less than moderate or no injury

Severity Levels 4 and 3 are “serious adverse health consequences” per FDA’s CDRH Health Hazard Evaluation Form Version 3-1 01/12/2007. Severity Levels 2 and 1 are not serious adverse health consequences per FDA’s HHE Form.

References:

1. Thomas, R. J. Particle size and pathogenicity in the respiratory tract. Virulence 4, 847–858 (2013).

2. Patwa, A. & Shah, A. Anatomy and physiology of respiratory system relevant to anaesthesia. Indian J. Anaesth. 59, 533–541 (2015).

3. Defense Mechanisms of the Respiratory System - Lung and Airway Disorders. Merck Manuals Consumer Version Available at: https://www.merckmanuals.com/home/lung-andairway-disorders/biology-of-the-lungs-and-airways/defense-mechanisms-of- the-respiratorysystem. (Accessed: 23rd May 2018)

4. Imre Salma, Imre Balásházy, Renate Winkler-Heil, Werner Hofmann, Gyula Záray,. Effect of particle mass size distribution on the deposition of aerosols in the human respiratory system, Journal of Aerosol Science, Volume 33, Issue 1, 2002, Pages 119-132, ISSN 0021-8502, https://doi.org/10.1016/S0021-8502(01)00154-9. (https://www.sciencedirect.com/science/article/pii/S0021850201001549)

5. Knowles, M. R. & Boucher, R. C. Mucus clearance as a primary innate defense mechanism for mammalian airways. J. Clin. Invest. 109, 571–577 (2002)

C. Estimation of Probability of Harm Resulting from Affected Units

Estimated quantity of affected devices (# in field, # in factory, # in distribution centers, etc.):	Between 2008 through March 2021, a total of 766,587 shipments of NIV System Devices (see list of devices above).
Number and type of injuries/number of deaths attributed to the problem with the device (if any):*	No instances of harm have been reported in NIV devices where foam degradation was alleged. Injuries = 0 Deaths = 0 In the case of long-term exposure, it should be noted that harm may not be immediately recognizable and may not be something that the customer would/could report. A total of 42 complaints were filed for foam degradation with NIV devices. The reported complaint rate for this failure mode is 0.005%. While no harm was reported for NIV devices, 10 reported cases of harm were reported for PAP devices. These complaints are detailed in CAPA 7211 and generally included complaints of headache, upper airway irritation, cough, chest pressure, and sinus infection. Attributable harm may be confounded by the additional use of ozone (alleged to be used in 5 of the 10 complaints) or PAP therapy in general.
Describe the factor(s) that need to occur to create the hazardous situation (reasonably foreseeable sequence or combination of events):	A hazardous situation is created when a patient uses an NIV device where the PE-PUR foam exhibits degradation. As described in Step II, Section A under Hazard Cause, foam may degrade when exposed to specific conditions. Once the foam starts to degrade, airborne particulates from degraded foam material could potentially enter the NIV system air flow path. The particulate must travel through the path outlined below. NIV Air Flow Path: Air enters through the inlet filter and into the blower box that contains the PE-PUR foam. From the blower box, the air continues through the angled elbow of blower and through the blower impeller. Air then travels through the angled outlet port where it may interface with an optional humidifier, continuing through the patient circuit. The patient circuit consists of a 6 ft tube, an angled connection interface, and mask, before reaching the patient airway. Note that the air flow path referenced above is a broad generalization of each of the devices in scope of this report.
Factors that might mitigate risk (e.g., safety mechanisms present in the design, instructions for use, current label warnings, etc.):	<u>Device inspection per device IFU</u>: Exposure to the hazard may be partially mitigated through device, tubing, and mask inspection. Device User Manuals instruct patients to “Periodically inspect electrical cords, cables, tubing, and accessories for damage or signs of wear.” Mask IFU’s instruct patients to “Inspect the mask parts regularly for damage or wear” and to clean the mask daily.

	However, patients may not detect the particles (e.g., because the particles are too small). Bacteria Filter: When used in a hospital or clinical setting (i.e. Sleep Lab), labeling recommends that an in-line bacteria filter (Part Number 342077) be placed in-line with the patient circuit whenever the device is used on multiple patients. When a bacterial filter is used within the patient circuit, particulate is unable to reach the patient. According to the Ambu 20801 performance sheet, the filter tested 99.97% effective on an inert test particle of 0.3µm. Based on the particle size report (detailed in Att 2), the bacteria filter will effectively filter out any foam particulate that could make its way up the patient circuit.
Would a user detect the hazardous situation prior to occurrence of harm? If so, describe how:	Detection of Foam Particulate: The particulate analysis (as detailed in CAPA 7211) demonstrates a variety of small and large particles that may or may not be detectable based on size and quantity. Small, black contaminants may become visible near the air outlet port or within the patient circuit. Daily cleaning of the mask and weekly cleaning of the tubing may remove trapped particles and increase the odds of detection.

Probability Estimate

Estimation of Probability that the Harm will occur:	Short/Intermediate-Term Hazard Exposure **2 (Occasional)** 'Remote probability' that use will cause harm; expected to cause harm rarely/ from time to time (e.g., with no clear trend) This Hazard has zero reports of harm from 2008 through March 2021 for NIV devices. While no harm was reported for NIV devices, 10 reported cases of harm were reported for PAP devices. These complaints are detailed in CAPA 7211 and generally included complaints of headache, upper airway irritation, cough, chest pressure, and sinus infection. Attributable harm may be confounded by the additional use of ozone (alleged to be used in 5 of the 10 complaints) or PAP therapy in general. Long-Term Exposure **2 (Occasional)** 'Remote probability' that use will cause harm; expected to cause harm rarely/ from time to time (e.g., with no clear trend) This Hazard has zero reports of harm from 2008 through March 2021
Comments: (Probability of Harm Rationale)	**Probability of Hazardous Situation Occurring (P1)** While Philips Respironics' testing and investigation to date indicates that the PE-PUR foam within the devices is degrading, and the degradation may be due to device exposure to certain conditions (e.g., environmental, disinfection using unauthorized cleaning agents) over a period of time, Philips Respironics is in the process of conducting additional studies to better understand: (1) the specific conditions that cause the foam to degrade; and (2) the rate of foam degradation when the device experiences such conditions. For example, if the device must experience certain environmental conditions for an extended period of time for the foam to degrade (e.g., high humidity, high temperature), not all users may subject their device to such conditions. Therefore, completion of these ongoing and planned studies will help Philips Respironics better estimate the reasonable worst-case probability of the foam degrading within the device population. See ongoing and planned investigational activities described in Step III, Section C. Although the observed complaint rate is 0.005%, as noted above, the complaint rate may not accurately reflect the probability of the failure because patients may not detect the particles and/or report the event to Philips Respironics. Nonetheless, based on the available information and test data collected to date, Philips Respironics estimates that the reasonable worst-case probability of the foam degrading in the device to be *occasional* over the device's useful life.

	Probability that Hazardous Situation will Lead to Harm (P2) The probability that the hazardous situation will lead to harm is dependent upon the amount of degraded foam a patient may inhale and/or ingest and may be exacerbated by the patient's underlying comorbidities. As noted in Step II, Section B, further investigations are ongoing and detailed in Step III, Section C. Short and long-term exposure to the hazard may cause generalized inflammation in patients that could facilitate clinical deterioration in certain patient populations as dictated by the underlying disease or associated comorbidities. As an inhalational therapy, it is possible that patients with low cardio-pulmonary reserve (e.g. COPD, CHF) may experience a meaningful deterioration in their function that requires medical intervention. Clinical events of this nature may not be easily linked to the hazardous situation or device use in general. Based on lab testing, exposure to the degraded foam and its components may lead to cellular DNA mutations. Such mutations may lead to uncontrolled cellular replication given a sufficient dose and duration of exposure that have not been determined. Patient related factors including bodily defenses, target tissue deposition, and immune function will also likely impact the development of the reasonable worst-case scenario harm. Additionally, a presumed lag time from exposure to harm development may make it difficult for patients to attribute their individual harm to the device usage. No severity 3 (Crucial) harm has been reported to date. It should be noted that harm in this case may not be immediately recognizable and may not be something that the patient would/could report. **Probability of Occurrence of Harm (P)** Taking into consideration P1 and P2, it is challenging to accurately estimate the probability of harm quantitatively. A probability of 2 (Occasional) was chosen as the reasonable worst-case scenario.

Considering the factors above, assess the probability that use of, or exposure to, the affected devices will cause future harm during the product's lifetime. Consider segments of the population most at risk (e.g. infants, elderly, pregnant women, critically ill patients, etc.).

Check (X) applicable level*	***Example of probability of harm***
___ **4** **(Always)**	Occurs 'every time'*
___ **3** **(Likely)**	'Reasonable probability' that use will cause harm*; good chance/ considerable certainty to cause harm
X **2** **(Occasional)**	'Remote probability' that use will cause harm*; expected to cause harm rarely/ from time to time (e.g., with no clear trend)
___ **1** **(Unlikely)**	'Not likely' that use will cause harm*; possible but improbable
___ **0** **(Inconceivable)**	Inconceivable; not possible

*** Corresponds with probability levels set forth in FDA's CDRH HHE Form Version 3-1 01/12/2007.**

***Note: If harm has already occurred as a result of the issue under review, then:**

- Probability level zero (0) and one (1) 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.
- Probability level 0 rarely applies to post-market risk evaluation in cases where harm has occurred.

Step III – Health Hazard Evaluation Conclusion

Probability	Severity			
	1	2	3	4
4	Unacceptable	Unacceptable	Unacceptable	Unacceptable
3	Acceptable	Unacceptable	Unacceptable	Unacceptable
2	Acceptable	Further Analysis Required[1)]	Unacceptable Short/Intermediate-Term Exposure Long-Term Exposure	Unacceptable
1	Acceptable	Acceptable	Further Analysis Required[1)]	Unacceptable
0	Acceptable	Acceptable	Acceptable	Acceptable

*These conclusions will be re-evaluated once the additional testing described in Section III.C is completed.

[1)] If the results of a risk evaluation fall into one of these two cells (3x1 or 2x2), then a risk/benefit analysis and/or appropriate justification must be documented in section C below.

Note:

- The original premarket risk/benefit analysis may be reused if still applicable as the evaluation to justify an acceptable risk.
- The above Risk Table helps assess whether the risk is acceptable or not; however, reviewer/approvers of this document make the final determination.
- Even if a risk is deemed "acceptable", action to address the issue may still be warranted.

A. Document the results of the Health Hazard Evaluation for each hazardous situation under review:

Short/Intermediate-Term Exposure

Severity: **3** / Probability: **2** = UNACCEPTABLE (acceptable/unacceptable)

Long-Term Exposure

Severity: **3** / Probability: **2** = UNACCEPTABLE (acceptable/unacceptable)

B. If the risk of the individual hazardous situation is acceptable, review the Risk Management File and consider combined impact of all the individual risks to evaluate whether overall residual risk of the device is still acceptable. Is the summary of all the risks acceptable or not acceptable?

UNACCEPTABLE (acceptable / unacceptable)

DreamStation ASV DreamStation ST, AVAPS A-Series BiPAP A40 BiPAP A30 BiPAP Hybrid A30 BiPAP V30 Auto OmniLab Advanced+ C-Series ASV C-Series ST/AVAPS	
C. Any additional information (if applicable):	The risk management files associated with these products will be evaluated and updated per the information above. As noted above, the Philips Respironics team is continuing to conduct additional investigational activities to better understand the myriad of variables and considerations related to the reported foam degradation. To ensure that we maintain our perspective and focus on our users, we have made conservative assumptions in identifying the severity and probability of the harms associated with this issue. As we complete the testing listed below, we will update this HHE (as required). ADDITIONAL TESTING CONSIDERATIONS: Accelerated PE-PUR Foam Life Testing • The goal of this testing is to develop a model to help us understand the foam degradation behavior at ambient conditions within the specified operating temperature and humidity ranges, in the presence or absence of ozone. • Preliminary results, at the experiments' mid-point, show visual separation between the ozone and non-ozone groups, within the operating temperature ranges, indicating that ozone does accelerate degradation at lower temperatures. These results are not yet final; therefore, this potential impact has not been considered in the overall residual risk rating. Ozone Cycling on PE-PUR Foam • The purpose of this benchtop testing is to understand how ozone impacts the visual and chemical breakdown of PE-PUR foam at ambient conditions. The outcome of this test could provide further confirmation on the hypothesis that ozone has a direct connection to the premature breakdown of device sound abatement foam. • Preliminary results indicate that PE-PUR foam exposed to various cycles of ozone at ambient temperatures show significant accelerated foam degradation, even after only one cycle. As these results are also not yet

	final, this potential impact has not been considered in the overall residual risk rating. Dosage Test • The goal of this test is to estimate the daily and total dosage of particulate being delivered to a patient over the device's expected use life. Foam Volatile Organic Compounds (VOC)Testing • As more details become known, additional information will be added to this section.
Health Hazard Evaluation Conclusion:	**Health Hazard Evaluation Medical Assessment – NIV** The Health Hazard Evaluation conducted by the Philips Respironics Team concluded that the Hazards described herein represent an unacceptable risk to patients. **Short/Intermediate-Term Exposure to Hazard: Severity 3; Probability 2** The severity of harm (level 3) recognizes the seriousness of any potential harm that may significantly impact the clinical status of patients and require additional medical intervention. Probability of harm (level 2) indicates a remote probability that device use will cause harm; expected to cause harm rarely/ from time to time (e.g., with no clear trend). **Long Term Exposure to Hazard: Severity 3; probability 2** The severity of harm (level 3) recognizes the seriousness of any potential malignancy and the need for medical intervention to preclude permanent impairment. Probability of harm (level 2) indicates a remote probability that device use will cause harm; expected to cause harm rarely/ from time to time (e.g., with no clear trend).

Step IV – Outcome approved by the following individuals:

Prepared By:

Signature Date

See EDMS for e-signature and date

Print Name and Title

s22 – Design Quality Engineer / Safety Risk Management

Approved By Director of BIU QARA:

Signature Date

See EDMS for e-signature and date

Print Name and Title

s22 – Head of Design Quality Engineering

Approved By VP of Corporate QA – HHS Q&R (or delegate):

Signature Date

See attached signature sheet

Print Name and Title

s22 – Head of Quality SRC

Approved By Credentialed Medical Professional:

Signature Date

See attached signature sheet

Print Name and Title

s22 – Medical Leader SRC

Approved By Credentialed Medical Professional:

Signature Date

See attached signature sheet

Print Name and Title

s22 – Medical Director Connected Care

Approved By Clinical Affairs Representative:

Signature Date

See EDMS for e-signature and date

Print Name and Title

s22 – Head of Clinical Affairs

Note: This form may be emailed or faxed to the person(s) above. Signature (electronic or fax) is required for all HHEs.

From: s22
To: s22
Cc: s22 ; s22 ; s22
Subject: RE: Philips CPAP/BPAP/Ventilator Recall - potential infringement notices [SEC=OFFICIAL, ACCESS=Legal-Privilege]
Date: Tuesday, 31 May 2022 8:34:22 AM
Attachments: image001.png
image002.png
image003.gif
image004.png
image005.gif
[D22-5527525] Philips Electronics Australia Ltd - Infringement notice- ARTG 327227.DOCX
[D22-5527525] Philips Electronics Australia Ltd - Infringement notice- ARTG 327227.tr5
[D22-5526553] Philips PE-PUR Infringement notices - DRAFT - Cover letter.DOCX
[D22-5526553] Philips PE-PUR Infringement notices - DRAFT - Cover letter.tr5

Hi s22

As just discussed, attached is the cover letter and one of the 10 infringement notices; there is one infringement notice for each ARTG entry that has devices with the defective foam. All of the infringement notices are found in E21-327521.

For your further consideration is the date (26 or 28 April 2021?) that you reasonably believe Philips Australia became aware of the devices being defective; this will be reflected in the cover letter and the infringement notices. A summary is provided below but happy to speak to you further regarding this.

Thanks

s22

Concerning conditions of inclusion, providing required information and if there was continued supply (or use) of knowingly defective goods

- The recall action impacted all product manufactured prior to 26 April 2021.
- On 26 April 2021 Philips published a statement in which they identified the risk to users of these devices with degradation of foam (attached).
- The 26 April announcement was followed on by a letter dated 28 April from Philips to their Australian customers advising of the foam degradation issue (attributing it to multiple factors) and that they would be in contact again as they address the issue - D21-2723486.
- This is the webpage where Philips Australia's announcements have been published https://www.philips.com.au/healthcare/e/sleep/communications/src-update?_ga=2.162671036.1209090897.1620711304-797588883.1586916367&_gl=1*1o8i7pq*_ga*Nzk3NTg4ODgzLjE1ODY5MTYzNjc.*_ga_2NMXNNS6LE*MTYyMDcxMTMwNC4xMC4xLjE2MjA3MTE3MTEuNjA).
- The earlier published advice about Philips applying a 'ship hold' to all stock has been superseded /overwritten with this current information, which I note commences with –

  "On April 26, 2021, Philips globally provided an important update to the market regarding proactive efforts to address identified issues with a component in certain products of our Sleep & Respiratory Care portfolio".
- On 28 June, Philips Australia referred to this earlier published advice as a 'ship hold' announcement (see D21-2783288 – row 5 in the table).
- We have no evidence that Philips Australia continued to supply affected units after 26 April.

s22
Director – Devices Post Market Reforms & Reviews Section

Medical Devices and Product Quality Division | Health Products Regulation Group
Medical Devices Surveillance Branch

Australian Government Department of Health
T: s22 M: s22 | E: s22 @health.gov.au
Location: Perth
PO Box 100, Woden ACT 2606, Australia

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: s22
Sent: Friday, 27 May 2022 9:11 AM
To: s22 @health.gov.au>
Cc: s22 @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>
Subject: RE: Philips CPAP/BPAP/Ventilator Recall - potential infringement notices [SEC=OFFICIAL, ACCESS=Legal-Privilege]

Hi s22

As previously discussed, the INs have been drafted as per your instructions.

I would be grateful for your consideration on the date (26 or 28 April 2021?) that you reasonably believe Philips Australia became aware of the devices being defective to enable final drafts for each of the INs to be generated. A summary is provided below.

Thanks

s22

Concerning conditions of inclusion, providing required information and if there was continued supply (or use) of knowingly defective goods

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s22
Director – Devices Post Market Reforms & Reviews Section

Medical Devices and Product Quality Division | Health Products Regulation Group
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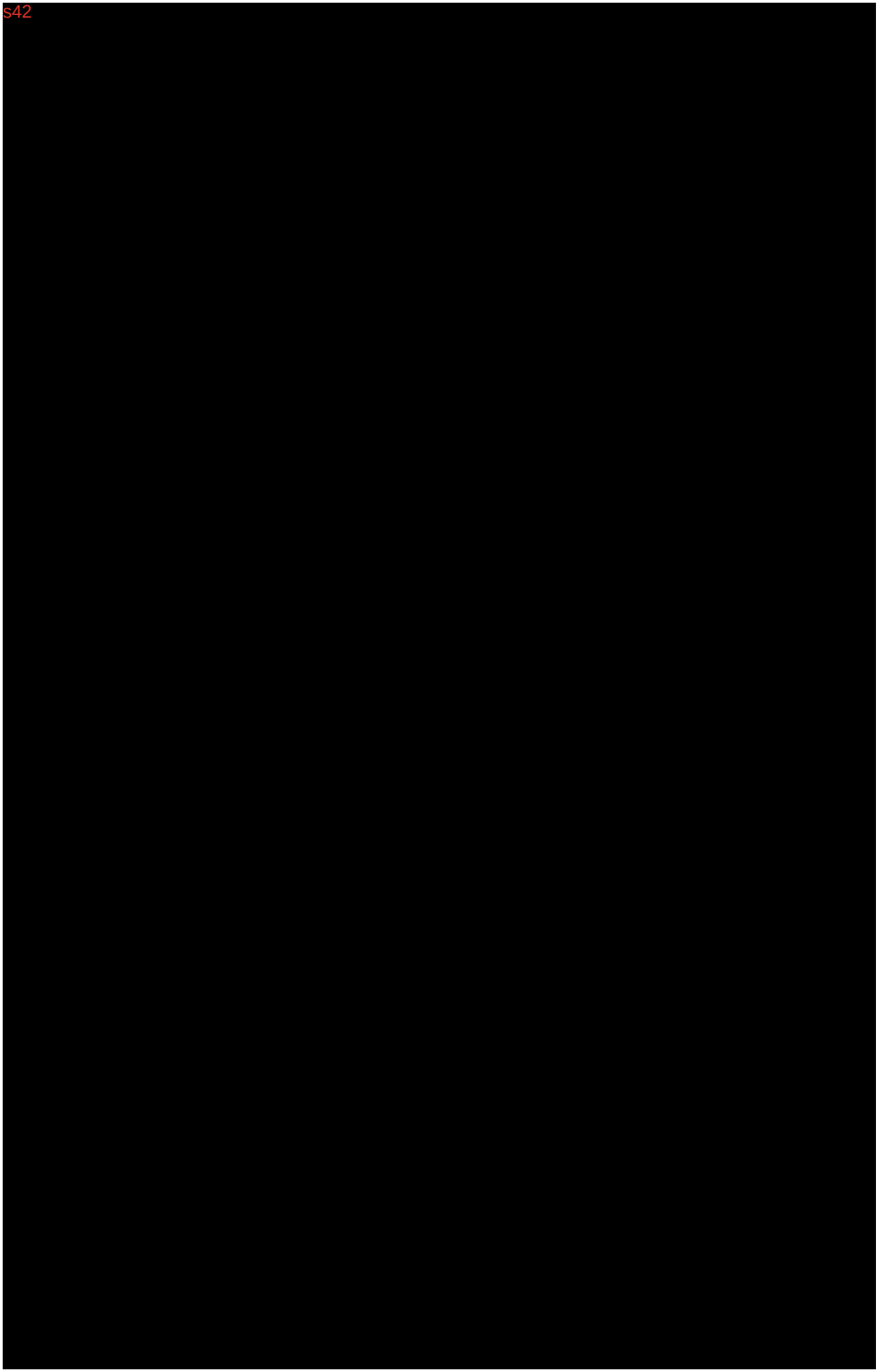
Australian Government Department of Health
T: s22 M: s22 | E: s22 @health.gov.au
Location: Perth
PO Box 100, Woden ACT 2606, Australia

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

s42

s42



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