1.First Consignee (Distributor/Retailer) – Field Safety Notice for Device Modification Notification Letter

Fisher & Paykel Healthcare Limited
15 Maurice Paykel Place, East Tamaki
P O Box 14 348, Panmure
Auckland, New Zealand
Telephone: +64 9 574 0100
Facsimile: +64 9 574 0158
Website: www.fphcare.com

[Date]

Chief Executive Officer
[Facility Address]

Attention: [head of appropriate department e.g. Chief Biomedical Engineer]

Field Safety Notice for Device Modification

AIRVO 2 / myAIRVO 2 User Instruction Update

FPH FSCA Identifier: FA-2016-001
Type of Action: Retail Level Device Modification

AFFECTED PRODUCT DETAILS:

The Fisher & Paykel Healthcare (FPH) AIRVO 2 / myAIRVO 2 humidifiers are designed to treat spontaneously breathing patients who would benefit from receiving high flow warmed and humidified respiratory gases. The AIRVO 2 / myAIRVO 2 is not intended for life support.

REASON FOR FIELD SAFETY NOTICE FOR DEVICE MODIFICATION:

FPH has updated the AIRVO 2 / myAIRVO 2 User Instructions to include a check that the speaker is audible prior to each patient use in order to ensure the speaker is functioning.

AFFECTED PRODUCT MODEL AND SERIAL NUMBERS:

Model Number (REF)		Affected Serial Numbers
AIRVO 2	PT101XX	120521YYYYYY - 160605YYYYYY
myAIRVO 2	PT100XX	

ACTIONS BEING TAKEN BY FISHER & PAYKEL HEALTHCARE:

The AIRVO 2 / myAIRVO 2 User Instructions have been updated to include a warning for the user to check speaker functionality before each patient use. This warning points to the speaker functionality check contained in all AIRVO 2 / myAIRVO 2 User Instructions.

ACTIONS REQUIRED FROM YOU:

For product in your inventory:

Step 1: Please perform the speaker functionality check contained in all AIRVO 2 / myAIRVO 2 User Instructions (located in the “Using AIRVO 2” or “Using myAIRVO2” sections): Turn the unit on and then remove the heated breathing tube. You should see the “check tube” visual signal and hear the speaker signal.

Step 2: If either signal is absent, do not use the unit and contact your FPH representative [insert contact name] to arrange for a replacement device.

Step 3: Please read the attached updated User Instruction for the affected product. Note the warnings in section 1, which state ‘*Prior to each (patient) use, ensure that the auditory alarm signal is audible by conducting the alarm system functionality check described in the Alarms section*’.

Step 4: Complete the attached ‘Response Form’ and return it to your FPH representative.

Step 5: Please ensure to include the updated User Instructions with each future AIRVO 2 / myAIRVO 2 sale.

For product you may have distributed:

Step 1: Please review your sales records and identify if any affected products have been distributed to your customers. Complete Section B 'Notification to Customers' on the 'Response Form' and return it to your FPH representative [insert contact name].

Step 2: If the affected products have not been distributed, please skip steps 2 - 7.

If you have distributed affected products to your customers, then create a list of affected customers using the 'Customer Tracking Sheet' provided in the email. Identify if each customer is a distributor, retailer, or hospital.

Step 3: Notify customers immediately via phone or email. Advise them to check if they have any of the affected products and instruct them to carry out the functionality check above.

Step 4: Create a 'Field Safety Notice for Device Modification Letter' and 'Response Form' using the distributor, retailer, or hospital templates provided in the email and edit the text in red.

Step 5: Send the 'Field Safety Notice for Device Modification Letter' together with a 'Response Form' and the updated User Instructions to all affected customers within **five (5) business days** of receiving this letter, using a courier system (mail with track and trace).

Step 6: Update the following fields on the 'Customer Tracking Sheet':

- Date the customers were sent the Letter
- The date each completed response form is received
- Tracking numbers of the letters sent to the customers

Note: All response forms must be kept and sent to your FPH representative [insert contact name].

Step 7: Where a customer fails to respond to the 'Field Safety Notice for Device Modification Letter' within **15 business days** of initial contact via letter, please follow up a minimum of **three times** via courier with a 'Follow Up Letter' once every further **15 business days**. Create a 'Follow Up Letter' using the template provided in the email. Enter the type of follow up (First, Second or Final) and the date on which you will send the letter. Please document the date and summary of the attempts made in the 'Customer Tracking Sheet' for records.

TRANSMISSION OF THIS FIELD SAFETY NOTICE FOR MEDICAL DEVICE MODIFICATION:
Please transmit this notice to all those persons within your organisation who need to be aware of it. If affected products have been distributed to any other customer or organisation, please notify them within **five (5) business days** of receipt of this notice.

Please be advised that FPH has notified all appropriate Regulatory Agencies of this Field Safety Notice for Device Modification, [including the HPRA].

We sincerely apologise for any inconvenience this Field Safety Notice for Device Modification may cause.

If you have any questions relating to the above actions or have any questions regarding the AIRVO 2 / myAIRVO 2 speaker function, please contact your FPH representative [insert name] via email at [email@fphcare.com] or directly at [enter telephone details]. Thank you for your co-operation and understanding in relation to this matter.

Yours Sincerely,

[Signature]
[Insert Regional Office sponsor name, position details]

2.First Consignee (Distributor/Retailer) – Field Safety Notice for Device Modification Response Form

Fisher & Paykel Healthcare Limited
15 Maurice Paykel Place, East Tamaki
P O Box 14 348, Panmure
Auckland, New Zealand
Telephone: +64 9 574 0100
Facsimile: +64 9 574 0158
Website: www.fphcare.com

Field Safety Notice for Device Modification Response Form

AIRVO 2 / myAIRVO 2 User Instruction Update

FPH FSCA Identifier: FA-2016-001
Type of Action: Retail Level

Please complete all of the details below and return this form to your Fisher & Paykel Healthcare Representative via the details below. A response is required even if you do not have or have not distributed any Affected Products.

Email: [insert FPH email address]
Fax: [insert FPH fax details]
Post: [insert FPH postal address]

Business Name: _____

Address: _____

_____

Fax: _____ Phone: _____

E-mail address: _____

Section A – Confirmation of Receipt

☐ I have received and read the updated AIRVO 2 / myAIRVO 2 User Instructions. I understand the additional check is to ensure the speaker is audible prior to each patient use.

Section B - Notification to Customers

☐ I have distributed affected AIRVO 2 / myAIRVO 2 units and I have read and understood my obligation to notify and send the updated User Instructions to all of my customers who have affected products.

- Number of affected customers: _____
- Number of affected products distributed: _____

Or

☐ I have not distributed any affected products.

Name: _____

Title: _____

Signed: _____

Date: _____

3.First Consignee (Hospital) – Field Safety Notice for Device Modification Notification Letter

Fisher & Paykel Healthcare Limited
15 Maurice Paykel Place, East Tamaki
P O Box 14 348, Panmure
Auckland, New Zealand
Telephone: +64 9 574 0100
Facsimile: +64 9 574 0158
Website: www.fphcare.com

[Date]

Chief Executive Officer
[Facility Address]

Attention: [head of appropriate department e.g. Chief Biomedical Engineer]

Field Safety Notice for Device Modification

AIRVO 2 / myAIRVO 2 User Instruction Update

FPH FSCA Identifier: FA-2016-001
Type of Action: Retail Level Device Modification

AFFECTED PRODUCT DETAILS:
The Fisher & Paykel Healthcare (FPH) AIRVO 2 / myAIRVO 2 humidifiers are designed to treat spontaneously breathing patients who would benefit from receiving high flow warmed and humidified respiratory gases. The AIRVO 2 / myAIRVO 2 is not intended for life support.

REASON FOR FIELD SAFETY NOTICE FOR DEVICE MODIFICATION:
FPH has updated the AIRVO 2 / myAIRVO 2 User Instructions to include a check that the speaker is audible prior to each patient use in order to ensure the speaker is functioning.

AFFECTED PRODUCT MODEL AND SERIAL NUMBERS:

Model Number (REF)		Affected Serial Numbers
AIRVO 2	PT101XX	120521YYYYYY - 160605YYYYYY
myAIRVO 2	PT100XX	

ACTIONS BEING TAKEN BY FISHER & PAYKEL HEALTHCARE:
The AIRVO 2 / myAIRVO 2 User Instructions have been updated to include a warning for the user to check speaker functionality before each patient use. This warning points to the speaker functionality check contained in all AIRVO 2 / myAIRVO 2 User Instructions.

ACTIONS REQUIRED FROM YOU:

Step 1: Please perform the speaker functionality check contained in all AIRVO 2 / myAIRVO 2 User Instructions (located in the “Using AIRVO 2” or “Using myAIRVO2” sections): Turn the unit on and then remove the heated breathing tube. You should see the “check tube” visual signal and hear the speaker signal.

Step 2: If either signal is absent, do not use the unit and contact your FPH representative [insert contact name] to arrange for a replacement device.

Step 3: Please read the attached updated User Instruction for the affected product. Note the warnings in section 1, which state ‘*Prior to each (patient) use, ensure that the auditory alarm signal is audible by conducting the alarm system functionality check described in the Alarms section*’.

Step 4: Complete the attached ‘Response Form’ and return it to your FPH representative.

TRANSMISSION OF THIS FIELD SAFETY NOTICE FOR MEDICAL DEVICE MODIFICATION:
Please transmit this notice to all those persons within your organisation who need to be aware of it. If affected products have been distributed to any other customer or organisation, please notify them within **five (5) business days** of receipt of this notice.

Please be advised that FPH has notified all appropriate Regulatory Agencies of this Field Safety Notice for Device Modification, [including the HPRA].

We sincerely apologise for any inconvenience this Field Safety Notice for Device Modification may cause.

If you have any questions relating to the above actions or have any questions regarding the AIRVO 2 / myAIRVO 2 speaker function, please contact your FPH representative [insert name] via email at [email@fphcare.com] or directly at [enter telephone details]. Thank you for your co-operation and understanding in relation to this matter.

Yours Sincerely,

[Signature]
[Insert sponsor name, position details]

4.First Consignee (Hospital) – Field Safety Notice for Device Modification Response Form

Fisher & Paykel Healthcare Limited
15 Maurice Paykel Place, East Tamaki
P O Box 14 348, Panmure
Auckland, New Zealand
Telephone: +64 9 574 0100
Facsimile: +64 9 574 0158
Website: www.fphcare.com

Field Safety Notice for Device Modification

AIRVO 2 / myAIRVO 2 User Instruction Update

FPH FSCA Identifier: FA-2016-001

Type of Action: Retail Level Device Modification

Please complete all of the details below and return this form to your Fisher & Paykel Healthcare Representative via the details below. A response is required even if you do not have or have not distributed any Affected Products.

Email: [insert FPH email address]
Fax: [insert FPH fax details]
Post: [insert FPH postal address]

Business Name: _____

Address: _____

_____

Fax: _____ Phone: _____

E-mail address: _____

Please tick the box in Section A.

Section A – Confirmation of Receipt
☐ I have received and read the updated AIRVO 2 / myAIRVO 2 User Instructions. I understand the additional check is to ensure the speaker is audible prior to each patient use.

Name: _____

Title: _____

Signed: _____

Date: _____

5.First Consignee (Distributor/Retailer or Hospital) – Non-Respondent Follow-Up Letter

Fisher & Paykel Healthcare Limited
15 Maurice Paykel Place, East Tamaki
P O Box 14 348, Panmure
Auckland, New Zealand
Telephone: +64 9 574 0100
Facsimile: +64 9 574 0158
Website: www.fphcare.com

[Date]

Fisher & Paykel Healthcare Field Safety Notice for Device Modification – [First Reminder/Second Reminder/Final Reminder]

FPH FSCA Identifier: FA-2016-001

Dear Valued Customer,

You were recently sent a Field Safety Notice for Device Modification associated with the AIRVO 2 / myAIRVO 2 User Instruction update (see below table).

AFFECTED PRODUCT MODEL AND SERIAL NUMBERS:

Model Number (REF)		Affected Serial Numbers
AIRVO 2	PT101XX	120521YYYYYY - 160605YYYYYY
myAIRVO 2	PT100XX	

This is your [first/second/final] reminder to complete the attached response form to acknowledge your receipt of this communication. Please complete the enclosed Field Safety Notice for Device Modification Response Form and return it to the following:

ATTN: [FA contact designee]
Email: [designee@fphcare.com]

Fax: XXXXXXXXXX; or

Post: Fisher & Paykel Healthcare
Attention: [FA contact designee]
[FPH address]

If you have any questions relating to the above actions please do not hesitate to contact your local Fisher & Paykel Healthcare Representative.

Yours Sincerely,
[Insert Signature & Name]

6.Second Consignee (Distributor/Retailer/Hospital) – Field Safety Notice for Device Modification Notification Letter

[Note: this is the template Field Safety Notice for Device Modification letter. Replace all text between brackets as necessary.]

[Insert your company letter head here]

[Date]

Chief Executive Officer
[Facility Address]

Attention: [head of appropriate department e.g. Chief Biomedical Engineer]

Field Safety Notice for Device Modification

AIRVO 2 / myAIRVO 2 User Instruction Update

FPH FSCA Identifier: FA-2016-001
Type of Action: Retail Level Device Modification

AFFECTED PRODUCT DETAILS:
The Fisher & Paykel Healthcare (FPH) AIRVO 2 / myAIRVO 2 humidifiers are designed to treat spontaneously breathing patients who would benefit from receiving high flow warmed and humidified respiratory gases. The AIRVO 2 / myAIRVO 2 is not intended for life support.

REASON FOR FIELD SAFETY NOTICE FOR DEVICE MODIFICATION:
FPH has updated the AIRVO 2 / myAIRVO 2 User Instructions to include a check that the speaker is audible prior to each patient use in order to ensure the speaker is functioning.

AFFECTED PRODUCT MODEL AND SERIAL NUMBERS:

Model Number (REF)		Affected Serial Numbers
AIRVO 2	PT101XX	120521YYYYYY - 160605YYYYYY
myAIRVO 2	PT100XX	

ACTIONS BEING TAKEN BY FISHER & PAYKEL HEALTHCARE:
The AIRVO 2 / myAIRVO 2 User Instructions have been updated to include a warning for the user to check speaker functionality before each patient use. This warning points to the speaker functionality check contained in all AIRVO 2 / myAIRVO 2 User Instructions.

ACTIONS REQUIRED FROM YOU:

Step 1: Please perform the speaker functionality check contained in all AIRVO 2 / myAIRVO 2 User Instructions (located in the “Using AIRVO 2” or “Using myAIRVO2” sections): Turn the unit on and then remove the heated breathing tube. You should see the “check tube” visual signal and hear the speaker signal.

Step 2: If either signal is absent, do not use the unit and contact your FPH representative [insert contact name] to arrange for a replacement device.

Step 3: Please read the attached updated User Instruction for the affected product. Note the warnings in section 1, which state ‘*Prior to each (patient) use, ensure that the auditory alarm signal is audible by conducting the alarm system functionality check described in the Alarms section*’.

Step 4: Complete the attached ‘Response Form’ and return it to your FPH representative.

[If you have distributed product to another distributor, please include the following section:]

For product you may have distributed:

Step 1: Please review your sales records and identify if any affected products have been distributed to your customers. Complete Section B 'Notification to Customers' on the 'Response Form' and return it to your FPH representative [insert contact name].

Step 2: If the affected products have not been distributed, please skip steps 2 - 7.

If you have distributed affected products to your customers, then create a list of affected customers using the 'Customer Tracking Sheet' provided in the email. Identify if each customer is a distributor, retailer, or hospital.

Step 3: Notify customers immediately via phone or email. Advise them to check if they have any of the affected products and instruct them to carry out the functionality check above.

Step 4: Create a 'Field Safety Notice for Device Modification Letter' and 'Response Form' using the distributor, retailer, or hospital templates provided in the email and edit the text in red.

Step 5: Send the 'Field Safety Notice for Device Modification Letter' together with a 'Response Form' and the updated User Instructions to all affected customers within **five (5) business days** of receiving this letter, using a courier system (mail with track and trace).

Step 6: Update the following fields on the 'Customer Tracking Sheet':

- Date the customers were sent the Letter
- The date each completed response form is received
- Tracking numbers of the letters sent to the customers

Note: All response forms must be kept and sent to your FPH representative [insert contact name].

Step 7: Where a customer fails to respond to the 'Field Safety Notice for Device Modification Letter' within **15 business days** of initial contact via letter, please follow up a minimum of **three times** via courier with a 'Follow Up Letter' once every further **15 business days**. Create a 'Follow Up Letter' using the template provided in the email. Enter the type of follow up (First, Second or Final) and the date on which you will send the letter. Please document the date and summary of the attempts made in the 'Customer Tracking Sheet' for records.

TRANSMISSION OF THIS FIELD SAFETY NOTICE FOR MEDICAL DEVICE MODIFICATION:
Please transmit this notice to all those persons within your organisation who need to be aware of it. If affected products have been distributed to any other customer or organisation, please notify them within **five (5) business days** of receipt of this notice.

Please be advised that FPH has notified all appropriate Regulatory Agencies of this Field Safety Notice for Device Modification, [including the HPRA].

We sincerely apologise for any inconvenience this Field Safety Notice for Device Modification may cause.

If you have any questions relating to the above actions or have any questions regarding the AIRVO 2 / myAIRVO 2 speaker function, please contact your FPH representative [insert name] via email at [email@fphcare.com] or directly at [enter telephone details]. Thank you for your co-operation and understanding in relation to this matter.

Yours Sincerely,

[Signature]
[Insert sponsor name, position details]

7.Second Consignee (Distributor/Retailer/Hospital) – Field Safety Notice for Device Modification Response Form

[Note: This is the template Field Safety Notice for Device Modification Response Form. Replace all text between brackets as necessary.]

[Insert your company letter head here]
[Date]

Field Safety Notice for Device Modification Response Form

AIRVO 2 / myAIRVO 2 User Instruction Update

FPH FSCA Identifier: FA-2016-001
Type of Action: Retail Level

Please complete all of the details below and return this form to your Fisher & Paykel Healthcare Representative via the details below. A response is required even if you do not have or have not distributed any Affected Products.

Email: [insert FPH email address]
Fax: [insert FPH fax details]
Post: [insert FPH postal address]

Business Name: _____

Address: _____

_____

Fax: _____ Phone: _____

E-mail address: _____

Section A – Confirmation of Receipt

☐ I have received and read the updated AIRVO 2 / myAIRVO 2 User Instructions. I understand the additional check is to ensure the speaker is audible prior to each patient use.

Section B - Notification to Customers

☐ I have distributed affected AIRVO 2 / myAIRVO 2 units and I have read and understood my obligation to notify and send the updated User Instructions to all of my customers who have affected products.

- Number of affected customers: _____
- Number of affected products distributed: _____

Or

☐ I have not distributed any affected products.

Name: _____

Title: _____

Signed: _____

Date: _____

8.Second Consignee (Distributor/Retailer/Hospital) – Non-Respondent Follow-Up Letter

[Note: this is the template Field Safety Notice for Device Modification Follow Up Letter. Replace all text between brackets as necessary.]

[Insert your company letter head here]

[Date]

Fisher & Paykel Healthcare Field Safety Notice for Device Modification – [First Reminder/Second Reminder/Final Reminder]

FPH FSCA Identifier: FA-2016-001

Dear Valued Customer,

You were recently sent a Field Safety Notice for Device Modification letter associated with the AIRVO 2 / myAIRVO 2 User Instruction update (see below table).

AFFECTED PRODUCT MODEL AND SERIAL NUMBERS:

Model Number (REF)		Affected Serial Numbers
AIRVO 2	PT101XX	120521YYYYYY - 160605YYYYYY
myAIRVO 2	PT100XX	

This is your [first/second/final] reminder to complete the attached response form to acknowledge your receipt of this communication. Please complete the enclosed Field Safety Notice for Device Modification Response Form and return it to the following:

ATTN: [FA contact designee]
Email: [designee@fphcare.com]

Fax: XXXXXXXXXX; or

Post: Fisher & Paykel Healthcare
Attention: [FA contact designee]
[FPH address]

If you have any questions relating to the above actions please do not hesitate to contact your local Fisher & Paykel Healthcare Representative.

Yours Sincerely,
[Insert Signature & Name]