LETTERS FOR EUROPEAN UNION MEDDEV – RT021

1.1. First Consignee (Distributor/Retailer) – Urgent FIELD SAFETY NOTICE Letter (RT021)

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]

Urgent FIELD SAFETY NOTICE

Fisher & Paykel Healthcare (FPH)
RT021 Catheter Mount

FPH FSCA Identifier: FA-2017-003
Type of Action: Hospital Level Product Removal Recall

AFFECTED PRODUCT DETAILS:

RT021 Catheter Mount
The RT021 Catheter Mount is a flexible connector facilitating connection to patients, intended to be used as part of a respiratory gas delivery system ('Affected Products').

REASON FOR RECALL:

FPH is initiating a voluntary recall due to an increased rate of split tubing cuffs in catheter mounts manufactured on specific dates (Figure 1).

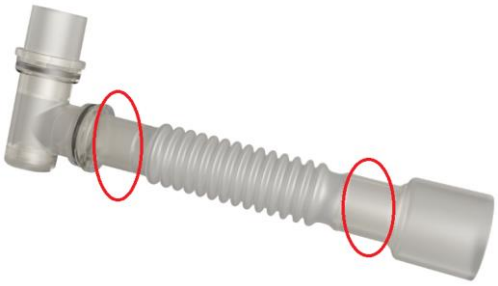

Figure 1: Catheter mount with tubing cuff locations indicated.

A split tubing cuff on the catheter mount may potentially cause a leak. FPH has so far received no reports of any adverse events, however there is potential that a leak could lead to patient hypoxemia if undetected.

AFFECTED PRODUCT MODEL AND LOT NUMBERS:

Model Number (REF)		Affected Lot Numbers (LOT)
Catheter Mount	RT021	From Lot 2100089358 to Lot 2100098462 and From Lot 2100190360 to Lot 2100241254

ACTIONS BEING TAKEN BY FISHER & PAYKEL HEALTHCARE:

FPH is initiating a voluntary recall to remove the Affected Products from the market.

ACTIONS REQUIRED FROM YOU:

For product in your inventory:

Step 1: Identify any Affected Products in your inventory by checking the REF and LOT number on the packaging.

Figure 2: Example of RT021 product box label showing affected Model Number (REF) and affected LOT Number.

Figure 3: Example of RT021 individual product label showing affected Model Number (REF) and affected LOT Number.

Step 2: Destroy by cutting in half and dispose of all Affected Products as per below (Figure 4).

Figure 4: RT021 Catheter Mount

Step 3: Complete Section A 'Inspection of Stock' on the 'Urgent Field Safety Notice Response Form' and return it to your FPH Representative [insert name]. This is required even if you do not have any of the Affected Products.

Step 4: Please contact your FPH Representative [insert name] if you require further assistance.

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 and complete Section B 'Notification to Customers' on the 'Urgent Field Safety Notice Response Form'. Please sign the completed 'Urgent Field Safety Notice Response Form' and return it to your FPH Representative [insert contact name].

Step 2: If none of the Affected Products have been distributed, please skip steps 3 – 7.

If you identify that any of the Affected Products have been distributed to your customers, then create a list of affected customers for tracking purposes using the 'Customer Tracking Sheet' provided in the email. Identify if each customer is a hospital, distributor or retailer.

Step 3: Notify customers immediately via phone or email. Advise them to check if they have any of the Affected Products. Inform them that further written instructions will follow.

Step 4: Create an 'Urgent Field Safety Notice Letter' and 'Response Form' using the distributor/retailer or hospital templates provided in the email and edit only the text in green.

Step 5: Send the 'Urgent Field Safety Notice Letter' and 'Response Form' 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 'Urgent Field Safety Notice Letter' and 'Follow Up Letters'.
- The date each completed 'Response Form' is received.
- Tracking numbers of the letters sent to customers.

Note: The 'Customer Tracking Sheet' and 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 'Urgent Field Safety Notice 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 attempts made in the 'Customer Tracking Sheet' for records.

Note:

FPH also reminds users to refer to the RT021 Catheter Mount User Instructions and reiterates the following:

- “Check all connections are tight before use.”
- “Perform a pressure and leak test on the breathing system and check for occlusions before connecting to a patient.”

TRANSMISSION OF THIS URGENT FIELD SAFETY NOTICE:
Please transmit this notice to all those persons within your organization who need to be aware of it. If Affected Products have been distributed to any other customer, please notify them regarding this Urgent Field Safety Notice within 5 business days upon receipt of this notice (as per above steps).

Please be advised that FPH has notified all appropriate Regulatory Agencies of this voluntary recall, [including BfArM].

We sincerely apologize for any inconvenience this recall may cause.

If you have any questions relating to the above actions, 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]

1.2. First Consignee (Distributor/Retailer) – Urgent FIELD SAFETY NOTICE Response Form (RT021)

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15 Maurice Paykel Place, East Tamaki
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Urgent FIELD SAFETY NOTICE Response Form

Fisher & Paykel Healthcare (FPH)
RT021 Catheter Mount

FPH FSCA Identifier: FA-2017-003
Type of Action: Hospital Level Product Removal Recall

Please complete all of the details below and return this form to your FPH 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 appropriate box in Section A and Section B.

Section A – Inspection of Stock

☐ I have identified and destroyed all Affected Products and disposed of them;

Product REF	Quantity Destroyed (pieces)
RT021	

Or;

☐ I did not have any Affected Products in my inventory

Continued on next page.

Section B - Notification to Customers

☐ I have distributed Affected Products and I have read and understood my obligation to notify all of my customers who have Affected Products.

- **RT021**
  - Number of Affected customers: _____
  - Number of Affected Products distributed: _____(pieces)

Or;

☐ I have not distributed any Affected Products.

Name: _____

Title: _____

Signed: _____

Date: _____

1.3. First Consignee (Hospital) – Urgent FIELD SAFETY NOTICE Letter (RT021)

Fisher & Paykel Healthcare Limited
15 Maurice Paykel Place, East Tamaki
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[Date]

Chief Executive Officer
[Facility Address]

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

Urgent FIELD SAFETY NOTICE

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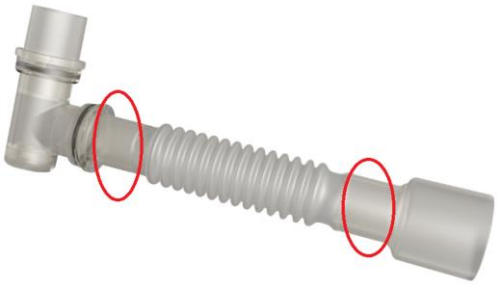

Figure 1: Catheter mount with tubing cuff locations indicated.

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RT021 Catheter Mount:

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Figure 4: RT021 Catheter Mount

Step 3: Complete Section A 'Inspection of Stock' on the 'Urgent Field Safety Notice Response Form' and return it to your FPH Representative [insert name]. This is required even if you do not have any of the Affected Products.

Step 4: Please contact your FPH Representative [insert name] if you require further assistance.

Note:

FPH also reminds users to refer to the RT021 Catheter Mount User Instructions and reiterates the following:

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We sincerely apologize for any inconvenience this recall may cause.

If you have any questions relating to the above actions, 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 & email]

1.4. First Consignee (Hospital) – Urgent FIELD SAFETY NOTICE Response Form (RT021)

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Urgent FIELD SAFETY NOTICE Response Form

Fisher & Paykel Healthcare (FPH)
RT021 Catheter Mount

FPH FSCA Identifier: FA-2017-003
Type of Action: Hospital Level Product Removal Recall

Please complete all of the details below and return this form to your FPH 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 appropriate box in Section A.

Section A – Inspection of Stock

☐ I have identified and destroyed all Affected Products and disposed of them;

Product REF	Quantity Destroyed (pieces)
RT021	

Or;

☐ I did not have any Affected Products in my inventory

Name: _____

Title: _____

Signed: _____

Date: _____