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URGENT MEDICAL DEVICE CORRECTION

paraPAC plus™ Model 300 and Model 310 Ventilator

07 February 2024

Dear Valued Customers:
Director of Nursing
Director of Material Management
Director of Risk Management

Smiths Medical is issuing this letter to notify you of a potential issue with the paraPAC plus™ Ventilators. The following information details the issue and the required steps for you to perform.

Issue:

- When a paraPAC plus™ ventilator is switched to the operating mode of 'Ventilate', paraPAC plus™ ventilators may intermittently provide continuous positive gas flow instead of the intended cycling like a human breath.

This non-cycling and continuous positive gas flow when in the cycling mode, is a malfunction, not allowing the ventilator to properly function as designed.

Potential Risk:
If the ventilator experiences the continuous positive gas flow instead of intended cycling like a human breath, it may result in delay of therapy, no ventilation, excessive tidal volume or excessive pressure. If the device does not allow for adequate expiration of the respiratory cycle, this may lead to hypoxia. These situations may potentially lead to serious patient injury or death, depending on the clinical situation.

To date, Smiths Medical has received eight (8) reports of serious injury, and zero (0) death potentially related to this issue since the launch of this product in 2010.

Affected Models:
This issue impacts all paraPAC plus™ ventilators, refer to Table 1.

Table 1: Affected Products(s)

Product Name	List Number
paraPAC plus™ plus kit without internal PEEP & CPAP	P300NXX*
paraPAC plus™ kit with internal PEEP & CPAP	P310NXX*

* List Numbers are specific to the country level.

Actions to be taken by the Customer:
There is no need to return or discontinue using your paraPAC plus™, at this time.
When using the device, all instructions, including warnings and cautions in the User Manual Doc. numbers (10018833-003 and/or 10026347-002) must be followed with heightened awareness. This is inclusive, but not limited to the following:

- Constant monitoring of the patient.
- Blood oxygenation and expired carbon dioxide levels should be monitored independently using pulse oximetry and capnography.
- All pre-use checks must be performed before each use.
- Alternative means of ventilation such as bag mask ventilation, must be available in the event of ventilator failure or malfunction.

If the paraPac plus™ ventilator experiences continuous flow, remove the ventilator from clinical use, set the device aside for repair and use another device or alternative means of ventilation. Report the continuous flow experience by filing a complaint, per instructions below.

For further inquiries, please contact Smiths Medical using the following information:

Smiths Medical Contact	Contact Information	Areas of Support
Global Complaint Management	globalcomplaints@icumed.com 1-(866)-216-8806	To report adverse events or product complaints
Technical Support	TSC.Support@icumed.com 1-800-241-4002, option 3,4 (M-F, 8:00 am-6:00 pm CT)	Additional information or technical assistance, including Technical Service Manuals
Field Corrections	icumed.custhelp.com/app/market-action or contact your sales representative	Questions about this Field Correction Notice

Smiths Medical's Actions:
Smiths Medical is sending this notification to all impacted paraPAC plus™ customers.

Customer Required Actions:

1. Please identify all paraPAC plus™ units in your possession.

2. Share this recall notification with all potential users of the devices to ensure they are aware of this recall and proposed mitigations. If the devices are used at another location, please ensure that this communication is delivered to these locations.

3. Complete and return the attached Customer Response Form to smithsmedical3488@sedgwick.com **within ten days of receipt** to acknowledge your understanding of this notification.

4. **DISTRIBUTORS:** If you have distributed potentially affected products to your customers, please immediately forward this notice to them. Request that they complete the response form and return it to smithsmedical3488@sedgwick.com.

Follow-up Actions by Smiths Medical:
Smiths Medical is currently investigating the issue and will provide an update once a solution has been identified.

General Information
This notification is being performed with the knowledge of regulatory authorities, including the US Food and Drug Administration (FDA).
Report any adverse health complaints experienced with the use of this product to Smith Medical, events may also be reported to the FDA's MedWatch Adverse Event Reporting Program:

Web: MedWatch website at www.fda.gov/medwatch
Mail: MedWatch, Hf-2, FDA, 5600 Fisher's Lane, Rockville, MD 20852-9787
Phone: 1-(888)-INFO-FDA
Fax: 1-(888)-FDA-0178

Smiths Medical is committed to providing quality products and service to our customers. We apologize for any inconvenience this situation may cause.

Sincerely,

Andy Mathein
Vice President, Quality

Enclosures:
Attachment 1 - Urgent Medical Device Correction
Attachment 2 - Customer Response Form
Attachment 3 - Frequently Asked Questions

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paraPac plus™ Model 300 and Model 310 Ventilator Field Action Frequently Asked Questions

Urgent Medical Device Correction
For EXTERNAL use

Smiths Medical is issuing an Urgent Medical Device Correction Notice (Notice) informing affected customers about potential risks associated with an issue with the paraPac plus™ Model 300 and Model 310 Ventilator. Smiths Medical is notifying each affected customer and authorized distributor.

If you have questions about the performance of your paraPac plus™ Model 300 and Model 310 Ventilator, please contact the relevant team at Smiths Medical's as outlined in the table included in Question 16 below.

1. Q What is the issue?

Smiths Medical is issuing a Notice to inform customers that when the ventilator is switched to the operating mode of "ventilate", the paraPac plus™ may intermittently provide continuously positive gas flow instead of the intended cycling like a human breath. The issue, associated risks, recommended user actions, and affected models are described in the notice.

The investigation has identified the root cause is associated with a component that has the potential to intermittently cause continuous positive gas flow.

2. Q If the root cause has been identified, what is the remediation action?

Qualification of the fix for the identified root cause is ongoing. Once qualification is complete, we will provide an update and begin scheduling service of all affected devices.

3. Q Is the device safe to continue to use?

Yes. There is no need to return or discontinue using your paraPAC plus™. When using the device, all instructions, including warnings and cautions in the User Manual Doc. numbers (10018833-003 and/or 10026347-002) must be followed with heightened awareness. This is inclusive, but not limited to the following:

- Constant monitoring of the patient.
- Blood oxygenation and expired carbon dioxide levels should be monitored independently using pulse oximetry and capnography.
- All pre-use checks must be performed before each use.
- Alternative means of ventilation such as bag mask ventilation, must be available in the event of ventilator failure or malfunction.

If the paraPAC plus™ ventilator experiences continuous flow, remove the ventilator from clinical use, set the device aside for repair and use another device or alternative means of ventilation and file a complaint as per instructions included in the customer letter.

4. **Q How long will it take to perform the corrective action?**

   The qualification of the fix is ongoing. When more precise information is available, we will follow up with a separate communication.

5. **Q Who will schedule the service of my device?**

   Smiths Medical employees will be contacting every customer directly to arrange for service of your device. This process will take time to complete and you will be contacted as service is ready to be scheduled.

6. **Q What does this mean for our devices that need standard service repairs or preventative maintenance?**

   Devices are to be maintained and repaired following normal process for PM and repair. Technical and repair support questions should be directed per the table in question 16.

7. **Q Can I fix the device at my own facility?**

   No, all paraPAC plus™ units must be serviced and repaired at a Smiths Medical facility by a Smiths Medical technician. Preventative Maintenance remains the responsibility of each customer and PM should be performed per Product Labeling.

8. **Q Will devices be able to be remediated onsite at the hospital/clinical facility by a Smiths Medical employee?**

   No, all paraPAC plus™ units can only be serviced and repaired at a Smiths Medical facility.

9. **Q Once there is a solution and I return my device for remediation, will there be a fee for the remediation?**

   Costs specifically associated with remediating this communicated issue will be performed by Smiths Medical at no charge to the customer including shipping, remediation and functional testing.

10. **Q What if my device is found to have additional issues regarding repair while being remediated?**

    If the device is found to be requiring repair beyond the specific remediation, this repair is not covered as part of the free of charge remediation.. Customers will be provided with a quote for how additional repairs can be carried out in conjunction with the remediation.

11. **Q Will Smiths Medical provide loaner ventilators?**

    No.

12. **Q Has the FDA been notified?**

    Yes.

13. Q When can customers expect to receive stock orders of the paraPac plusTM Model 300 and Model 310 Ventilators?

All production of Parapac Plus is currently on hold so there is no availability of paraPac plusTM plus ventilators. We will provide an update once products are available for release.

14. Q Do we have an alternative product to use in lieu of this product?

No, we do not have an alternative product.

15. Q Is the information available online?

Yes. The Notice, and FAQs, can be found at https://www.icumed.com/support/customer-communications-and-clinical-bulletins.

16. Q Who should I contact if I have additional questions?

Smiths Medical Contact	Contact Information	Areas of Support
Global Complaint Management	globalcomplaints@icumed.com 1-(866)-216-8806	To report adverse events or product complaints
Technical Support	TSCSupport@icumed.com https://icumed.custhelp.com/ 1 (800) 241-4002, Option 3, 4	Additional information or technical assistance, including Technical Service Manuals
Field Corrections	icumed.custhelp.com/app/market-action or contact your sales representative	Questions about this Field Correction Notice

smiths medical

6000 Nathan Lane N.
Minneapolis, MN 55442

URGENT MEDICAL DEVICE CORRECTION: RESPONSE FORM

paraPAC plus™ Model 300 and Model 310 Ventilator

07 February 2024

Check your inventory and complete the information below, even if you do not have the affected product.

Complete this form and return it to Sedgwick via fax at 1-833-254-2595 or email to smithsmedical3488@sedgwick.com. If you have questions about this form please call Sedgwick at 1-844-593-4005 (M-F, 8am-5pm ET).

Name of Hospital / Facility	
Hospital / Facility Address	
Telephone Number	
Name and Title of Person Completing this Form	
Signature of Person Completing this Form	
Date	
If Purchased through a distributor, please list distributor name/location here for traceability purposes	

☐ **YES,** I have affected product, I have notified users in my facility and I have followed the instructions provided to me (complete and return this form to Sedgwick via the fax/e-mail above).

☐ I have **NO** affected product (complete and return this form to Sedgwick via the fax/e-mail above)

☐ Devices transferred/no longer owned; please indicate new owner contact information:

- Business Name: _____
- Address/City/State/ZIP: _____
- Contact Name: _____
- Contact Phone/E-mail Address: _____

- Have you distributed the product further to the retail level? ☐ **YES** ☐ **NO**
  - If yes, have you notified your retail customers and asked them to contact Sedgwick at 1-844-593-4005 (M-F, 8am-5pm ET) to obtain a response form? **YES** ☐ **NO** ☐ (If no, explain below)

If you have distributed the product further, please provide the list of your retail customers, inclusive of customer name, address, city, state, zip code, telephone number and quantity of product distributed along with your completed response form to the contact information listed above so Smiths Medical can verify effectiveness of the recall notification to the appropriate level.

Adverse events and complaints associated with the use of these products should be reported and emailed to Smiths Medical's Global Complaint Management Department (globalcomplaints@icumed.com) or to the FDA at the contact information provided with this notification.

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