

**URGENT MEDICAL DEVICE CORRECTION**  
**paraPAC plus™ Model 300 and Model 310 Ventilator**

31 May 2024:

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

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

**Issue:**

Smiths Medical became aware of an issue related to a potential for the patient outlet connector to loosen/detach from the paraPAC Plus™ P300 and P310 ventilators impacting the active ventilation function.

**Potential Risk:**

If the patient outlet connector is either loosened or detached; potential identified hazardous situations include extended interruption of therapy, no ventilation, delay of therapy and reduced tidal volume.

In such situations, the patient may experience hypoxia, bradycardia, hypotension, respiratory arrest or asphyxia. This may lead to serious patient injury or death, depending on the clinical state of the patient.

To date, Smiths Medical has received one (1) report of serious injury and one (1) report of death potentially related to this issue.

**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.

Please refer to Appendix A for associated serial numbers.

**Customer Required Actions:**

Medical Device Correction Notice: paraPac™plus Model 300 and Model 310 Ventilator  
Smiths Medical Ref: FA2405-01

1. Please identify all affected paraPAC plus™ units in your possession.
2. Perform an inspection to determine if your devices are affected, per the instructions below:
  - a. First perform a visual inspection to determine if the outlet connector is disconnected.
  - b. Second evaluate the connector physically to determine if the outlet connector is loose or moves when placing a patient circuit on the connector or when removing it.
  - c. If outlet connector remains tight after physical inspection, you can continue use of the device with heightened awareness and following all pre-use checks as per the user manual.
  - d. If the outlet connector moves or feels loose, the device must be removed from use and repaired by Smiths Medical. Report the event to Global Complaint Management at [globalcomplaints@icumed.com](mailto:globalcomplaints@icumed.com).
3. Every use thereafter of every device, pre-use checks must be completed as described in the user manual and extra caution must be taken in inspecting the outlet connector prior to use and placing the patient circuit on the connector and during removal.
  - a. 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.
  - b. This is inclusive, but not limited to the following:
    - All pre-use checks must be performed before each use.
    - Constant monitoring of the patient
    - Blood oxygenation and end tidal carbon dioxide levels should be monitored independently using pulse oximetry and capnography.
    - Alternative means of ventilation such as bag mask ventilation, must be available in the event of ventilator failure or malfunction.
  - c. The paraPAC plus™ is also equipped with the following design mitigations & alarms:
    - Low Pressure/Disconnect Alarm: Disconnection/Detachment of the Patient Outlet connector would trigger low pressure/disconnect alarm.
    - Pressure Monitor: Disconnection/Detachment of the Patient Outlet connector would be indicated by no movement of the manometer needle.
4. Share this recall notification with all potential users of the devices to ensure they are aware of this recall and proposed mitigations.
5. Complete and return the attached Customer Response Form to [smithsmedical5253@sedgwick.com](mailto:smithsmedical5253@sedgwick.com) **within ten days of receipt** to acknowledge your understanding of this notification.
6. **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 [smithsmedical5253@sedgwick.com](mailto:smithsmedical5253@sedgwick.com).

#### Follow-up Actions by Smiths Medical:

Smiths Medical is sending this notification to all impacted paraPAC plus™ customers.

Smiths Medical is currently investigating the issue. Smiths Medical will contact the affected customers to schedule the remediation once the investigation is complete and a solution has been identified to initiate remediation efforts to affected devices.

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

Smiths Medical Contact	Contact Information	Areas of Support
Global Complaint Management	<a href="mailto:globalcomplaints@icumed.com">globalcomplaints@icumed.com</a> 1-(866)-216-8806	To report adverse events or product complaints
Device Correction Inquiries	<a href="https://icumed.custhelp.com/app/market-action">https://icumed.custhelp.com/app/market-action</a>	For any questions regarding this action
Technical Support	1-(800)-241-4002, option 3	Additional information or technical assistance
Sedgwick	Phone number: 1-888-912-7084 (M-F 8am – 5pm ET) Fax: 1-844-449-8503	Questions about completion of the response form

### 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](http://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

Appendix A - Impacted Product Serial List

**URGENT MEDICAL DEVICE NOTIFICATION: RESPONSE FORM**  
**paraPAC plus™ Model 300 and Model 310 Ventilator**

**31 May 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 1-844-449-8503 or email to [smithsmedical5253@sedgwick.com](mailto:smithsmedical5253@sedgwick.com). If you have questions about this form please call Sedgwick at 1-888-912-7084 (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). Please fill out the table below.

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 1-888-912-7084 (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](mailto:globalcomplaints@icumed.com)) or to the FDA at the contact information provided with this notification.**



























































































































































