Urgent Medical Device Recall Notification (Update)

Date: January 8, 2024
Manufacturer: Percussionaire Corporation
Reference: 1000524541-12/12/2023-001-R
Affected Product: High Frequency Transport Phasitron Breathing Circuit Kit
Product #: A50506-D
UDI-DI: 00849436000334

Dear Customer,

Percussionaire is providing you with this u version of the recall communication about the Phasitron Breathing Circuit, A50605-D, sent to you on December 12, 2023.

The following modifications have been made to this communication:

- The notification header was updated from *Urgent Field Safey Notification* to *Urgent Medical Device Recall.*
- Patient risk information in the following table has been expanded with additional detail on the potential risk to a patient if the defective device is used.
- Complaint information related to this product defect was updated and provided in the table to following table.
- The Distributor/Customer Actions were revised to reference reporting of adverse event or device quality issues to Percussionaire/Sentec Customer Service or FDA MedWatch.

There have been no changes made to the actions required of this recall. Please still complete the following:

- Review the attached revised Medical Device Recall information. Please send back Acknowledgement Form, acknowledging that this updated information has been received, as well as requested customer action has been taken.
- Please send **Attachment A** to customers who have been shipped A50605-D (affected lots referenced on following page) from June 2023 to the present date. A Pre-Use Checklist has been included with this letter to aid the customer in the identification of defective product.

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As we always want to provide the best quality of product offered, we appreciate your continued support and efforts to aid in resolving this issue. Percussionaire apologizes for any inconvenience this notice might cause. If there are any additional questions, please contact the Customer Service Department at customerservice.us@sentec.com.

Regards,

Gina Cunsolo
Regulatory Affairs Manager
Percussionaire Corp.

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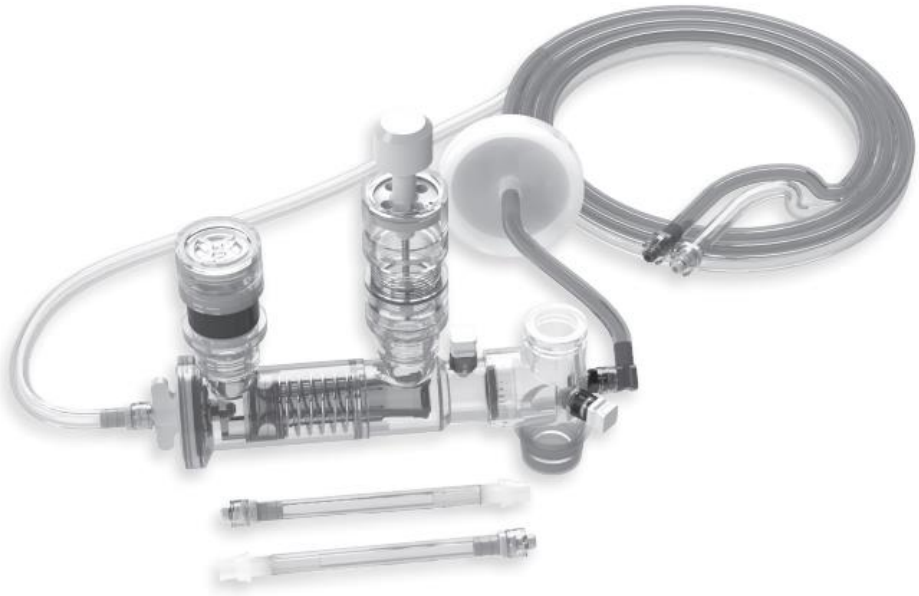
Product Name:	High Frequency Transport Phasitron Breathing Circuit
Product Part Number:	A50605-D
Potential Lots Affected #:	WO05216, WO05254, WO05321, WO05392, WO05559, WO05588, WO05684, WO05749, WO05896, WO05930, WO06028
Product Image:	

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Label example:	
Indications for Use:	The Phasitron® breathing circuit kit is intended to be used with a Percussionaire® HFPV system for either hospital or prehospital use where emergency care is being provided, including intrahospital or external hospital transport.
Description of Issue:	Percussionaire has become aware of a recent manufacturing issue related to the A50605-D, Phasitron Breathing Circuit. Due an error in assembly of two components within the Breathing Circuit, the pressure output of the Phasitron has been noticed to be affected and can have severe impact to the end user if used.
Patient Risk:	The Phasitron pressure output can be impacted with this defect, which may contribute, but is not limited to, the following patient adverse reactions: • Pneumothorax • Pneumomediastinum • Acute lung injury (barotrauma) requiring intervention ranging from thoracentesis to (if already in respiratory failure) temporary placement on extracorporeal membrane oxygenation (ECMO).
Complaints received	4 complaints received total. • 2 complaints received related to the following adverse events with

related to product defect:	patients ○ Pneumomediastinum ○ Pneumothorax • 2 complaints defect found prior to patient use
Actions Taken by Percussionaire:	• Notify all customers shipped affected lots of A50605-D. • Replace all product returned with new, unaffected product. • Percussionaire to update internal manufacturing and inspection processes to prevent similar incidents from occurring.
Actions Taken by Healthcare Providers:	• Complete and Return Acknowledgement form (attached). • Complete Pre-Check Checklist prior to patient use. • Prioritize the return of all impacted product. • Report any adverse reactions or quality problems experienced with the use of this product to Percussionaire/Sentec Customer Service department via email (customerservice.us@sentec.com) or FDA's MedWatch Adverse Event reporting program either online or by regular mail or fax.

Customer Acknowledgement Form

Reply form for the High-Frequency Transport Phasitron
Breathing Circuit, A50605-D, Medical Device Recall Notice

Please complete this form in its entirety to acknowledge you have received this information and send it back to **customerservice.us@sentec.com** for Regulatory action traceability purposes. If you have product on site, please complete the following Pre-Use Check list attached to identify if the product may be defective. Once notification of defective products is sent to Percussionaire Customer Service, a Return Authorization form will be sent back to initiate your product exchange.

Do you have impacted product on site?	☐ Yes ☐ No ☐ To Be Determined
Amount to be Returned:	

Name of Healthcare Provider/ Distributor/ Customer	
Address of Healthcare Provider/ Distributor/ Customer	
Name of Representative:	
Position:	
Email address/Phone Number:	
Signature:	
Date:	

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Urgent Medical Device Recall Notification (Update)

A50605-D Pre-Use Check, For use with TXP®-2D

Please complete the below steps in the following order. If your product is marked as "Fail" for any of the below line items, contact the customer service department, **customerservice.us@sentec.com**, using the above form for information on product exchange.

Step	Instruction	Pass/Fail
1.	Connect Percussionaire® breathing circuit and A50605-D to TXP-2D	
2.	Connect neonatal test lung patient connection.	
3.	Open **PEEP valve** to full counterclockwise position, "Open" position.	
4.	Rotate TXP-2D **Frequency** control knob to full clockwise position.	
5.	Rotate **Amplitude** control knob full counterclockwise.	
6.	Observe a frequency of 185-250 bpm.	
7.	Observe a Mean Pressure (MAP) between 20 and 40 cmH2O.	
8.	Rotate **PEEP valve** from "Open" to "Closed" position-observing an increase in Mean pressure. **Change of less than 5 cmH2O = Fail**	
9.	**Rotate PEEP valve** from "Closed" to "Open" position-observing a decrease in Mean pressure. **Change of less than 5 cmH2O = Fail**	
10.	Rotate **Amplitude** control knob clockwise.	
11.	Observe a gentle decrease in amplitude until "off" at the full clockwise position.	
12.	Rotate **Amplitude** control knob to full counterclockwise position.	
13.	Rotate **Frequency** control knob slowly to full counterclockwise position.	
14.	Observe a smooth increase in frequency.	
15.	Observe a frequency of >600bpm.	
16.	Observe a Mean Pressure (MAP) between 20 and 40 cmH2O.	
17.	Rotate Frequency control knob to full clockwise position	
18.	Rotate **Amplitude** control knob to the full "off" clockwise position.	
19.	Pre-Use Check Complete.	

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Urgent Medical Device Recall Notification (Update)

A50605-D Pre-Use Check, For use with Bronchotron®

Please complete the below steps in the following order. If your product is marked as "Fail" for any of the below line items, contact the customer service department, **customerservice.us@sentec.com**, using the above form for information on product exchange.

Step	Instruction	Pass/Fail
1.	Connect Percussionaire® breathing circuit and A50605-D to Bronchotron	
2.	Connect a Siemens®-style 1-liter ventilator test lung to the Phasitron®.	
3.	Open **PEEP valve** to full counterclockwise position, "Open" position.	
4.	Rotate the **OPERATIONAL PRESSURE** knob full counterclockwise to the stop (off) position.	
5.	Connect the Bronchotron® to the remote gas source.	
6.	Turn the **OPERATIONAL PRESSURE** knob clockwise to start the Bronchotron® until it reached 40 psig.	
7.	Turn the **OPERATIONAL PRESSURE** knob until it reaches 40 psig.	
8.	Turn off **OSCILLATORY CPAP** (full clockwise).	
9.	Turn the green **PULSATILE FLOWRATE** knob to the full counterclockwise position.	
10.	Turn the green **OSCILLATORY CPAP** knob counterclockwise until the multimeter display registers an AEP of 10 cmH_2O.	
11.	Set inspiratory time and expiratory time to 2.0 seconds to get a rate of ~ 15 (Adult/Peds).	
12.	Adjust the grey **PULSE FREQUENCY** control knob until the multimeter display registers a frequency of 500-550.	
13.	Turn the green **PULSATILE FLOWRATE** knob until the multimeter display registers an AIP of 20 cmH_2O.	
14.	Check for AIP (high reading) of 20 ± 1 and AEP (low reading) of 10 ± 1	
15.	Rotate **Pulse Frequency** control knob slowly to full counterclockwise position.	
16.	Observe a smooth increase in frequency.	
17.	Observe a maximum frequency of >600bpm.	
18.	Observe a Mean Pressure (MAP) between 10 and 20 cmH2O.	
19	Rotate **Pulse Frequency** control knob slowly to full clockwise position.	
20.	Observe a frequency of 185-250 bpm.	
21.	Observe a Mean Pressure (MAP) between 5 and 15 cmH2O.	
22.	Rotate **PEEP valve** from "Open" to "Closed" position-observing an increase in Mean pressure. **Change of less than 5 cmH2O = Fail**	
23.	Rotate **PEEP valve** from "Closed" to "Open" position-observing a decrease in Mean pressure. **Change of less than 5 cmH2O = Fail**	
24.	Increase the operational pressure to 50 psig.	

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25.	Rotate Green **PULSATILE FLOWRATE** Knob either by increasing or decreasing to verify an AIP of 50 cmH_2O.	
26.	Rotate Green **OSCILLATORY CPAP** Knob either by increasing or decreasing to verify will reach an AEP of 20 cmH_2O.	
27.	Return the pulsatile flowrate to an AIP of 20 cmH_2O and oscillatory CPAP to an AEP of 10 cmH_2O.	[redacted]
28.	Turn on the disconnect alarm.	
29.	Trigger the failsafe alarm by pinching off clear Phasitron® tubing.	
30.	Trigger the low-pressure alarm by disconnecting test lung.	
32.	Turn off the Bronchotron® by rotating the **OPERATIONAL PRESSURE** regulator	[redacted]
33.	Pre-Use Check Complete.	