Urgent Medical Device Notification

Date: December 11, 2024
Manufacturer: Percussionaire Corporation
Reference: 1000524541-12/12/2024-003-C
Affected Product: VDR4 Phasitron Breathing Circuit Kit
Product #/UDI#:

Product Name	Model	UDI#
Phasitron Kit, VDR, Single Patient, 5pk	A50094-D A50094-D-5PK	00849436000259

This document is intended for physicians, health care professionals and users of these medical devices. This letter contains important information for the continued safe and proper use of your equipment.

Your Institution has been identified as a customer/user of the Percussionaire Phasitron Breathing Circuits identified.

Please review the following information to be aware of the contents of this communication. It is important to understand the implications of this communication.

Dear Customer,

The purpose of this letter is to notify you that Percussionaire has recently become aware of a potential issue related to the VDR4 Phasitron Breathing Circuits in which under specific use conditions the circuit may “stick “and fail to oscillate for a short duration in lots identified below.

Reason for the Notification:

Percussionaire is conducting an Urgent Medical Device Notification due to recently becoming aware through one customer complaint that the venturi component transiently stopped

oscillating while in use. The patient experienced a slight desaturation (low oxygen). To date Percussionaire has not become aware of any other adverse events related to this issue.

The VDR4 Phasitron is intended to be used for continuous and controlled ventilation of patients. The venturi component of the Phasitron aids in the pulsatile flow of air/oxygen to the patient and moves at a quick rate for effective performance. Percussionaire has identified certain models of VDR4 Phasitron Breathing Circuits that are susceptible to this issue of the venturi temporarily sticking within the Phasitron body. After internal testing, it was discovered that the stalling of the venturi primarily occurs at lower pressures at or below average airway pressures of 8 cmH2O.

If the venturi sticks, the system continues to deliver pressures and volumes, but with reduced amplitude. The set values return when the venturi resumes oscillation.

Risk to Health:

The health consequences relate to reduced pressures and volumes that can be delivered when the venturi is stalled with the potential for mild hypoxemia and/or hypoventilation. These consequences compare to the sequelae for common clinical conditions such as the presence of secretions in or leaks around the endotracheal tube.

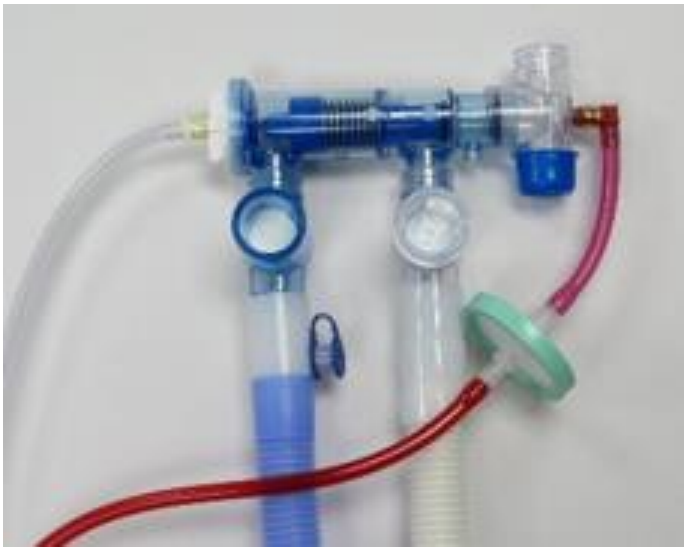
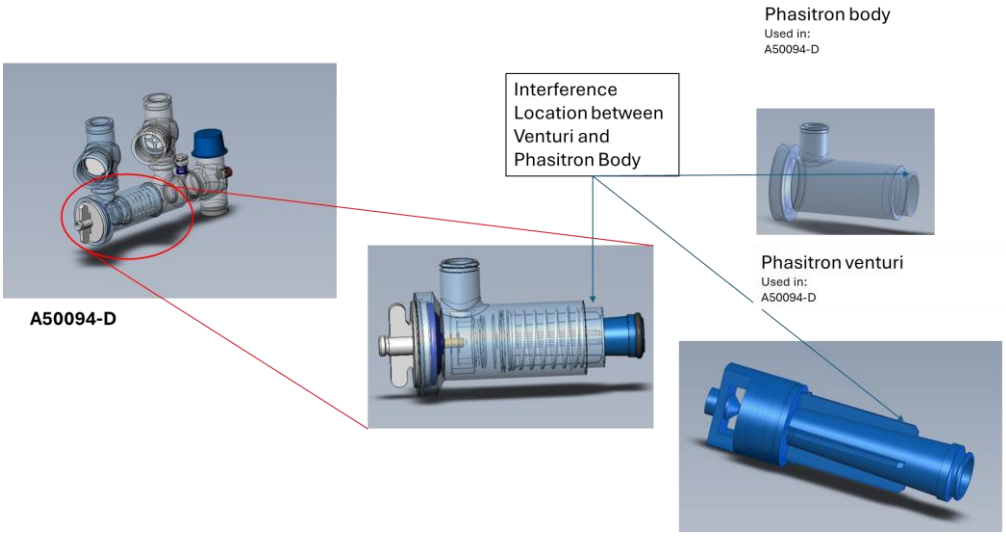
The most at-risk patients would be patients with limited physiologic reserve who might suffer from a brief period of hypoventilation. However, these are not usually managed with the lower pressures under which the problem has been observed and reproduced to occur.

Actions to be taken by Customer/User:

- Complete and Return Acknowledgement form (see Appendix 1) after reviewing and implementing the requested actions by December 31, 2024.
- A supplemental Phasitron pre-use check has been developed to evaluate potential circuits for this issue. Please post the instructions provided in Appendix 2 in all areas of your facility. This additional pre-use check is to be completed for each new Phasitron breathing circuit after completion of the existing pre-use check for circuits in the lots identified below. The pre-use check is not required for circuits not in the specified lots.
- If a product malfunction is identified, please reach out to FSCA@sentec.com for an exchange of product.

- Report any adverse events to regulatory.percussionaire@sentec.com and/or to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.
    - Online: By completing and submitting the report at www.accessdata.fda.gov/scripts/medwatch
    - Regular mail or Fax: Download the form from www.fda.gov/MedWatch/getforms.htm or call 800 332-1088 to request a reporting form, then complete and mail it to the address on the pre-addressed form or submit by fax to 800-332-0178
- Report any quality problems experienced with the use of this product to Percussionaire/Sentec Customer Service department via email to FSCA@sentec.com.

Part Number/ Product Name:	**A50094-D-5PK** - Phasitron Kit, VDR, Single Patient, 5pk	
Potential Lots Affected #:	WO04294 WO04424 WO04764 WO05070 WO05186 WO05460 WO05685 WO05910 WO06388	WO06576 WO06883 WO07095 WO07196 WO07317 WO07405 WO07450 WO07696

Product Image:	 
Indications for Use:	The Phasitron® breathing circuit kit is intended to be used for continuous ventilation intended for controlled ventilation of patients.

Actions taken by Percussionaire:

- Notify all customers that were shipped affected product.
- Provide supplemental pre-use check instructions to test affected product prior to use.
- If a product malfunction is identified, Percussionaire is replacing the product with unaffected product. Please reach out to FSCA@sentec.com for an exchange of products.
- Implementation of additional process inspection controls of products to ensure device meets expected design specifications.

We apologize for any inconvenience this notice might cause. If there are any additional questions related to the updated instructions or other questions, please contact FSCA@sentec.com.

Kind regards,

Caroline Möller, Ph.D.
VP Regulatory Affairs
Sentec AG

Appendix 1. Customer Acknowledgement Form

Reply form for Phasitron Breathing Circuit, Sticking Venturi

Please complete this form in its entirety to:

- acknowledge you have identified and tested affected products.
- acknowledge receipt of this information and completion of the requested actions.

Please send the completed form to FSCA@sentec.com by **December 31, 2024.**

By signing the below, the following is acknowledged:

"I confirm that I understand the instructions of the supplemental Phasitron pre-use check in Appendix 2, the pre-use check is to be completed for each new Phasitron breathing circuit within the affected lots before use, and I have posted the supplemental pre-use check instructions in all areas of my facility."

Name of Healthcare Provider/ Customer	
Address of Healthcare Provider/ Customer	
Name of Representative:	
Email address/Phone Number:	
Date / Signature:	
Pre-Use Check and Replacement:	☐ **Product tested according to Appendix 2, Pre-Use Check** ☐ **Product failed Pre-Use Check. Indicate below:** A50094-D: Lot#:_____ Qty: _____ A50094-D-5PK: Lot#:_____ Qty: _____

	☐ **All product passed Pre-Use Check.**
IMPORTANT!: If the product fails the pre-use check referenced in Appendix 2, please dispose of the device per facility disposal protocol and contact FSCA@sentec.com for product replacement.	

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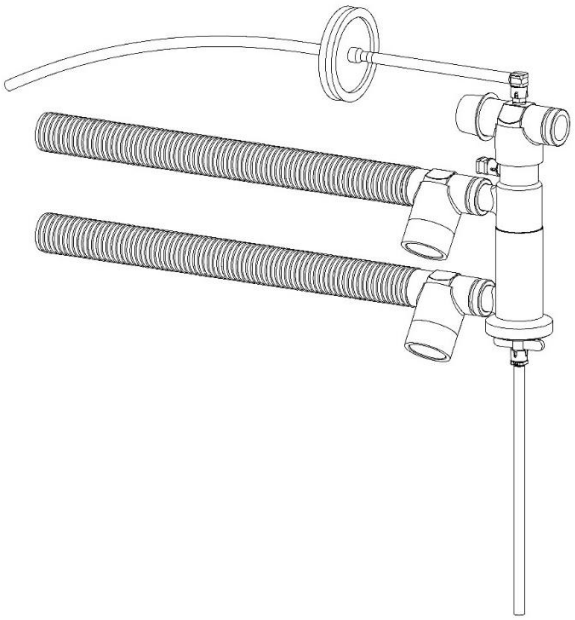
Appendix 2: Supplemental Pre-Use Check, for use with Phasitron Breathing Circuits (Venturi Oscillation Pre-Use Check)

(Please post this checklist in all areas Phasitron Breathing Circuits are used)

In addition to the required system Pre-Use Check (refer to VDR-4 Instruction for Use -P20078), please complete the below steps prior to each new circuit use in the following order. If your product is marked as "Fail" after completing the below, please dispose of device per facility disposal protocol and contact the Field Safety Corrective Actions (FSCA) department, **FSCA@sentec.com**, using the above form for information on product replacement.

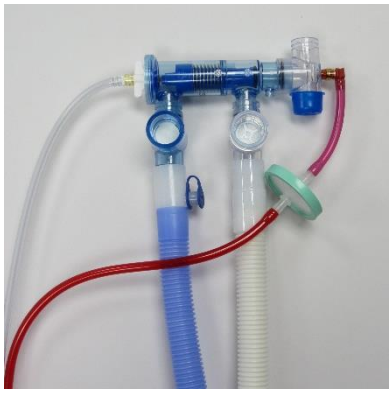
Affected Product Name	Model #
Phasitron Kit, VDR, Single Patient, 5pk	A50094-D A50094-D-5PK



Venturi Oscillation Pre-Use Check

This supplemental pre-use check must be completed before any ventilation is started on a new patient, when a new circuit is used, and after each circuit cleaning. If any abnormal function is noted, do not start ventilation.

Procedure

1.	Connect gas supply hoses to the VDR-4.	
2.	Pressurize gas supply hoses with hospital air and oxygen.	
3.	Set up the Phasitron with a ventilator circuit according to the hospital protocol.	

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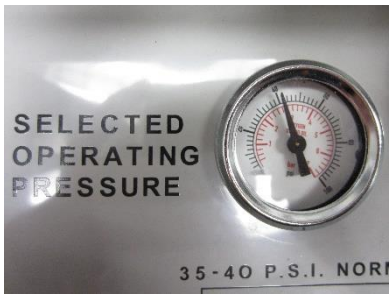
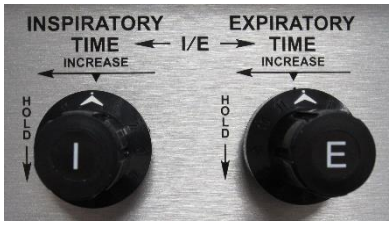
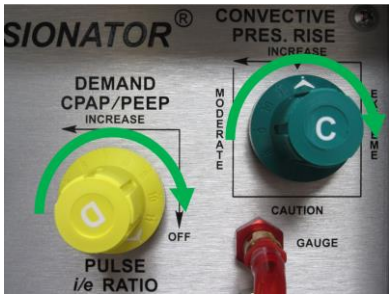
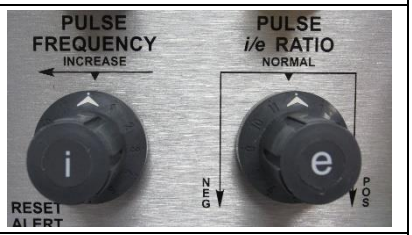
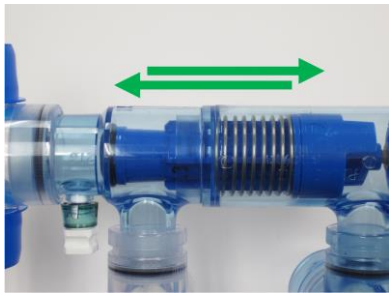
4.	Cap both Phasitron ports.	
5.	Turn the operating pressure knob to reach a static pressure of 42 psig.	
6.	Set the **PULSATILE FLOWRATE** knob fully to the right to the "Off" position.	
7.	Set the **INSPIRATORY TIME** and **EXPIRATORY TIME** knobs to the 12:00 position (arrow up).	

8.	Set the **OSCILLATORY CPAP/PEEP** knob fully to the left to the "On" position.	
9.	Set **DEMAND CPAP/PEEP** and **CONVECTIVE PRES. RISE** fully to the right to the "Off" position.	
10.	Set the **PULSE FREQUENCY** and **PULSE i/e RATIO** knobs to the 12:00 position (arrow up).	
11.	Turn **NEBULIZATION** to the "Off" position.	

12.	Turn the VDR-4 **MASTER** switch to the "On" position.	
13.	Turn **DEMAND CPAP/PEEP** knob to the 12:00 position (arrow up) and allow at least 15 seconds for the Digital Multimeter (DM) to switch to **Active** mode.	
14.	Reduce the **DEMAND CPAP/PEEP** to achieve a Mean Airway Pressure (MAP) of 3-4 cmH2O according to the DM. Observe that the DM remains on and in **Active** mode.	

15.	While observing the Venturi in the Phasitron, slowly turn the **PULSATILE FLOWRATE** knob very slightly to the left to achieve a MAP of 3-4 cmH2O. The Pulse Frequency should be displayed on the DM.	
16.	Ensure that the Pulse Frequency Rate is 500-600 Cycles Per Minute (CPM). Adjust if needed using the **PULSE FREQUENCY** knob only.	
17.	Observe the Venturi for 5 seconds or more. Look for oscillations of the Venturi.	
18.	If the Venturi is not moving or moving intermittently and erratically, discontinue use of the circuit and replace it with another circuit.	

19.	If the Venturi is oscillating, function is considered normal.	
20.	Oscillation Pre-Use Check is complete.	

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