PERCUSSIONAIRE®

Urgent Medical Device Notification

Date: February 3, 2025
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
Control Unit Tester	A51001-VDR4	N/A
VDR W/SWIVEL T SINGLE PATIENT PHASITRON	PRT-991	N/A
VDR4 HUMIDIFICATION ADAPTER KIT, CASE OF 10	PRT-992	N/A
VDR4 Humidification Kit with Cross Tee, Case of 10	PRT-993	NA

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. This is a revised letter, originally sent on December 16 and 23rd. Additional updates have been updated to the Risk to Health section of this document. The latest changes are underlined for ease of reference.

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,

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Urgent Medical Device Notification

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 for circuits 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 or additional customer reports of malfunction 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. 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. Internal testing determined that the stalling of the venturi occurs at lower pressures at or below average airway pressures of 8 cmH2O which may be used on neonatal patients.

When the Phasitron is stuck, the venturi does not fully engage in the forward position leading to partial venting of the output to the expiratory port during pulse delivery. The partial leak reduces the pressures and volumes delivered to the patient. The set values return when the venturi resumes oscillation.

Risk to Health:

The Phasitron malfunction and the resulting decrease in ventilation pressures may lead to hazards such as hypoxia (lack of oxygen), or hypercapnia (excess carbon dioxide in the blood), depending on the severity and duration of the malfunction if the patient is unable to breathe adequately without the ventilator support. Device malfunction will require health care personnel (HCP) to intervene and find an alternative device, which may also lead to a delay in medical care.

The most at-risk patients would be patients with limited physiologic reserve who might suffer from a brief period of hypoventilation. In particular, pediatric patients are at risk due to the

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low pressures at which affected devices may fail.

Actions to be taken by Customer/User:

1. Please review all inventory for impacted lots referenced in the table below.
2. An enhanced Phasitron pre-use check has been developed to evaluate circuits for this issue which replaces the standard pre-use verification until affected products have been replaced at your facility. Please post the instructions provided in Appendix 2 in all areas of your facility. This enhanced pre-use check is to be completed for each new Phasitron breathing circuit in the lots identified below.
3. If product fails the pre-use check found in Appendix 2, **DO NOT USE** and dispose per your institutional protocol and contact FSCA@sentec.com for product exchange.
4. When using the Phasitron breathing circuit on a patient:
    - Ensure that patients are closely monitored using pulse oximetry and/or CO2 monitoring to detect changes in patient condition due to potentially impaired Phasitron function.
    - Verify venturi movement visually and audibly. The venturi component produces a loud noise and can be seen opening and closing through the translucent Phasitron body when functioning properly. The absence of venturi movement should be recognized by a lack of visible or audible motion by users, which indicates device malfunction."
    - An alternative device should always be available in case of Phasitron failure.
5. If a product malfunction is identified during use, please **IMMEDIATELY STOP USE** of the device and dispose according to your institutional protocol and contact FSCA@sentec.com for product exchange.

6. Complete and Return Acknowledgement form (see Appendix 1) **after reviewing and implementing the requested actions by February 28, 2025.**

7. After receipt of replacement product:
    - Dispose remaining product from affected lots per facility protocol.

- 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.

<table>
<tr><td>Part Number/
Product Name:</td><td>A50094-D-5PK - Phasitron Kit, VDR, Single Patient, 5pk
A51001-VDR4- Control Unit Tester
PRT-991- VDR W/SWIVEL T SINGLE PATIENT PHASITRON
PRT-992- VDR4 HUMIDIFICATION ADAPTER KIT, CASE OF 10
PRT-993 - VDR4 Humidification Kit with Cross Tee, Case of 10</td></tr>
<tr><td>Potential Lots
Affected #:</td><td>
<table>
<tr><td>A50094-D-5PK</td><td>WO04294
WO04424
WO04764
WO05070
WO05186
WO05460
WO05685
WO05910
WO06388</td><td>WO06576
WO06883
WO07095
WO07196
WO07317
WO07405
WO07450
WO07696</td></tr>
<tr><td>A51001-VDR4</td><td>WO04750
WO06701</td><td></td></tr>
<tr><td>PRT-991</td><td>WO04733</td><td></td></tr>
<tr><td>PRT 992</td><td>WO045667</td><td></td></tr>
<tr><td>PRT-993</td><td>WO04745
WO04832
WO04893</td><td></td></tr>
</table>
</td></tr>
</table>

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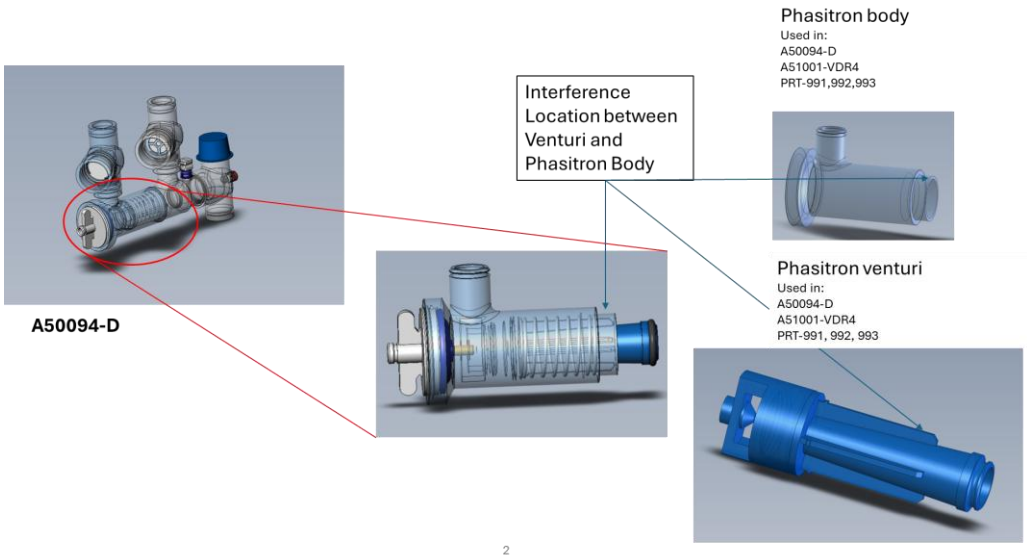
		WO04893 WO05309 WO06523 WO07080 WO07283 WO04893
Product Image:	 	

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:

1. Notify all customers that were shipped affected product.
2. Provide enhanced pre-use check instructions to test affected product prior to use.
3. If a product malfunction is identified, Percussionaire is replacing the circuit with unaffected product. Please reach out to FSCA@sentec.com for an exchange of products.
4. Implementation of additional in-process inspection controls of products to ensure new production devices meet expected design specifications.
5. Provide conforming product for exchange beginning in February of 2025.

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.

Regards,

Gina Cunsolo
Regulatory Affairs Manager
Percussionaire Corp.

Appendix 1. Customer Acknowledgement Form

Reply form for Phasitron Breathing Circuit, Sticking Venturi

Please complete this form in its entirety to:

1. Acknowledge that you have identified affected lots in your inventory, and note them in the table below.
2. Acknowledge the Enhanced Pre-Use Check (Appendix 2) has been posted in all areas of your facility where the Breathing Circuits are used.
3. Before receipt of replacement product:
    - Acknowledge that all products that fail the Enhanced Pre-Use Check (Appendix 2) or during use will not be used and will be disposed per facility protocol.
4. After receipt of replacement product:
    - Acknowledge that all remaining affected products will be disposed per facility protocol.

Please send the completed form to FSCA@sentec.com by **February 28, 2025.** Percussionaire intends to have ample inventory to exchange products by February 2025.

By signing the below, the following is acknowledged:
"I confirm that I have identified all affected products in my inventory. I understand the instructions of the 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:	
Signature/ Date:	
Do you have affected product onsite?	☐ **Yes – please identify below for product exchange.** A50094-D: Lot#:_____ Qty: _____ A50094-D-5PK: Lot#:_____ Qty: _____ A51001-VDR4: Lot#:_____ Qty: _____ PRT-991: Lot#:_____ Qty: _____ PRT-992: Lot#:_____ Qty: _____ PRT-993: Lot#:_____ Qty: _____ ☐ **No affected product on site.**
IMPORTANT! If any affected product fails the pre-use check referenced in Appendix 2, or fails during use, immediately discontinue use and dispose of the circuit per facility disposal protocol and contact FSCA@sentec.com for product replacement.	

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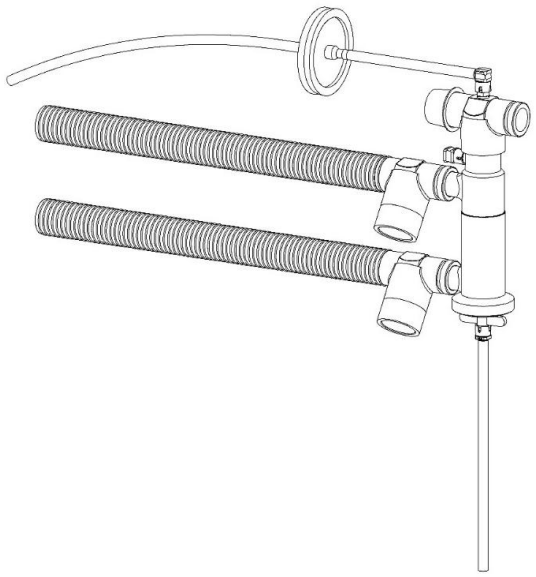
Appendix 2: Enhanced Pre-Use Check, for use with Phasitron Breathing Circuits (VDR4 System Pre-Use Check)

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

Please complete the below steps prior to each new circuit use in the following order. If your product fails any of the steps below, please dispose of device per facility disposal protocol and contact the Field Safety Corrective Actions (FSCA) department, **FSCA@sentec.com**, using the form in Appendix 1 for information on product replacement.

Affected Product Name	Model #
Phasitron Kit, VDR, Single Patient, 5pk	A50094-D A50094-D-5PK
Control Unit Tester	A51001-VDR4
VDR W/SWIVEL T SINGLE PATIENT PHASITRON	PRT-991
VDR4 HUMIDIFICATION ADAPTER KIT, CASE OF 10	PRT-992
VDR4 Humidification Kit with Cross Tee, Case of 10	PRT-993

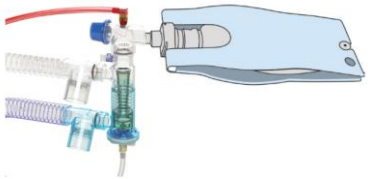


Pre-Use Check

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 hospital air supply hose to VDR®-4. Listen for blender alarm, then disconnect air hose.
2. Connect hospital oxygen supply hose to VDR®-4 and disconnect air hose. Listen for blender alarm.
3. Connect hospital air supply hose to VDR®-4.
4. Turn Monitron® II "ON."
5. Connect Phasitron® patient port to a test lung (such as Vadi 210 or equivalent).



6. Perform all tests using your standard heater/humidification setup, set up according to your hospital protocol.
7. Turn operating pressure knob until it reaches a static 42 psig.
8. Turn VDR®-4 "ON."
9. Turn off OSCILLATORY PEEP/CPAP, DEMAND CPAP, and CONVECTIVE PRES. RISE (full clockwise).
10. Set the PULSATILE FLOWRATE control to AIP of 30 cmH_2O as read on DM or manometer.

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11. Set pulse frequency to 500.
    - Set PULSE i/e RATIO with arrow at the 12:00 position (straight up) for a 1:1 i/e ratio.
    - Set inspiratory time and expiratory time to:
    - 2.0 seconds to get a convective rate of ~15 (adult/large peds)
    - 1.5 seconds to get a convective rate of ~20 (small peds)
    - 1.0 second to get a convective rate of ~30 (neonatal)
12. Set oscillatory CPAP/PEEP to AEP of 5 cmH_2O as read on Digital Multimeter (DM) or manometer.
13. Check Monitron® II for appropriate rise and fall on waveform.
14. Verify pulse frequency will go greater than 700 and less than 200.
15. Return pulse frequency to 500.
16. Manually compress test lung and hold as tightly as possible.
    - Verify pulsatile flowrate will achieve AIP of 50 cmH_2O.
    - Verify oscillatory CPAP will reach a minimum AEP of 18 cmH_2O. (Release hold on test lung).
17. Return pulsatile flowrate to an AIP of 30 cmH_2O and OSCILLATORY CPAP control to an AEP of 5 cmH_2O.
18. Verify a gradient of 8-10 cmH_2O when convective pressure rise is applied.

NOTE: *Convective pressure rise will begin after approximately 0.7 seconds have passed from the start of the inspiration cycle.*

19. Increase convective pressure rise until failsafe alarm sounds. Observe that ventilation continues at lower settings. Turn convective pressure rise off and then press red button to reset.

20. Remove the test lung. Cap both Phasitron ports.

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21. Set the PULSATILE FLOWRATE knob fully to the right to the “Off” position.

22. Set the OSCILLATORY CPAP/PEEP knob fully to the left to the “On” position.

23. 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.

24. 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.

25. While observing the Venturi in the Phasitron, slowly turn the PULSATILE FLOWRATE knob very slightly to the left to achieve a MAP of 4-5 cmH2O. The Pulse Frequency should be displayed on the DM.

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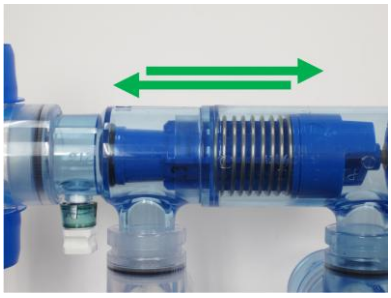
26. Ensure that the Pulse Frequency Rate is 500-600 Cycles Per Minute (CPM). Adjust if needed using the PULSE FREQUENCY knob only.

27. Observe the Venturi for 5 seconds or more. Look for oscillations of the Venturi. If the Venturi is not moving or moving intermittently and erratically, discontinue use of the circuit and replace it with another circuit.



28. Lower high-amplitude pressure alarm below set pulsatile flowrate to trigger the high-pressure alarm. Press reset on Monitron® to clear audible alarm.

29. Trigger low-amplitude pressure alarm by disconnecting test cap. Press reset on Monitron® II to clear audible alarm.

30. Turn off VDR®-4 and Monitron® II. Silence alarm on Monitron® II by pressing any button.

31. Switch nebulizer on and listen for gas flow, then switch off.

✓ Pre-use check is complete.

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