

PERCUSSIONAIRE®
Urgent Medical Device Correction

Date: November 18, 2024
Manufacturer: Percussionaire Corporation
Reference: 1000524541-08/21/2024-001-C
Affected Product: Phasitron 5 In-Line Valve
Product #: P-5-TEE, P5-TEE-20
UDI-DI: 00849436000723

Dear Customer,

The purpose of this letter is to advise you that Percussionaire is voluntarily issuing this **Urgent Medical Device Correction** for the Phasitron 5 In-Line Valve (REF: P5-TEE, P5-TEE-20), which requires your attention. **Serious injuries have or could occur due to the misuse of this product. We have reports of six serious injuries.**

Your Institution has been identified as a customer/user of the Percussionaire In-Line Valve product which enables the delivery of IPV therapy in-line with a ventilator.

Reason for Corrective Action:

The current P5-TEE In-Line Valve is shipped with a blue cap within the packaging to plug the Phasitron 5 breathing circuit's expiratory port when IPV therapy is being given via in-line with a ventilator and to protect the connection port of the P5-TEE when the Phasitron is not attached. Per the Instructions for Use (P20020, Rev E) provided with the Phasitron 5 and P5-TEE, Warnings instruct that the cap is to be removed when providing therapy directly to a patient's airway via mouth, mask, or directly connected to endotracheal tube.

It has recently been identified that there has been an increase in reported adverse events due to the failure to remove this blue cap when transitioning from IPV in-line therapy to therapy applied directly to the patient's airway. Failure to remove this cap when providing therapy directly to the patient airway can result in excessive pressure being provided to the patient, and therefore potentially causing harm.

We are aware of 6 complaints related to this misuse, all involving serious adverse events involving cardiac arrest, pneumothorax, and tracheobronchial tear.

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This Notice provides updated instructions and labeling to reinforce safe and proper operation while reducing the potential for accidental misuse. Future design enhancements will be introduced to further mitigate risk.

Risk to Health:

If the blue cap remains on the Phasitron 5 after in-line use and while therapy is given directly to the patient's airway, there is a potential for overpressure. The misuse of leaving the blue cap on the Phasitron 5 expiratory port while providing therapy directly to the patients' airways can have severe or life-threatening results. This condition may contribute to, but is not limited to, the following patient adverse reactions:

- Pneumothorax
- Cardiac Arrest
- Tracheobronchial tear

Actions to be taken by Customer/User:

- Complete and Return Acknowledgement form (see Appendix 1) after reviewing and implementing the requested actions below by December 13, 2024.
- Review the updated instructions for proper in-line use (see Appendix 3) and updated IFU (see Appendix 4):

Appendix 2 provides clarification on proper use of the In-Line Valve. The revised directions instruct that the blue cap provided with the P5-TEE is to be used as a protective cap ONLY. The protective cap is only to be placed on the in-line valve (P5-TEE) Phasitron 5 port connection when therapy is not being provided to prevent any particles from entering the In-Line Valve. **The updated instructions warn that the Phasitron 5 expiratory port should remain open and unobstructed when giving treatment.** There is no adverse impact to product performance or therapy provided with this change.

IMPORTANT NOTE: These updated instructions differ from the prior IFU (P20020 Rev E) depicting the cap applied to the Phasitron 5 expiratory port. Responsible healthcare providers and clinical educators should review this change and, if necessary, revise institutional protocols and procedures related to use of the P5-TEE. For full instructions on administering in-line treatment, and associated warnings, please follow the updated Instructions for Use In-Line Valve (Appendix 4).

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- Print and post updated instructions for proper In-Line Valve use (Appendix 3) throughout your facility for adequate distribution of new information to users.
- Communicate and train with the newly presented instructions for proper use to primary users of IPV therapy, specifically for in-line use.
- Review institutional protocols related to P5-TEE inline use and update as needed to conform with the updated instructions.
- Re-label current product by placing the sticker provided by Percussionaire on each individual P5-TEE bag in stock below the current product label as indicated in Appendix 2 (stickers to be provided via mail). DO NOT obstruct current product labeling.
- 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.
- Report any quality problems experienced with the use of this product to Percussionaire/Sentec Customer Service department via email to FSCA@sentec.com.

Product and Distribution Information:

Product Name:	In-Line Valve			
Product Part Number:	P5-TEE-20 (pack of 20)/ P5-Tee (individual)			
Potential Lots Affected #:	240620	240610	240418	
	240326	230612	WO07066	
	WO07010	WO06020	WO05019	
	WO04884	WO04827	WO04756	
	WO04714	WO04656	WO04625	
	WO04596	WO04553	WO04398	
	WO04356	WO04061	WO03846	
	WO03748	WO03688	--	

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Product Image:	 <i>Figure 1. P5-TEE – No Cap</i>  <i>Figure 2. P5-TEE – With Cap. When no therapy is provided the P5-TEE port is plugged with the blue cap to prevent external contamination from entering the port.</i>  <i>Figure 3. Proper configuration for P5-TEE use with the Phasitron 5. The cap should only be used to plug the P5-TEE and not used on the Phasitron.</i>
Indications for Use:	The IPV® In-Line Valve is intended to be used to provide IPV® (Intrapulmonary Percussive Ventilation) therapy to patients while assisted by Conventional Mechanical Ventilation (CMV) using pressure-control, volume-control, SIMV-PC etc., when direct connection of IPV® is not indicated. For use only with Percussionaire® IPV® Control Devices. Compatible with all Percussionaire®

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	single-patient Phasitrons.
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Actions taken by Percussionaire:

- We are notifying all customers that were shipped affected lots of the In-Line-Valve (P5-TEE) and providing updated instructions **to only use the blue cap as a protective cap** and reinforce the warning that the Phasitron5 expiratory port shall remain open when providing therapy via in-line or directly to patient's airway via mouth, mask, or directly connected to endotracheal tube (see Appendix 3).
- Percussionaire is updating product User Manuals and Instructions for Use to clarify proper in-line use procedures.
- We will ship precautionary stickers to each customer with the intent for customers to add stickers to all products in stock including those for the affected lots.
- Percussionaire is in process of updating the design of the In-Line Valve (P5-TEE) to include a tethered cap to restrict potential misuse on the Phasitron expiratory port. These are anticipated to begin to ship by March 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.

Gina Cunsolo
Regulatory Affairs Manager
Percussionaire Corp.

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Appendix 1: Customer Acknowledgement Form

Reply form for the P5-TEE In-Line Valve,
Medical Device Urgent Corrective Action

Please complete this form in its entirety to acknowledge you have received this information and implemented the requested actions and send to FSCA@sentec.com for Regulatory action traceability purposes by December 13, 2024.

- That you have read and understood the updated instructions provided in Appendices 2 through 4 of this document.
- That the appropriate personnel have been engaged to implement and educate on the updated instructions.
- That products in stock have been relabeled with the supplied stickers (to be provided by Percussionaire via mail).

Print and Sign

Date

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

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Appendix 2: Precautionary Sticker and Placement Information

Placement of Precautionary Stickers may vary due to the current placement of the product information label. Refer to Options #1 and #2 to follow.



**URGENT
MEDICAL
DEVICE
CORRECTION**

The blue cap should only be used to maintain cleanliness of the In-Line Valve when not in use, as shown below.



P20231 Rev A



 **Correct Use**

The expiratory port on the Phasitron® 5 should always remain unobstructed when delivering IPV therapy.

 **Incorrect use can have life-threatening result**



 **Incorrect Use**

Never obstruct the expiratory port of the Phasitron® 5 when delivering IPV therapy.

SCAN
FOR MORE
INFORMATION



Example of Sticker to be provided.

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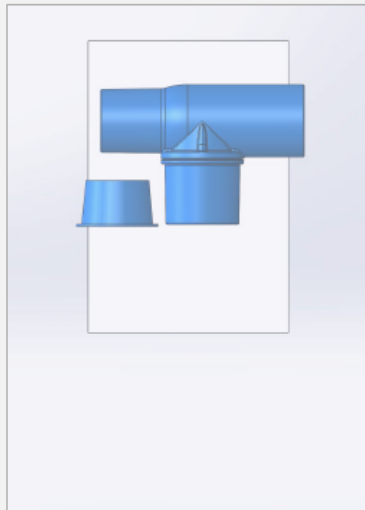
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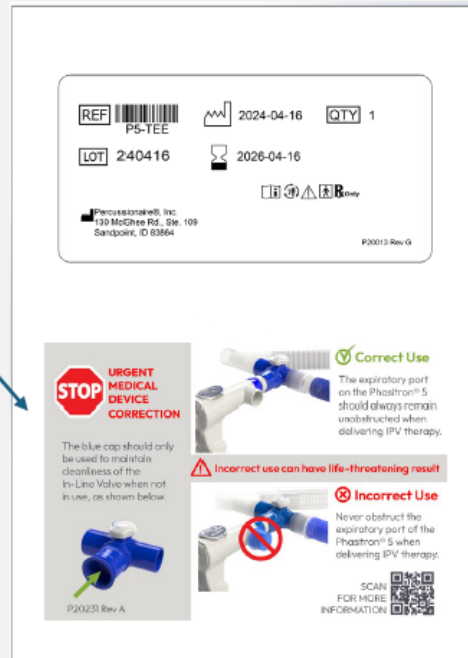
Option #1: Label Affixation (Front of Bag)

Please affix provided label PN, P20231, to the P5-TEE bag, as indicated, below the product information label.

Note: Do not cover/obstruct current product labeling.



*Rear of Bag
(Translucent side showing internal contents)*



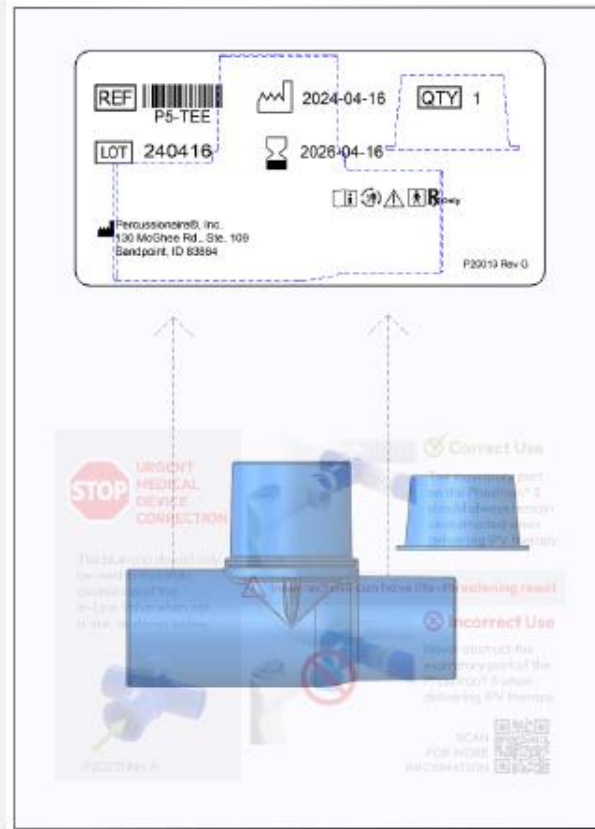
*Front of Bag
(White non-Translucent side)*

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Front of Bag

Note: To apply label more easily,

- Without opening the bag, gently slide the contents within the bag behind product information label.
- This allows a flat surface to adhere provided sticker to bag.

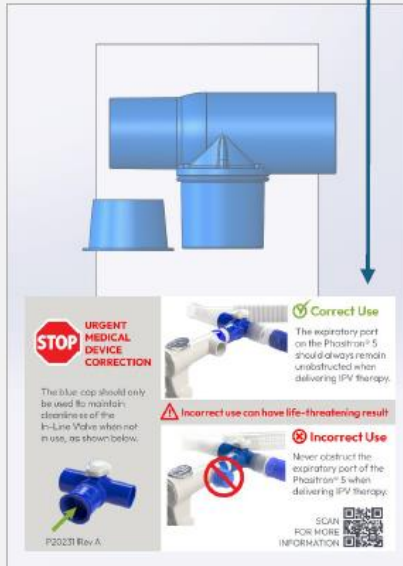
**White non-Translucent side shown semi transparent for reference only.*

Urgent Medical Device Correction

Option #2: Label Affixation (Rear of Bag)

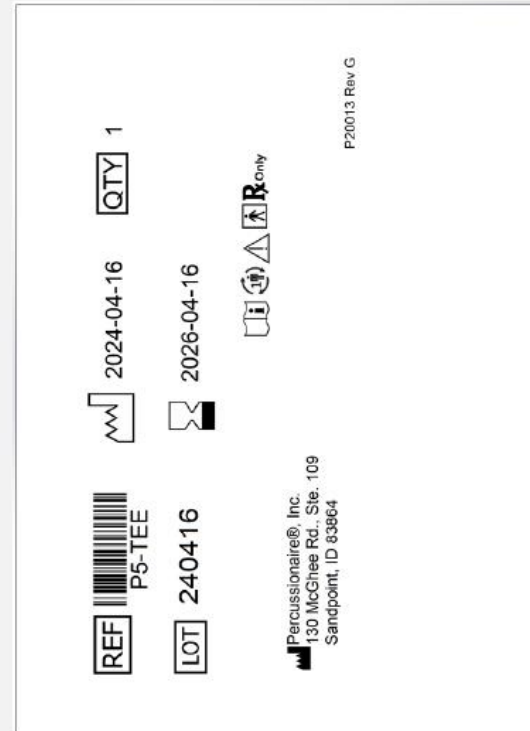
Please affix provided label PN, P20231, to the P5-TEE bag, as indicated, on translucent side (Rear of Bag).

Note: Do not cover/obstruct current product labeling.



Rear of Bag

(Translucent side showing internal contents)



Front of Bag

(White non-Translucent side)

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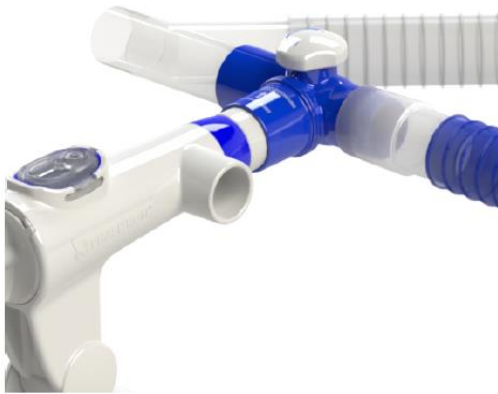


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Appendix 3: Appropriate P5-TEE Blue Cap Use

Please print this page and post appropriately throughout facility for adequate distribution of information.



Correct Use

The expiratory port on the Phasitron® 5 should always remain unobstructed when delivering IPV therapy.

The blue cap should only be used to maintain cleanliness of the In-Line Valve when not in use, as shown below.



Incorrect Use

Never obstruct the expiratory port of the Phasitron® 5 when delivering IPV therapy.

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Appendix 4: Updated P5-TEE Instructions for Use

The following section of the Instructions for Use has been updated to reflect proper use of the In-Line Valve. Refer to the full updated Instructions for Use on the next page (P20020 Rev F).

sentec.

In-Line Valve



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P20020 Rev F
Date of Release: 2024-07

IPV® In-Line Valve Setup

Pediatric to Adult Application: recommended to install as close to the patient wye as allowable.
Neonatal Application: recommended to install on dry side of heater, in between heater and inspiratory limb.
Insert IPV® In-Line Valve into inspiratory limb of ventilator circuit.

⚠ **CAUTION:** Ensure pressure relief adjustment valve is closed.

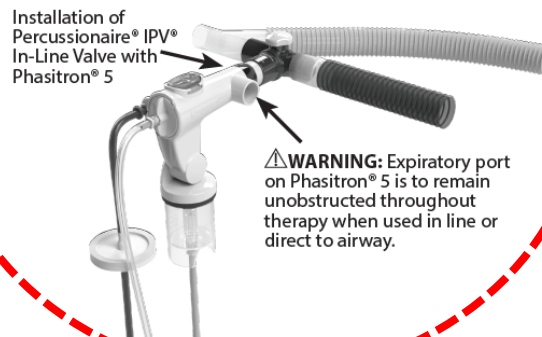
⚠ **CAUTION:** Allow ventilator to cycle with valve in place.



⚠ **WARNING:** Ensure IPV® In-Line Valve is inserted into inspiratory side of ventilator circuit.

Adding Phasitron 5® to In-Line Valve

Fill nebulizer with 15 to 20 cc of normal saline or prescribed medication. Aerosol consumption approximately .75 cc per minute.



Administering Treatment

⚠ **CAUTION:** Note the current ventilator alarm and mode settings. Pressure-control mode is recommended or follow

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