PERCUSSIONAIRE®

Urgent Medical Device Correction

Leak issue with all IPV® In-Line Valves

Date:	September 15, 2025
Manufacturer:	Percussionaire Corporation
Reference:	1000524541-07/31/2025-001-C
Affected Product:	In-Line Valve
Product #:	P5-TEE, P5-TEE-20
UDI-DI:	00849436000723

This document contains important information for the continued Safe and Effective use of your equipment

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain a copy with the equipment Instruction for Use.

Dear Customer,

The purpose of this letter is to advise you that Percussionaire is issuing this Urgent Medical Device Correction for the IPV® In-Line Valve (REF: P5-TEE, P5-TEE-20), which requires your attention. **Serious injuries may occur if updated instructions are not followed properly when using this product. One serious adverse event has been reported.**

Your Institution has been identified as a customer/user of the Percussionaire In-Line Valve, P5-TEE, product, which enables the delivery of IPV therapy in-line with a ventilator.

Reason for Corrective Action:

The current In-Line Valve (P5-TEE) is used to provide Intrapulmonary Percussive Ventilation (IPV) therapy to patients while assisted by Conventional Mechanical Ventilation (CMV).

It has been recently identified through a reported adverse event that the In-Line Valve may

Percussionaire Corp:
130 McGhee Road, Suite 109
Sandpoint, Idaho 83864
+1 208 263 2549

www.percussionaire.com
YouTube
Toll Free +1 800 850 7205

European Office:
Sentec AG/Ringstrasse 39
CH-4106 Therwil, Switzerland
+49 891 9476 222

create a leak in the ventilator circuit when IPV therapy is not being delivered, even when the pressure relief valve is fully closed. This leak will be evident during newly required ventilator cycling steps found in the Instructions for Use (refer to Appendix 2). The extent of the leak is situation-dependent and rarely clinically significant. However, for neonates and infants, particularly those with small tidal volumes (<50ml) or those weighing <10kg, it can represent a substantial fraction of the intended ventilation.

Currently, we have received one reported event wherein four instances of this issue were observed in, one of which resulted in an adverse event. Four neonatal patients experienced hypoventilation with hypercapnia. In one out of the four patients, medical intervention was required to identify the cause and resolve the issue.

This Notice provides updated instructions and labeling to reinforce safe and proper operation, as well as evaluate the impact on ventilation. Future design enhancements will be introduced to the product to improve the pressure relief seal and remove the leak.

Risk to Health:
If the impact of the leak is not identified or compensated for, patients may be at risk for hypoventilation if delivered tidal volumes are inadequate (assessed through the exhaled tidal volumes measured by the ventilator). Depending on the severity and fragility of the patient's condition, unrecognized hypoventilation could lead to respiratory acidosis, hypoxemia, or respiratory failure.

For pediatric patients > 2 years (or > 10 kg) through adults, the leak amounts are not expected to lead to adverse health consequences.

For pediatric patients < 2 years (or < 10 kg), the leak may lead to mild to moderate hypoventilation and associated hypoxemia if not detected and addressed early, resulting in compromised cardiopulmonary function.

The greatest risk population is neonates and infants with target tidal volumes < 50 mL, especially in the case of uncuffed endotracheal tubes. The potential relative magnitude of the leak if unrecognized and uncompensated, could significantly compromise cardiopulmonary function. In extreme cases, this could result in moderate to severe hypoventilation and hypoxemia, leading to respiratory acidosis, hypoxemia, respiratory failure, loss of consciousness, or cardiac complications such as pulmonary hypertension, arrhythmia, reduced preload or cardiac output, or cardiac arrest. These conditions may necessitate medical intervention and

could result in permanent impairment if not recognized and addressed early.

The IPV® In-Line Valve may create a leak in the ventilator circuit even when the pressure relief valve is fully closed. Until a design update has been implemented, we advise adjusting ventilator settings for neonates* and infants* to ensure exhaled tidal volumes are adequate. Alternatively, consider removing the IPV® In-Line Valve from the circuit when IPV® therapy is not being delivered.

Warning: The In-Line Valve should not be used in neonates and infants who are at high risk of cardiopulmonary or neurological compromise due to unrecognized hypoventilation.

Actions to be taken by Customer/User to prevent risk/harms to the patient:

- Complete and Return Acknowledgement form (see Appendix 1) after reviewing and implementing the requested actions by **September 30, 2025**.
- Review the updated instructions for proper in-line use and updated IFU (see Appendix 2):

  Appendix 2 provides updates to the In-Line Valve Instructions for Use. The revised directions instruct that upon initial placement of the In-Line Valve, the user should allow the ventilator to complete two or more cycles, making any necessary setting adjustments to compensate for potential leaks and ensure exhaled tidal volumes are adequate. **The updated instructions warn that the IPV In-Line Valve may create a leak in the ventilator circuit even when the pressure relief knob is fully closed. Until a design update has been implemented, we advise adjusting ventilator settings for neonates and infants to ensure exhaled tidal volumes are adequate. Alternatively, consider removing the IPV In-Line Valve from the circuit when IPV therapy is not being delivered. The In-Line Valve should not be used in neonates and infants who are at high risk of cardiopulmonary or neurological compromise due to unrecognized hypoventilation.**

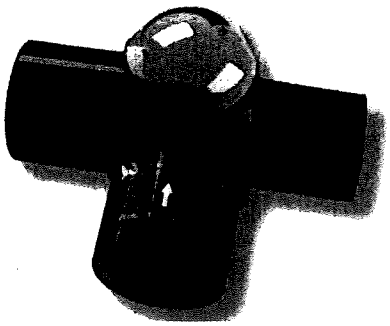
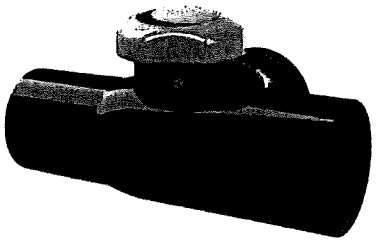
  IMPORTANT NOTE: These updated instructions differ from the current IFU (P20020 Rev F) posted on the Sentec website. Responsible healthcare providers and clinical educators should review this change and, if necessary, revise institutional protocols and procedures related to the use of the In-Line Valve (P5-TEE). For complete instructions on administering in-line treatment and associated warnings, please follow the updated Instructions for Use for the In-Line Valve (Appendix 2).

- Print and post updated instructions for proper In-Line Valve use (Appendix 2) throughout your facility to ensure adequate distribution of new information to users.
- Communicate and train primary users of IPV therapy, specifically those using it in-line with a ventilator, on the new instructions.
- Review institutional protocols related to In-Line Valve use and update as needed to conform to the updated instructions.
- Re-label current product by placing the sticker provided by Percussionaire on each individual In-Line Valve bag in stock below the current product label as indicated in Appendix 3 (stickers to be provided by Percussionaire/Sentec via mail). Additional stickers can be requested at FSCA@sentec.com.
- 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 #:	

240326	250116
240418	250324
240610	250616
240620	241121
230612	WO04827
240826	WO04884
241118	WO06020
241203	WO05019
250111	WO04756

Product Image:	 *Figure 1. P5-TEE – Front*  *Figure 2. P5-TEE – Back.*
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® single-patient Phasitrons.

Actions taken by Percussionaire:

- We are notifying all customers who received affected lots of the In-Line Valve (P5-TEE) and providing updated instructions (Appendix 2).
- Percussionaire is updating Instructions for Use for the In-Line Valve (P5-TEE) and to clarify proper in-line use procedures.
- Percussionaire will update the design of the In-Line Valve (P5-TEE) to eliminate the potential leak.
- All future products will be labeled with precautionary stickers until the new design has been implemented (Appendix 3).
- We will ship precautionary stickers (Appendix 3) to each customer to add stickers to all affected products in stock.

Percussionaire Corp:
130 McGhee Road, Suite 109
Sandpoint, Idaho 83864
+1 208 263 2549

www.percussionaire.com
YouTube
Toll Free +1 800 850 7205

European Office:
Sentec AG/Ringstrasse 39
CH-4106 Therwil, Switzerland
+49 891 9476 222

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.

Appendix 1: Customer Acknowledgement Form

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

Please complete this form in its entirety to acknowledge the requested actions and send it to FSCA@sentec.com for Regulatory action traceability by September 30, 2025.

By signing this form, you acknowledge:

- That you have read, understood, and posted the updated instructions provided in Appendix 2.
- That you have forwarded this notice to any individuals that need notification within your organization or any organization where the affected devices are used or have been transferred.
- That products in stock will be re-labeled with the precautionary stickers supplied (to be provided by Percussionaire via mail).

_____ _____

Signature Date

Name of Healthcare Provider/ Distributor/ Customer	
Address of Healthcare Provider/ Distributor/ Customer	
Name of Representative (Print):	
Position:	
Email Address & Phone Number:	

PERCUSSIONAIRE®

Urgent Medical Device Correction

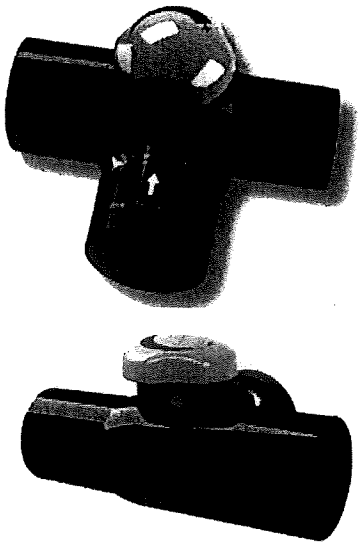
Please post in the appropriate areas of your facility for visibility.

Appendix 2: Updated P5-TEE Instructions for Use

The following section is being added to the In-Line Valve Instructions for Use (P20020 Rev G).

⚠ PLEASE BE ADVISED – UPDATE TO IFU IN PROCESS

We are in the process of updating our Instructions for Use for the **IPV® In-Line Valve.** The changes we are implementing are as follows.



New NOTE: The IPV In-Line Valve may create a leak in the ventilator circuit, even if the pressure relief knob is fully closed, which may reduce delivered (exhaled) tidal volumes.

New NOTE: If adequate exhaled tidal volumes cannot be achieved with the In-Line Valve in place, consider removing the In-Line Valve from the circuit when IPV therapy is not being delivered or choose a different treatment configuration (e.g., direct to artificial airway).

⚠ **New WARNING:** Insufficient exhaled tidal volumes may lead to hypoventilation.

⚠ **New WARNING:** The In-Line Valve should not be used in neonates* or infants* who are at high risk of cardiopulmonary or neurological compromise due to unrecognized hypoventilation.

*Indications for the use of IPV therapy in patients under two years of age vary by geography and by device.

New WORKFLOW:

<u>At initial placement of the In-Line Valve in the inspiratory limb:</u> ***(either at the patient wye or on the dry side of the humidifier)***	<u>At completion of IPV treatment when performed with In-Line Valve:</u>
Allow the ventilator to complete two or more cycles and adjust settings, if necessary, to compensate for any potential leaks and to <u>ensure exhaled tidal volumes are adequate.</u>	1. Close pressure relief adjustment valve and turn off IPV device in quick succession. 2. Restore ventilator settings noted before treatment and reassess the patient. 3. Allow the ventilator to complete two or more cycles and adjust settings, if necessary, to <u>ensure exhaled tidal volumes are adequate.</u>

Percussionaire Corp:
130 McGhee Road, Suite 109
Sandpoint, Idaho 83864
+1 208 263 2549

www.percussionaire.com
YouTube
Toll Free +1 800 850 7205

European Office:
Sentec AG/Ringstrasse 39
CH-4106 Therwil, Switzerland
+49 891 9476 222

Appendix 3: Precautionary Sticker and Placement Information

Precautionary Sticker placement provided on the following page.

The IPV In-Line Valve may create a leak in the ventilator circuit even when the pressure relief knob is fully closed.

Adjust ventilator settings to ensure delivered (exhaled) tidal volumes are adequate OR remove from circuit when IPV is not in use.

⚠**WARNING:** The In-Line Valve should not be used in neonates or infants who are at high risk of cardiopulmonary or neurological compromise due to unrecognized hypoventilation.

Scan for more information

P20255 (A)

Example of Sticker to be provided

PERCUSSIONAIRE®

Urgent Medical Device Correction

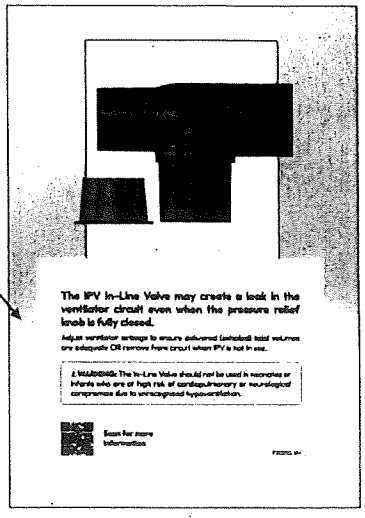
In-Line Valve Precautionary Sticker Application

Please apply sticker to current product in inventory as demonstrated below.

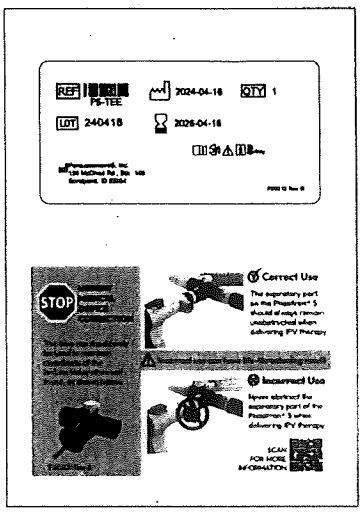
Please affix provided label PN, P20255, to the P5-TEE bag, as indicated, below the product information label.

Note: Do not cover/obstruct current product labeling.

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.



Rear of Bag
(Translucent side showing internal contents)



Front of Bag

Percussionaire Corp:
130 McGhee Road, Suite 109
Sandpoint, Idaho 83864
+1 208 263 2549

www.percussionaire.com
YouTube
Toll Free +1 800 850 7205

European Office:
Sentec AG/Ringstrasse 39
CH-4106 Therwil, Switzerland
+49 891 9476 222