sentec.

IPV® 1 System

Instruction Manual

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The IPV® 1 may be covered by one or more patents.

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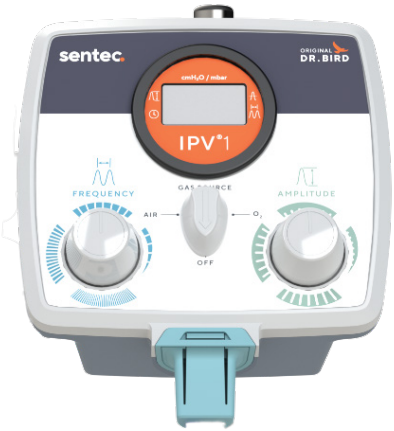
This manual was originally released and supplied in English. For a list of available translations, visit global.sentec.com/manuals

⚠ **CAUTION**: Federal law (U.S.) restricts this device to sale by or on the order of a physician.

Table of Contents

1. System Overview

The IPV® 1 System consists of the IPV® 1 control unit and the Phasitron® 5 with Unified Connector. These devices work together to deliver IPV® therapy, which provides high-frequency percussive flow that works around obstructions, breaks up and loosens secretions and mucus plugs, recruits the lungs, and enables the expiratory flow necessary to move those secretions outward. The Phasitron® breathing circuit's unique sliding venturi creates an open system that dynamically responds to the resistance and compliance of the patient lung during therapy. The In-Line Valve is an optional accessory that allows IPV® therapy to be delivered in-line with a ventilator.



IPV® 1
(Ref. Codes S00065, S00065-EU)

Phasitron® 5 with Unified Connector
(Referred to as Phasitron® breathing circuit)
(Ref. Code P5-UC)

In-Line Valve
Accessory for in-line use
(Ref. Code P5-TEE)

2. Introduction & Contact Details

This manual contains information for operating the IPV® 1 therapy system. Before operating the IPV® 1, the user must thoroughly read and understand these instructions for use.

It is the user's responsibility to follow the safety information included in this Instruction Manual to avoid risk to the patient.

It is the user's responsibility to follow the instructions for use included in this manual.

It is the user's responsibility to keep this manual for future reference, ideally near the device to ensure correct operation.

Related Documents and Resources

For the current version of this manual, visit global.sentec.com/manuals

For additional information and resources visit global.sentec.com/product-support/ipv

Technical Assistance

For technical information and assistance, to request service, or to order parts, contact your local Sentec partner. Contact details are available at sentec.com/contact

You may also contact one of our service locations:

Europe/Switzerland Technical Service:
service@sentec.com | +41 61 726 97 60

Europe/Germany Technical Service:
service.de@sentec.com | +49 6196 56163-0

3. Symbols

The tables below summarize symbols that may be used on the IPV® 1 (including all its related parts), on the packaging, and in the associated documentation.

These symbols indicate information essential for proper use; the order of their appearance is not prioritized.

Symbol	Name	Description of Symbol
	Manufacturer	Indicates the medical device manufacturer.
	Country of manufacture	Identifies the country of manufacture of products. (CC to be replaced by country code.) The date of manufacture may be added adjacent to this Medical Device Symbol.
	Use-by date	Indicates the date after which the medical device is not to be used.
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified.
	Medical Device	Indicates that the device is a medical device.
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Unique Device Identifier	Indicates a carrier that contains Unique Device Identifier information.
	Quantity	Indicates the number of pieces included.
	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.

Symbol	Name	Description of Symbol
	Keep dry	Indicates a medical device that needs to be protected from moisture.
	Temperature limitation	Indicates the temperature limits to which the medical device can be safely exposed (upper and lower limits of temperature are indicated adjacent to the upper and lower horizontal lines).
	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed (humidity limitation are indicated adjacent to the upper and lower horizontal lines).
	Atmospheric pressure limitation	Indicates the atmospheric pressure limits limitation to which the medical device can be safely exposed (atmospheric pressure limits are indicated adjacent to the upper and lower horizontal lines.)
	Single patient multiple use	Indicates a medical device that may be used multiple times (multiple procedures) on a single patient.
	Importer	Indicates the entity importing the medical device (into the EU).
	WARNING / CAUTION	Indicates that caution is necessary when operating the device or control close to where the symbol is placed or that the current situation needs operator awareness or operator action to avoid undesirable circumstances.
	Prescription only	Caution: Federal law (U.S.) restricts this device to sale by or on the order of a physician.

Symbol	Name	Description of Symbol
	WEEE (Waste Electrical and Electronic Equipment)	European consumers are obliged by law to dispose Waste Electrical and Electronic Equipment (WEEE) according to the WEEE Directive 2012/19/EU. Follow local and state regulations on waste disposal.
	CE Mark	Indicates that the device complies with applicable EU regulations.
	EU Authorized Representative	Indicates the authorized representative in the European Community/European Union.
	UK Responsible Person	Name and address of the authorized representative's registered place of business.
	Swiss authorized representative	Name and address of the authorized representative's registered place of business.
	MR Unsafe	An item which poses unacceptable risk to the MR Unsafe patient, medical staff, or other persons within the MR environment.
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	Batteries Contained in Equipment	Class 9 - UN3091 - Lithium metal batteries contained in or packed with the equipment, but not attached to the source.
	Type BF Applied Part	Type BF Applied Parts are those parts which provide a higher degree of protection against electric shock, particularly regarding allowable Patient Leakage Current and Patient Auxiliary Current than that of the Type B applied part.
	Weight of Medical Device	Indicates the weight of the medical device alone.

Symbol	Name	Description of Symbol
	Weight of Medical Equipment	Indicates the weight of the medical equipment including the control unit, accessories, patient circuits, and the pole clamp assembly.
	Do not use if package is damaged and consult instructions for use	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.
	Safe Working Load	Indicates the maximum weight capacity which the medical device or accessory can safely support.
	Intertek Certification mark	Indicates that the device has been tested by a qualified, independent testing laboratory and certifies its compliance to national safety standards.

The following table includes symbols applied on the device or shown on the Digital Display.

Symbol	Name	Description of Symbol
	Do Not Spray	Indicates liquids or cleaners should not be sprayed into specific area.
	Caution/Warning Symbol	Indicates that caution is necessary when operating the device or control close to where the symbol is placed or that the current situation needs operator awareness or operator action to avoid undesirable circumstances.
	Mandatory action: refer to instruction manual/ booklet	Indicates that the instruction manual must be read.
	Do not block the bleed port	Indicates the instruction of not blocking the bleed port on the back of the control unit.

Symbol	Name	Description of Symbol
O_2	Oxygen	Indicates gas source of oxygen.
AIR	Air	Indicates gas source of air.
	Pulse Frequency	Represents the number of pulses per minute.
	Pulse Amplitude	Calculated from measuring the difference between the peak and minimum pulse pressure, averaged over 5 seconds.
	Mean Airway Pressure (MAP)	The average pressure sampled at the output of the Phasitron® over 5 seconds.
	Session timer	The total usage time up to 59 minutes and 59 seconds (59:59).
	Battery depletion	The battery icon appears on the display to indicate the batteries need to be changed.

4. Intended Use & Contraindications

Indications for Use

IPV® 1 System is indicated for Intrapulmonary Percussive Ventilation therapy providing airway clearance, lung expansion and recruitment, and the treatment and prevention of pulmonary atelectasis for pediatric and adult patients in professional healthcare facilities.

The IPV® 1 System may be used with patient interfaces, such as a mouthpiece, a face mask, directly connected to an artificial airway, or in-line with a ventilator.

Intended Patient Population

The IPV® 1 System is intended for adult and pediatric (2 years old and older) patient populations.

Intended Use Environment

The IPV® 1 System is intended to be used in the hospital, clinical environment, or other institutions (physician's office) that have respiratory treatment facilities.

Intended User Profile

The IPV® 1 System is intended to be used by healthcare professionals (including respiratory therapists), clinically trained in Airway Clearance Therapy, and trained on the Sentec IPV® systems.

Expected Clinical Benefits

The IPV® 1 System delivers IPV® therapy which provides high-frequency percussive flow that works around obstructions, recruits the lungs, breaks up and loosens secretions and mucus plugs, and enables the expiratory flow necessary to move those secretions outward. IPV® therapy is used in many respiratory conditions where the following clinical and/or physiological benefits are desired:

- Lung recruitment
- Improved gas exchange
- Decreased work of breathing
- Reduced escalation of ventilatory support
- Improved lung function
- Increased secretion mobilization
- Decreased length of stay

Contraindications

Absolute Contraindications:

- Untreated tension pneumothorax
- Untrained or unskilled operator

Relative Contraindications:

- History of recurring or spontaneous pneumothorax
- Persistent pulmonary air leak
- Recent pneumonectomy
- Radiographic evidence of blebs or other causes of severe pulmonary fragility
- Pulmonary hemorrhage within past 24 hours
- Active Vomiting
- Zephyr valve placement within the past 30 days
- Unrepaired transesophageal fistula
- Premature infant in IVH/Neuroprotective protocol
- New tracheostomy before removal of sutures
- Lung transplant within the past 5 days
- Tracheal or esophageal surgery before removal of sutures

⚠ **WARNING**: The intended user must continue to monitor the patient for progression of symptoms. If contraindication occurs during therapy, discontinue the treatment.

5. Warnings & Cautions

This section includes important safety information for the user.

Pay close attention to the Warnings and Cautions, and their associated consequences. Always exercise appropriate caution while using the IPV® 1 System.

⚠ WARNINGS

A Warning alerts the reader about a situation which, if not avoided, could result in death or serious injury.

General Warnings	• No modification of this equipment is allowed by any unauthorized personnel. • All persons providing IPV® treatment must be trained in the use of Sentec/Percussionaire® devices. • Do NOT use the IPV® 1 System as a life support device. • Supplemental oxygen must be prescribed for patients for whom it is indicated. • The intended user must monitor the patient for exposure to excessive pressure, as there is no alarm or warning when exposure to excessive pressures is reached. • An IPV® treatment mobilizes secretions. Drainage techniques (such as controlled coughing and suctioning) are particularly important for patients with reduced ability to spontaneously cough. • Do NOT use with uncooperative patients. • Do NOT operate the IPV® 1 System in a Magnetic Resonance Imaging (MRI) environment. • The batteries used in this device may present a risk of fire or chemical burn hazard if mistreated. Do not recharge, disassemble, heat above 100°C (212°F), or incinerate. Replace with type recognized CR123A only, or Ref. Code B13350. Use of another battery type may present a risk of fire or explosion. • Do NOT cover the IPV® 1 during use. Do NOT place objects on top of the IPV® 1.

	• Use only the cleaning and disinfecting procedure recommended by the manufacturer.
Before first use	Before the first use of the IPV® 1, be sure to complete the Pre-Use Check to ensure proper operation.
Setup	Ensure the patient circuit is oriented correctly. Carefully follow setup directions given in the instructions for use.
Guidelines	Instructions in the manual are suggested guidelines for trained healthcare professional and clinicians working under a supervising physician. Carefully select settings based on clinical judgment, the needs of the patient, and the benefits, limitations, and characteristics of IPV® 1. Always follow hospital or institutional protocols.
Breathing circuits	• Do not substitute any other breathing circuit for the Phasitron® breathing circuit. Third-party circuits have not been tested by Sentec; performance and safety cannot be guaranteed. • Do NOT change the assembly of the breathing circuit. • Do not operate the system if there are any indications of physical damage, faulty conditions, or malfunction.
Patient interface	For mask delivery of IPV® therapy, always make sure the mask is appropriately sized, covering the mouth and nose but not the eyes or overlapping the chin. Take special care with mask fit for patients under 5 years of age.

Infection control	• Dirty or contaminated equipment is a potential source of infection. Never reuse single patient components or accessories between patients. The Phasitron® breathing circuit is for single patient use. Replace the entire circuit when it cannot be made clean 'as new.' • Disassemble the Phasitron® for cleaning. • Rinse the Phasitron® after each use with water and allow to air dry. Visually inspect interior and exterior of all parts.
Pre-use check	Complete the Pre-Use Check prior to initial use of the IPV® 1 and with each new Phasitron® breathing circuit.
Residual risk/ information to the patient	The trained healthcare professional must instruct the patient to notify them if they experience increased shortness of breath, change in heart rate, or fatigue.

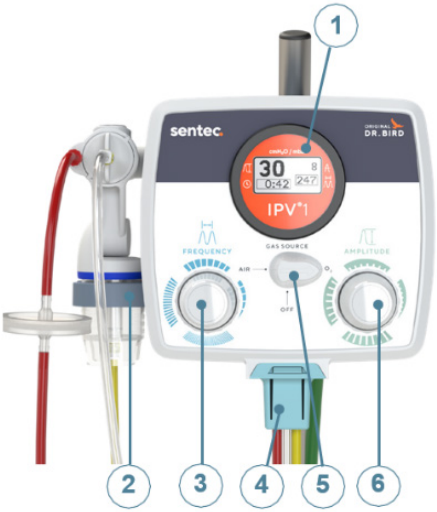
⚠ CAUTIONS

The term Caution is used for the statement of a hazard alert that warns the reader of a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property.

Cautions/ precautions	• The trained healthcare professionals should evaluate how their patients tolerate the treatment. Adjust the settings up or down as appropriate. Auscultation and observation of the mechanical vibrations of the chest and abdomen are primary indicators of effective treatment. • Care should be taken to appropriately suction secretions as they mobilize into the upper airways. • Use only genuine Sentec/Percussionaire® parts and accessories. • Do NOT use the device if any problems are noted. Contact qualified service technician.
Alteration/ assembly	Carefully follow assembly instructions outlined in this instruction manual.

Cleaning and disinfection	**IPV® 1 control unit:** • Only use non-abrasive cotton cloths, cleaning wipes, and paper towels. • Use of cleaning methods not outlined in these instructions for use may damage the control unit. • Clean as recommended. Do NOT spray any liquid directly onto the device. **Breathing Circuit:** • Disconnect the tubing from Phasitron® before cleaning. • Do NOT wash or submerge the hydrophobic filter or tubing. Use a clean, damp cloth to wipe the exterior of the tubing. • Use of cleaning methods not outlined in instruction manual may damage parts of the Phasitron® breathing circuit.
Patient interface	For patients under 5 years of age without an artificial airway, always use a mask instead of a mouthpiece to deliver IPV® therapy.
Clinician training	All persons operating the IPV® 1 must read and understand the manual before using the device.
Malfunctions / maintenance	Maintenance is to be performed by authorized service technicians only. Send the device for maintenance and service following the recommendations provided in this manual.

6. Components & Accessories



IPV® 1 System Overview – Device Front

1. Digital Display

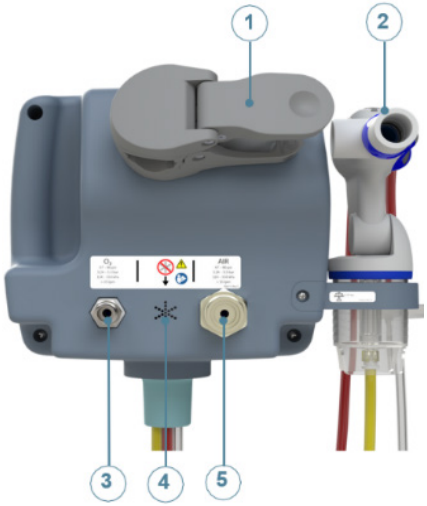
2. Phasitron® Holder
provides a resting place for the Phasitron® breathing circuit when not in use.

3. Frequency Control Knob
determines the rate of high-frequency percussive pulses delivered to the patient.

4. Unified Connector Port
provides easy connection of the Phasitron® breathing circuit.

5. Gas Source Selector
turns ON the IPV® 1 and allows selection of AIR/O_2 or turns the device OFF to stop therapy.

6. Amplitude Control Knob
determines the pressure delivered to the patient.



IPV® System Overview – Device Back

1. Pole Clamp
easily attaches to a roll stand

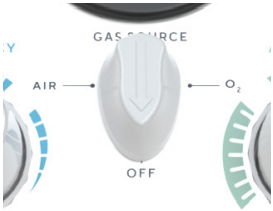
2. Phasitron® breathing circuit

3. O_2 (Oxygen) Connector

4. Bleed Port

5. Air Connector

Control Functions

Control	Function
	GAS SOURCE knob turns ON the IPV® 1 and allows selection of: • AIR • O_2 (oxygen) • Turns OFF the IPV® 1 to stop the therapy. Starting position: OFF
	FREQUENCY knob determines the rate of high frequency percussive pulses delivered to the patient. Starting position: Rotated fully to the left.
	AMPLITUDE knob determines the pressure delivered to the patient. Starting Position: Rotated fully to the right.

Digital Display Overview

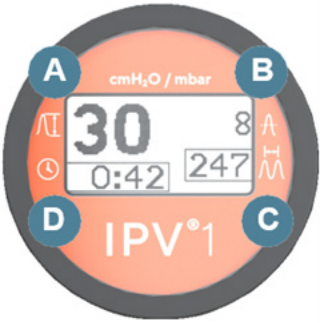
The Digital Display monitors and shows the patient's feedback values during treatment sessions.

The Digital Display features six operating modes:

Sleep, Wake, Active, Report, Fault, and POST (Power On Self Test). See Section 14, Digital Display Modes.

NOTE: The display will not awaken until the IPV® 1 detects back pressure from the Phasitron® breathing circuit.

The screen shows patient's feedback values:



A - Pulse Amplitude

B - Mean Airway Pressure (MAP)

C - Pulse Frequency

D - Session Timer

⚠ **CAUTION**: In some clinical situations pressure signal noise can create inaccuracies on the Digital Display frequency readings.

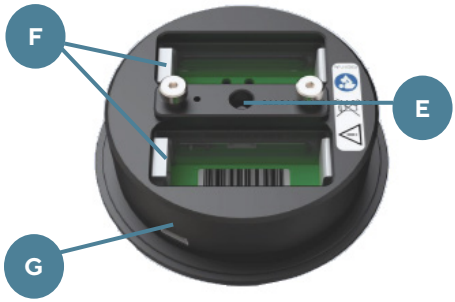
E - Measuring port

⚠ **CAUTION**: Do not insert any object into the measuring port.

F - Battery slots

G - USB serial port (Service use only)

⚠ **CAUTION**: The Digital Display has a USB serial port that is used for factory/service use only.



For instructions on how to change the batteries, see Section 15.

⚠ **WARNING**: The batteries used in this device may present a risk of fire or chemical burn hazard if mistreated. Do not recharge, disassemble, heat above 100°C (212°F) or incinerate. Replace with battery type recognized CR123A only, or Ref. Code B13350. Use of another type may present a risk of fire or explosion.

Phasitron® 5 with Unified Connector

⚠ **WARNING**: Do not perform IPV® treatment without saline solution or other liquids in the Phasitron® nebulizer to ensure airway hydration.

⚠ **WARNING**: Do not occlude the expiratory port.

⚠ **WARNING**: Strangulation Hazard. Exercise caution around small children.

See also Phasitron® 5 with Unified Connector Instructions for Use.

The patented Phasitron® 5 with Unified Connector with unique sliding venturi is an open system that dynamically responds to the resistance and compliance of the patient's lung during therapy.

The Phasitron® kit also includes:

- A mouthpiece as patient configuration option that fits on the patient port.

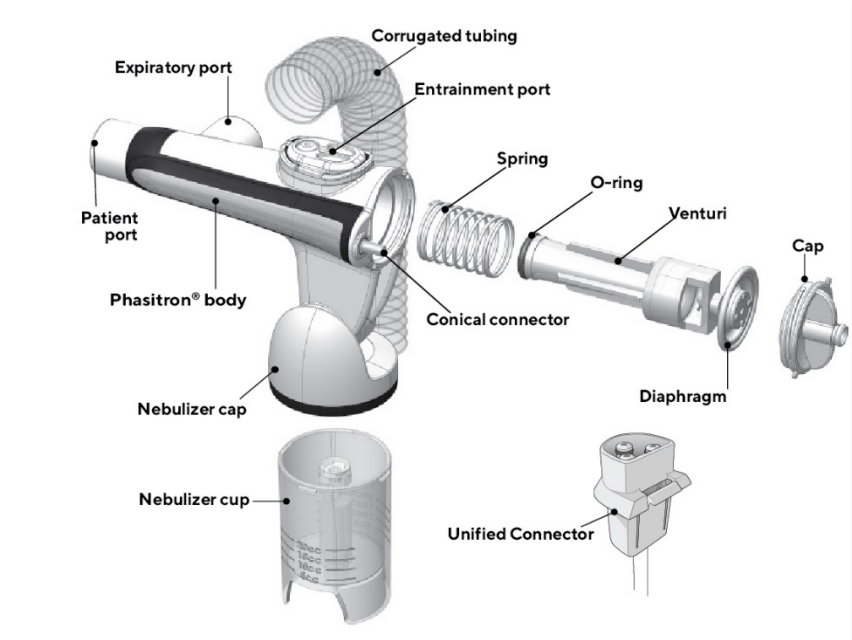
- A blue corrugated tube that fits on the expiratory port to direct condensation away from the patient.

Single patient multiple use

Type BF Applied Part

⚠ **WARNING**: Use only genuine Sentec/Percussionaire® parts and accessories that are specifically designed for use with the IPV® 1 device. Performance is not guaranteed with any third-party equipment.

Phasitron® Components



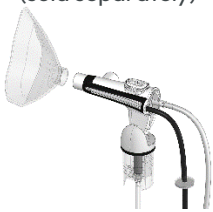
Phasitron® Configurations

The Phasitron® breathing circuit can be used to deliver IPV® therapy via mouthpiece, mask, or direct to endotracheal tube or tracheostomy (See Section 8).

Direct to airway
(endotracheal tube or tracheostomy)

With mouthpiece
(included)

With face mask
(sold separately)

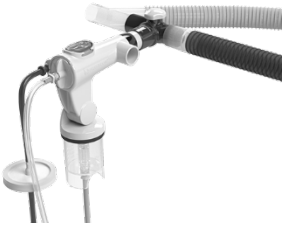


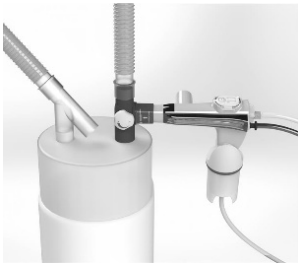
⚠ **WARNING**: For mask delivery of IPV® therapy, always make sure the mask is appropriately sized, covering the mouth and nose but not the eyes or overlapping the chin. Take special care with mask fit for patients under 5 years of age.

⚠ **CAUTIONS**:

- For patients under 5 years of age without an artificial airway, always use a mask instead of a mouthpiece to deliver IPV® therapy.
- When delivering IPV® therapy via mask, it is recommended to use a resuscitation mask or similar non-vented mask.

The Phasitron® breathing circuit can also be used to deliver IPV® therapy in-line with a ventilator using the In-Line Valve (See Section 9).



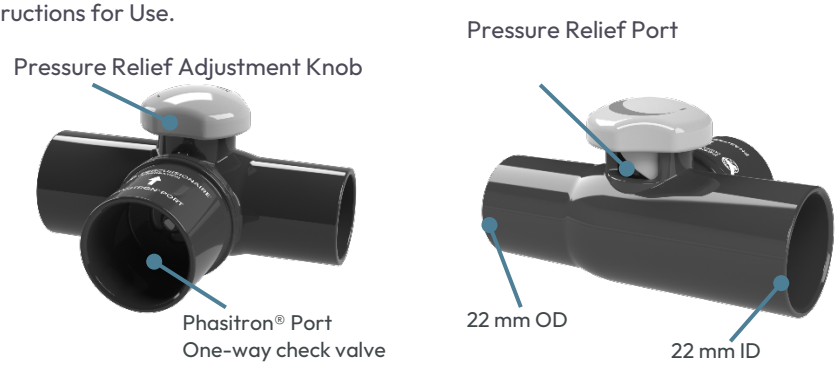


⚠ **WARNING:** Expiratory port on Phasitron® is to remain unobstructed throughout therapy when used in line or direct to airway.

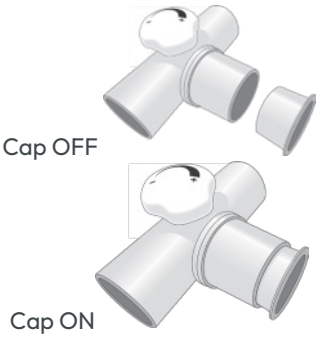
⚠ **CAUTION:** Ensure IPV® In-Line Valve is inserted into the inspiratory limb of the ventilator circuit.

In-Line Valve

See Section 9 for Treatment Workflow for in-line use as well as In-Line Valve Instructions for Use.



The In-Line Valve may be used to provide IPV® therapy in line with a ventilator.



The In-Line Valve is provided with a cap to close the Phasitron® port when IPV therapy is not being actively delivered.

7. Initial Setup & Assembly

This section provides instructions for the initial set up and testing of the IPV® 1 System.

Set up process:

- Step 1: Inspect incoming packaging.
- Step 2: Attach IPV® 1 to a Roll Stand.
- Step 3: Activate the Digital Display.
- Step 4: Connect the IPV® 1 to Gas Source (AIR or O_2).
- Step 5: Assemble and connect the Phasitron® breathing circuit.
- Step 6: Perform a Pre-Use Check.

⚠ **WARNING**: Complete the Pre-Use Check prior to initial use, and/or with Phasitron® breathing circuit replacement.

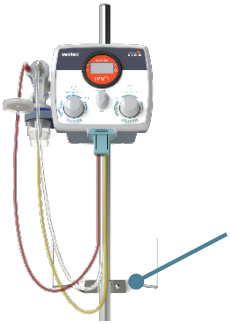
Step 1: Inspect the Device and Packaging

Do not use the device if:

- The packaging or sealing label on the IPV® 1 are damaged or appear to have been tampered with.
- The packaging has been exposed to environmental conditions outside of those specified for the IPV® 1.

In such a case, return the IPV® 1 to Sentec. Items must be shipped in the original packaging or in other packaging providing the same degree of protection.

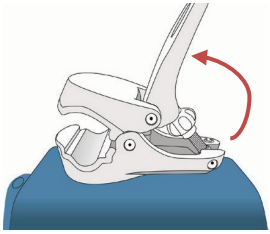
Step 2: Attach the IPV® 1 Device to a Roll Stand



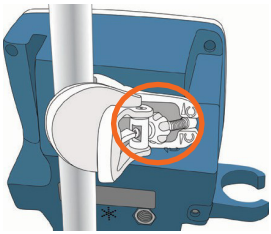
The IPV® 1 mounts onto a standard 19 mm to 38 mm (0.75 to 1.5-inch) hospital roll stand.

Stand Bracket Kit (Ref. Code A50289)

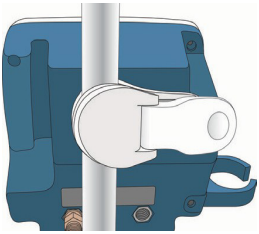
To attach the device onto roll stand pole:



1. Open the clamp



2. Use the adjuster nut to set to pole thickness.



3. Close and lock the pole clamp.

⚠ **CAUTION**: Risk of pinching and minor injury. When attaching the IPV® 1 onto a roll stand, take care to avoid placing hands or fingers near adjustable parts. Failure to do so may result in pinching or minor injury. Follow the instructions carefully.

Step 3: Activate the Digital Display

⚠ **WARNING**: The batteries used in this device may present a risk of fire or chemical burn hazard if mistreated. Do not recharge, disassemble, heat above 100°C (212°F) or incinerate. Replace with battery type recognized CR123A only, or Ref. Code B13350. Use of another type may present a risk of fire or explosion.

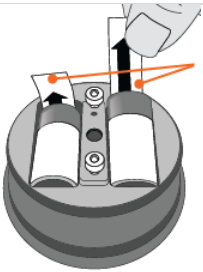
⚠ **CAUTION**: Do NOT install the Digital Display into the device until the POST test is complete and the screen is blank (indicating the Sleep mode).

⚠ **CAUTION**: The Digital Display has a USB serial port that is used for factory/ service use only.

When setting up the IPV® 1 device for the first time, the Digital Display must be removed to access the battery-disconnect tabs for removal.

NOTE: When the display powers ON for the first time, it will ensure the correct atmospheric pressure calibration at startup.

1. Twist the Digital Display to the left and remove from the housing.



2. Remove the batteries and the two battery-disconnect tabs.

3. Install the batteries back into display.

   NOTE: Positive terminals face the same direction.

4. The Power On-Self-Test (POST) will run automatically. The test should take about 30 seconds.

   ⚠ **CAUTION**: Do NOT insert any object into the measuring port.

5. When the POST ends, the Digital Display will enter Sleep Mode indicated by the screen going blank. The Digital Display is now ready to be reinstalled into the housing of the IPV® 1.

⚠ **CAUTION**: Do NOT install the Digital Display into the device until the POST test is complete and the screen is blank (indicating the Sleep mode)

6. Reinsert the Digital Display into the housing of the IPV®1 and twist to the right to secure.

Step 4: Connect the IPV® 1 to a Gas Source

The IPV® 1 requires gas source of 47-80 psi and with a flow rate of at least 35 lpm.

The device can be operated using either pressurized air or pressurized oxygen. A blender may also be used to customize oxygen concentrations.

NOTE: Low flow blenders may not provide sufficient flow rates.

To operate the IPV® 1 device using oxygen, connect one end of a hose with the appropriate fitting to the O_2 connector on the back of the IPV® 1 and the other end to the gas supply.

To operate the IPV® 1 device using air, connect one end of a hose with the appropriate fitting to the AIR connector on the back of the IPV® 1 and the other end to the gas supply.

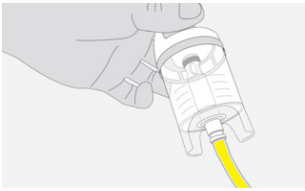
⚠ **CAUTION**: Do NOT spray any liquid or cleaning agent into the bleed port.

⚠ **CAUTION**: Do NOT block the bleed port.

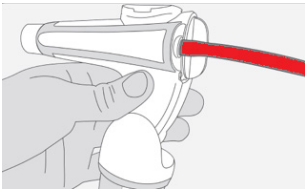
Step 5: Assemble the Phasitron®

NOTE: The connector of each tube will only fit to the coordinating connector on the Phasitron®.

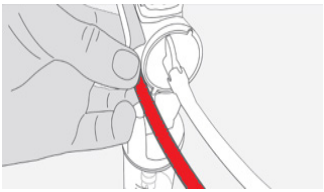
Connecting tubing to Phasitron®:



Connect the quick-connect fitting of the yellow tube to the nebulizer cup.

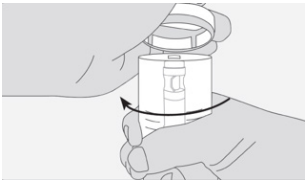


Press the red tube onto the conical connector at rear of the Phasitron®.



Connect the quick-connect fitting of the clear tube to the cap at the rear of the Phasitron®.

Adding saline solution or other liquids to the nebulizer cup:

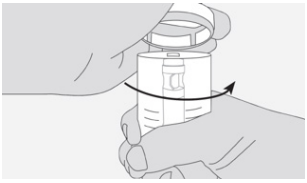


Opening the nebulizer:

1. Twist nebulizer cup as shown to open.
2. Place a maximum of 20 ml of saline solution or other liquids as indicated in the nebulizer cup.

NOTE: Saline solution or other liquid is not required to perform a Pre-Use Check.

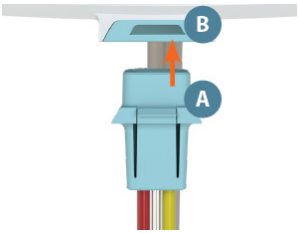
NOTE: Aerosol consumption: approximately 0.75 - 1 ml per minute.



Closing the nebulizer:

Apply the cap and twist the nebulizer cup as shown to close.

Connecting Phasitron® to IPV® 1:



Connect the breathing circuit to the IPV® 1 by depressing the tab on the Phasitron® Unified Connector (A) and inserting it into the Unified Connector port on the IPV® 1 device (B).

Step 6: Perform a Pre-Use Check

⚠ **WARNING**: Complete the Pre-Use Check prior to initial use of the IPV® 1 and with each new Phasitron® breathing circuit.

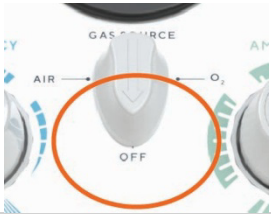
⚠ **CAUTION**: Do NOT use the device if any problems are noted. Contact a qualified service technician.

NOTE: In the event the IPV® 1 does not pass the pre-use, consult troubleshooting section within the IPV® 1 Instruction Manual. If the issue persists, contact Sentec for technical service.

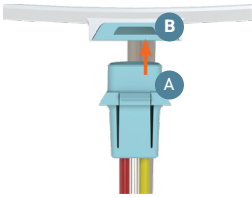
NOTE: Displayed values are for illustrative purposes only.

NOTE: Saline solution or other liquid is not required to perform a Pre-Use Check.

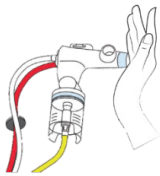
1. Ensure that the **GAS SOURCE** knob is in the **OFF** position, before connecting the IPV® 1 to the gas source supply from the wall (AIR or O_2).



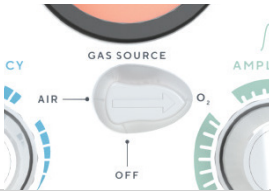
2. Connect the breathing circuit to the IPV® 1 by depressing the tab on the Phasitron® Unified Connector (A) and inserting it into the Unified Connector port on the IPV® 1 device (B).



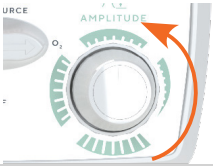
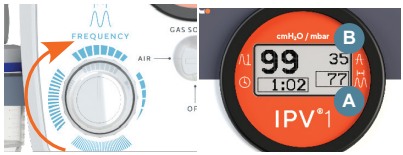
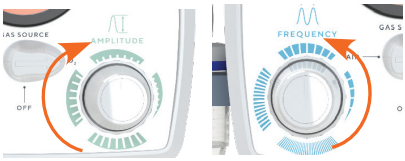
3. Press the patient port of the Phasitron® into a gloved palm for duration of test. Ensure free airflow of other Phasitron® openings.



4. Rotate the **GAS SOURCE** knob to the AIR or O_2 setting, depending on connection made in step 1.



Continued on the next page.

5. Rotate the **AMPLITUDE** knob fully to the left.	
6. Select a **FREQUENCY** between 300- 350 cycles/minute (A) and ensure that the MAP (B) on the Digital Display is between 20-60 cmH_2O.	
7. Rotate the **FREQUENCY** knob fully to the right to reach a range of 60-100 (A) and ensure the MAP (B) is between 25-60 cmH_2O.	
8. Return knobs to their recommended starting positions: rotate **AMPLITUDE** knob fully to the right (OFF) and **FREQUENCY** knob fully to the left (fastest frequency).	

8. Treatment Workflow

This section provides instructions for delivering IPV® therapy when not set up in-line with a ventilator. The workflow below is appropriate for mouthpiece, mask, or direct to artificial airway delivery of IPV® therapy. Treatment workflow for delivery of IPV® therapy in-line with a ventilator can be found in Section 9.

⚠ **WARNINGS**:

- Follow your institutional protocols for infection control.
- The Phasitron® breathing circuit is for single patient use. Do not reuse between patients.
- Do not occlude the expiratory port.
- Do not perform IPV® treatment without saline solution or other liquids in the Phasitron® nebulizer to ensure airway hydration.
- If the patient is showing signs of respiratory distress (e.g. wheezing, color change around the mouth, lips, or fingernail, or drop in oxygen saturation level, etc.), discontinue the IPV® therapy immediately. Reassess patient's condition and seek medical attention if there is no improvement.

1. Ensure the device knobs are in their correct starting positions:
    a. Rotate the AMPLITUDE knob fully to the right (OFF).
    b. Rotate the FREQUENCY knob fully to the left (highest/fastest).
    c. Point the GAS SOURCE knob to OFF.
2. While ensuring the GAS SOURCE knob is in the OFF position, connect the IPV® 1 to the appropriate gas source. (See Section 6.)
3. Prepare and connect the Phasitron® to the IPV® 1.
    a. Assemble the Phasitron® and fill the nebulizer cup with 15-20 ml of saline solution or other liquids as indicated. (See Section 6.)
    b. Connect the Phasitron® breathing circuit by depressing the tab on the Unified Connector and inserting it into the Unified Connector port of the IPV® 1 device.
4. If needed, perform a Pre-Use Check (See Section 6). Be sure to return knobs to their starting positions.

⚠ **WARNING**: Complete the Pre-Use Check prior to initial use of the IPV® 1 and with each new Phasitron® breathing circuit.

5. Assess and prepare the patient:

    a. Confirm desired patient interface (mouthpiece, mask, or direct to endotracheal tube or tracheostomy)
    NOTE: Treatment workflow instructions for In-Line Use are available in Section 8.

    b. Position the patient in an upright position as tolerated. If the patient is unable to sit upright, elevate the head and shoulders using pillows.
    NOTE: IPV® therapy can be performed in any patient position. Always use good clinical judgement.

    c. Assess the patient's heart and respiratory rate, and auscultate the patient for breath sounds. Always follow institutional guidelines.

6. Activate the IPV® 1 device by pointing the GAS SOURCE knob to the connected source (AIR or O_2).

    NOTE: The Digital Display will not awaken until the IPV® 1 detects back pressure from the Phasitron®.

7. Connect the Phasitron® to the patient via the desired interface (mouthpiece, mask, endotracheal tube, or tracheostomy)

    NOTE: For instructions specific to delivering IPV® therapy in-line with a ventilator, see Section 9.

8. Gradually increase the AMPLITUDE by turning the knob to the left to obtain adequate chest wiggle and aeration of pulses throughout lung fields. Auscultate to confirm.

9. As the patient acclimates to the therapy, decrease the FREQUENCY by turning the knob to the right, assessing for patient tolerance.

    NOTE: Both amplitude and frequency can be adjusted to increase or decrease the amount of chest wiggle.

10. Rotate between fast and slow frequencies every few minutes, continuing the therapy for 15-20 minutes or per hospital protocol, monitoring the patient throughout treatment and suctioning as necessary.

    NOTE: A trained healthcare professional must monitor the patient throughout the therapy.

11. Turn the IPV® 1 Gas Source knob to OFF, and return the knobs to their starting positions - Amplitude: fully to the right (OFF); Frequency: fully to the left (highest/fastest). Assess and attend to the patient as needed.
12. Disconnect the Phasitron® by depressing the tab on the Unified Connector and removing it from the Unified Connector port.
13. Disassemble, rinse or clean, and store the Phasitron® for the next treatment as described in Section 11.
14. Repeat treatment every 6-8 hours or according to hospital protocol or physician orders.

9. Treatment Workflow – In-Line Use

To prevent injury or equipment damage, read these warnings before assembly.

⚠**WARNINGS:**

- All persons providing IPV® treatment must be trained in the use of Sentec/Percussionaire® devices, and therapy on ventilated patients should exclusively be performed by healthcare professionals trained on how to operate the ventilator.
- Do NOT use the IPV® 1 System as a life support device.
- Supplemental oxygen must be prescribed for patients for whom it is indicated.
- The intended user must monitor the patient for exposure to excessive pressure, as there is no alarm or warning when exposure to excessive pressures is reached.
- An IPV® treatment mobilizes secretions. Drainage techniques (such as controlled coughing and suctioning) are particularly important for patients with reduced ability to spontaneously cough.
- The trained healthcare professional must instruct the patient to notify them if they experience increased shortness of breath, change in heart rate, or fatigue.
- Patients must be monitored for signs of respiratory distress during IPV® therapy in line with a ventilator.
- Patients may require suctioning to remove secretions from their upper airways during IPV® therapy in line with the ventilator. Ensure there is proper suctioning equipment available prior to delivering IPV® therapy in line with a ventilator.
- If the patient is showing signs of respiratory distress (e.g. wheezing, color change around the mouth, lips, or fingernail, or drop in oxygen saturation level, etc.), discontinue the IPV® therapy immediately. Reassess patient's condition and seek medical attention if there is no improvement.

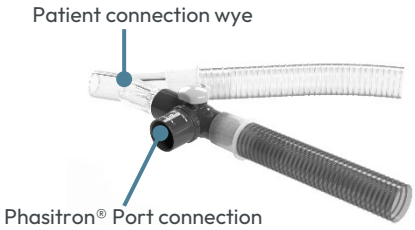
⚠ **CAUTIONS**:

- Read these instructions before setting up and using your IPV® In-Line Valve.
- The trained healthcare professionals should evaluate how their patients tolerate the treatment. Adjust the settings up or down as appropriate. Auscultation and observation of the mechanical vibrations of the chest and abdomen are primary indicators of effective treatment.
- It is recommended to utilize CO_2 measurements before and after treatments and assess PaO_2/ SpO_2 as secondary indicators.

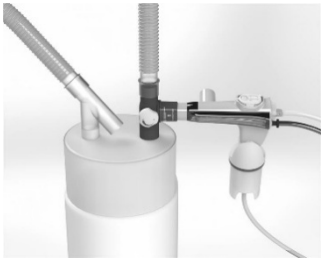
Initial Placement of In-Line Valve

1. Install the In-Line Valve in the patient circuit.
   The IPV® In-Line Valve may be inserted into the inspiratory limb of the ventilator circuit in either of the following configurations:

a.Close to the patient wye



b. Dry side of the humidifier



   a. Install the In-Line Valve as close to the patient wye as allowable.

   b. Install the In-Line Valve on the dry side of the humidifier.

      NOTE: If a passive humidification system is used, remove or bypass the Heat and Moisture Exchanger (HME) during therapy.

   ⚠ **WARNING**: Follow your institutional protocols before disconnecting the ventilator inspiratory limb prior to installation of IPV® In-Line Valve.

   ⚠ **WARNING**: Do not perform IPV® treatment without saline solution or other liquids in the Phasitron® nebulizer to ensure airway hydration.

   ⚠ **CAUTION**: Ensure IPV® In-Line Valve is inserted into the inspiratory limb of the ventilator circuit.

2. Insert provided cap into the Phasitron® port of the In-Line Valve, verify the Pressure Relief Port is closed, and ensure no leaks are present.

⚠ **WARNING**: Ensure Pressure Relief Port is closed when not providing IPV® therapy.
⚠ **CAUTION**: Allow ventilator to cycle two or more cycles with valve in place to ensure no leak is present.

Delivering IPV® Therapy

1. Ensure the device knobs are in their correct starting positions:
    a. Rotate the AMPLITUDE knob fully to the right (OFF).
    b. Rotate the FREQUENCY knob fully to the left (highest/fastest).
    c. Point the GAS SOURCE knob to OFF.
2. While ensuring the GAS SOURCE knob is in the OFF position, connect the IPV® 1 to the gas supply from the wall (AIR or O_2). See Section 6.
3. Prepare and connect the Phasitron® to the IPV® 1:
    a. Assemble the Phasitron® and fill the nebulizer cup with 15-20 ml of saline solution or other liquids as indicated. See Section 6.
    b. Connect the Phasitron® breathing circuit by depressing the tab on the Unified Connector and inserting it into the Unified Connector port of the IPV® 1 device.
4. If needed, perform a Pre-Use Check (See Section 6), being sure to return knobs to their starting positions.
   ⚠ **WARNING**: Complete the Pre-Use Check prior to initial use of the IPV® 1 and with each new Phasitron® breathing circuit.
5. Assess and prepare the patient:
    a. Position the patient in an upright position as tolerated. If the patient is unable to sit upright, elevate the head and shoulders using pillows. NOTE: IPV® therapy can be performed in any patient position. Always use good clinical judgement.
    b. Assess the patient's heart and respiratory rate, and auscultate the patient for breath sounds. Always follow institutional guidelines.
6. Note the current ventilator alarm and mode settings.
   NOTE: If adjustments are made to the ventilator when IPV® system is

connected in-line to accommodate the additional flow added to the ventilator circuit, ensure that original settings and alarms are restored after therapy is complete.

7. Activate the IPV® 1 device by pointing the GAS SOURCE knob to the connected source (AIR or O_2).
   NOTE: The Digital Display will not awaken until the IPV® 1 detects back pressure from the Phasitron®.

8. Remove the cap from the In-Line Valve Phasitron® port, replacing it with the Phasitron®.
   ⚠ **WARNING**: Expiratory port on Phasitron® is to remain unobstructed throughout therapy when used in line or direct to airway.

   NOTE: If a passive humidification system is used, remove or bypass the Heat and Moisture Exchanger (HME) during therapy.

   NOTE: You may see an increase in ventilator pressure readings when IPV® 1 is initially placed in-line.

   ⚠ **CAUTION**: Ventilator reported Mean Airway Pressures will increase slightly with the administration of IPV® in-line therapy with the ventilator. The trained healthcare professional needs to be aware of this effect and monitor the patient closely for any adverse side effects.

9. Gradually increase the amplitude by turning the knob to the left to obtain adequate chest wiggle and aeration of pulses throughout lung fields. Auscultate to confirm.

   NOTE: You may see an increase in ventilator pressure readings when IPV® is initially placed in-line.

   NOTE: A trained healthcare professional must monitor the patient throughout the therapy.

10. Allow the ventilator to complete at least two ventilator cycles, evaluating its response to the addition of IPV® therapy, and monitor and assess the patient.

11. As the patient acclimates to the therapy, decrease the FREQUENCY by turning the knob to the right, assessing for patient tolerance.

12. Modify the ventilator settings, alarms, and sensitivity, and adjust the Pressure Relief Port as needed. Auscultate to confirm pulses throughout lung fields are maintained.

    NOTE: Any ventilator adjustments during IPV® therapy in-line with a ventilator must be performed by a trained healthcare professional.

    NOTE: IPV® therapy can be delivered in-line in any ventilator mode, but generally pressure control mode is preferred.

    NOTE: If peak pressure alarms are frequent or higher than institutional protocol, consider gradually adjusting the Pressure Relief Port.

    NOTE: If delivering IPV® therapy in-line with the ventilator while in volume control mode, the additional flow from IPV® therapy may bring the PIP close to the high pressure limit alarm of the ventilator. The Pressure Relief Port on the In-Line Valve may be adjusted as needed to minimize alarms while maintaining chest wiggle.

13. Rotate between fast and slow frequencies every few minutes, continuing the therapy for 15-20 minutes or per hospital protocol, monitoring the patient throughout treatment and suctioning as necessary.

    NOTE: A trained healthcare professional must monitor the patient throughout the therapy.

    NOTE: Both amplitude and frequency can be adjusted to increase or decrease the amount of chest wiggle.

    NOTE: Faster/higher frequencies provide secretion mobilization and quickly improve gas exchange. Slower/lower frequencies loosen thicker secretions and help recruit the lung

    NOTE: If the ventilator alarms, ensure the trained healthcare professional who is managing the ventilator, assesses the patient and determines how to manage the alarm.

14. Turn the IPV® 1 Gas Source knob to OFF, return the patient to the ventilator settings noted in step 6, assess the patient and adjust as needed.

    NOTE: If adjustments are made to the ventilator when IPV® system is connected in-line to accommodate the additional flow added to the ventilator circuit, ensure that original settings and alarms are restored after therapy is complete.

15. Disconnect the Phasitron® from the In-Line Valve, and re-insert the cap into the Phasitron® port of the In-Line Valve, and ensure the Pressure Relief Port is closed. Leave the In-Line Valve in place in the ventilator circuit for the next IPV® treatment.

    NOTE: Replace the In-Line Valve whenever you replace the ventilator circuit or per hospital protocol.

    NOTE: The In-Line Valve is single-patient multiple use. Do not use for multiple patients.

    ⚠ **WARNING**: Follow your institutional protocols for infection control.

16. Disconnect the Phasitron® from the IPV® 1 by depressing the tab on the Unified Connector and removing it from the Unified Connector Port.

17. Disassemble, rinse or clean, and store the Phasitron® for the next treatment as described in Section 11.

18. Repeat treatment every 6-8 hours or according to hospital protocol or physician orders.

10. Treatment Considerations

Configurations

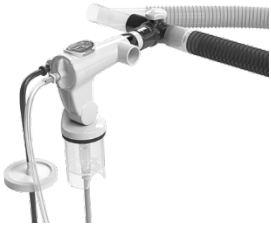
The Phasitron® breathing circuit can be used to deliver IPV® therapy via mouthpiece, mask, direct to endotracheal tube or tracheostomy, or in-line with a ventilator using the in-line valve.

Direct to airway
(endotracheal tube or tracheostomy)

With mouthpiece
(included)

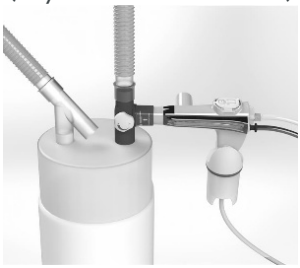
With face mask
(sold separately)

In-Line with Ventilator



In-Line Option A:
(Close to patient wye)

In-Line Option B:
(Dry side of the humidifier)



⚠ **WARNINGS**:

- Follow your institutional protocols for infection control.
- Do not perform IPV® treatment without saline solution or other liquids in the Phasitron® nebulizer to ensure airway hydration.
- Do not occlude the expiratory port.
- If the patient is showing signs of respiratory distress (e.g. wheezing, color change around the mouth, lips, or fingernail, or drop in oxygen saturation level, etc.), discontinue the IPV® therapy immediately. Reassess patient's condition and seek medical attention if there is no improvement.

- The trained healthcare professional must instruct the patient to notify them if they experience increased shortness of breath, change in heart rate, or fatigue.
- The Phasitron® breathing circuit is for single patient use, do not reuse between patients.

General Considerations:

- Faster/higher frequencies provide secretion mobilization and quickly improve gas exchange.
- Slower/lower frequencies mobilize thicker secretions and help recruit the lung.
- Rotate between faster and slower frequencies every few minutes or as indicated by the patient's response to therapy, lung condition, or type of secretions being suctioned.
- It is recommended to perform therapy for 15-20 minutes every 6-8 hours, or per provider orders.
- A trained healthcare professional must monitor the patient throughout the therapy.
- Evaluate patient tolerance throughout the treatment and adjust settings to maintain chest wiggle.

⚠ **CAUTION:** Care should be taken to appropriately suction secretions as they mobilize into the upper airways.

⚠ **CAUTION:** It is recommended to utilize CO_2 measurements before and after treatments and assess PaO_2/ SpO_2 as secondary indicators.

⚠ **CAUTION:** The trained healthcare professionals should evaluate how their patients tolerate the treatment. Adjust the settings up or down as appropriate. Auscultation and observation of the mechanical vibrations of the chest and abdomen are primary indicators of effective treatment.

Mouthpiece Considerations:

- Instruct the patient to inhale and exhale through the pulses until a visible chest wiggle is observed throughout the whole chest and/or percussions can be auscultated in all lung fields.
- Most patients will initially allow percussions to leak through their lips or nose, preventing an observable chest wiggle.
- Advise the patient to relax, taking normal (spontaneous) breaths through the pulses whenever they desire.
- Instruct the patient to keep their lips and cheeks tight.
- Some patients may require a nose clip to prevent venting from the nose.
- If the patient is unable to maintain a tight lip seal or prevent nose venting, mask delivery may be preferred to achieve desired treatment effect.

Mask Considerations:

⚠ **WARNING** For mask delivery of IPV® therapy, always make sure the mask is appropriately sized, covering the mouth and nose but not the eyes or overlapping the chin. Take special care with mask fit for patients under 5 years of age.

⚠ **CAUTION:** For patients under 5 years of age without an artificial airway, always use a mask instead of a mouthpiece to deliver IPV® therapy.

⚠ **CAUTION:** When delivering IPV® therapy via mask, it is recommended to use a resuscitation mask or similar non-vented mask.

Direct to Artificial Airway Considerations:

- For patients coming off respiratory support, consider starting treatment with some amplitude (i.e. the amplitude knob pointing straight up) then quickly titrate to target the MAP delivered by previous support settings.

⚠ **WARNING**: Expiratory port on Phasitron® is to remain unobstructed throughout therapy when used in line or direct to airway.

In-Line Use Considerations:

- IPV® therapy can be delivered in-line in any ventilator mode, but generally pressure control mode is preferred.
- If adjustments are made to the ventilator when IPV® system is connected in-line to accommodate the additional flow added to the ventilator circuit, ensure that original settings and alarms are restored after therapy is complete.
- If a passive humidification system is used, remove or bypass the Heat and Moisture Exchanger (HME) during therapy.
- Replace the In-Line Valve whenever you replace the ventilator circuit or per hospital protocol.

⚠ **WARNING**: Expiratory port on Phasitron® is to remain unobstructed throughout therapy when used in line or direct to airway.

⚠ **WARNING**: Do not occlude the expiratory port.

⚠ **CAUTION**: Ventilator reported Mean Airway Pressures will increase slightly with the administration of IPV® in-line therapy with the ventilator. The trained healthcare professional needs to be aware of this effect and monitor the patient closely for any adverse side effects.

11. Cleaning

Cleaning - IPV® 1 & Digital Display

⚠ **WARNING:** Only clean per approved cleaning procedure and with approved cleaning agents.

⚠ **CAUTIONS:**

- Do not allow liquids to access the control unit.
- Take care not to damage or scratch the Digital Display with fingernails, rings, or jewelry.
- Do not use detergents with ammonia, detergents with abrasives, steel wool, abrasive sponges, steel blades, or cloth with steel thread.
- Use of hydrogen peroxide-based cleaners can discolor the bezel of the Digital Display. However, this discoloration does not affect the performance, integrity, or usage of the IPV® 1 or the Digital Display.

Always clean the IPV® 1 between patients and when visibly soiled.

Perform a visual inspection to ensure soil has been removed.

Refer to document “IPV 1 Compatible Cleaning and Disinfection Solutions” (PAC_ENG_LIT_778) for an overview of tested and recommended products (visit global.sentec.com/manuals).

NOTE: As the number of available cleaning and disinfection agents varies from country to country and from hospital to hospital, it is not possible to provide a complete list of all suitable cleaning and disinfection agents. The listed name brand products may be substituted by other name brand products of equivalent composition. Refer to the instructions for use of the respective manufacturers for preparation, application, and disposal of the cleaning agents.

NOTE: Sentec makes no claims regarding the efficacy of the listed chemicals or processes as a means for controlling infection. Consult your hospital’s infection control officer or epidemiologist. To clean or sterilize mounted devices or accessory equipment, refer to the manufacturers’ instructions for the devices or equipment.

Cleaning - Roll Stand

⚠ **CAUTIONS:**

- Do not use strong chemicals or solvents such as acetone or trichloroethylene.
- Do not use steel wool or other abrasive material.
- Never submerge or allow liquids to enter the mounting assembly.
- Wipe away any excess cleaning agent using a water-dampened cloth; do not allow cleaning agent to sit on stand assembly.

Clean the roll stand with the most mild, non-abrasive solutions commonly used in the hospital environment (e.g. diluted bleach, ammonia, or alcohol solutions). Use a clean, lint-free, non-abrasive cloth for best results.

Dry the stand assembly thoroughly after cleaning.

We recommend testing cleaning solutions on a small, non-visible area of the mounting assembly to verify compatibility (will not damage stand).

Cleaning/Rinsing Phasitron®

⚠ **WARNINGS:**

- Rinse the Phasitron® after each use with water and allow to air dry. Visually inspect interior and exterior of all parts.
- The Phasitron® breathing circuit is for single patient use, do not reuse between patients.

After each use:

1. Disassemble the Phasitron® as described, see page 36.
2. Rinse the Phasitron® with water and allow to air dry as described, see page 37.
3. Reassemble the Phasitron® as described, see page 37.

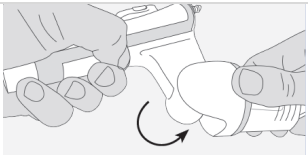
If the Phasitron® becomes visibly soiled or otherwise contaminated, clean the Phasitron® circuit as described, see page 38.

Disassembling Phasitron® for Cleaning/Rinsing

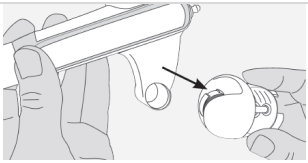
When disassembling the Phasitron® breathing circuit, visually inspect the exterior of all parts, including the tubing, for corrosion, discoloration, pitting, and missing O-rings.

To disassemble the Phasitron® before cleaning/rinsing:

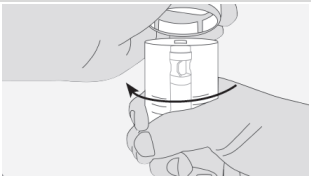
Make sure you have disconnected the tubing before cleaning.



1. Gently rotate the nebulizer cup towards the rear of the Phasitron® body until it stops.

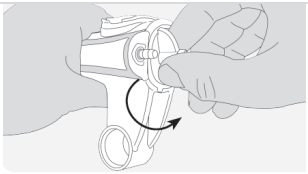


2. Pull the nebulizer cup to separate it from the Phasitron® body.

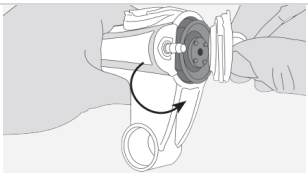


3. OPEN the nebulizer cup: While holding the nebulizer cap, twist the nebulizer cup to the left.

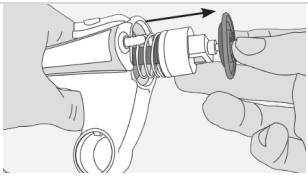
Discard any unused saline solution or other liquids in accordance with hospital/institutional protocol.



4. Unscrew the white cap on the rear of the Phasitron® body to remove it.



5. Remove the white cap.



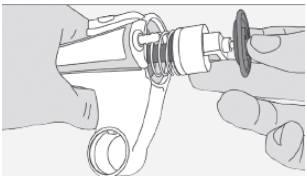
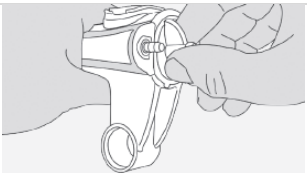
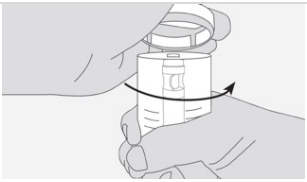
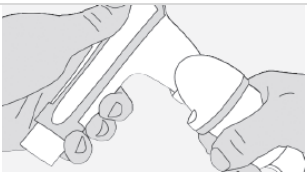
6. Remove the sliding venturi and the spring from the Phasitron® body.

Rinsing the Phasitron®

Rinse the Phasitron® components with water. Allow to air dry before reassembling.

Reassembling the Phasitron®

To reassemble the Phasitron® after cleaning/rinsing:

	1. Insert the sliding venturi and the spring into the Phasitron® body.
	2. Screw the white cap on the rear of the Phasitron® body until stop.
	3. CLOSE the nebulizer cup: While holding the nebulizer cap, twist the nebulizer cup to the right.
	4. By aligning the notch, insert the nebulizer cup into the Phasitron® body, then rotate to lock.

Overview of Cleaning the Phasitron®

⚠ **WARNINGS:**

- The breathing circuit is for single patient multiple use, do not disinfect and reuse the Phasitron® breathing circuit for more than one patient.
- Dirty or contaminated equipment is a potential source of infection. Never reuse single patient components or accessories between patients. The Phasitron® breathing circuit is for single patient use. Replace the entire circuit when it cannot be made clean 'as new.'

Optional cleaning is recommended maximum once per day as described below, but do not reuse for multiple patients.

Discard per facility protocol or after 30 days or 270 uses.

If the Phasitron® becomes visibly soiled or otherwise contaminated, clean the Phasitron® as described below.

To clean the parts (For disassembly, see page 36) of the Phasitron®:

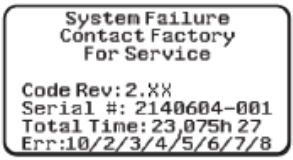
1. Thoroughly rinse each of the disassembled parts (except for the tubing and filter) under warm running water for approximately ten seconds.
2. Hand wash all parts of the Phasitron® (including accessories) in warm soapy water using a fragrance free Dawn® liquid soap.
   ⚠ **CAUTION**: Do not wash or submerge the hydrophobic filter or tubing. Use a clean, damp cloth to wipe the exterior of the tubing.
3. Rinse thoroughly with water.
4. Gently shake all washed parts to remove as much water as possible; allow to air dry or wipe dry with clean, lint-free cloth.
5. Wipe the exterior of the tubing using an approved alcohol-based cleaner.
6. Repeat cleaning steps if needed.

Once the Phasitron® is dry, reassemble (For reassembly, see page 37) and store in a sealable plastic bag in a dry, clean location.

12. Troubleshooting

⚠ **CAUTION:** If you notice any unexplained changes in the performance of the IPV® 1 or the Phasitron® breathing circuit (e.g. if either device makes unusual noise, or is dropped or damaged in any way), discontinue use and contact an authorized service technician.

Status of the device	Solution
Slow or no percussions	1. Check that the inlet gas source is properly connected. 2. Check the device to ensure the Gas Source is turned ON to the correct source, make sure Amplitude is NOT fullly rotated to the right (OFF), and adjust Frequency knob to the left for faster/higher rate. If the issue persists, contact Sentec for technical service.
Digital Display is OFF	The Digital Display must detect at least 7 cmH_2O in the patient monitoring (red) line to wake. 1. Turn the device ON and occlude the end of the Phasitron®, i.e. with a gloved hand. 2. Increase the Amplitude so a pressure can be registered. If the display still doesn't wake, check all connections. 3. Finally, check the batteries in the Digital Display. If the issue persists, contact Sentec for technical service.

Status of the device	Solution
Nebulizer not aerosolizing	1. Ensure there is liquid present in the nebulizer cup and check for flow out of the nebulizer. 2. Disconnect the yellow tubing and verify flow. 3. If flow is present, turn the Gas Source knob to the OFF position and reconnect the yellow tubing to the nebulizer cup. If the issue persists, contact Sentec for technical service.
Pre-Use Check, Pressure, and/or Frequency values are not met	Inadequate gas supply flow or pressure, ensure the device pressure specification for wall gas and flow are met, as defined in the Technical Specification section. If the issue persists, contact Sentec for technical service.
'System Failure' screen on the Digital Display 	Remove then replace the batteries (See section 15.) If the 'System Failure' screen recurs contact Sentec for technical service.
Battery depletion icon appears on the Digital Display 	Replace the batteries in the Digital Display by following the instructions below. See Section 15.

Contact your local Sentec partner for technical service.

For contact details, see Section 2.

13. Principles of Operation

The IPV® 1 device operates pneumatically, independent of electrical energy, delivering variable-frequency and variable-amplitude percussive flow to patients via a breathing circuit. The breathing circuit includes the Phasitron® 5 with Unified Connector, which utilizes a sliding venturi assembly to convey kinetic energy from the IPV® 1 and dynamically entrain additional gas or air as necessary, adjusting to the patient's compliance and resistance. The Phasitron® generates subtidal gas bursts with high flow and low pressure. These variable bursts create a continuous pulsed gas flow to the alveolar spaces, facilitating mucus and debris clearance. This percussive flow also allows gas to traverse narrowed bronchioles and reinflate collapsed alveoli, effectively reversing atelectasis. This process is entirely gas-driven, with no reliance on electrical power, and relies on the IPV® 1 for control and delivery.

14. Digital Display Modes

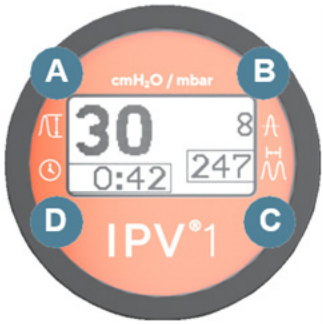
The Digital Display on the front panel of the IPV® 1 device provides feedback of:

A - Pulse Amplitude

B - Mean Airway Pressure (MAP)

C - Pulse Frequency

D - Session Timer



The Digital Display has six different operating modes:

Sleep, Wake, Active, Report, Fault, and Power-On Self-Test (POST).

Sleep Mode

In Sleep mode, the display is OFF, but the microcontroller continues to sample and calculate the pressure at the measuring port 5 times a second.

Over any 3-second period, if the pressure is greater than 7 cmH_2O/hPa at the Phasitron® patient-delivery port for more than 1 second, the display enters Wake mode.

Wake Mode

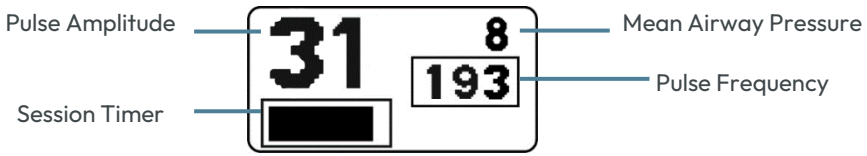
To wake up the display, ensure the IPV® 1 Amplitude is greater than 7 cmH_2O/hPa at the Phasitron® patient-delivery port for more than 1 second.

The display remains on for the first 15 seconds, showing the bar-graph timer. If session is stopped within 12 seconds, the display enters Report mode. After 15 seconds, the current session continues counting from 16 seconds, then turns into Active mode.

Active Mode

At 16 seconds, the display enters Active mode, a numeric display of:

- **Pulse Amplitude** - Calculated from the pressure measurements at the moment of instantaneous peak and trough amplitude averaged over 5 seconds.
- **Mean Airway Pressure (MAP)** - Is the average pressure sampled at the output of the Phasitron® over 5 seconds. At 100 samples per second, this is an average of 500 measurements.
- **Session Timer** – Displayed in minutes and seconds, the Session Timer displays the total usage time of the current session. The timer can display a maximum of 59 minutes and 59 seconds. If session has stopped for more than 5 minutes, the timer resets and starts over.
- **Pulse Frequency** – Represents the number of pulses per minute.

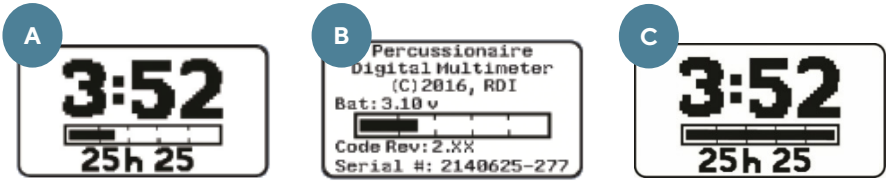


NOTE: To display the most recent session duration time, see Report mode below.

⚠ **CAUTION**: In some clinical situations pressure signal noise can create inaccuracies on the Digital Display frequency readings.

Report Mode

The Session Timer and the Total Usage Timer (A) are displayed for 2 seconds, followed by the System Information Page (B) for 2 seconds, alternating. The alternating page display continues for 5 minutes, or until session resumes and the display enters Active Mode.

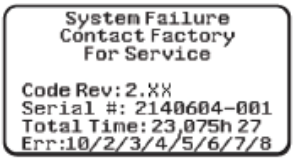


During the 5-minute period, a horizontal bar graph indicates the time by moving from left to right at a fixed rate. After 5 minutes of no usage, the system information page is no longer displayed, and the time display (C) flashes, 2 seconds on, 2 seconds OFF, for an additional 25 minutes. The display enters Sleep mode after 25 minutes.

NOTE: When the IPV® 1 is turned OFF, the measurements will drop to zeros after a few seconds.

Fault Mode

The display has both hardware and software fault detection. The dedicated hardware watchdog runs on an independent clock source and can continue to operate even if the main microprocessor's clock fails, or the microcontroller pauses in any way. The independent fault detection is reset each time a valid pressure reading (free of hardware and software errors) is obtained. The software fault detection watchdog detects when a software task fails to complete within a specified time, logs the error, and resets the processor.



In Fault mode, the display will show an error message on the display stating, "Contact Factory for Service."

The displayed information includes: the software revision, Digital Display serial number, the total usage time, and an error code for the exclusive use of the factory. (See System Failure Note below.)

In all other modes, the software continuously monitors the hardware for errors and verifies that each data sample is valid. If an error is detected, the software logs the error and reboots the processor. Rebooting allows the display to recover from a transient error. After reboot, the processor returns to the same mode it was in before the reboot. If more than one error is detected in any 10-second period, it is considered “fatal,” and the software enters Fault mode.

NOTE: If “System Failure” screen is displayed, remove batteries for 30 seconds. Replace batteries (note that positive terminals face the same direction) and wait 30 seconds until the screen turns OFF.

If POST mode runs correctly, the display may be used. If “System Failure” screen recurs, contact technical service.

NOTE: A fault may be triggered by a very high continuous pressure for more than 5 seconds during Wake and Active modes.

NOTE: The Digital Display will display a “System Failure” error message when pressures exceeding 150 cmH_2O or greater is detected for 5 seconds or longer.

NOTE: A fault will occur if the Digital Display is installed into the IPV® 1 during the POST check.

Fault Logging

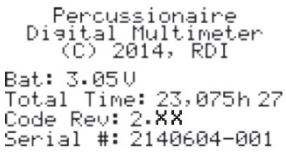
The software keeps track of several types of hardware and data faults specific to the display; it does not record patient-related data. All faults are logged in the microcontroller’s memory and are retained even if the batteries are removed. If multiple faults happen within 10 seconds of each other, the display stops normal operation and enters Fault mode. In this mode, a subset of the collected fault information is shown on the display. This data is intended for service use only.

The user can exit the Fault mode by removing and replacing the batteries. This resumes normal operation of the IPV® 1 display but does not erase the faults stored in memory or fix the problem that caused the fault.

NOTE: For instructions on how to change the batteries, see Section 15.

Power-On Self-Test Mode

The Power-On Self-Test (POST) is a succession of built-in diagnostic tests, specific to the display itself, performed by the Digital Display when batteries are installed. These diagnostic tests do not apply to the operation of the IPV® 1; those tests are covered in the Pre-Use Check Section (see Section 7).

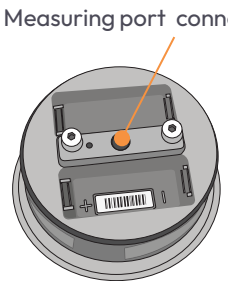


When batteries are installed in the Digital Display, the software displays the System Information page for 15 seconds. This page includes the battery voltage, total usage time, software revision, and serial number.

This start-up mode allows the software to perform tests on the hardware that are part of POST. If any errors are detected in POST, the display enters Fault mode.

The POST check requires that the measurement port be left disconnected and exposed to the atmosphere for the entire duration.

Rear view of Digital Display



⚠ **CAUTION**: Do NOT insert any object into the measuring port.

⚠ **CAUTION**: Do NOT install the Digital Display into the device until the POST test is complete and the screen is blank (indicating the Sleep mode.)

15. Maintenance & Service

IPV® 1 Control Unit

It is mandatory to perform an annual preventive maintenance service consisting of a thorough cleaning and a functional evaluation. Contact Sentec for technical service. (See Section 2):

⚠ **WARNING**: No modification of this equipment is allowed by any unauthorized personnel. Do not disassemble the device. Service the device by authorized personnel only. There are no field serviceable spare parts for service.

⚠ **CAUTION**: If you notice any unexplained changes in the performance of the IPV® 1 device or Phasitron® breathing circuit, e.g., if either device is making unusual sounds, or if either device is dropped or damaged in any way, discontinue use and contact authorized service personnel.

Roll Stand

Periodically inspect the mounting assembly fasteners. If needed, tighten, and adjust the fasteners.

Phasitron® 5 with Unified Connector

Service/repair is not available for the Phasitron® 5 with Unified Connector as these are single patient devices. Clean between uses as described but do not reuse for multiple patients. Discard per facility protocol or after 30 days or 270 uses.

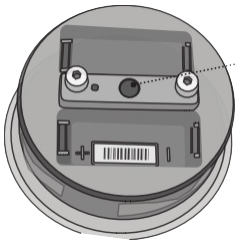
Replacing the Batteries of the Digital Display

Replace the batteries when the Digital Display shows the low battery indicator (Battery capacity is nearing depletion.)

⚠ **WARNING**: The batteries used in this device may present a risk of fire or chemical burn hazard if mistreated. Do not recharge, disassemble, heat above 100°C (212°F) or incinerate. Replace with battery type recognized CR123A only, or Ref. Code B13350. Use of another type may present a risk of fire or explosion.

⚠ **CAUTION**: The Digital Display has a USB serial port that is used for factory/ service use only.

Rear view of Digital Display



1. Twist the Digital Display to the left and remove from the housing.
2. Remove the old batteries.
3. Install two new CR123A batteries (Ref. Code B13350) with positive terminals facing the same direction.
4. The Power On-Self-Test (POST) will run automatically. The test should take about 30 seconds.

   NOTE: Leave the measuring port disconnected and exposed to atmosphere for the entire duration of the POST.
5. When the POST ends, the Digital Display will enter Sleep Mode indicated by the screen going blank. The Digital Display is now ready to be reinstalled into the housing of the IPV® 1.

   ⚠ **CAUTION**: Do NOT install the Digital Display into the device until the POST test is complete and the screen is blank (indicating the Sleep mode.)
6. Reinsert the Digital Display into the housing of the IPV®1 and twist to the right to secure.

16. Warranties

Limited Warranty

The manufacturer warrants to the initial purchaser that each new IPV® 1 will be free from defects in workmanship and materials for two years from date of first use (proof of delivery will be required). The manufacturer's sole obligation under this warranty is to, at its own choice, repair or replace any component – for which the manufacturer acknowledges the warranty coverage – with a replacement component.

Warranty Exclusions and System Performance

Sentec can neither guarantee nor verify product performance characteristics, nor accept warranty or product liability claims, if the recommended procedures are not carried out, if the product has been subject to misuse, neglect or accident, if the product has been damaged by extraneous causes, or if accessories other than those recommended by Sentec are used.

17. Incident Reporting

Report any serious incident that has occurred in relation to the IPV® 1 System to Sentec (regulatory.percussionaire@sentec.com) and/or to the competent authority of the country where the incident occurred. If you are not sure whether an incident is a reportable event, you can contact Sentec first.

18. Technical Specifications

IPV® 1 Control Unit Specifications

Dimensions (W x H x D)	23.79 cm x 18.31 cm x 17.53 cm (9.4” x 7.2” x 6.9”)
Weight	1.45 kg (3.2 lb)
Phasitron® Holder Safe Working Load	4.54 kg (10 lb)
Operating range	18°C to 26°C (64.4°F to 78.8°F)
Storage and Transport	-30°C to +60°C (-22°F to 140°F) Up to 75% relative humidity
Atmospheric Pressure	Operating: 700 to 1060 hPa Storage: 500 to 1100 hPa
Gas Source	Wall Gas: 47-80 psi, 3.24-5.5 bar Flow: >35 lpm
Pulse interval ratio	Automatic
Run Time	Non-continuous
Aerosol Flow	25 lpm (0.75 - 1 ml per minute liquid consumption rate)
Pulse Amplitude	0 to 50 cmH_2O/hPa at 100 cycles per minute using Siemens®-style 1L test lung
Pulse Frequency	100-300 pulses per minute * Frequency dependent on Gas Supply Pressure and Amplitude setting.

Mean Airway Pressure	0-50 cmH_2O
Sound	During operation, the system will generate no more than 65dBA at a distance of 0.3m (12 inches)
Required Maintenance	Annual preventive maintenance
Expected Useful Life	5 years
Essential Performance	• Frequency not to go below 60 cycles per minute. • Minimum amplitude pressure not to exceed 7cmH_2O.
Digital Display	
Pressure Range	1-99 cmH_2O/hPa
Pressure Resolution	±1 cmH_2O/hPa
Pressure Accuracy	Greater of ±0.5% of reading or 1 cmH_2O/hPa
Battery Type	Display uses (2) CR123A batteries (Ref. code B13350)
Battery Duration	3,250 Operational hours at 35°C (95°F)
Device Classification	
Degree of Protection against Electrical Shock	Type BF Applied Part
Patient Applied Part	Phasitron® 5 UC, Face Mask, Mouthpiece, or In-Line Valve
Mode of Operation	Intermittent (20 minutes ON - 30 Minutes off)

Accessories	
Breathing Circuit	Phasitron® 5 with Unified Connector (Ref. Code P5-UC)
In-Line Valve	IPV® In-Line Valve (Ref. Code P5-TEE)
Roll stand	Ref. Code B13611
Stand Bracket kit	Ref. Code A50289

The IPV® 1 has undergone validation for performance with the following ventilator: Medtronic PB-980. The IPV® 1 may be used with other ventilators which haven't been validated but it is advised to closely monitor the patient.

See also the Phasitron® 5 with Unified Connector Instructions for Use for technical specifications.

See also the In-Line Valve Instructions for Use for technical specifications.

19. Compliance & Disposal

Standards

This device is designed to conform to the following standards:

- IEC 60601-1: Medical electrical equipment – Part 1: General requirements for safety
- IEC 60601-1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests
- IEC 62304: Medical device software — Software life cycle processes
- IEC 60601-1-6: Medical electrical equipment – Part 1-6: General requirements for safety and essential performance - Collateral Standard: Usability
- IEC 62366-1: Medical devices — Part 1: Application of usability engineering to medical devices
- ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing (Biocompatibility)
- ISO 18562-1 Biocompatibility Evaluation of Breathing gas Pathways in Healthcare Applications - Part 1 Evaluation and Testing within a Risk Management Process
- ISO 14971: Application of Risk Management for Medical Devices

WEEE Disposal:

European consumers are obliged by law to dispose of Waste Electrical and Electronic Equipment (WEEE) according to the WEEE Directive 2012/19/EU.

1. All electrical and electronic waste must be stored, collected, treated, recycled, and disposed of separately from other waste.
2. Consumers are obliged by law to return electrical and electronic devices at the end of their service lives to the public collection points set up for this purpose or point of sale. Details to this are defined by the national law of the respective country.
3. The batteries of the Digital Display are not rechargeable. Dispose of the old batteries in accordance with local, state, federal, and international laws.

Manufacturer's Declaration - Electromagnetism

The following tables contain the manufacturer's declarations for the IPV® 1 System electromagnetic susceptibility, electromagnetic emissions, electromagnetic immunity, recommended separation distances between IPV® 1 System and portable and mobile RF communications equipment, and a list of compliant cables.

Environment of Use: The device is intended for use in institutional/hospital environments. The IPV® 1 System does not connect to hospital/institutional mains or network and is solely pneumatic and battery operated.

⚠ **WARNING**: Portable and mobile RF communications equipment can affect the performance of the IPV® 1 System. Use the IPV® 1 System according to the information contained in this addendum and the Instruction Manual.

⚠ **WARNING**: The IPV® 1 System should not be used adjacent to or stacked with other equipment, except as specified in the Instruction Manual. If adjacent or stacked use is necessary, the IPV® 1 System should be observed to verify normal operation in the configurations in which it will be used.

⚠ **WARNING**: Avoid exposure to known sources of EMI (electromagnetic interference) such as diathermy, lithotripsy, electrocautery, RFID (Radio Frequency Identification), and electromagnetic security systems such as anti- theft/electronic article surveillance systems, metal detectors. Note that the presence of RFID devices may not be obvious. If such interference is suspected, reposition the equipment, if possible, to maximize distances.

Electromagnetic Susceptibility

The IPV® 1 System complies with the requirements of IEC 60601-1-2 (EMC Collateral Standard), which includes E-field susceptibility and ESD requirements. However, even though the device is compliant at the levels of immunity specified in the standard, certain transmitting devices (cellular phones, walkie talkies, cordless phones, paging transmitters, etc.) emit radio frequencies that could interrupt operation if located in a range too close to the IPV® 1 System. It is difficult to determine when the field strength of these devices becomes excessive. Practitioners should be aware that radio frequency emissions are additive, and that the IPV® 1 System must be located a sufficient distance from transmitting devices to avoid interruption. Consult with your institution's biomedical engineering department in case of interrupted operation, and before relocating any life support equipment.

⚠ **WARNING**: Do not operate the IPV® 1 System in a Magnetic Resonance Imaging (MRI) environment.

Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment Guidance:
RF Emissions CISPR 11	Group 1	The IPV® 1 System uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

Emissions Test	Compliance	Electromagnetic Environment Guidance:
RF Emissions CISPR 11	Class A	The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR11 Class A). If it is used in a residential environment (for which CISPR 11 Class B is normally required) this equipment might not offer adequate protection to radio frequency communication services. The user might need to take mitigation measures, such as relocating or re-orientating the equipment. This device complies with 47 CRF 15 Federal Communications Commission Rules (FCC) for radio frequencies devices. (1) the IPV® 1 does not cause harmful interference received, including interference that may cause undesired operation. Changes or modifications not expressly approved by Sentec can void the user authority to operate the device.

Electromagnetic Immunity

Immunity Test	Compliance level	Electromagnetic Environment Guidance:
Electrostatic Discharge (ESD) IEC 61000-4-2	+ 8 kV contact + 2, 4, 8 and 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Electromagnetic Proximity

Proximity Test	IEC 60601 Test Level	Compliance level	Electromagnetic Environment Guidance:
IEC 61000-4-3	385 MHz: 27 V/m @ 18 Hz pulse modulation	27 V/m	The IPV® 1 System is suitable for the electromagnetic environment of typical hospital settings.
	450 MHz: 28 V/m @ FM modulation	28 V/m	
	710 MHz, 745 MHz, 780 MHz: 9 V/m @ 217 Hz pulse modulation	9 V/m	
	810 MHz, 870 MHz, 930 MHz: 28 V/m @ 18 Hz pulse modulation	28 V/m	
	1720 MHz, 1845 MHz, 1970 MHz: 28 V/m @217 Hz pulse modulation	28 V/m	
	2450 MHz: 28 V/m @217 Hz pulse modulation	28 V/m	
	5240 MHz, 5500 MHz, 5785 MHz: 9 V/m @ 217 Hz pulse modulation	9 V/m	

20. Terms & Abbreviations

Term / Abbreviation	Definition
Active Mode	The Digital Display actively measures the pressure, computes the parameters, and displays them on the display. The Active mode display metrics include pulse frequency and mean airway pressure.
Airway Clearance Therapy (ACT)	Airway clearance technique to clear the respiratory airways of mucus and other secretions from the lungs.
cmH_2O	Centimeters of water – unit of measurement for pressure.
Electromagnetic Interference (EMI)	Unwanted noise or interference in an electrical path or circuit caused by an outside source. EMI can cause electronics to operate poorly, malfunction, or stop working completely.
Fault Detection	The Digital Display has both hardware and software fault detection, a dedicated watchdog that runs on an independent clock source and can continue to operate even if the main microprocessor's clock fails or if the microcontroller pauses in any way.
Fault Logging	The Digital Display software keeps track of several types of hardware and data faults. All faults are logged into the microcontroller's memory and are retained even if the batteries are removed.
Fault Mode	The Digital Display shows an error message on the display stating, "System Failure" and "Contact Factory for Service," and stays in this mode until both batteries are removed. The displayed information includes the software revision, Digital Display serial number, total usage time, and an error code.
ID	Inside Diameter

Term / Abbreviation	Definition
In-Line Valve	Accessory for IPV® (Intrapulmonary Percussive Ventilation) therapy to patients while assisted by Conventional Mechanical Ventilation (CMV), when direct connection to IPV® is not indicated.
IPV® therapy	Intrapulmonary Percussive Ventilation: type of airway clearance therapy provided by a device that delivers air and aerosol to the lungs at frequencies of 100 to 300 cycles per minute.
Lung Recruitment	Opening up collapsed alveoli to improve oxygenation.
Mean Airway Pressure (MAP)	The average pressure sampled at the output of the Phasitron® over 5 seconds.
Magnetic Resonance Imaging (MRI)	Magnetic Resonance Imaging: MRI scanners use strong magnetic fields, magnetic field gradients, and radio waves to generate images of the organs in the body.
Nebulizer	A device for producing a fine spray of liquid, used, for example, for inhalation.
OD	Outside Diameter
Phasitron® Breathing Circuit	Refers to the entire single patient interface or kit known as the Phasitron® 5 with Unified Connector, including mouthpiece, tubing, and connectors.
Phasitron® Patient Port	The part of the Phasitron® breathing circuit that delivers percussive pulses to the patient.
Power-On Self-Test (POST)	The initial set of diagnostic tests performed by the Digital Display right after it's powered on, with the intent to check for any hardware related issues. During this test, the display shows the system information page.
Pulse Amplitude	Calculated from measuring the difference between the peak and minimum pulse pressure, averaged over 5 seconds.

Term / Abbreviation	Definition
Pulse Frequency	Represents the number of pulses per minute.
Radio Frequency Identification (RFID)	A technology that uses radio waves to transfer data from an electronic tag, called RFID tag, attached to an object, through a reader for the purpose of identifying and tracking the object.
Report Mode	Mode that displays the session timer and total usage time, alternating with the system information page.
Session Timer	Total usage time of the current session up to 59 minutes and 59 seconds (59:59).
Sleep Mode	The display is OFF, but the Digital Display continues to measure pressure at the measuring port. If the Digital Display senses the preset startup pressure, it becomes active.
System Failure	When the Digital Display is in Fault mode, an error message is displayed stating “System Failure” and “Contact Factory for Service.” The display stays in Fault mode until both batteries are removed.
System Information Page	When the Digital Display is in Report mode, the System IPV® 1 System Instruction Manual 47 Information page is displayed for 2 seconds, alternating with the Session Timer. This page displays the copyright, battery life, software revision and the serial number.
Total Usage timer	Displays the total amount of time (shown in HH:MM) the device has been operated.
Transient Error	An error that will resolve itself.
UC	Unified Connector
Wake Mode	After the POST test, the Digital Display enters Wake mode and is active for the first 15 seconds of use.

Care with Confidence

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