sentec.

IPV® 1 System
Instruction Manual

Percussionaire®, IPV®, TRUE-IPV® and Phasitron® are registered trademarks.

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

This manual was originally released and supplied in English. For a list of available translations, contact customerservice.uk@sentec.com. This manual may be revised or replaced at any time. Ensure this manual is the most current applicable version. To obtain the most recent version, contact Sentec customerservice.uk@sentec.com or visit sentec.com.

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

Intended Purpose/Populations and Indications for Use may vary per global region. Please contact your site's product representative or customer service for any questions.

Table of Contents

1. Introduction

The IPV® 1 System is intended for patients needing an Airway Clearance Therapy (ACT) for mobilization of secretions, lung expansion therapy, or the treatment and prevention of pulmonary atelectasis.

The IPV® 1 System is designed specifically for non-continuous institutional/hospital use to provide airway clearance and lung recruitment therapy. The system comprises a controller unit and breathing circuit called a Phasitron® 5 UC. The patented Phasitron® 5 UC with unique sliding venturi is an open system that dynamically responds to the resistance and compliance of the patient lung during therapy.

About This Instruction Manual

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 instructions given and to keep the instructions for use near the device to ensure correct operation. If the safety instructions are not followed, the patient may be at risk.

This section contains the following:

- Related documents and additional resources
- Symbol definitions
- Safety information, including warnings and cautions
- Technical assistance information

Related Documents and Resources

The current version of this manual, specifications, clinical studies, and additional information is available at:
customerservice.uk@sentec.com

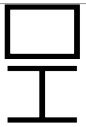
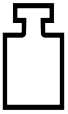
Glossary of Symbols

The table below summarizes 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
	Manufacturer	Indicates the medical device manufacturer.
	Date of Manufacture	Indicates the date when the medical device was manufactured.
	Country of Manufacture	Identifies the country of manufacture of products. (CC to be replaced by country code.)
	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.
	Catalogue number	Indicates the manufacturer's catalogue 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.
	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.
	Keep dry	Indicates a medical device that needs to be protected from moisture.
	Temperature limit	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 indicated adjacent to the upper and lower horizontal lines).

Symbol	Name	Description
	Atmospheric pressure limitation	Indicates the atmospheric pressure limits to which the medical device can be safely exposed.
	Single patient - multiple use	Indicates a medical device that may be used multiple times (multiple procedures) on a single patient.
	Mandatory action: refer to Instruction manual	Indicates that the instruction manual must be read.
	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.
	Prescription only	Caution: Federal Law (U.S.) restricts this device to sale by or on the order of a physician.
	Unique device identifier	Indicates a carrier that contains unique device identifier information.
	CE Marking	Indicates that the device complies with applicable EU regulations.
	European Representative	Indicates the authorized representative in the European Community/European Union.
	MR Unsafe	An item which poses unacceptable risk to the patient, medical staff, or other persons within the MR environment.
	Do not block bleed port	Indicates the instruction of not blocking the bleed port on the back of the control unit.
	WEEE	Indicates that the product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling.
O_2	Oxygen	Indicates gas source of Oxygen.
AIR	Air	Indicates gas source of air.

Glossary of Symbols, continued

Symbol	Name	Description
	Caution	General Caution - Indication that caution is necessary when operating or cleaning the device to avoid undesirable circumstances.
	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.
	Weight of Medical Equipment	Indicates the weight of the medical equipment including the control unit, accessories, patient circuits, and the pole clamp assembly.
	Safe Working Load	Indicates the allowable weight limits which the medical device or accessory can safely support.
	Do Not Spray	Indicates liquids or cleaners should not be sprayed into specified area.

Safety Information

This section contains important information for users. Please 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** indicates the possibility of injury, death, or other serious adverse reaction associated with the use or misuse of the device.

General Warnings	• Do not use the IPV® 1 System as a life support device. Supplemental oxygen must be prescribed for patients for whom it is indicated, and the O_2 saturations should be monitored. • 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. • The intended user must continue to monitor the patient for progression of symptoms and re-evaluate the indications for therapy. • Continuous clinical supervision is mandatory during treatment of children (2 years old and older), disabled patients, patients with an artificial airway, or an unresponsive patient. • The IPV® 1 System cannot be used in an MRI environment. • The cell used in this device may present a risk of fire of chemical burn hazard if mistreated. Do not recharge, disassemble, heat above 100°C (212°F), or incinerate. Replace cell with type recognized CR123A only, or Sentec Part #B13350. Use of another cell may present a risk of fire or explosion.
Alteration/Assembly	Carefully follow assembly instructions outlined in this instruction manual. Assembly deviation/alteration could cause the IPV® 1 to malfunction.
Before Using Equipment	Before activating the IPV® 1, be sure to complete pre-checks to ensure proper operation.
Breathing Circuits	• Do not substitute any other breathing circuit for the Phasitron® 5 UC breathing circuit. • Do not change the configuration of the breathing circuit. • The Phasitron® 5 UC breathing circuit is specifically designed for use with the IPV® 1. • Do not use any third-party circuits as their use has not been tested by Sentec; performance and safety cannot be guaranteed.
Patient Interface	Do not use a mouthpiece during IPV® 1 therapy for patients less than five years of age. Make sure the mask is appropriately sized, covering the mouth and nose but not the eyes, and not overlapping the chin. Do not affix mask to patient.
Guidelines	Instructions in the manual are suggested guidelines for trained respiratory therapists 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.
Infection Control	Dirty or contaminated equipment is a potential source of infection. Never attempt to reuse single-patient components or accessories between patients. The Phasitron® 5 UC breathing circuit is for single patient use. Replace the entire circuit when it cannot be made clean "as new."

⚠ Warnings, continued

Pre-Use Checks	Complete pre-use checks before starting therapy on a patient. Do not use the device if any problems are noted. Contact a qualified service technician. Failure to comply could cause injury or death to the patient.
Setup	Ensure the patient circuit is oriented correctly. Carefully follow setup directions given in the instructions for use.
Residual Risk/ Information to the Patient	The patient must notify the physician and the RN (Registered Nurse) or the RRT (Registered Respiratory Therapist) if they experience increased shortness of breath; significant changes in heart rate or rhythm, blood pressure, or skin color; marked diaphoresis; fatigue; or emesis.

⚠ Precautions

A **CAUTION** indicates the possibility of a problem with the device associated with its use or misuse, such as a device malfunction, device failure, device damage, or other property damage.

Cautions/Precautions	• All persons providing IPV® treatment must be trained in the use of Sentec devices. • Therapists should evaluate how their patients tolerate the treatment. 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 parts and accessories.
Cleaning and Disinfection	IPV® 1 Controller: • Clean as required. Do not spray any liquid directly onto the device. • Only use non-abrasive cotton cloths, cleaning wipes, and paper towels. • Use any cleaning and disinfection solutions and products with caution. • Use only the cleaning and disinfecting procedure recommended by the manufacturer. Breathing Circuit: • Disconnect tubing from Phasitron® 5 UC before cleaning. • Do not wash or submerge the hydrophobic filter or tubing harness. Use a clean, damp cloth to wipe the exterior of the tubing harness. • Use of cleaning methods not outlined in these instructions for use may damage parts of the Phasitron® 5 UC breathing circuit kit.
Clinician Training	All persons providing IPV® therapy must be trained in the use of the IPV® 1, the functions, and the settings. All persons operating the IPV® 1 must read and understand the manual before using the device.
Do NOT Cover Device	Do not cover the IPV® 1 during use. Do not place objects on top of the IPV® 1.
Malfunctions	Do not use the device if any problems are noted. Contact qualified service technician.

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.

Technical Assistance

For technical information and assistance, to request service, or to order parts, use one of the following methods of contact:

- Email: customerservice.uk@sentec.com

2. Indications for Use/Intended Purpose

The IPV® 1 System is intended to be used to augment ventilation of spontaneously breathing adult and pediatric patients within the hospital/clinical/physician's office environment to provide Airway Clearance Therapy (ACT) by clinically trained professionals or respiratory technicians.

The IPV® 1 control unit is a reusable controller intended to be used exclusively with the single-patient Phasitron® 5 UC breathing circuits. The IPV® 1 controller and the Phasitron® 5 UC are sold non-sterile.

Intended Patient Population

ACT using the IPV® 1 System is intended for adult and pediatric (2 years old and older) populations.

Intended Use Environment

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

Intended User Profile

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

Indications for Use

The IPV® 1 System is used where Airway Clearance Therapy (ACT) is indicated. ACT is indicated for mobilization of secretions, lung expansion therapy, and the treatment and prevention of pulmonary atelectasis.

Expected Clinical Benefits of IPV®

The IPV® 1 System is a form of IPV® used for ACT. During operation, the system provides a continuous, dense aerosol mist to reduce the adhesive and cohesive forces of retained airway secretions. IPV® is used in many respiratory conditions where the following clinical and/or physiological benefits are desired:

• Lung recruitment	• Improved lung function
• Improved gas exchange	• Increased secretion mobilization
• Decreased work of breathing	• Decreased Length of Stay
• Reduced escalation of ventilatory support	

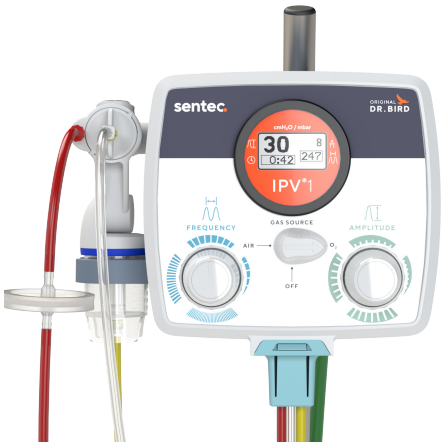
Contraindications

• Untreated tension pneumothorax	• Untrained or unskilled operator
• History of pneumothorax	• Myocardial infarction
• Pulmonary hemorrhage	• Vomiting
• Recent pneumonectomy (without functioning chest tube)	• Pulmonary air leak

3. Principles of Operation

The IPV®1 device operates pneumatically, independent of electrical energy, delivering variable-frequency and variable-amplitude oscillatory ventilation to patients via a breathing circuit. This circuit includes the Phasitron® 5 UC, which utilizes a sliding venturi assembly to convey kinetic energy from the IPV® 1 and dynamically entrain additional oxygen or air as necessary, adjusting to the patient's compliance and resistance. The Phasitron® 5 UC 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 via a counter-current effect. The smooth, laminar 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.

The aim of airway clearance therapy is to reduce airway obstruction caused by secretions occupying the airway lumen and so help to prevent respiratory tract infections, and to re-expand collapsed areas of the lung, thus supporting improved gas exchanges and decreased inflammatory response.



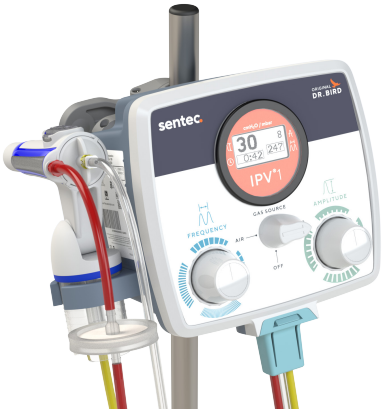
4. Description

The IPV® 1 System consists of devices which provide Intrapulmonary Percussive Ventilation (IPV®), a form of Airway Clearance Therapy (ACT).
The IPV® therapy system is designed specifically for noncontinuous institutional/hospital/physician's office use and 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. The breathing circuit with unique sliding venturi is an open system that dynamically responds to the resistance and compliance of the patient lung during therapy.

ACT techniques all have a series of different physiological mechanisms used for "unblocking" the obstruction:

- Increase of expiratory flow
- Oscillation of the airflow
- Increase in gas exchange

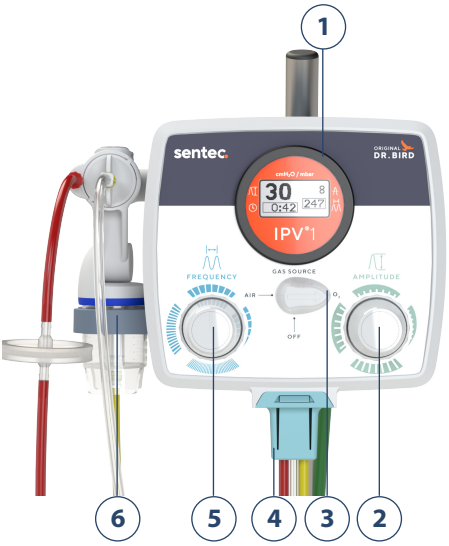
IPV® 1 System



IPV® 1

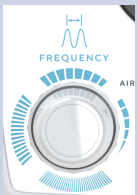
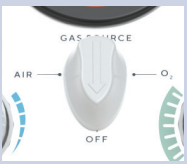
Phasitron® 5 UC

Front Panel



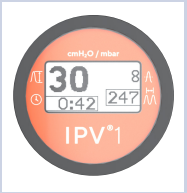
1. Digital Display
2. AMPLITUDE Adjustment Knob
3. GAS SOURCE Selector Knob
4. Breathing Circuit Connector
5. FREQUENCY Adjustment Knob
6. Phasitron® 5 UC Holder

Control Functions

Control	Functions
	**FREQUENCY** determines the rate of high-frequency percussive pulses delivered to the patient.
	**AMPLITUDE** determines the pressure delivered to the patient.
	**GAS SOURCE** selects air or oxygen or turns IPV® 1 off to stop therapy.

Control Functions, continued

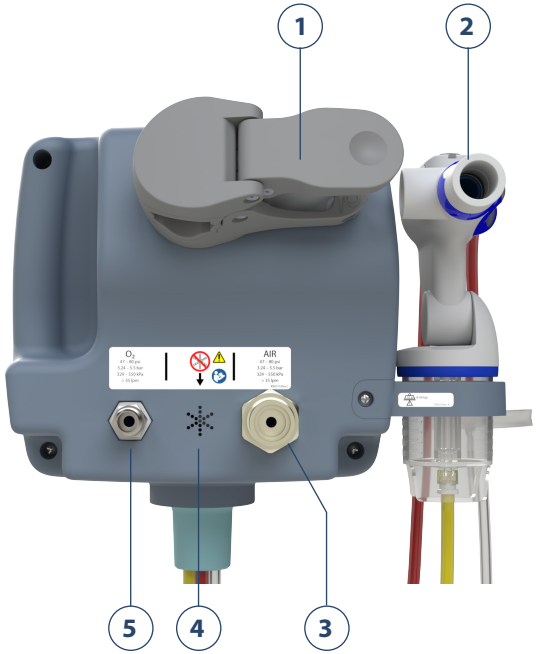
4.



Digital Display reads and displays Mean Airway Pressure (MAP), Pulse Frequency, Session Time, and Pulse Amplitude.

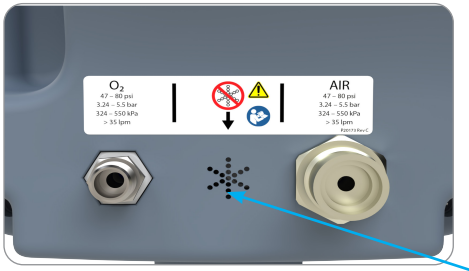
NOTE: *Refer to Chapter 5, Digital Display.*

Back Panel



1. Pole Clamp
2. Phasitron® 5 UC
3. AIR Connector
4. Bleed Vent
5. Oxygen (O_2) Connector

Blended Gas/Air Connection



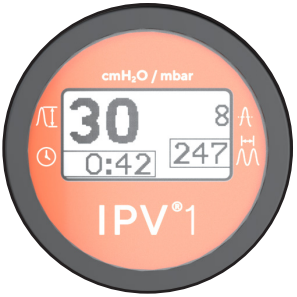
The IPV® 1 connects to hospital single gas source or blended gas. Single or dual air/oxygen gas connections are standard.

⚠ **CAUTION: Do not spray liquids or cleaners into the Bleed port.**

⚠ **CAUTION: Do not block the Bleed port.**

5. Digital Display

A digital display found on the front panel of the IPV® 1 device provides feedback of the patient proximal airway pressures, pulse frequency, and elapsed treatment time.

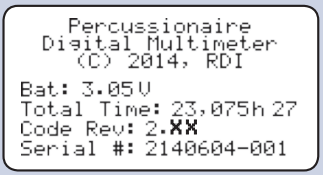


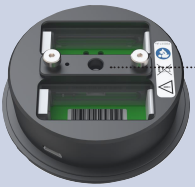
The display has six different operating modes: POST, Wake, Active, Report, Sleep, and Fault.

Note: The display will not awaken until feedback from proximal line on the Phasitron® 5 UC sees pressure.

POST (Power-On Self-Test)

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.





Measuring port connection

⚠(Do not insert any object into this port)

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.

⚠**WARNING:** *Do not install the digital display into the IPV® 1 until the POST check is complete and the screen is blank (indicating Sleep mode).*

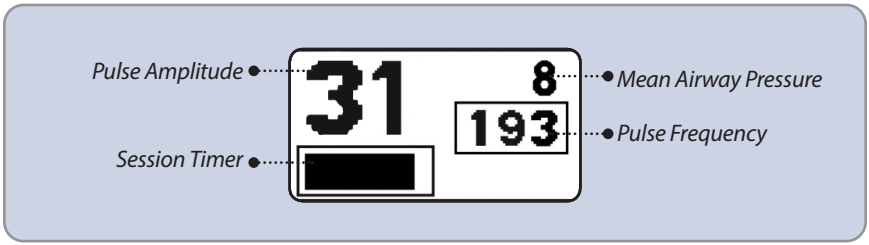
Wake Mode

To wake up the display, ensure the IPV® 1 Amplitude is greater than 7 cmH_2O/hPa at the Phasitron® 5 UC 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

Display Metrics: Pulse Frequency, Mean Airway Pressure, Session Timer, Pulse Amplitude.



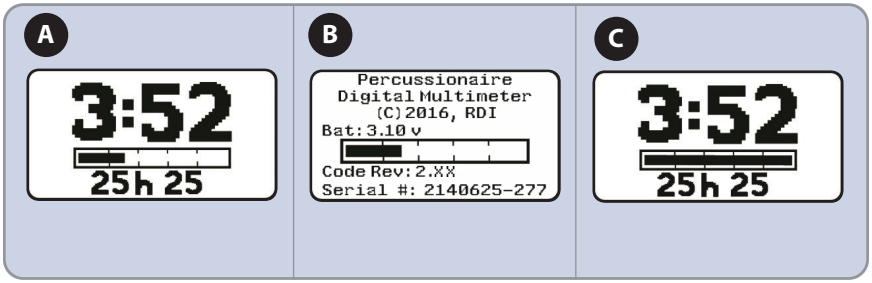
At 16 seconds, the display enters Active mode, a numeric display of Pulse Amplitude, Pulse Frequency, Mean Airway Pressure, and the Session Timer.

- **Pulse Amplitude** - calculated from the pressure measurements at the moment of instantaneous peak and trough amplitude averaged over 5 seconds.
- **Pulse Frequency** – the current measurement.
- **Mean Airway Pressure (MAP)** - averages Pulse Amplitude 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 is the total session 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.

NOTE: *To display most recent session duration time, see Report mode next page.*

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.

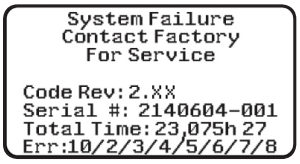
NOTE: *When the IPV® 1 is turned off, the measurements will drop to zeros after a few seconds.*

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® 5 UC patient-delivery port for more than 1 second, the display enters Wake mode.

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.)

NOTE: *Pressure faults are triggered by a very high continuous pressure for more than 5 seconds during Wake and Active modes.*

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 runs correctly, the display may be used. If System Failure screen recurs, contact customer support.*

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

2. A fault will occur if the Display Module is installed into the IPV® 1 during the POST check.

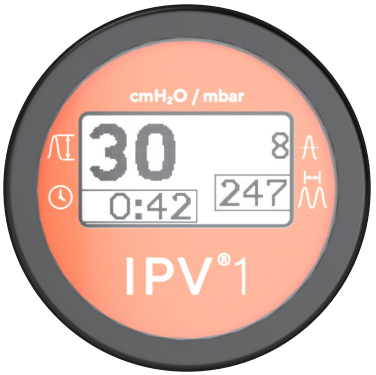
Fault Logging

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 changing batteries, refer to Changing Display Module Batteries in Chapter 12.*

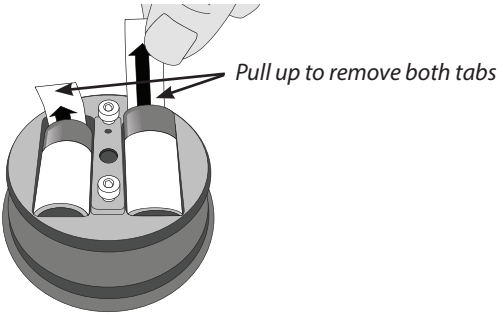
Digital Display - Setup



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.

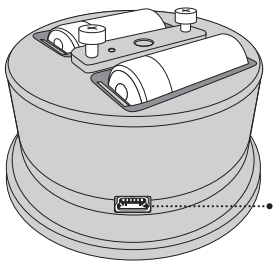
NOTE: *When the display powers on for the first time, it will ensure the correct atmospheric pressure calibration at startup.*

1. Press in on the display's bezel and twist counterclockwise (left) approximately 20 degrees.
2. Gently pull on the display's bezel to remove it from the IPV® 1 housing.
3. Remove the two battery-disconnect tabs to insert the batteries.
4. When the screen goes blank, the display is ready to be reinstalled into the IPV® 1.



NOTE: *Refer to display instructions POST mode (page 13) to verify display operation.*

Digital Display - Setup, continued



Side view of display module

Installing batteries: note positive terminals face same direction.

6. Setup

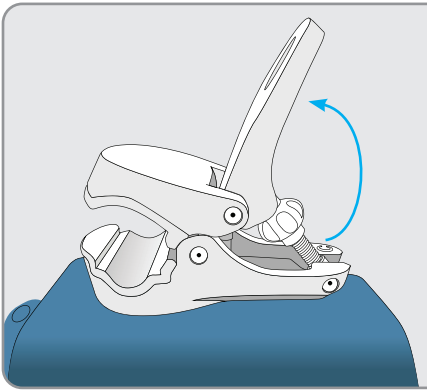
IPV® 1 Mounted to Standard Roll Stand

Roll Stand Assembly

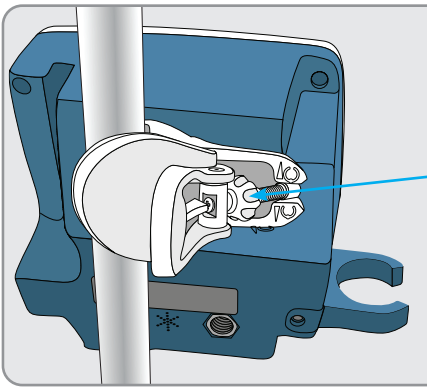
The IPV® 1 mounts onto a standard 19 mm to 38 mm (0.75- to 1.5-inch) hospital roll stand assembly.

Attaching IPV® 1 to Stand

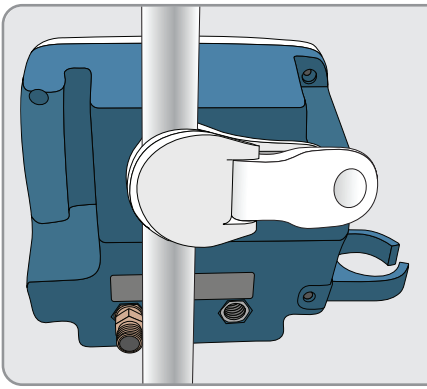
To mount device onto pole:



Open clamp.



Use adjuster nut to set pole thickness.



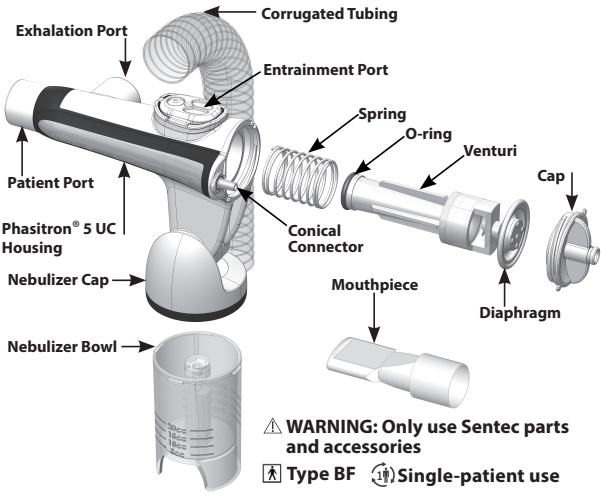
Close and lock clamp.
⚠**WARNING:** Do not force close clamp mount with tool or excessive force, damage may occur to the clamp.

Breathing Circuit - Phasitron® 5 UC

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

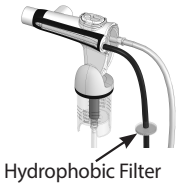
Only use Sentec accessories designed specifically for use with the IPV® 1 device. Function is not guaranteed with any third-party equipment.

Breathing Circuit - Phasitron® 5 UC - Components



Breathing Circuit - Phasitron® 5 UC - Configurations

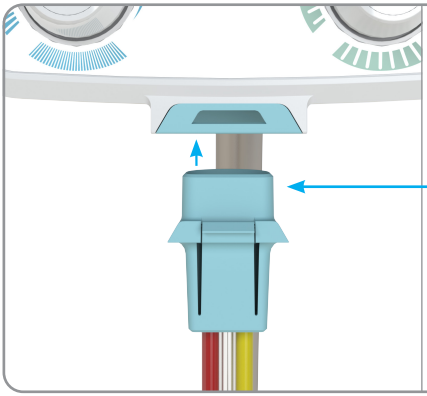
The Phasitron® 5 UC breathing circuit can be used with a mouthpiece or face mask. It can also be used without a mouthpiece or mask.

		
Without mouthpiece or mask	With mouthpiece (included)	With face mask (sold separately)

⚠ **CAUTION:** It is recommended to use a resuscitation mask or similar non-vented mask for all patients under five years of age. International guidelines recommend that an appropriately sized face mask should cover the mouth and nose, but not the eyes, and should not overlap the chin. Careful consideration must be given to mask size, fit,and hold; a good seal with minimized leak is important for establishing effective therapy.

⚠ **CAUTION:** Due to the requirements for physiological and neurological development, using a mouthpiece during therapy is not recommended for patients less than five years of age.

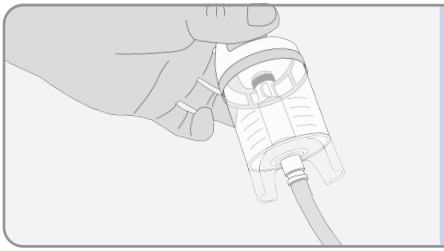
Breathing Circuit - Connecting to the IPV® 1



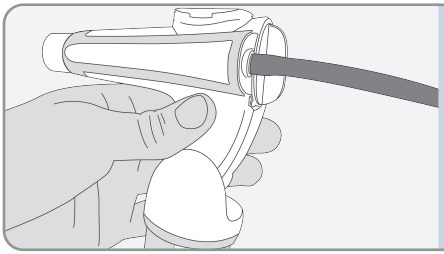
The Phasitron® 5 UC breathing circuit connects into the bottom of the IPV® 1 device.

Connecting Tubing to Phasitron® 5 UC

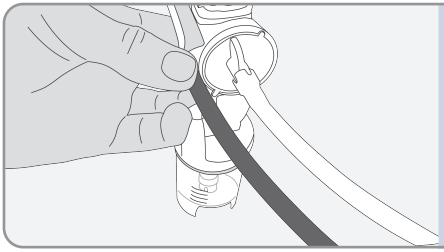
NOTE: *The tubing connectors will only fit onto the correct part.*



Connect yellow tubing quick-connect fitting to nebulizer bowl.

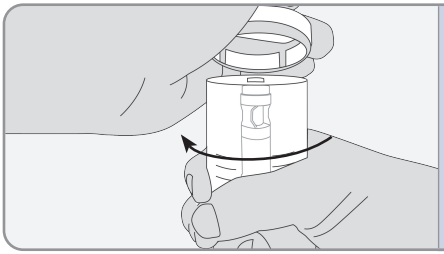


Press red tubing onto conical connector at rear of Phasitron® 5 UC body.



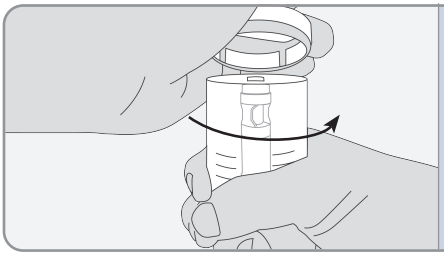
Connect the clear tubing quick-connect fitting to the cap at the rear of the Phasitron® 5 UC body.

Adding Liquid Solution



OPEN nebulizer:

Twist nebulizer bowl to the left to open. Add liquid solution, e.g., saline, as directed by physician.

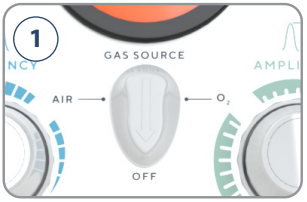


CLOSE nebulizer:

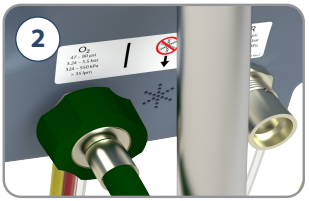
Apply the lid and twist the nebulizer bowl to the right to close.

7. Pre-Use Check

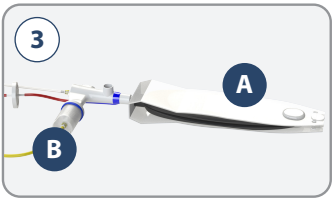
1. Verify the **GAS SOURCE** knob in the "**OFF**" position.



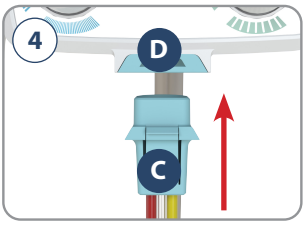
2. Connect the IPV® 1 to medical oxygen or air gas supply.



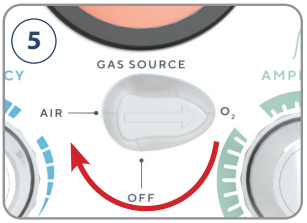
3. Connect a Siemens®-style 1-liter ventilator test lung **(A)** to the Phasitron® 5 UC **(B)**.



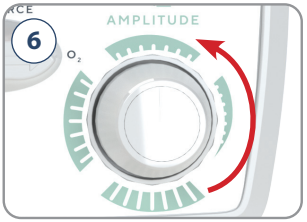
4. Connect the Phasitron® 5 UC's Unified Connector **(C)** to the IPV® 1 **(D)**.



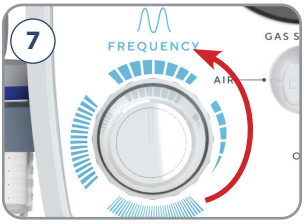
5. Rotate **GAS SOURCE** knob to the **AIR** or **O_2** setting, depending on connection made in step #2.



6. Rotate the **AMPLITUDE** control knob fully counterclockwise.

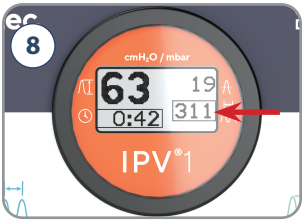


7. Rotate the **FREQUENCY** control knob fully counterclockwise.



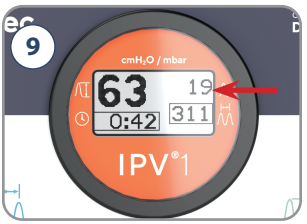
8. Confirm frequency rate of 300 or above.

NOTE: *Displayed pressure and time are for illustrative purposes only.*

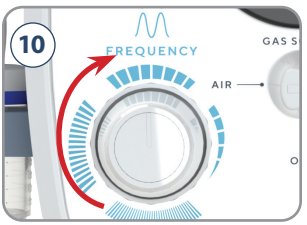


9. Verify the mean airway pressure (MAP) indicated on the digital display is greater than 15 cmH_2O.

NOTE: *Displayed pulse amplitude, time, and frequency are for illustrative purposes only.*

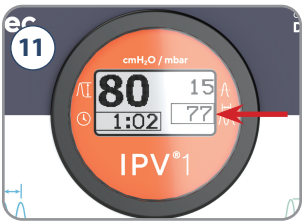


10. Rotate the **FREQUENCY** control knob fully clockwise.

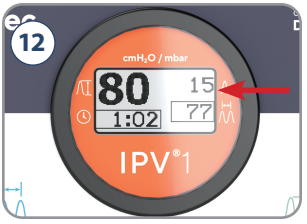


11. Confirm frequency rate of 100 or below.

NOTE: *Displayed pulse amplitude, time, and mean airway pressure (MAP) are for illustrative purposes only.*

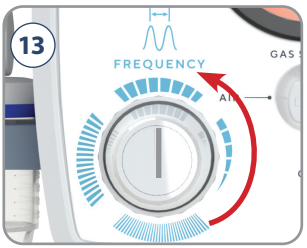


12. Verify the mean airway pressure (MAP) indicated on the digital display is greater than 10 cmH_2O.

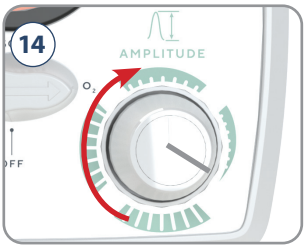


NOTE: *Displayed pulse amplitude, time, and frequency are for illustrative purposes only.*

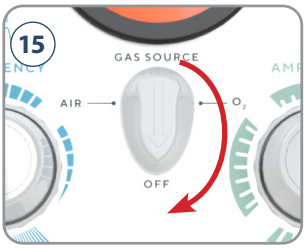
13. Rotate the **FREQUENCY** control knob to the center, straight up position.



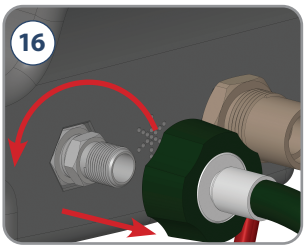
14. Rotate the **AMPLITUDE** control knob fully clockwise.



15. Rotate the **GAS SOURCE** knob to the "**OFF**" position.



16. Disconnect gas source supply.



8. Prepare for Patient-Airway Connection

To prepare for patient-airway connection, complete the following steps:

1. Rotate **AMPLITUDE** control knob clockwise to stop **(off)**.
2. Connect the IPV® 1 to medical gas source. Ensure **GAS SOURCE** switch is switched to **OFF**.
3. Make sure patient is in an upright, comfortable position or lying with head and shoulders elevated by pillows.

NOTE: *Patient's gravitational position is not a factor with IPV®.*

4. Auscultate patient for breath sounds, heart and respiratory rate, or follow institutional guidelines.
5. Add liquid solution, e.g., saline, as directed by physician, into nebulizer bowl to a maximum of 20 cc.
6. Connect Phasitron® 5 UC breathing circuit kit to the IPV® 1 device.
7. Rotate the **FREQUENCY** control knob fully counterclockwise.
8. Connect Phasitron® 5 UC to the patient using mouthpiece, mask, or direct connection to an artificial airway.

9. Administer IPV® Therapy

To administer IPV therapy, complete the following steps:

1. Turn IPV® 1 on by rotating **GAS SOURCE** knob to relevant gas source. Slowly rotate **AMPLITUDE** control knob until a visible chest wiggle is observed.
2. When using a mouthpiece, instruct the patient to inhale and exhale through the pulses until a visible chest wiggle is observed throughout the whole chest or percussions can be auscultated in all lung fields.

NOTE: *Most patients will initially allow percussive bursts of air to leak through their lips or nose at the expense of an observable chest movement (wiggle).*

3. Start to notice the chest movement (wiggle), as the patient exhales through the mouthpiece. Advise the patient to relax, taking normal (spontaneous), breaths through the pulses whenever they desire.
4. Instruct the patient to keep their lips and cheeks tight. As the patient learns to prevent air from leaking out of the lip seal around the mouthpiece, the **FREQUENCY** control knob can be gradually rotated clockwise.

NOTE: *Some patients may require a nose clip to prevent venting from the nose, or an appropriate-size mask if unable to maintain a tight lip seal or venting through the nose.*

9. Administer IPV® Therapy, continued

5. After the patient obtains the ability to prevent the leaking of percussive air deliveries from the nose and around the lips, the entire Pulse Frequency range should be scanned by rotating the **FREQUENCY** control knob. This works to raise secretions from the bronchial airways.

NOTE: *Pay attention to patient comfort and make treatment adjustments accordingly.*

6. As the learning period progresses, the selected source pressure may be increased for effective endobronchial percussion by assessing chest percussion (wiggle).

7. Continue IPV® therapy for 15 to 20 minutes, or per orders.

8. When treatment is complete, turn the IPV® 1 off by rotating the **GAS SOURCE** knob to **OFF**. The Phasitron® 5 UC should be rinsed or cleaned and stored in a clean bag, or per hospital infection control policy, until the next treatment.

NOTE: *The Phasitron® 5 UC breathing circuit kit is for SINGLE patient use only.*
NOTE: *It is advised to follow manufacturer's recommendation for cleaning (Chapter 10).*

10. Cleaning and Maintenance Protocol

Always clean the controller between patients and when visibly soiled. Use only approved cleaning wipes (CaviWipe®) to wipe the controller and stand to remove excess soil. Use additional CaviWipes if needed to remove visible soil. A visual inspection should be performed to ensure soil has been removed.

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.*

⚠ **CAUTION:** Do not spray any cleaning solution onto the controller or stand.

⚠ **CAUTION:** Do not allow liquids to access the controller.

Digital Display

Take care not to damage or scratch the digital display with fingernails, rings, or jewelry.
Do not apply pressure to the digital display.
Use CaviWipes if needed to remove visible soil.
A visual inspection should be performed to ensure soil has been removed.

⚠ **CAUTION:** Do NOT use detergents with ammonia, detergents with abrasives, steel wool, abrasive sponges, steel blades, or cloth with steel thread.

⚠ **CAUTION:** 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 display module.

Roll Stand Assembly

The roll stand assembly may be cleaned with 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.

10. Cleaning and Maintenance Protocol, continued

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

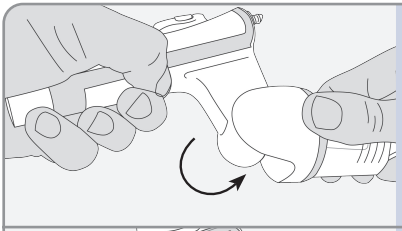
⚠ **CAUTION:**

- 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.

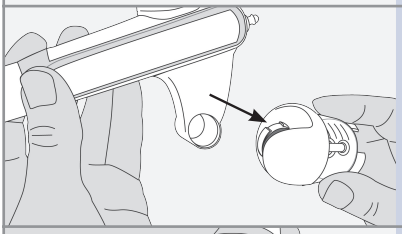
Breathing Circuit - Phasitron® 5 UC

It is not necessary to clean the Phasitron® 5 UC breathing circuit after each use. However, rinsing with sterile water is advised. Cleaning instructions are applicable for a single patient using a Phasitron® 5 UC breathing circuit multiple times between applications.

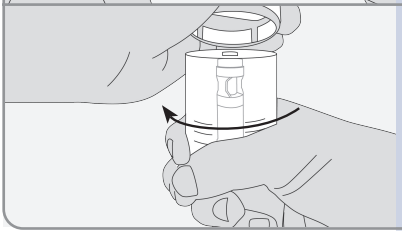
NOTE: *When disassembling the Phasitron® 5 UC breathing circuit kit, visually inspect the exterior of all parts, including the tubing, for corrosion, discoloration, pitting, and missing O-rings.*



1. Gently rotate nebulizer bowl towards the rear of the Phasitron® 5 UC until it stops.

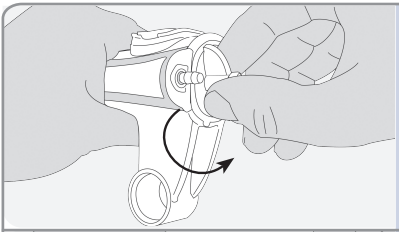


2. Separate nebulizer from the Phasitron® 5 UC.

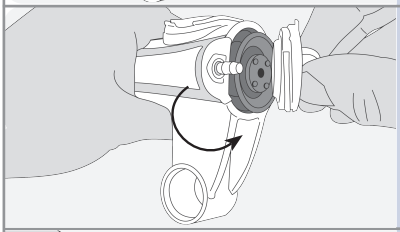


3. While holding the nebulizer cap, twist the nebulizer bowl to remove it from the cap.

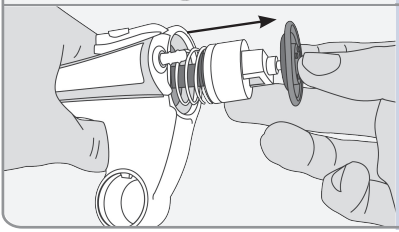
Discard any unused liquid in accordance with hospital/institutional protocol.



4. Twist the white cap on the rear of the Phasitron® 5 UC to remove.



5. Remove the cap.



6. Remove the sliding venturi and spring from the Phasitron® 5 UC body.

Breathing Circuit - Phasitron® 5 UC - Cleaning Process

To clean the Phasitron 5® UC, complete the following steps:

1.	Thoroughly rinse each of the disassembled parts (except for tubing harness) under warm running tap water for approximately ten (10) seconds.
2.	Add fragrance-free liquid soap to a clean bowl or basin filled with warm water.
3.	Hand wash all parts of the Phasitron® 5 UC breathing circuit kit (including accessories) in the warm soapy water.
	NOTE: *Do not wash or submerge the tubing harness.*
4.	Rinse all parts thoroughly using sterile water.
5.	Gently shake all parts to remove as much water as possible and air dry on a clean, lint-free cloth or paper towel.
6.	Use a clean, damp cloth to wipe the exterior of the tubing harness using an approved alcohol-based cleaner.
7.	Reassemble the Phasitron® 5 UC breathing circuit kit and place in a clean bag until the next use.

⚠ **WARNING:** Do not disinfect the Phasitron® 5 UC breathing circuit kit for reuse for more than one patient.

NOTE: *The Phasitron® 5 UC breathing circuit is a single-patient device.*

11. Troubleshooting

⚠ **CAUTION:** If you notice any unexplained changes in the performance of the IPV® 1 controller unit or Phasitron® 5 UC 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.

Problem	Action
No pressure delivery from device	Ensure inlet gas source is on. Check that **AIR** or **O_2** is switched on.
No percussions	Ensure inlet gas source is on. Check that **AIR** or **O_2** is switched on and **AMPLITUDE** control is not in the "**OFF**" position.
Slow Pulse Frequency	Adjust **FREQUENCY** knob for higher rate.
Pulse Frequency, but stalls	Device needs service. Contact authorized service personnel.
No display	Check batteries are installed and are fully charged. Ensure patient or test lung (not provided) is attached to the Phasitron® 5 UC. Ensure Amplitude control is not in the "OFF" position and a greater than 7 cmH_2O pressure is achieved.
Nebulizer not aerosolizing	Ensure a liquid solution is present in nebulizer.
IPV® 1 will not clamp to pole of roll stand assembly.	Check for missing rubber insert.

12. Service

IPV® 1 Device

It is recommended to perform an annual preventive maintenance service consisting of a thorough cleaning and a functional evaluation (contact customer service representative).

Roll Stand Assembly

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

Breathing Circuit - Phasitron® 5 UC

The Phasitron® 5 UC with Unified Connector breathing circuit is single patient use only. Clean as instructed in this manual. Replace as necessary.

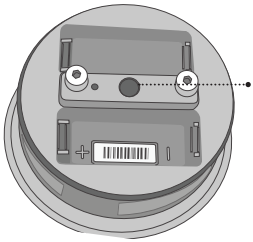
Service

If the IPV® 1 is not functioning as it should, if it makes unusual noises, or if there are any concerns about device performance or condition, immediately **discontinue use**. Contact customer service at customerservice.uk@sentec.com.

Changing Display Module Batteries

Displays a low battery indicator when battery capacity is nearing depletion.

Rear view of display module



1. Press on the display's bezel and twist counterclockwise (left) approximately 20 degrees.
2. Gently pull on the display module's bezel to remove it from the housing.
3. Remove the two old batteries.
4. Install two new CR123A batteries Sentec Part #B13350) with positive terminals facing the same direction.
5. Wait 30 seconds until the display turns off (blank screen, indicating sleep mode).
6. Install the display back into the housing and twist clockwise until the stop is felt.

NOTE: *Do not install display module into the device until the POST test is complete and the screen is blank, indicating sleep mode.*

The display module has a USB serial port that is used for factory/service use only.

⚠**CAUTION:** Do not insert any object in the measuring port connection; it may cause irreparable damage.

⚠**WARNING:** The cell 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 cell with type recognized CR123A only, or Sentec Part# B13350. Use of another cell may present a risk of fire or explosion.

Disposal of Equipment

At the end of useful life of a unit, dispose of in accordance with local, state, federal, and international laws.

European consumers are obliged by law to dispose of Waste Electrical and Electronic Equipment (WEEE) according to the WEEE Directive 2002/96/EC.

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.

13. 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.

Any serious incident that has occurred in relation to the IPV® 1 System has to be reported to Sentec (regulatory.percussionaire@sentec.com) and/or to the competent authority of the country where the incident occurred. If unsure whether an incident is a reportable event, contact Sentec.

14. Technical Specifications

Controller	
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 (MAP)	0-50 cmH_2O
Required Maintenance	Annual preventive maintenance
Expected Useful Life	5 years
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
Battery Duration	3,250 Operational hours at 35°C (95°F)
Accessories	
Breathing Circuit	Phasitron® 5 UC with Unified Connector

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.

Manufacturer's Declaration

The following tables contain the manufacturer's declarations for the IPV® 1 System 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 battery operated.

⚠**WARNING:** Portable and mobile RF communications equipment can affect the performance of the IPV® 1 System. Install and 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:** The use of accessories and cables other than those specified, with the exception of parts sold by Sentec as replacements for internal components, may result in increased emissions or decreased immunity of the IPV® 1 System.

⚠**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 Emissions

The IPV® 1 System is intended for use in the electromagnetic environment of typical hospital/institutional environments specified below. The user of the IPV® 1 System should ensure that it is used in such an environment.

The IPV® 1 System does not connect to hospital/institutional mains or network, and is solely battery operated.

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.
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.

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 Emissions, continued

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	

15. Glossary

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): Loosens thick, sticky mucus so it can be cleared from the lungs.

Amplitude: controls the operating pressure of the entire unit.

Atelectasis/Atelectatic lung: a complete or partial collapse of the entire lung or area (lobe) of the lung. It occurs when the tiny air sacs (alveoli) within the lung become deflated or possibly filled with fluid.

Blended Gas/Air: the oxygen and air blended according to the prescribed fraction of inspired oxygen (FIO_2) and delivered to the patient through high-frequency percussive ventilation.

Device: this refers to the IPV® 1 unit.

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.

Entrained air: the captured ambient air that is automatically drawn in and adjusts to the resistance of the lung.

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.

Frequency: the rate of the high-frequency pulses delivered by the IPV® 1.

IPV® therapy: a 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.

Magnetic Resonance Imaging (MRI): MRI scanners use strong magnetic fields,

magnetic field gradients, and radio waves to generate images of the organs in the body.

Mean Airway Pressure (MAP): the average pressure lungs are exposed to during mechanical ventilation both during inspiration and expiration.

Nebulizer: a device for producing a fine spray of liquid, used, for example, for inhaling a prescribed medication.

Phasitron® 5 UC breathing circuit: refers to the entire single-patient interface or kit known as the Phasitron® 5 UC with Unified Connector, including mouthpiece, Phasitron® 5 UC tubing, and connectors.

Phasitron® 5 UC patient-delivery port: the part of the Phasitron® 5 UC breathing circuit kit 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.

Proximal Airway Pressure: pressure measured at the proximal airway (closest to the patient).

Pulsatile Flow: the flow created by the Phasitron® 5 UC is known as Pulsatile Flow, which provides the alveoli with fresh air while gently washing out CO_2 and secretions.

Pulse Amplitude: calculated from the pressure measurements at the moment of instantaneous peak and trough amplitude averaged over 5 seconds.

Pulse Frequency: the high-frequency percussive endobronchial delivery rate of subtidal volumes to the lungs.

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: the session time up to 59 hours and 59 minutes (59:59) before it automatically resets.

Sleep Mode: the display is off, but the display module continues to measure pressure at the measuring port. If the display module 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 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: a timer that displays the total number of time the device has been operated.

Transient error: an error that will resolve itself. Most typically these errors manifest as a connection to the database server being dropped. Transient errors can occur, for example, when hardware or network failure happens.

Wake Mode: after the POST test, the digital display enters Wake mode and is active for the first 15 seconds of use.

sentec.

Percussionaire®, 130 McGhee Rd., Suite 109, Sandpoint, Idaho 83864
EC REP MDSS GmbH, Schiffgraben 41, 30175 Hannover, Germany
sentec.com +1.208.263.2549

CE 0123

P20220 Rev B
Date of Release: 2024-08