INOGEN**TAV**®
TIDAL ASSIST VENTILATOR
INSTRUCTIONS FOR USE

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Introduction

The Tidal Assist Ventilation (TAV®) System provides you with three delivery modes: Pulse mode (similar to pulsed-dose systems), Constant mode (similar to continuous flow in other devices), and Tidal Assist mode. The Tidal Assist mode provides an additional "boost" to your breathing and is designed to enhance your ability to perform everyday activities of daily living and to exercise.

This instruction manual includes important information on how to properly use and maintain the TAV® system. Please read it carefully before using your TAV® system.

Glossary

Bypass Valve: In the event of a TAV® system failure, the bypass valve allows the device to still provide oxygen flow. The bypass valve is activated by pulling out the bypass valve stem (see pages 5, 14).

Caution: In this document, "caution" indicates the possibility of a problem with the device associated with its use or misuse. Such problems may include device malfunctions, device failure, damage to the device, or damage to other property.

Constant Mode: This mode is similar to continuous flow mode on other devices. It provides a steady stream of oxygen at the set flow rate. Compared to Pulse Mode, this mode generally provides more oxygen to your lungs, and may be better suited for situations where a higher demand for oxygen is needed, such as during exertion. Although it provides more oxygen than Pulse Mode, Constant Mode generally provides less oxygen to your lungs than Tidal Assist Mode.

Continuous Flow Oxygen: Oxygen is constantly flowing. On the TAV® System, this is called Constant Mode.

DISS Outlet: Diameter Index Safety System outlet. These threaded outlets are used on medical gas devices to ensure that the correct medical gas is used as required by each device. The TAV® regulator adapter requires a male DISS outlet.

EMC: Electromagnetic compatibility (see Appendix A)

Nasal Pillow Interface: The TAV® System uses a custom designed nasal "pillow" interface. This special interface allows proper delivery of the special delivery modes available on the TAV®. Only the Inogen brand nasal pillow interface should be used with the TAV® System.

Pulse Mode: This mode is similar to the "pulsed-dose" mode on other devices. It provides a short "pulse" of oxygen at the start of each inhalation and is designed to conserve oxygen use. This mode may be best suited for situations in which you have a limited supply of oxygen, such as when you are using a small portable oxygen tank.

Pulsed-dose Oxygen: Pulsed-dose devices provide oxygen flow for only a short period at the start of each breath. This allows oxygen use to be minimized. On the TAV® system, this is called Pulse Mode.

Regulator: A pressure regulator controls the pressure coming from the gas source (e.g., oxygen tank) that is delivered to a device. The TAV® System includes a custom regulator adapter for use when connecting to DISS-style fittings. The TAV® regulator adapter should always be used when connecting the TAV® device to standard oxygen tank regulators, hospital wall oxygen outlets or to air sources.

Respiratory Insufficiency: Conditions in which the ability to breathe and/or to oxygenate is lower than normal.

Tidal Assist Mode: This mode provides a larger pulse of gas at the start of each inhalation, and it generally increases the tidal volume to your lungs. This mode may be best for situations requiring greater volume assist, such as those involving vigorous activity or exertion.

Tidal Volume: Tidal volume is the amount of air moved into and out of the lungs during a single breath. When using the Tidal Assist Mode, tidal volume is normally increased compared to Pulse Mode or Constant Mode.

WARNING: In this document, a "warning" indicates the possibility of injury, death, or other serious outcomes may be associated with the use or misuse of the device.

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Intended Use

The Inogen Tidal Assist Ventilator (TAV), with accessories, is a volume assist ventilator intended to aid adult patients with respiratory insufficiency. It is designed for patients who are capable of spontaneously breathing a minimum tidal volume of 3.5cc/kg of predicted body weight. The device is designed for continuous applications such as patient ambulation, physical therapy, occupational therapy, respiratory therapy, and other rehabilitation efforts in an institutional or home care environment. The device is intended for operation by trained personnel, patients or caregivers under the direction of a physician.

Contraindications

The TAV® System is not designed for patients who cannot spontaneously breathe or who are fully dependent on mechanical ventilation.

Adverse Effects

- As is common with other forms of oxygen therapy, the following side effect may arise during therapy with the system:
    - º Drying or irritation of nasal passages

Cautions

- Please read the entire Instructions for Use before using the TAV® system.
- Do not use the TAV® Ventilation System in magnetic resonance imaging (MRI) environments. MRI equipment may cause electronic components in the ventilator to malfunction.
- Do not expose the TAV® system to excessive heat or moisture.
- Federal (USA) law restricts the sale of this device on or by the order of a physician.

CAUTION
🚭 **No Smoking**
🔥 **No Open Flame**

Warnings

- Not to be used for life support applications.
- Not intended for use by patients who breathe more than 40 breaths per minute or patients who consistently fail to trigger the device.
- The Tidal Assist flow setting 4 does not support a breath rate higher than 25 bpm and Tidal Assist flow setting 5 does not support a breath rate higher than 20 bpm.
- The use of the Tidal Assist ventilation system requires moderate patient participation; therefore, you must be able to understand and comply with instructions. If you take strong sedatives or other medications that may inhibit mental capacity, you should not use the system without proper medical supervision.
- Expert clinical judgment should be exercised in the appropriate use and selection of device settings for each individual patient. Inappropriate patient selection or selection of TAV® settings may result in suboptimal delivery of oxygen and/or breathing assistance to the patient. Please consult with your doctor before using the TAV® System.
- If the TAV® System malfunctions, you may not receive the appropriate therapy. A readily available alternate or backup means of delivering your therapy should always be available.
- The TAV® System is designed for use with oxygen sources that comply with local regulations for medical oxygen.
- Oxygen supports combustion. Oxygen should not be used while smoking or in the presence of an open flame.
- Turn off the oxygen source when not using the TAV® System. Oxygen delivered into the tubing may accumulate within the TAV® device enclosure. Oxygen which has accumulated within in the device enclosure or tubing could pose a risk of fire.

- Please note that it is unsafe to:
    - ° Use any non-Inogen accessories, parts, or materials not described in the instructions for use.
    - ° Connect the TAV® device or nasal pillow interface to other equipment not described in the instructions for use.
    - ° Modify the TAV® device or nasal pillow interface in any way not described in the instructions for use.
- Due to its length, the nasal pillow interface could pose a risk of strangulation.
- Do not leave the TAV® device or interface unattended with children.
- The TAV® System and battery contain electronic waste that should be appropriately disposed of according to your local ordinances.
- Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, and walkie-talkies can affect this equipment and should be kept a minimum distance away from the equipment, per the separation distances indicated in the EMC section of this manual (Appendix A).
- Medical electrical equipment such as this device needs special precautions regarding electromagnetic compatibility (EMC) and needs to be operated according to the EMC information provided in this manual (Appendix A).
- This device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.
- The nasal pillow interface is intended for single-patient use. Do not share or reuse.

The TAV® System

AA Battery

TAV® Controller

TIDAL ASSIST™

Pulse — Constant

1 2 3 4 5

Low Battery

Breath Alarm — Flow Alarm

Silence Alarm

INOGEN**TAV**
TIDAL ASSIST VENTILATOR

Nasal Pillow Interface

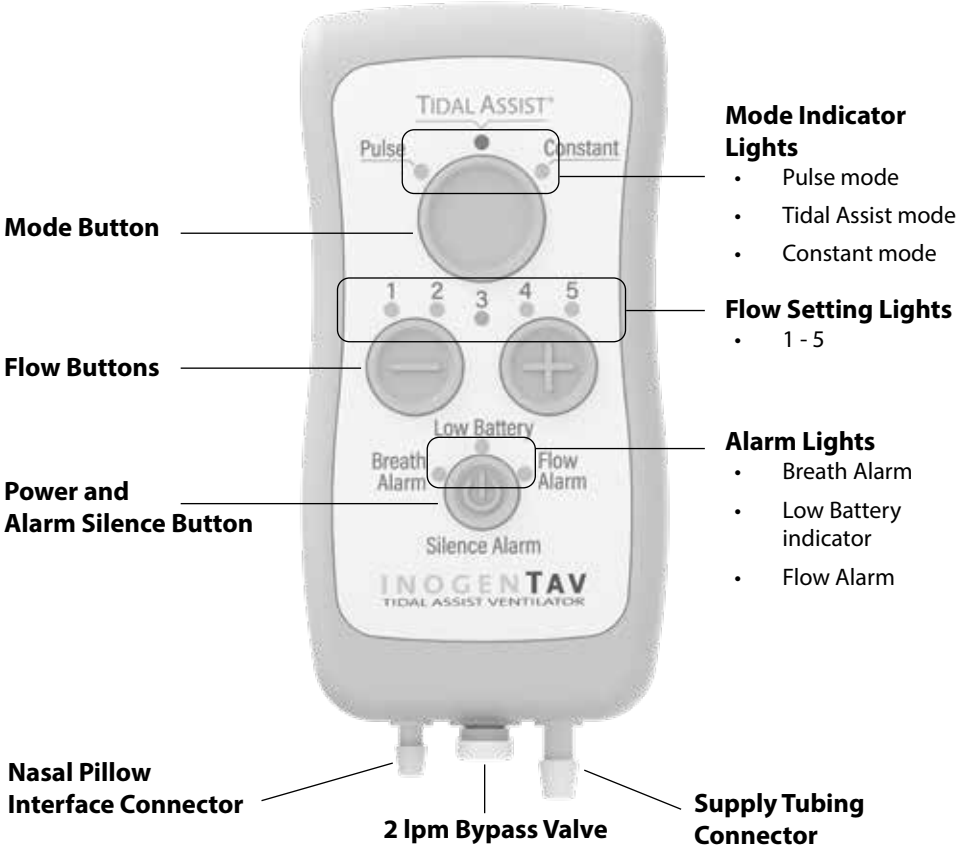**Regulator Adaptor (sold separately)***

Supply Tubing

Note: The TAV® System and battery contain electronic waste that requires appropriate disposal according to your local ordinances.

*For use when connecting to DISS connectors or to hospital wall outlets.

Device Controls and Indicators

Mode Indicator Lights
- Pulse mode
- Tidal Assist mode
- Constant mode

Mode Button

Flow Setting Lights
- 1 - 5

Flow Buttons

Alarm Lights
- Breath Alarm
- Low Battery indicator
- Flow Alarm

Power and Alarm Silence Button

TIDAL ASSIST®

Pulse   Constant

1 2 3 4 5

Low Battery
Breath Alarm   Flow Alarm
Silence Alarm

INOGEN **TAV**
TIDAL ASSIST VENTILATOR

Nasal Pillow Interface Connector

2 lpm Bypass Valve

Supply Tubing Connector

Inserting the Battery

Note: Only AA alkaline batteries should be used. Other battery types will not damage the system; however, the operating life may be less, and the low battery indicator will be inaccurate. Batteries with a voltage >2.5V should never be used, as they may affect the accuracy of the electronic system.
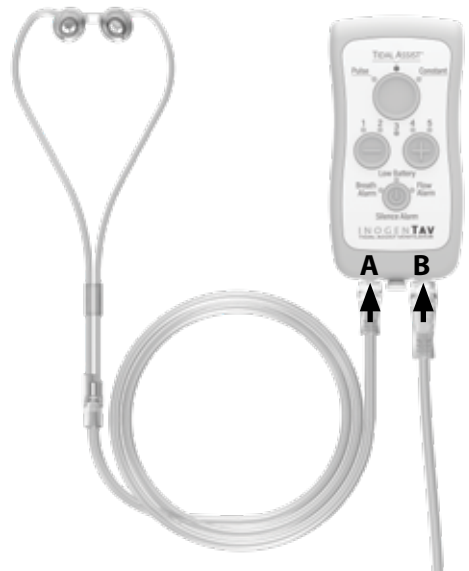
To insert a battery:

1. Place both thumbs on the battery cover door. Slide the battery cover forward.

2. Gently swing the cover back.

3. Insert a fresh AA battery with the negative (flat) end placed against the spring. If replacing a battery, remove the used battery first. Ensure unit is off before replacing a used battery.

4. Swing the cover to the forward position.

5. Place both thumbs on the battery cover door. Slide the battery door back until a slight click is felt.

Device Connections

When looking at the front of the device, the small connector on the bottom left side (A) is for connecting your nasal pillow interface.

The large connector on the bottom right side (B) is for connecting the supply tubing from the gas source (see page 8).

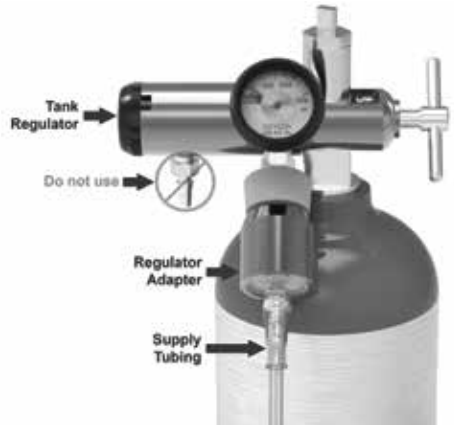## Connecting the Nasal Pillow Interface

Attach the nasal pillow interface tubing to the small connector on the bottom left side of the device. Make sure that the tubing is pressed firmly onto the connector.

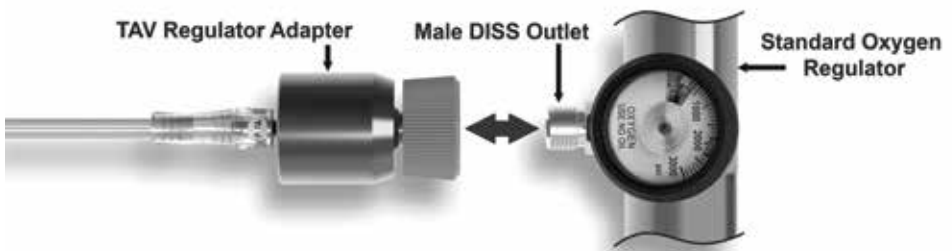# Connecting to Gas Sources with DISS Fittings

Note: Do not connect the TAV® system to the standard oxygen barb on the regulator (shown below). Always use the provided regulator adapter when connecting to pressure sources greater than 28psig.

1. Attach one end of the supply tubing to the connector on the bottom right of the device.

2. Attach the other end of the supply tubing to the Regulator Adapter. Make sure that both ends of the supply tubing are firmly pressed onto each connector.

3. Always ensure the blue Regulator Adapter is connected to the TAV® device before connecting to the gas source.

The TAV® device is connected to standard DISS fittings using the Regulator Adapter accessory. The Regulator Adapter must be used when connecting the TAV® device to hospital wall oxygen. Attach the TAV® Regulator Adapter to the threaded DISS outlet of the gas source. Hand tighten the connector until it is snug. Always ensure the Regulator Adapter is connected to the TAV® device before connecting to the gas source.

Note: To ensure proper operation, the TAV® Regulator Adapter must be used when connecting to DISS connectors or to hospital wall outlets that output 40 to 87 psig with greater than 20 LPM capability.

Gas sources must be equipped with a standard threaded male DISS connector in order to connect the TAV® Regulator Adapter. DISS = Diameter Index Safety System.

Connecting to Compatible Oxygen Concentrators

Note: Only connect the TAV® system to compatible oxygen concentrators that have the TAV® logo (shown below).

TAV® Logo

Supply Tubing

1. Attach one end of the supply tubing to the connector on the bottom right of the device.

2. Attach the other end of the supply tubing to a TAV® compatible oxygen concentrator. Make sure that both ends of the supply tubing are firmly pressed onto each connector.
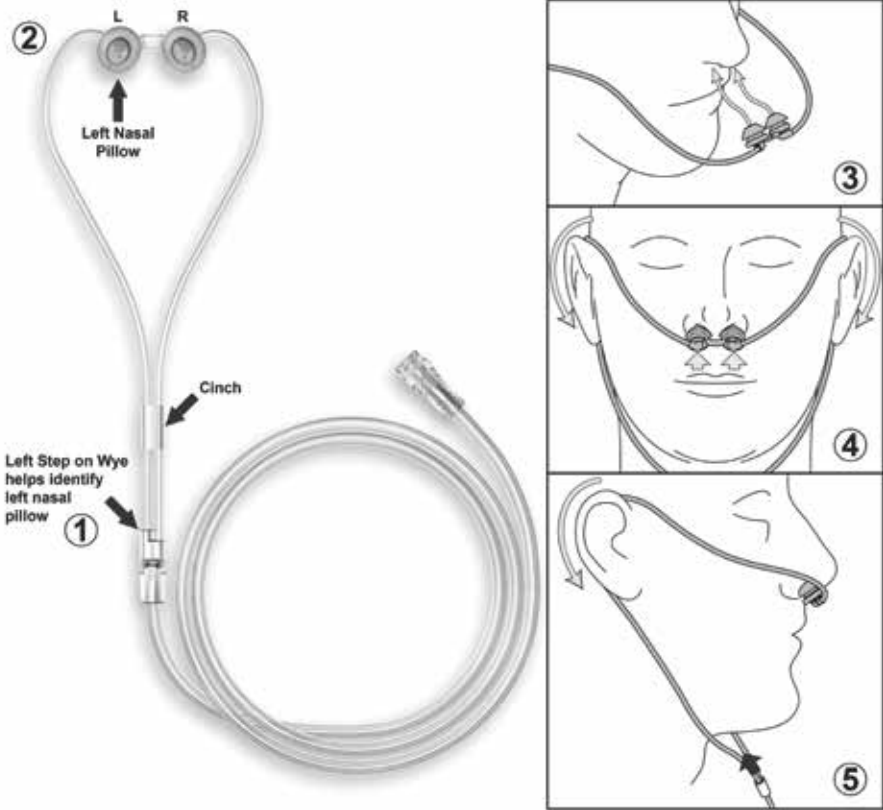
3. Turn the flow meter knob max counter-clockwise when connected to the TAV.

See the concentrator's Instructions For Use (IFU) for operating instructions.

Note: To ensure proper operation, the TAV® device must be connected to a TAV® compatible oxygen concentrators. Compatible concentrators are labeled with the TAV® logo Turn the flow meter to Max when the TAV device is connected or the system will not operate properly. The TAV device will not operate properly when connected to concentrators without the TAV® logo. Contact Inogen or visit www.TidalAssist.com for a list of compatible concentrators.

Putting on the Nasal Pillow Interface

The TAV® system provides 3 modes of operation and 5 flow settings for each mode. The mode and flow settings can be changed based on your prescribed level of therapy.

Before turning on the device, make sure that the supply tubing and the nasal pillow interface are connected. Also make sure that the gas supply is turned on.

The nasal pillow interface has a left side and a right side. Follow these 5 steps to ensure the best fit:

1. Find the small step located on the Wye of the interface tubing. This step identifies the left side of the pillows interface.

2. Hold the interface tubing limb with the offset in your left hand. The openings of the nasal pillow interface will be facing you.

3. Insert the pillows into your nose, making sure each pillow is securely inside each nostril. It may help to check and adjust the fit using a mirror.

4. Use one hand to hold the pillows in your nose while using the other hand to loop the thin tubing over each ear.

5. When correctly inserted, the nasal pillow interface should appear as shown in picture 5, and the cinch is now free to secure comfortably.

Note: The nasal pillow interface is intended for single patient use only. Do not share the interface.

Basic Device Operation

The TAV® system provides 3 modes of operation and 5 flow settings for each mode. The mode and flow settings can be changed based on your prescribed level of therapy. Before turning on the device, make sure that the supply tubing and the nasal pillow interface are connected. Also make sure that the gas supply is turned on.

1. **Turn the device ON:**
   Press and hold the power button for 1 full second until the lights turn on and the device beeps.

2. **Select the breathing mode:**
   Press the top mode button to select the desired mode. The light for the selected mode will blink.

   º Pulse (pulsed-dose)

   º Tidal Assist

   º Constant (continuous flow)

3. **Select the flow rate:**
   Use the -/+ buttons to select the prescribed flow setting (1-5). The green light for the selected flow rate will blink. Each press on the -/+ buttons decreases or increases the flow setting by 1 unit.

4. **Turn the device OFF*:**
   Press and hold the power button for 3 full seconds until the lights turn off and the device beeps twice.

Using Pulse Mode

Pulse Mode provides oxygen therapy similar to "pulse-dose" or "conserver" type oxygen devices. In Pulse Mode, the TAV® device provides a measured dose of oxygen at the start of each breath. The amount of oxygen depends on the selected flow setting.

Before turning on the device, make sure that the supply tubing and nasal pillow interface are connected. Also make sure that the gas supply is turned on.

1. **Turn the device ON (if off):**
   Press and hold the power button for 1-second until the lights turn on and the device will beep.

2. **Select the breathing mode:**
   Press the top mode button to select the Pulse mode. The light for pulse mode will blink.

3. **Select the flow rate:**
   Use the -/+ buttons to select the prescribed oxygen flow setting (1-5). The green light for the selected flow rate will blink. Each press on the -/+ buttons decreases or increases the flow rate setting by 1 unit.

Using Tidal Assist Mode

Tidal Assist Mode provides a larger pulse of supply gas at the start of each breath than the Pulse Mode with additional volume assist with room air. The amount of volume assist and delivered source gas depend upon the selected flow setting.

Before turning on the device, make sure that the supply tubing and nasal pillow interface are connected. Also make sure that the gas supply is turned on.

1.   **Turn the device ON (if off):**
Press and hold the power button for 1 full second until the lights turn on and the device beeps.

2.   **Select the breathing mode:**
Press the top mode button to select the Tidal Assist mode. The Tidal Assist mode light will blink.

3.   **Select the flow setting:**
Use the -/+ buttons to select the prescribed flow rate (1-5). The green light for the selected flow rate will blink. Each press on the -/+ buttons decreases or increases the flow rate setting by 1 unit.

Using Constant Flow Mode

Constant Mode provides a steady flow of oxygen all the time.

Before turning on the device, make sure that the supply tubing and the nasal pillow interface are connected. Also make sure that the gas supply is turned on.

1. **Turn the device ON (if off):**
    Press and hold the power button for 1 full second until the lights turn on and the device beeps.

2. **Select the breathing mode:**
    Press the top mode button to select the Constant mode. The light for constant flow mode will blink.

3. **Select the flow setting:**
    Use the -/+ buttons to select the prescribed oxygen flow rate (1-5). The green light for the selected flow rate will blink. Each press on the -/+ buttons decreases or increases the flow rate setting by 1 unit.

Using the Bypass Valve

Note: Use the bypass valve only if the device does not operate. Standard TAV® modes will not work properly when the bypass valve is opened.

If your TAV® device stops working (e.g., because of a dead battery), the Bypass Valve may be used to deliver a constant flow of oxygen at about 2 lpm. Do not use the **Bypass Valve** for normal operation.

Follow the steps below to use the bypass valve.
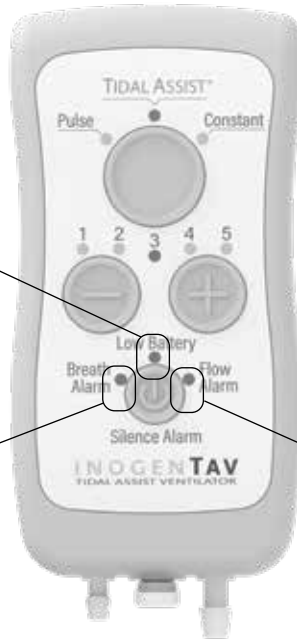

1. **Pull the bypass valve (arrow)**

2. **A green colored band will be visible when the valve is open.**

Alarms and Low Battery Indicator

The TAV® device alerts you if the flow output from the device is too low or too high compared to your selected settings. It also provides a lighted indicator when the battery needs to be replaced.

Low Battery Indicator: The yellow low battery light will turn on when the battery has about 2 days of life remaining. Replace the battery at your soonest convenience.

Breath Alarm: This alarm indicates that the user is not triggering the device or the breath rate is too fast or too slow for the current setting. You will see the yellow "breath alarm" light flash and hear a series of beeps.

Flow Alarm: This alarm indicates that the flow output is not the same as the set flow. You will see the red "flow alarm" light flash and hear a series of beeps

What to do:

1. Check the patient
2. Check nasal pillow interface fit
3. Check tubing for kinks and leaks.
4. Check that all tubing connections are securely attached.
5. Turn the device OFF, and then back ON.
6. If the problem persists, turn off the device and contact customer support for assistance. Use Bypass Valve if needed.

What to do:

1. Check tubing for kinks and leaks.
2. Check that all tubing connections are securely attached.
3. Check gas source
4. If using a cylinder regulator, make sure the Regulator Adaptor is being used.
5. Turn the device OFF, and then back ON.
6. If the problem persists, turn off the device and contact customer support for assistance. Use Bypass Valve if needed.

To silence an alarm: Briefly press the ⏻ button to silence the alarm for 1 minute. If the problem persists, the alarm will sound again after 1 minute.

Note: The alarm light will stay on until the problem is corrected.

Warning: A brief press of the alarm button will silence the alarm - the alarm light will stay on. Holding down the button for longer than 3 seconds will turn off the TAV® device.

Cleaning and Maintenance
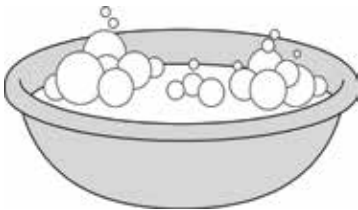
Device Cleaning and Maintenance:

Weekly and as needed:

- Wipe the external surfaces of the device with a slightly damp cloth or 70% isopropyl alcohol.

DO NOT ALLOW YOUR DEVICE TO GET OVERLY WET
Doing so may cause the TAV® device to malfunction

Nasal Pillow Interface Cleaning and Maintenance

Before Each Use:
- Inspect your nasal pillow interface and make sure it is clean and free of any debris or build-up. If needed, use the periodic cleaning method (below) to clean the nasal pillow interface.
- Inspect your nasal pillow interface for any damage (e.g., tears, loose parts, etc.). Replace the nasal pillow interface with a new one if you see any damage.

Periodically (or as needed):
- Clean your nasal pillow interface using warm water and liquid dish soap:
    - ° Submerge the nasal pillow interface in a pan of lukewarm, clean drinking water with a small amount of liquid dish soap (e.g., Dawn®). Agitate and wipe gently to remove any debris.
    - ° Rinse the pillows thoroughly using warm, clean drinking water.
    - ° To dry, hold the nasal pillow interface with the pillows-end facing down. Shake the nasal pillow interface gently to remove any excess water from the pillows or tubing.
    - ° To remove any water remaining inside the pillows or tubing:

* Connect the nasal pillow interface and gas source to the TAV® device.

* Turn the gas source and TAV® device on.

* Place the TAV® device in the Constant flow mode.

* Turn the flow setting up to 5 for at least 10 seconds until any trapped water has been cleared from the tubing.

º When finished, make sure your nasal pillow interface is clean and free of debris. If not, clean again.

Monthly (or as directed by your health-care provider):
• Replace your nasal pillow interface with a fresh one supplied by your medical supplier.

WARNING: Do not subject the Nasal Pillows Interface to heat sterilization, hot water pasteurization, autoclaving, radiation sterilization, ethylene oxide gas sterilization, or attempt to clean it in a dishwasher or microwave oven. Doing any of these may damage the nasal pillow interface and impair oxygen delivery.

General Troubleshooting

Problem	Possible Causes	What To Do
Device won't turn on	No battery installed	Install battery as shown on page 6.
	Battery installed backwards	Check to make sure spring contact is against "-" (flat) side of battery. Remove and flip battery if necessary.
	Power button was not held down long enough	Hold power button down for one full second until lights flash and a beep is heard.
	Battery not making good contact with terminals	Remove and reinsert battery as shown on page 6.
	Dead battery	Remove battery and replace it with a new one as shown on page 6.
	Device malfunction	• Open the bypass by pulling out the stem (page 14). The TAV® will deliver a constant flow at 2 LPM. • Contact Customer Support at 888-599-1105 as soon as possible.
Device won't turn off	Power button was not held down long enough	Hold power button down for 3 full seconds until lights turn off and the device beeps twice.

Problem	Possible Causes	What To Do
Device does not trigger during inhalation **(Pulse and Tidal Assist modes)**	Nasal Pillow Interface is not connected to device	Ensure the interface is connected to the TAV® device.
	Nasal Pillow Interface is not properly inserted into the nose	Ensure the interface is inserted into the user's nose.
	Gas supply line is not connected to device	Ensure the supply line is connected to the TAV® device.
	Empty oxygen cylinder or gas source turned off	• Replace cylinder if empty • Turn on gas source if off
	Trigger threshold was not calculated correctly by system	• Disconnect interface from device. • Turn device off and then back on. • After beep is heard, reconnect the interface to the device.
	Mouth breathing	Make sure the user is inhaling through their nose.
Device triggers un-expectedly **(Pulse and Tidal Assist modes)**	Trigger threshold was not calculated correctly by system	• Disconnect interface from device. • Turn device off and then back on. • After beep is heard, reconnect the interface to the device.
	Patient interface tubing has been accidentally bumped.	• Position tubing to prevent it from being bumped.
Device malfunction	Device does not operate correctly	• Remove and reinsert battery. • If device continues to malfunction: • Open the bypass by pulling out the stem. The TAV® device will deliver a constant flow at 2 LPM. • Contact Customer Support at 888-599-1105 as soon as possible.

Alarm Troubleshooting

What You See and Hear	Possible Causes	What To Do
"Breath Alarm" light is flashing Device is beeping	The TAV® device detects that the user is not triggering the device, the breath rate is too fast, or too slow for the current setting.	1. Check the patient. 2. Check nasal pillow interface fit. 3. Check tubing for kinks and leaks. 4. Check that all tubing connections are securely attached. 5. Turn the device OFF and then back ON 6. If the problem persists, stop using the system and contact Customer Support at 888-599-1105. 7. If needed, open the bypass by pulling out the stem (page 14). The TAV® will deliver a constant flow at 2 LPM.
"Flow Alarm" light is flashing Device is beeping	The device detects that the flow output is not the same as the set flow.	1. Check tubing for kinks and leaks. 2. Check that all tubing connections are securely attached. 3. Check gas source. 4. If using a cylinder regulator, wall source or air source, make sure the Regulator Adaptor is used and is connected to a DISS connector. 5. If using an oxygen concentrator, ensure that the concentrator is TAV® compatible and that the flow meter knob is turned max counter-clockwise. See the concentrator's Instructions for Use (IFU) if the problem persists. 6. Turn the device OFF, and then back ON. 7. If problem persists, stop using the system and contact Customer Support at 888-599-1105. 8. If needed, open the bypass by pulling out the stem (page 14). The TAV® will deliver a constant flow at 2 LPM.
"Low Battery" light is on solid	The battery should be replaced.	Remove battery from device and replace with a new one.

What You See and Hear	Possible Causes	What To Do
"Breath Alarm" and "Flow Alarm" lights are on solid **Device is sounding a continuous tone**	The device has detected a fault preventing it from operating correctly.	1. Make sure the Bypass Valve is closed (fully pushed in) 2. Turn the device OFF, and then back ON. 3. If problem persists, stop using the system and contact Customer Support at 888-599-1105. 4. If needed, open the bypass by pulling out the stem (page 14). The TAV® will deliver a constant flow at 2 LPM.

Technical Specifications

Product Name: Tidal Assist Ventilator (TAV) System

Model No: VC-100 (Controller), RP-1000 (Nasal Pillow Interface)

Electrical:

- 1.5 VDC (one alkaline battery, Type AA/LR6)

  Note: The use of other batteries (like "heavy duty" or 1.5V rechargeable cells) will not damage the system, but the battery life and accuracy of the low battery indication may be affected.

Battery Life:

- Approximately 90 days (at 8 hours of use/day)

Operating Temperature/Humidity:

- 41°F ~ 104°F (5°C ~ 40°C)
- 15% ~ 93% RH non-condensing
- 700 ~ 1060 hPa

Storage Temperature/Humidity/Air Pressure:

- -13°F ~ 158°F (-25°C ~ 70°C)
- 10% ~ 93% RH non-condensing
- 700 ~ 1060 hPa (-1,000 to ~10,000 feet)

Enclosure Rating:

- IP22 (ingress protection)

  IP22 means that the TAV® device is designed to not allow touching of any hazardous parts of the device for objects > 12.5mm (e.g., fingers). In addition, the TAV® enclosure provides protection against dripping water up to an angle of 15 degrees.

Alarm Volume:

- 65 - 80 dBA (measured at 1 m)

Weight and Dimensions:

- Approximately 3.8 ounces with battery (108 grams)
- Approximately 5.25 (W) x 2.5 (H) x 0.9 (D) inches

Predicted Life:

- 3 years for TAV® device
- 30 days for Nasal Pillow Interface (after use has begun)

Product Contents:

- TAV® Device
- Nasal Pillow Interface
- Regulator Adaptor
- AA battery
- Instructions for Use and Quick Reference Guide
- Warranty Card

Trigger sensitivity

- -0.054 cmH2O

Note: The TAV® System and battery contain electronic waste that requires appropriate disposal according to your local ordinances.

Oxygen Delivery Performance

Pulse Mode:

Setting	Delivered O2 Volume/Breath (ml)	Maximum breath rate (BPM)	Accuracy
1	10	40	
2	20	40	
3	30	40	± 15%
4	40	40	
5	50	40	

Tidal Assist Mode:

Setting	Delivered O2 Volume/Breath (ml)	Maximum breath rate (BPM)	Accuracy
1	50	40	
2	100	40	
3	150	33	± 10%
4	200	25	
5	250	20	

Constant Mode:

- 1 – 5 LPM, ±15%

Air Delivery Performance

Delivered Oxygen Concentration: 21%

Accuracy (relative to Oxygen Delivery Performance): Within 10%

Oxygen Cylinder Duration - Pulse Mode

The following tables provide approximate duration times for B (M-6) and E (M-24) oxygen tanks. Please note that these figures are only meant to serve as a guide.

Note: Actual tank durations will depend on your actual breathing rate, the initial fullness of the tank, and other factors such as leaks and gauge accuracy.

Table 1: Cylinder Size B (M-6) 150 liters when full

	Breaths per Minute									
	12	14	16	18	20	22	24	26	28	30
Flow Setting	Tank duration in hours									
1	20.8	17.9	15.6	13.9	12.5	11.4	10.4	9.6	8.9	8.3
2	10.4	8.9	7.8	6.9	6.3	5.7	5.2	4.8	4.5	4.2
3	6.9	6.0	5.2	4.6	4.2	3.8	3.5	3.2	3.0	2.8
4	5.2	4.5	3.9	3.5	3.1	2.8	2.6	2.4	2.2	2.1
5	4.2	3.6	3.1	2.8	2.5	2.3	2.1	2.0	1.8	1.7

Table 2: Cylinder Size E (M-24) 616 liters when full

	Breaths per Minute									
	12	14	16	18	20	22	24	26	28	30
Flow Setting	Tank duration in hours									
1	85.6	73.3	64.2	57.0	51.3	46.7	42.8	39.5	36.7	34.2
2	42.8	36.7	32.1	28.5	25.7	23.3	21.4	19.7	18.3	17.1
3	28.5	24.4	21.4	19.0	17.1	15.6	14.3	13.2	12.2	11.4
4	21.4	18.3	16.0	14.3	12.8	11.7	10.7	9.9	9.2	8.6
5	17.1	14.7	12.8	11.4	10.3	9.3	8.6	8.0	7.3	6.8

Example 1: M6 tank, breaths/minute = 16, flow setting = 3

- Using table 1, find the breath rate of 16 at the top of the table
- Move down from 16 until you reach the row for flow setting = 3
- The approximate tank duration for this example = 5.2 hours

Example 2:E tank, breaths/minute = 18, flow setting = 2

- Using table 2, find the breath rate of 18 at the top of the table
- Move down from 18 until you reach the row for flow setting = 2
- The approximate tank duration for this example = 28.5 hours

Oxygen Cylinder Duration - TAV® Mode

The following tables provide approximate duration times for B (M-6) and E (M-24) oxygen tanks. Please note that these figures are only meant to serve as a guide.

Note: Actual tank durations will depend on your actual breathing rate, the initial fullness of the tank, and other factors.

Please note that TAV® flow setting 4 does not support a breath rate higher than 25 bpm and TAV® flow setting 5 does not support a breath rate higher than 20 bpm.

Table 1: Cylinder Size B (M-6) 150 liters when full

| Flow Setting | Breaths per Minute | | | | | | | | | | |
	12	14	16	18	20	21	22	23	24	25	30
	Tank duration in hours										
1	4.2	3.6	3.1	2.8	2.5	2.4	2.3	2.2	2.1	2.0	1.7
2	2.1	1.8	1.6	1.4	1.3	1.2	1.1	1.1	1.0	1.0	0.8
3	1.4	1.2	1.0	0.9	0.8	0.8	0.8	0.7	0.7	0.7	0.6
4	1.0	0.9	0.8	0.7	0.6	0.6	0.6	0.5	0.5	0.5	NA
5	0.8	0.7	0.6	0.6	0.5	NA	NA	NA	NA	NA	NA

Table 2: Cylinder Size E (M-24) 616 liters when full

| Flow Setting | Breaths per Minute | | | | | | | | | | |
	12	14	16	18	20	21	22	23	24	25	30
	Tank duration in hours										
1	17.1	14.7	12.8	11.4	10.3	9.8	9.3	8.9	8.6	8.2	6.8
2	8.6	7.3	6.4	5.7	5.1	4.9	4.7	4.5	4.3	0.4	3.4
3	5.7	4.9	4.3	3.8	3.4	3.3	3.1	3.0	2.9	2.7	2.3
4	4.3	3.7	3.2	2.9	2.6	2.4	2.3	2.2	2.1	2.1	NA
5	3.4	2.9	2.6	2.3	2.1	NA	NA	NA	NA	NA	NA

Example 1: M6 tank, breaths/minute = 16, flow setting = 3
- Using table 1, find the breath rate of 16 at the top of the table
- Move down from 16 until you reach the row for flow setting = 3
- The approximate tank duration for this example = 1.0 hours

Example 2:E tank, breaths/minute = 18, flow setting = 2
- Using table 2, find the breath rate of 18 at the top of the table
- Move down from 18 until you reach the row for flow setting = 2
- The approximate tank duration for this example = 5.7 hours
- The approximate tank duration for this example = 6.3 hour

Oxygen Cylinder Duration - Constant Mode

The following tables provide approximate duration times for B (M-6) and E (M-24) oxygen tanks. Please note that these figures are only meant to serve as a guide.

Note: Actual tank durations will depend on the initial fullness of the tank and other factors such as leaks and gauge accuracy.

Table 1: Cylinder Size B (M-6) 150 liters when full

Flow Setting	Tank duration in hours
1	2.5
2	1.3
3	0.8
4	0.6
5	0.5

Table 2: Cylinder Size E (M-24) 616 liters when full

Flow Setting	Tank duration in hours
1	10.3
2	5.1
3	3.4
4	2.6
5	2.1

Example 1: M6 tank, flow setting = 3
- Using table 1, find flow setting of 3
- The approximate tank duration at 3 lpm = 0.8 hours

Exampe 2: E tank, flow setting = 2
- Using table 2, find flow setting of 2
- The approximate tank duration at 2 lpm = 5.1 hours
- The approximate tank duration at 2 lpm = 5.7 hours

Icons

Icon	Where Used	Meaning
AA + (battery)	Back of device, inside of battery cover	AA battery, alkaline
(refer to manual symbol)	Back of device, label	Refer to User Manual
(power button)	Front of device	Power button
(power button) Silence Alarm	Front of device	Alarm silence (power button)
(crossed-out wheelie bin)	Back of device, label	Product contains electronic waste and must be disposed of accordingly
NON STERILE	Cover of Instructions for Use	Product is non-sterile
(Type BF patient figure)	Back of device, label	Product provides Type BF electrical patient isolation
(factory symbol)	Back of device, label	Manufactured by
℞	Cover of Instructions for Use Back of device, label	Prescription use only
(MR crossed out)	Back of device, label	Not for use in MRI environment

Appendices

Appendix A: EMC Information

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC EMISSIONS		
The TAV® system is intended for use in the electromagnetic environment specified below. The user of this system should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF Emissions CISPR 11	Group 1	The TAV® device uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The TAV® system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
The TAV® system is intended for use in the electromagnetic environment specified below. The user of this system should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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 %.
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not applicable	Not applicable. This system does not have power supply lines or input/output lines.

Appendix A: EMC Information

Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not applicable	Not applicable. This system does not connect to mains power or to earth ground.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in UT) for 0,5 cycle 40 % U_T (60 % dip in UT) for 5 cycles 70 % U_T (30 % dip in UT) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Not applicable	Not applicable. This system does not connect to mains power.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the A.C. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity

The TAV® system is intended for use in the electromagnetic environment specified below. The user of this system should assure that it is used in such an environment.

Immunity test	**IEC 60601 test level**	**Compli-ance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not applicable	Not applicable. This system does not connect to mains power or to earth ground.

Appendix A: EMC Information

Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	20V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance
			80 MHz to 800 MHz
			800 MHz to 2.5 GHz
			where is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and is the recommended separation distance in meters (m).
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey1, should be less than the compliance level in each frequency range.
			Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

Appendix A: EMC Information

**Recommended separation distances between
portable and mobile RF communications equipment and the TAV® system**

The TAV® device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (Watts)	Separation distance according to frequency of transmitter (meters)		
	150 kHz to 80 MHz	**80 MHz to 800 MHz**	**800 MHz to 2.5 GHz**
0.01	Not applicable	0.018	0.035
0.1	Not applicable	0.057	0.11
1	Not applicable	0.18	0.35
10	Not applicable	0.57	1.1
100	Not applicable	1.8	3.5

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Appendix B: Altitude Compensation

The TAV® system's flow output can vary if the system is used in locations that are significantly above or below sea level. The following table allows you to estimate the amount of change in the flow. Depending on the altitude of your location, the actual flow rate will be increased or decreased by the indicated percentage.

Altitude (feet)	Pressure (mbar)	Approximate Error in Delivered O2		
		Pulse Mode	Tidal Assist Mode	Constant Mode
-2000	1088	3%	1%	5%
0	1013	0%	0%	1%
500	995	0%	0%	0%
1000	977	-1%	-1%	-1%
2000	942	-2%	-1%	-3%
4000	874	-5%	-3%	-6%
6000	810	-7%	-4%	-10%
8000	751	-10%	-6%	-13%
10000	695	-12%	-7%	-16%
12000	643	-15%	-8%	-20%
14000	595	-18%	-10%	-23%

Examples:

1. The flow setting on your TAV® device is set at 3 lpm and the altitude is 4,000 ft.

    Find 4,000 feet on the table:

    º   Pulse Mode change = 5% (Volumes will be about 5% lower compared with sea level)

    º   Tidal Assist Mode change = 3% (Volumes will be about 3% lower compared with sea level)

    º   Constant Mode change = 6% (Flows will be about 6% lower compared with sea level)

2. The flow setting on your TAV® device is set at 4 lpm and the altitude is 7,000 ft.

    Average the 6,000 and 8,000 foot entries in the table:

    º   Pulse Mode change = -8.5%

    º   Tidal Assist Mode change = 5%

    º   Constant Mode change = -11.5%

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