

FAQ

V-Com™ Clinical & DME

Purchasing & Reimbursement FAQ:

Q: What is the Part Number/SKU for the V-Com™?

A: React Health will be selling this product by the Case Only. A Case of 50 will be SKU 1004. The React Health invoice and packaging slip will note: VCOM SKU 1004 is a case of 50 units.

Q: Do you have samples of the V-Com™ available?

A: Yes, please request an individual sample from your Sales Executive.

Q: What is the minimum purchasing quantity?

A: These are sold by the case only, 50 units to the case.

Q: Is the V-Com™ eligible for reimbursement?

A: Currently we are not aware of any reimbursement for the device. Patients

should inquire directly with their provider for specific coverage information.

Q: What is the MAP/MSRP for the V-Com™ device?

A: React Health will be enforcing MAP and MSRP for this item.

- MAP (Minimum Advertised Price): \$30
- MSRP (Manufacturer's Suggested Retail Price): \$35

Device FAQ

Q: What does the V-Com™ actually do within the circuit?

A: V-Com™ provides comfort without compromising therapy. V-Com™ is designed to attenuate or soften the peak inspiratory flow that is often troublesome to new CPAP patients (and noninvasive ventilation patients). The highest flow rates generated by the PAP device occur during inspiration when the device generates both the exhaust flow and the patient flow (for tidal volume). Flow in a PAP circuit is turbulent, not laminar, and pressure changes by the square of the flow rate. Therefore, V-Com™ has its maximum comforting effect during the high inspiratory flows.

During expiration, flow from the PAP device is the lowest during the respiratory cycle.

Since the V-Com™ effect is flow-dependent, V-Com™ has minimal effect on expiratory positive airway pressure (EPAP), which is principally responsible for therapy.

Expiratory upper airway resistance increases¹ and end-expiratory pharyngeal cross-sectional area decreases¹ in the breaths preceding a hypopnea or apnea resulting in inspiratory pharyngeal instability.² EPAP overcomes this phenomenon and maintains pharyngeal patency directly³ from "splinting" of the airway and indirectly from the increased functional residual capacity.⁴ By maintaining EPAP, V-Com™ maintains therapy while providing comfort.

Before the invention of V-Com™, a clinician's only option to increase comfort and initial tolerance was to decrease the pressure settings, which also decreases EPAP. This both compromises therapy and increases the risk of rebreathing CO₂ from lower exhaust flow. In contrast, V-Com™ does not increase the risk of rebreathing CO₂ because EPAP and exhaust flow are maintained. Adding V-Com™ to the PAP circuit is far superior to the alternative of lowering the set pressures.

The V-Com™ device is not therapy; it is an accessory in the PAP circuit that is designed to increase initial comfort to therapy. Increasing comfort may lead to improved early tolerance. Early tolerance has been shown to increase long-term adherence*.

(continued on back)

(continued from front)

Q: Where is the V-Com™ device placed in the positive airway pressure (PAP) circuit?

A: V-Com™ should be placed between the circuit tube (hose) and the interface (mask). The male end of the V-Com™ inserts into the 22 mm connector of the tube (hose) coming from the PAP device. The female end (22 mm) of the V-Com™ accepts the 22 mm connector on the mask or mask tubing.

Q: What type of patients can potentially benefit from the V-Com™ Device?

A: The short answer is that any number of patient types can benefit from the pressure relief that the V-Com™ device provides. Here are examples of some patient types:

Newly Diagnosed Patients using PAP therapy for the first time:

The ability of a patient to become compliant to therapy is based on many factors. If a patient struggles to find therapy comfortable, this could potentially limit their ability to become compliant to therapy. Starting newly diagnosed patients off with a V-Com™ is a great way to give them every opportunity for compliance.

Patients in their initial period of compliance (first 90 days): Patients in their initial 90 days of compliance but who are NOT meeting the minimum usage requirements to gain ongoing reimbursement from their insurance company are excellent target patients for V-Com™. Offer a patient who has already been set up an additional advantage to gain compliance to therapy through increased comfort to therapy.

Existing PAP patients who have a change in Prescription: Existing patients who have adjusted well to their original prescription may still have difficulty when the pressure is increased to accommodate a change in prescription. Add the V-Com™ with the new prescription to offer a smooth transition to a higher pressure.

Retail Patients: Many PAP patients actively seek out every opportunity to take advantage of options that make therapy more tolerable and more comfortable. These patients often pay retail for these items. Add V-Com™ to your retail showroom on your online presence.

support of the V-Com™ in their circuit and choose to utilize the V-Com™ longer term. It is really up to the patient and what works best for them.

Q: Does the V-Com™ require a prescription?

A: The V-Com™ itself does not require a prescription. We always recommend that patients speak to their Care Team prior to the use of the V-Com™.

Patient Frequently Asked Questions:

Q: How do patients clean the V-Com™?

A: Soap, water, and a small brush. We have created a document specially for patients on the use and cleaning of the device.



Q: Are there any patient types, devices or patient should NOT be used with or that requires special consideration?

A: Yes - V-Com™ has not yet been tested in adaptive servo ventilation (ASV), Bilevel ST Devices and average volume-adjusted pressure support breathing circuits. This is also noted in the Instructions for Use (IFU).

Q: How long does a patient need to use the V-Com™ Device?

A: The length of time can vary depending on the patient. Over weeks or months, some patients develop tolerance to the peak flows and pressures of PAP therapy. Once a patient can easily tolerate the peak flows and pressures of PAP therapy, the V-Com™ device may be removed from the circuit. Other patients find that they like to keep the

Q: Can the V-Com™ be used in other companies PAP devices (Philips, ResMed) ?

A: React Health has tested the V-Com™ for use in its devices and found it to perform as designed. Testing results are available on our website at www.reacthealth.com. We cannot speak to the utilization of this device in other manufacturer's devices. We recommend reaching out to them directly for additional information.

Q: If the patient decides to remove the V-Com™ from their circuit, should they throw the V-Com™ away?

A: We recommend keeping your V-Com™. After cleaning and drying the V-Com™ per the instructions, the V-Com™ can be placed in its heavy duty, resealable plastic package and stored with the patient's PAP equipment/supplies. Should the patient have a change to their pressure settings in the future, the V-Com™ device may be beneficial to acclimating to the new, increased pressure. If the V-Com™ is showing signs of wear, it should be replaced.

4. Heinzer R et al. Lung volume and continuous positive airway pressure requirements in obstructive sleep apnea. *Am J Respir Crit Care Med* 2005;172(4):114-117

1. Tamisier R et al. Expiratory changes in pressure: flow ratio during sleep in patients with sleep-disordered breathing. *SLEEP 2004;27(2):240-248.*

2. Morrell M et al. Retropalatal cross-sectional area preceding on apnea. *Am J Respir Crit Care Med* 1998;158(8):1974-1981.

3. Gugger M et al. Effect of reduced expiratory pressure on pharyngeal size during nasal positive airway pressure in patients with sleep apnoea; evaluation by continuous computed tomography. *Thorax* 1992;47(10):809-813.