



Home NIV Program for COPD



Using home NIV for the management of hypercapnic COPD

This program offers COPD treatment guidelines to physicians to help appropriately target and qualify patients for noninvasive ventilation. It aims to reduce the number of COPD hospital readmissions by providing patients with effective therapy and offering patient monitoring capabilities for successful follow-up.



The COPD Challenge

In 2012, over one million COPD patients experienced an acute exacerbation that resulted in a hospitalization.¹ At \$9,500 per average admission,¹ the estimated cost to the U.S. health care system is over \$49 billion dollars.¹ Furthermore, approximately 22% of these patients are readmitted within 30 days.² Each hospitalization is also a tremendous burden on COPD patients and their families. These hospitalizations are a major cost to the U.S. health care system each year. In order to address these costs, Medicare is planning to add COPD to the list of diagnoses targeted for reductions in readmissions. Hospitals, Medicare, insurance providers and patients are looking for better solutions to the long-term care of COPD patients.³

Why NIV for COPD?

If COPD sufferers are admitted to a medical center due to an acute exacerbation, they are often placed on ventilation. But, once they are discharged, the standard therapy is either pharmacology or oxygen.

Oxygen can address hypoxia caused by impaired gas exchange in the lung tissue – Type 1 respiratory failure. However, oxygen does not address hypercapnia caused by ventilatory failure – Type 2 respiratory failure.

There is strong scientific evidence that noninvasive ventilation (NIV) therapy is an effective option for most COPD patients that are hospitalized. Using NIV to treat COPD patients with Type 2 respiratory failure in a home environment is not often considered.

Research points to the fact that the use of NIV at home:

- Reduces admissions and minimizes costs from the perspective of the hospital⁴
- Reduces recurrence of acute hypercapnic respiratory failure following an initial event by up to two-thirds in the first 30 days following the event⁵
- Leads to a better quality of life^{6,7}

Data Monitoring for Successful Patient Follow-up

Remote monitoring of COPD patients can help determine:

- If a patient is compliant and continuously using NIV therapy for the recommended timeline
- The patient's respiratory rate at home, which can help the physician identify and possibly prevent an acute exacerbation⁸

¹ Perera et al. Acute exacerbations of COPD in the United States: inpatient burden and predictors of cost and mortality. COPD 2012;9:131–44.

² National Quality Forum #1891, October 26, 2012.

³ Boutwell A. Time to get serious about hospital readmissions. Health Affairs Blog, October 12, 2012. <http://healthaffairs.org/blog/2012/10/10/time-to-get-serious-about-hospital-readmissions> (accessed November 20, 2014).

⁴ Tuggey JM, Plant PK and Elliott MW. Domiciliary non-invasive ventilation for recurrent acidotic exacerbations of COPD: An economic analysis. Thorax 2003;58(10):867–71.

⁵ Cheung et al. A pilot trial of non-invasive home ventilation after acidotic respiratory failure in chronic obstructive pulmonary disease. Int J Tuberc Lung Dis 2010;14:642–9.

⁶ Tsolaki et al. One-year non-invasive ventilation in chronic hypercapnic COPD: Effect on quality of life. Respir Med 2008;102(6):904–11.

⁷ Duiverman et al. Nocturnal non-invasive ventilation in addition to rehabilitation in hypercapnic patients with COPD. Thorax 2008;63(12):1052–7.

⁸ Yanez et al. Monitoring breathing rate at home allows early identification of COPD exacerbations. Chest 2012;142(6):1524–9.

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ResMed's Bilevel Solution

VPAP™ COPD

Provides care for the unique needs of COPD patients and offers an easy transition from hospital to home.

VPAP COPD features:

- Integrated oxygen entrainment support: provides oxygen and warmed, humidified air in one circuit
- Default settings optimized for COPD: minimize air trapping and improve synchrony and comfort
- Support for pressures to 30 cm H₂O

EasyCare Online

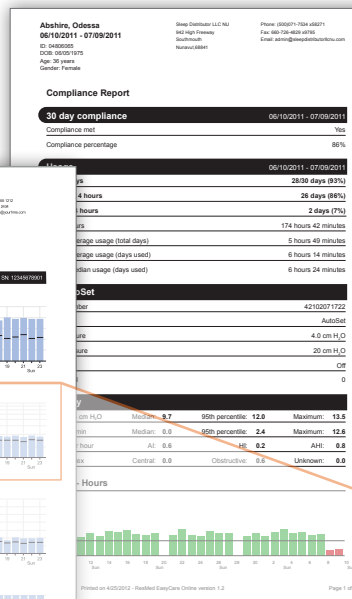
ResMed's EasyCare Online therapy monitoring is a comprehensive solution that empowers you to help patients achieve better therapy outcomes and manage their condition post-discharge.

Usage reports make it easy to identify patients who are not following their treatment plan so you can proactively pinpoint and address issues. Critical respiratory parameters provide additional insight into patient therapy:

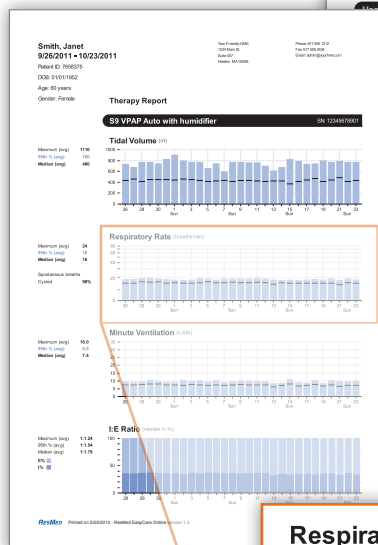
- Respiratory rate
- Minute ventilation
- Tidal volume
- I:E ratio



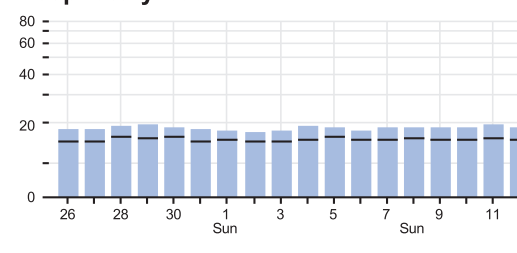
USAGE AND COMPLIANCE REPORT



THERAPY REPORT



Respiratory Rate (breaths/min)



These are sample reports. Patient identification and therapy data is representative only.



Home NIV Program for COPD

Qualifications and prescriptions

COPD Qualification Guidelines for Home NIV

Complete this form to qualify hypercapnic COPD patients for home noninvasive ventilation therapy.

(Qualifications based on 2012 Medicare guidelines)

Patient Name: _____	DOB: _____	Room: _____
1. Formal sleep testing is not required if physician determines that sleep apnea is not the predominant cause of awake hypercapnia or nocturnal O₂ desaturation. i. Sleep apnea has been considered and ruled out: <input type="checkbox"/> YES		
2. Please attach a printed report of the following: An arterial blood gas draw done while patient is awake, breathing the patient's prescribed FiO₂, shows PaCO₂ ≥ 52 mm Hg. i. Patient was awake during arterial blood gas draw: <input type="checkbox"/> YES ii. Blood draw was done on patient's prescribed FiO ₂ : <input type="checkbox"/> YES		
3. Please attach a printed report of the following: Sleep oximetry demonstrates oxygen saturation ≤ 88% for a cumulative 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing oxygen at 2 LPM or the patient's prescribed FiO₂ (whichever is higher). i. Oxygen saturation ≤ 88% for ≥ 5 minutes: <input type="checkbox"/> YES ii. Oximetry recording was performed for at least 2 hours: <input type="checkbox"/> YES iii. Oximetry recording was performed nocturnally: <input type="checkbox"/> YES iv. Patient was breathing 2 LPM oxygen or _____ (the patient's prescribed FiO ₂ , whichever is higher): <input type="checkbox"/> YES		



Physician Order for Home NIV

VPAP™ COPD Prescription			
PATIENT NAME		DATE	
Prescription Settings	Range of Settings:	COPD Default Settings:	
IPAP	_____ (4–30 cm H ₂ O)	<input type="checkbox"/> 13 cm H ₂ O	
EPAP	_____ (3–25 cm H ₂ O)	<input type="checkbox"/> 5 cm H ₂ O	
Ti Min	_____ (0.1–4.0 sec)	<input type="checkbox"/> 0.3 sec	<input type="checkbox"/> Titrate to patient comfort
Ti Max	_____ (0.3–4.0 sec)	<input type="checkbox"/> 1.0 sec	<input type="checkbox"/> Titrate to patient comfort
Rise Time	_____ (Min 100–900 ms)	<input type="checkbox"/> 150 ms	<input type="checkbox"/> Titrate to patient comfort
Trigger	_____ (Very low–very high)	<input type="checkbox"/> Medium	<input type="checkbox"/> Titrate to patient comfort
Cycle	_____ (Very low–very high)	<input type="checkbox"/> High	<input type="checkbox"/> Titrate to patient comfort
Oxygen Bleed: Oxygen in line at _____ Lpm			
Recommended: <input type="checkbox"/> VPAP COPD tri-pack — includes VPAP™ COPD, H5i™ humidifier, ClimateLine ^{MAX} ™ Oxy, alarms		Or select from the following: Tubing: <input type="checkbox"/> ClimateLine ^{MAX} ™ Oxy <input type="checkbox"/> ClimateLine™ <input type="checkbox"/> Standard <hr/> Humidification: <input type="checkbox"/> H5i™ humidifier	
Mask: <input type="checkbox"/> Patient preference <input type="checkbox"/> Full face <input type="checkbox"/> Nasal <input type="checkbox"/> Pillows			
PHYSICIAN SIGNATURE			DATE
PHYSICIAN ADDRESS			NPI #

Patient Follow-up

Suggested NIV follow-up:* <ul style="list-style-type: none"> DME RT to follow up with patient post NIV setup within 7 days EasyCare Online to be reviewed post NIV home setup: <ul style="list-style-type: none"> <input type="checkbox"/> Patient to be monitored daily <input type="checkbox"/> At 7 days after setup <input type="checkbox"/> After day 7, weekly for the first 30 days, monthly after 30 days Patient scheduled for follow-up visit with physician within 61–90 days post-discharge <p>Appointment with: _____</p> <p>Appointment date: _____ Appointment time: _____</p>
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*The suggested follow-up guidelines are intended to help ensure patient compliance and detect early issues with NIV therapy. Existing protocols within your own facility should always supercede the baseline recommendations.

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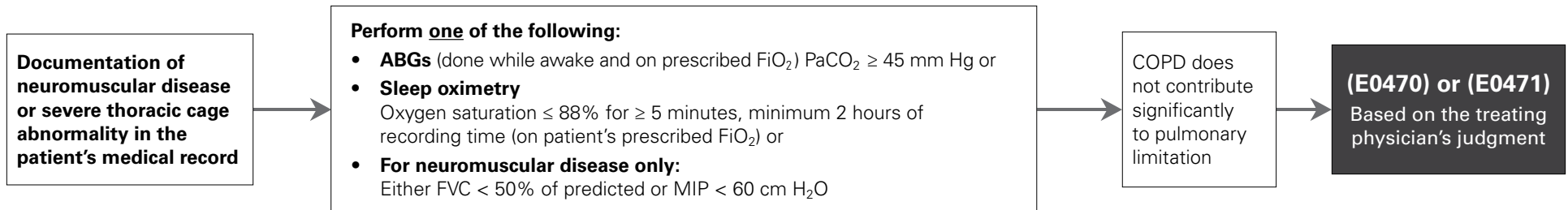
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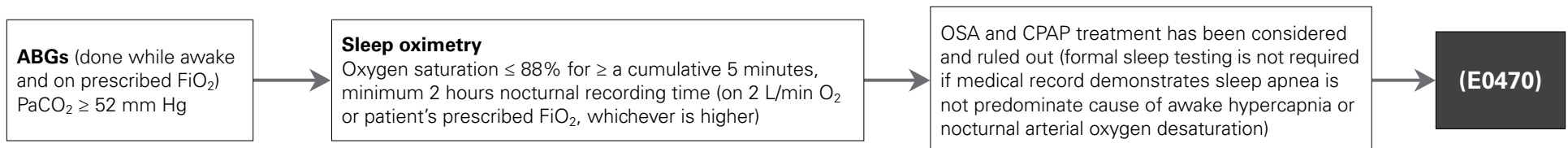
Respiratory Assist Device (RAD) Qualifying Guidelines

CMS revision effective date: December 2014

I. Restrictive Thoracic Disorders



II. COPD



For COPD patients to qualify for a RAD with backup rate (E0471):

Situation 1 After period of initial use of an E0470; **ABG** (done while awake and on prescribed FiO_2) shows PaCO_2 worsens ≥ 7 mm Hg compared to original ABG result; **facility-based PSG** demonstrates oxygen saturation $\leq 88\%$ for \geq a cumulative 5 minutes, minimum 2 hours nocturnal recording time while on an E0470 and not caused by obstructive upper airway events (ie, $\text{AHI} < 5$).

Situation 2 No sooner than 61 days after initial issue of E0470; **ABG** (done while awake and on prescribed FiO_2) shows $\text{PaCO}_2 \geq 52$ mm Hg; **Sleep oximetry** on an E0470 demonstrates oxygen saturation $\leq 88\%$ for \geq a cumulative 5 minutes, minimum 2 hours nocturnal recording time (on 2 L/min O_2 or patient's prescribed FiO_2 , whichever is higher).

Respiratory Assist Device (RAD) Documentation Requirements for Continued Coverage Beyond First 3 Months

Patients on an E0470 or E0471 device must be reevaluated no sooner than 61 days after initiating therapy.

Required Documentation

- Progress of relevant symptoms
- Signed and dated statement by treating physician declaring patient using average 4 hours per 24-hour period and patient benefiting from use

ResMed E0470 and E0471 Devices

E0470–Bilevel without a backup rate:

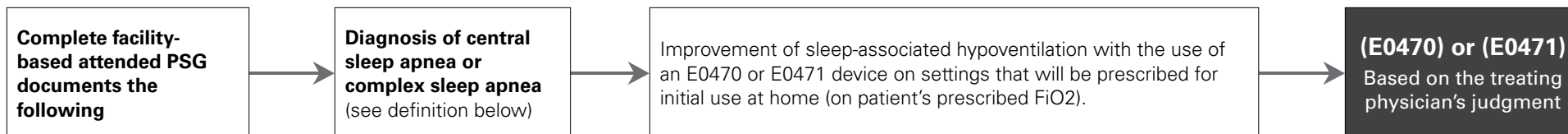
- AirCurve™ 10 VAuto
- AirCurve™ 10 S
- VPAP™ COPD

E0471–Bilevel with a backup rate:

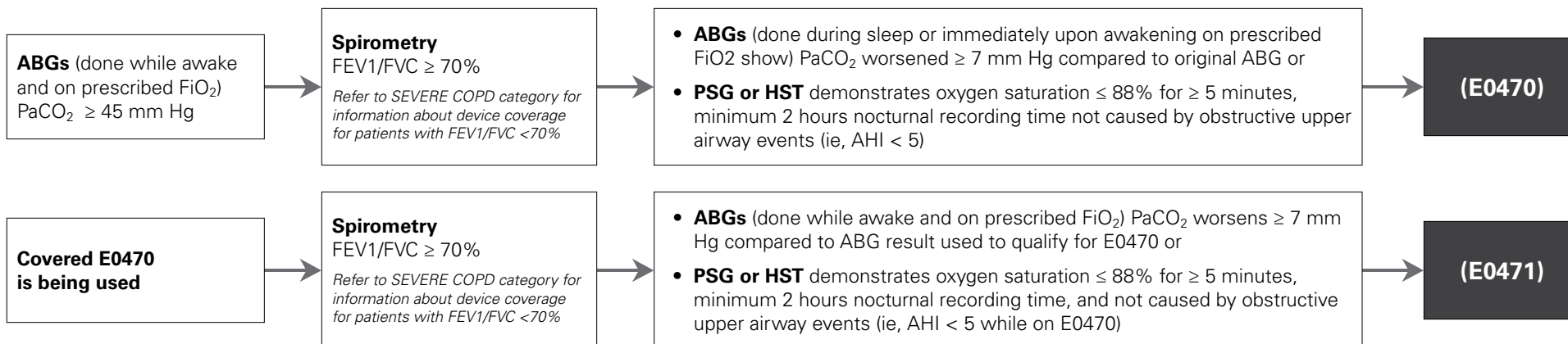
- AirCurve 10 ST
- AirCurve 10 ASV
- VPAP ST-A
- Stellar™*

* For invasive use, code E0472

III. Central Sleep Apnea or Complex Sleep Apnea



IV. Hypoventilation



A diagnosis of **central sleep apnea (CSA)** requires all of the following:

1. An apnea–hypopnea index ≥ 5; and
2. Sum total of central apneas plus central hypopneas > 50% of the total apneas and hypopneas; and
3. CAHI* ≥ 5 per hour; and
4. Presence of either sleepiness, difficulty initiating or maintaining sleep, frequent awakenings, or non restorative sleep, awakening short of breath, snoring, or witnessed apneas; and
5. No evidence of daytime or nocturnal hypoventilation

Note: Not all types of HST are appropriate for the evaluation of CSA or CompSA as necessary parameters are not monitored.

*For CSA diagnosis, central apnea–central hypopnea index (CAHI) is defined as the average number of episodes of central apnea and central hypopnea per hour of sleep without the use of a PAP device.

**For CompSA, the CAHI is determined during the use of a PAP device after obstructive events have disappeared.

Complex sleep apnea (CompSA) is a form of central apnea identified by all of the following:

1. PSG demonstrates the persistence or emergence of central apneas or central hypopneas upon exposure to CPAP or an E0470 device when titrated to the point where obstructive events have been effectively treated (AHI < 5 per hour); and
2. After resolution of the obstructive events, the sum total of central apneas plus central hypopneas is > 50% of the total apneas plus hypopneas; and
3. After resolution of the obstructive events, CAHI** ≥ 5 per hour

Ventilator with Non-Invasive Interfaces: Please reference ResMed's Ventilator Reimbursement Fast Facts: PN 1017230.

This information is provided as of the date listed, and all coding and reimbursement information is subject to change without notice. It is the provider's responsibility to verify coding and coverage with payors directly. For a full description of the policy go to www.cms.hhs.gov.

ResMed reimbursement hotline, dial **1-800-424-0737** and select **option 4**.



ResMed

Noninvasive Ventilation Therapy

Treating your respiratory conditions



ResMed.com

Noninvasive ventilation (NIV)— treating your respiratory conditions

If you have a breathing problem due to weak muscles or a lung condition, your clinician may recommend a type of therapy called noninvasive ventilation.

Human lungs serve as a collection and distribution center for oxygen and carbon dioxide (see page 4 for details). When you have a respiratory condition, NIV therapy can support your breathing and help your body perform these functions more effectively.

ResMed offers a wide range of devices for every patient's individual needs:

- The VPAP™ range includes ResMed's premium NIV systems, ideal for nighttime ventilation.
- ResMed's ventilators are light, quiet and portable, providing nondependent patients with quality ventilation night and day.



What is NIV?

NIV is a form of assisted ventilation, providing air to your airways and lungs. This therapy is called “noninvasive” because it delivers air via a mask or mouthpiece—unlike invasive types of ventilation that require the insertion of a tube in the windpipe.

A ventilation device enhances your breathing and helps reduce the amount of effort required when taking a breath.

Your clinician will prescribe the level of pressure best suited to your therapy needs.



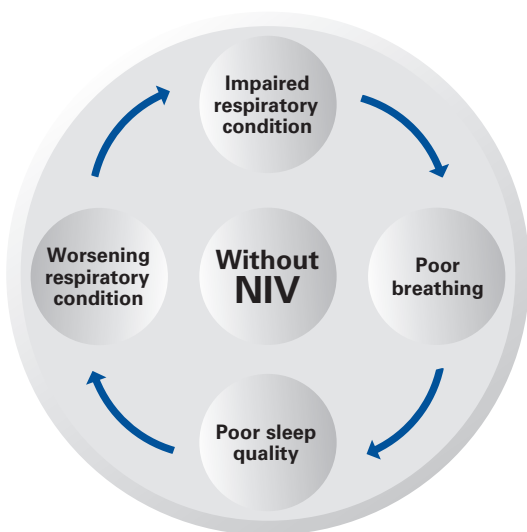
What are the benefits of NIV?

- **Can make day-to-day activities easier:**

By easing the work of breathing, effective NIV therapy may give you more energy and flexibility to pursue everyday activities.

- **Helps alleviate a range of symptoms:**

Morning headaches, daytime fatigue and shortness of breath are just some of the daytime symptoms that may occur due to inadequate ventilation—that is, low levels of oxygen (O_2) and accumulated carbon dioxide (CO_2). By managing CO_2 and O_2 levels in your body, NIV therapy helps relieve symptoms over time to improve your quality of life.



Without NIV, poor breathing during sleep can worsen the respiratory condition, setting up a cycle of deterioration.

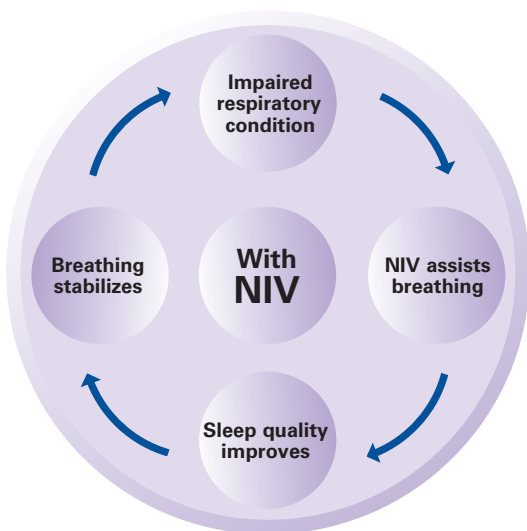
- **Reduces the risk of worsening infection:**

NIV helps improve sleep quality. The more rested you are, the sooner you are likely to recover from colds and other infections. Improved sleep is the first line of defense against such infections.

- **Reduces time in hospital:**

Studies* indicate that NIV reduces hospitalization by stabilizing your breathing and improving the quality of your sleep. Adequate ventilation may help avoid respiratory failure. Often prescribed for treatment in your own home, NIV is effective and more convenient.

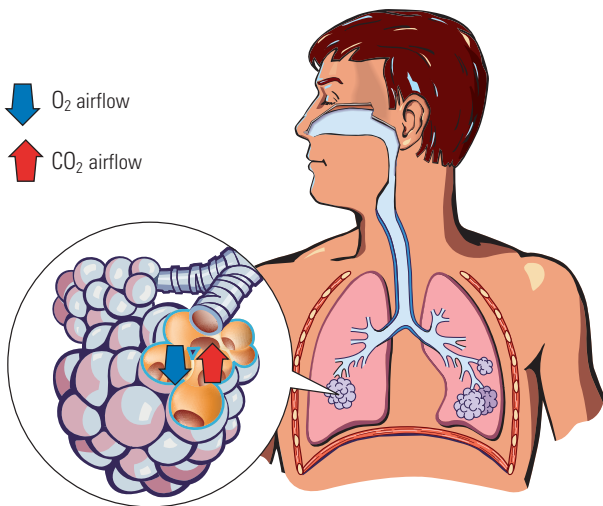
* References to specific studies available on request



Effective NIV therapy can break the cycle and may prevent certain conditions from worsening.

How do my lungs function?

- Think of your lungs as a collection and distribution center. They collect O_2 from the air you breathe and distribute it to the rest of your body. They collect CO_2 from your body and remove it through the air that you breathe out.
- Our lungs consist of millions of alveoli—small air sacs. Through the walls of these air sacs, O_2 and CO_2 are exchanged between the lungs and blood.



Healthy lung function: As seen in the magnified view, air can flow quite easily into and out of the alveoli (small air sacs in the lungs).

What types of diseases can affect my respiratory system?

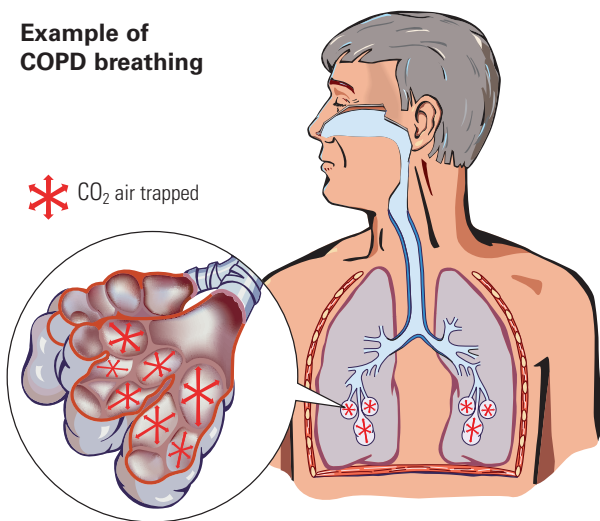
Three main types of diseases can weaken your lungs, chest wall or chest wall muscles, impairing their performance.

- **Restrictive diseases:** As the name suggests, these diseases restrict movement of the lungs, preventing adequate ventilation. This can be seen where there are weakened chest wall muscles or abnormalities in the chest wall.
- **Obstructive diseases:** The obstruction or narrowing of small airways in the lungs causes these diseases, which are often characterized by difficulty exhaling.
- **Obesity hypoventilation syndrome (OHS):** This condition is defined by a combination of obesity and a high level of carbon dioxide in the blood. During spontaneous breathing at rest, people with OHS need significantly greater effort to breathe than those of normal weight.

How do these diseases affect my breathing?

- Consistent airflow to your lungs with an adequate volume of air is essential to balance levels of O_2 and CO_2 in your body.
- When the body consumes O_2 to generate energy and maintain activities, CO_2 is produced.
- When your respiratory system is impaired and the air delivery is limited, levels of O_2 and CO_2 in your body become unbalanced.
- You may hear the term “hypoventilation,” which literally means under-ventilated.

Example of COPD breathing



The obstruction or narrowing of small airways can cause CO_2 to remain trapped inside the lungs.

How does NIV help my breathing?

- NIV assists in the ventilatory process by increasing the volume of air moving in and out of your lungs.

How does a ResMed ventilator benefit my therapy?

Designed for excellence in noninvasive ventilation, ResMed's ventilators offer you a range of unique therapy benefits.

- **Responding to you:**

ResMed ventilators sense when you breathe in and when you breathe out, matching their rhythm to yours.

- **Responding to your condition:**

The adjustable settings can be customized to your individual needs.

- **Improving your quality of life:**

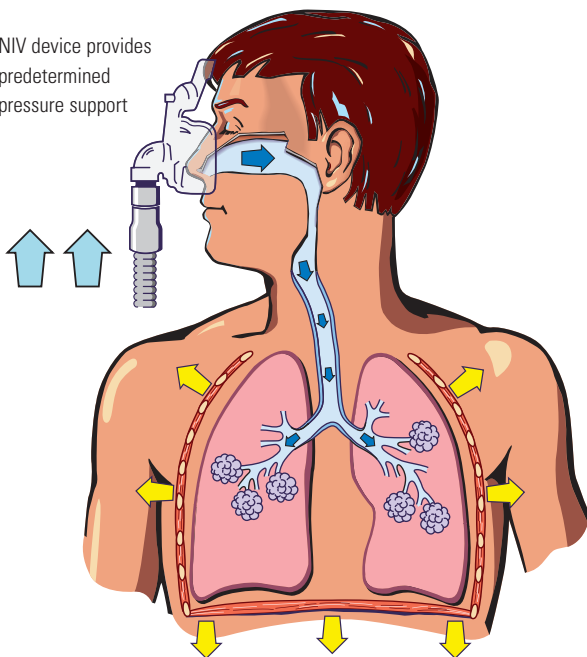
ResMed's range of ventilators have been specially designed for whisper-quiet therapy and to help improve your quality of life.

How does NIV work?

- ResMed NIV devices support your breathing by providing a predetermined level of pressure support when you breathe in (inhalation) and less pressure when you breathe out (exhalation).

Inhalation

NIV device provides predetermined pressure support

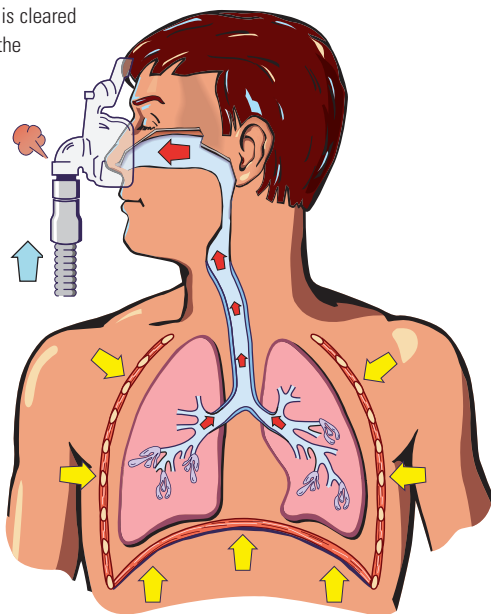


- Pressure support (the difference between the inhalation and exhalation pressures) increases the amount of air moving in and out of your lungs.
- The steady, lower pressure keeps your airway and alveoli open and to clears out exhaled CO_2 through a vent in the mask.

Exhalation

Exhaled CO_2 is cleared out through the mask vent

NIV device applies less pressure



What does therapy involve for me?

- Your clinician may prescribe NIV therapy for use at night while you sleep. And in some cases, they may recommend daytime use as well.
- Therapy involves wearing a mask that is specially selected to suit your facial features and nasal structure. You can choose from ResMed's broad range of high quality masks to complement your ventilation device for optimal therapy outcomes.



- Your specialist or clinician determines the necessary therapy settings on your device.
- Depending on your condition, therapy may also involve periodic review of your progress. Your specialist or clinician determines whether any adjustments or changes are necessary over time.
- NIV therapy is often part of a comprehensive care program. This may include one or more of a range of remedial measures, such as proper nutrition, physical therapy, pulmonary rehabilitation, oxygen supplementation and medication.



How can I familiarize myself with NIV?

Getting accustomed to your therapy is well worth the effort and is important for your health and well-being. A few simple steps, detailed below, can help you.



Step 1

When starting therapy, hold the mask in your hand (do not put it on yet). Connect the mask to the tubing and the tubing to the ventilator. Then turn on the ventilator.



Step 2

Now hold the mask to your face and take a few deep breaths, in and out (through your nose if you're using a nasal mask). When there is air leakage around the mask, the ventilator automatically generates a higher airflow to compensate.



Step 3

After about 5-10 consecutive breaths, when you feel confident breathing on your device, put on the mask system. If you use your ventilator while lying down, tighten or loosen the headgear straps as required, so that the mask seals. Finding the right balance between seal and comfort is critical, so balancing strap tension is important. Remember that your ventilator instantly responds to leaks, so you don't need to overtighten the mask around your head. ResMed's headgear can be easily attached or detached from the mask, so it is easy for you to take your mask off quickly at any time.



Step 4

Once you manage to breathe for 30–40 minutes at a time, try using therapy at night while you sleep. You may wake up after a few hours, but you will soon get accustomed to the therapy. If the mask does not seal or remains uncomfortable, consult your NIV specialist—a number of solutions are available.



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