ZOLL®

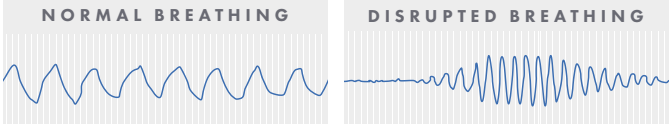
Frequently Asked Questions

Contents

Central Sleep Apnea

What is Central Sleep Apnea (CSA)?

Central sleep apnea is a sleep breathing disorder in which your brain does not send regular signals to your breathing muscle (diaphragm). These inconsistent signals from your brain lead to pauses in breathing or shallow breathing that are called apneas or hypopneas. These events may disrupt your sleep and cause your blood oxygen levels to drop (hypopnea).[1]



What is the Apnea Hypopnea Index (AHI)?

The apnea hypopnea index is a common metric used by sleep clinicians to measure how many apnea events occur per hour of sleep. The AHI includes all types of apnea and hypopnea events, including central apneas, obstructive apneas, mixed apneas, and hypopneas.

What is the difference between Central Sleep Apnea (CSA) and Obstructive Sleep Apnea (OSA)?

Obstructive sleep apnea (OSA) and central sleep apnea (CSA) are both types of sleep apnea.

In OSA, the breathing muscles (e.g. diaphragm) are activated appropriately but a narrowing of the passages in the upper airway (the tongue or throat) cause a blockage that prevents air from flowing freely. The obstruction can be due to bodily features or a relaxation of the muscles in the chest and neck during sleep.[1]

In CSA, the brain fails to send regular signals to the diaphragm. The lack of consistent signals leads to irregular nighttime breathing.[1]

Some people have both OSA and CSA and this is sometimes called complex sleep apnea. Determining how to address complex sleep apnea will take consideration and consultation with your physician regarding managing the complete picture of your sleep breathing disorders.

What causes central sleep apnea?

The American Association of Sleep Medicine categorizes adult CSA into five types based on the etiology, or cause of the disease:[2]

- Central sleep apnea with Cheyne-Stokes breathing. Cheyne-Stokes is a specific pattern of breathing with a gradual increase and decrease in breathing followed by periods of absent or shallow breathing
- Central sleep apnea due to a medical disorder without Cheyne-Stokes breathing
- Central sleep apnea due to high altitude periodic breathing
- Central sleep apnea due to a medication or substance use
- Primary central sleep apnea (not caused by other issues listed above)

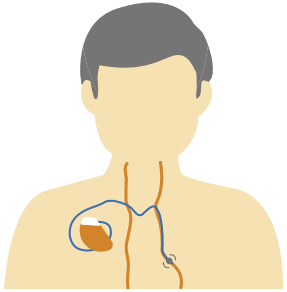
remedē® System

What is remedē?

remedē is a pacemaker-like device that stimulates your breathing muscles (via the phrenic nerve) to restore a normal breathing rate and rhythm during sleep. It is fully implantable and activates automatically each night.[3]

How does remedē work?

remedē activates automatically each night to send signals to your diaphragm from the phrenic nerve to restore a normal breathing pattern. The signals cause your diaphragm to contract, drawing air into your lungs, just as in normal breathing. **rem**edē also monitors breathing signals while you sleep. Because the device is implanted and activates automatically, it does not require wearing a mask or other equipment at home.[3]



When will remedē activate at night?

The **rem**edē System is programmed to automatically begin therapy each night when **all three** of the following programmable conditions are met:

1) **Sleeping hours:** It is within your normal sleeping times; (for example, 11:00 PM to 6:00 AM)

2) **Sleeping posture:** You are in a sleeping posture (for example, a horizontal position)

You are reclined past your programmed sleeping angle

3) **Activity:** Your activity level is representative of a sleeping or resting condition

AND you are still

Can I pause or turn remedē off?

If you roll over, sit up, or get out of bed, the therapy will pause and resume once the above three conditions are once again met.[3]

Therapy pauses if you roll

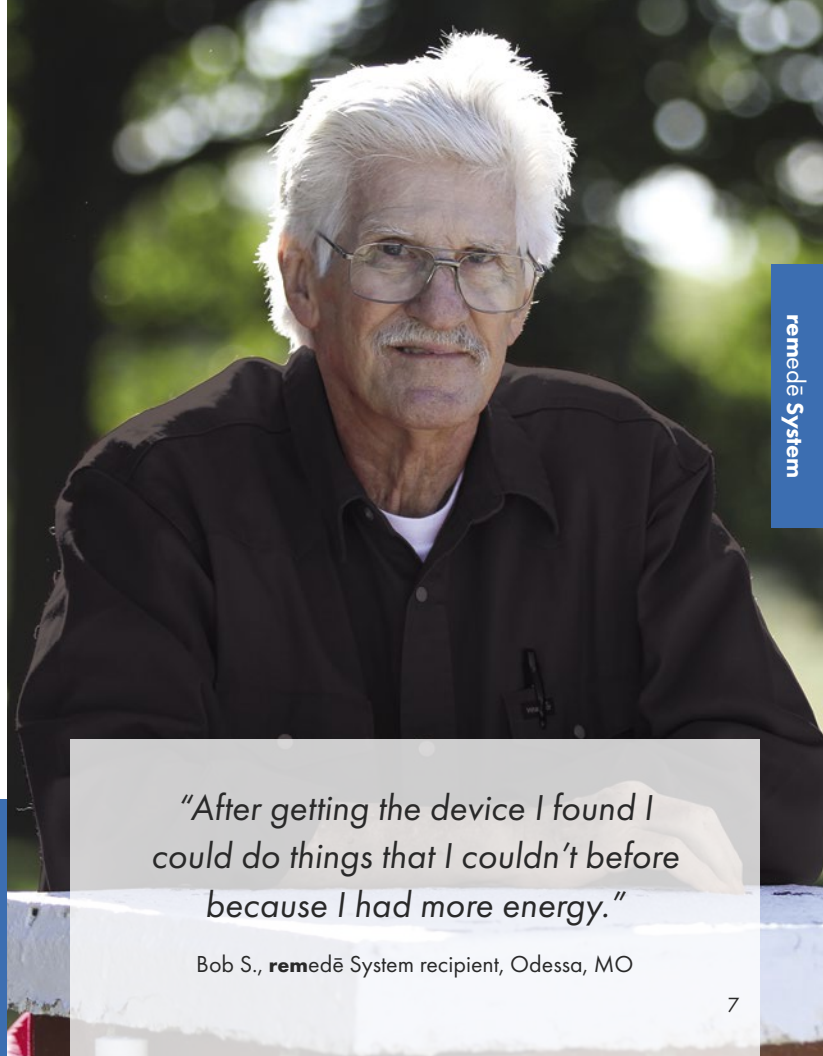
OR when you sit up

What does remedē feel like?

In our experience, most people describe their first breaths with **rem**edē as taking a breath that you didn't plan on. Once activated, **rem**edē is designed to turn on once you are already asleep and operate without waking you up.[4]

We encourage you to hear how patients describe **rem**edē by visiting the following website:

remede.zoll.com/patients/hear-from-others



remedē System

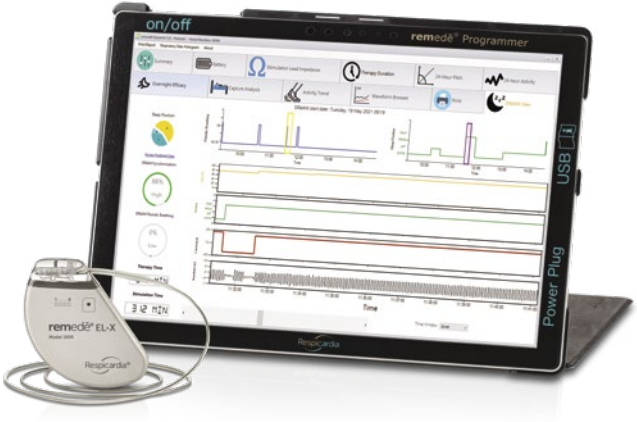
"After getting the device I found I could do things that I couldn't before because I had more energy."

Bob S., **rem**edē System recipient, Odessa, MO

Eligibility for **rem**edē

Who is a candidate for remedē?

remedē is FDA-approved for adults with moderate to severe central sleep apnea. **rem**edē is contraindicated for people with an active infection and people known to require magnetic resonance imaging (MRI).[3]



Is a person with both central and obstructive sleep apnea eligible for remedē?

remedē is FDA-approved for adults with moderate to severe central sleep apnea.[3] Consult with your doctor to determine whether you are a candidate for **rem**edē.

Am I ever able to get an MRI if I have remedē?

remedē is contraindicated for people known to require magnetic resonance imaging (MRI). Talk to you doctor about the safest and most effective approach if an unanticipated need for imaging were to arise.[3]

Eligibility for remedē

Can someone with remedē use additional therapies for OSA?

Prior to FDA approval, **rem**edē was studied without additional forms of apnea therapy such as CPAP masks. The published clinical data, as well as the data on **remede.zoll.com**, reflects use of the **rem**edē therapy alone.

However, following FDA approval, physicians have used other therapies such as CPAP in conjunction with **rem**edē to further reduce apneic events caused by OSA. The FDA approval does not exclude the use of additional therapies.

Coverage and Cost

How much will I have to pay for remedē?

The hospital will work with your insurance plan to determine what, if any, of the cost is billed to you. Talk to your physician about insurance coverage, as many insurance companies work with clinicians to evaluate coverage for **rem**edē based on your individual case.

Is this therapy covered by insurance?

remedē is generally being reviewed for approval by insurance providers on a case-by-case basis. After determining that you are a candidate for **rem**edē, your doctor and their office staff will work with your insurance provider on securing coverage for the procedure.

What happens if the procedure is denied by my insurance company?

In most cases, you are able to appeal a denial by your insurance company and request further review of your case. Ask your physician about the **rem**edē Patient Access Program, which provides resources for supporting insurance prior authorization appeals.

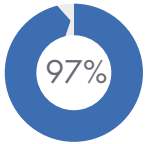
You can also speak to a reimbursement specialist at Respicardia by calling **952-540-4470** or email questions to **reimbursement@remede.zoll.com**

Efficacy and Safety

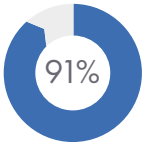
How effective is remedē?

The **rem**edē System works to continuously and automatically monitor and stabilize the breathing pattern, restoring sleep throughout the night.

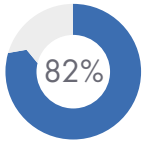
In a clinical research study evaluating patients after 12 months of therapy, **rem**edē has been shown to significantly reduce the effects of CSA:[5]



97% reduction in the median Central Apnea Index



91% of patients had a reduction in the number of sleep apnea events per hour



82% of patients had an improvement in quality of life

95% of patients would get **rem**edē again

Note: At 6 months, 48% of patients without therapy had a positive change in apnea events per hour, 13% of the control group had an improvement in quality of life, and control group patients experienced a 4% increase in the median Central Apnea Index.

What are the risks associated with the remedē procedure or therapy?

As with any surgically implanted device, there are risks related to the implant procedure which may include, but are not limited to, pain, swelling and infection. Once the **rem**edē System is implanted and the therapy is activated, some people may experience discomfort from the therapy and/or from the presence of the device. The majority of these events are resolved on their own or by adjusting the therapy settings. The **rem**edē System may not work for everyone. There are additional risks associated with removing your system. If you and your doctor decide to remove the system, another surgery will be required.[3]

Be sure to talk with your doctor so that you thoroughly understand all of the risks and benefits associated with the implantation of the **rem**edē System.

How long does the battery last?

The latest models of the **rem**edē System have batteries that typically last between 4-6 years. Some people may not need replacement for over 6 years. However, if higher levels of therapy are needed to normalize breathing, the battery may need to be replaced in 2 years or less.[3]

Where can I learn more about remedē?

Read more about **rem**edē, access a schedule of upcoming webinars about **rem**edē, ask a question, or speak with a **rem**edē patient by visiting **remede.zoll.com** or by scanning the QR Code below.

Procedure

What happens during the procedure?

The **rem**edē System is placed during a minimally invasive procedure by a cardiologist. The system is a battery powered device placed under the skin in the upper chest area with two small thin wires (leads), one to deliver the therapy (stimulation lead) and one to sense breathing (sensing lead).[3]

Is there anything I need to do to prepare before the procedure?

This will vary by patient and provider. Talk to your physician about what preparation is recommended.

How long will I stay in the hospital for the procedure?

The **rem**edē System is placed during a minimally invasive outpatient procedure by a cardiologist. Some patients go home the same day, while others may stay overnight for observation.

Post-Procedure Care

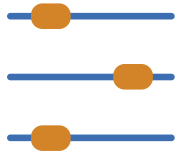
Will I have any limitations following the procedure?

Follow all advice from your doctor after the procedure. Most people can resume normal activity 7-10 days after the procedure. In most cases, your doctor will advise you to not raise your arm above the shoulder on the side the device is placed for 1-3 months.[7]

What follow up visits are required?

You typically return about one month after implant to activate therapy. During this time, you recover and the device collects data on your sleeping and breathing patterns.[7]

At the visit, the clinician will activate and program **rem**edē to meet your needs. People typically return for additional clinic appointments to adjust programming and titrate the therapy. Once optimized, most clinicians will follow up 1-2 times per year.[7]



Will TSA/metal detectors or airplane travel be a problem for me if I get the device?

You should talk to your doctor about any specific concerns. Electronic equipment such as that designed to prevent theft and airport metal detectors may affect the **rem**edē System. Alert security personnel about the System and request a manual search if possible. If walking through a surveillance system, do not remain near this system longer than needed.[7]

Long-term benefits of the **rem**edē System

Do people feel better after getting the remedē System?

82% of people implanted with the **rem**edē System reported an improvement in their quality life at 6 months. At 12 months, this had increased to 91% of people.[5,6] Keep in mind that there are risks associated with any implantation procedure. The most common risks are similar to those of other implant procedures, including risk of infection.

What are the long-term results of the remedē System?

Long-term clinical trial results reported follow-up out to 5 years have been published. The reported data shows consistent and sustained results of the **rem**edē System in reducing AHI, central apneas, arousals, and oxygen desaturation events.[8]

Can I speak with someone who has had the device for many years?

Yes, many of the patients that were involved in the **rem**edē pivotal trial have had their devices for 5+ years. Email **info@remede.zoll.com** and we can connect you with these patients so you can hear directly from them what **rem**edē has meant to them.

References

[1] Javaheri S., Dempsey J.A. (2013) Central sleep apnea. *Compr Physiol.* 2013; 3:141–163.

[2] Sateia MJ. (2014) International classification of sleep disorders-third edition: highlights and modifications. *Chest.* 2014; 146(5):1387-1394.

[3] FDA PMA P160039, Supplement 006, Physician Manual.

[4] https://www.remede.zoll.com/patients/hear-from-others/.

[5] Costanzo M, et al. Sustained Twelve Month Benefit of Phrenic Nerve Stimulation for Central Sleep Apnea. *Am J Cardiol* 2018;121:1400-8.

[6] Costanzo M, et al. Transvenous neurostimulation for central sleep apnoea: a randomised controlled trial. *The Lancet.* 2016; 388: 974–82.

[7] **rem**edē System Patient Manual

[8] Costanzo M, et al. Transvenous Phrenic Nerve Stimulation for Treatment of Central Sleep Apnea: Five-Year Safety and Efficacy Outcomes. *Nat Sci Sleep.* 2021;13:515-526 https://doi.org/10.2147/NSS.S300713

Important Safety Information
The **rem**edē® System is indicated for moderate to severe Central Sleep Apnea (CSA) in adult patients. Your doctor will need to evaluate your condition to determine if the **rem**edē System is right for you. You will not be able to have an MRI or diathermy (special heat therapies) if you have the **rem**edē System implanted. The **rem**edē System may be used if you have another stimulation device such as a heart pacemaker or defibrillator; special testing will be needed to ensure the devices are not interacting. As with any surgically implanted device, there are risks related to the surgical procedure itself which may include, but are not limited to, pain, swelling, and infection. Once the therapy is turned on, some patients may experience discomfort from stimulation and/or from the presence of the device. The majority of these events are resolved either on their own or by adjusting the therapy settings. The **rem**edē System may not work for everyone. There are additional risks associated with removing your system. If you and your doctor decide to remove the system, another surgery will be required. Be sure to talk with your doctor so that you thoroughly understand all of the risks and benefits associated with the implantation of the **rem**edē System. For further information, please visit remede.zoll.com, call 952-540-4470 or email info@remede.zoll.com. **Indication for use:** The **rem**edē System is an implantable phrenic nerve stimulator indicated for the treatment of moderate to severe Central Sleep Apnea (CSA) in adult patients. **Contraindications:** The **rem**edē System is contraindicated for use in patients with an active infection or patients known to require magnetic resonance imaging (MRI). See the Instructions for Use for complete information regarding the procedure, indications for use, contraindications, warnings, precautions, and potential adverse events.
Rx Only.
The **rem**edē® System, **rem**edē® EL System, and **rem**edē® EL-X System have received FDA approval.
The **rem**edē® System model 1001 has received CE Mark approval.

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