

remedē[®] Reports



Custom Therapy Made Simple.

The **remedē**[®] System is a proven, implantable sleep therapy specifically designed for treating adults with moderate to severe Central Sleep Apnea (CSA) in a way that closely resembles the body's natural physiology. It has been shown to provide long-term benefits to reduce the severity of CSA and improve sleep, breathing, and quality of life.

The System includes an interactive tablet with **remedē** Reports, an enhanced software designed to deliver actionable information so you can quickly and easily tailor therapy for your patient.

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STREAMLINED NAVIGATION

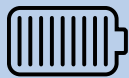
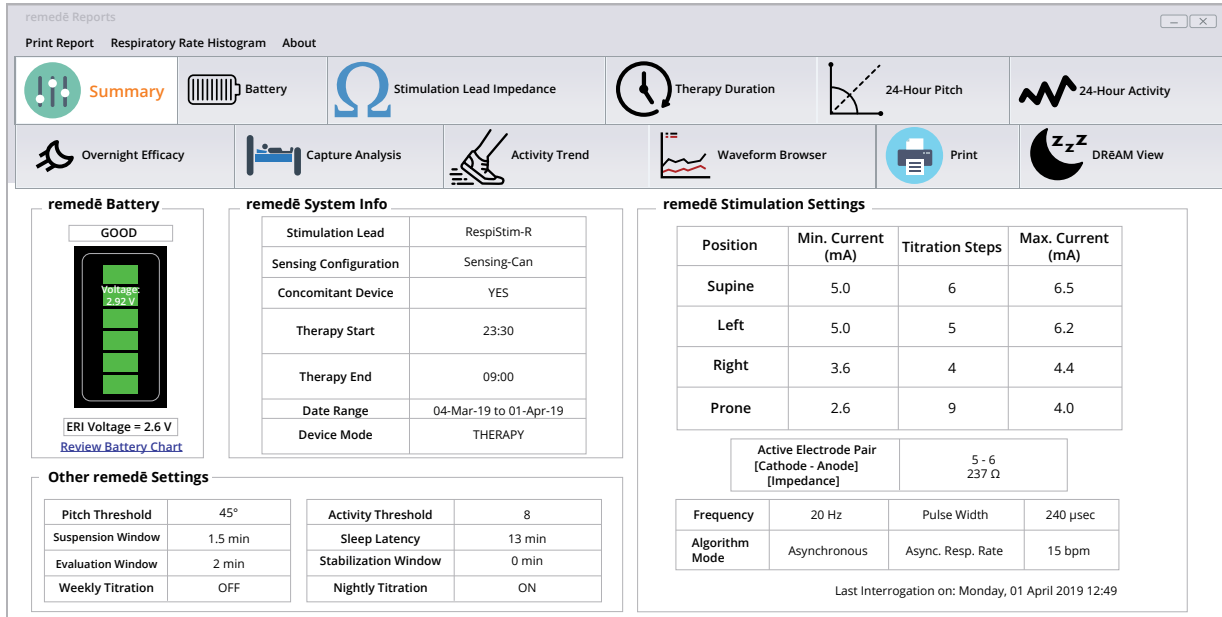
The NAVIGATION display consolidates key information into a single application and is organized using selectable tabs that allow for detailed review of collected diagnostic data.



Summary

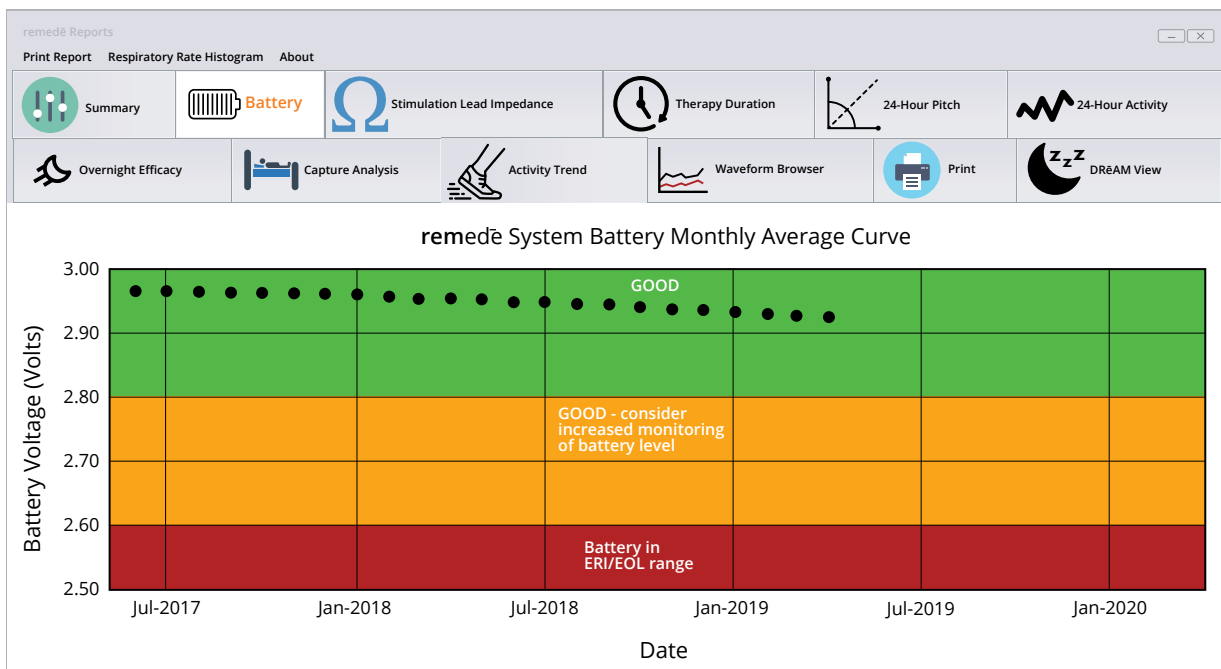
The SUMMARY display contains a single screen overview of the **remedē** Implantable Pulse Generator (IPG) for a quick review of device setup and therapy parameters including:

- Battery status display with color indicator bars to help guide monitoring frequency
- System information with relevant therapy configuration and schedule
- Detailed stimulation settings for each sleeping posture



Battery

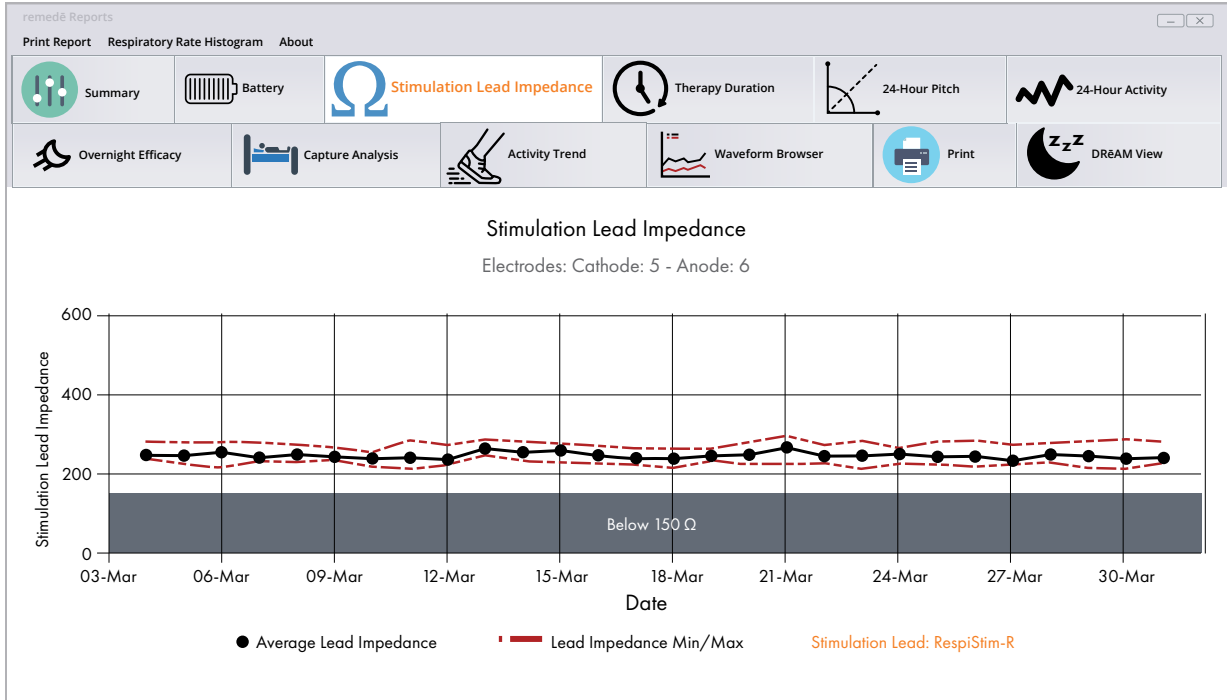
The Battery tab contains a long-term trend (60 months) of monthly average **remedē** IPG battery voltage measurements.





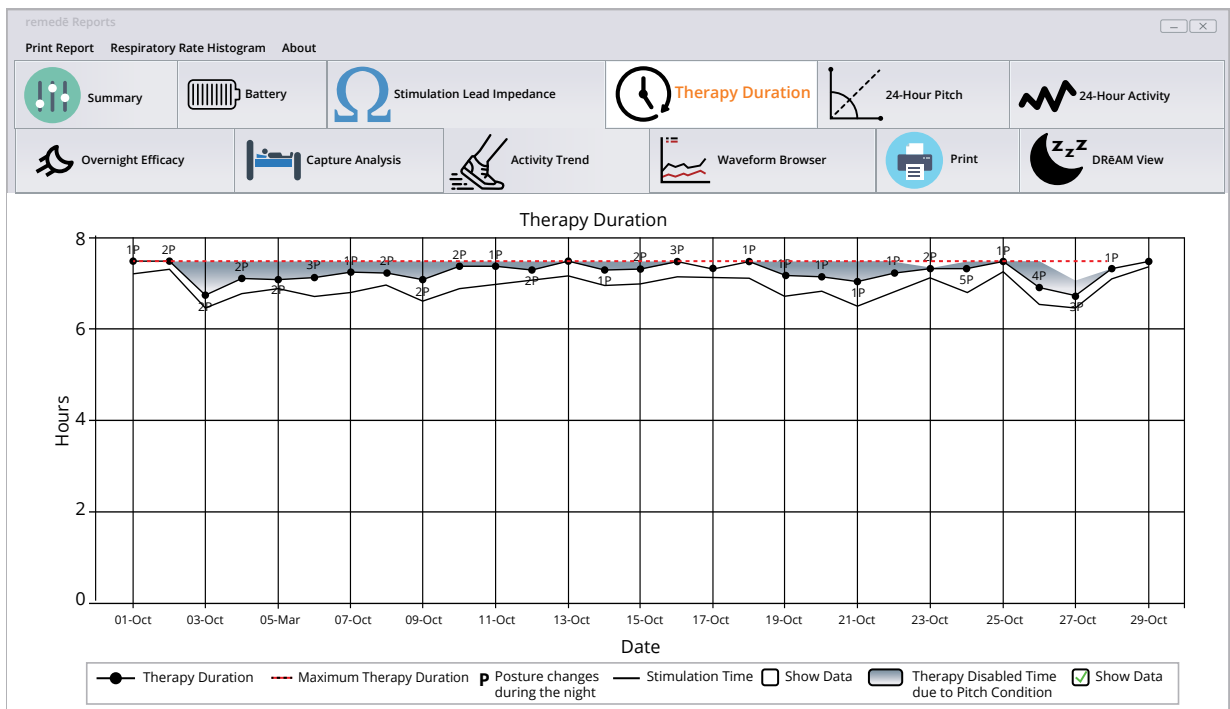
Simulation Lead Impedance

The Stimulation Lead Impedance tab contains the daily average stimulation lead impedance measurements.



Therapy Duration

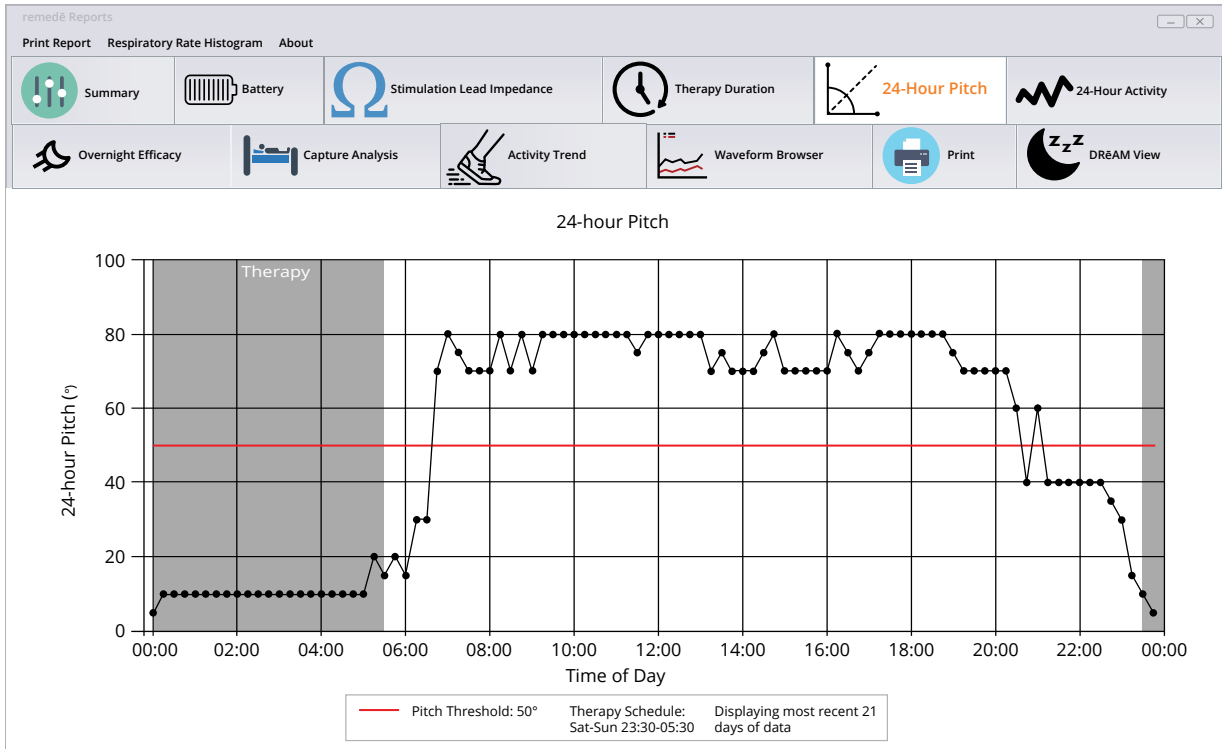
The Therapy Duration graph shows the amount of time that therapy was delivered each night.





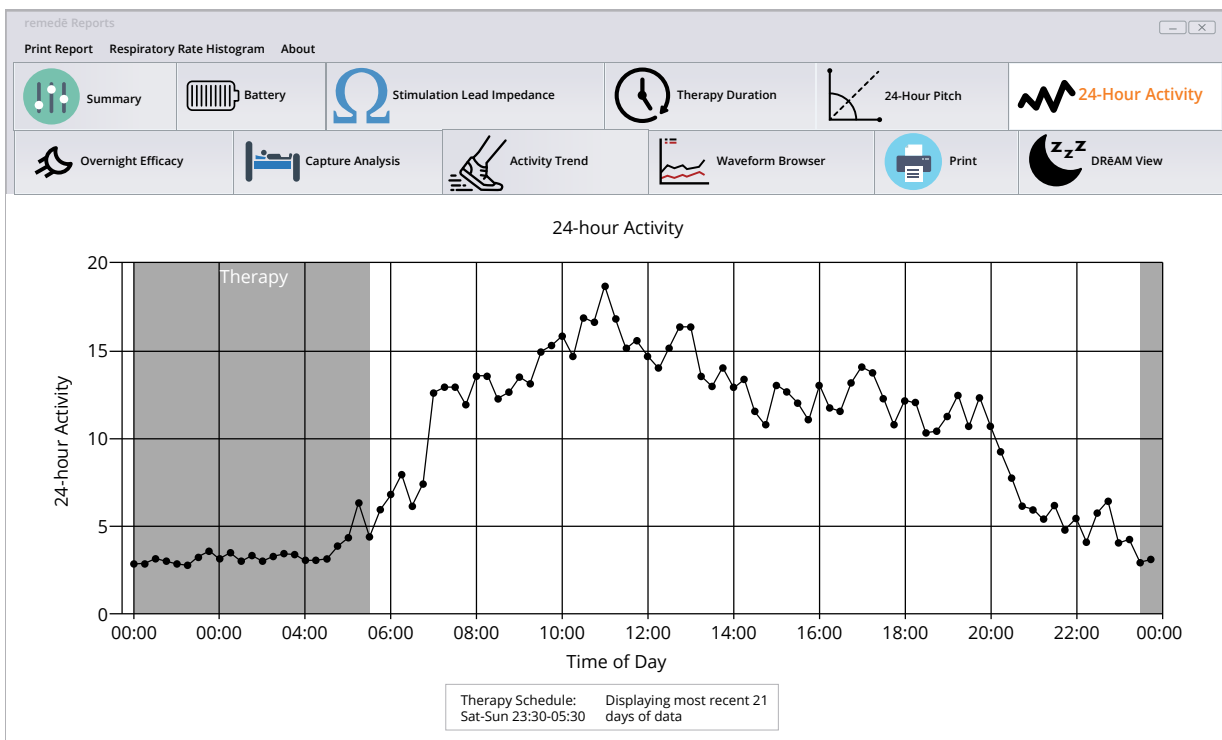
24-hour Pitch

The 24-Hour Pitch graph shows the patient's pitch position by hour of the day.



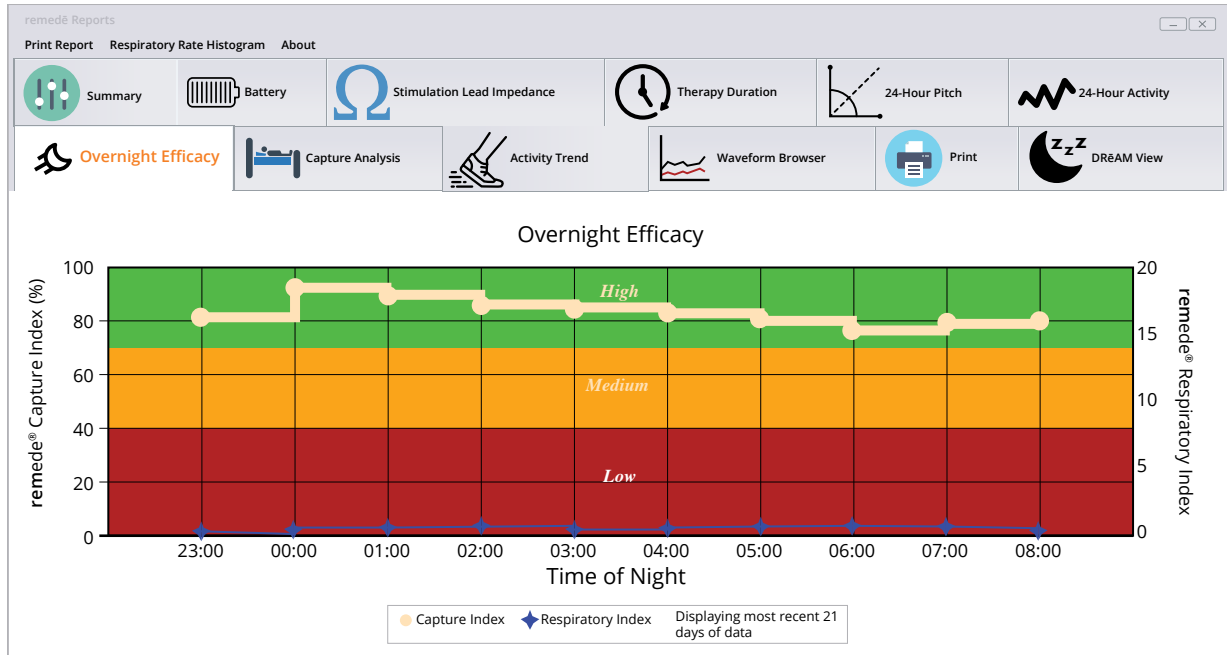
24-hour Activity

The 24-Hour Activity graph displays the patient's average activity by hour of the day.



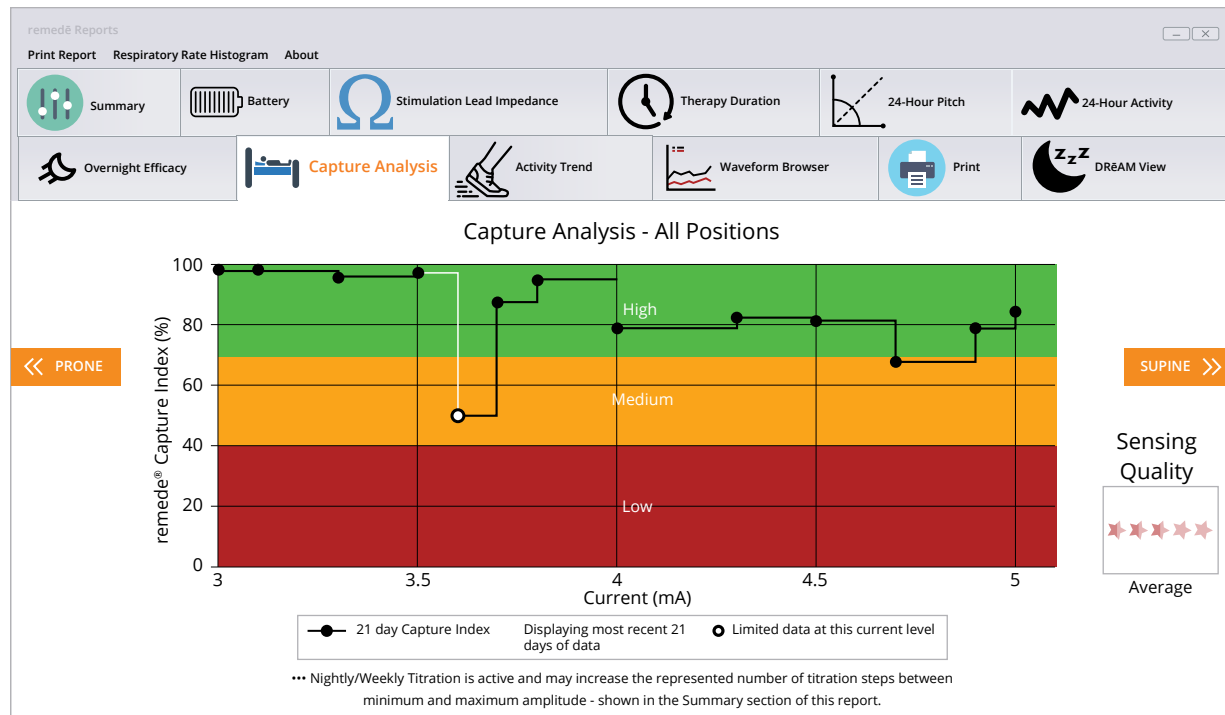
Overnight Efficacy

The Overnight Efficacy tab contains a 21-day average therapy efficacy graph with both the **remedē** Capture Index and the **remedē** Respiratory Index shown per each hour of the night.



Capture Analysis

The Capture Analysis trend report contains a 21-day average **remedē** Capture Index data organized by both delivered stimulation current and sleeping posture.

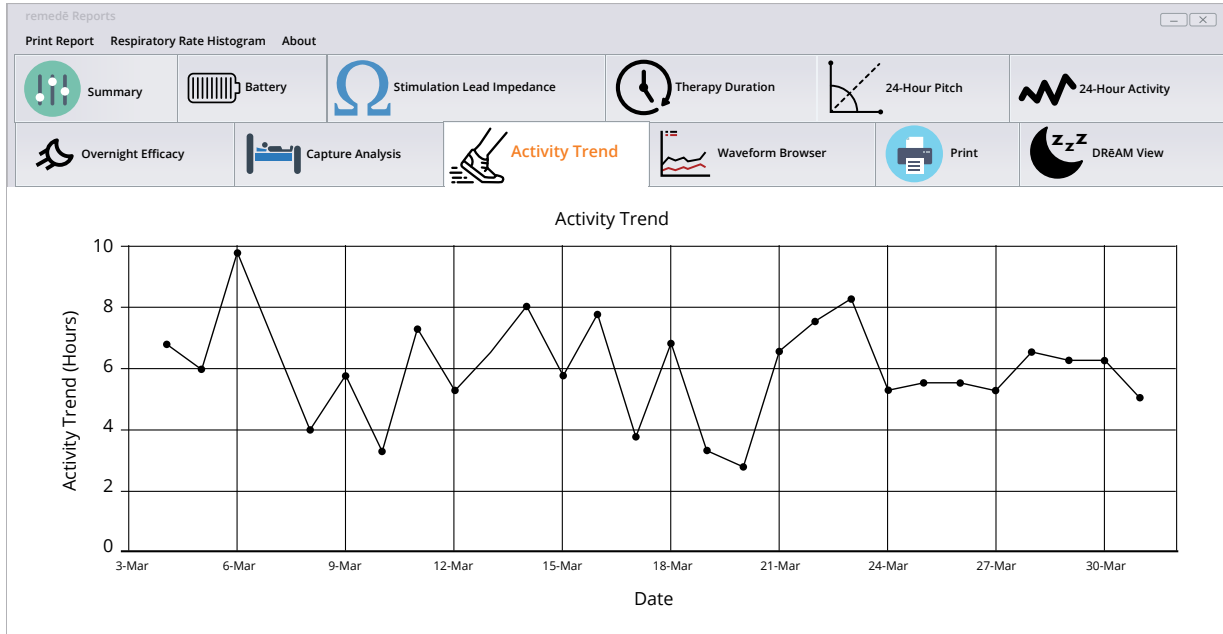


*** Nightly/Weekly Titration is active and may increase the represented number of titration steps between minimum and maximum amplitude - shown in the Summary section of this report.



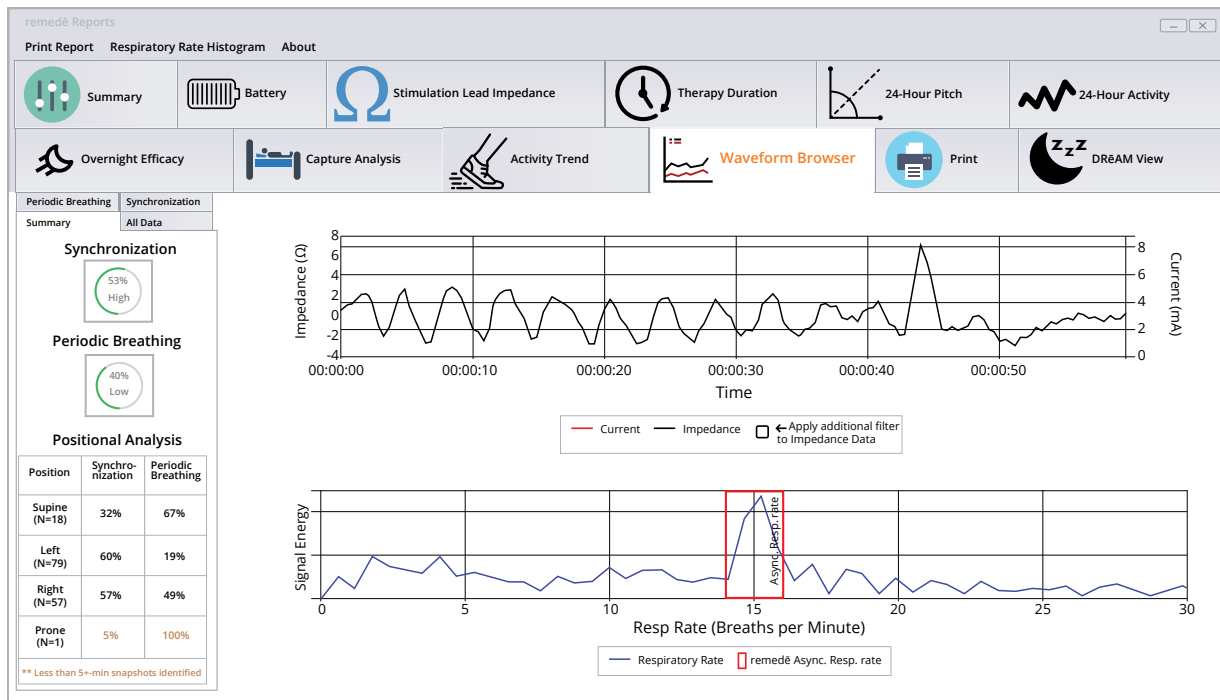
Activity Trend

The Activity Trend report contains a recent trend of daily activity measured in hours/day.

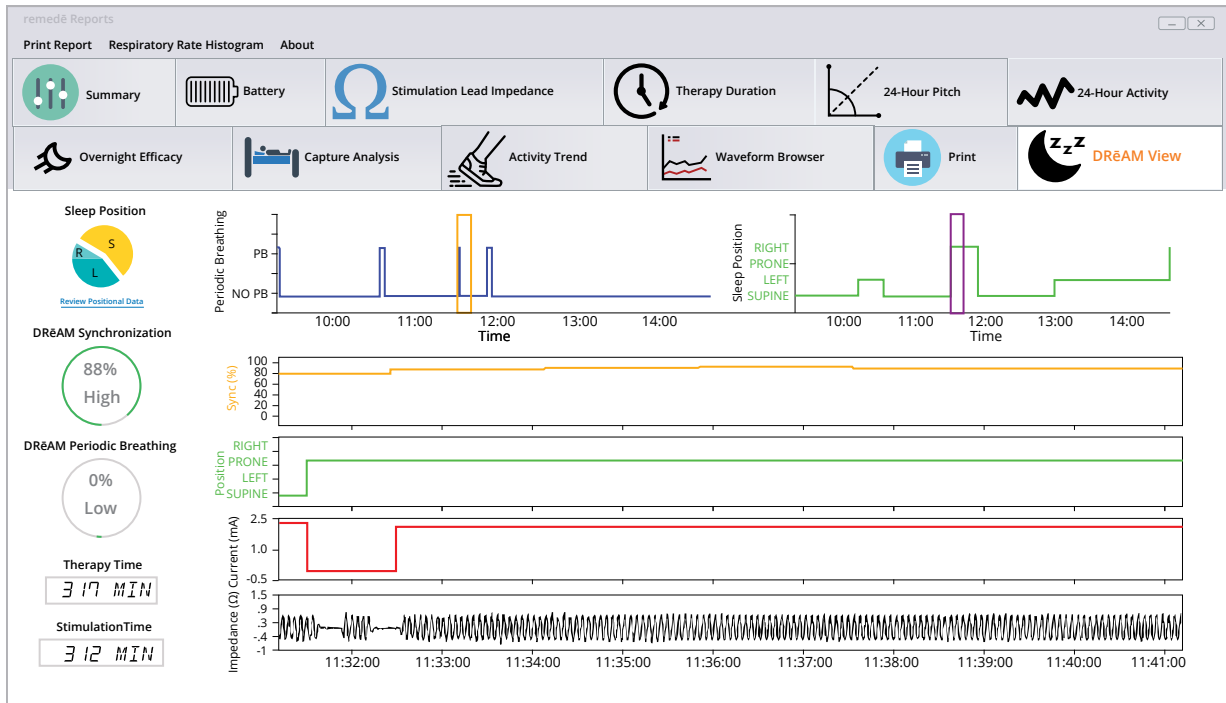


Waveform Browser

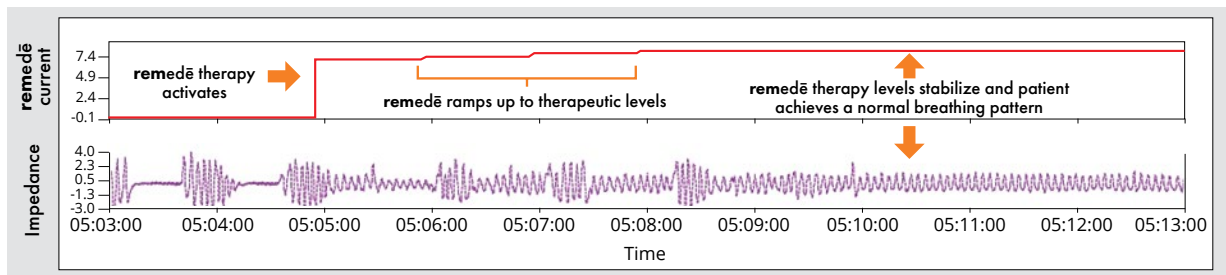
The Waveform Browser tab contains an automated, condensed review of all respiratory waveform data collected by the **remedē** IPG. All collected waveforms are available for review individually and are sorted by time/date of collection or by evidence classification.



DRēAM View is an enhancement to **remedē** Reports package available with **remedē** EL and EL-X. DRēAM View provides full-night, continuous, breath-by-breath visibility into the patient's nighttime breathing.



Pinpoint how **remedē** therapy ramps up, resolving periodic breathing and establishing a more regular rhythm.



For detailed information on **remedē** Reports, refer to the **remedē** Activation binder.
For software questions, call technical services at 1-866-788-1109.

For questions

email customer care@remede.zoll.com or call **1-866-788-1109**

Important Safety Information

The **remedē** System is indicated for moderate to severe Central Sleep Apnea (CSA) in adult patients. A doctor will need to evaluate the patient's condition to determine if the **remedē** System is appropriate. The **remedē** System should not be implanted during an active infection and patients will not be able to have diathermy (special heat therapies). The device is MR Conditional. The conditions and precautions can be found in the **remedē** System MRI guidelines manual. The **remedē** System may be used with 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 **remedē** System may not work for everyone. There are additional risks associated with removing the system. If it is decided to remove the system, another surgery will be required. Be sure to understand all the risks and benefits associated with the implantation of the **remedē** System. For further information please visit remede.zoll.com, call 952-540-4470 or email info@remede.zoll.com. **Contraindications:** The **remedē** System is contraindicated for use in patients with an active infection. See the Instructions for Use for complete information regarding the procedure, indications for use, contraindications, warnings, precautions, and potential adverse events.

Rx Only. The **remedē** System, **remedē** EL System, and **remedē** EL-X System have received FDA approval.

The **remedē** System model 1001 has received CE Mark approval.

ZOLL MEDICAL CORPORATION

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