

Waveform Analysis and Grading in Upper Airway Stimulation

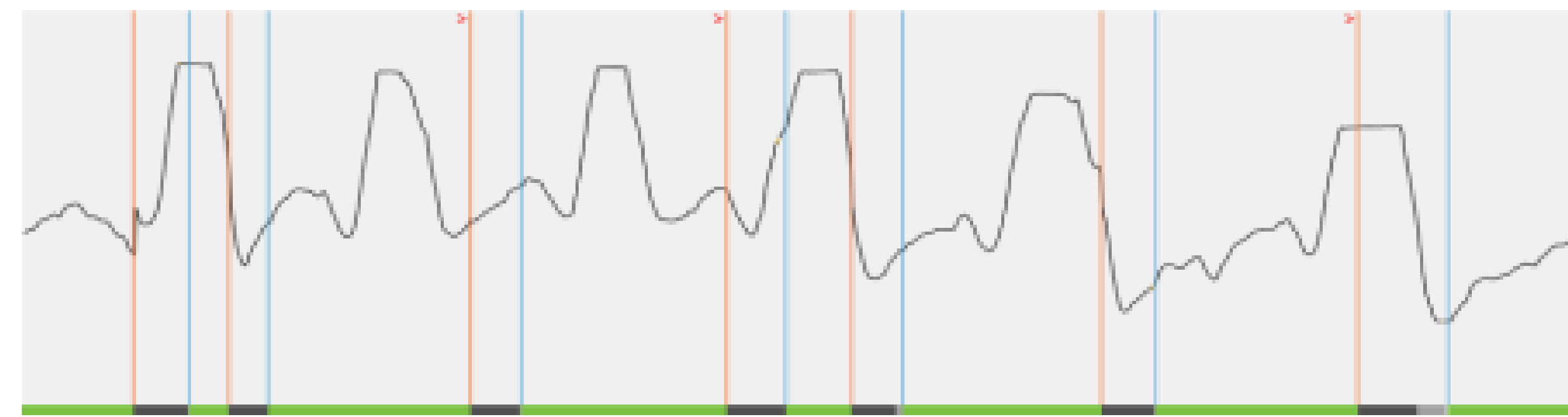
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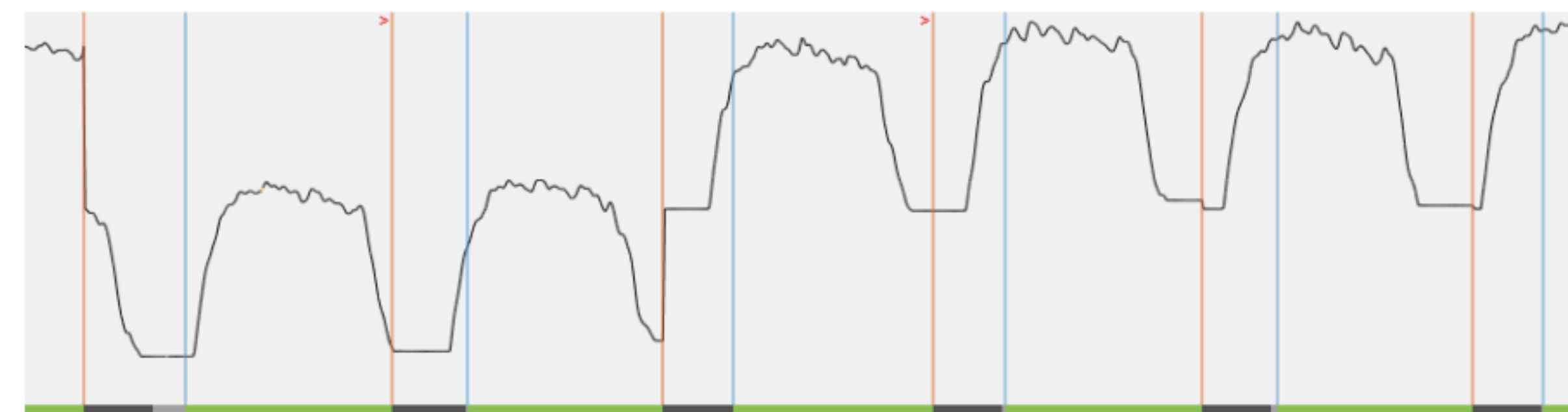
Background

Upper airway stimulation (UAS) is an effective treatment for moderate to severe obstructive sleep apnea (OSA) in cases of CPAP intolerance or failure. Current UAS devices work by stimulating the hypoglossal nerve resulting in tongue protrusion and enlargement of the retroglossal airway. Other studies have highlighted the multilevel effect of UAS including improvement at the level of the palate. The UAS device by Inspire Medical Systems (Minneapolis, MN) achieved FDA approval in 2014 and remains the only system with FDA approval. The three-part system is placed via two incisions including a stimulator cuff placed around the medial hypoglossal nerve branches via a modified submandibular incision and an internal pulse generator (IPG) and respiratory sensory placed via an incision over the second intercostal space. Intuitively, timing nerve stimulation to commence with end-expiration and continue through inspiration is optimal, however experimental data are limited. Heiser et al. demonstrated that inverting the respiratory sense lead and reducing the sensitivity of the sensing lead both worsened outcomes in three patients previously successfully treated with UAS. Anecdotal evidence suggests that in cases of respiratory sense lead failure there is worsening of subjective response which often brings patients back for consultation. In order to emphasize the importance of the respiratory sensing function, we present a standard protocol for interrogating and reading the sensing lead data along with a novel grading system.

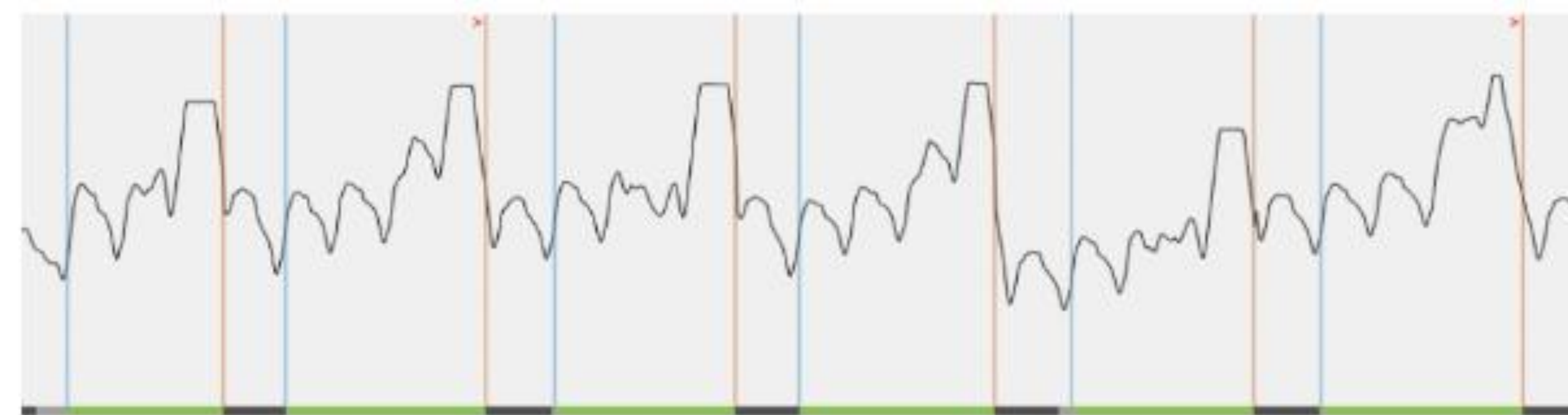
Excellent: Waveform demonstrates repeatable pattern with strong rise and fall and no vascular signal



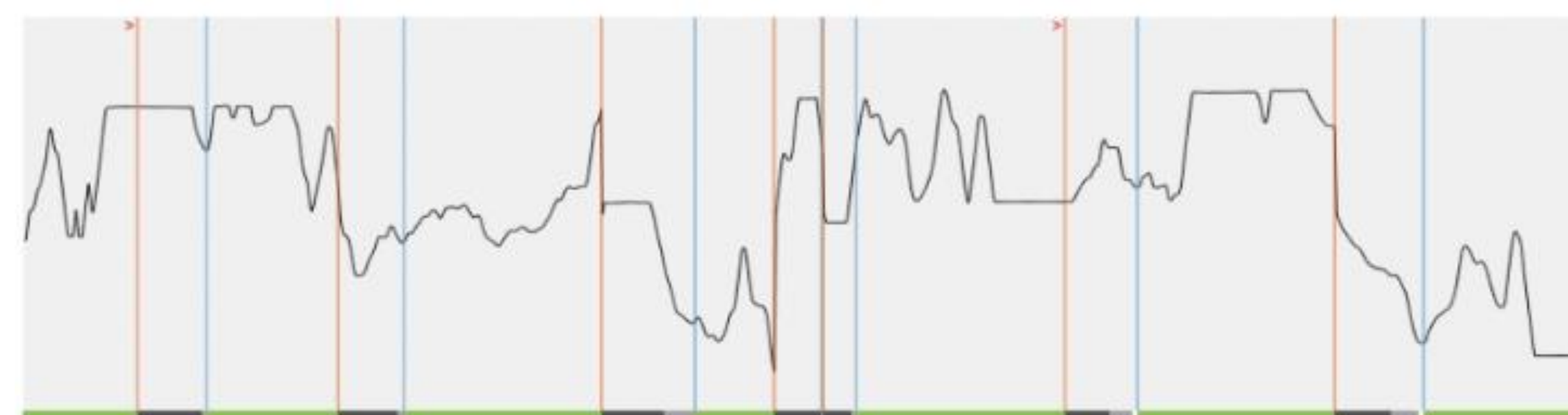
Adequate: Discernable rise and fall in at least 2/3 of captured waveforms, noise and/or vascular signal less than 1/3rd of waveform amplitude



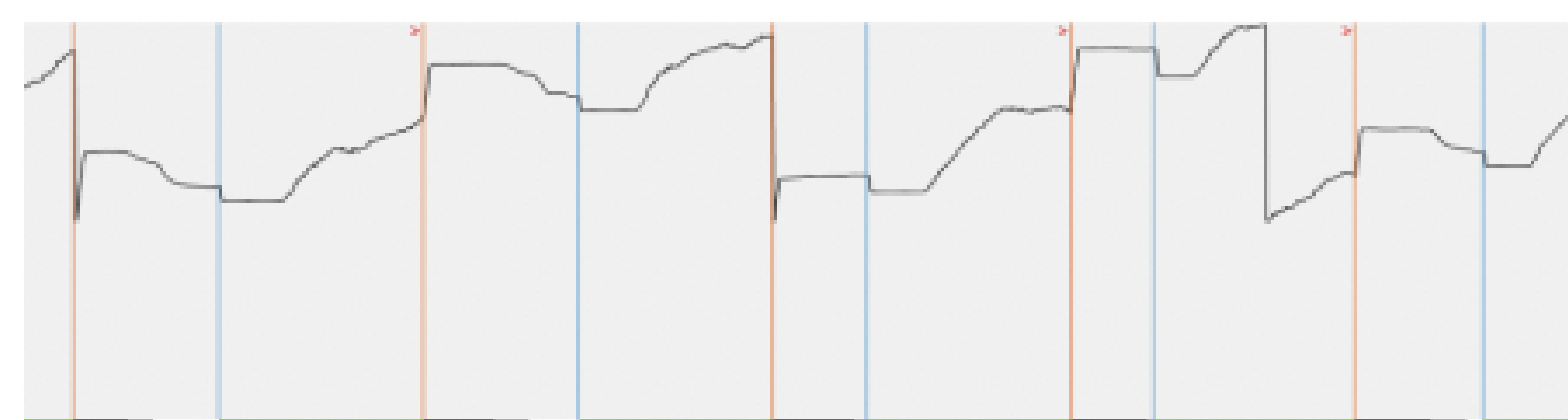
Poor: Noise and/or vascular signal more than 1/3rd of waveform amplitude



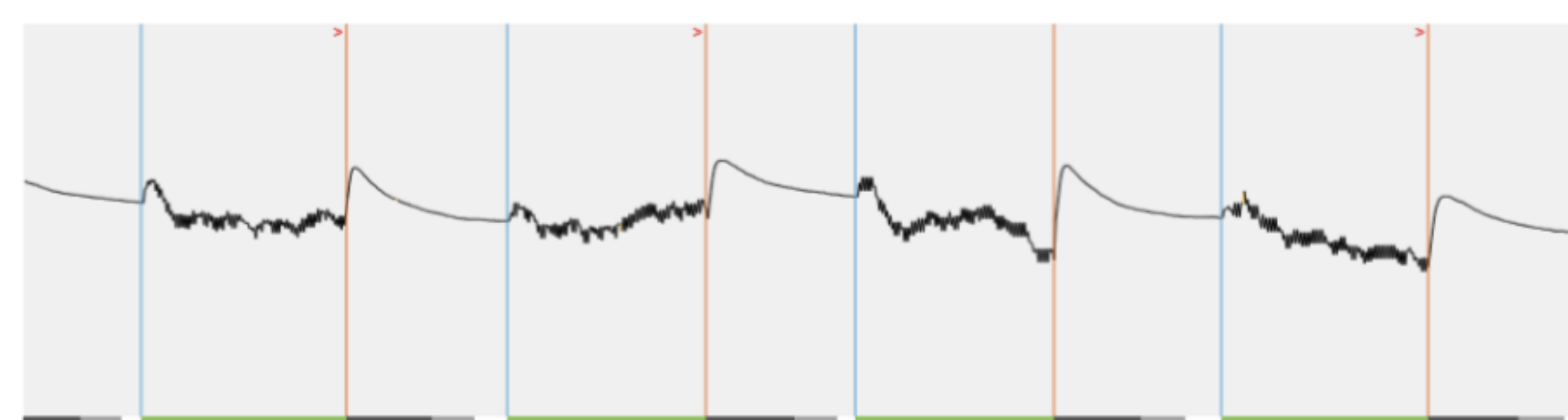
OR lack of repeatable/discernable pattern



Pathologic: Demonstrating current leakage



High frequency noise



Methods

The studied population comprised UAS patients (n=192) from a single surgeon's database at an academic tertiary referral medical center. Intra-operative and follow-up sensing lead waveforms were recorded, de-identified, and analyzed. Here, we present our approach to waveform analysis and a grading system: Excellent, adequate, poor, pathologic.

Conclusions

Heiser et al. demonstrated that inverting the respiratory sense lead and reducing the sensitivity of the sensing lead both worsened outcomes in three patients previously successfully treated with UAS [1]. Anecdotal evidence suggests that in cases of respiratory sense lead failure there is worsening of subjective response which brings patients back for consultation. To emphasize the importance of the respiratory sensing function, we present a standard protocol for interrogating and reading the sensing lead data along with a novel grading system.

References

1. Steffen A, Sommer JU, Strohl K, et al. Changes in breath cycle sensing affect outcomes in upper airway stimulation in sleep apnea. *Laryngoscope Investig Otolaryngol.* 2020;5(2):326-329.
2. Lou B, Hahn S, Korotun M, Quintero L, Shikowitz M, Greenberg H. Space invader: pleural penetration of a hypoglossal nerve stimulator sensor lead. *J Clin Sleep Med.* 2021;17(11):2329-2332.

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Disclosures: None