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The purpose of these case studies are to provide guidance on how to interpret the data included in the GEMPro reports.

## CASE STUDY 1: Bruxism Associated with Airway Compromise

### CASE STUDY # 1

#### BRUXISM ASSOCIATED WITH AIRWAY COMPROMISE

The patient is a 66-year-old male. He has had three heart attacks, the last at age 50. He also was diagnosed with diabetes at the age of 56 and diagnosed with moderate Sleep Apnea at the age of 57 and was prescribed APAP (AutoPAP) at that time. He was compliant with APAP therapy for 6 months and discontinued therapy and has been uncompliant since. Visual tooth inspection shows Attrition involving 6 teeth with exposed dentin. He has had no tooth restorations. He agreed to be studied with the GEMPro Sleep Wellness monitor and performed a three-night study.

Night 1: Baseline

Night 2: ResMed APAP

Night 3: Occlusal Guard

**Results:** The Baseline study showed the previously diagnosed Sleep Apnea was likely still present with significant oxygen desaturation and snoring. The majority of the oxygen desaturations did occur while sleeping on his back although some desaturations were observed on his left side. The heart rate seemed to increase during O2 desaturation times. Significant parafunctional EMG was also noted. Several events over 75% of the Waking Maximum Bite Force were detected. There was also a moderate amount of snoring at 34% of test time. The oxygen desaturations on the second night test wearing APAP had significant improvement. There was 0% time under 85% during the night compared to 2% time and the percentage time under 89% was also reduced. **Parafunctional EMG activity improved dramatically while the patient was wearing APAP compared to the Baseline study.** There were no events greater than 25% of the Waking Maximum Bite Force detected. Snoring was reduced to 0.1% while wearing APAP. The third night study wearing the occlusal splint showed no improvement in oxygen desaturations. In fact, there was a worsening of the O2 saturation minimum level to 74% from 80% on the baseline study. Notably however, the parafunctional EMG also resolved using the occlusal guard. Snoring was also resolved wearing the occlusal guard. Although the enamel was protected wearing the occlusal guard, the SPO2 oxygen desaturations worsened.

**Conclusion:** This patient likely has abnormal parafunctional EMG activity as an associated disorder to the previously diagnosed Sleep Apnea. Both therapy with APAP and a occlusal guard did resolve the abnormal parafunctional EMG, however the occlusal guard worsened the severity of the oxygen desaturations. The patient was consulted and agreed to wear his APAP to not only resolve his airway dysfunction but also to potentially resolve his parafunctional EMG activity and excessive tooth wear. The patient agreed to be compliant wearing APAP

# Case Study 1 – BASELINE Test 1

## SpO2 Analysis



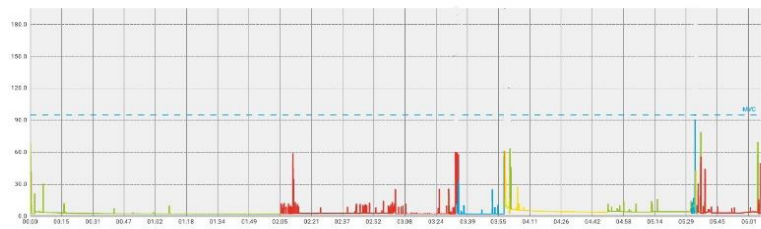
time of study at or below 85%      time of study at or below 89%      time of study at or below 92%

**2 %**                      **17 %**                      **68 %**

## HR Analysis



## Bruxism Analysis

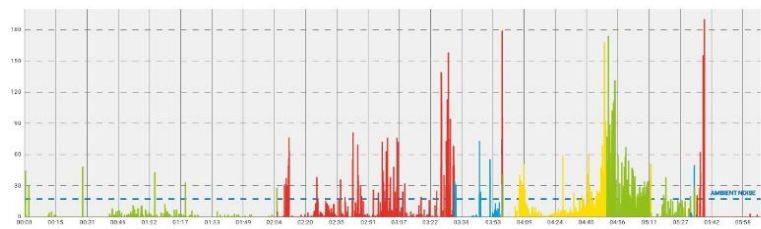


Number of Events

> 10% of Cal Max      > 25% of Cal Max      > 50% of Cal Max      > 75% of Cal Max      > 100% of Cal Max

**281**                      **25**                      **11**                      **26**                      **0**

## Audio Signal



## Position Analysis



SpO2 MAX [%]

**98**

SpO2 MIN [%]

**80**

HR MAX [bpm]

**81**

HR MIN [bpm]

**50**

NIGHT MAX FORCE

**124**  
µV

BIOCAL MAX FORCE

**134**  
µV

TIME OF SNORE

**34 %**

Caption:



Significant O2 desaturations

Significant Min SpO2 and time Under 85% and 89%

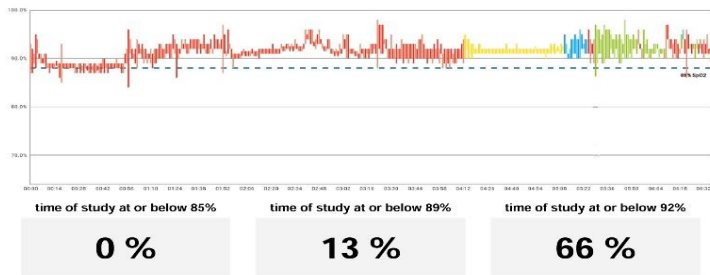
Heart Rate normal, increases during O2 desaturations

Moderate parafunctional EMG with 26 events detected greater than 75% of the Waking Mean Bite Force

Moderate Snore detected at 34% of test time.

# CASE STUDY 1 - THERAPY Auto-PAP: Test 2

## SpO2 Analysis



SpO2 MAX [%]

**98**

SpO2 MIN [%]

**84**

Improved O2 desaturations from BASELINE. No time under 85% and improved time under 89%

## HR Analysis



HR MAX [bpm]

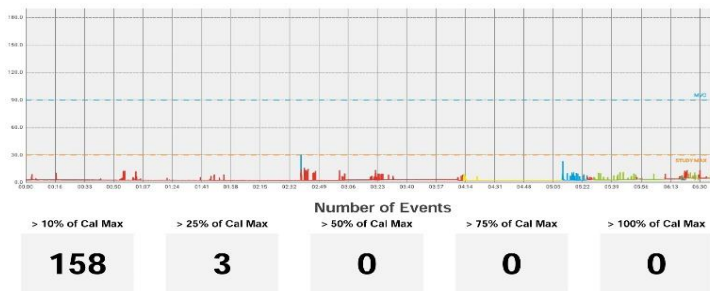
**89**

HR MIN [bpm]

**53**

Normal Heart Rate

## Bruxism Analysis



NIGHT MAX FORCE

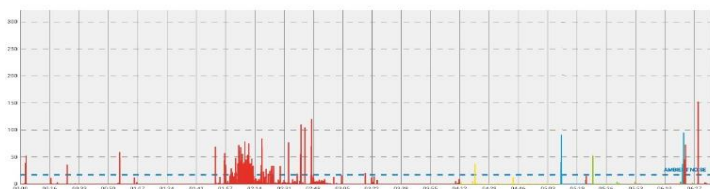
**30**  
µV

BIOCAL MAX FORCE

**102**  
µV

Normal EMG

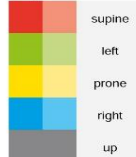
## Audio Signal



TIME OF SNORE

**0.1 %**

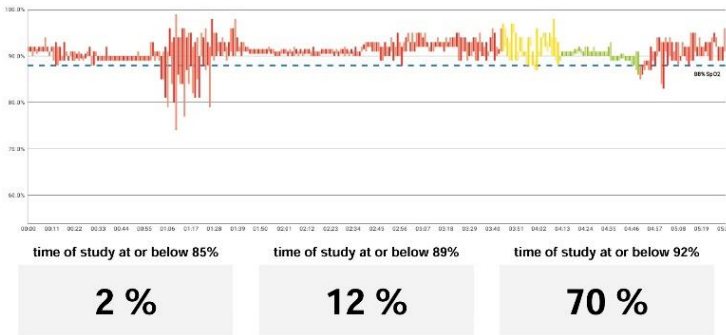
Caption:



No Snoring Noted

# CASE STUDY 1 - THERAPY – OCCLUSAL GUARD: Test 3

## SpO2 Analysis



SpO2 MAX [%]

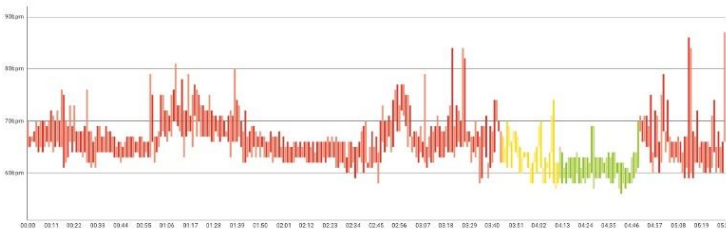
**99**

Significant O2 desaturations  
Min SaO2 read of 74% is worse than BASELINE of 80%.

SpO2 MIN [%]

**74**

## HR Analysis



HR MAX [bpm]

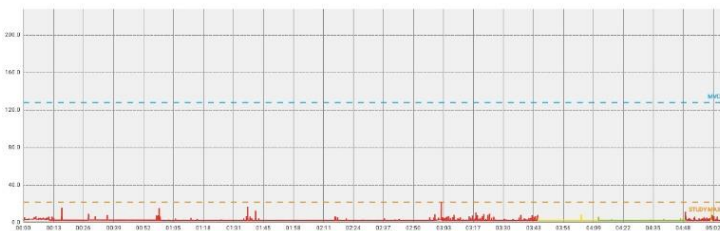
**87**

Normal Heart Rate.  
Heart rate increases during oxygen desaturations

HR MIN [bpm]

**56**

## Bruxism Analysis



NIGHT MAX FORCE

**22**  
µV

Normal EMG Activity

BIOCAL MAX FORCE

**140**  
µV

Number of Events



## Audio Signal

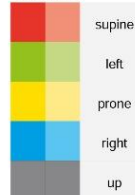


TIME OF SNORE

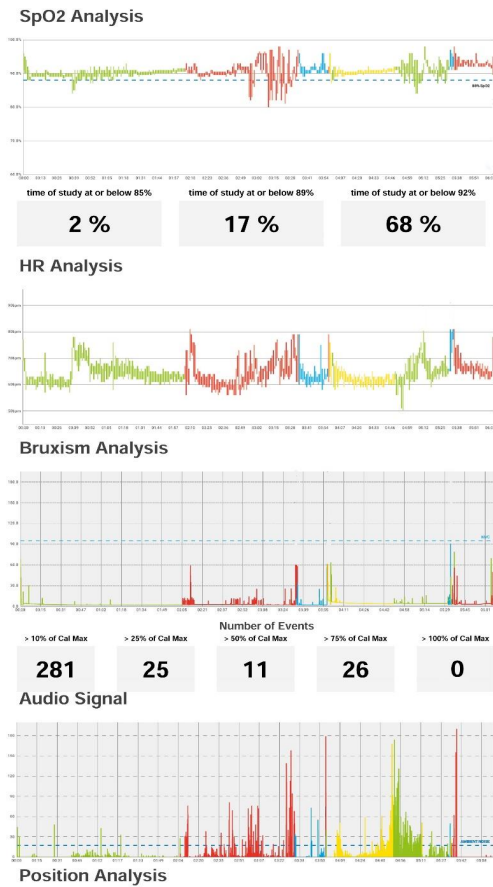
**0.1 %**

No Snoring Noted

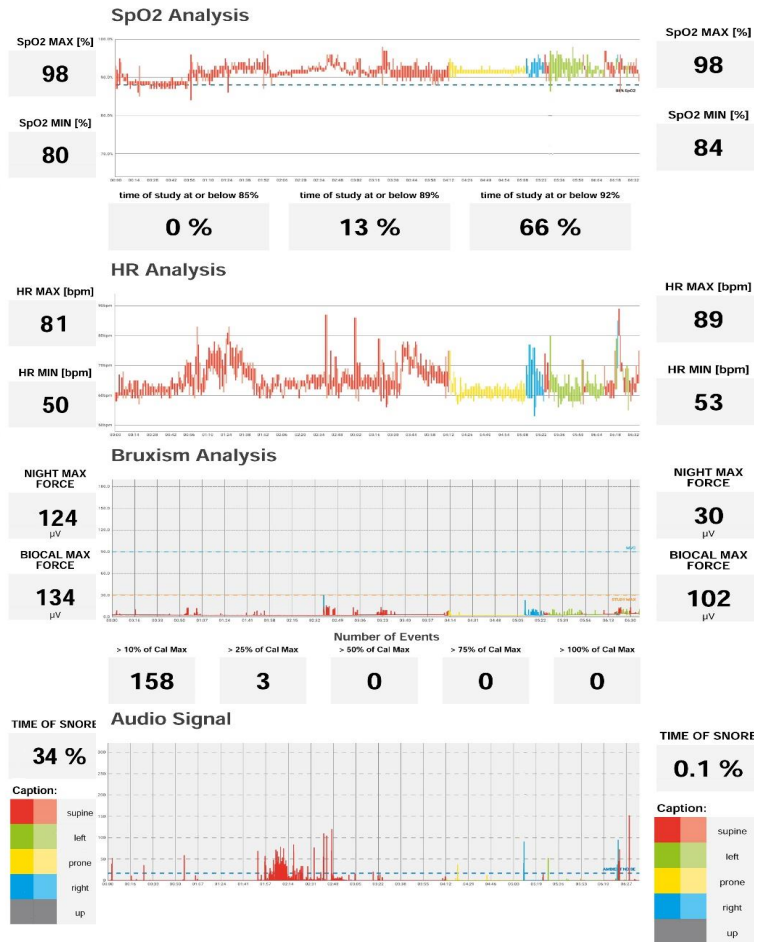
Caption:



## BASELINE Test 1



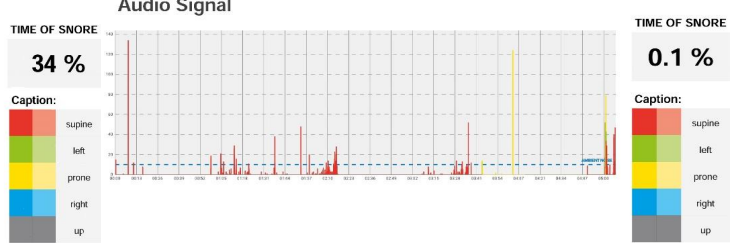
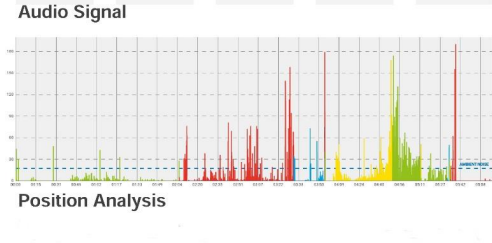
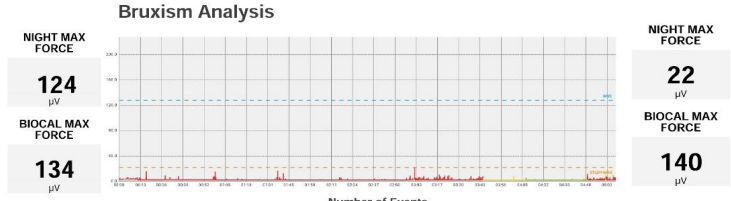
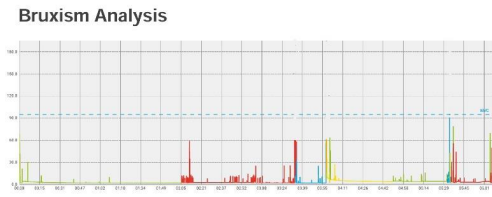
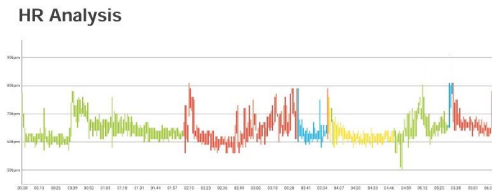
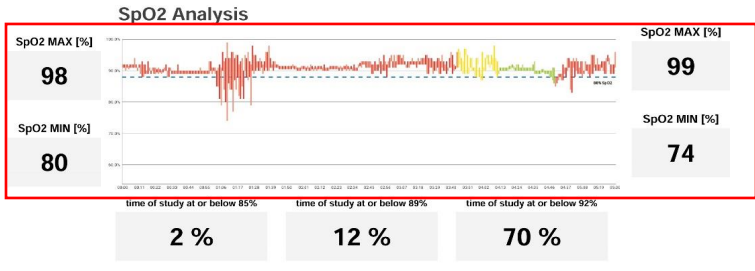
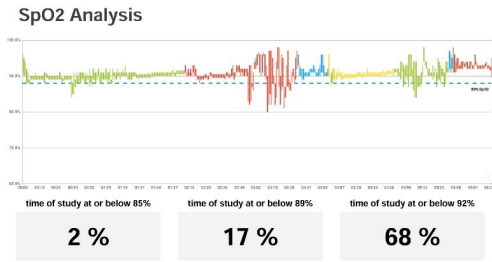
## THERAPY Auto-PAP: Test 2



Comparing the baseline study to the therapeutic night on A-PAP clearly demonstrates how well the A-PAP device improves the SPO2 oxygen desaturations. Interestingly, the frequency and strength of the parafunctional activity dramatically improved while on A-PAP.

# BASELINE Test 1

# OCCLUSAL GUARD: Test 3



On the same patient wearing an occlusal guard the SPO2 desaturations worsened however the guard was very effective at eliminating the parafunctional activity and snoring.

## CASE STUDY # 2

### IDIOPATHIC BRUXISM CASE REPORT

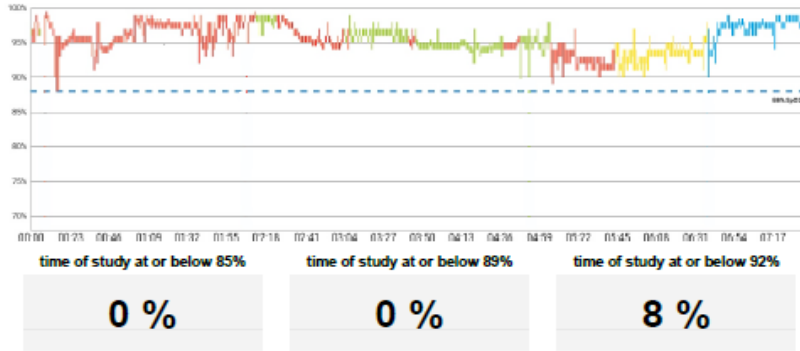
A 56-year-old female, suffers from idiopathic Bruxism. She has had 12 previous tooth reconstructions. She had 4 crowns by the age of 30. She developed severe TMD in her late 30's and was administered braces and appliances to correct her occlusion. By the age of 50, the original 4 crowns had been replaced and 8 additional teeth had to be restored. In addition, she has destroyed 8 protective appliances in the past 5 years. The Baseline study indicates significant night time EMG activity with bite forces 3 times the magnitude of her ability to bite while awake. The cause of this Bruxism is not associated with an airway compromise due to the absence of any significant night time oxygen desaturations. She wears occlusal splints on both the upper and lower teeth. Recently, her upper occlusal splint was fabricated out of a harder material. A baseline test, wearing no protective splints, and a therapy test, wearing the protective splints, was obtained to insure the protective splints did not cause an airway obstruction.

**Results:** Based on the baseline study for this patient her previous diagnosis of idiopathic bruxism which means the parafunctional EMG activity occurs in the absence of any detectable airway issues was confirmed. This was evidenced by normal blood oxygenation saturation and no snoring in the presence of severe parafunctional EMG activity with 42 clenches or grinds at 75% or greater of her waking calibration maximum level. Her dentist decided to fabricate a more robust occlusal guard to reduce the amount of replacements. A repeat study was performed to ensure the new occlusal guard did not introduce an airway issue while protecting the restorations and remaining enamel.

**Conclusion:** This patient has benefited from a customized bite guard with anterior guidance made from a reinforced material to improve durability. Her restorations are adequately protected and the airway functioning was maintained. With the occlusal guards her EMG night time bite magnitude decreased from 3 times her waking bite force to 50% of her waking bite force. Her knowledge of how hard she clenches at night has motivated her to always wear her occlusal guards. She is aware not wearing them puts her in danger of not only damaging her restorations but also creating new TMD symptoms. In addition, no significant snoring was observed.

# CASE STUDY 2: Baseline Idiopathic Bruxism – Night 1

## SpO2 Analysis



SpO2 MAX [%]

**99**

Normal SPO2 reading

SpO2 MIN [%]

**88**

Caption:



HR MAX [bpm]

**84**

Normal Heart Rate

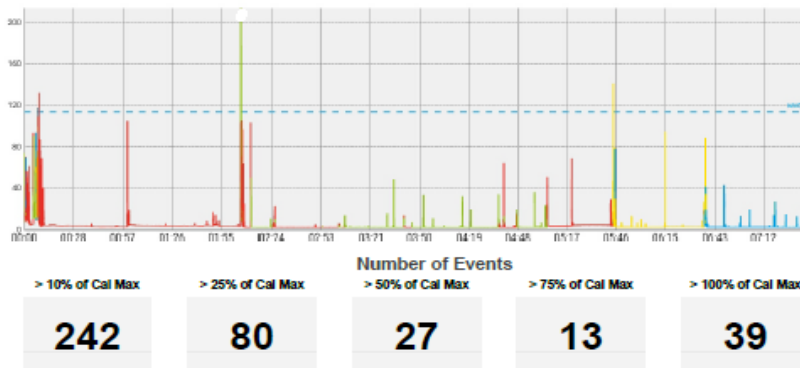
HR MIN [bpm]

**54**

## HR Analysis



## Bruxism Analysis



NIGHT MAX FORCE

**397**  
µV

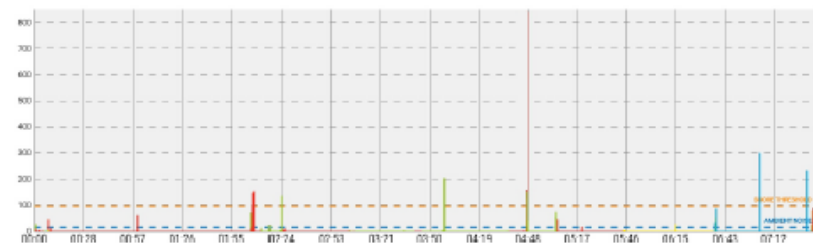
Abnormal EMG  
Night Time force is nearly 4x the waking maximum clench force

BIOCAL MAX FORCE

**113**  
µV

40 EMG events measured were greater than the maximum waking clench force.

## Audio Signal



TIME OF SNORE

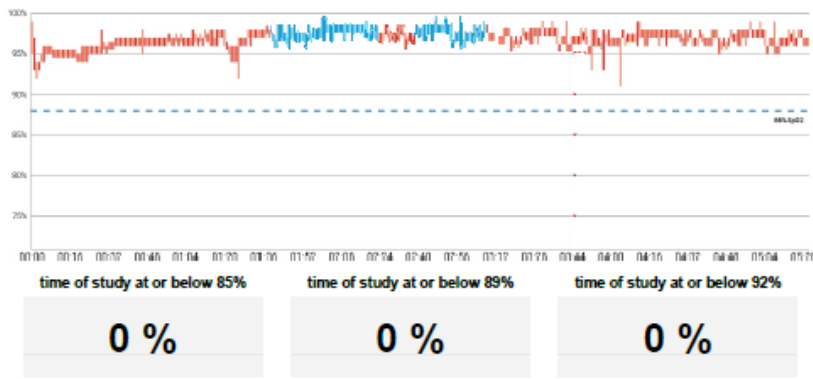
**0.6 %**

No Snoring Noted



# CASE STUDY 2: Therapy Reinforced Night Guard – Night 2

## SpO2 Analysis



SpO2 MAX [%]

**99**

Normal SPO2 reading

SpO2 MIN [%]

**91**

Caption:



Normal Heart Rate

HR MAX [bpm]

**83**

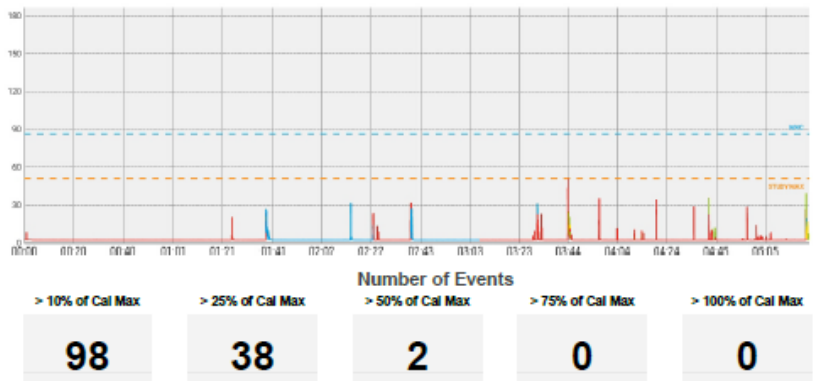
HR MIN [bpm]

**62**

## HR Analysis



## Bruxism Analysis



NIGHT MAX FORCE

**51**  
µV

Normalized EMG Activity

BIOCAL MAX FORCE

**95**  
µV

Night Time force is within normal limits and the restorations are protected

## Audio Signal



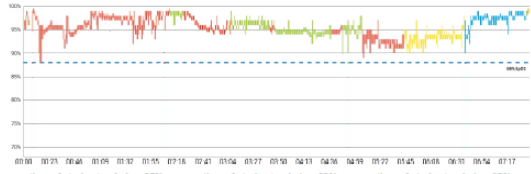
TIME OF SNORE

**0.2 %**

No Snoring Noted

# CASE STUDY 2: SIDE BY SIDE

## SpO2 Analysis



SpO2 MAX [%]

**99**

SpO2 MIN [%]

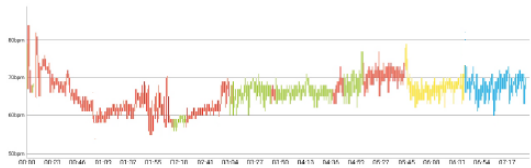
**88**



time of study at or below 85%    time of study at or below 89%    time of study at or below 92%

**0 %**    **0 %**    **8 %**

## HR Analysis



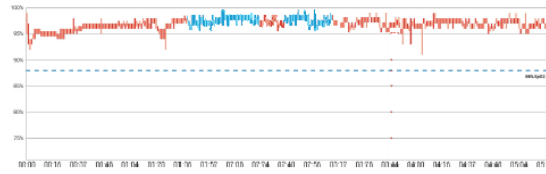
HR MAX [bpm]

**84**

HR MIN [bpm]

**54**

## SpO2 Analysis

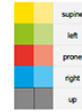


SpO2 MAX [%]

**99**

SpO2 MIN [%]

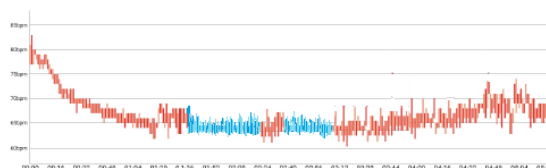
**91**



time of study at or below 85%    time of study at or below 89%    time of study at or below 92%

**0 %**    **0 %**    **0 %**

## HR Analysis



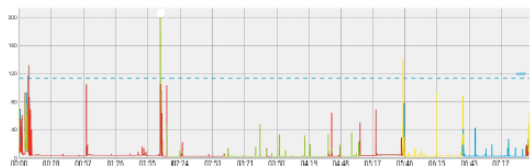
HR MAX [bpm]

**83**

HR MIN [bpm]

**62**

## Bruxism Analysis



NIGHT MAX FORCE

**397**

BIOCAL MAX FORCE

**113**

Number of Events

> 10% of Cal Max    > 25% of Cal Max    > 50% of Cal Max    > 75% of Cal Max    > 100% of Cal Max

**242**    **80**    **27**    **13**    **39**

## Bruxism Analysis



NIGHT MAX FORCE

**51**

BIOCAL MAX FORCE

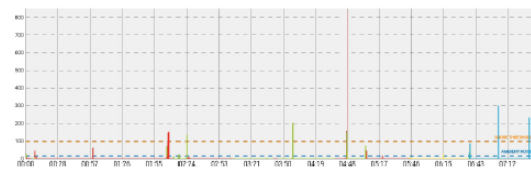
**95**

Number of Events

> 10% of Cal Max    > 25% of Cal Max    > 50% of Cal Max    > 75% of Cal Max    > 100% of Cal Max

**98**    **38**    **2**    **0**    **0**

## Audio Signal



TIME OF SNORE

**0.6 %**

## Audio Signal



TIME OF SNORE

**0.2 %**

## CASE REPORT 3: Snoring Only

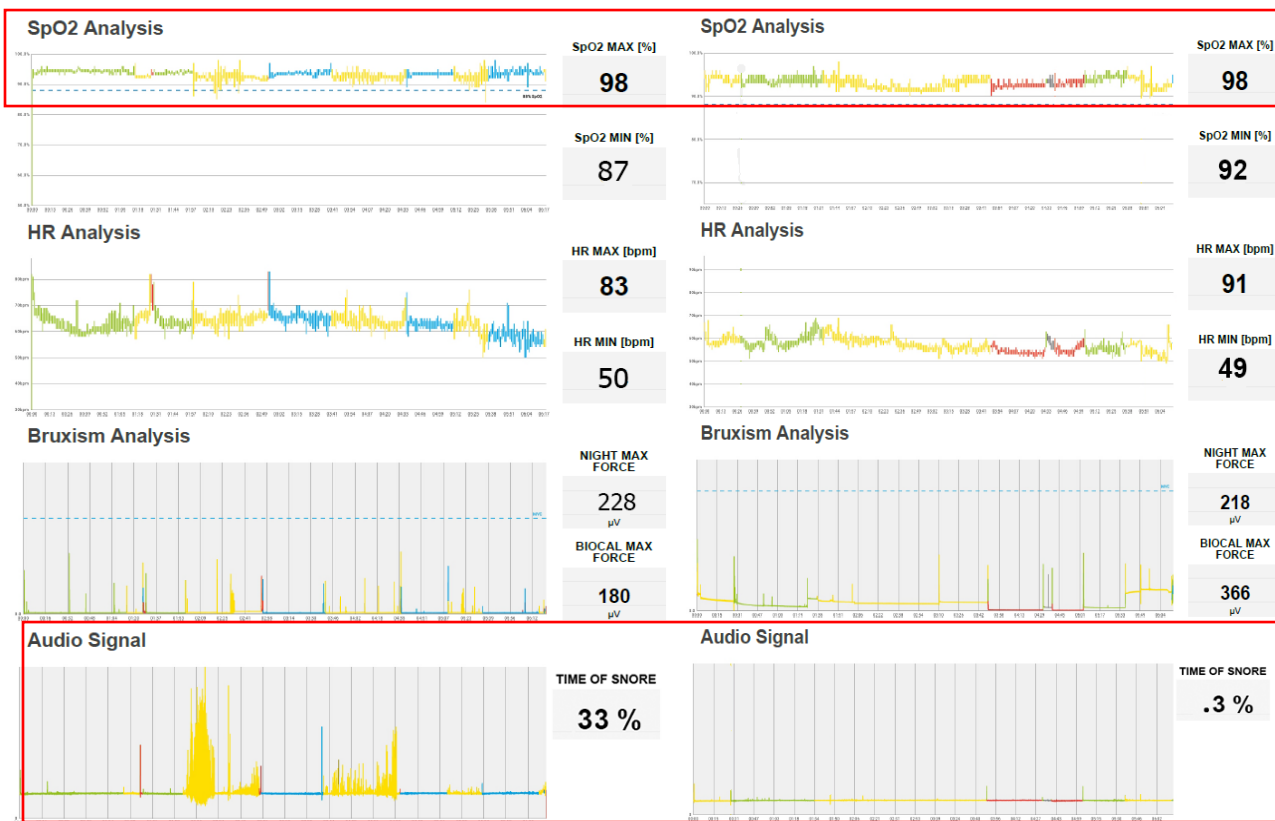
This is a 41-year-old patient with a complaint of snoring. Patient has no significant OSA related medical co-morbidities such as Obesity, High Blood Pressure or Diabetes. His spouse has asked him to resolve his snoring issue. This patient does not report being excessively tired during the day. As a result, the GEMPro overnight wellness assessment was ordered to screen for airway related issues and ensure snoring is not a sign of an underlying sleep apnea issue.

**Results:** The baseline GEMPro report indicated this patient is at a low risk for sleep apnea evidenced by normal levels of blood oxygen during sleep. As a result of this test, the dentist decided to treat the patient for their primary complaint of snoring.

**Conclusion:** The treatment recommended was a dual arch snore guard called the Silent Nite™ by Glidewell Laboratories. The Silent Nite™ resolved the patient's complaint of snoring while maintaining the integrity of the airway.

### Baseline with Snoring

### Silent Nite™ Snoring Resolved



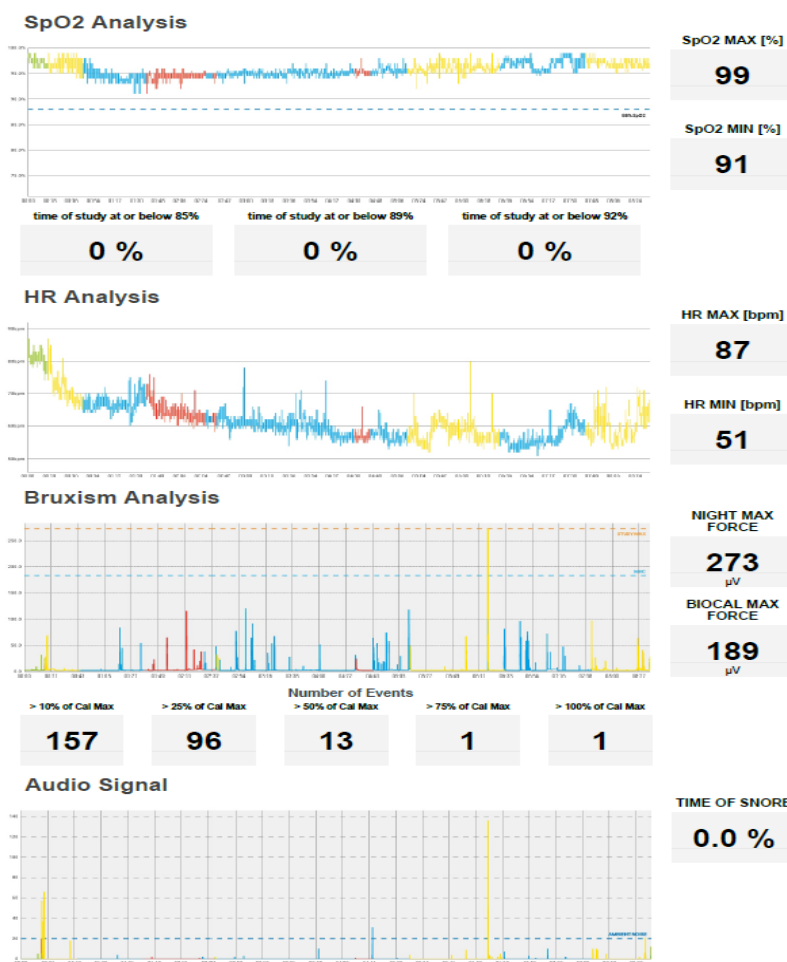
## CASE RPEORT 4: Pediatric Patient

This is a 10-year-old patient with visible attrition and level 1 wear (two anterior teeth with visible dentin). She has a moderately high and narrow arch. There are no reports of snoring or behavioral symptoms associated with ADD or ADHD. The purpose of the study was to establish what role, if any, the mildly narrow/high arch is impacting the airway due to the more than expected level of tooth wear for a patient this age.

**Results:** Neither the number of oxygen desaturations or time below 92% indicate the airway has been negatively impacted. In addition, no significant snoring was noted the night of the test. However, there was a significantly high frequency and strength of parafunctional EMG activity noted. Her maximum Night Time Max forces exceeded her BioCal Maximum Waking Bite Force (273 vs 189). There were 15 events during her sleep that measured 50% or greater than her calibration strength. In the Bruxism graph, when the orange dotted line is above the blue dotted line this indicates the patient's parafunctional activity while asleep is stronger than the maximum waking clench value.

**Conclusion:** The patient was recommended to have a protective appliance administered and a follow-up study to insure the protective appliance does not compromise the airway.

### PEDIATRIC BASELINE:



Normal SPO2 reading

Caption:



Normal Heart Rate

Abnormal EMG Activity

Orange line is above Blue dotted line indicating the EMG strength is greater while asleep than the measured maximum waking clench.

15 EMG events measured were at least 50% of the maximum waking clench strength

No Snoring Noted

# CASE STUDY # 6

## AIRWAY COMPROMISE then BRXPro

This is a 69-year-old male. Approximately 12 years ago, he was diagnosed with Moderate Sleep Apnea. He refused to be prescribed C-PAP because he knew he would not be compliant wearing it but was familiar with a dental sleep appliance called the Silencer. He chose an oral appliance for therapy so an impression was taken and he was fitted and successfully titrated. He was compliant wearing the Silencer for 8 years. He broke the pin after 8 years using the Silencer. He was aware of the DDME BRX PRO appliance which uses a similar anterior hinge to position the mandible. He was fitted with the BRX PRO and has used it for 2 years. He has the impression material replaced approximately every six months. Alex agreed to have a two-night test performed with the GEMPro comparing his baseline with no therapy against a night wearing his BRX PRO. Below are the results of those tests. It is important to note the BRXPro is FDA cleared for treating Bruxism.

### Results:

Snoring was not detected either night so those graphs are not shown. The baseline study shows significant O2 desaturations indicating that his previous diagnosis of Moderate Obstructive Sleep Apnea was still present. The night wearing the BRX PRO had significant reduction in O2 desaturations. Alex does not sleep well without the BRX PRO and is very compliant wearing the appliance. Although Alex's Bruxism was not severe in the Baseline test, it was reduced wearing the BRX PRO.

Baseline – No Therapy	BRXPro
<p><b>SpO2 Analysis</b></p> <p>SpO2 MAX [%] <b>99</b></p> <p>SpO2 MIN [%] <b>75</b></p> <p>time of study at or below 85% <b>5 %</b></p> <p>time of study at or below 89% <b>18 %</b></p> <p>time of study at or below 92% <b>48 %</b></p>	<p><b>SpO2 Analysis</b></p> <p>SpO2 MAX [%] <b>99</b></p> <p>SpO2 MIN [%] <b>86</b></p> <p>time of study at or below 85% <b>0 %</b></p> <p>time of study at or below 89% <b>2 %</b></p> <p>time of study at or below 92% <b>55 %</b></p>
<p><b>HR Analysis</b></p> <p>HR MAX [bpm] <b>102</b></p> <p>HR MIN [bpm] <b>65</b></p>	<p><b>HR Analysis</b></p> <p>HR MAX [bpm] <b>96</b></p> <p>HR MIN [bpm] <b>63</b></p>
<p><b>Bruxism Analysis</b></p> <p>NIGHT MAX FORCE <b>59</b> µV</p> <p>BIOCAL MAX FORCE <b>140</b> µV</p> <p>Number of Events</p> <p>&gt; 10% of Cal Max <b>166</b></p> <p>&gt; 25% of Cal Max <b>21</b></p> <p>&gt; 50% of Cal Max <b>2</b></p> <p>&gt; 75% of Cal Max <b>0</b></p> <p>&gt; 100% of Cal Max <b>0</b></p>	<p><b>Bruxism Analysis</b></p> <p>NIGHT MAX FORCE <b>135</b> µV</p> <p>BIOCAL MAX FORCE <b>280</b> µV</p> <p>Number of Events</p> <p>&gt; 10% of Cal Max <b>65</b></p> <p>&gt; 25% of Cal Max <b>4</b></p> <p>&gt; 50% of Cal Max <b>1</b></p> <p>&gt; 75% of Cal Max <b>0</b></p> <p>&gt; 100% of Cal Max <b>0</b></p>

