



## Explanation of Test Report (ver 2.1)

The following is a detailed explanation of the Snap Diagnostics test report prepared by our medical consultants. In this explanation we review each section of the report. You should become familiar with each report element for your own education. However, please note that during our initial sales presentation we may focus on a subset of the information presented.

### Demographics Section

RESPIRATORY ANALYSIS			
<b>Name:</b>	Mario Gomez	<b>Height:</b>	5' 11"
<b>Birth Date:</b>	03/27/1964	<b>Weight:</b>	250 lb
<b>Age:</b>	55 years old	<b>BMI:</b>	34.9
<b>Sex:</b>	male	<b>Neck Circumference:</b>	43.2 cm
<b>Referred By:</b>	Kimberly Ashton, M.D.	<b>Service Date:</b>	08/15/2018

The patient's height and weight is required to calculate BMI (body mass index), to determine relative obesity.

When combined with the circumference of the patient's neck, an initial treatment PAP (Positive Airway Pressure) can be calculated using a clinically validated formula (the Miljeteig-Hoffstein formula).

- When ordering auto-titrating PAP, the upper and lower pressure settings can be ordered in reference to the calculated initial treatment PAP pressure.
- When ordering fixed pressure CPAP, the calculated initial treatment pressure can be the ordered CPAP pressure.

### History and Comments Section

The History section is a list of the clinical indications that were marked in the testing documentation given to Snap by the Referring Provider.

**History:** Observed apneas, hypertension, loud snoring and gasping during sleep.

**Comment:**

This is an important section. In order to qualify for a sleep test, it is important to document the clinical indications that caused the sleep test order. Examples include: habitual loud snoring, observed apnea, daytime fatigue, elevated sleepiness scale. We use the Epworth and at times

the StopBang as self-report measurements of daytime sleepiness and risk of sleep apnea, respectively.

The clinical indications, coupled with objective sleep test data as determined by Snap testing, (a) can facilitate third party reimbursement for patient testing and (b) allow the sleep test results to be accepted to qualify a patient for apnea treatment if ordered by the treating provider.

The comment line presents any special conditions or information important to share about the test. For example, if data channels were missing or if the patient underwent treatment on the testing night. It might also reference comments from the Snap Laboratory team about the test (e.g., if channels were missing or study was incomplete).

## *Recording Time and Sleep Time Section*

There are two “times” provided in the report: (a) Total Recording Time and (b) Analyzed Sleep Time. These two values are determined by the technician’s manual review of the raw data. The two time values are used to calculate various clinical indices, which will be described in more detail later.

<b>Total Recording Time:</b> 355 min	<b>Analyzed Sleep Time:</b> 343 min
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Note that 200 minutes of sleep time will normally encompass at least two complete sleep cycles (Stage 1 through REM sleep), which is generally accepted as a good data set for each night. However, testing of six hours on each night is often a requirement for some insurance payors to accept the test results.



Clinical studies consistently demonstrate that testing for three nights will improve patient outcomes by reducing the errors associated with “First Night Effect” and “Night-to-Night variability” that are commonly reported in peer review scientific literature. <sup>1</sup>

<sup>1</sup> Mosko et al., 1988; Meyer et al., 1993; Littner, 2000; Le Bon et al., 2000.

## Apnea Analysis Section

All respiratory events are identified during analysis including normal breathing, apnea, hypopnea, snoring as well as other respiratory sounds such as wheezing and stridor.

The data are provided in a tabular format as well as a summary paragraph. Please note the four sections of clinical findings. Each are explained below.

## Apnea Information.

RESPIRATORY FINDINGS:					
APNEAS		HYPOPNEAS		CALCULATED INDICES	
Total Number of Apneas:	71	Total Number of Hypopneas:	189	Total Apnea Index:	12.4
Num. of OBS Apneas:	67	Num. of Hypopneas 4%:	126	Hypopnea Index:	33.1
Num. of Central Apneas:	4			Hypopnea 4% Index:	22.0
Avg. Apnea Duration:	31 sec	Avg. Hypopnea Duration:	34 sec	Cen. Apnea Index:	(0.7) 1.5 %
OXIMETRY DESATURATIONS				MaxDen10 <sub>RDI</sub> :	80.0
				REI:	33.3
Time below 88%: 24 min (7%)		Oximetry baseline:	99 %	AHI:	34.5
Number of desaturations:	196	Lowest desaturation:	74 %	RDI:	45.5

The first column presents the information about total apneas as well as a breakdown of the obstructive apnea (OBS) and central apnea episodes.

Apnea is defined as a cessation of breathing for at least 10 seconds. The report will classify Central Apnea versus Obstructive Apnea events and separately indicate the number of Obstructive Apnea events and Central Apnea events. A Central Apnea is defined as a complete cessation of breathing (no respiratory flow and no effort to breathe) whereas an Obstructive Apnea is defined with an absence of airflow despite often vigorous efforts to breathe.

The average Apnea Duration is the total duration of all apnea events (including both central and obstructive) divided by the total number of apnea events (including both central and obstructive) occurring during the recorded sleep time.

## Hypopnea Information.

The second column presents details of the hypopneas. A hypopnea is defined as a least a 50% reduction in airflow lasting a minimum of 10 seconds. Partial reductions in airflow (Hypopneas) accompanied by drops in blood oxygen levels and have been documented to be clinically significant events. They often occur more frequently than apneas.

RESPIRATORY FINDINGS:		
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Num. of OBS Apneas: 67	Num. of Hypopneas 4%: 126	Hypopnea Index: 33.1
Num. of Central Apneas: 4		Hypopnea 4% Index: 22.0
Avg. Apnea Duration: 31 sec	Avg. Hypopnea Duration: 34 sec	Cen. Apnea Index: (0.7) 1.5 %
OXIMETRY DESATURATIONS		MaxDen10 <sub>RDI</sub> : 80.0
		REI: 33.3
Time below 88%: 24 min (7%)	Oximetry baseline: 99 %	<b>AHI: 34.5</b>
Number of desaturations: 196	Lowest desaturation: 74 %	RDI: 45.5

A second hypopnea count is also reported for the number of hypopnea events in which the level of oxygen desaturation was four percent or greater below the pre-event baseline. This total is labeled Hypopnea 4%.

The average Hypopnea Duration is the total duration of all hypopnea events divided by the total number of hypopnea events occurring during the recorded sleep time.

## *Oximetry Desaturation Information.*

A summary of the oximetry results are also provided, including:

- The time the patient spent below oxygen saturation of 88% (in minutes and % of sleep time)
- The number of oxygen desaturations
- The oximetry baseline
- The lowest oxygen desaturation during the recording

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OXIMETRY DESATURATIONS		MaxDen10 <sub>RDI</sub> : 80.0
		REI: 33.3
Time below 88%: 24 min (7%)	Oximetry baseline: 99 %	<b>AHI: 34.5</b>
Number of desaturations: 196	Lowest desaturation: 74 %	RDI: 45.5

## Calculated Indices Information.

RESPIRATORY FINDINGS:		
APNEAS	HYPOPNEAS	CALCULATED INDICES
Total Number of Apneas: 71	Total Number of Hypopneas: 189	Total Apnea Index: 12.4
Num. of OBS Apneas: 67	Num. of Hypopneas 4%: 126	Hypopnea Index: 33.1
Num. of Central Apneas: 4		Hypopnea 4% Index: 22.0
Avg. Apnea Duration: 31 sec	Avg. Hypopnea Duration: 34 sec	Cen. Apnea Index: (0.7) 1.5 %
OXIMETRY DESATURATIONS		MaxDen10 <sub>RDI</sub> : 80.0
Time below 88%: 24 min (7%)	Oximetry baseline: 99 %	REI: 33.3
Number of desaturations: 196	Lowest desaturation: 74 %	<b>AHI: 34.5</b>
		<b>RDI: 45.5</b>

The third column are many indices that are calculated from the apnea and hypopnea episodes.

**Total Apnea Index:** This is the number of apnea episodes per hour of sleep time.

**Hypopnea Index:** This is the number of hypopnea episodes per hour of sleep time.

**Hypopnea 4% Index:** This is the number of hypopnea episodes with a desaturation of 4% of more from pre-event baseline per hour of sleep time.

**Cen. Apnea Index:** The number in parentheses is the number of central apnea episodes per hour of sleep time. The % listed represents the percent of abnormal respiratory episodes that are central. It is calculated by dividing the numerator of central events by the denominator of the total number of abnormal events (all apneas and hypopneas).

**MaxDen10<sub>RDI</sub>:** This index is the highest rate of abnormal breathing that the patient demonstrated during periods of the recording no less than ten minutes in duration. This is an indicator of the potential episodic changes in severity of apnea for the patient. For example, respiratory changes that may correspond to body position or sleep stage.

**There are three indices that describe the level of sleep apnea; each are described below.**

**AHI:** The Apnea Hypopnea Index (AHI) is the number of abnormal respiratory events per hour of sleep. Note: While all apnea events are included in the numerator, hypopneas are only included when the desaturation is 4% or greater from the patient's pre-event baseline. The sleep time is used for the denominator.

**RDI:** The Respiratory Disturbance Index (RDI) is the number of abnormal respiratory events per hour of Sleep Time. NOTE: All apnea events and all hypopnea events included in the nominator. The sleep time is used for the denominator.



**REI:** The Respiratory Event Index (REI) is the number of abnormal respiratory events per hour of recording time. While all apnea events are included in the numerator, hypopneas are only included when the desaturation is 4% or greater from the patient's pre-event baseline. The recording time is used for the denominator.

## Considerations Section

Each Snap Test report now includes a page that is a listing of common considerations when managing the risk of sleep apnea in patients. The statements are a collection of published guidelines and/or recommendations of the American Academy of Sleep Medicine and American Academy of Dental Sleep Medicine. These statements are provided for the convenience of the ordering and / or treating provider for every patient regardless of the outcomes of the testing session. Note: There are two options to adjust the language in this section (see page 12).

### **CONSIDERATIONS:**

The following considerations represent clinical guidelines published by American Academy of Sleep Medicine. They are intended for a medical provider familiar with the patient history to consider if that medical provider elects to treat this patient.

Positive Airway Pressure (PAP) is the treatment of choice for mild, moderate and severe OSA and should be offered as an option for all patients (Consensus). Alternative therapies may be offered depending on the severity of the OSA and the patient's anatomy, risk factors and preferences (Epstein et al. AASM Clinical Guideline. J Clin Sleep Med. 2009: 5[3]).

The AASM and AADSM recommend the use of a custom, titratable Oral Appliance for (a) patients with primary snoring or (b) patients that are either not tolerant of PAP or that prefer an alternative to PAP versus no treatment (AASM & AADSM Clinical Practice Guideline, J Clin Sleep Med. 2015;11[7]).

Note: Prior to a trial of Oral Appliance, patients with severe OSA should have an initial trial of nasal CPAP because greater effectiveness has been shown with this intervention than the use of Oral Appliances (Epstein et al. AASM Clinical Guideline. J Clin Sleep Med. 2009: 5[3]).

Successful dietary weight loss may improve the RDI in obese patients with OSA (Epstein et al., 2009).

Consider surgical procedures as a secondary treatment for obstructive sleep apnea when outcome on PAP is inadequate or the patient is PAP-intolerant (Epstein et al., 2009).

If treatment includes oral appliance, surgical procedure or weight loss, consider repeating sleep test to assess therapy effectiveness (Epstein et al., 2009; Ramar et al., 2015).

If CPAP therapy is considered appropriate, the predicted initial CPAP pressure is 9 cm H<sub>2</sub>O (Miljeteig and Hoffstein, 1993). If Auto-titrating PAP is considered appropriate, the treating pressure will be selected by the device's internal software.



## Snoring Analysis

All snoring events are identified and spectrally analyzed during Snap Diagnostics analysis. Snoring represents the vibration of structures in the upper airway as well as some degree of airway compromise or resistance. Habitual loud irregular snoring is the cardinal symptom of obstructive sleep apnea syndrome (OSAS) and is also thought to be a correlate of the upper airway resistance syndrome (UARS). Recent science has suggested that severe snoring alone – even in the absence of apnea – can reduce life span and negatively impact health.

<b><u>Snoring Data:</u></b>			<b><u>Overall Snoring Loudness:</u></b>	
Snoring Index:	543.0		Max Relative Loudness:	19 dB (Moderate degree)
Primary Vibration Frequency:	80 Hz		Average Relative Loudness:	12 dB (Moderate degree)
Palatal like Vibration Freq: (type1,2)	80 Hz			
<b><u>Snoring Distribution by Type:</u></b>			<b><u>Snoring Distribution by Loudness:</u></b>	
Type 1:	108	88 %	Ampl.Dist.Index(RES85%):	19 dB (Marked)
Type 2:	11	9 %	Ampl.Dist.Index(34W85%):	19 dB (Marked)
Type 3:	4	3 %		
Type 4:	0	0 %	Resistance Occurrence Percentage	69 %
Type WL:	0	0 %	(% of respiratory events with 1-4 or WL Type sound)	

Snap Diagnostics testing is unique in its ability to identify and spectrally profile all snoring events into 5 categories. No other product in the market provides these data. With clinical correlation, these categories may help identify the most likely sites of sound generation and airway compromise. Surgical alteration or reduction of structures of the Velopharynx (soft palate) has been shown to reduce the incidence and amplitude of Type 1 & 2 snoring, suggesting that Type 1 & 2 snoring represents Velum-like (palatal) snoring. Type 4 and WL snoring is characterized by more clearly defined higher frequency sound, which in contrast to Types 1 & 2 snoring, may increase subsequent to surgical reduction of the soft palate, suggesting that it is non-Velum in origin.

- Snoring index is the number of snores per hour of recorded sleep time. Note that it has not shown to be a good indicator of sleep apnea or pathology per se.
- Primary vibration frequency is the fundamental frequency of all snoring events.
- Palatal-like (Types 1 & 2) vibration frequency is the fundamental frequencies for types 1 & 2 snoring. High levels of types 1 & 2 snoring are predictive of success for patients who are considering Uvulopalatal reduction surgery (i.e. LAUP or UPP).



- Snoring distribution type is a tabular listing of the total number of, and relative percentage of, all snoring types.
- Overall snoring loudness
  - Max Relative Loudness is the average loudness of the loudest 10% of all snoring events
  - Average Relative Loudness is the average of all snoring events

### *Snoring Ranges*

Mild = 0 – 10 dB

Moderate = 10 – 20 dB

Severe >20 dB

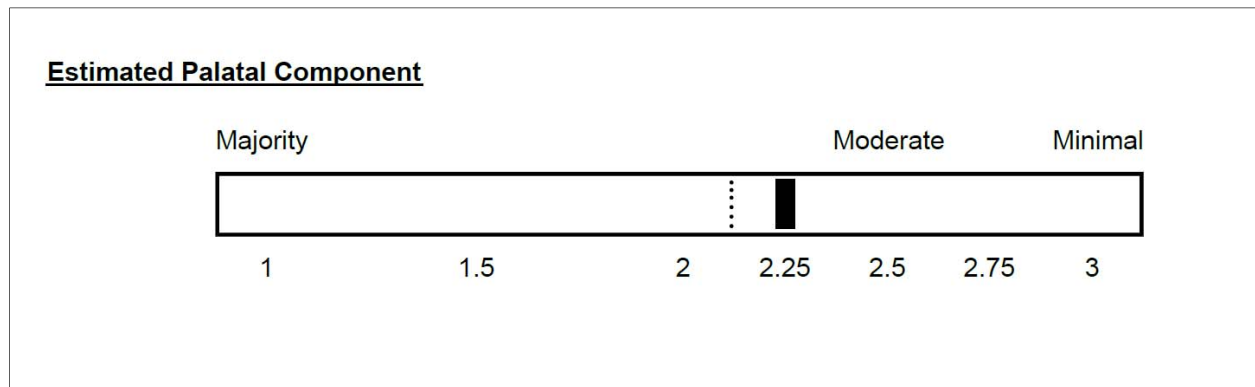
NOTE: Snap snoring loudness is measured relative to the sound of normal breathing at the opening of the mouth/nose and where 0dB in Snap's units are equivalent to roughly 65dB SPL.

*This is important, because we correct data to reflect the annoyance level rather than pure loudness. This is more clinically relevant information.*

- Snoring distribution loudness is a tabular listing of the relative loudness of Types 1 & 2 (velum-like) vs. Types 3, 4, and WL (non-velum-like) snoring.
  - Amplitude Distribution (Resp. 85%) is the relative loudness of Types 1&2 snoring events relative to the loudness of Types 3, 4 and WL and respiratory or breathing sounds. Greater than 8 dB suggests a significant velum-like dominance.
  - Amplitude Distribution (34W 85%) is the relative loudness of Types 1 & 2 snoring events relative to the amplitude of Types 3, 4, and WL snoring. An amplitude distribution greater than 8 dB suggests a significant velum-like dominance.
- Resistance occurrence percentage is the percentage of all respiratory events whose spectral profile suggests increased resistance in airflow.
- Estimated Palatal Component (Distribution Index) represents the average of the weighted distribution of snoring type

## *Interpreting Our Snoring Analysis Requires Special Knowledge.*

Due to the specialized nature of the snoring, an interpretation will always be provided by a Snap Diagnostics Medical Director.



The following guidelines are used to assess the relative Velum-like component of overall snoring amplitude and distribution.

	Type 1 & 2 (%)	Amplitude Distribution
Minimal	< 70%	< 4 dB
Moderate	< 80%	4 – 7 dB
Majority	≥ 80%	> 7 dB

## *OPTIONAL Snap Test Report Features*

There are three “optional” features that you can configure with a Snap Test report. Two are provided on additional pages, including: (1) a form in which you can order medical treatment and (2) a histogram that graphically depicts the patient’s disturbed breathing activities. The third optional element is how the Considerations section is provided. Each of these three optional features are further described below.



**If there are any questions about how to activate, deactivate, or use the optional report features, please contact Snap support.**

### *1. OPTIONAL Medical Order for Treatment*

Each Snap Test Report can include a form that can be used to order treatment for your patient. This feature is optional and is turned off by default, when a medical office initiates Snap Sleep Testing services.

A medical provider(s) can elect to activate (or deactivate) the optional page at any time by contacting Support at Snap Diagnostics.

NOTE: Once this feature is activated, the Snap Test report will ALWAYS include a form that a provider can use if they want to order treatment. It is always the responsibility of the ordering medical provider to decide if he/she wants to order treatment for each patient.

### *2. OPTIONAL Histogram of Clinical Findings*

Each Snap Test Report can include a page that graphically depicts the patient’s disturbed breathing activities. This feature is optional and is turned off by default, when a medical office initiates Snap Sleep Testing services.

A medical provider(s) can elect to activate (or deactivate) the optional page at any time by contacting Support at Snap Diagnostics.

NOTE: Once this feature is activated, the Snap Test report will ALWAYS include an additional page that shows the clinical events graphically across the night.

### 3. OPTIONAL Adjustments to the Considerations Section

Page 6 of this explanation shows the language in the standard Considerations Section.

We also allow you the option to either expand the dental language in the Considerations page (see below) or eliminate the Considerations page entirely from the report.

The following exemplifies how the Consideration section reads with expanded Dental language.

#### **CONSIDERATIONS:**

The following considerations represent clinical guidelines published by American Academy of Sleep Medicine. They are intended for a medical provider familiar with the patient history to consider if that medical provider elects to treat this patient.

The AASM and AADSM recommend the use of a custom, titratable Oral Appliance for (a) patients with primary snoring or (b) patients that are either not tolerant of PAP or that prefer an alternative to PAP versus no treatment (AASM & AADSM Clinical Practice Guideline, J Clin Sleep Med. 2015;11[7]).

The American Academy of Dental Sleep Medicine recommends that Oral appliances should be fitted by qualified dental personnel who are trained and experienced in the overall care of oral health, the temporomandibular joint, dental occlusion and associated oral structures.

Use of PAP and Oral Appliance in combination can improve compliance and improve treatment outcomes with patients with severe sleep apnea compared to use of PAP alone (White et al. 2011).

Note: Prior to a trial of Oral Appliance, Patients with severe OSA should have an initial trial of nasal CPAP because greater effectiveness has been shown with this intervention than the use of Oral Appliances (Epstein et al. AASM Clinical Guideline. J Clin Sleep Med. 2009: 5[3]).

Successful dietary weight loss may improve the RDI in obese patients with OSA (Epstein et al., 2009).

Consider surgical procedures as a secondary treatment for obstructive sleep apnea when outcome on PAP is inadequate or the patient is PAP-intolerant (Epstein et al., 2009).

If treatment includes oral appliance, surgical procedure or weight loss, consider repeating sleep test to assess therapy effectiveness (Epstein et al., 2009; Ramar et al., 2015).

If CPAP therapy is considered appropriate, the predicted initial CPAP pressure is 8 cm H<sub>2</sub>O (Miljeteig and Hoffstein, 1993). If Auto-titrating PAP is considered appropriate, the treating pressure will be selected by the device's internal software.