**Target Customers:**

Hospitals and clinics (Neurology, Cardiology, Cardiothoracic Surgery, ENT, Psychiatry, Dentistry, Oral Surgery).

**Medical Use :**

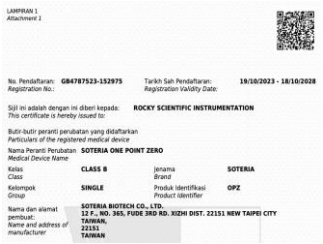
Upper Airway Narrowing Analysis

**Medical Certifications:**

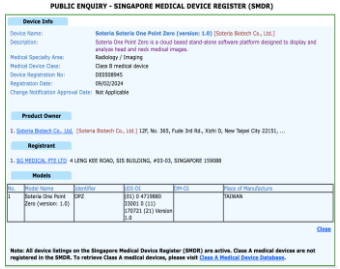
- CE (Europe)
- FDA (Taiwan)
- MDA (Malaysia)
- HAS (Singapore)
- FDA (Lithuania)


CE Mark

TFDA



Malaysia MDA



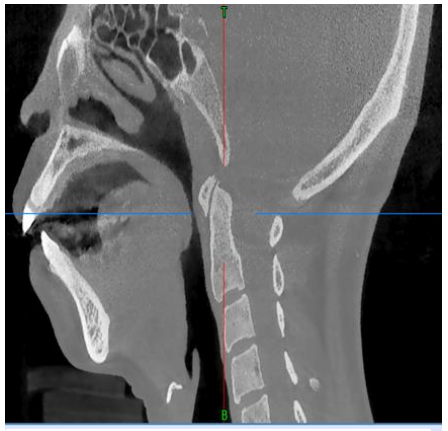

Singapore HSA

**Patents:**

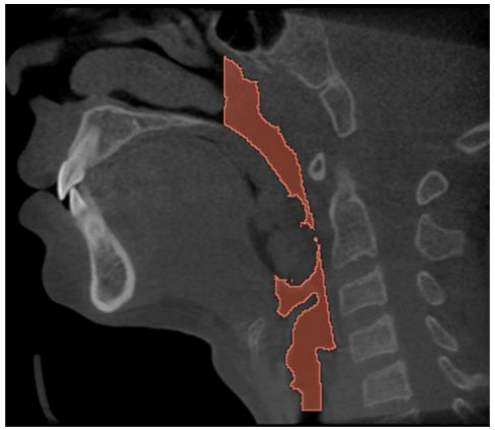
Taiwan
China
United States
Japan
Singapore
United Arab Emirates
Europe (under review)

# Do you know if you have airway obstruction issues?

# What conditions can cause airway obstruction?



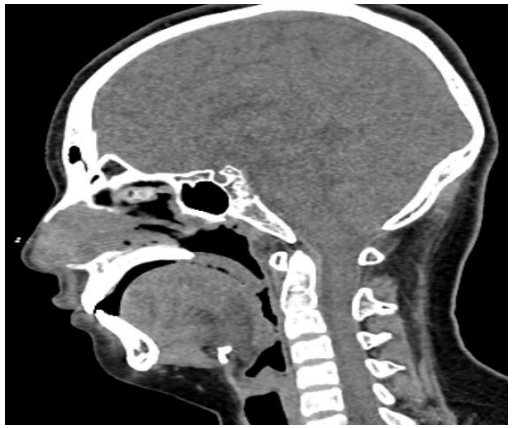
Retracted mandible



Enlarged tonsils

Enlarged adenoids

Obese BMI>28

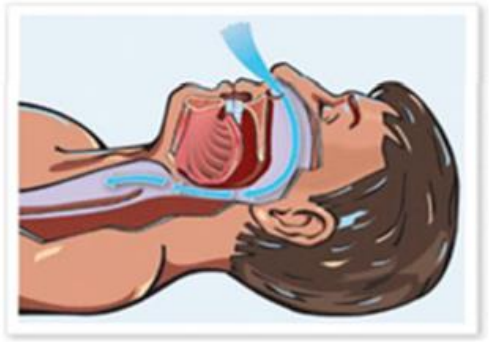


Elongated soft palate

# Do you know that airway obstruction can cause obstructive sleep apnea?

Sleep-Disordered Breathing is abnormal breathing pattern or insufficient ventilation during sleep.

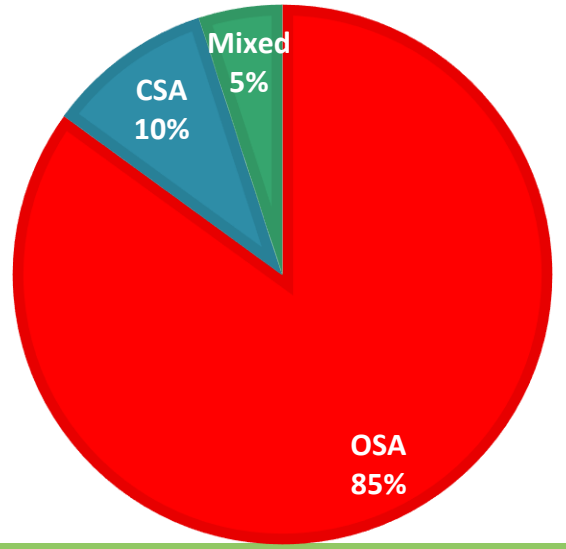
The most common one is the Obstructive Sleep Apnea (OSA, ~85%).



Normal airway

Partially obstructed airway

Obstructed airway



# A large, underpenetrated market

Advantage of the service – Finding OSA patients faster


Among the world’ s 30-69 years old, 1 billion have OSA, and 425 million have moderate to severe OSA.

RESEARCH NEWS

## Up to 15% of Children Have Sleep Apnea, But 90% Go Undiagnosed

Published on February 26, 2019

Children are grossly underdiagnosed for sleep-disordered breathing (SDB), which includes obstructive sleep apnea (OSA), and the symptoms may be wrongly attributed to behavior issues, according to research in the *Journal of the American Osteopathic Association*.

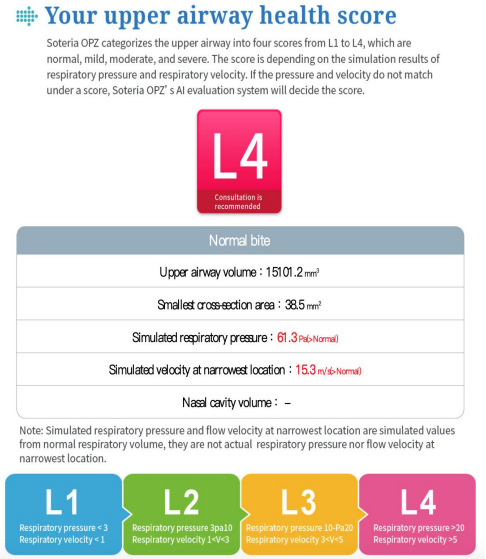
# Diagnosis Process

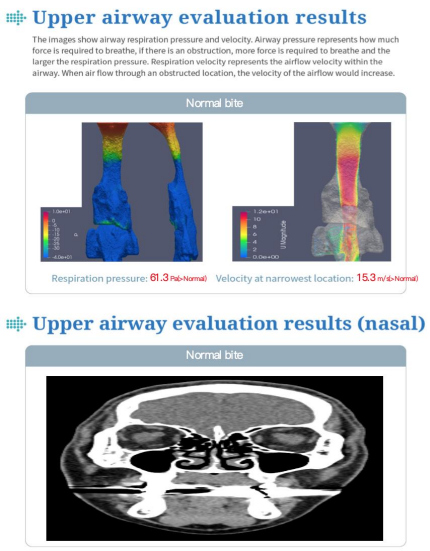
CT/CBCT

DICOM Images


DICOM Images

AI Server




Airway Analysis Report

1. Upper Airway Scan (CT/CBCT)
2. Upload Images to AI Server
3. Read Airway Pressure & Velocity Analysis Report
4. Make Diagnosis & Treatment Plan

# Airway Analysis Report


The report assesses the degree of airway narrowing, with four levels ranging from L1 to L4, corresponding to normal, mild, moderate, and severe. The assessment criteria are based on airway pressure and airflow velocity, which are obtained by simulating breathing conditions.
Clinical comparison involves blind testing with obstructive sleep apnea patients at sleep centers, with accuracy of more than 88%

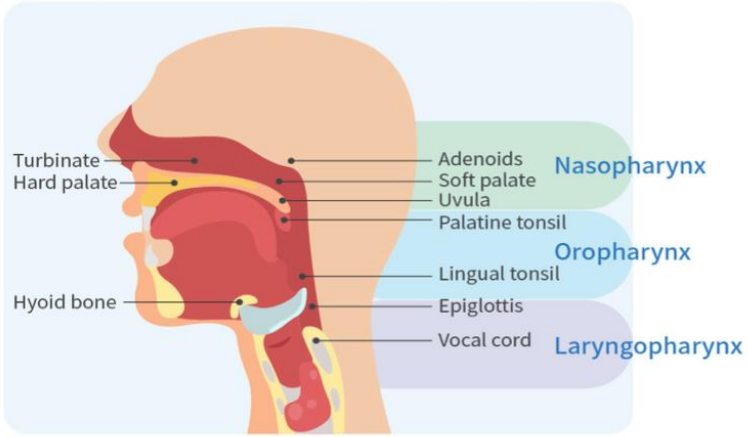
Publications

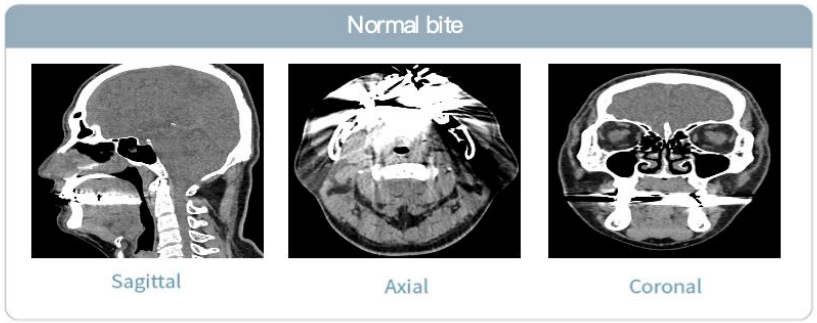
1.Prediction of Moderate to Severe Obstructive Sleep Apnea Using Neck Computed Tomography With Computational Fluid Dynamics Study, Pulmonary Medicine , 2022.
2. Pediatric obstructive sleep apnea: Computational fluid dynamics analysis of upper airway, J Dent Sci. 2022.
3. Computational fluid dynamics study in children with obstructive sleep apnea, Clinical Otolaryngology, 2023.
4. Association Between Obstructive Sleep Apnea, Its Treatment, and Alzheimer's Disease: Systematic Mini-Review, Aging Neurosci., 2021.

# Airway Analysis Report

## CBCT scan images

Sagittal view – can observe the cross-section in sagittal plane.
Axial view – can observe the airway in the smallest cross-section and the lateral size. Coronal view – can observe the cross-section in coronal plane.
Using the normal bite scan and mandible protrusion scan to observe the changes in the airway cross-section. In the normal bite scan, obstruction of the airway due to enlargement of tonsils, base of tongue or retraction of the mandible can be observed. In the mandible protrusion scan, observation on the expansion of the airway to determine the effectiveness of oral appliance treatment.

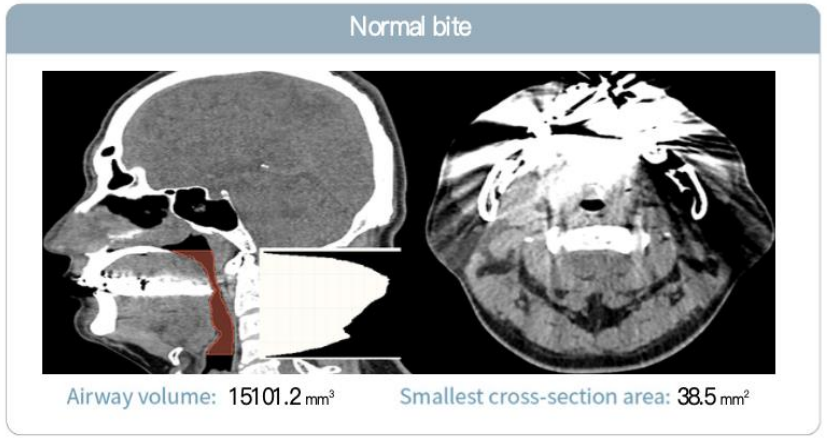


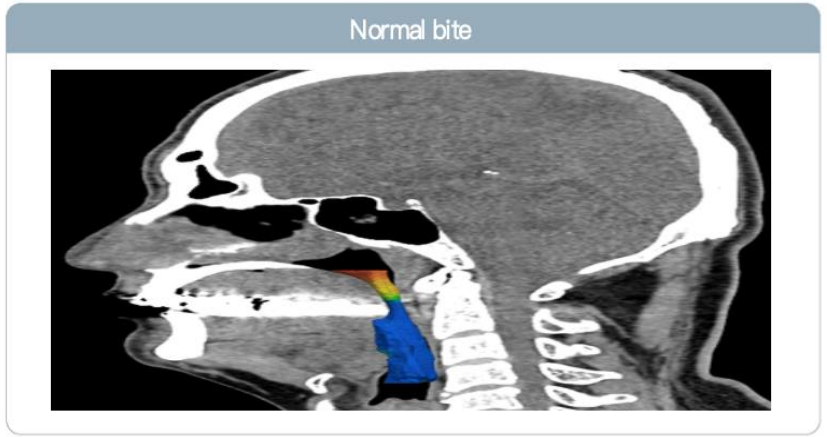

The report shows three cross-sectional views, helping patients understand the scanned area and potential location of obstruction.

## Upper airway evaluation results

The images show airway volume and the smallest cross-section area. The area highlight in read is the area for the calculation. The middle bar diagram is the cross-section area distribution. The axial view shows the smallest cross-section area. Using the normal bite scan and mandible protrusion scan to observe the changes in the airway cross-section. In the normal bite scan, obstruction of the airway due to enlargement of tonsils, base of tongue or retraction of the mandible can be observed. In the mandible protrusion 5mm scan, observation on the expansion of the airway to determine the effectiveness of oral appliance treatment.




The images show the sagittal view of the airway with respiration pressure. The changes in color represents changes in pressure and can determine the location of the obstruction and its severity. The bigger the color variation, the more severe the obstruction.




The area highlight in red is the region being analyzed. The middle graph shows the change in cross-sectional area, and the view on the right is the smallest cross-sectional area of the airway.

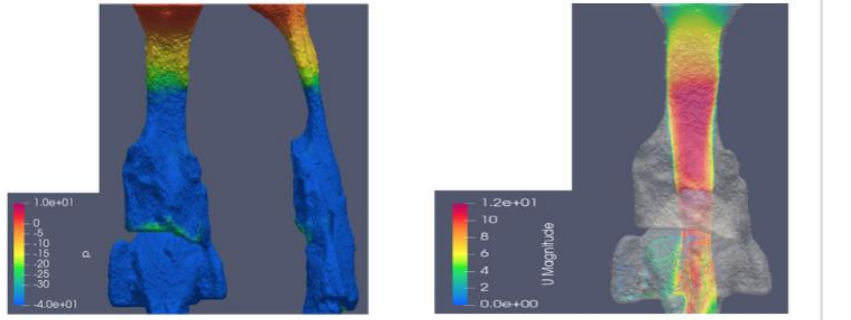
The colors within the airway represent the changes in airway pressure. The areas where the color changes indicate regions of airway obstruction, providing doctors with a clear understanding of the location and extent of the obstruction. As shown in the figure, there are two areas where the pressure color changes, indicating two sites of obstructions.

# Airway Analysis Report

## Upper airway evaluation results

The images show airway respiration pressure and velocity. Airway pressure represents how much force is required to breathe, if there is an obstruction, more force is required to breathe and the larger the respiration pressure. Respiration velocity represents the airflow velocity within the airway. When air flow through an obstructed location, the velocity of the airflow would increase.

Normal bite




Respiration pressure: 61.3 Pa(>Normal) Velocity at narrowest location: 15.3 m/s(>Normal)

## Upper airway evaluation results (nasal)

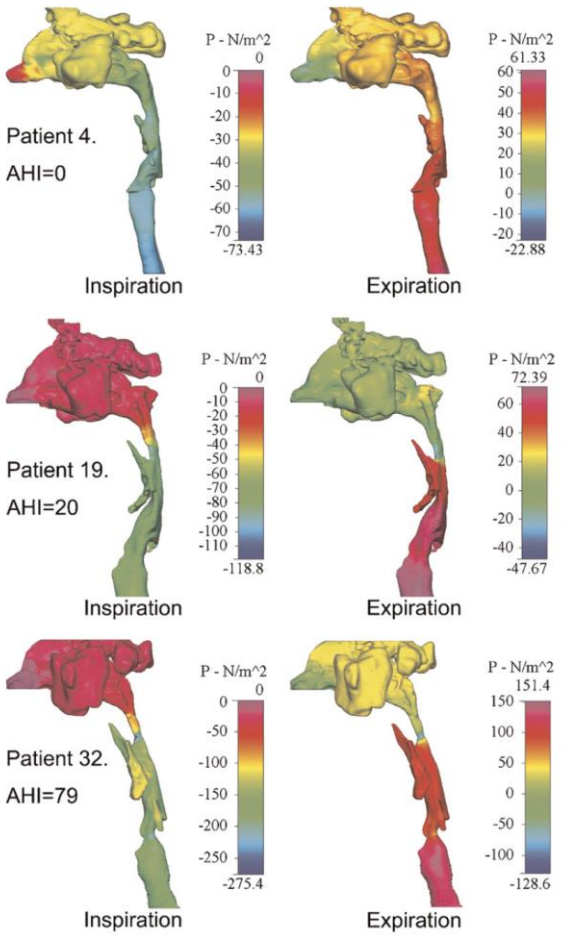
Normal bite

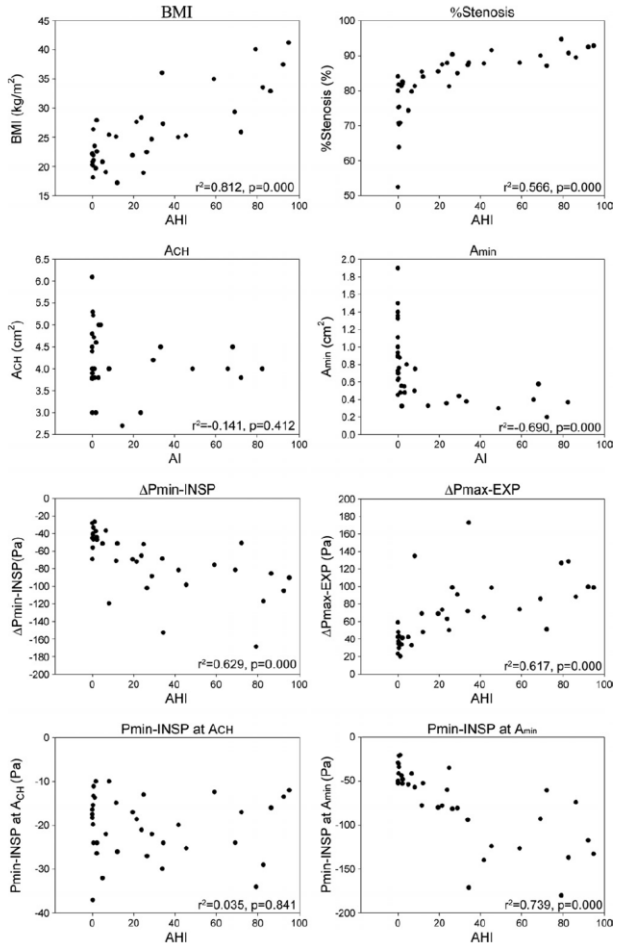
Image on the left shows the airway pressure distribution during inhalation, with a frontal view and a lateral view of the airway. From the airway pressure change diagram, the locations and extent of airway narrowing can be observed. The airway pressure color ranges from 10 Pa (red) to -40 Pa (blue). During inhalation, the airway is in a negative pressure state; therefore, the pressure at the top of the airway is red, and as it moves downward, the more severe the narrowing, the more distinct the color difference in pressure.

Image on the right shows the distribution of airflow velocity during inhalation. The airflow velocity color ranges from 0 m/s (blue) to 12 m/s (red). The more severe the narrowing, the closer the velocity color is to red. From the airflow velocity image, it can be seen that due to the excessive airflow speed, the air does not fill the entire airway, leaving many airway cavities. This is also why the accuracy was not high in the past when analyzing airway narrowing using only airway volume and cross-sectional area.

20% of patients are having nasal obstruction issues such as deviated septum and turbinate hypertrophy, which can be seen through this cross-section view.

# AI Upper Airway Evaluation(together with home sleep test for precision)




## Prediction of Moderate to Severe Obstructive Sleep Apnea Using Neck Computed Tomography With Computational Fluid Dynamics Study

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[1] Department of Internal Medicine, Taichung Hospital, Ministry of Health and Welfare, Taichung, Taiwan, [2] Department of Health Services Administration, China Medical University, Taichung, Taiwan, [3] Department of Healthcare Administration, Central Taiwan University of Science and Technology, Taichung, Taiwan, [4] Department of Chemistry, Point Loma Nazarene University, San Diego, CA, United States

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**Background:** Moderate to severe obstructive sleep apnea (OSA) is associated with cardiovascular disease. Polysomnography is time intensive and difficult to access for diagnosis of OSA. Neck computed tomography (CT) provides upper airway delineation but not diagnostic criteria for moderate to severe OSA. We explored neck CT with computational fluid dynamics (CFD) study for airway pressure and airflow velocity to predict moderate to severe OSA.

**Methods:** Enrolled from February 1, 2020, to June 30, 2021, patients with OSA with overnight oxygen desaturation (sPO2 <90%) received awake neck CT with a CFD study of their airway pressure and airflow velocity. CTL12 and CTL34 were defined as airflow velocity <3 and ≥3 m/s, respectively, and airway pressure <10 and ≥10 pa, respectively, in the narrowest upper airway.

**Results:** Sixty-two patients (42 male and 20 female; mean age: 50.4 ± 14.6 years) were included; 12 and 50 patients had mild OSA and moderate to severe OSA, respectively. The minimum sPO2 in the supine position was 80.7 ± 9.1%. The total time of sPO2 <90% at overnight oximetry was 29.3 ± 51.1 min. Most (85.5%) neck CT examinations with CFD study presented CTL34. Patients with CTL34 had a lower minimum sPO2 in the supine position (78.4 vs. 88.1%, $P = 0.004$) and longer duration of sPO2 <90% at overnight oximetry (33.9 vs. 1.9 min, $P = 0.001$) than those with CTL12. The values of the area under the receiver operating characteristic curves of airway pressure and of airflow velocity at the narrowest upper airway were 0.788 and 0.733, respectively.

**Conclusion:** Neck CT with CFD study of airway pressure and airflow velocity may provide a quick prediction of moderate to severe OSA.

**Keywords: obstructive sleep apnea, overnight oxygen desaturation, computed tomography, computational fluid dynamics, airway pressure, airflow velocity**

J Craniofac Surg 2012;23: 401- 405

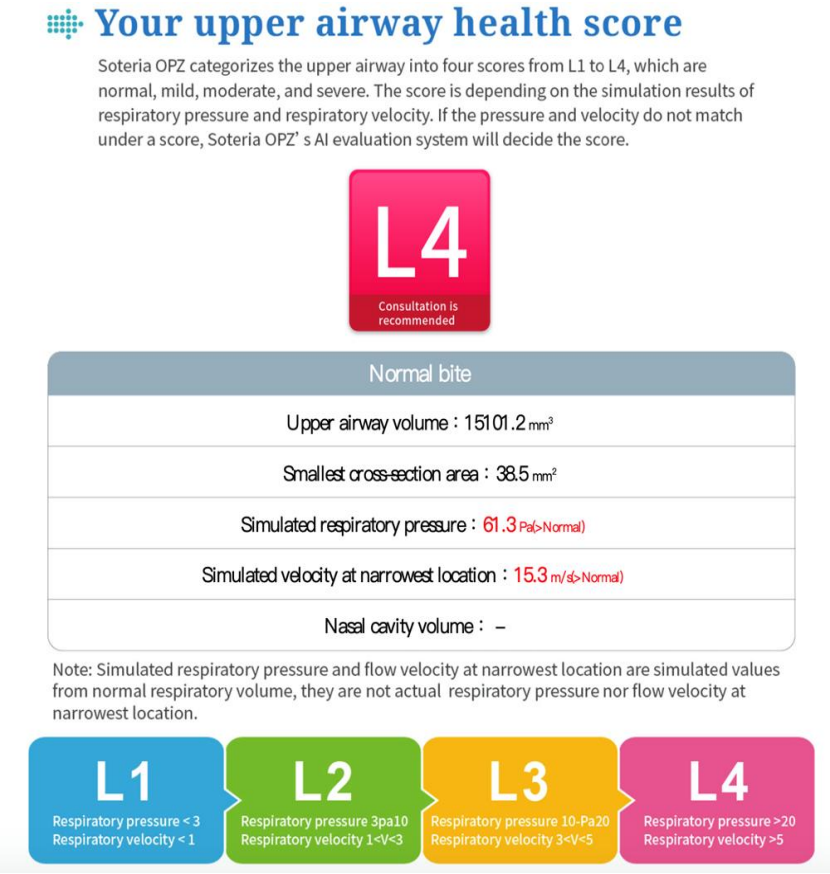
*Pulmonary Medicine , 2022*

# Use Cases

Obstructive sleep apnea assessments, with an estimated 30.5% of people in Singapore having moderate to severe OSA.

Pre-surgery assessments for ENT and Craniofacial surgeries which has led to a 50% and 60% annual increase respectively in 3 hospitals in Taiwan.

Partnering with an oral appliance company to identify suitable patients for their products.

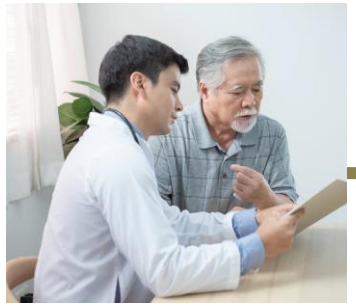


# Incremental income of Hospital- Obstructive sleep apnea assessments

OSA is highly prevalent with an estimated **30.5%** of people in Singapore having moderate-severe OSA, of which up to **91%** are undiagnosed.

https://www.healthxchange.sg/news/all-about-osa

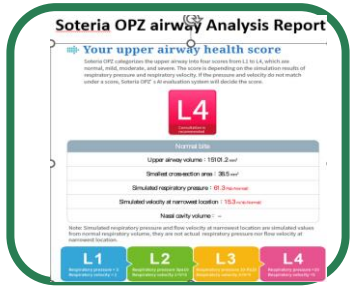
1 Patient use home sleep test for possible OSA



2 Evaluate by doctor

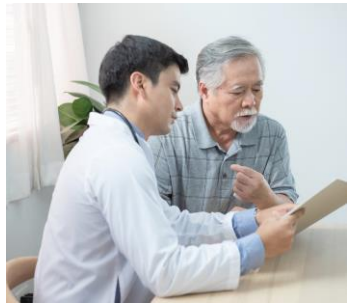

3 CT Scan, upload the image

4




Soteria OPZ to analyze and simulate the airflow velocity and pressure within the upper airway and generates a report

5

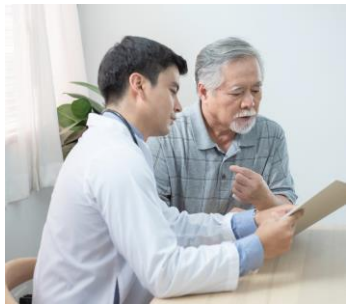


Use the report to evaluate upper airway obstruction severity and location.
Doctors and patients then use the information to determine the treatment options. (e.g. soft tissue surgery, MMA, CPAP… etc.)

# Incremental income of Hospital-ENT pre-surgery assessments

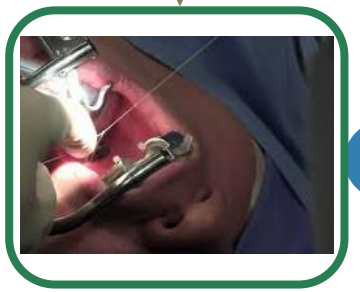
Our Airway analysis report quickly identifies upper airway obstruction issues, leading to a 50% annual increase in ENT surgeries at three hospitals in Taiwan. This service is incorporated into pre-surgery assessments and is covered by medical insurance.

**Patient**

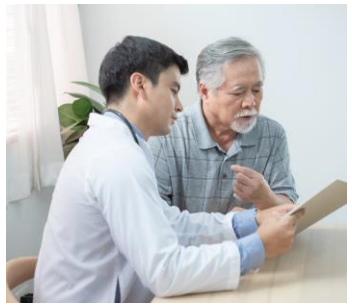


1 Evaluate by doctor

2 Know the location of obstruction via evaluation report by Soteria to increase surgery success rate



3 e.g. Uvulopalato-pharyngoplasty



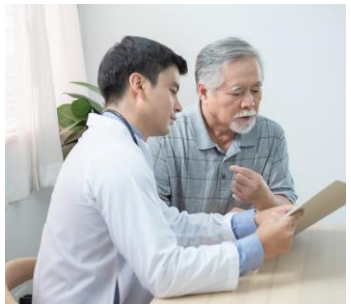
4 Revisit the doctor

5 Evaluate treatment effectiveness after surgery

# Incremental income of Hospital-Craniofacial  Surgery pre-surgery assessments

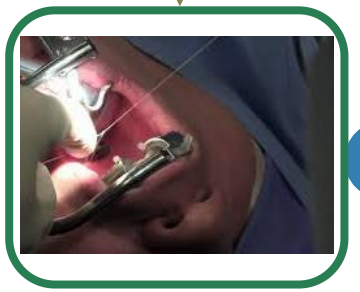
Our Airway analysis report quickly identifies upper airway obstruction issues, leading to a 60% annual increase in craniofacial surgeries at two hospitals in Taiwan. This service is incorporated into pre-surgery assessments and is covered by medical insurance.

**Patient**



1 Evaluate by doctor

2 Know the location of obstruction via evaluation report by Soteria to increase surgery success rate



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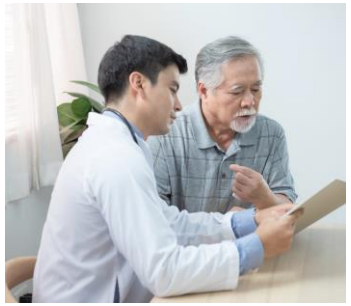
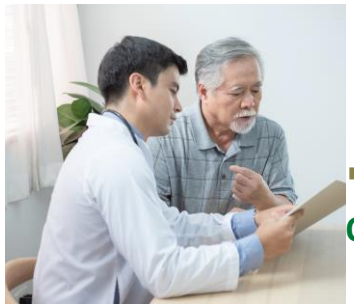


4 Revisit the doctor

5 Evaluate treatment effectiveness after surgery

# Cooperative partner: Oral appliance company



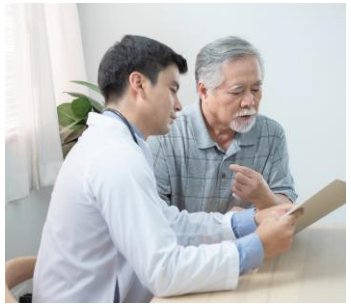
OSA Patient


1 Evaluate by doctor

2 CT Scan, upload the image

3 Using the solution to determine if patient is suitable for OA treatment

4 Making Oral Appliance



5 Oral Appliance Fitting


6 Home Sleep Monitoring