DROWZLE®

DROWZLE® is a digital platform that uses a smartphone for in-home detection of obstructive sleep apnea (OSA) in adults. Since it is deployed by the patient's own phone, DROWZLE® provides testing to many patients for whom in-lab PSG or conventional home sleep testing may not be an acceptable option.

Unlike traditional HSTs, there are no sensors to attach to the body, making testing extremely easy. As an added benefit, there is no equipment to track down, retrieve, and disinfect prior to distributing to another patient.

HOW DROWZLE® WORKS

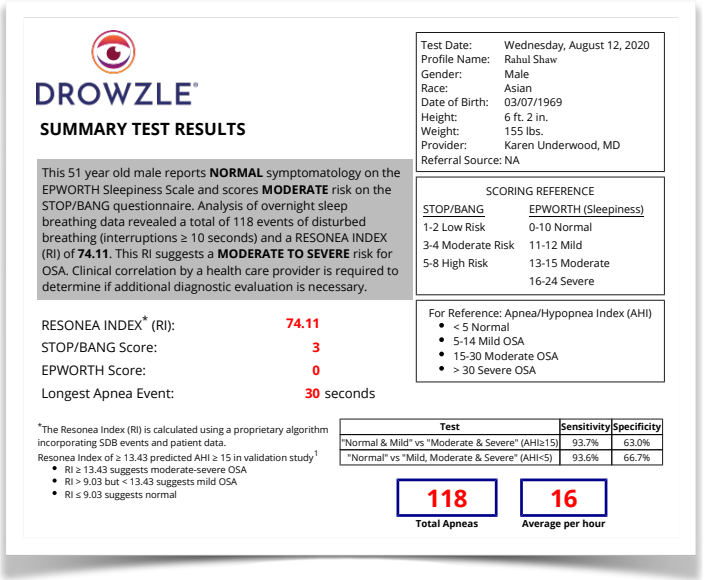
DROWZLE® collects relevant symptom, co-morbidity and functional quality-of-life data from the patient and combines this information with an overnight breathing analysis to give both the patient and the provider an easy to read report with actionable results.

The patient records their breathing by placing the phone near their pillow and activating the program to record and analyze their sleep breathing disturbances overnight. In the morning, both the patient and provider receive their respective reports.

DROWZLE® shortens the evaluation time for OSA and motivates patients to take action.

THE RESONEA INDEX (RI)

Unlike conventional HSTs, DROWZLE® does not report an Apnea Hypopnea Index (AHI). Instead, DROWZLE® produces the Resonea Index (RI), a clinically validated, proprietary algorithmic calculation based on an analysis of sleep breathing patterns and clinical measures (e.g. signs and symptoms) that are closely related to the presence of OSA. By combining diverse clinical elements with a physiologic measure, the RI is a simple composite score that provides a broader clinical representation of a patient's OSA status.



DROWZLE®

SUMMARY TEST RESULTS

Test Date:	Wednesday, August 12, 2020
Profile Name:	Rahul Shaw
Gender:	Male
Race:	Asian
Date of Birth:	03/07/1969
Height:	6 ft. 2 in.
Weight:	155 lbs.
Provider:	Karen Underwood, MD
Referral Source:	NA

This 51 year old male reports **NORMAL** symptomatology on the EPWORTH Sleepiness Scale and scores **MODERATE** risk on the STOP/BANG questionnaire. Analysis of overnight sleep breathing data revealed a total of 118 events of disturbed breathing (interruptions ≥ 10 seconds) and a RESONEA INDEX (RI) of **74.11**. This RI suggests a **MODERATE TO SEVERE** risk for OSA. Clinical correlation by a health care provider is required to determine if additional diagnostic evaluation is necessary.

SCORING REFERENCE

STOP/BANG	EPWORTH (Sleepiness)
1-2 Low Risk	0-10 Normal
3-4 Moderate Risk	11-12 Mild
5-8 High Risk	13-15 Moderate
	16-24 Severe

For Reference: Apnea/Hypopnea Index (AHI)
- < 5 Normal
- 5-14 Mild OSA
- 15-30 Moderate OSA
- > 30 Severe OSA

RESONEA INDEX* (RI):	74.11
STOP/BANG Score:	3
EPWORTH Score:	0
Longest Apnea Event:	30 seconds

*The Resonea Index (RI) is calculated using a proprietary algorithm incorporating SDB events and patient data.
Resonea Index of ≥ 13.43 predicted AHI ≥ 15 in validation study[1]
- RI ≥ 13.43 suggests moderate-severe OSA
- RI > 9.03 but < 13.43 suggests mild OSA
- RI ≤ 9.03 suggests normal

Test	Sensitivity	Specificity
"Normal & Mild" vs "Moderate & Severe" (AHI≥15)	93.7%	63.0%
"Normal" vs "Mild, Moderate & Severe" (AHI<5)	93.6%	66.7%

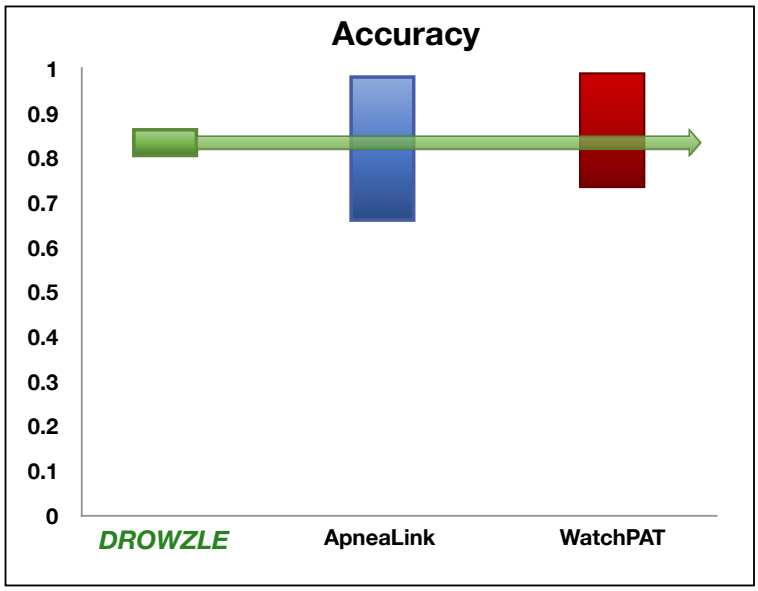
118 Total Apneas

16 Average per hour

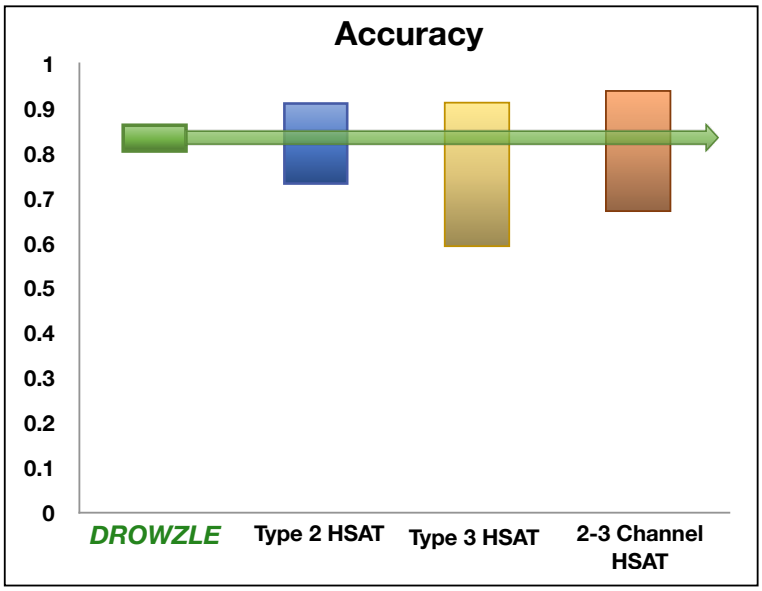
CLINICALLY VALIDATED ACCURACY

Data from a clinical trial with simultaneous smartphone recordings and in-lab polysomnograms:[1]

- The Resonea Index (RI) was compared to PSG the for detection of normal/mild vs. moderate/severe OSA.
- It was demonstrated that the RI can accurately predict OSA with a sensitivity of 93.6% for normal/mild and 93.7% for moderate/severe OSA.
- The RI accuracy is within the range of what has been reported for popular HSTs as well the range reported in the AASM guidelines for each type of HST.[2]



Accuracy ranges for popular HSTs[2] compared to DROWZLE[1]



Accuracy ranges *as reported in the AASM guidelines* for each type of HST[2] compared to DROWZLE[1]

	DROWZLE	Type 2 HSAT	Type 3 HSAT	2-3 Channel HSAT
Sensitivity (Range)	0.94	0.88 - 0.97	0.62 - 1.0	0.66 - 0.96
Specificity (Range)	0.63 - 0.67	0.50 - 0.77	0.25 - 0.97	0.62 - 1.0

Sensitivity and specificity ranges *as reported in the AASM guidelines* for each type of HST[2] compared to DROWZLE[1]

DROWZLE® - FDA CLEARED

In 2019, the US Food and Drug Administration cleared DROWZLE® as the first mobile home sleep test for in-home screening of adults with suspected sleep breathing disorders, such as obstructive sleep apnea (OSA). The full Indication for Use statement is located on the company's web site at https://www.resonea.com/drowzle-pro/

1. Narayan S et al; Noncontact identification of sleep-disturbed breathing from smartphone-recorded sounds validated by polysomnography; Sleep and Breathing 2018; doi.org/1007/s11325-1695-6
2. Published reference sources for product comparisons available upon request

DROWZLE®