FULCARE

OSA & OHS Screening

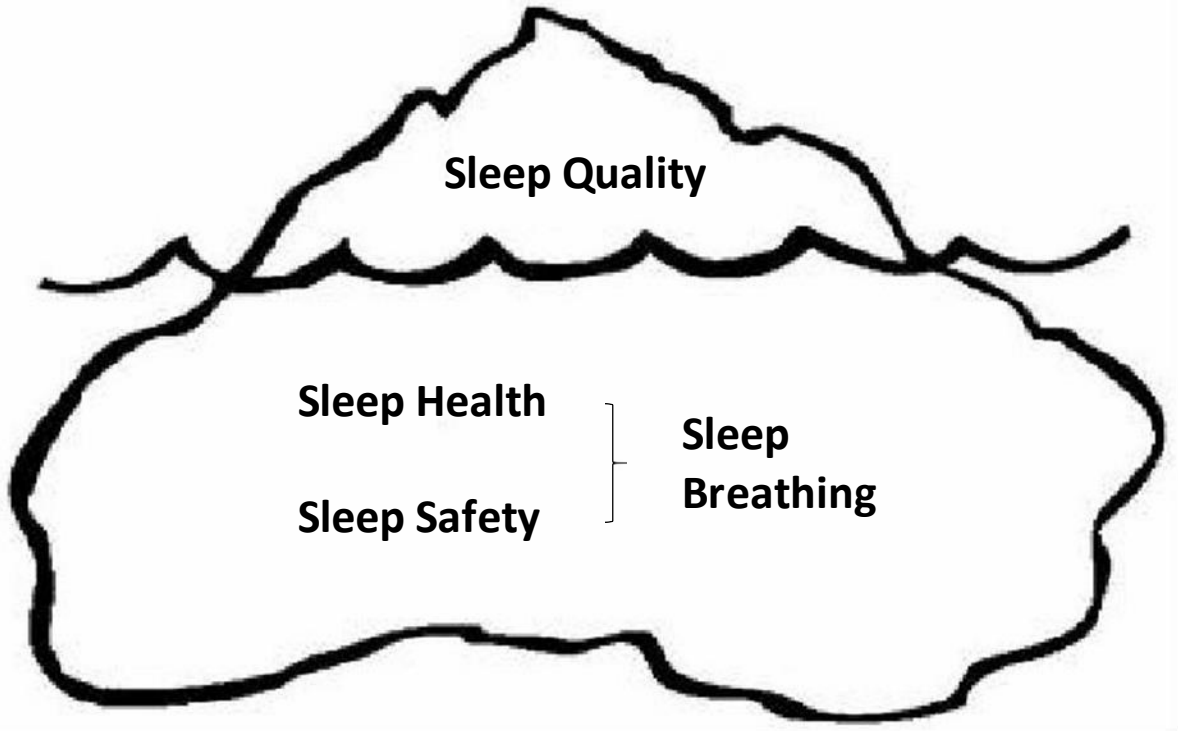
New Sleep Breathing Monitoring and Analysis Authorization System

V2.0 2019.02

I. About OSA & Hazards of OSA

Sleep Is A Nationwide Topic

China Sleep Quality Index 2013-2017 report shows 50.3% of the population has sleep problem. Insomnia, more dreams, tired after waking up are the major problems for people with bad quality sleep.



Iceberg Theory of Sleep Problems

Obstructed Sleep Apnea (OSA)

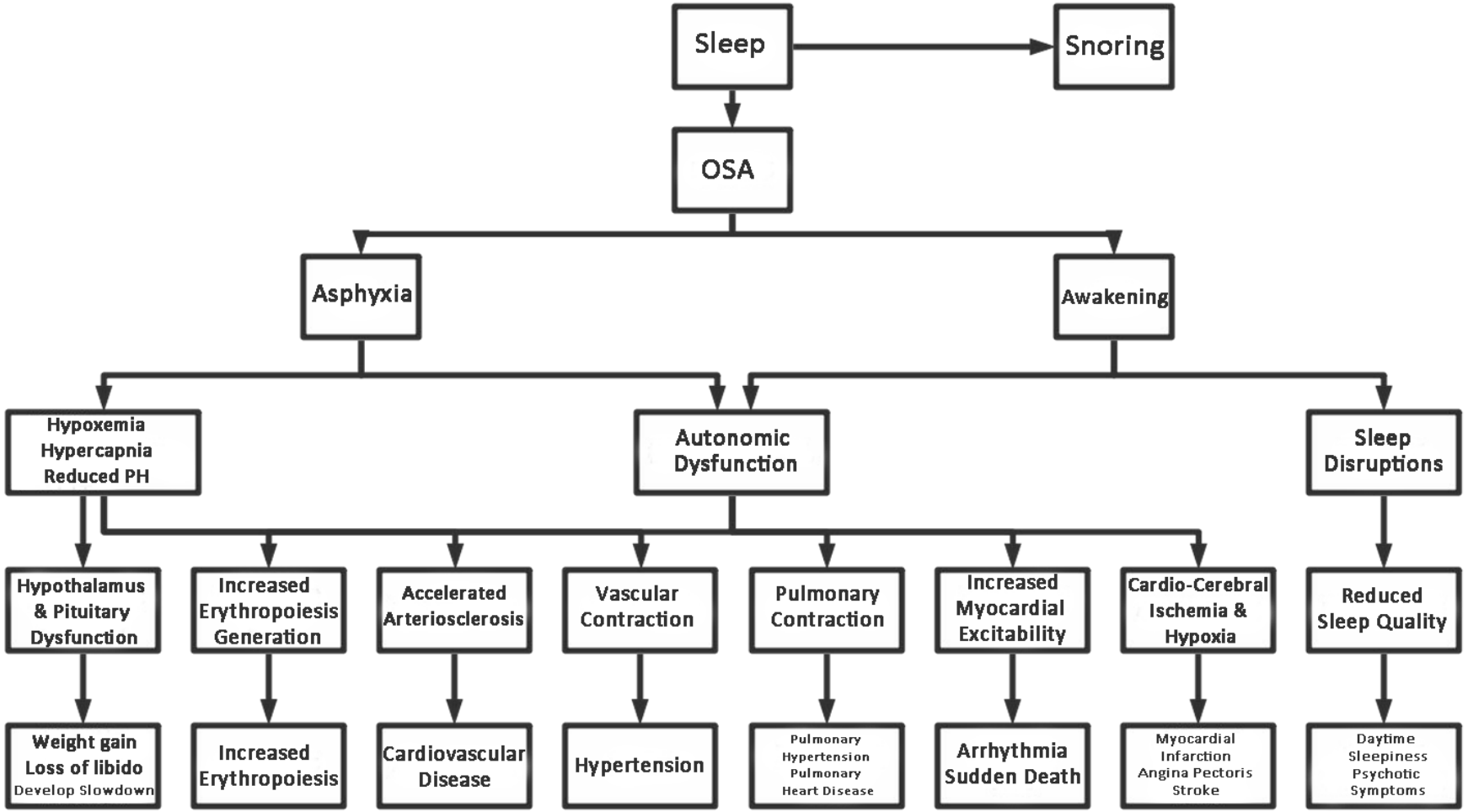
Repeated breathing pauses or hypoventilation caused by various reasons, leading to hypoxemia, hypercapnia, sleep disruptions and, therefore, causing a series of a series of pathophysiological changes in the body.

"It has been confirmed that the prevalence rate of its population is about 2%-7%." Among them, the prevalence rate is higher in people over 30 years old, about 3-7% in men and 2-5% in women. The prevalence rate in people over 65 years old can reach 20-40%. Because of tonsillar adenoid hypertrophy, children are a high-risk group.

Symptoms of OSA (Clinical Manifestations)

Most common (>60%)	Common (10%-60%)	Rare (<10%)
Snoring	Helium at night	Night bedwetting
Daytime sleepiness, fatigue and weakness	Loss of libido	Frequent wakefulness
Night breathing stop	Morning dry mouth, headache,	Cough at night,
Abnormal sleep movement at night,	Sweating at night	Insomnia, dreams,
personality change	Pharyngitis for a long time	Chest pain
Nocturia	Morning tongue numb	
Not relieved after sleeping		

Damages of OSA to Multiple Systems



- OSA is a systemic disease
- OSA patients' health resources consumptions are twice as much as healthy people

OSA Hazards: An Authoritative Guide

SN	Lesion Or Problem	SN	Lesion Or Problem
1	Cause or aggravate high blood pressure (high blood pressure at night and morning)	13	Respiratory failure
2	Coronary heart disease, nocturnal angina and cardiac infarction	14	Night bronchial asthma (asthma for short)
3	Severe arrhythmia, ventricular premature beats, tachycardia sinus arrest, sinus block, and atrioventricular block at night	15	Mental disorders: anxiety, depression, language confusion, behavioral bizarre, personality changes, visual hallucinations and auditory hallucinations
4	Type 2 diabetes and insulin resistance	16	
5	Recurrent left heart failure at night	17	Secondary erythrocytosis and increased blood viscosity
6	Cerebral thrombosis	18	Enuresis
7	Seizure	19	Sexual dysfunction: impotence and loss of libido
8	Dementia	20	Gastroesophageal reflux
9	Pulmonary hypertension, overlap syndrome and pulmonary heart disease	21	Neurasthenia
10	Pregnancy hypertension pre-eclampsia	22	Renal impairment
11	Liver damage	23	Aggravated obesity
12	Pediatric developmental retardation intelligence is lower than the normal level of children of the same age	24	Major traffic accident

Guidelines for the diagnosis and treatment of obstructive sleep apnea hypopnea syndrome (2011 revision) clearly shows the possible lesion or problems caused by OSA

Experts' Consensus on Sleep Apnea and Cardiovascular Disease

1. Mechanisms that trigger or aggravate cardiovascular disease

- Chronic intermittent hypoxia, carbon dioxide retention, increased chest vacuum, repeated arousal and abnormal sleep structure caused by apnea, on the basis of which cause autonomic dysfunction, oxidative stress and inflammatory response, vascular endothelial cell damage, blood flow Increased viscosity, hypercoagulable state, abnormal fiber dissolution system and endocrine abnormalities.

2. The relationship between OSA and hypertension

- For details, see the Experts' Consensus on Clinical Diagnosis and Treatment of Obstructive Sleep Apnea-Related Hypertension.

3. The relationship between OSA and coronary heart disease

- The prevalence of coronary heart disease in OSA patients is 20-30%;
- The 5-year mortality rate of OSA patients with coronary heart disease increased by 62%;

Hazards of OSA: Cardiovascular Disease

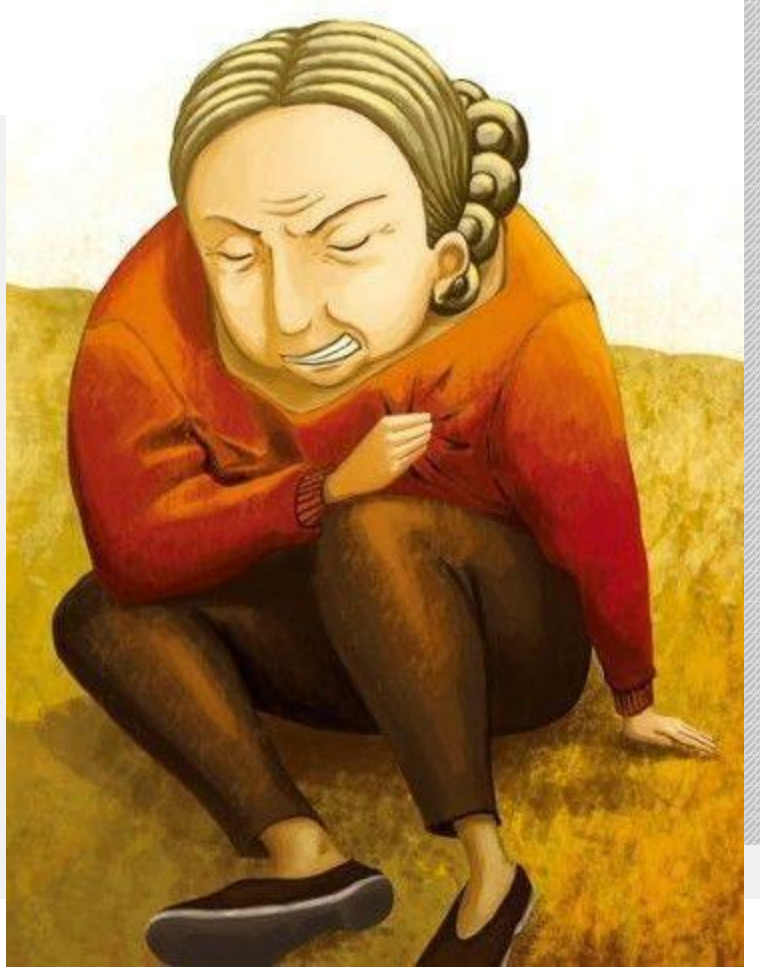
4. The relationship between OSA and arrhythmia

- 100% of OSA patients have greater heart rate variability during sleep, and a slower heart rate is the most typical ECG change in OSA patients during sleep;
- More than 80% of patients have significant sinus bradycardia during apnea, and more than 50% of patients with severe OSA have transient paroxysmal ventricular tachycardia;

5. The relationship between OSA and heart failure

- OSA is a risk factor for promoting, inducing, and aggravating heart failure;

6. The incidence of pulmonary hypertension in OSA patients is 35 - 45 . 3 %



- Although OSA is very common and its harm is multifaceted and serious, it has long been lack of awareness and attention to this disease, and the lack of necessary diagnostic equipment and experience, so a considerable proportion of patients have not been diagnosed and treated in time.

The Hazard of OSA: High Blood Pressure

Experts' Consensus on Clinical Diagnosis And Treatment Of Obstructive Sleep Apnea-Associated Hypertension

01 The Relationship Between OSA & Hypertension

- 50% to 92% of OSA patients have hypertension, and 30% to 50% of hypertensive patients are accompanied by OSA
- The risk factor for hypertension in patients with moderate to severe OSA is three times higher than in those without OSA;
- 83% of patients with refractory hypertension combined with OSA;
- A large percentage of OSA patients present with high blood pressure at night and in the morning;
- In the seventh report of the American Committee for the Evaluation and Prevention of Hypertension in 2003, OSA has been clearly identified as one of the major causes of secondary hypertension;

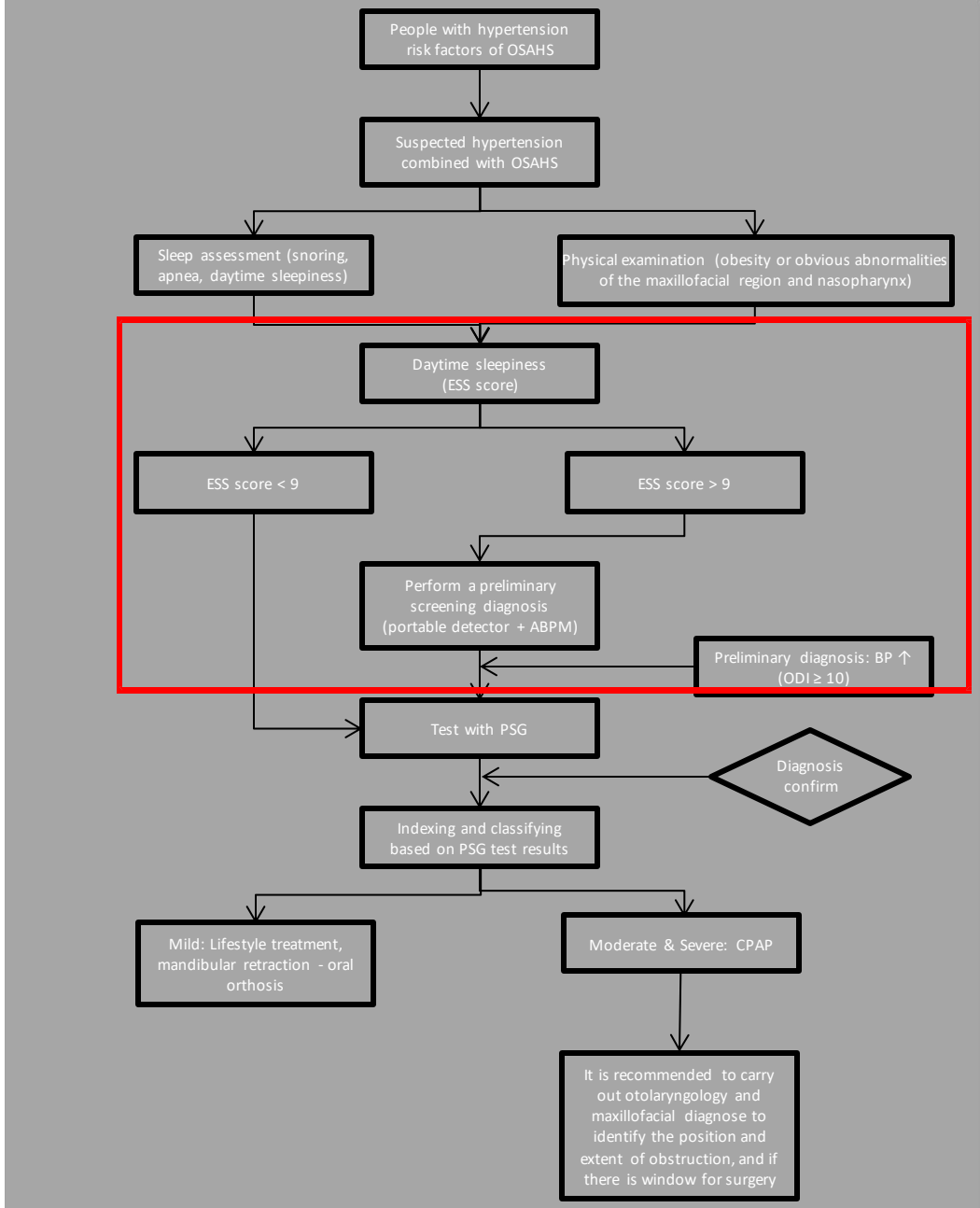
02 Mechanism of OSA-Induced Hypertension

- Repeated episodes of intermittent hypoxia, hypercapnia, neurological and humoral dysregulation, and sympathetic nervous system interactions can cause increased heart rate, increased myocardial contractility, increased cardiac output, and increased systemic vascular resistance. All above are important mechanisms leading to high blood pressure.

Hazards of OSA: High Blood Pressure

Obstructive Sleep Apnea-Associated Hypertension
High risk population

- Obesity;
- Abnormal anatomical structure with nasopharynx and maxillofacial;
- Snoring during sleep, daytime sleepiness, headache in the morning, dry mouth;
- Single bed drug has poor antihypertensive effect;
- Refractory hypertension or occult hypertension, morning high blood pressure, or high blood pressure rhythm that is “non-sick” or “reverse”;
- Repeated episodes of uncontrollable angina at night;
- Arrhythmia that is difficult to correct at night;
- Refractory congestive heart failure;
- Refractory diabetes and insulin resistance;
- Unexplained pulmonary hypertension;
- Unexplained nighttime wakefulness or nocturnal episodes;



Hazards of OSA: Stroke (Stroke/Cerebrovascular Disease)

The relationship between OSA and stroke

- Stroke is the second cause of death for humans and the leading cause of death in China. China now has more than 7 million patients with strokes, the first in vascular disease;
- OSA is an independent risk factor for stroke;
- 50% to 70% of stroke patients have sleep-related respiratory disorders, 90% of whom are OSA;
- The 2011 American Heart and Stroke Association has classified sleep-disordered breathing as a risk factor for primary prevention of stroke;
- Patients with stroke and OSA have severe neurological deficits, long hospitalization and rehabilitation, increased stroke recurrence and increased mortality;

Pathophysiological mechanism of OSA-induced stroke

- The sensitivity of the respiratory center is reduced, the autoregulation of the cerebral vessels is impaired, and the pressure of the cerebrospinal fluid is significantly increased;
- Changes in sleep structure and excessive sympathetic excitation;
- Increased intrathoracic pressure and decreased cerebral blood flow;
- REM brain blood flow and oxygen imbalance between supply and demand lead to interruption of blood circulation in the brain, stroke;
- Long-term chronic hypoxia causes erythrocytosis, increased blood viscosity, and slowed blood flow;
- External carotid atherosclerosis; oxidative stress;

Experts' Consensus on Diagnosis And Treatment Of Obstructive Sleep Apnea And Stroke

Hazards of OSA: Diabetes

Experts' Consensus on Obstructive Sleep Apnea and Diabetes

01

Relationship between OSA and Diabetes

- The prevalence of diabetes in China is 9.7 %, with an estimated 97 million people;
- The prevalence of diabetes in OSA patients is > 40%, while the prevalence of OSA in diabetic patients is 23%;

02

The Malignant Cycle of OSA and Type 2 Diabetes

- Increased sympathetic activity, intermittent hypoxia, hypothalamic-pituitary-adrenal dysfunction, systemic inflammatory response, adipocytokines, and sleep deprivation can all lead to insulin resistance; autonomic dysfunction caused by diabetes can also increase OSA danger;

03

Screening OSA For Type 2 Diabetes Mellitus and Metabolic Syndrome Patients

- Snoring, daytime sleepiness; obesity, insulin resistance, difficulty in controlling diabetes; refractory refractory hypertension; nocturnal angina; nocturnal refractory arrhythmia; refractory congestive heart failure; epilepsy; senile dementia; nocturia; sexual dysfunction; Personality changes; chronic cough of unknown cause; unexplained polycythemia.

Hazards of OSA: Pregnancy OSA

Experts' Consensus on The Diagnosis And Treatment Of Obstructive Sleep Apnea Syndrome During Pregnancy (Draft)

Prevalence of OSA during pregnancy

- The overall incidence of OSA in pregnant women was 11.4%, and the prevalence of OSA in early and late pregnancy was 10.5% and 26.7%, respectively, which was higher than that in non-pregnant women of childbearing age (5%).
- Studies of high-risk pregnant women (including chronic hypertension, pre-eclampsia, GDM, pre-pregnancy obesity, or previous poor maternal history) have shown that the prevalence of OSA in the early, middle, and late stages of pregnancy is 30.4%, 33.3%, and 32.0%, respectively.

Maternal Complications

- Fragmentation and hypercapnia can lead to an increased risk of pregnancy-related hypertension.
- The resulting inflammation and oxidative stress also enhance insulin resistance and are a risk factor for gestational diabetes mellitus (GDM).

Fetal Complications

- Hypoxemia occurs repeatedly during sleep during pregnancy, and it is more likely to develop hypertensive disorder complicating pregnancy, both of which cause a decrease in placental perfusion. It can eventually lead to fetal complications such as premature delivery, fetal growth restriction (FGR), low birth weight and neonatal asphyxia. Even academic reports on fetal malformations and stillbirths.
- Dynamic monitoring also found that when pregnant women had apnea, the fetal heart rate slowed down and fetal movements decreased significantly.

Hazards of OSA: Children

Draft Guidelines for The Diagnosis And Treatment Of Children OSA Hypopnea Syndrome

01

Definition

- Partial or complete upper airway obstruction frequently occurs during sleep, disturbing normal ventilation and sleep structure in children and causing a series of pathophysiological changes. It is a disease that seriously endangers the health and growth of children. It can occur in any stage from newborn to adolescent, and is more common in preschool children.

02

Hazards

- Sleep snoring, mouth breathing, belching, repeated awakening, enuresis, excessive sweating, hyperactivity, anxiety, depression, etc., occasionally daytime sleepiness;
- Long-term mouth breathing can lead to obvious malformation of the maxillofacial region, forming an "adenoid face";
- In severe cases, cognitive deficits, inattention, memory loss, learning difficulties, behavioral abnormalities, growth retardation, etc. may occur;
- Hypertension, pulmonary hypertension, right heart failure and other cardiovascular diseases;

03

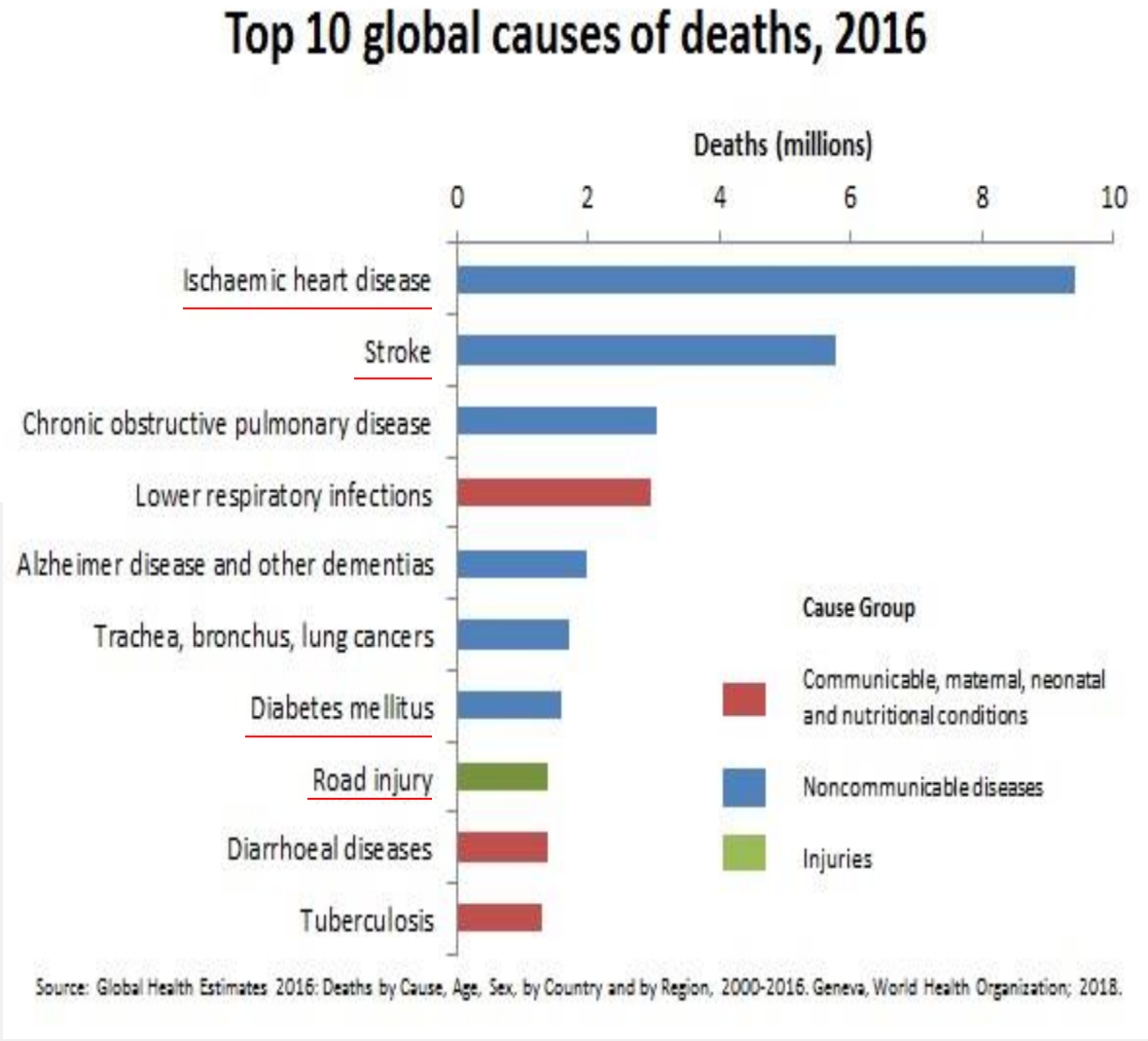
Etiology / Population

- The prevalence of obstructive sleep apnea (OSA) in children is 1.2 to 5. 7 %
- Nasal: Common chronic rhinitis (infectious, allergic), sinusitis, nasal polyps, nasal swelling, etc. Nasopharyngeal and oropharynx: The most common causes are adenoid hypertrophy and tonsil hypertrophy.
- Throat and trachea: Congenital laryngeal cartilage softening, throat, laryngeal cyst and tracheal stenosis. Craniofacial deformity
- Factors affecting neuromodulator: Reduced whole body muscle tone (Down's syndrome, neuromuscular disease).

OSA – A Life Threat

The World Health Organization announced the top ten causes of death in the world in 2016, four related to OSA

- *See The Respiratory Surgeon's Mission, Responsibility And Responsibility From The Recent WHO Ranking Of All-Cause Mortality In The World.*



Hazards of OSA: Scientific Studies

Obstructive Sleep Apnea as a Risk Factor for Stroke and Death

H. Klar Yaggi, M.D., M.P.H., John Concato, M.D., M.P.H., Walter N. Kernan, M.D., Judith H. Lichtman, Ph.D., M.P.H., Lawrenc M.D.

Article Figures/Media

42 References 1387 Citing Articles

Sleep Apnea, Aldosterone, and Resistant Hypertension

Nov
N Er
DOI

Eduardo Pimenta, David A. Calhoun, Suzanne Oparil

Show more

https://doi.org/10.1016/j.pcad.2008.02.004 Get rights and content

Original article

Pulmonary hypertension in obstructive sleep apnea hypopnea syndrome

Abou Shehata ME [a], Mohamed E. El-Desoky [a], Abd El-Razek Maaty [b], Amina M. Abd-ElMaksoud [a], Lucy A. Suliman [a]

Reduced Sleep Duration or Quality: Relationships With Insulin Resistance and Type 2 Diabetes

, Rachel Leproult, Karine Spiegel

10.1016/j.pcad.2008.10.002 Get rights and content

Cardiovascular Complications of Obstructive Sleep Apnea Syndrome: Evidence from Children

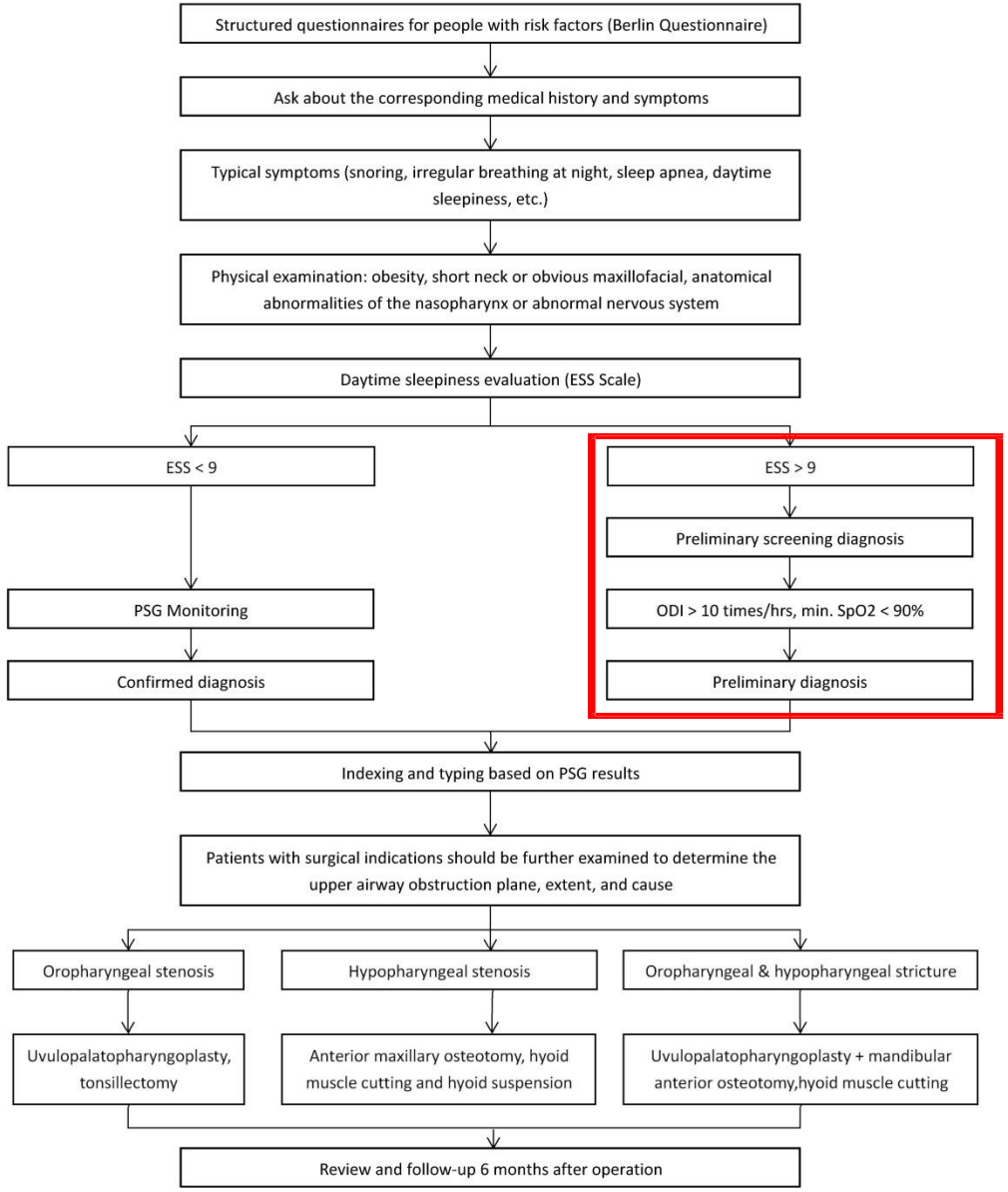
Rakesh Bhattacharjee, Leila Kheirandish-Gozal, Giora Pillar, David Gozal

Show more

https://doi.org/10.1016/j.pcad.2008.03.002 Get rights and content

II. Current Diagnosis and Therapy Situation

OSA Diagnosis Path



Epworth Sleepiness Scale

Name: Today's date:

In general ESS scores can be interpreted as follows:

0-5 Lower Normal Daytime Sleepiness

6-10 Higher Normal Daytime Sleepiness

11-12 Mild Excessive Daytime Sleepiness

13-15 Moderate Excessive Daytime Sleepiness

16-24 Severe Excessive Daytime Sleepiness

Sitting and reading _____ ___

Watching TV _____ ___

Sitting, inactive in a public place (e.g. a theatre or a meeting) _____ ___

As a passenger in a car for an hour without a break _____ ___

Lying down to rest in the afternoon when circumstances permit _____ ___

Sitting and talking to someone _____ ___

Sitting quietly after a lunch without alcohol _____ ___

In a car, while stopped for a few minutes in the traffic _____

Registration

Sleep Medicine Dept

Wear Monitoring Devices

Test Report

1 – 2 nights in hospital

Adult OSA severity and apnea hypopnea index (AHI) and/or the basis for judging the degree of hypoxemia

Degree	AHI (Times/H)
Mild	5 - 15
Moderate	>15 - 30
Severe	>30
Degree	**Min. SpO2 (%)**
Mild	85 - 90
Moderate	80 - <85
Severe	<80

Children OSA severity and apnea hypopnea index (AHI) and/or the basis for judging the degree of hypoxemia

Degree	AHI (Times/H)
Mild	5 - 15
Moderate	>15 - 30
Severe	>30
Degree	**Min. SpO2 (%)**
Mild	85 - 90
Moderate	80 - <85
Severe	<80

OSA Diagnosis: PSG-Standard

OSA Diagnosis: PSG

To Patient

- Very few beds available in the sleeping center
- Polysomnography is rare
- Long queue waiting period
- Poor comfort
- First night effect
- High cost of diagnosis and treatment

To Hospital

- High site demand
- Polysomnography is very expensive
- Operation is complicated (about 40 minutes)
- Technician training period is long
- Limited number of patients
- Low cost-effectiveness ratio

OSA Screening: Grassroots Version

阻塞性睡眠呼吸暂停低通气综合征
诊治指南(基层版)

阻塞性睡眠呼吸暂停低通气综合征诊治指南(基层版)写作组

阻塞性睡眠呼吸暂停低通气综合征(obstructive sleep apnea hypopnea syndrome,OSAHS)是指患者在睡眠过程中反复出现呼吸暂停和低通气。临床上可和昏力及胃障碍、顺回性瘫住吸吸及咽灸、不明原因的肺动脉高压和肺心病、继发性红细胞增多症及血液黏滞度增高、难治性哮喘、不明原因的白天低氧血症以及呼吸衰竭等。

1. 诊断标准:主要根据病史、体征和 PM 监测或 PSG 监测结果。临床有典型的夜间睡眠打鼾伴呼吸暂停、日间嗜睡(ESS 评分≥9 分)等症状,查体发现咽腔狭窄、扁桃体肿大、悬雍垂粗大、腺样体增生,AHI >5 次/h 者可诊断 OSAHS;对于日间嗜睡不明显(ESS 评分 <9 分)者,AHI ≥10 次/h,或 AHI ≥5 次/h 同时存在认知功能障碍、高血压、冠心病、脑血管疾病、糖尿病和失眠等 1 项或 1 项以上 OSAHS 合并症者也可确诊。

2. OSAHS 病情分度:应当充分考虑临床症状、合并症情况、AHI 及夜间 SpO_2 等实验室指标,根据 AHI 和夜间最低 SpO_2 将 OSAHS 分为轻、中、重度,其中以 AHI 作为主要判断标准,夜间最低 SpO_2 作

诊治水平,特别是提高基层医疗单位的诊治水平,我们在《阻塞性睡眠呼吸暂停低通气综合征诊治指南(2011 年修订版)》[1]的基础上,组织了国内部分呼

⑱妊娠期高血压疾病或先兆子痫;⑲肾功能损害;⑳肝功能损害;㉑肥胖加重;㉒重大交通事故。

4. 简易诊断方法和标准:用于基层缺乏专门诊断仪器的单位,主要根据病史、体检、SpO_2 监测等,其诊断标准如下:①至少具有 2 项主要危险因素,尤其是表现为肥胖、颈粗短或有小颌或下颌后缩、咽腔狭窄或有扁桃体Ⅱ度肥大、悬雍垂肥大、或甲状腺功能低下、肢端肥大症或神经系统明显异常;②中、重度打鼾(打鼾程度的评价见表 3)、夜间呼吸不规律或有屏气和憋醒(观察时间应不少于 15 min);③夜间睡眠节律紊乱,特别是频繁觉醒;④白天嗜睡(ESS 评分 >9 分);⑤SpO_2 监测趋势图可见典型变化、氧减饱和指数(ODI) >10 次/h;⑥引起 1 个或 1 个以上重要器官损害。符合以上 6 条者即可做出初步诊断,有条件的单位可进一步进行 PSG 或 PM 监测。

Easy diagnostic methods and standards

The unit for the lack of specialized diagnostic equipment at the grassroots level is mainly based on medical history, physical examination, SpO_2 monitoring, etc. The diagnostic criteria are:

1. Observation: obesity, maxillofacial/throat abnormalities;
2. Subjective evaluation: high Berlin questionnaire score;
3. Subjective inquiry: frequent awakening at night;
4. Subjective evaluation: ESS score > 9 points;
5. Objective monitoring: The typical change of the SpO_2 monitoring trend graph shows that the oxygen desaturation index (ODI4) is >10 times/h;
6. Causing damage to one or more vital organs;

A preliminary diagnosis can be made if the above conditions are met.

BMC Pulm Med. 2015; 15: 24.
Published online 2015 Mar 20. doi: 10.1186/s12890-015-0017-z
PMCID: PMC4407425
PMID: 25880649

Validation of overnight oximetry to diagnose patients with moderate to severe obstructive sleep apnea

Liang-Wen Hang, Hsiang-Ling Wang, Jen-Ho Chen, Jiin-Chyr Hsu, Hsuan-Hung Lin, Wei-Sheng Chung,✉ and Yung-Fu Chen✉

Researchers studied a total of 616 experimenters, using PSG and fingertip oximeters for sleep monitoring, followed by data comparison analysis

Table 3

Diagnosis of severe patients with AHI = 30 as the threshold using different combination of salient features

Data	Predictive index (%)	Multiple variables: NC, BMI, ESS, ODI	Multiple variables: ODI, ESS	Multiple variables: ODI, BMI	Multiple variables: ODI	Single variable: ODI2	Single variable: ODI3	Single variable: ODI4T	Single variable: ODI4A
Dataset 1 (N = 616)	Accuracy	90.42	90.58	90.58	90.42	87.2	89.5	87.8	89.8
	Sensitivity	88.07	87.01	86.31	87.36	91.6	86.0	85.7	90.6
	Specificity	92.44	93.65	94.25	93.05	83.3	92.4	89.7	89.1
	AUC	0.958	0.956	0.954	0.957	0.938	0.942	0.912	0.913
	Cutoff	-	-	-	-	27.2	18.4	11.2	13.7
Dataset 2 (N = 540)	Accuracy	90.18	90.37	89.81	90.55	87.6	90.0	88.5	89.3
	Sensitivity	86.07	88.18	88.60	89.87	91.6	86.6	88.7	89.5
	Specificity	93.39	92.07	90.75	91.08	84.4	92.7	88.4	89.1
	AUC	0.952	0.946	0.950	0.953	0.945	0.946	0.913	0.913
	Cutoff	-	-	-	-	27.2	18.4	10.4	13.7

PSG results | Oximeter results

Note: ODI is the combination of ODI2 and ODI4A.

Diagnosis of patients with severe OSA with different parameter combinations based on AHI=30

Table 4

Diagnosis of moderate to severe patients with AHI = 15 as the threshold using different combination of salient features

Data	Predictive index (%)	Multiple variable: NC, BMI, ESS, ODI	Multiple variable: ODI, ESS	Multiple variable: ODI, BMI	Multiple variable: ODI	Single variable: ODI2	Single variable: ODI3	Single variable: ODI4T	Single variable: ODI4A
Dataset 1 (N = 616)	Accuracy	86.85	87.82	87.01	87.33	87.2	89.5	87.8	89.8
	Sensitivity	88.67	89.87	87.95	87.71	91.6	86.1	85.7	90.6
	Specificity	83.08	83.58	85.07	86.56	83.3	92.4	89.7	89.1
	AUC	0.938	0.935	0.927	0.921	0.918	0.920	0.870	0.869
	Cutoff	-	-	-	-	21.2	9.5	7.3	8.5
Dataset 2 (N = 540)	Accuracy	87.96	88.14	87.59	87.77	87.6	90.0	88.5	89.3
	Sensitivity	89.39	89.97	88.82	88.53	91.6	86.6	88.7	89.5
	Specificity	85.34	84.81	85.34	86.38	84.4	92.7	88.4	89.1
	AUC	0.941	0.939	0.940	0.924	0.925	0.927	0.872	0.875
	Cutoff	-	-	-	-	21.2	9.5	7.3	7.3

PSG results | Oximeter results

Note: ODI is the combination of ODI2 and ODI4A.

Diagnosing patients with moderate to severe OSA with different parameter combinations based on AHI=15

以ODI为核心的OSA筛查可行性研究

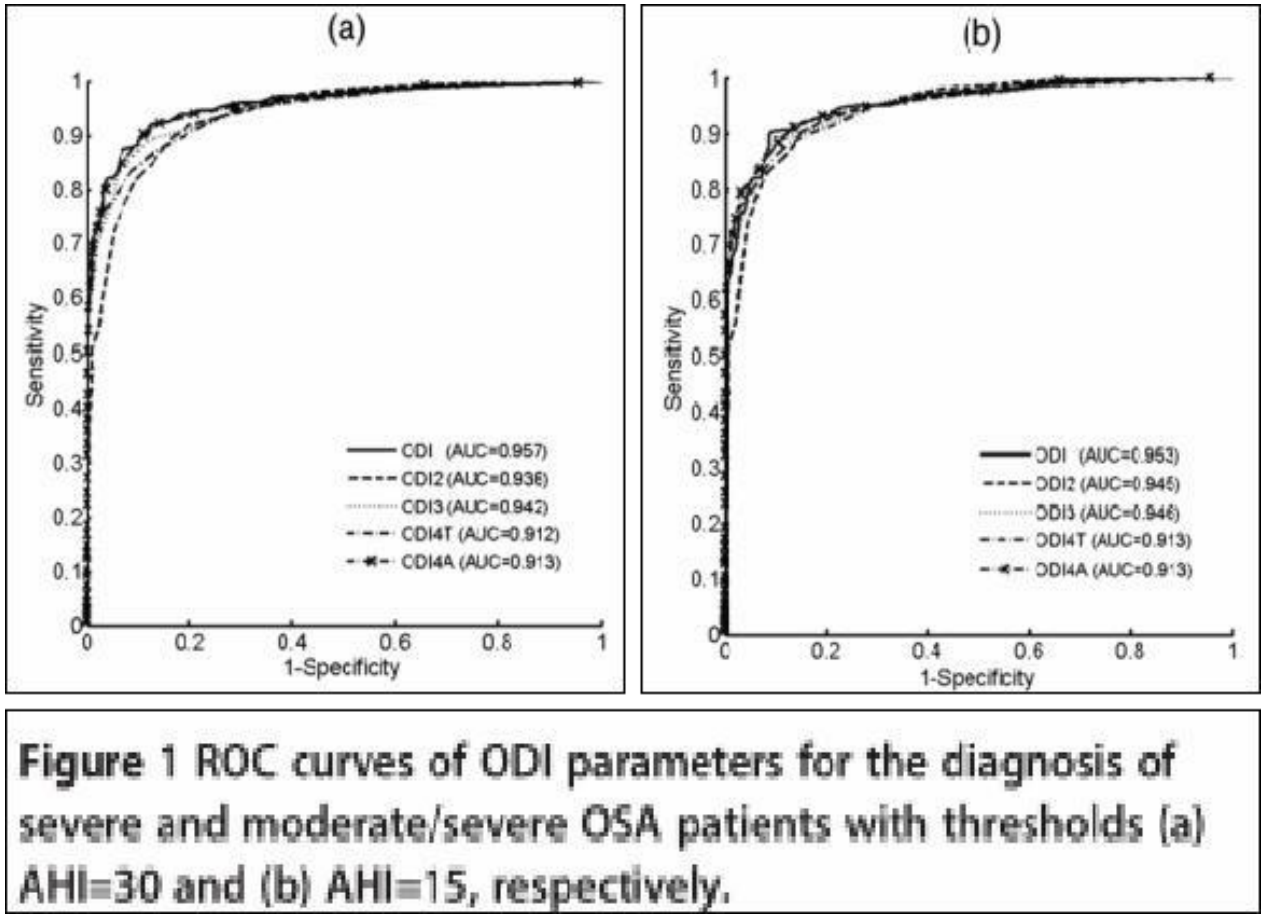


Figure 1 ROC curves of ODI parameters for the diagnosis of severe and moderate/severe OSA patients with thresholds (a) AHI=30 and (b) AHI=15, respectively.

From the oximeter results, the ODI index is diagnosed in patients with OSA

- Accuracy is 90.42%~90.55%
- Sensitivity is 89.36%~89.87%
- Specificity is 91.08%~93.05%
- AUC is 0.953~0.957

Conclusion

Through continuous monitoring of blood oxygen saturation, the calculated ODI index can be used as a screening diagnostic indicator for OSA with high accuracy.

III Our Solution

Development

- In 2014, C+ co-founds with GE Chengdu Monitor & Ventilator Team and determined the development direction of reflective vital sign monitoring technology and products.
- In 2015, finish development of the first generation of vital signs monitoring band was completed;
- In 2016, completed the clinical trial of West China Hospital and Sichuan Provincial Hospital of Traditional Chinese Medicine, and obtained the national medical device certificate Class II (No. 20162210019)
- In 2017, start to develop a new OSAscreening program based on wearable vital signs monitoring equipment, including Peking University People's Hospital, First Medical Chaoyang Hospital, West China Hospital, Sichuan Provincial People's Hospital, Chongqing Xinqiao Hospital, Shanghai Zhongshan Hospital, Guangdong Provincial People's Hospital and other more than 50 nationally renowned top three hospitals in the Department of Sleep Medicine completed clinical application verification, and obtained the recognition and recommendation of most sleep medicine experts including Han Fang, chairman of the Chinese Medical Association Sleep Medicine Association.
- 2018.10, finish development of a new sleep apnea syndrome screening system, comprehensive optimization of screening efficiency, and submission of medical software certification applications for the software system and new business model patent applications for the business.
- 2019.01, the OSA monitoring analysis and authorization software system for the new sleep apnea syndrome screening obtained the medical device certification (No. 20192210022), and applied for the business of C+ only through the Sichuan Provincial People's Hospital Health Management Center. Special charge code.

It costs totally 10 million USD, and lasted for 4 years, completing product development, clinical research and obtaining registration.

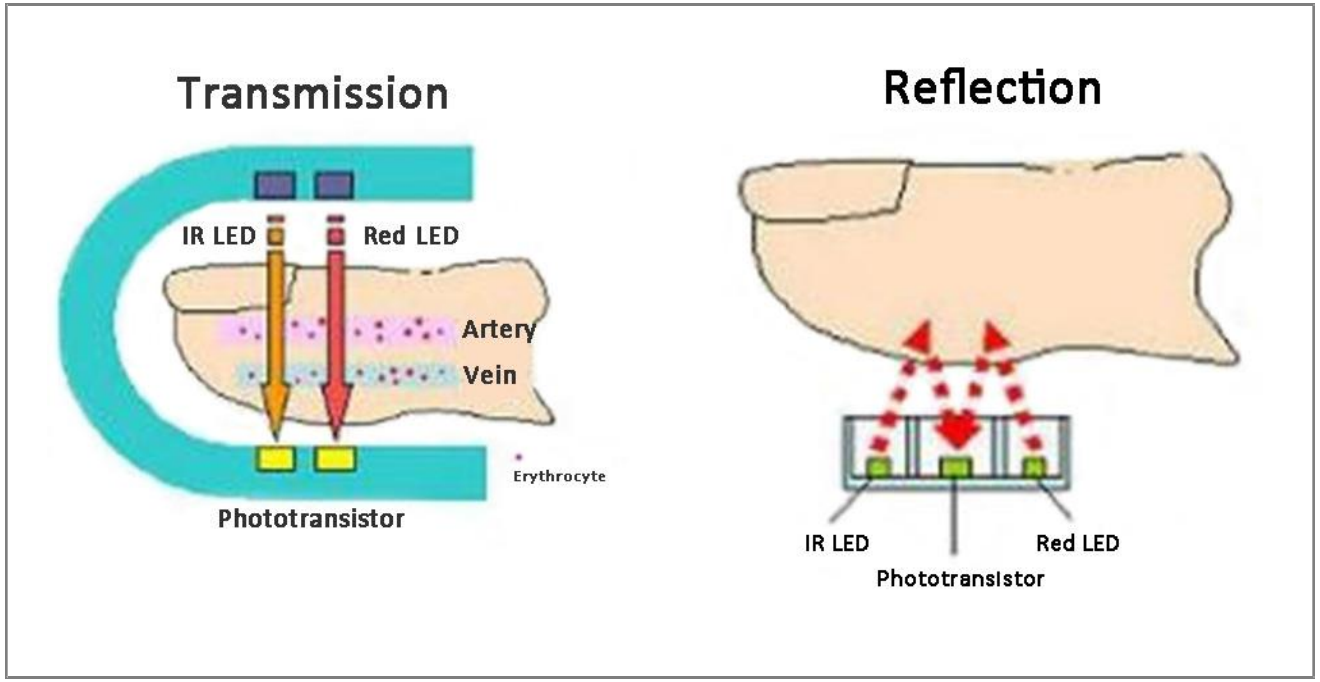
Monitoring of Blood Oxygen

Blood oxygen saturation (SpO2, abbreviated as blood oxygen) is the percentage of oxygen-bound oxyhemoglobin (HbO2) in the blood that accounts for the total capacity of the combined hemoglobin (Hb), that is, the concentration of blood oxygen in the blood. It is an important physiological parameter of the respiratory cycle.

$$SpO_2 \approx \frac{HbO_2}{HbO_2+Hb} \text{ x } 100\%$$

Time	**1950s**	**1970s**	**1970 - 1980**	**2010**	**2016**
Method	Electrochemical method	Optical method (transmission)			Optical method (reflection)
Principle	Collect arterial blood, measure arterial partial oxygen pressure (PaO2) and calculate arterial oxygen saturation (SaO2)	Detect changes in blood absorption of light and measure the percentage of oxyhemoglobin (HbO2) in total hemoglobin (Hb)			
Product					
Name	Blood gas analyzer	Multi Parameter Monitor	Finger Oximeter	Wrist watch oximeter	Wearable oximeter
Application	Critically ill inpatients	Real time bedside monitoring in hospital	Blood oxygen mornitoring in/out hospital	Continuous blood oxygen mornitoring in/out hospitals	
Advantages	Accurate, a lot of indexes available	Transmission method standard, continuous data	Small, portable, cost effective	Continuous data can be used for OSA screening	
Limitations	Invasive, professional operation	Expensive, limited units, hard to move around	Data collection at 1 place	Not comfortable, accessories easy to come off	/

Technical Principle and Challenges Of Reflective Blood Oxygen Monitoring



3 Technical Challenges

- Weak signal acquisition: the signal amplitude is attenuated by 20-30 times
- Motion interference noise challenge
- Environmental light interference challenge

Product Developments

1G
Wrist Band

2G
Smart Ring

3G
Sticky Button

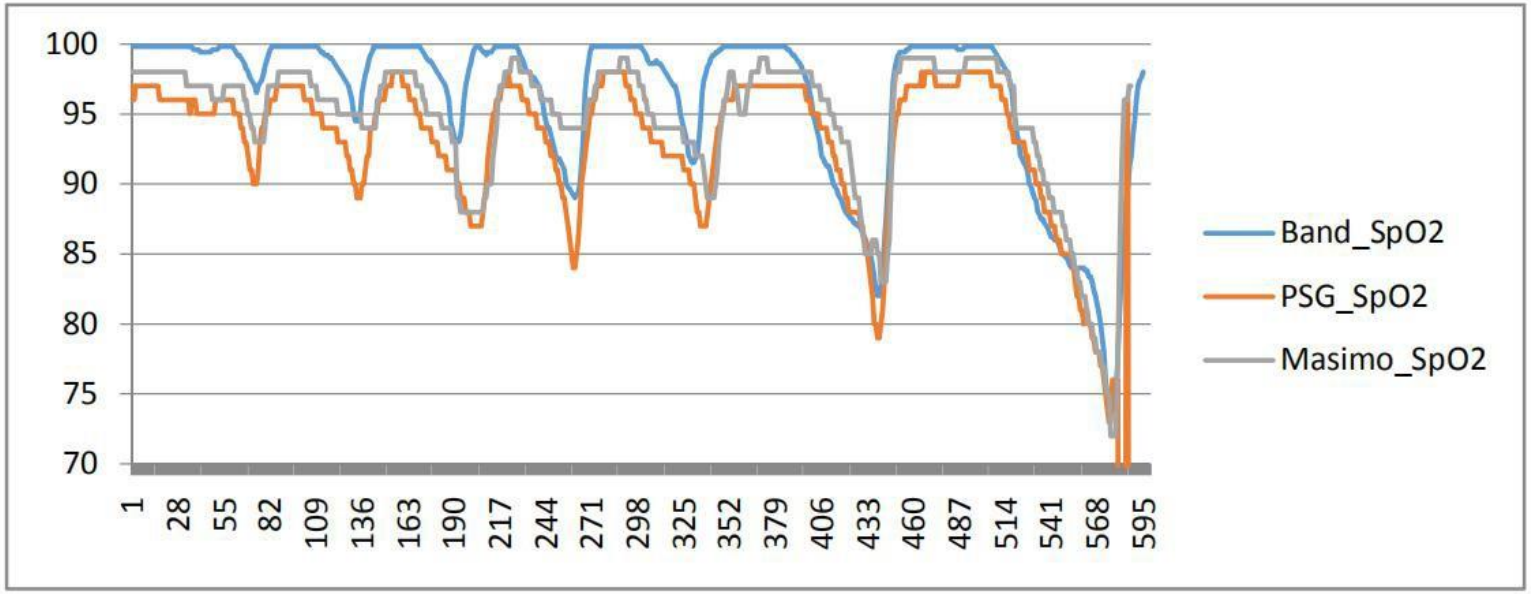
Product Shape and Algorithm Iteration

- Data is getting more and more stable
- smaller and smaller
- easier to wear

Data Accuracy Comparison

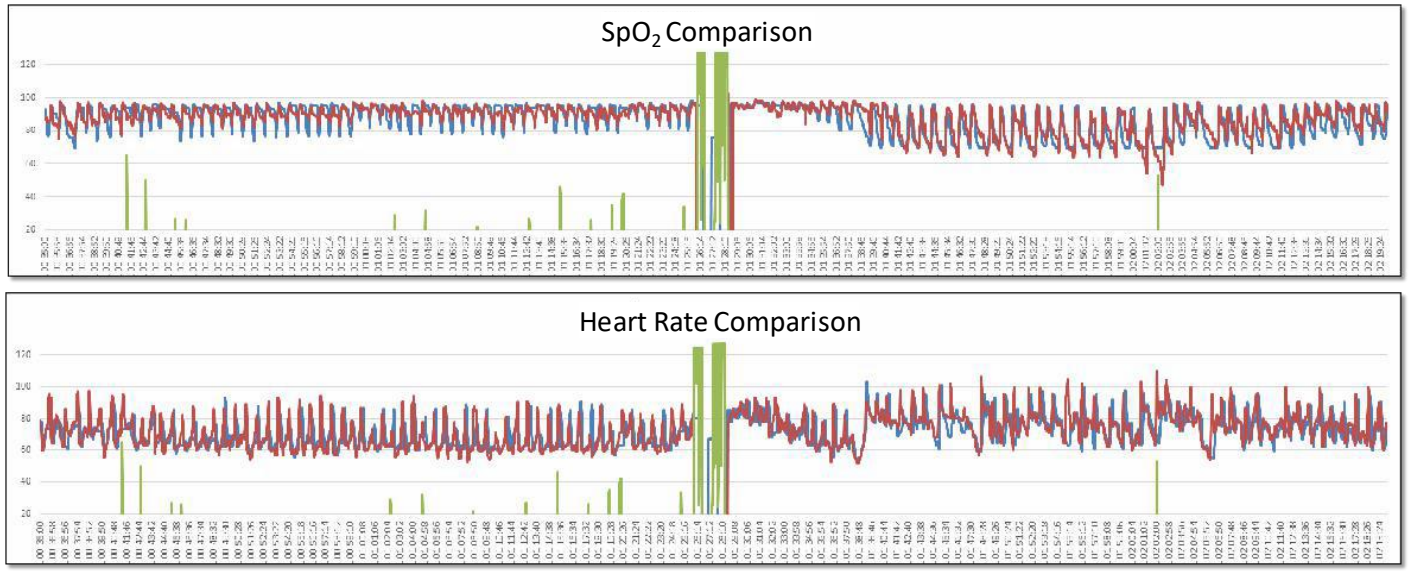
Clinical Value Realization Challenge

According to Beer-Lambert's law, the ratio R/IR should be nonlinear as a function of arterial oxygen saturation (SaO2), but since biological tissue is a complex optical system with strong scattering, weak absorption, and anisotropy, Fully in line with the classic Beer- Lambert's law, it leads to difficulties in expressing mathematical models of the relationship between red and infrared absorbance relative changes (R/IR = r) and arterial oxygen saturation (SaO2). Calibration refers to the experimental method to determine the correspondence between R/IR and SaO2, i.e. the calibration curve (i.e. r-SpO2 curve).



Comparison of blood oxygenation trends between Button and other blood oxygen devices

West China Hospital Clinical Trial (100 OSA Cases of PSG Comparison Test)



Red curves: PSG Data

Blue curves: Button Data

Green: Wrist Movement Data

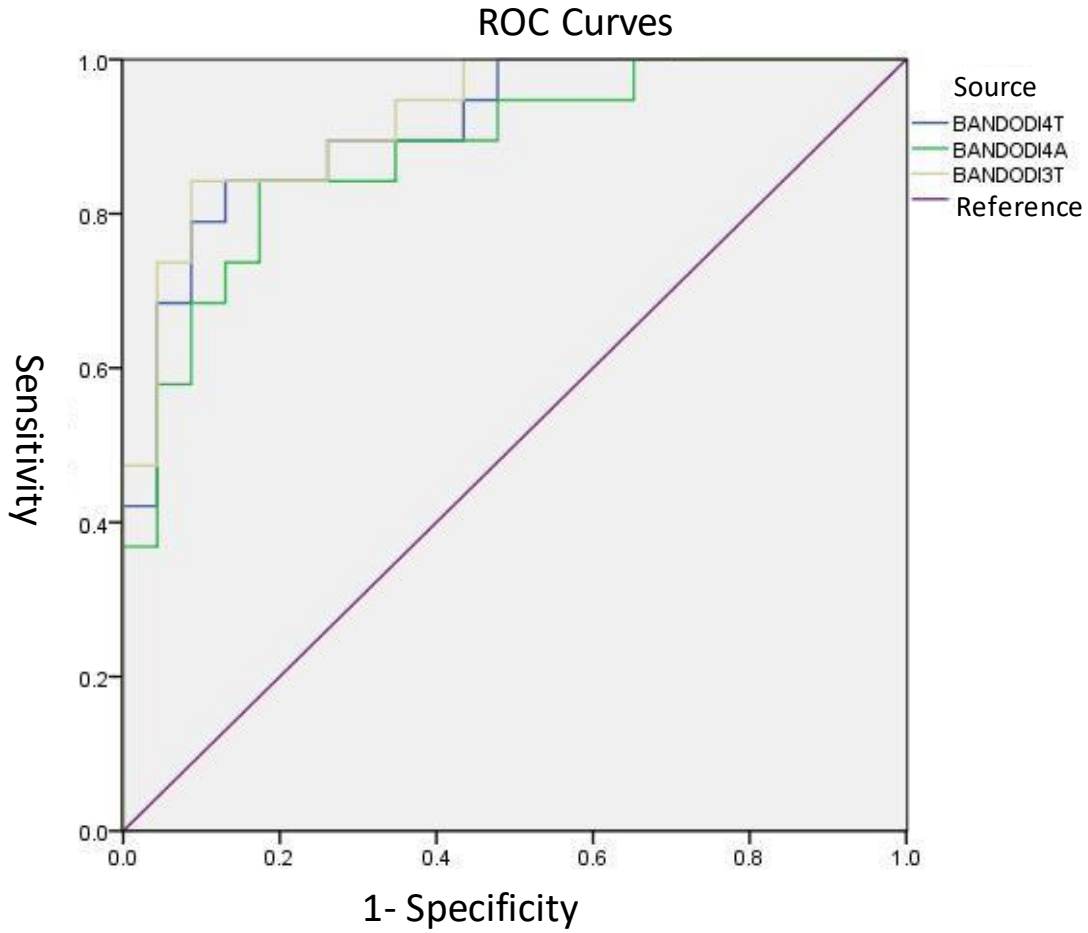
Case Study

- Patient Info: 42 years old, male
- Device Info: Philips Alice 5 PSG v.s Button
- Test time: 2015/8/11 0:00am to 07:00am

Preliminary Results

- Continuous monitoring at night (1 time/second) Oxygen saturation and heart rate PSG data and Button data are highly consistent
- Increased wrist motion monitoring of the Button can help determine the limb movement intensity of the patient

West China Hospital Clinical Trial (100 OSA Cases of PSG Comparison Test)



ROC curve obtained with PSGODI4T=15 as the threshold

Test result variable	Area under the curve
ODI*4T*	0.907
ODI*4A*	0.877
ODI*3T*	0.931

Area under ROC curve and diagnostic accuracy

High	0.90-1.00 = excellent (A)	
Mid	0.80-0.90 = good (B)	0.70-0.80 = fair (C)
Low	0.60-0.70 = poor (D)	0.50-0.60 = fail (F)

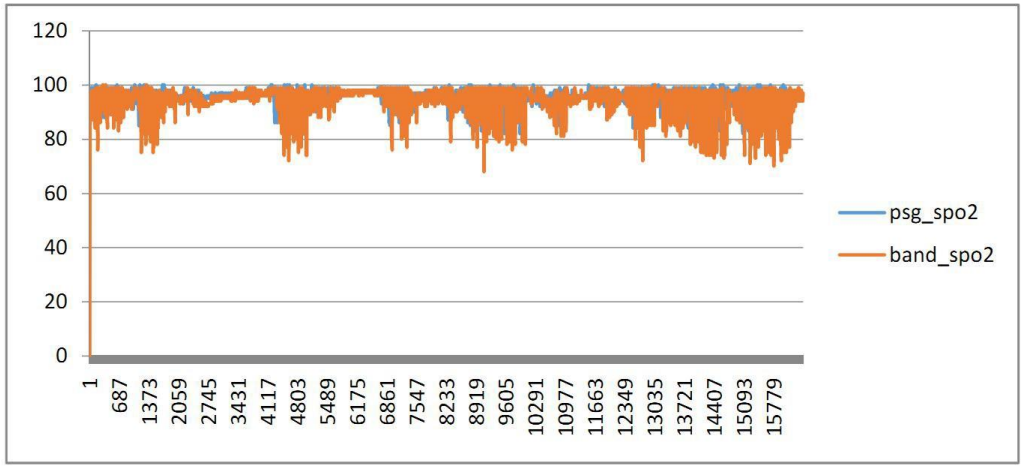
Numerical analysis of ODI4T calculations:

- Sensitivity: 85.00%
- Specificity: 85.00%
- Accuracy: 85.71%

Note:
ODI3T: The 3% oxygen reduction is used as the threshold, and the mean value of the maximum 20% blood oxygen value in the first minute before the point is the baseline, and the calculated oxygen reduction index is calculated.
ODI4T: The 4% oxygen reduction is used as the threshold, and the mean value of the maximum 20% blood oxygen value in the first minute before the point is the baseline, and the calculated oxygen reduction index is calculated.
ODI4A: The oxygen decrement index calculated by taking the 4% oxygen reduction threshold and the mean value of the blood oxygen value throughout the sleep time as the baseline.

Peking University People's Hospital Sleep Center Clinical Trial Calibration Test Data (Partial)

Peking University People's Hospital Sleep Center Clinical Trial Calibration Test Data (Partial)

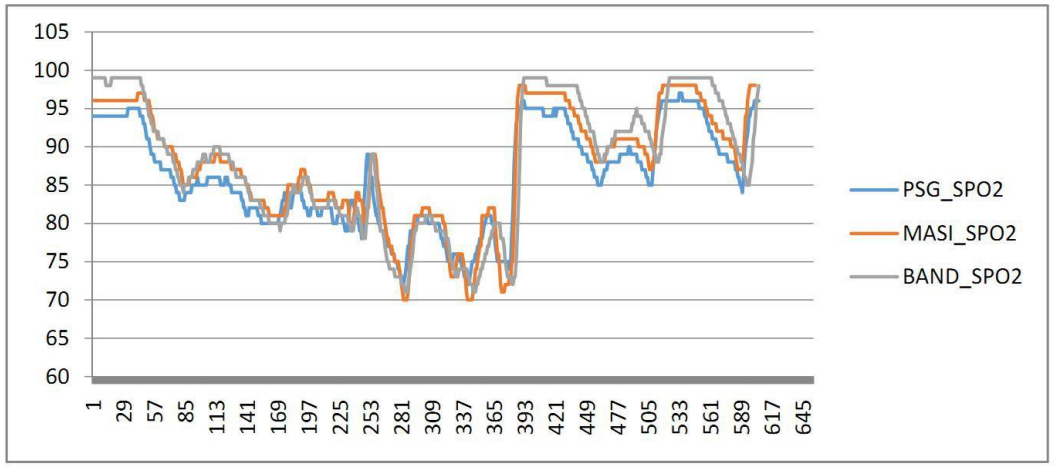


▲

Comparison with PSG

Comparison with PSG & Masimo

▼



- President to Be of Asian Sleep Medicine Society
- Chairman of China Sleep Research Association

HAN FANG

ISSN 2348 – 0319 International Journal of Innovative and Applied Research (2017)
Volume 5, Issue 8
41-46

Journal home page: http://www.journalijiar.com

INTERNATIONAL JOURNAL
OF INNOVATIVE AND APPLIED RESEARCH

RESEARCH ARTICLE

COMPARISON OF OXYGEN SATURATION AND HEART RATE BY SENSE WEAR ARMBAND AND ELECTROCARDIOGRAPH MONITOR IN ELDERLY PATIENTS.

Jianghua Zhou, MD[1,2], Li Luo, PHD [1], Ming Yang, PHD [1], Hui Wang, PHD[1], Shan Hai, PHD[1] and *Birong Dong, MD[1].

1. The Center of Gerontology and Geriatrics, West China Hospital, Sichuan University, Chengdu, China.
2. Chengdu Fifth people's Hospital.

Corresponding Author: **Birong Dong.**

Abstract:

Background: Wearable devices that measure continuous arterial oxygen saturation by heart oximetry (SpO2) and heart rate (HR) are commonly used in many applications, such as in the military, homecare units, hospitals, sports training and emergency monitoring systems.

Objective: The purpose of this study was to verify the accuracy between two types of monitor devices over an extended period of time and to compare the values of SpO2 indicated by a Sense Wear Armband (SWA produced by iCareTech Healthcare Co., Ltd., China) to those obtained using a table electrocardiogram monitoring device (IPM12 produced by Mindray Biological Medical Electronic Co., Ltd., China), which is a device widely used in hospitals.

Materials and Methods: Thirty-three adults (22 male, 11 female; 80.8±10.3 years) wore a SWA on the medial side of their right wrist and an Electrocardiograph(ECG) monitoring system as reference measures for SpO2 and HR. The difference of the two devices for estimating SpO2 and HR was assessed using the paired Student's t test. To evaluate the extent of agreement between measures of SpO2 and HR, Pearson correlations, intra-class correlations (ICC) and Bland-Altman analysis were conducted.

Results: The result of the Bland-Altman analysis demonstrated that the agreement was good when SpO2 was assessed by the two methods and was moderate when HR was assessed by similar devices. The correlation between the HR assessed by the two devices was statistically significant (ICC ranged from 0.95 to 0.99; $p < 0.001$). However, the correlation when SpO2 was assessed by similar devices was lower than HR and the difference was statistically significant (ICC ranged from 0.37 to 0.94; $p<0.05$).

Conclusions: These findings suggest that the SWA provides valid measures of SpO2 and HR compared to the conventional hospital device. Well-designed studies are needed to explore the accuracy of wearable devices used in different people of different states(e.g. in motion or rest state) when SpO2 and HR are assessed.

Professional Paper
West China Hospital

·论 著·

C+手环对成人睡眠呼吸暂停低通气综合征的初筛价值

刘恒 邝爱玲 苏小芬 虢慧芝 严惠婵 张挪富

【摘要】 **目的** 探讨C+手环对成人睡眠呼吸暂停低通气综合征（sleep apnea hypopnea syndrome，SAHS）的初筛价值。**方法** 对145例疑似SAHS患者同时进行多导睡眠图（polysomography，PSG）与C+手环监测，分别统计PSG监测所得睡眠呼吸暂停低通气指数（apnea hypopnea index，AHI）、PSG与C+手环监测所得氧减饱和度指数（oxygen desaturation index，ODI4）、平均血氧饱和度（$MSaO_2$）、最低血氧饱和度（$LSaO_2$）以及血氧饱和度<90%占整个记录时间的百分比（TS90%）。**结果** C+手环监测所得ODI4与PSG监测所得AHI两者显著相关（$r=0.711$，$P<0.001$）。C+手环与PSG监测所得ODI4、$LSaO_2$、$MSaO_2$以及TS90%进行相关性分析（r分别为0.708、0.575、0.486、0.631，P值均<0.001）。分别以PSG-AHI≥5次/h作为诊断SAHS的阳性标准，C+手环监测所得ODI4≥5次/h作为诊断SAHS的初筛标准，配对χ^2检验显示差异无统计学意义（$\chi^2=1.71$，$P>0.05$，Kappa值=0.524，$P<0.001$）。以PSG-AHI≥5次/h作为诊断SAHS的阳性标准，以C+手环监测所得ODI4≥11.45次/h作为SAHS初筛标准，灵敏度为77.4%，特异度为83.9%，以ODI4≥15.45次/h作为初筛标准，其对应特异度为90.3%，灵敏度为68.9%。**结论** C+手环对SAHS有一定的初筛价值，可作为一种便携式筛查工具。

【关键词】 睡眠呼吸暂停低通气综合征；睡眠呼吸暂停低通气指数；氧减饱和度指数；初筛

Value of C plus band for the screening of sleep apnea hypopnea syndrome *Liu Heng, Kuang Ailing, Su Xiaofen, Guo Huizhi, Yan Huichan, Zhang Nuofu. The First Affiliated Hospital of Guangzhou Medical University, Guangzhou Institute of Respiratory Disease, the State Key Laboratory of Respiratory Disease, National Research Center of Clinical Medicine, Guangzhou 510120, China*

Corresponding author: Zhang Nuofu, Email: nfzhanggird@163.com

【Abstract】 **Objective** To explore the value of C plus vital sign monitoring band for the screening of sleep apnea hypopnea syndrome (SAHS). **Methods** One hundred and forty-five suspect SAHS patients are monitored for polysomography (PSG) and C plus band. Apnea hypopnea index (AHI), oxygen desaturation index 4 (ODI4), the mean SaO_2 ($MSaO_2$), the lowest SaO_2 ($LSaO_2$), the total time with oxygen saturation level <90% were calculated. **Results** There was a significant correlation between C plus band-OID4 and PSG-AHI ($r=0.711$, $P<0.001$). ODI4, $LSaO_2$, $MSaO_2$ and the total time with oxygen saturation level<90% showed a significant correlation ($r=0.708, 0.575, 0.486, 0.631$, P values all less than 0.001). When PSG-AHI≥5 events per hour was setting as the threshold value to diagnose SAHS, ODI4 ≥5 events per hour of C plus band as the screening criteria, paired chi square test showed no statistical difference ($P>0.05$), kappa=0.524, $P<0.001$. When PSG-AHI≥5 events per hour was setting as the threshold value to diagnose OSAHS, ODI4≥11.45 events per hour of C plus band identified patients at a sensitivity of 77.4% and a specificity of 83.9%, ODI4≥15.45 events per hour of C plus band identified patients at a specificity of 90.3% and a sensitivity of 68.9%. **Conclusions** The C plus band was proved as a portable and reliable device of screening patients who were suspected SAHS.

【Key words】 Sleep apnea hypopnea syndrome; Apnea hypopnea index; Oxygen desaturation index four; Screening

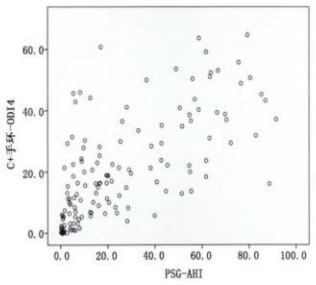
DOI: 10.3760/cma.j.issn.1673-436X.2017.09.008

作者单位：510120 广州医科大学附属第一医院 广州呼吸疾病研究所 呼吸疾病国家重点实验室 国家呼吸疾病临床研究中心

通信作者：张挪富，Email: nfzhanggird@163.com

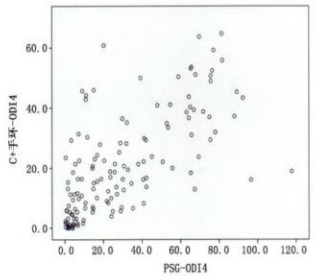
$MSaO_2$均数分别为0.939±0.414、0.924±0.474；$LSaO_2$均数分别为0.769±0.140、0.696±0.122。

2.3 PSG与C+手环相关性分析 分别对C+手环OID4与PSG监测所得AHI、C+手环与PSG监测所得ODI4、$LSaO_2$、$MSaO_2$以及TS90%进行相关性分析。分别对所有患者C+手环监测所得ODI4与PSG监测所得AHI以及ODI4进行相关性分析（r值分别为0.711、0.708，P值均<0.001），相关强度均为强相关（图1、2）；分别对C+手环与PSG监测所得$LSaO_2$、$MSaO_2$以及TS90%进行相关性分析（r值分别为0.575、0.486、0.631，P值均<0.001），相关强度均为中等程度相关。



注：ODI4为氧减饱和度指数；PSG为多导睡眠图；AHI为睡眠呼吸暂停低通气指数

图1 C+手环-ODI4与PSG-AHI相关分析散点图



注：ODI4为氧减饱和度指数；PSG为多导睡眠图

图2 C+手环-ODI4与PSG-ODI4相关性分析散点图

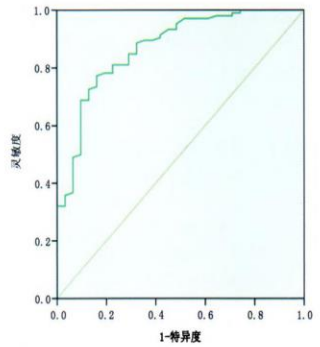
2.4 C+手环和PSG诊断SAHS结果比较 137例成功同时完成PSG与C+手环监测的受试者中有106例患者诊断为SAHS，其中轻度33例，中度29例，重度44例；31例患者诊断为非SAHS。以C+手环-ODI4≥5次/h为初筛阳性标准，全部受试者中共有113例初筛阳性，24例初筛阴性，113例C+手环初筛阳性中，真阳性99例，假阳性14例；24例C+手环初筛阴性中，真阴性16例，假阴性7例。C+手环和PSG诊断SAHS结果比较见表1。根据表1计算可得，C+手环筛查OSAHS灵敏度为93.4%（99/106），特异度为54.8%（17/31），假阳性率为70%，假阴性率为6.6%，配对χ^2检验检验PSG和C+的差异无统计学意义（$\chi^2=1.71$，$P>0.05$），Kappa检验显示两者一致性一般（Kappa=0.524，$P<0.001$）。

表1 137例受试者C+手环和PSG诊断SAHS结果比较（例）

PSG诊断结果	C+手环初筛结果		总计
	阳性	阴性	
阳性	99	7	106
阴性	14	17	31
总计	113	24	137

注：PSG为多导睡眠图；SAHS为睡眠呼吸暂停低通气综合征

2.5 ROC曲线和C+手环最佳筛查诊断值 以PSG-AHI≥5次/h作为诊断SAHS的“金标准”，绘制ROC曲线，利用ROC曲线查找C+手环监测所得ODI4用于筛查SAHS的最佳诊断值。得出C+手环对SAHS最佳诊断值为ODI4≥11.45次/h，其对应灵敏度为77.4%，特异度为83.9%，约登指数=0.613，曲线下面积为0.871，95%可信区间为0.799～0.942，$P<0.001$。ROC曲线见图3。当C+手环监测所得ODI4≥15.45次/h，其对应特异度可达90.3%，灵敏度为68.9%。



注：AHI为睡眠呼吸暂停低通气指数

图3 C+手环-受试者工作特征曲线（AHI≥5次/h）

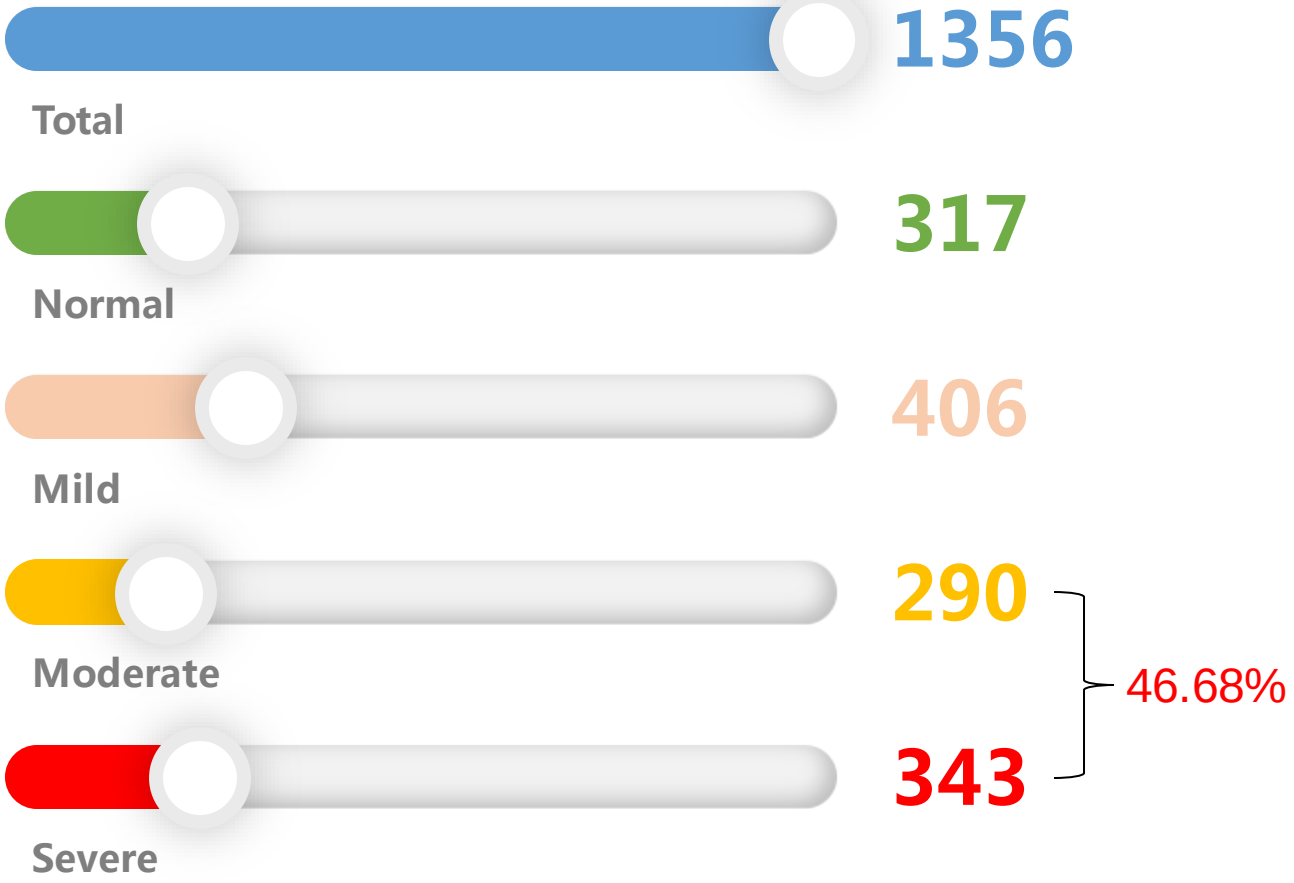
Professional Paper

National Institute of Respiratory Disease

The First Affiliated Hospital of Guangzhou Medical University

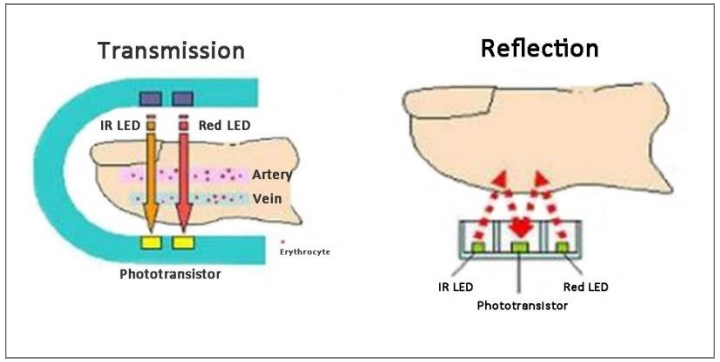
Shanghai Children's Medical Center ENT Dept.

2018.9-2019.2 Screening amount and distribution of results



Product Solution (Button)

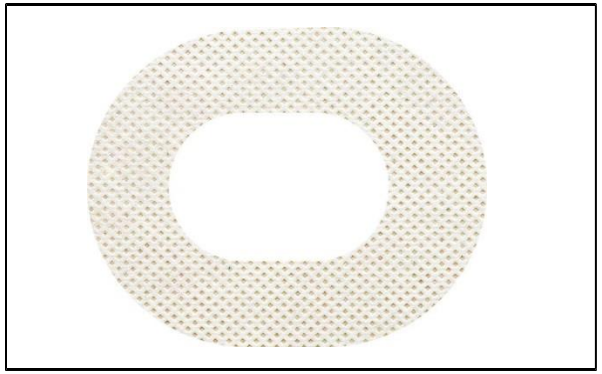
Core product, Chuan Device Registration Approval No. 20162210019



Product Solution (Patients)

Button

29x23x7.5



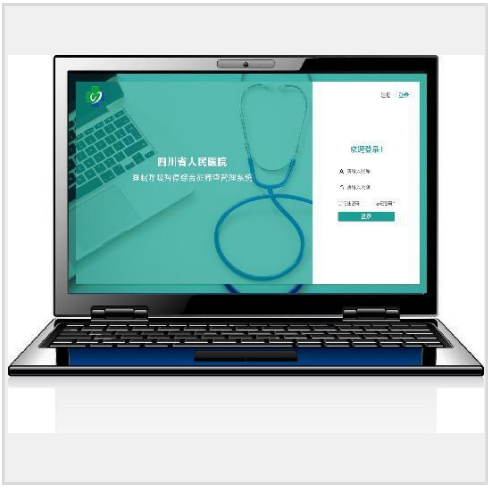
3M Medical Double Tape

Product Solution (Hospital Departments)

Core Products

Button
(with double tape)

Portable Charger
(With 40 Buttons)



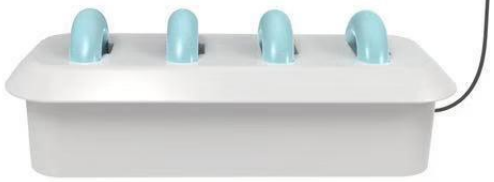
OSA Screening
Management System
(Windows Client)

OSA Monitoring, Analyzing
& Authorizing Software
(CFDA)

- Large-size portable charging box or fixed charging cabinet are available for big quantity;
- Other required hardware, e.g. computers, printers, etc. are optional

Product Solution (Hospital Departments)

Work Station

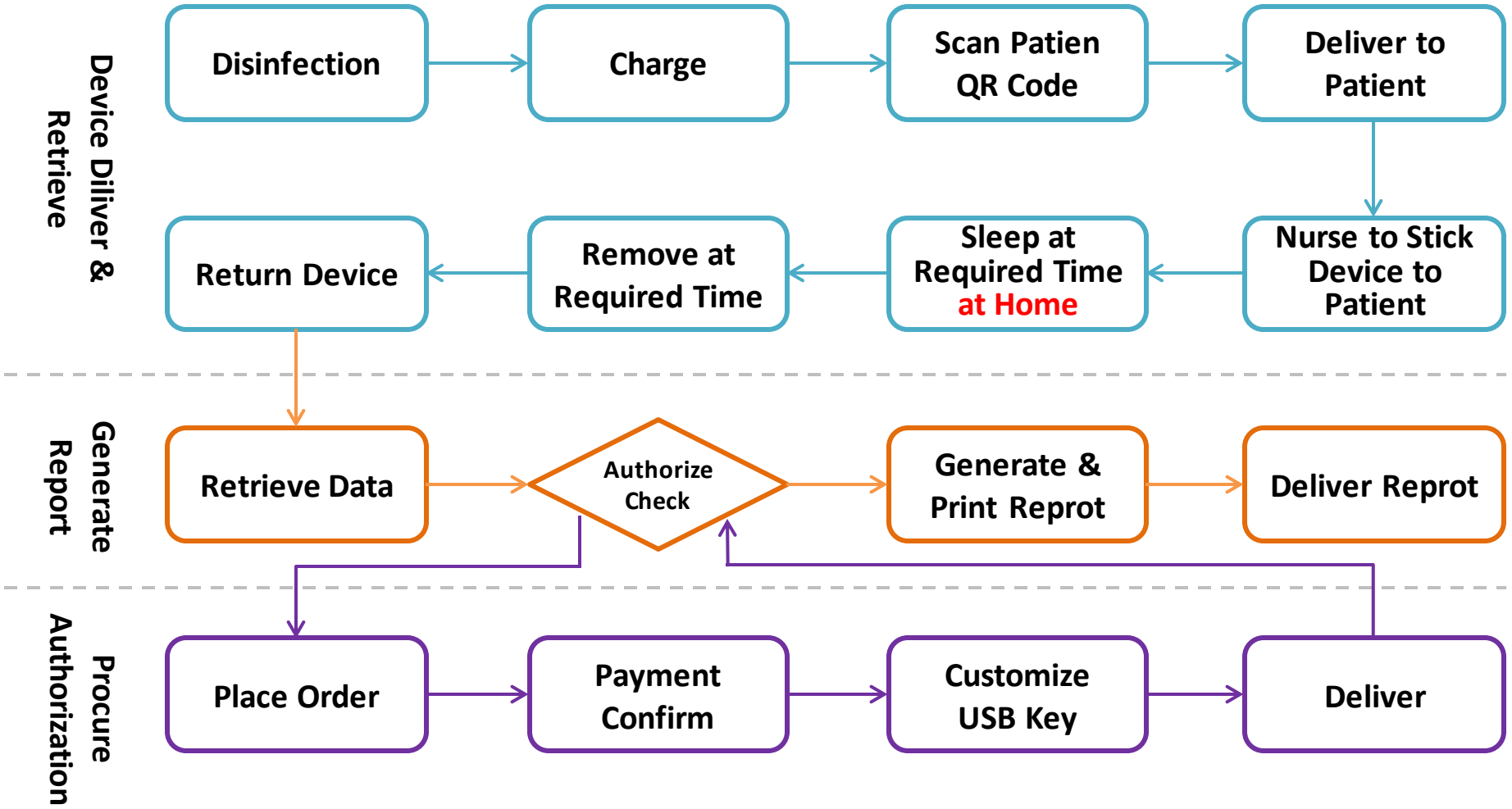


Data Collection

Authorization Module

Scanner

Operation Process



Application Range

All hospitals of different classes and clinics

Physical Examination/Health Management Center, Respiratory, Otolaryngology, Sleep Center, Cardiology, Endocrinology, Pediatrics, Geriatrics

Above 3 years' old

中华人民共和国医疗器械注册证

注册证编号：川械注准 20162210019

注册人名称	成都艾克尔特医疗科技有限公司
注册人住所	成都高新区交子大道 333 号 2 栋 1 单元 8 层 802、803 号
生产地址	成都市温江区海峡科技园科兴西路 688 号华银工业港 20 区 103 号
代理人名称	不适用
代理人住所	不适用
产品名称	生命体征监护手环
型号、规格	WT1
结构及组成	产品主要由电源系统、生理信号采集系统、主处理及控制系统、存储器、显示屏、腕带及 C+生活 App 软件组成，C+生活 iOS App 版本号为 2.0，Android App 版本号为 2.0。
适用范围	产品适用于对成人多项生理参数进行实时或周期监测、数据存储回顾、超限提示。监护参数包括：血氧饱和度、心率和腕部皮肤温度。
附　件	产品技术要求
其他内容	无
备　注	无

审批部门：四川省食品药品监督管理局　　批准日期：2016 年 1 月 8 日
有效期至：2021 年 1 月 7 日

中华人民共和国医疗器械注册证

注册证编号：川械注准 20192210022

注册人名称	成都云卫康医疗科技有限公司
注册人住所	成都高新区益州大道中段 1858 号天府软件园 G 区 3 栋 10 层 1001、1002 号
生产地址	成都高新区益州大道中段 1858 号天府软件园 G 区 3 栋 10 层 1001、1002 号
代理人名称	不适用
代理人住所	不适用
产品名称	睡眠呼吸监测分析及授权软件
型号、规格	SRM-MC100、SRM-MC500、SRM-MC1000、SRM-SC100、SRM-SC500、SRM-SC1000
结构及组成	产品主要由发放管理模块、回收管理模块、报告管理模块、设备管理模块、云端功能模块、授权模块组成。产品承载媒介为 U 盘，发行版本号为 V1.1.0。
适用范围	产品适用于配合穿戴式血氧监护（测）仪分析管理相关数据，供呼吸睡眠监测用，不具有自动分析诊断功能。
附　件	产品技术要求
其他内容	无
备　注	原《分类目录》产品分类编码为 6870

审批部门：四川省药品监督管理局　　批准日期：2019 年 1 月 24 日
有效期至：2024 年 1 月 23 日

中华人民共和国
医疗器械注册变更文件

注册证编号：川械注准 20162210019

产品名称	生命体征监护手环
变更内容	1. **产品名称变更为：**穿戴式血氧监护仪； 2. **注册人住所变更为：**成都高新区益州大道中段 1858 号天府软件园 G 区 3 栋 10 层 1001、1002 号； 3. **型号规格变更为：**WT1、WD1； 4. **结构组成变更为：**本产品主要由电源系统、生理信号采集系统、主处理及控制系统、存储器、显示屏、腕带及云卫康 App 软件组成（WT1 使用云卫康 iOS App 版本号为 2.0，Android App 版本号为 2.0；WD1 使用云卫康 iOS App 版本号为 4.2，Android App 版本号为 4.2）； 5. **产品适用范围变更为：**产品适用于对成人多项生理参数进行实时或周期监测、数据存储回顾、超限提示。监护参数包括血氧饱和度、心率和腕部皮肤温度（WT1）； 6. **产品技术要求变更**情况详见《四川省第二类医疗器械变更情况对比表》。
备　注	本文件与“川械注准 20162210019”注册证共同使用。

审批部门：四川省食品药品监督管理局　　批准日期：2017 年 6 月 22 日

Charge Code

Charge Code Application

- Fee Name: Sleep Apnea Syndrome Screening (Reflex Technology)
- Current progress: Filed by Sichuan Provincial People's Hospital

Charging Code Scheme 1

- Sleep Respiratory Monitoring (310604001): 300-600 RMB / time * 50%

Charging Code Scheme 2 (excluding Shenzhen)

- Sleep breathing monitoring screening test (310604002): 80-150 RMB / time
- 7 hours blood oxygen monitoring (310701028): 2-4 RMB / hour * 7 hours = 14-28 RMB / time
- ESS score (cost of work): 10-20 RMB / time
- Report (cost of work): 10 RMB

Total: 114-208 RMB

OSA Screening Report (Instance)

BASIC INFO

Name	Zhang Desheng	Sex	Male	Age	39
Height	170cm	Weight	62Kg	BMI Index	21.5
Total Time	22569	Started At	2018-10-23 00:36	Ended At	2018-10-23 06:00
Duration	05:23	Device SN	717201333	Results	Severe

SpO_2 DISTRIBUTION

<70% (min)	0	Avg. SpO_2 (%)	91
<75% (min)	0.4	ODI4 (times/hrs)	32.1
<80% (min)	2	ODE (mins/hrs)	11.6
<85% (min)	14.5	Max. OD	21
<90% (min)	102.4	Longest OD Duration	70
<95% (min)	270.6	Min. SpO_2	72

HR DISTRIBUTION

Max. HR (bpm)	95	Avg. HR (bpm)	57.1
Min. HR (bpm)	40		

DATA EXPLANATION

1. Test started from 2018-10-23 00:36 has valid data of 5:13:53;

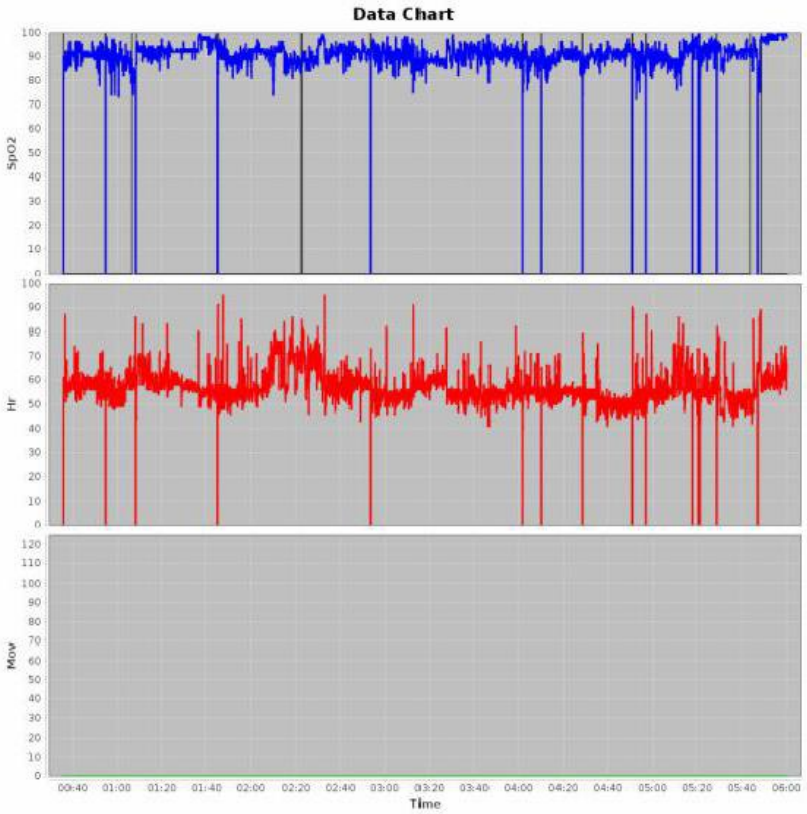
2. Totally 168 times of oxygen deduction events happened, ODI = 32.1 times/hrs;

3. Totally 102.4 mins with SpO2 < 90%, taking 32.6% of the total test time;

4. Minimum SpO2 = 72.0%, happened at
2018-10-23 04:52:33, lasts for 2 sec

DOCTOR'S OPINION

Technician: Doctor: Review: Date:



Report Interpretation

Avg. SpO_2 (%)	91
ODI (times/hrs)	32.1
ODE (mins/hrs)	11.6
Max. OD	21
Longest OD Duratior	70
Min. SpO_2	72

The conclusions of the report are combined with the judgment and trend graphs of the two to give a normal, mild, moderate and severe risk classification.

Based on ODI4 and the lowest blood oxygen value, comprehensive analysis based on guidelines

ODI4 judgment standard, unit: times / hour

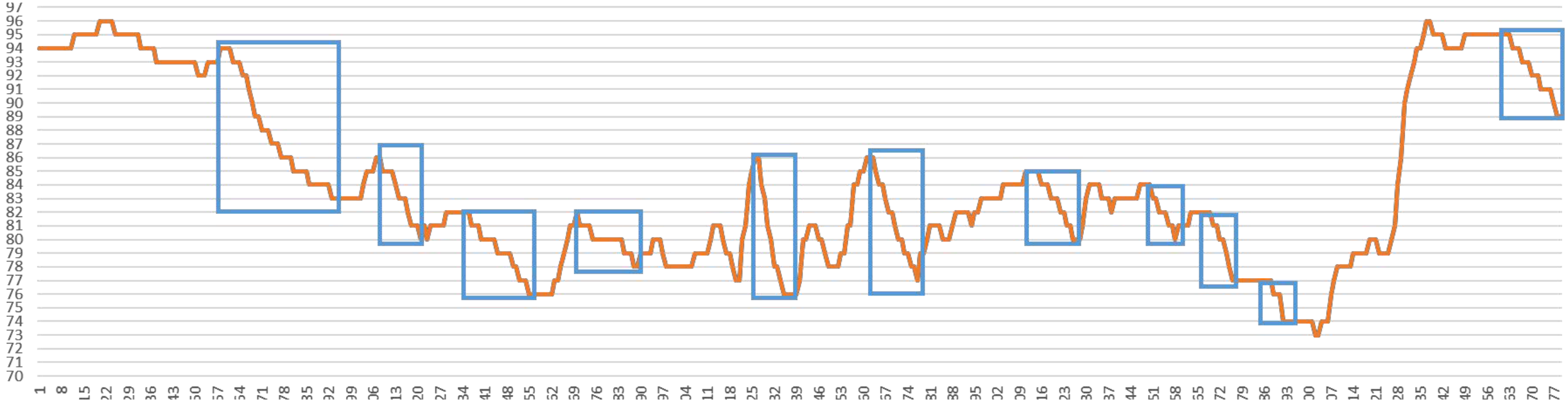
- <5, normal
- 5-15, for mild risk
- 15-30, moderate risk
- >30 for severe risks

Minimum blood oxygenation criteria

- >90%, normal
- 85%-90%, mild hypoxia
- 80%-85%, moderate hypoxia
- 60%-80%, severe hypoxia

Detailed Explanation of ODI4

All night blood oxygen trend diagram expansion (partial)



ODI 4 is the abbreviation of Oxygen Desaturation Index, which refers to the number of times the hourly oxygen saturation index drops by ≥ 4%. It is one of the core indicators for judging the apnea and hypopnea events and risk of sleep apnea hypopnea syndrome. The curve inside the blue box below is a typical ODI 4 event that occurs in a patient.

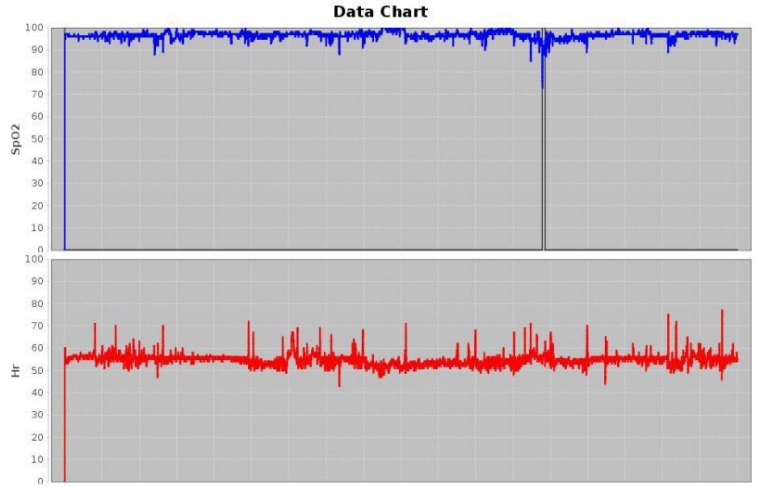
Judgment of Data Trend Graph

Trend of blood oxygenation rate in patients with typical sleep apnea hypopnea syndrome

- As shown above in the red box, blood oxygen continues to fall - picking up for a period of time, the corresponding heart rate appears irregular rise - fall back.

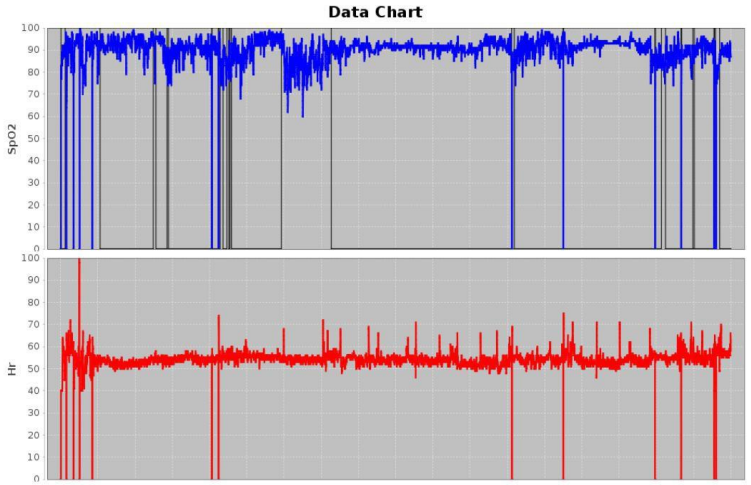
Comparison of Trend Graphs of Different Risk Levels

Normal



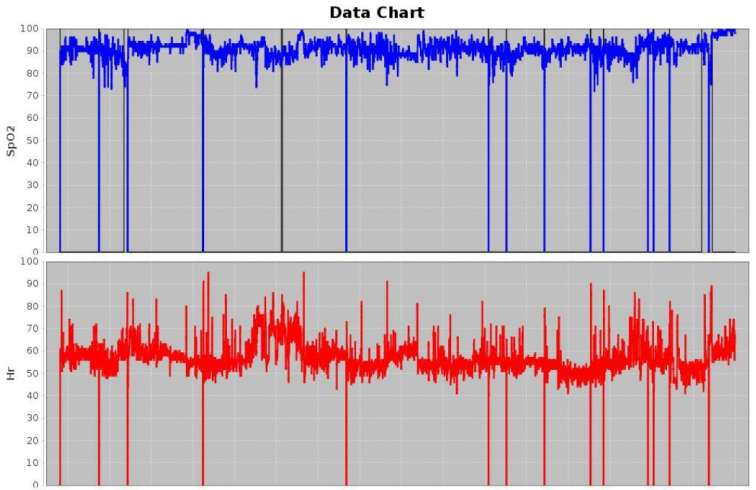
ODI4：2.7　Min. SpO_2: 91%

Moderate



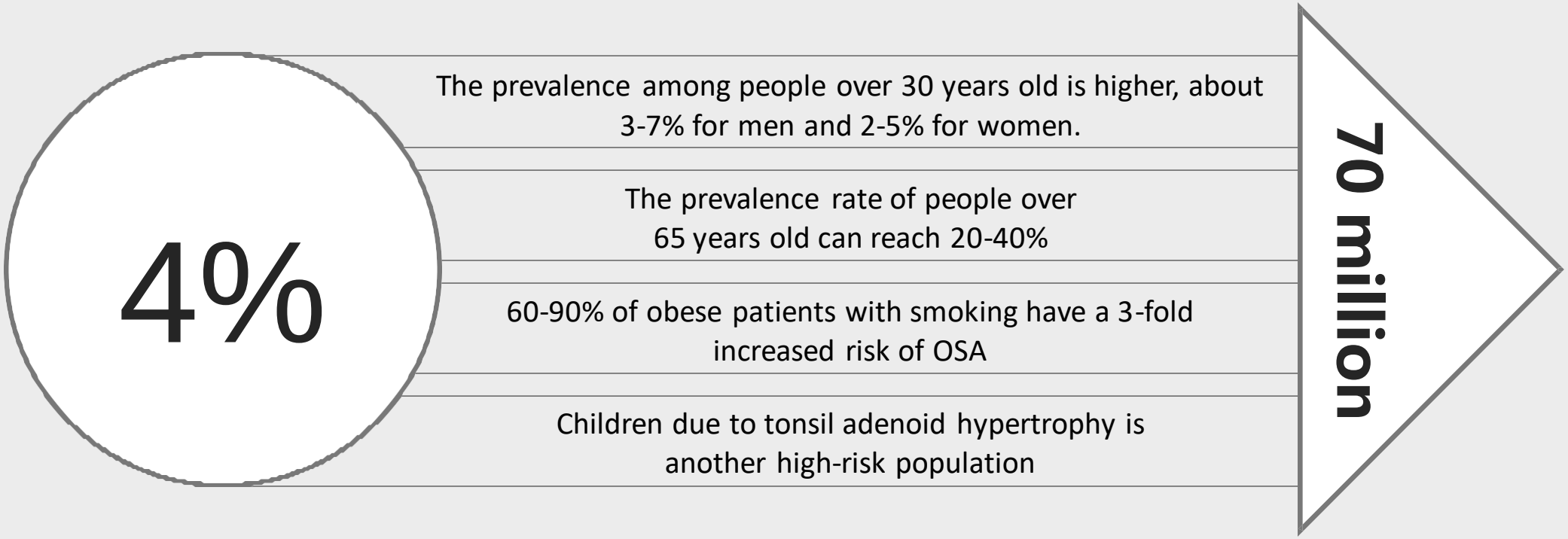
ODI4：26　Min. SpO_2: 72%

Severe



ODI4：32.1　Min. SpO_2: 68%

IV Market & Comparison



Patient population size

Only **2 ‰** patients get diagnosis and treatment

Comparison

Item	PSG	Portable Sleep Monitoring	Newest Solution	Previous Solution	Traditional Solution	Sleep Monitoring "Ball"
Picture						
Work Principle	Continuous monitor nighttime breathing (chest and abdomen movement, nasal airflow), oxygen saturation, electroencephalogram, electro-oculogram, electrocardiogram, heart rate, body motion and other indicators	Chest and abdomen exercise, nasal airflow, blood oxygen saturation, heart rate	Continuous blood oxygen saturation, heart rate, body motion, algorithm analysis of ODI and other indicators	Continuous blood oxygen saturation, heart rate, body motion, algorithm analysis of ODI and other indicators	Continuous blood oxygen saturation, heart rate, body motion, algorithm analysis of ODI and other indicators	Wireless radar monitors breathing and snoring
OSA Purpose	Diagnosis Standard	Screening	Screening	Screening	Screening	Screening
Accuracy	☆☆☆☆☆	☆☆☆☆½	☆☆☆☆	☆☆☆☆	☆☆☆☆	☆☆☆
Wearing Method	Professional technician pastes and bundles	Professional technician pastes and bundles	3M medical human body double-sided adhesive paste on the arm	Set on the thumb (ring) / wrist (wristband)	Wrist watch, finger wear	No need to wear, place the bedside strictly as required
Unit Price	10,000 – 200,000USD	10,000 – 200,000USD	Variable package, purchase as per demand	400USD	460USD (China) 3000USD (Imported)	
Ex Hospital Test	×	×	√	√	√	
Manufacturer	Philips, Resmed, Weinmann, NOX	Philips, Resmed, Contec			NIHON KOHDEN, Contec, Oranger	Megahealth
Hardware CFDA	√	√	√	√	√	√
Software CFDA	√	√	√	×	×	×
Profit Model	Hardware sales, software maintenance	Hardware sales	Hardware sales, Software authorization (per patient)	Hardware sales, share report income (rental)	Hardware sales, rental	Hardware sales

Advantages

A

Low Cost

1/10 of medium PSG

B

Space Saving

Button + charging device, can be used outside of hospital, no specific room required

C

Simple Operation

Stick to the arm. Finished!

D

Very Comfortable

No cable, No foreign body sensation, no need to stay overnight in the hospital

E

Authoritative & Reliable

Based on guidelines, thousands of clinical data, over 50 top three hospital applications

FULCARE

THANKS

birkin.tang@fulcare.cn
www.fulcare.cn