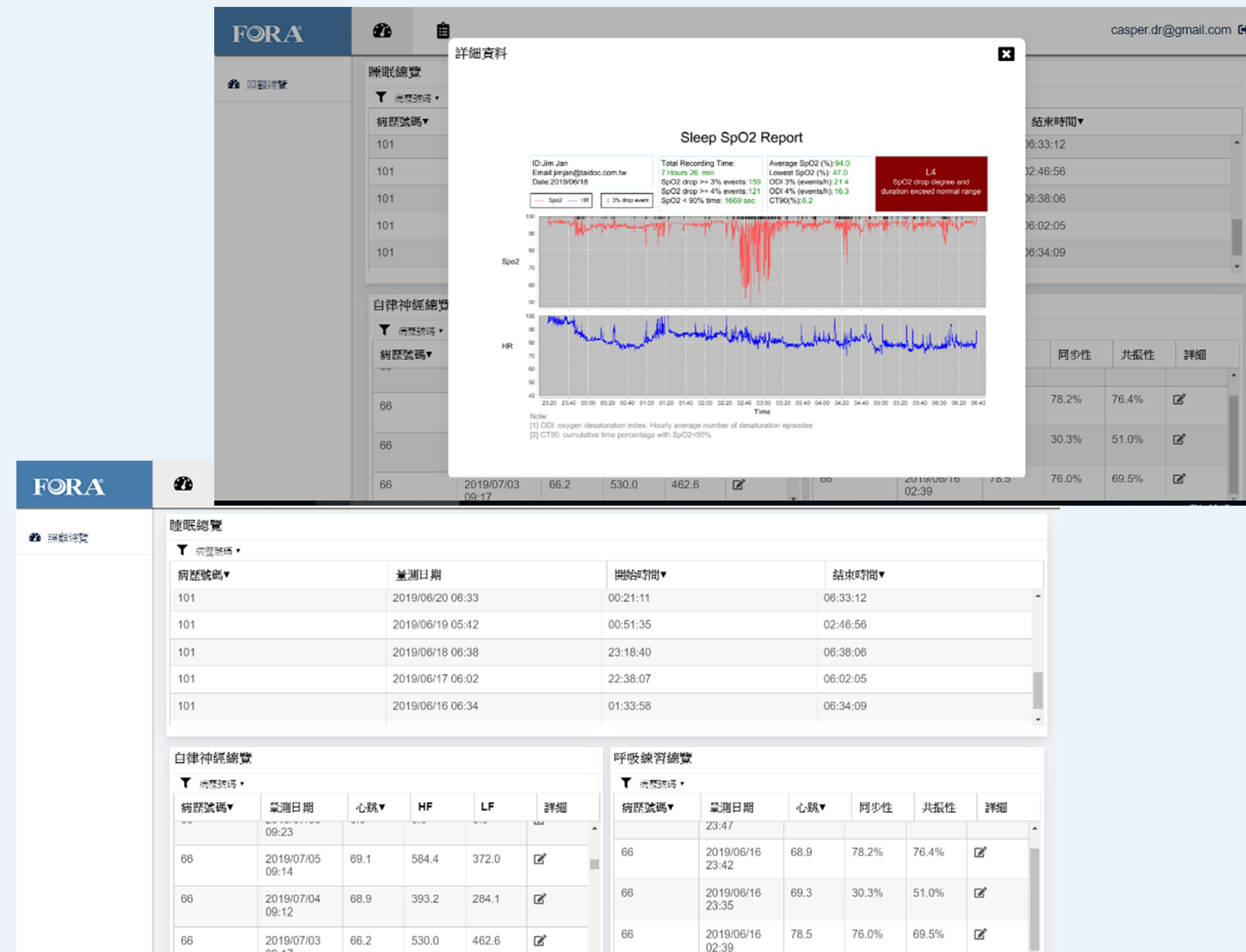
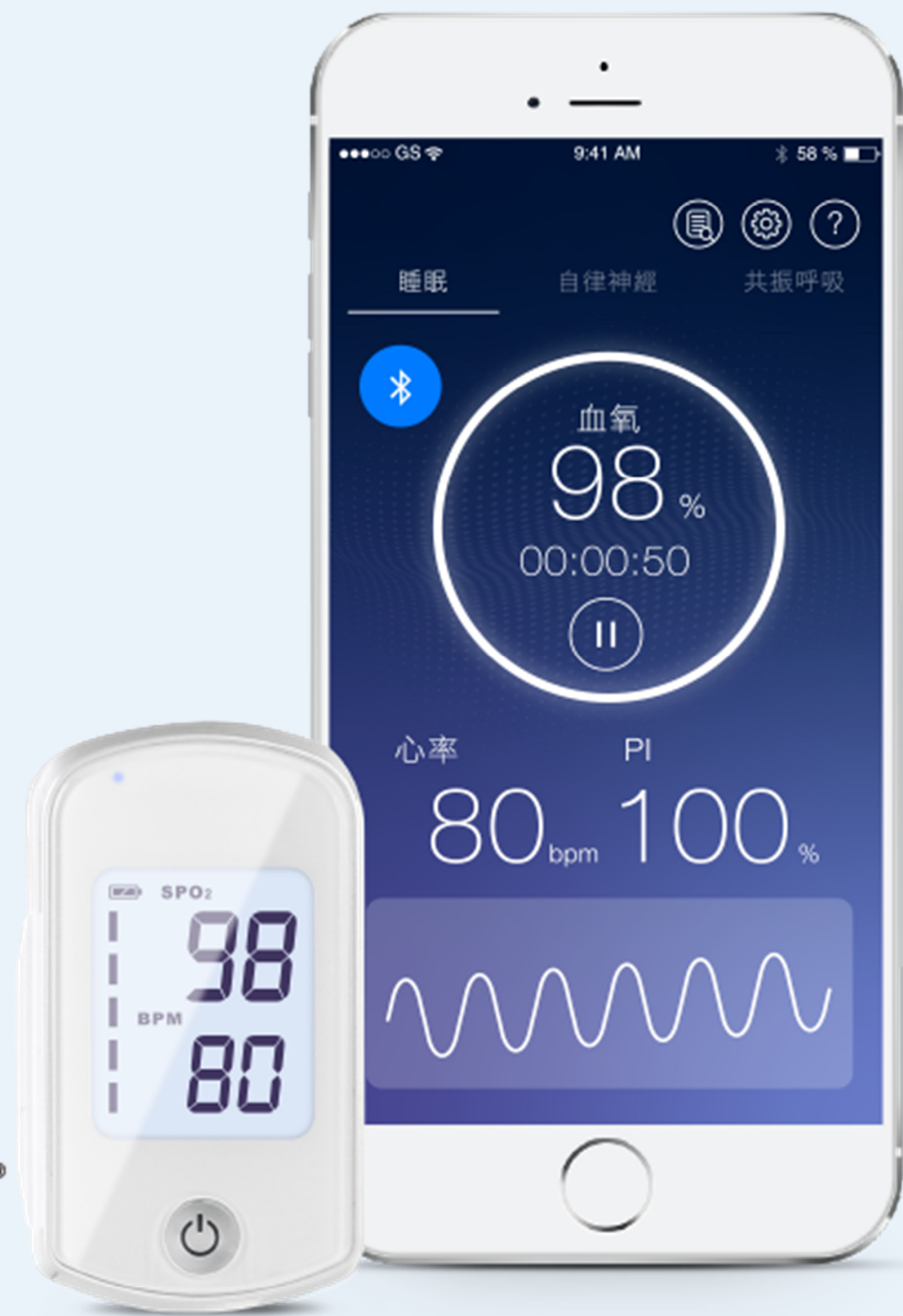


# FORA O2 Sleep Wellness Sleep SpO2/HRV/Breath All-in-One



# System Overview

- FORA (TD8255) Bluetooth Pulse Oximeter certified by FDA, CE, and TFDA; performance qualified by Taiwan hospital and US Care Institute
  - Accurate
  - Low Perfusion Support (PI: ~0.1%)
  - Adaptable to differences of finger size, skin, and color
  - Good Stability to prevent false detection of SpO2 drop or rise event (e.g. ODI)
  - Good Sensitivity and quick response time to correctly detect SpO2 drop and rise event (e.g. ODI)
  - Comfortable and biocompatible material for longtime wearing
- iFORA O2 App provides 3 main analysis functions, supporting iOS and Android platform
  - Sleep SpO2 Analysis
  - HRV Analysis
  - Resonance Breathing (HRV Biofeedback)
- Cloud server provide analysis function and support remote subject management

# Sleep SpO2 Analysis

- Theory basis: study showed ODI has high correlation with AHI [1]; study used ODI3%, ODI4%, CT90% for sleep apnea home screening had good performance [2]
- Record overnight SpO2 and Heart Rate, and provide analysis report with parameters related to sleep apnea
  - 'ODI 3%' , 'ODI 4%' , 'CT90%' , average SpO2, lowest SpO2, SpO2 drop events.
- Classify overall results into 4 Levels for the recordings > 4 hours, refer to the criterion in the study [2].

L1

'ODI 3%' < 5

SpO2 variation is in normal range

L2

'ODI 3%' 5~10 and 'ODI 4%' < 5  
double check Epworth Sleepiness Scale (ESS)

SpO2 drop 3% events per hour is a little high

L3

'ODI 3%' > 10 or 'ODI 4%' > 5  
consult physician

SpO2 drop 3% and 4% events per hours exceed normal range

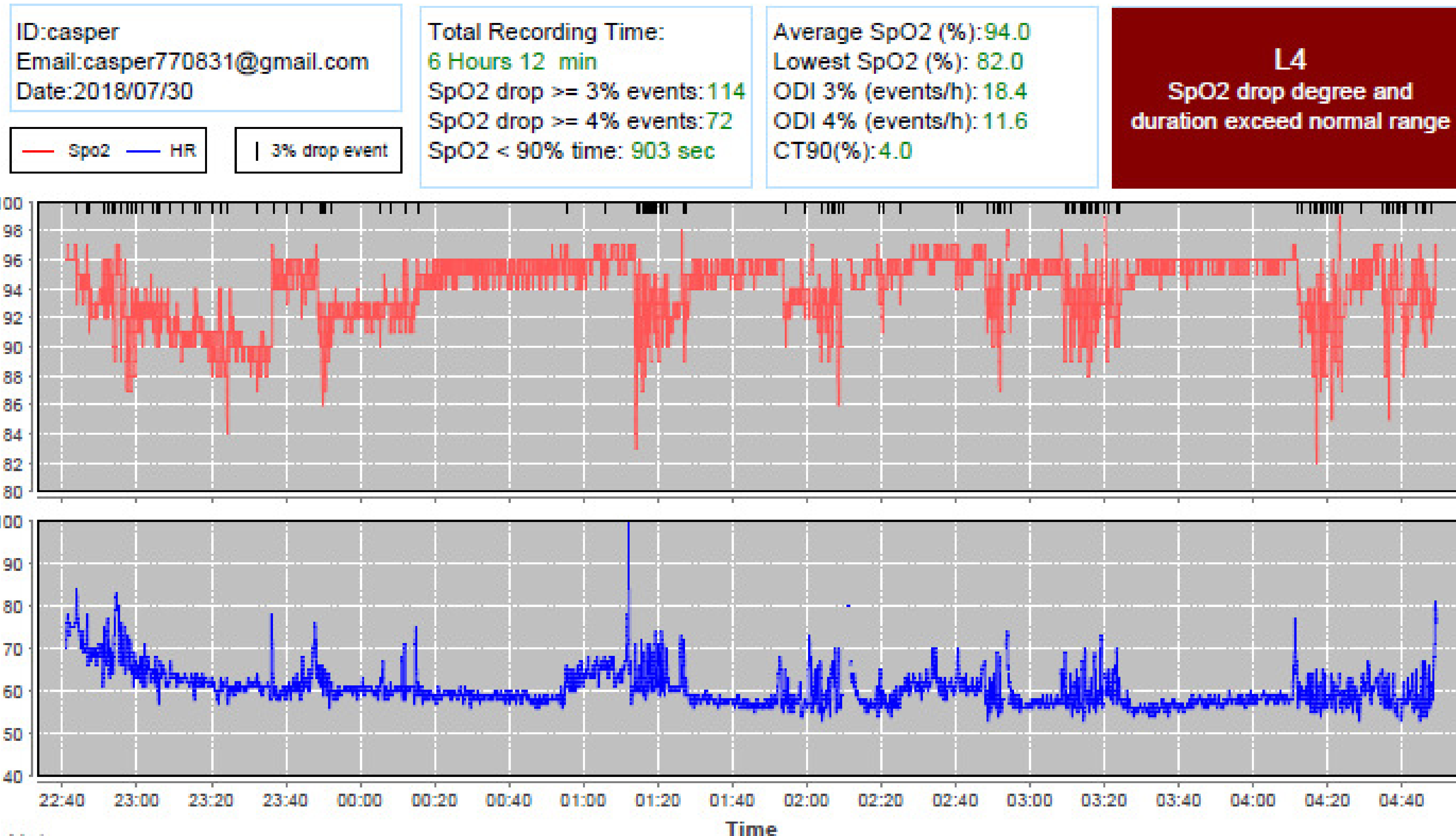
L4

CT90% > 1%  
consult physician

SpO2 drop degree and duration exceed normal range

# Sleep SpO2 Report Example

## Sleep SpO2 Report



Note:

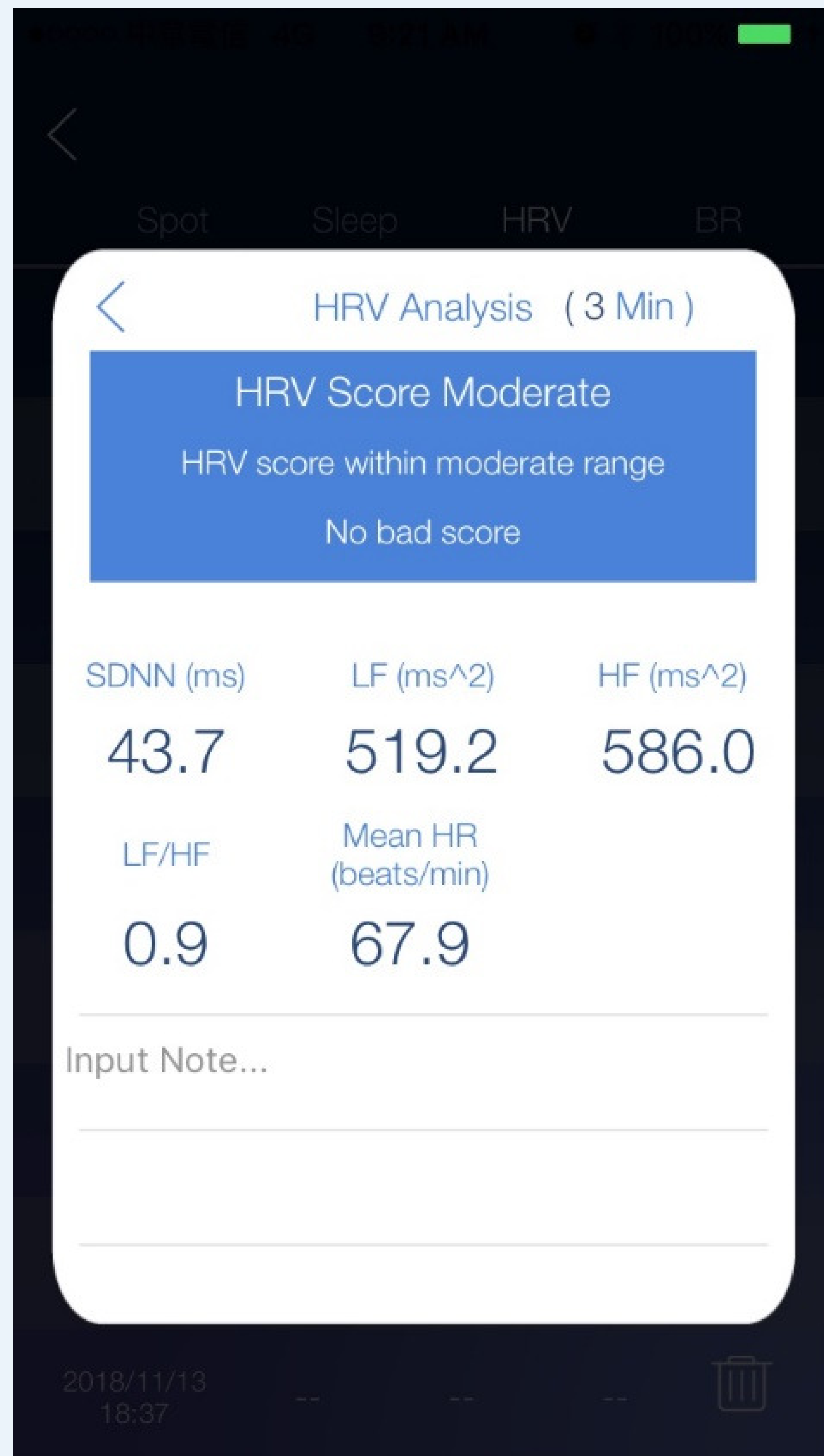
[1] ODI: oxygen desaturation index. Hourly average number of desaturation episodes

[2] CT90: cumulative time percentage with SpO2 < 90%

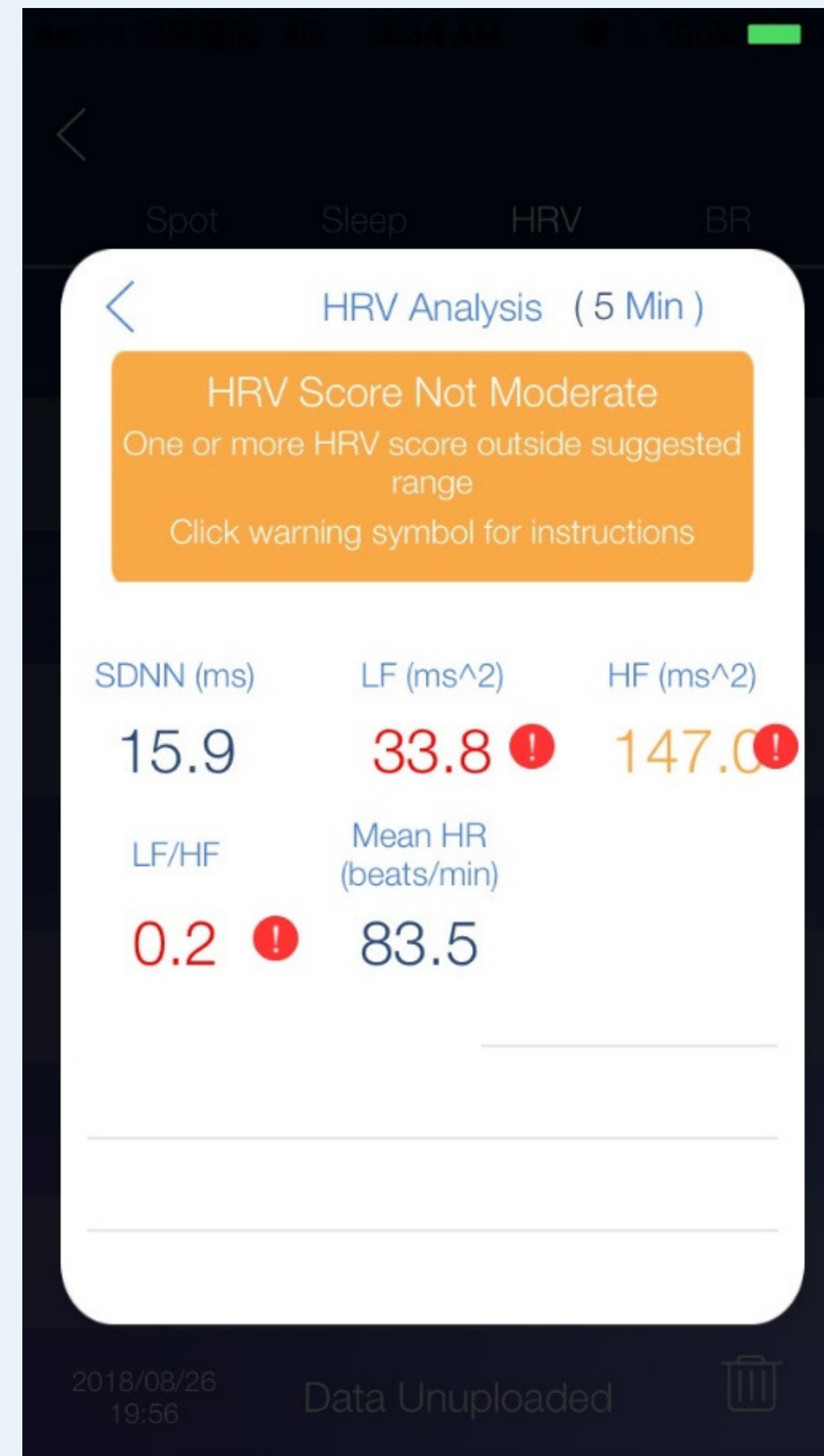
# HRV Analysis

- Support 3 Minute and 5 Minute Mode
- Use both time domain and frequency domain HRV analysis to estimate SDNN, LF, HF, LF/HF [3]
- Use multi-level anti-noise and respiratory rate estimation algorithm to ensure analysis accuracy
  - remove noisy portion of measured signal, and use noise-resistant analysis algorithm
  - show analysis fail if detecting obvious motion or unqualified signal quality
  - estimate respiratory rate and take breathing effects into consideration
- Use heart rate 、 LF 、 HF 、 LF/HF to classify overall HRV scores into 5 levels
  - Not Moderate (score outside suggested typical range)
  - Strong (score higher than suggested typical range)
  - Moderate (score within suggested typical range)
  - Breathing Master (suggested score range is special)
  - Unclassified (suggested measure again)
- Analysis heart rate, LF, HF, LF/HF score with individual suggested typical range

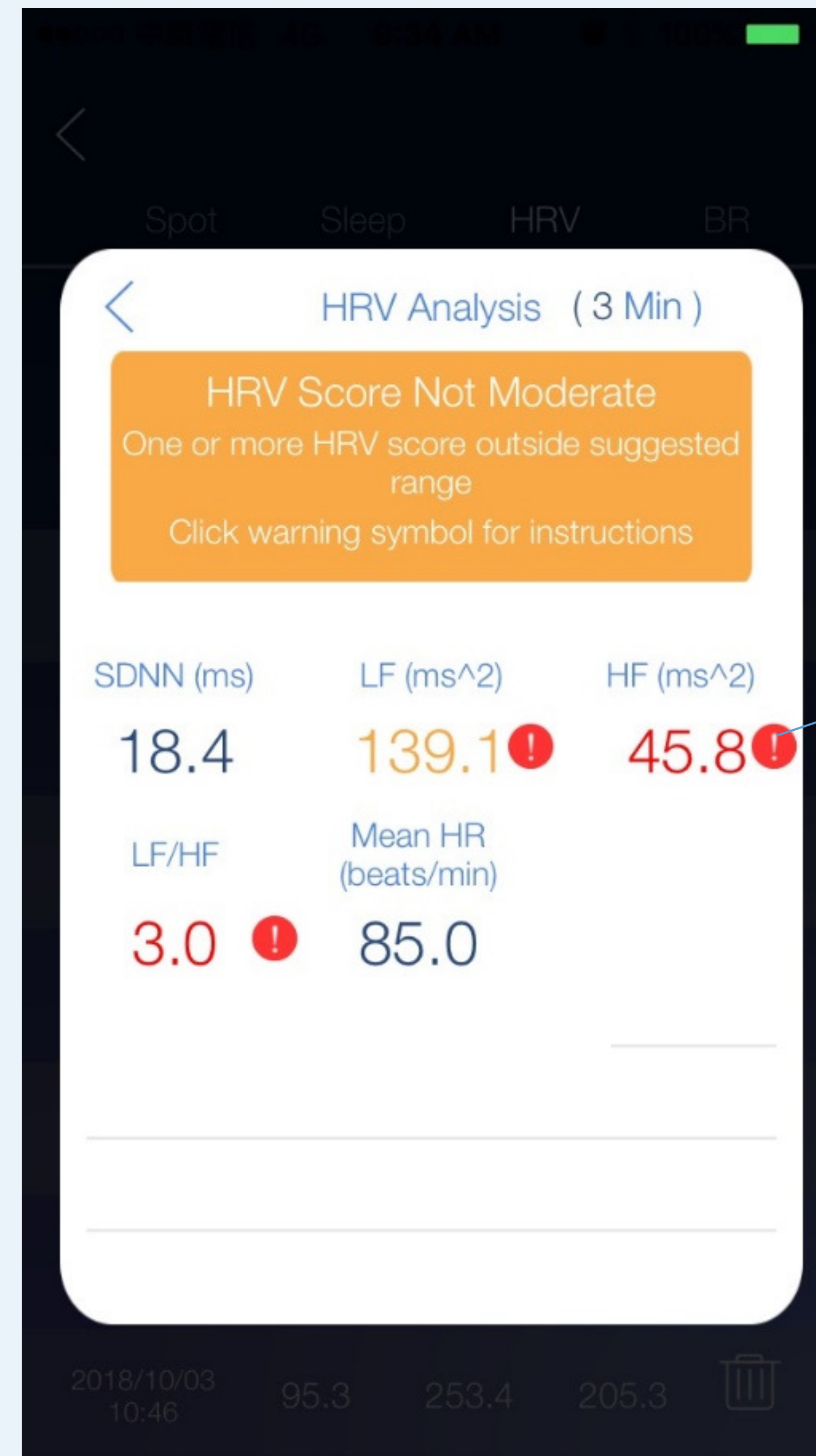
# HRV Analysis Result Example



age 32 (Female)



age 72 (Female)  
hypothyroidism



age 50 (Male)  
hypertension  
sleep apnea

**Parasympathetic (HF)**  
**Low**

**Recommended lower bound > 200**  
For User Awake, Calm, and Sitting Quietly

Possible causes and risks:

- Sleep disorder
- Anxious, over stressed
- Not recovered after exercise
- Smoke
- Hypertension, diabetes
- Menopausal (e.g.insomnia)
- Other diseases

**More....**

# HRV Biofeedback

- Breathing frequency: number of breaths per minute

4.5 Bpm, 5 Bpm, 5.5 Bpm, 6 Bpm, 6.5 Bpm, 7 Bpm, 7.5 Bpm

- Exercise Duration: 3 Min, 5 Min, 10 Min

- Animation Guide: Inhale and Exhale following the pace of the ball .

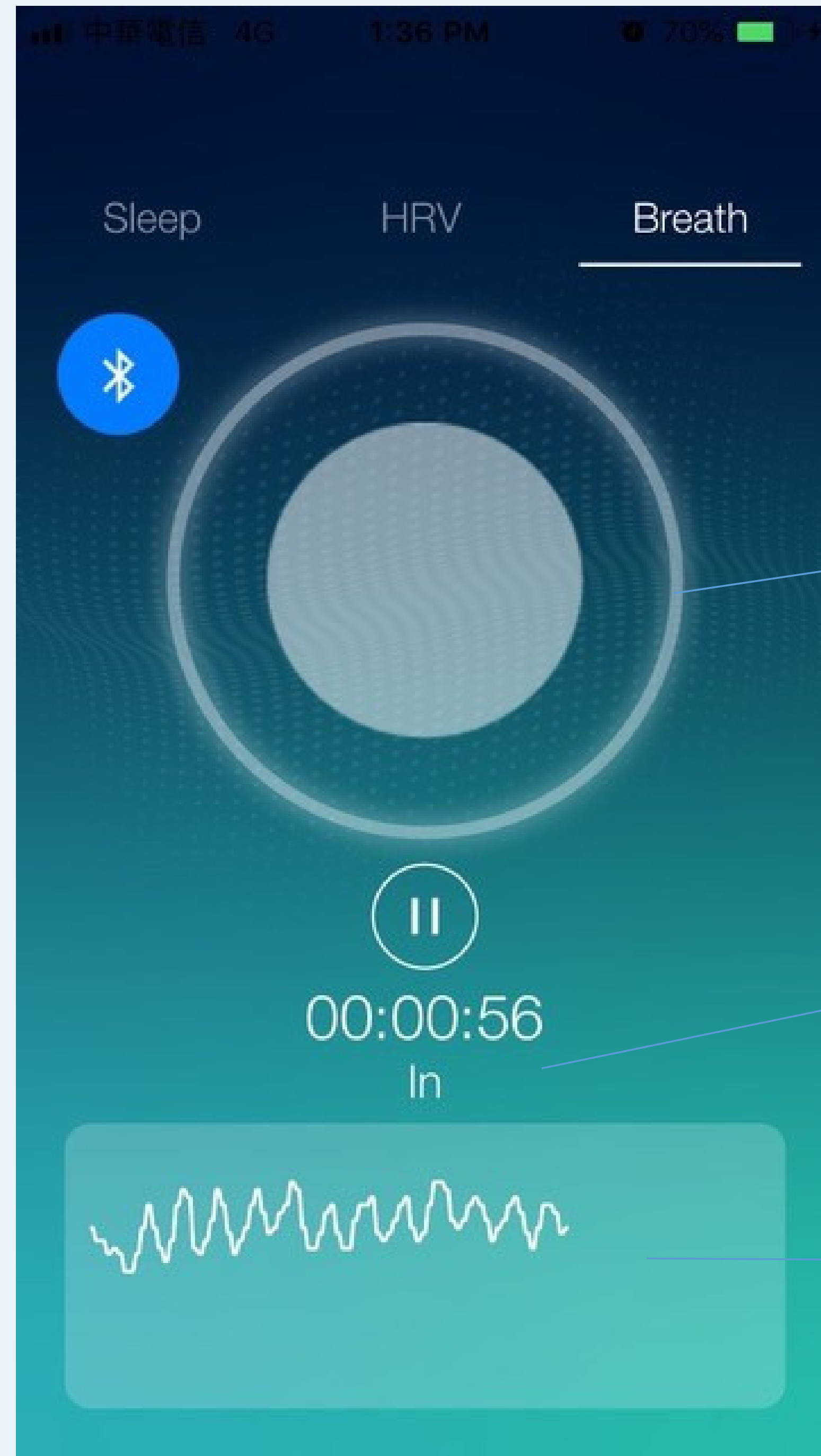
- Coherence (0~100%):

the degree of synchronization of inhalation and exhalation following the pace of the App. The higher the value the better (higher synchronization)

- Resonance (0~100%):

the degree of body resonance with the practiced breathing frequency. The higher the value, the more suitable the frequency (higher resonance)

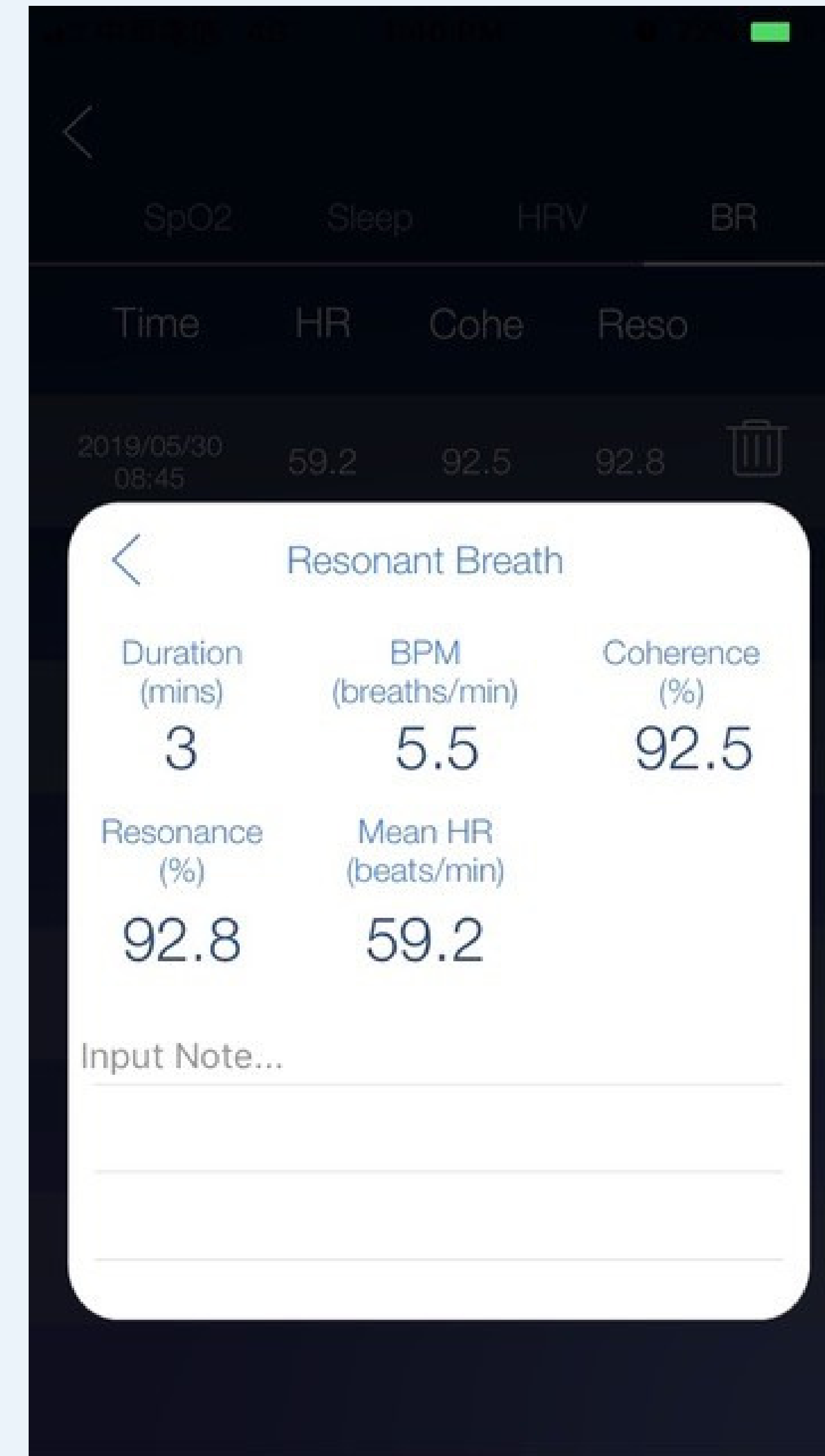
# HRV Biofeedback Example



Visual Guidance

Text Guidance

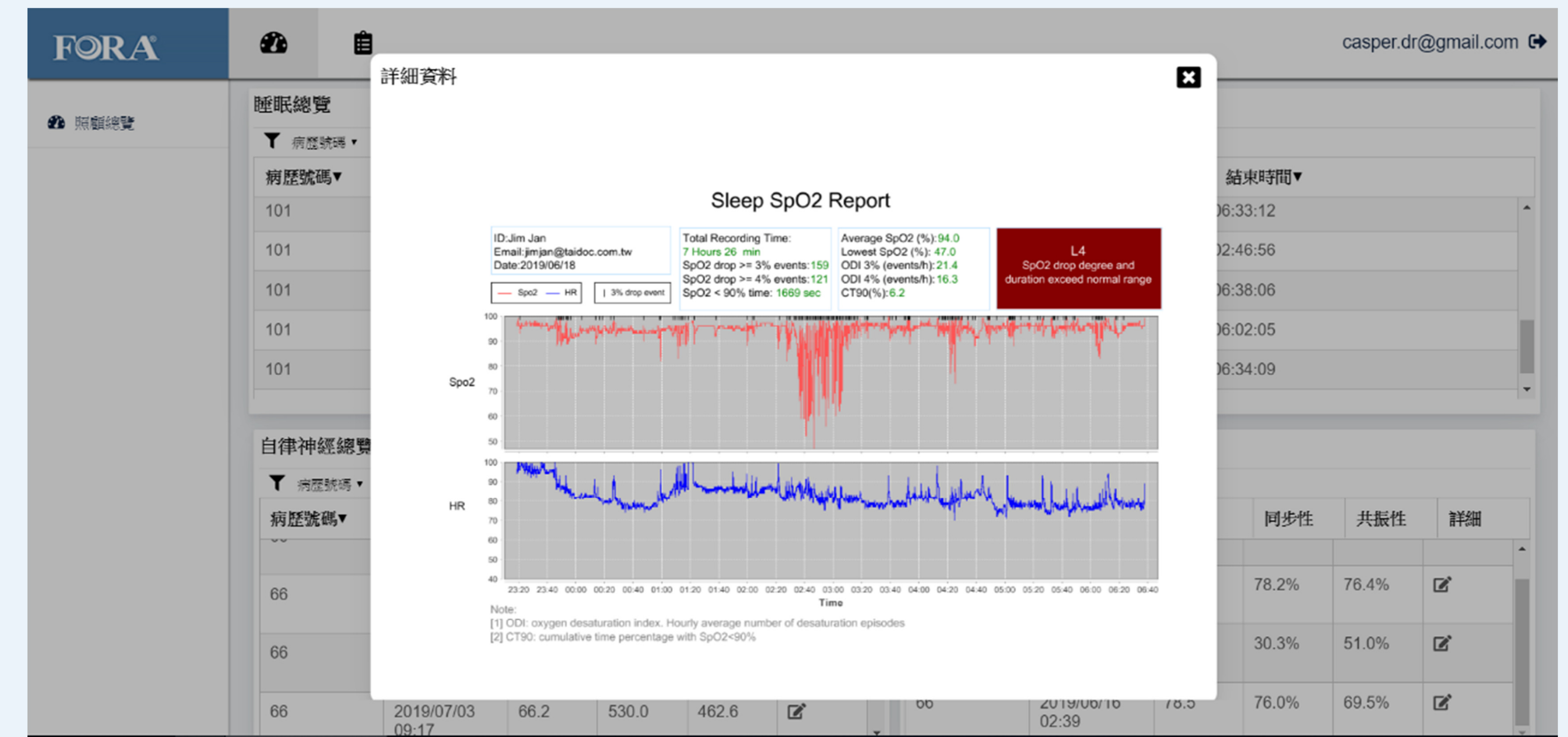
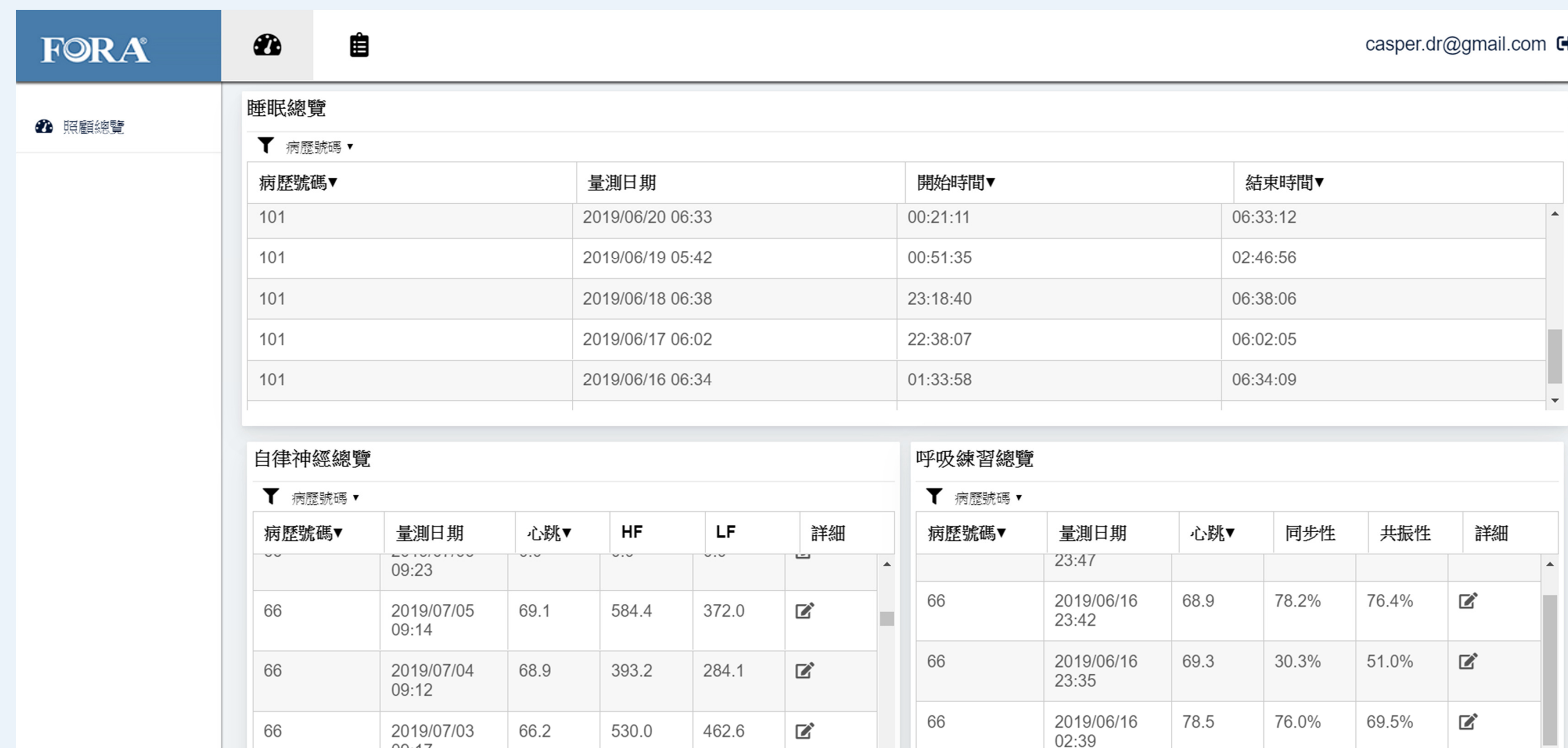
Heart Rate Feedback





# Cloud Management System

- Provide summary of recent Sleep SpO2, HRV, HRV Biofeedback analysis results for all authorized subjects (authorized to the Care Group)
- Provide profile and detail analysis information for each authorized subject.



# Reference

- [1] Oxygen desaturation index from nocturnal oximetry: a sensitive and specific tool to detect sleep-disordered breathing in surgical patients. *Anesth Analg*. 2012 May; 114(5):993- 1000
- [2] The Usefulness of Sleep Apnea Syndrome Screening using a Portable Pulse Oximeter in the Workplace. *J Occup Health* 2007; 49: 1-8.
- [3] Heart rate variability: standards of measurement, physiological interpretation and clinical use. Task Force of the European Society of Cardiology and the North American Society of Pacing and Electrophysiology. *Circulation*. 1996 Mar 1;93(5):1043-65.