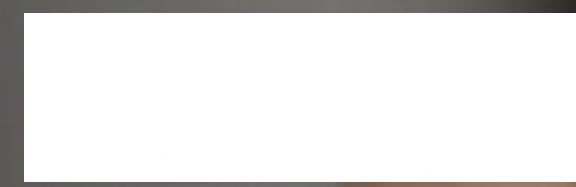




Rooti, The Future of Medical Care

Introducing Rooti Rx System



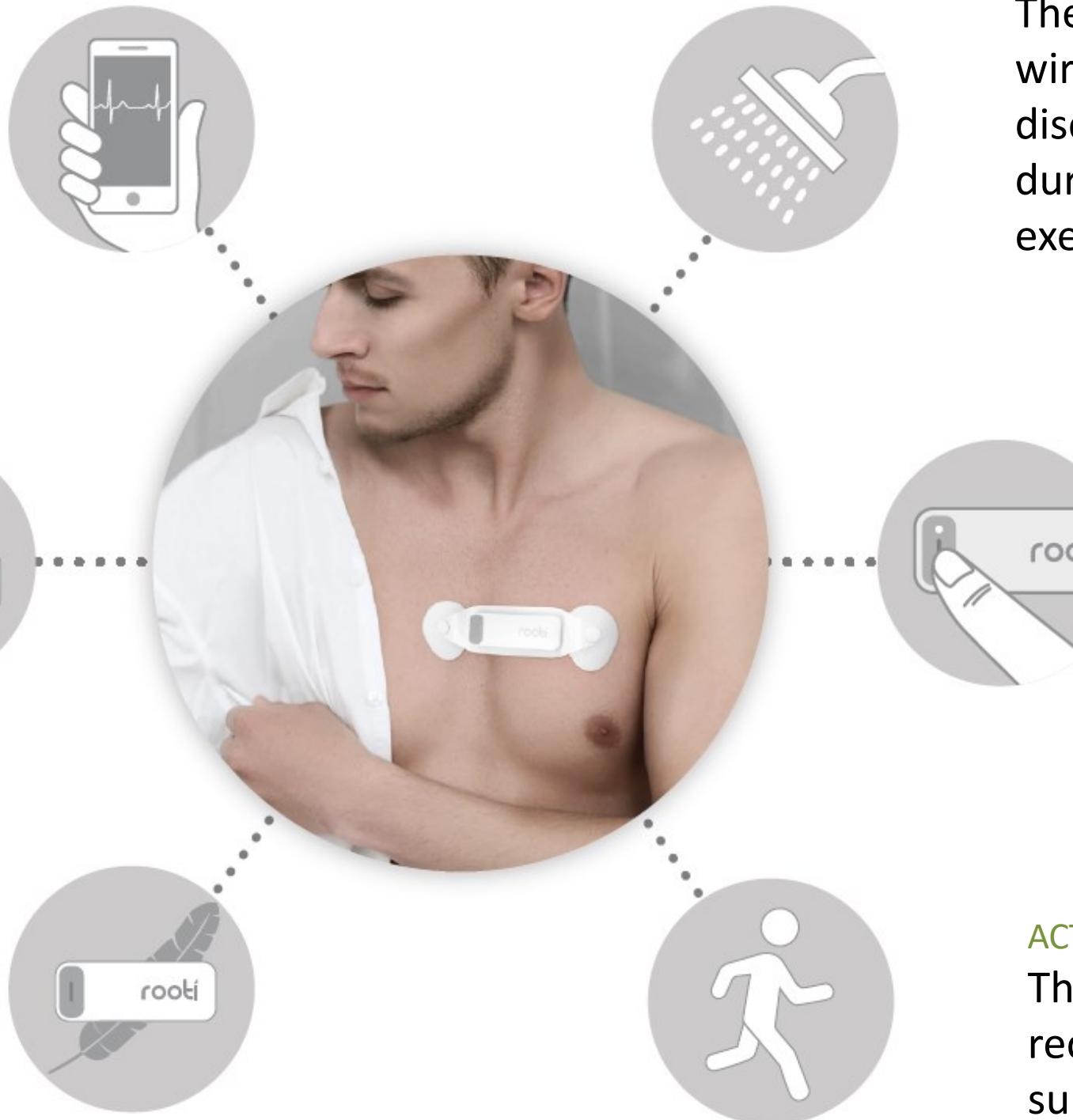
The up to **7** days record ECG monitoring system is equipped with **AI**. Through big data learning, high-accuracy analysis reports are completed within **24** hours, which greatly improves the diagnosis rate by 3-5 times. Create a new world standard for ECG analysis.



More features of RootiRx

PREVIEW MODE

allows the doctor to check the signal prior to recording, which translates to less invalid recordings and better diagnostic yield.



ACTIVITY FRIENDLY

The IP58 water-resistant, wireless, single-use patch is discreet, yet reliable, even during showering or moderate exercise.

WI-FI UPLOAD

built-in Wi-Fi, allowing recordings to be directly uploaded to the RootiCare database anywhere there is Wi-Fi internet.

LIGHT WEIGHT

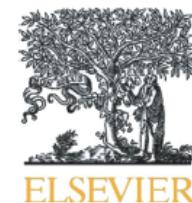
Weighing in at 14 grams, RootiRx brings ECG monitoring technology to the modern day, leaving cumbersome Holter monitors behind.

REAL TIME EVENT TAG

The user can simply press the button to tag an event if he/she feels uncomfortable, and RootiRx automatically tags the event for further analysis by your doctor.

ACTIVITY RECORDING

The motion sensor of RootiRx records a user's daily activity and supplements the ECG data for a more detailed diagnosis.



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The quality of ECG data acquisition, and diagnostic performance of a novel adhesive patch for ambulatory cardiac rhythm monitoring in arrhythmia detection

1. The overall average beat per minute correlation rate between RootiRx and standard 12 channels Schiller Holter was 99%

2. 51.8% of the subjects found arrhythmia after 24 hours, proving that long-term monitoring can effectively improve the diagnosis rate.

The quality of ECG data acquisition, and diagnostic performance of a novel adhesive patch for ambulatory cardiac rhythm monitoring in arrhythmia detection[☆]

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ECG patch monitoring device
Cardiac arrhythmias

ABSTRACT

Background: Short and long ambulatory electrocardiographic monitoring with different systems is a widely used method to detect cardiac arrhythmias. In this study, we aimed to evaluate the effectiveness of a novel monitoring device on cardiac arrhythmia detection.

Methods: We used two different protocols to evaluate device performance. For the first one, 36 healthy subjects were enrolled. The standard 12-lead, 24-h Holter monitoring and the novel single lead electrocardiogram (ECG) Patch Monitor (EPM) device (BeyondCare®, Rooti Labs Ltd., Taipei, Taiwan) were simultaneously applied to all subjects for 24 h. The quality of ECG data acquisition of novel system was compared to that of standard Holter. The second phase included 73 patients that were referred from our outpatient arrhythmia clinic for evaluation of their symptoms relevant to the cardiac arrhythmias. Advanced algorithms, statistical methods (cross-correlation method, Pearson's correlation coefficient, Bland-Altman plots) were used to process and verify the acquired data.

Results: The overall average beat per minute correlation between BeyondCare® and standard 12-lead Holter was found 98% in 33 healthy subjects. The mean percentage of invalid measurements in BeyondCare® was 1.6% while the Holter's was 1.7%. In the second protocol of the study, prospective data from 67 patients who were referred for evaluation of their symptoms relevant to cardiac arrhythmias, showed that the mean BeyondCare® wear time was 4.7 ± 0.5 days out of five total days per protocol. The mean analyzable wear time was 93.6%. The water-resistant design enabled 73.5% of the participants to take a shower. 7.3% of participants had minor skin irritations related to the electrodes. Among the patients with detected arrhythmia (40.2% of all patients), 29.6% had their first arrhythmia after the initial two days period. A clinically significant pause was detected in one patient, ventricular tachycardia was detected in four patients, and supraventricular tachycardia was detected in 15 patients. Paroxysmal atrial fibrillation was identified in seven patients. Three of them had their first episodes after the second day of monitoring.

Conclusion: BeyondCare® Patch was well-tolerated and allowed prolonged time periods for continuous ECG monitoring, may result in an improvement in clinical accuracy and detection of arrhythmias by cloud-based artificial intelligence operating system.

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15 Rhythm Types Detection

Atrial fibrillation

Ventricular tachycardia

Complete heart block

Ventricular couplet

Second degree AV block (type I and type II)

Ventricular triplet

Pause > 2sec

Ectopic atrial rhythm

Supraventricular tachycardia

Junctional rhythm

Ventricular bigeminy

Idioventricular rhythm

Ventricular trigeminy

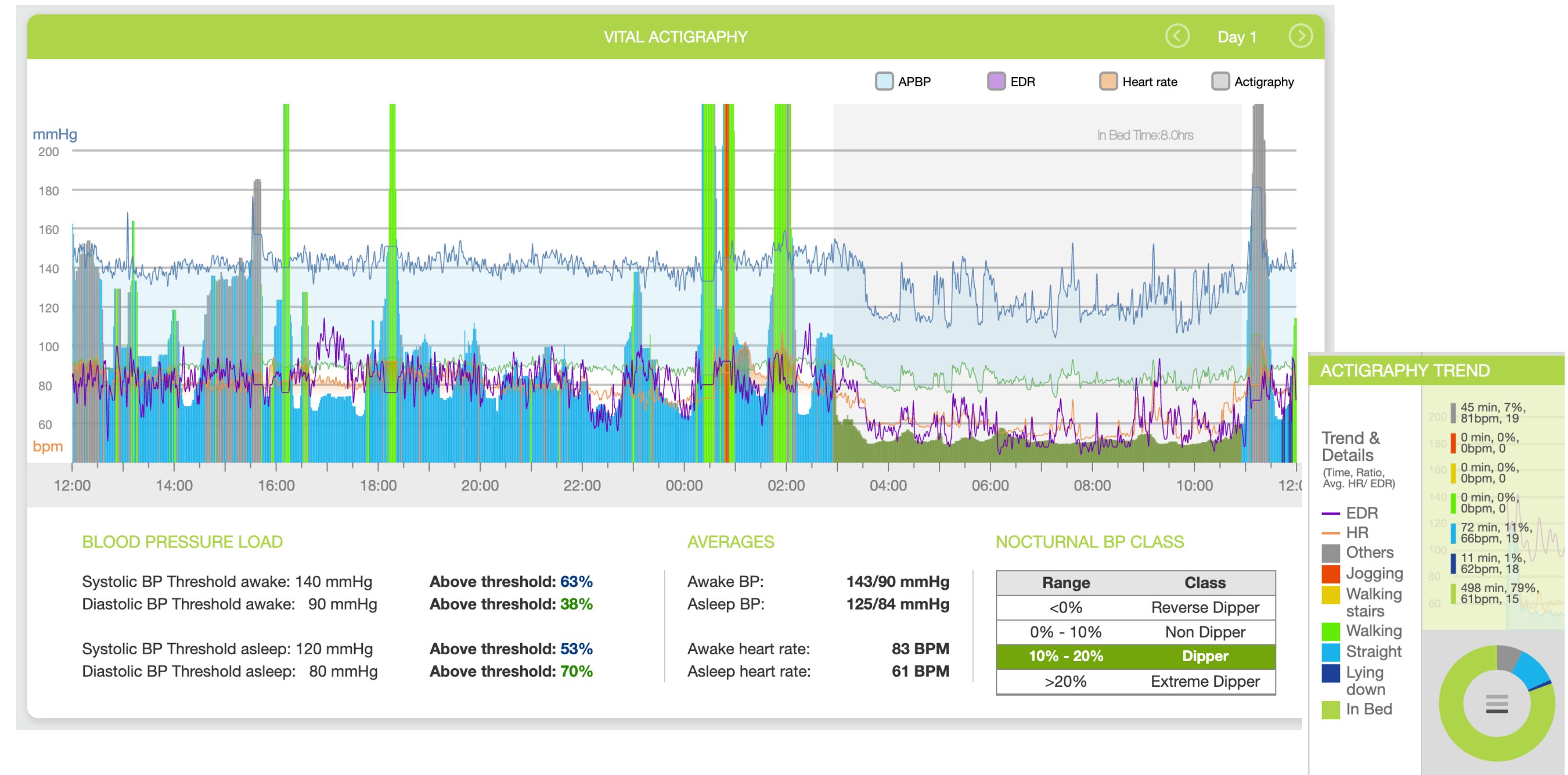
Sinus rhythm

- The precision of the algorithms was proven by comparing with MIT-BIH (Beth Israel Hospital) Arrhythmia Database, 44 cases of 30 min recording & American Heart Association ECG database, 134 cases (excluded VF) of 30 min recording
- N: SEN 99.77 / PPV 99.78 ; V: SEN 98.71 / PPV 97.99 ; A: SEN 86.27 / PPV 90.08 ; F: SEN 91.76 / PPV 92.65
- Clinical Validation by major medical center in Turkey, Taiwan, Italy
- More than 2 billion minutes of annotated ECG data established

Not only the ECG but also more insights

- A. Ambulatory Blood Pressure Estimation with Activity types
- B. Sleep Apnea Screening and Sleep Quality Assessment
- C. The Balance of Autonomic nervous system & 24hrs HRV

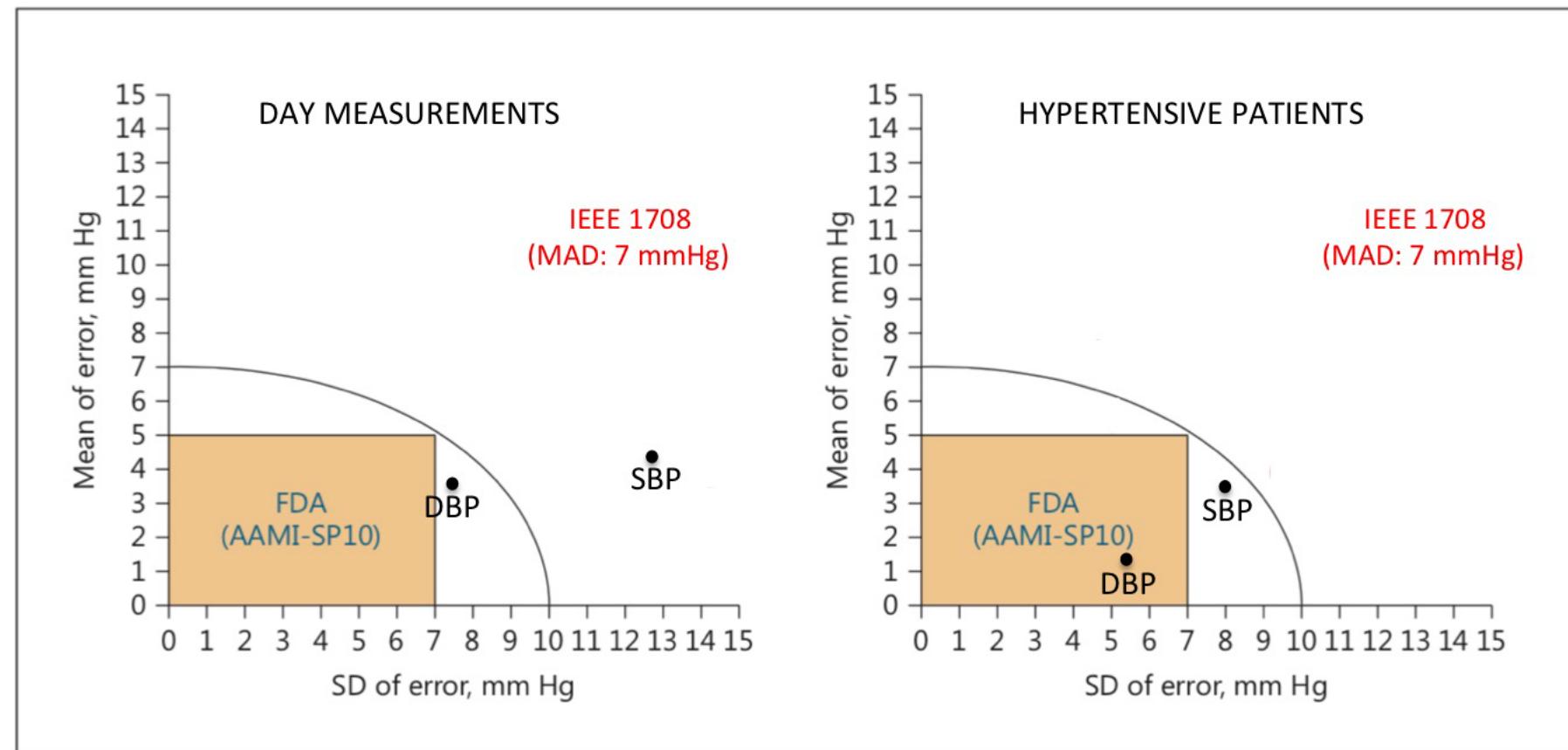
Ambulatory Blood Pressure Estimation with Activity Types



Ambulatory Blood Pressure Estimation with Activity types

Clinical validation published at the European Hypertension Society 2019

100 consecutive patients were included in the study. BP was measured simultaneously by the cuffless (CL-BP, Rooti RX ,Rooti Labs TM) and a standard device (CBP, Spacelabs TM 90207) over the 24 hours



Mean and standard deviation of the absolute SBP and DBP differences between the reference C-BP device and the new CL-BP device according to the FDA's standard (absolute BP differences $\leq 5 \pm 8$ mm Hg) and the IEEE 1708's standard (mean absolute BP difference < 7 mm Hg). SD, standard deviation; MAD, mean absolute difference; SBP, systolic blood pressure; DBP, diastolic blood pressure.

In this clinical study CL-BP estimates were somewhat most accurate on male and overweight subjects SBP: $r = 0.71$, $p = 0.10$ - DBP: $r = 0.77$, $p = 0.004$.

AMBULATORY BLOOD PRESSURE MONITORING BY A NOVEL CUFFLESS DEVICE IN CLINICAL PRACTICE
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Centro Studi Ipertensione e Malattie Vascolari – Istituto Clinico Verano Brianza
Policlinico di Monza - Italy

Objective
Cuffless blood pressure (BP) measurements are believed to be a potentially alternative to cuff-occlusion based BP measurement to eliminate some of the inconveniences of the latter approach. A wearable cuff-less monitoring device was developed for ambulatory BP monitoring. We assessed the accuracy of a new cuffless BP device with an ECG sensor compared to a standard oscillatory BP device for BP measurements over the 24 hours.

Design and method
100 consecutive patients were included in the study. BP was measured simultaneously by the cuffless (CL-BP, Rooti RX ,Rooti Labs TM) and a standard device (C-BP, Spacelabs TM 90207) over the 24 hours. Calculations included 24 hour mean systolic (S) BP, the mean diastolic (D) BP and the heart rate (HR). Correlations between the CL-BP and C-BP measurements were also sought using Pearson's correlation coefficients and Bland-Altman plots.

Results
Using the C-BP device, the 24 hour SBP value for the cohort was 125.4 ± 10.9 mmHg (mean \pm SD); the corresponding DBP value being 75 ± 8.3 mmHg. Mean SBP/DBP were somewhat higher with the CL-BP device, i.e. $131.1 \pm 15.9/80.2 \pm 9.7$ mmHg. The correlation coefficients between the two sets of values was significant (SBP: $r = 0.58$, $p = 0.006$ - DBP: $r = 0.65$, $p=0.0002$). Mean absolute SBP and DBP disagreements between CL-BP and C-BP were 5.7 ± 13.1 mmHg and 5.2 ± 7.7 mm Hg, respectively. Better SBP and DBP correlations for SBP and DBP was found 1) in patients with BMI > 25 (SBP: $r = 0.65$, $p = 0.13$ - DBP: $r = 0.70$, $p = 0.009$) compared to those with BMI < 25 (SBP: $r = 0.52$, $p = 0.02$ - DBP: $r = 0.51$, $p = 0.06$) and 2) males compared to females (males: SBP: $r = 0.71$, $p = 0.10$ - DBP: $r = 0.77$, $p = 0.004$) (females: SBP: $r = 0.41$, $p = 0.03$ - DBP: $r = 0.45$, $p = 0.008$).

Conclusions
In our study population a CL-BP device estimated 24 hour mean SBP and DBP somewhat differently from the classical oscillometric Spacelab device, with a moderate correlation. CL-BP estimates were somewhat most accurate on male and overweight subjects.

Sleep Apnea Screening and Sleep Quality Assessment

CVHR	Cross-matching ECG analysis with the number of occurrences of CVHR to evaluate sleep apnea	Sleep 1 06/10, 03:17 06/10, 11:35	Sleep 2 06/11, 02:55 06/11, 10:55	Sleep 3 06/12, 01:22 06/12, 10:44	Sleep 4 06/13, 02:46 06/13, 10:57	
Chest Effort	Chest movement measured from a high-precision tri-axis accelerometer for the respiration	In Bed Sleep Quality Onset Latency Waso	8 hr 18 min 93% 27min 7min	8 hr 0 min 89% 40min 13min	9 hr 22 min 90% 52min 2min	8 hr 11 min 87% 54min 7min
Body Postures	Body postures during sleep from accelerometer help doctors analysis postural apnea and sleep quality	*CVHRI (/hr) in Supine in Nonsupine S/Nons Ratio	12 11.0 14.9 0.7	15 18.7 6.5 2.9	9 10.3 6.2 1.7	15 13.5 17.3 0.8
SLEEP STAGES						
*CEI (/hr) in Supine in Nonsupine S/Nons Ratio						
REM Light Sleep Deep Sleep						
25.4% 65.4% 9.2%						
22.4% 71.2% 6.4%						
25.1% 66.1% 8.8%						
21.0% 69.2% 9.8%						
BODY POSITIONS						
Upright In sleep position						
7min, 1.4% 318min, 63.7%						
6min, 1.2% 320min, 66.5%						
5min, 0.9% 312min, 55.4%						
11min, 2.2% 341min, 69.3%						
In sleep position						
Supine Right Left Prone						
98min, 19.6% 76min, 15.2% 0min, 0.0%						
17min, 3.5% 138min, 28.7% 0min, 0.0%						
187min, 33.2% 59min, 10.5% 0min, 0.0%						
133min, 27.0% 7min, 1.4% 0min, 0.0%						

Association between CVHR or CEI and risk of moderate-to-severe obstructive sleep (AHI >=15) and S/Nons Ratio (supine/non supine >2) can help the doctor to confirm whether the apnea is caused by posture or not.

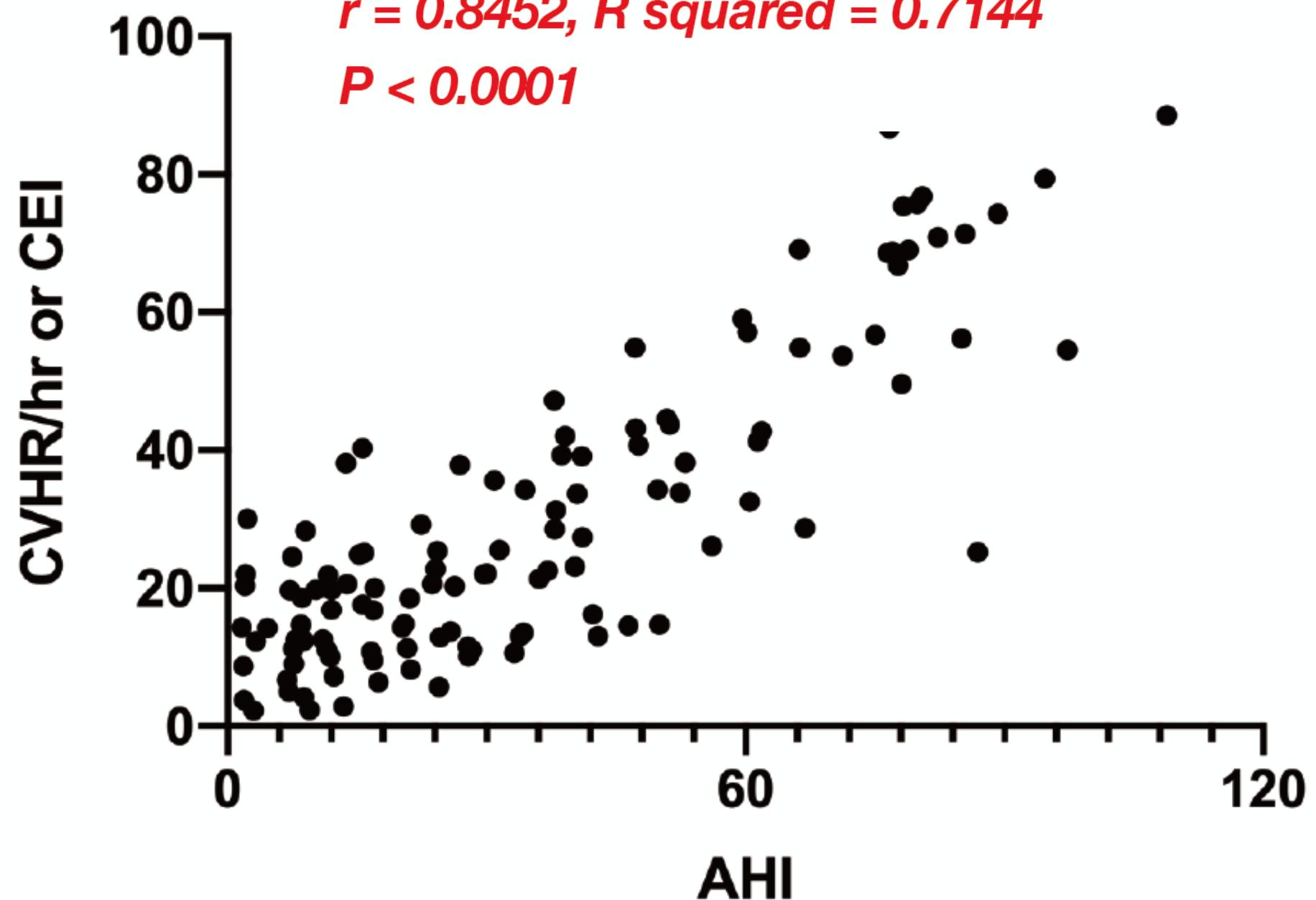
The frequency of getting up at night is very important to determine the quality of sleep. May be due to problems with the prostate hyperplasia or heart failure caused by breathing difficulties.

AHI Correlation

- 119 subjects from two hospitals were included in this study
- Overnight PSG and ambulatory ECG monitoring were performed simultaneously
- The SVM model were trained by scikit-learn library and using ten-fold cross validation to evaluate model performance

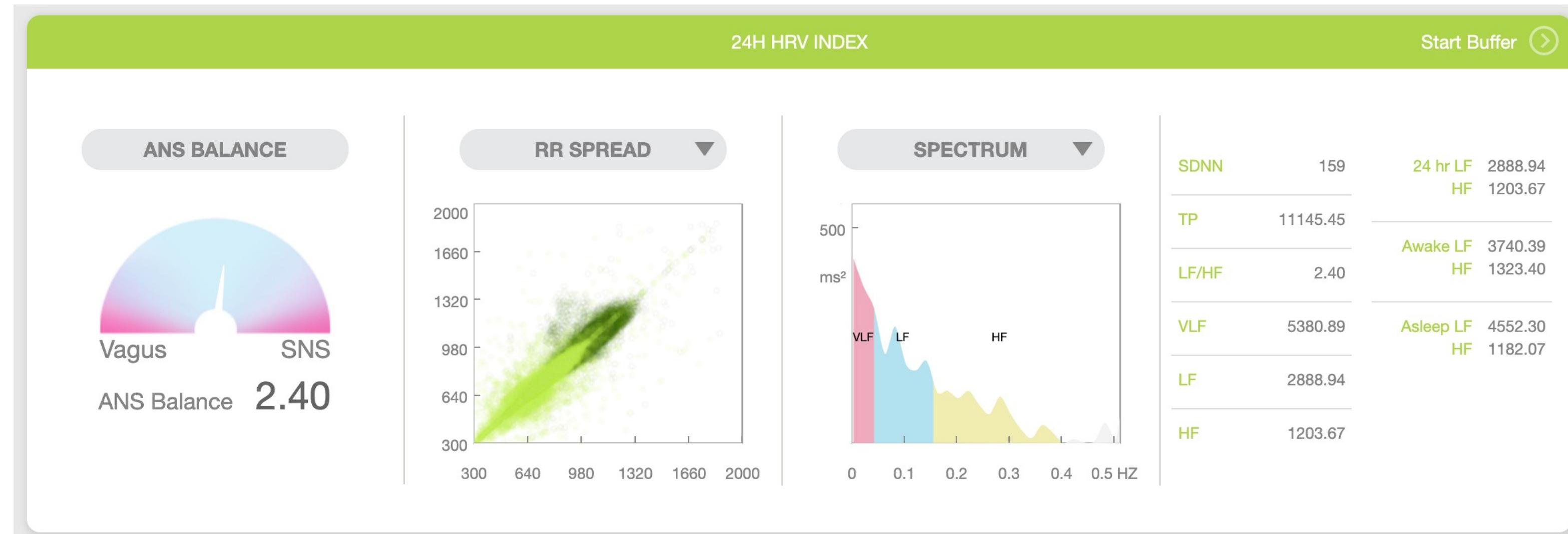
Pearson correlation
95% CI: 0.7846 to 0.8898

$r = 0.8452$, $R^2 = 0.7144$
 $P < 0.0001$



The Balance of Autonomic nervous system & 24hrs HRV

HRV Know your inner self

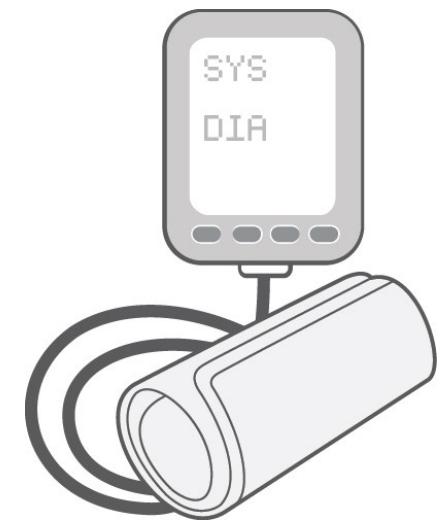
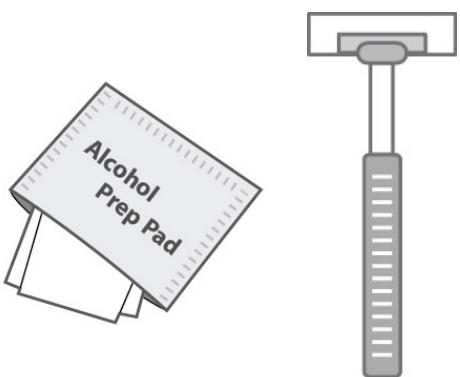
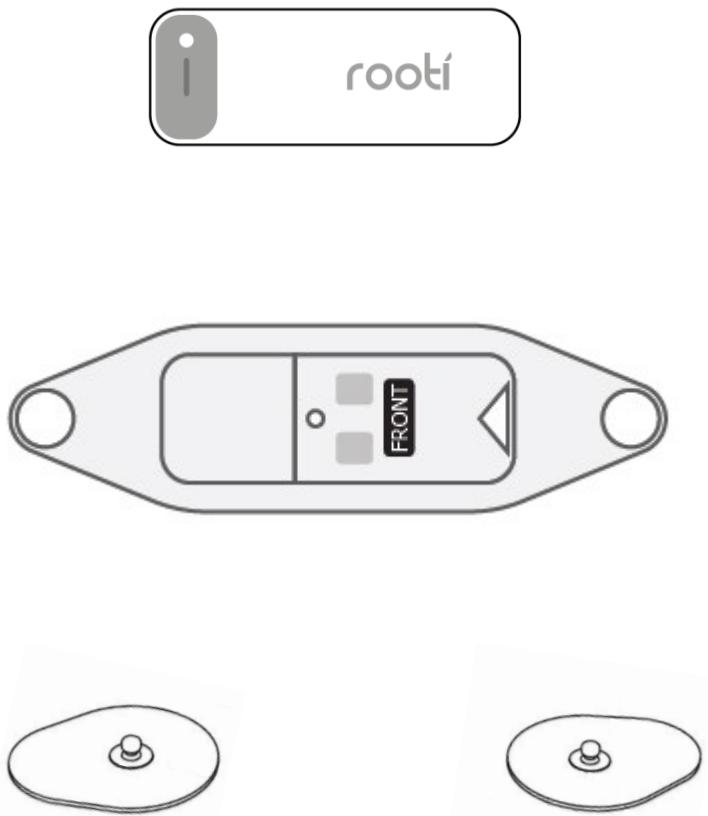
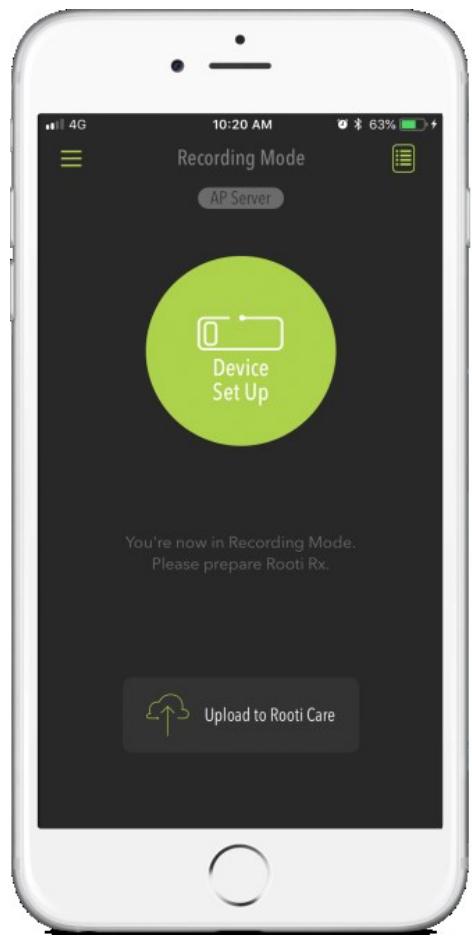


HRV is a method for assessing the effects of stress on your body with higher time interval variation links to good health and a high level of fitness, whilst decreased HRV is linked to stress, fatigue and even burnout.

Data flow



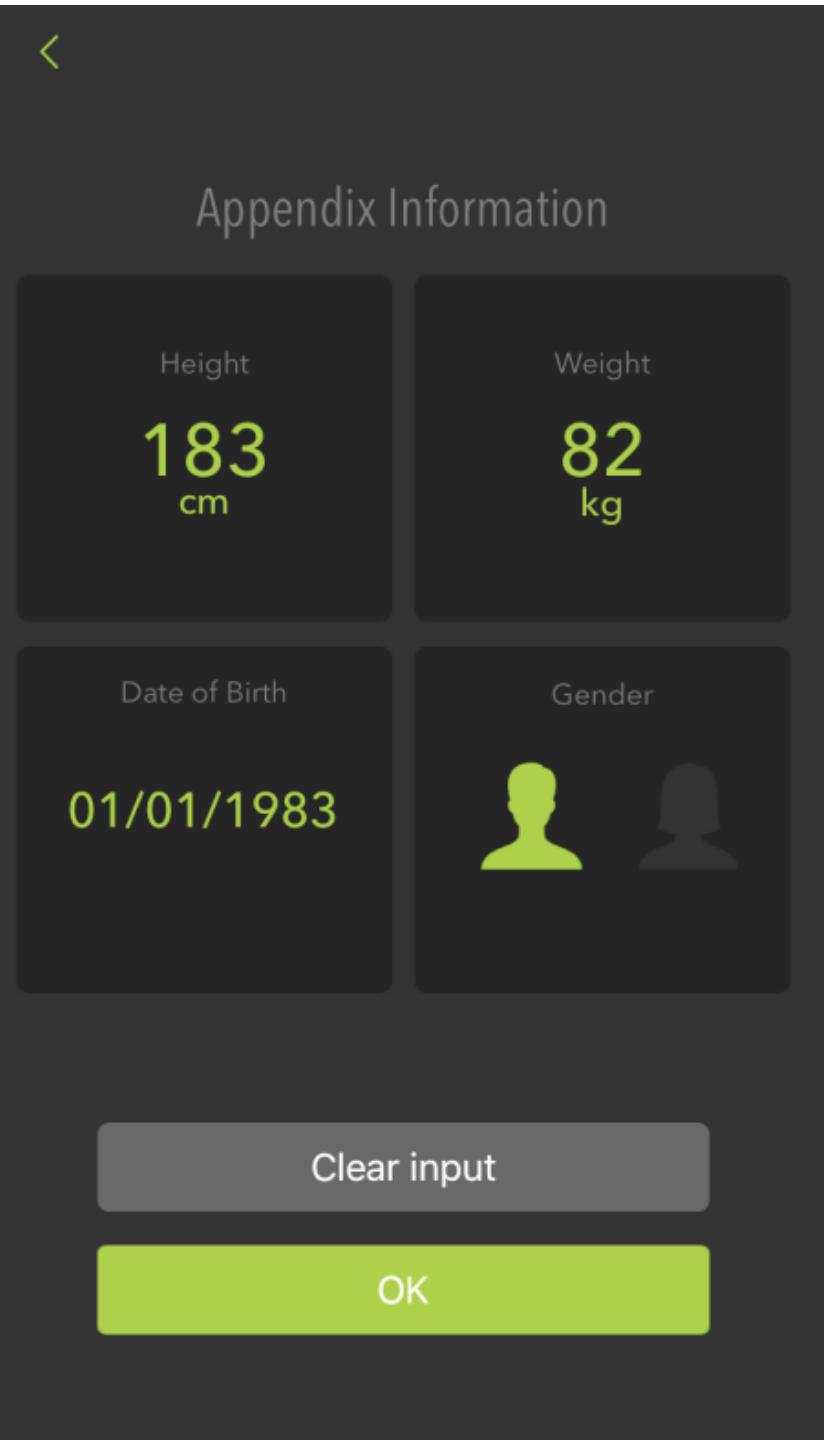
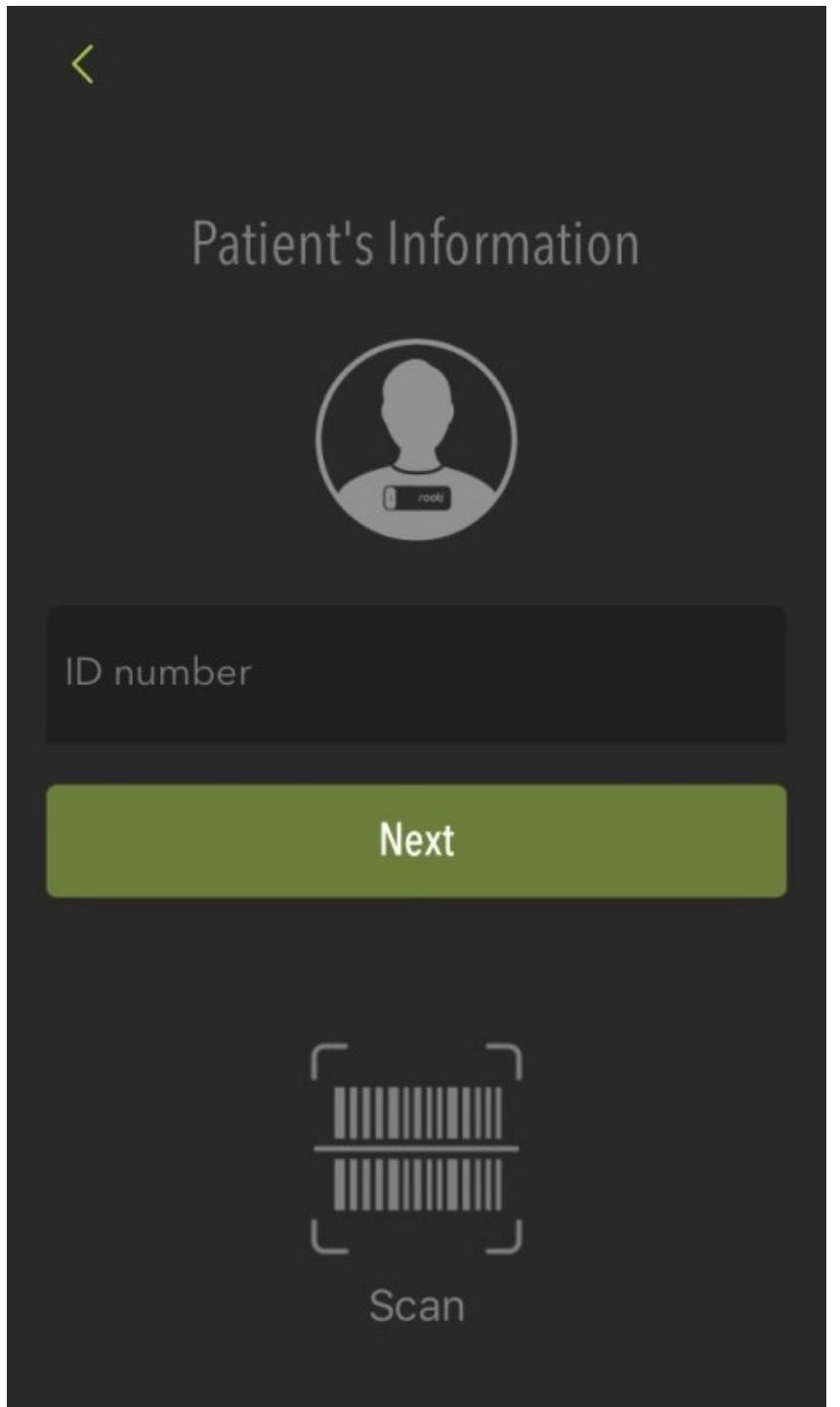
Set up - preparation



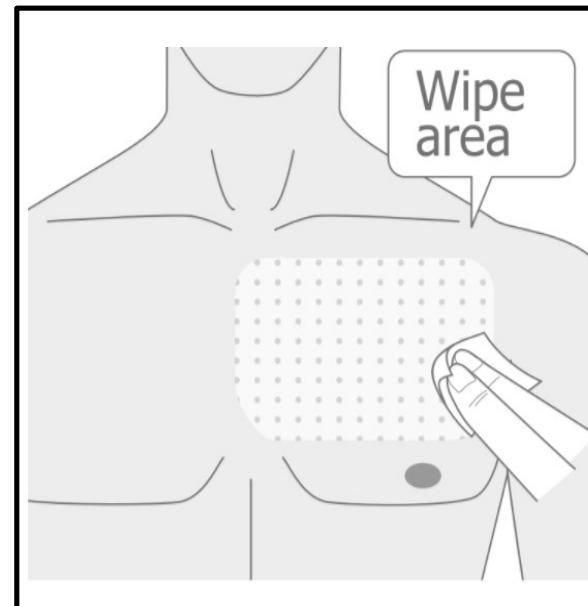
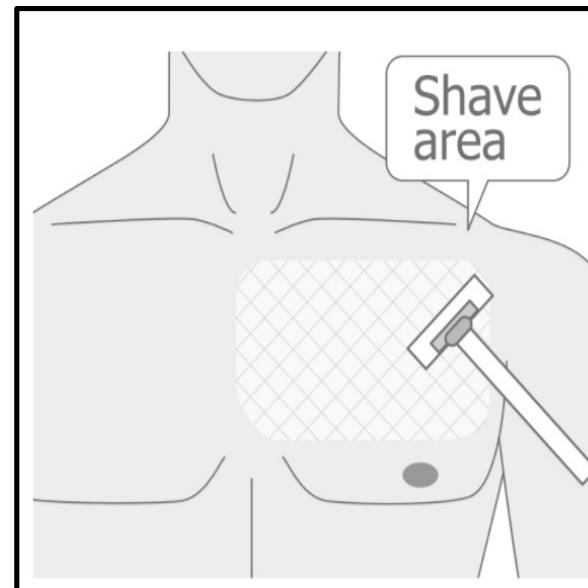
- iOS Device
- Rooti Rx
- Patch
- ECG electrodes
- Alcohol pad
- Razer
- BP monitor

Set up

Step 1 : Key in patient's Information

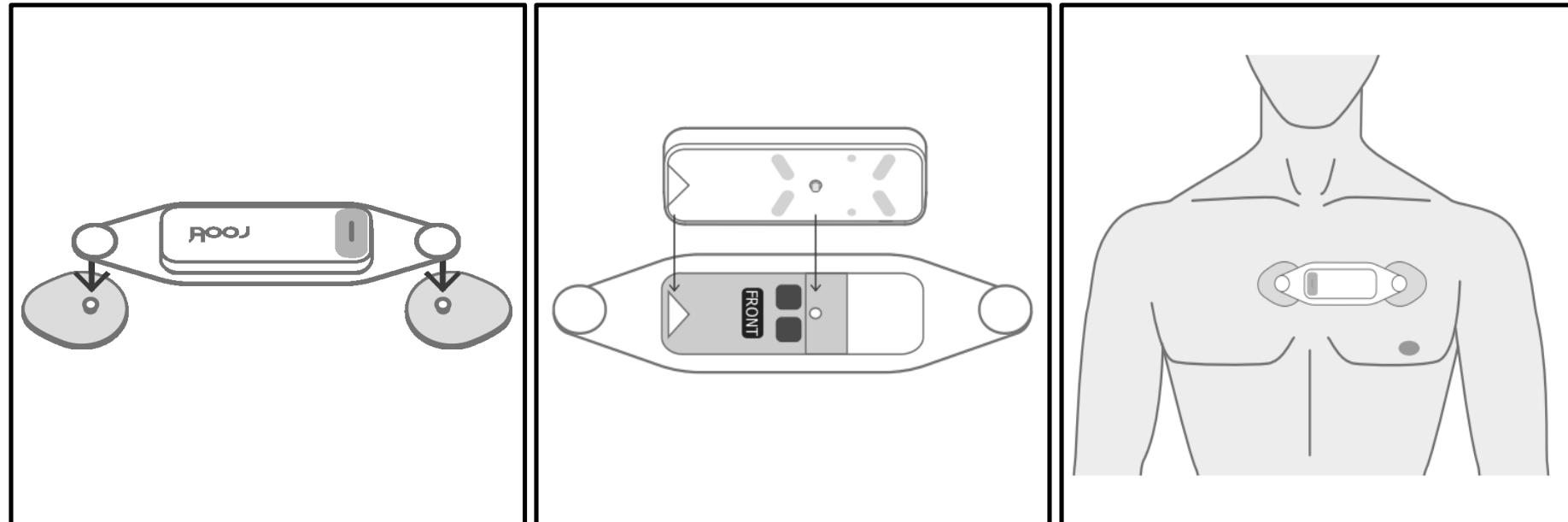


Step 2 : Skin prepare

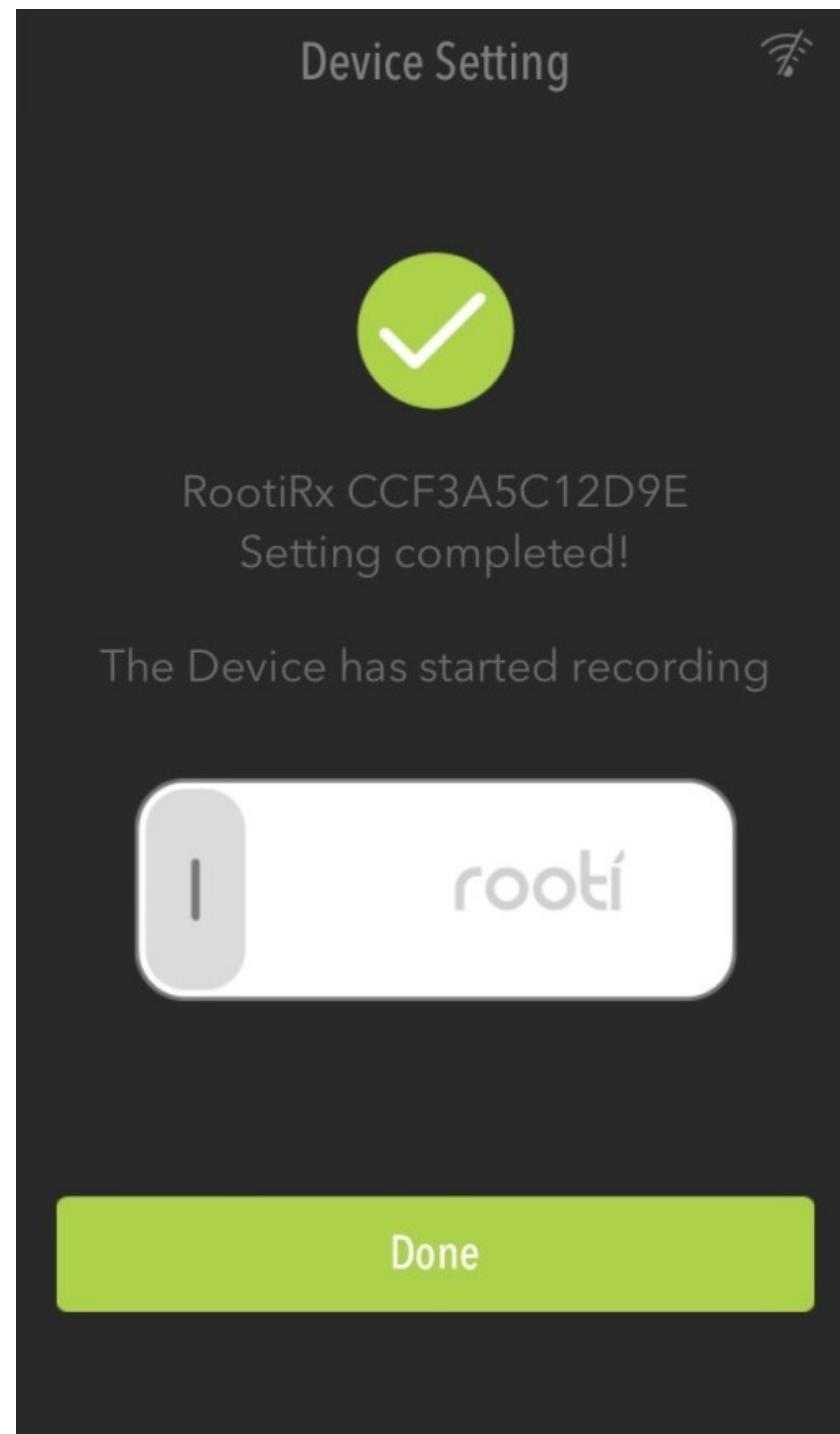


Set up

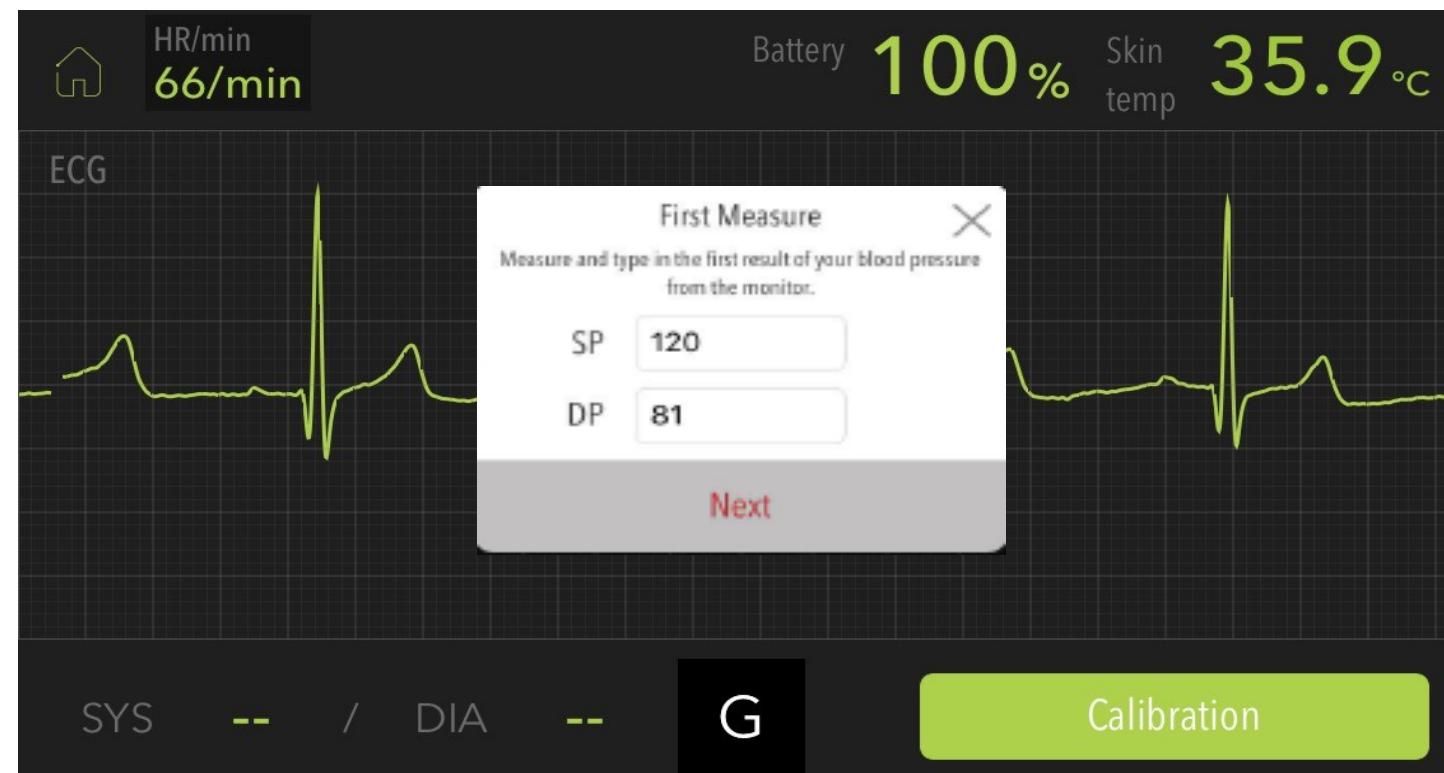
Step 3 : RootiRx assemble and attach



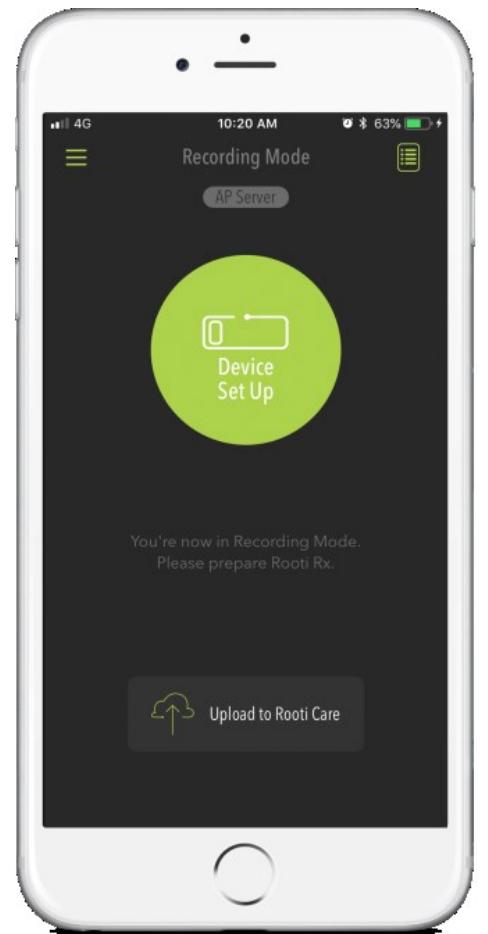
Step 5 : Setting completed !



Step 4 : Conduct BP calibration



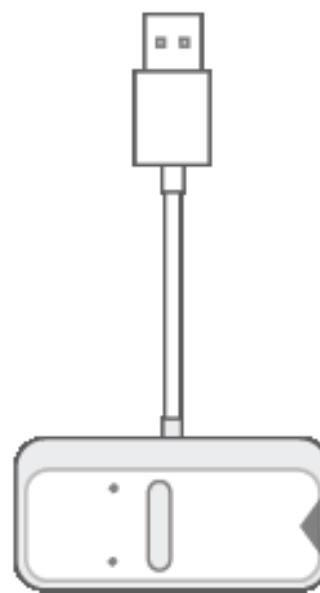
Upload - preparation



- iOS Device



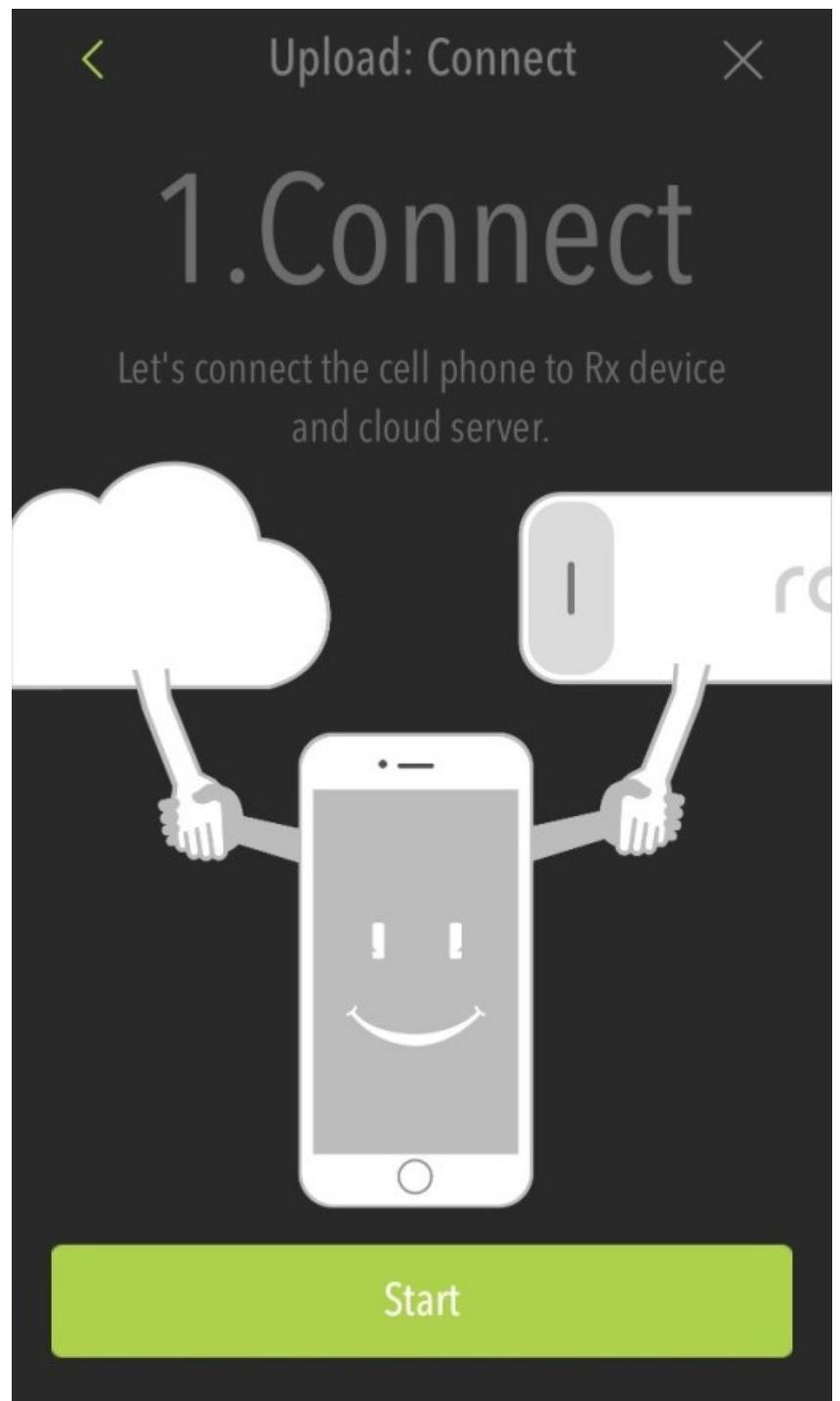
- RootiRx Device



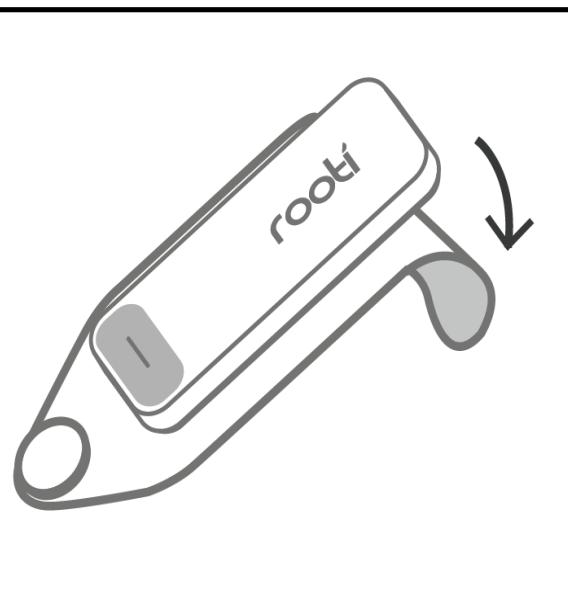
- Charging Dock

Upload

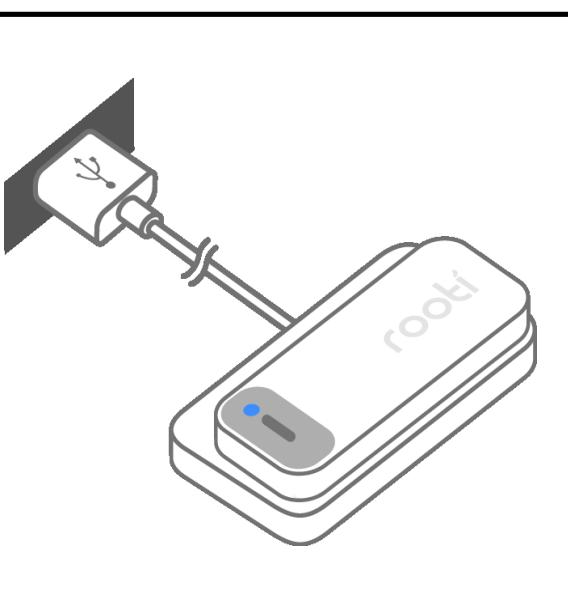
Step 1 : Connect Wi-Fi



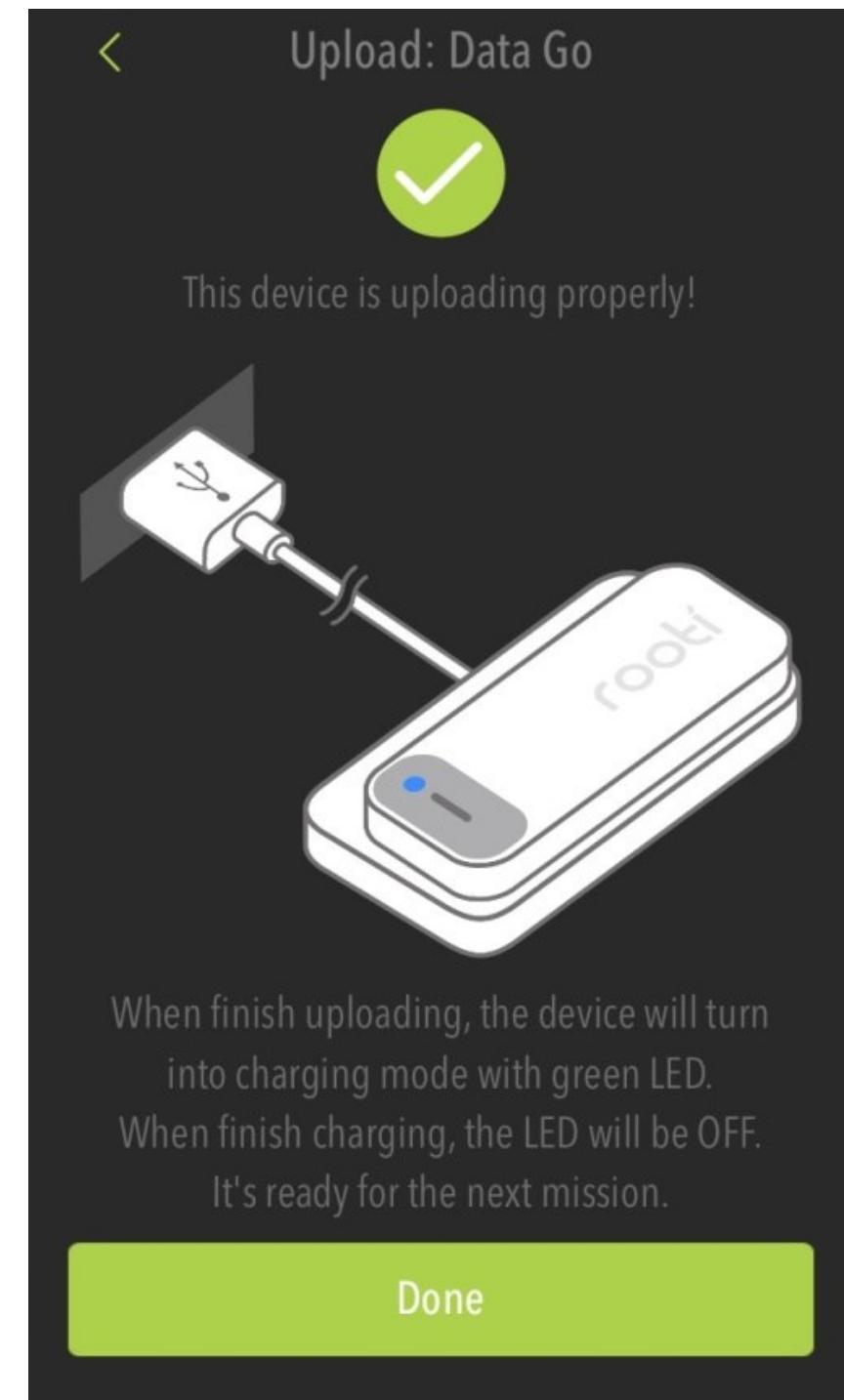
Step 2 : Remove the patch



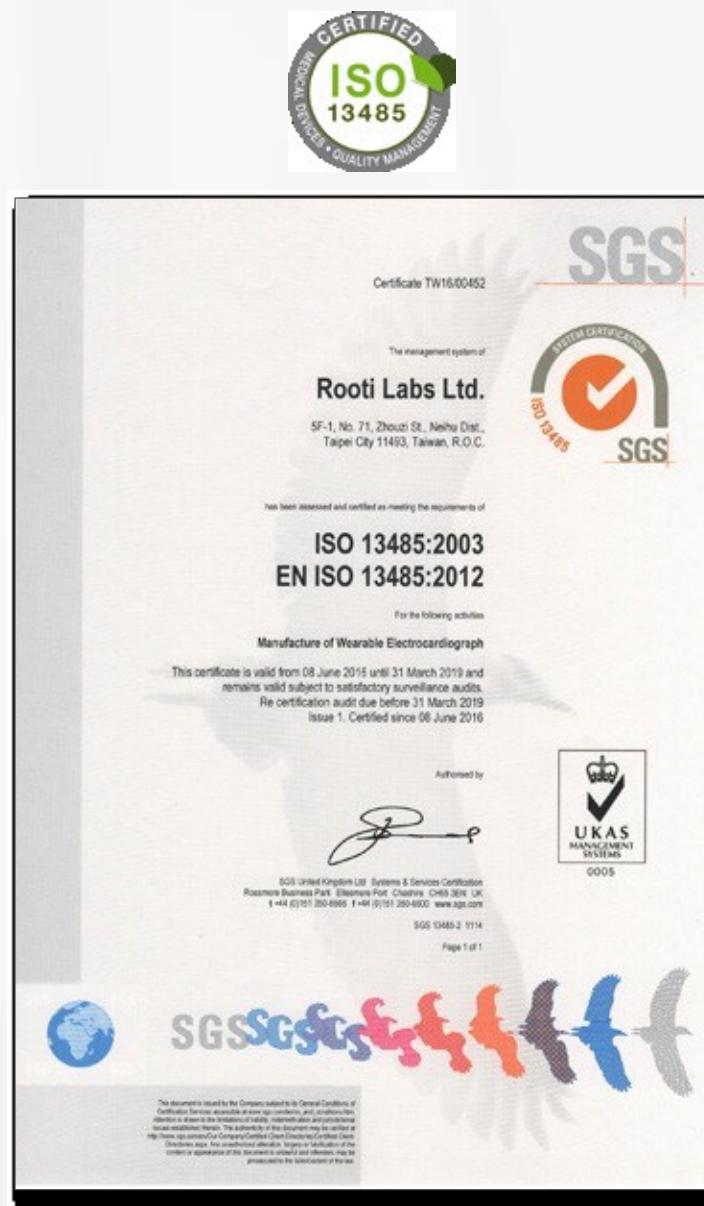
Step 3 : Place into charging dock



Step 3 : Uploading start !

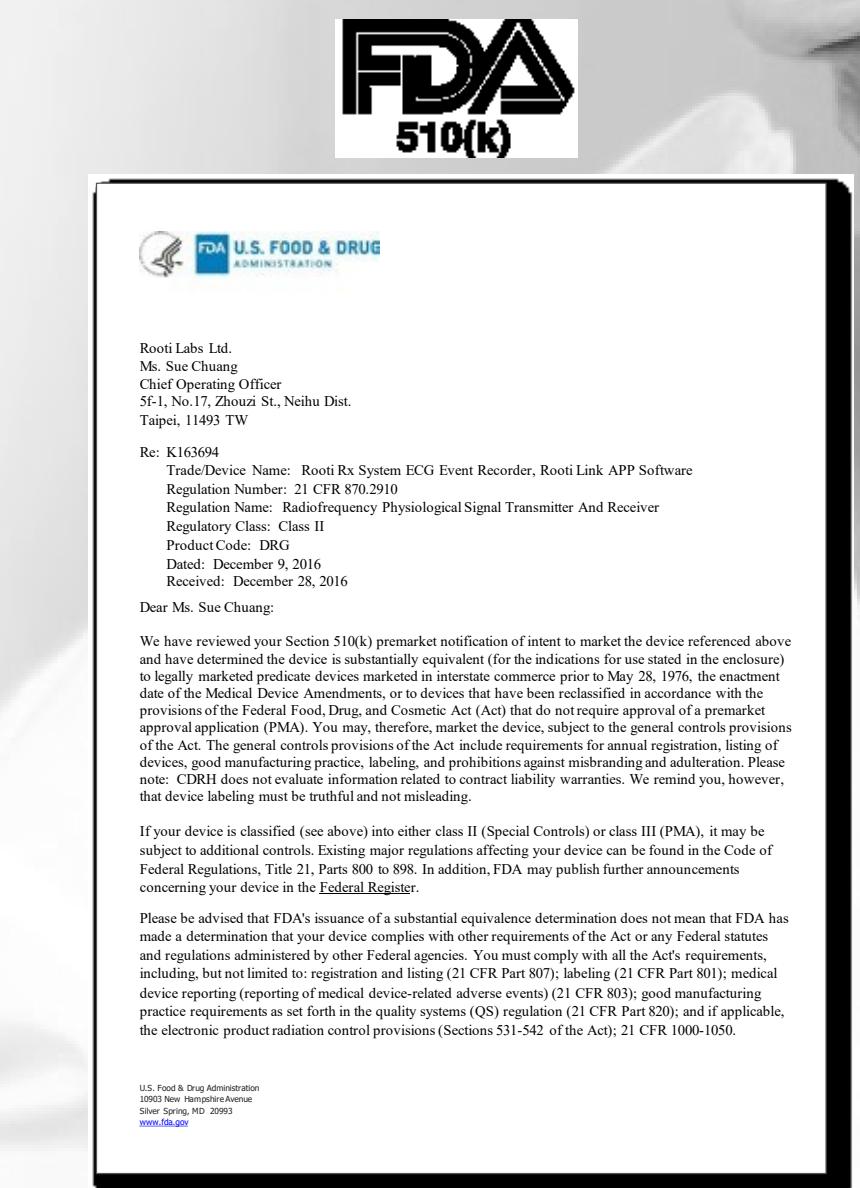


Certifications



ISO 13485 & CE Marking

November 2016



FDA 510k

November 2017



TGA Certificate

March 2018

- ISO13485 approval in 2016, specifies requirements for a quality management system
- CE clearence in 2016, 93/42/EEC Medical Devices Directive, Class IIa, Annex V (production Quality Assurance)
- TFDA Clearance in 2017, Class IIa, Cardiovascular Monitoring Devices
- FDA 510(K) Clearance in 2017, Class IIa, Cardiovascular Monitoring Devices
- TGA approval in 2018, Electrocardiographic Long-term Ambulatory Recorder

Let's Embrace the Future Together.



medical