

Mintti Heartbook-MCT

Intended use:

The device is intended for the use in ECG monitoring at home or healthcare environment on human over 18 years old.

Contraindications:

It should not be used in such cases:

- Pediatric use

People with cardiac pacemakers are forbidden.

Side effects: There are no known side effects.

- Patient Profile

More than 18 years old persons who meet indications but do not meet contraindications.

- User profile

The device is intended to be used by Cardiologist and Cardiac Surgeons on adult patient over 18 years old. The operator must be able to read English.

Major technical parameters A.1.1

Basic parameter

1.Size: 54mm (Length)*61mm(Width)*9.0 mm(Height)

2.Shell material: ABS+antibacterial plastics

3.Net weight: 20g

4. Battery capacity: $\geq 170\text{mAh}$
5. Indicator light status: Flashing, Steady Internal
6. power supply: DC 3.7V
7. Sample rate: 500Hz
8. Charging time : <2 hour
9. Standby time: $\geq 60\text{days}$
10. Continuous monitoring time: $\geq 70\text{h}$
11. Charging voltage: DC 5.0V-0.2A
12. Operating Current: $\leq 20\text{mA}$
13. Data transmission: Bluetooth 4.0
14. Channel number: Single channel
15. IP protection class: Acquisition unit IP22, charging unit IPX0;
16. App Software name: MCT-H1 Software version: 1.1
17. APP software configuration requirements:
 - App system: Smart phone, tablet PC
 - Processor: Dual Core 1.0GHz and above
 - Capacity: 4G and above
 - Memory size: 1G and above
 - Display Screen: 1280×720dpi and above
 - Operation system: Android5.0 and above, IOS 9.0 and above
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A.1.2 Database

The standard database applied for analysis & evaluation in this device is contributed by: MIT Database:

Massachusetts Institute of Technology- Beth Israel hospital database of arrhythmias (48 records, 30 minutes each record)

1.Major Technical Parameters (1)Input dynamic range: The output signal relative input signal discontinuous scale for no larger than 30 μ V.

(2)Input impedance: within full range of frequency single-end input impedance is no less than 2.5M Ω .

(3)System noise: No higher than 30 μ V (p-v) RTI.

(4)Gain control and stability: No more than $\pm 10\%$ of fix gain of the device .

(5)The input signal rebuild accuracy range: 1.25mm ~ 15mm by frequency response when the input is 200ms.

(6)Common-mode rejection: For within 60s duration the output signal ranges no higher than 1 mGV p-vn RTI.

(7)Minimum detection signal: Apparent deflection occurs once a sinusoidal signal 10Hz / 50 μ V (peak value) is applied at a speed of 25mm / s for scanning and recording and with gain 10mm / mV.

(8)Monitoring time: No less than 70h for continuous monitoring. 2.Heart rate

calculation formula For calculating the heart rate, we need filter ECG data by LPF, then apply LPF data for curve integral to obtain the ECG vector whose peak value is further examined, then evaluate RR interval validity to have recent heart rates for an average before reaching the final heart rate.