



Hicardi+®

Mobile Cardiac Telemetry for
central patient monitoring of real-time ECG



Access patient's real-time ECG whenever and wherever *Best-in-class mobile cardiac telemetry for remote monitoring*

HiCardi+® is a wearable medical device to monitor patient's cardiac signs.

- Compact, patch-type electrocardiogram device.
- Allows real-time analysis of 15 different types of arrhythmias.
- Assists physicians in proactive heart disease management.
- Facilitates remote and centralized patient monitoring.

List of arrhythmia detected (15 classifications)

(NSR) Normal Sinus Rhythm

1. (VFIB) Ventricular Flutter/Fibrillation
2. (PVC) Premature Ventricular Contraction
3. (VTAC) Ventricular Tachycardia
4. (BGM) Ventricular Bigeminy
5. (TGM) Trigeminy
6. (CPT) Couplet
7. (TPT) Triplet
8. (SBRD) Sinus Bradycardia

(ASYS) Asystole, EMD

9. (ATAC) Atrial Tachycardia
10. (STAC) Sinus Tachycardia
11. (SVT) Supra-Ventricular Tachycardia
12. (PACED) Paced Rhythm
13. (PAC) Premature Atrial Contraction
14. (AF) Atrial Fibrillation
15. (AFT) Atrial Flutter



HiCardi+® system consists of:

SmartPatch™ (Patch-type electrocardiogram device)

- Built-in algorithm for instant diagnosis of arrhythmias.
- Tracks continuous patient physiological data.
- Wireless data transfer to SmartView™ app via Bluetooth.

SmartView™ (Smartphone application)

- Displays patient's ECG, respiration, heart rate, and skin temperature.
- Delivers vital signs to a data server/cloud using "Gateway" function.
- Enables remote monitoring by HCPs through LiveStudio™.

LiveStudio™ (Cloud-based server accessible via web browser)

- Facilitates remote, real-time monitoring and ECG interpretation.
- Displays status of up to 128 patients on HCPs' computer screen.
- Features include visual and audio alarm and generating physician report.





Electrocardiogram

Measures heart rate accurately with a sampling rate of 500Hz.



Arrhythmia Detection

Identifies 15 arrhythmias in real-time.



Respiration Measurement

Utilizes anti-motion technology for reliable data capture.

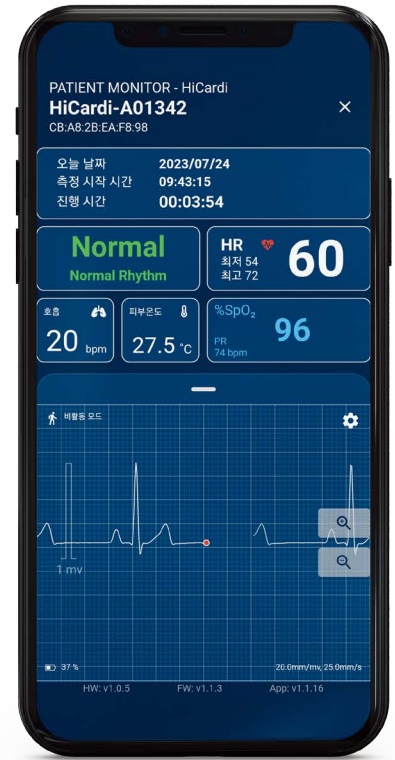


Temperature Monitoring

Measurement of skin temperature.



HiCardi+®



Physician report generated

It displays and records the status of multiple patients in real-time. At times of arrhythmia, records can be revisited for printing and reporting.

Visual and audio alarm

The real-time alarm assists HCPs to take an immediate intervention against critical condition of patients.

Web-based software

Because LiveStudio™ is an Internet browser, it requires no installation. Authorized HCPs can simply access the LiveStudio™ anytime, anywhere.

monitoring mode ▼



screening mode ▼



Why HiCardi+® ?

- Centralized patient monitoring.
- Pre-ECG diagnosis capability as a CE certified medical device.
- Expertise in detecting 15 types of arrhythmia events.
- Simultaneous supervision of multiple patients in a web environment.
- Wireless patch-style design for easy application.
- Reduces workload for HCPs.
- Cost-effective through reusable solutions.
- Compatibility with cardiac defibrillators.
- Tracks posture status, including activities like lying down, walking, and running. *Not a feature of a medical device

Application

Hemodialysis Unit	- Allows immediate response to dialysis emergencies. - Conveniently monitors dialysis patients.
Convalescent Hospital	- Enables efficient bedside patient monitoring. - Facilitates prompt emergency response for specific patients (elderly/self-expression impaired).
Cardiology (CV) /Cardiothoracic Surgery (CS)	- Improves ECG monitoring quality and convenience for patients. - Applicable to inpatients and outpatients undergoing cardiac surgery.
Nuclear Medicine	- Enhances convenience for both healthcare professionals and patients in radioactive isolation beds. - Allows patients to stay active within their isolation rooms. - Reduces the need for medical staff to frequently enter and exit the isolation room.
General Surgery (GS)	Centralizes monitoring of post-operative patients.
Pediatric	Approved for use in pediatric patient care.
Rehabilitation	Assist in managing rehabilitation patients with activity monitoring. *Not a feature of a medical device

Arrhythmia detection accuracy

ACCURACY (AHA DB)		SENSITIVITY	PREDICTIVITY
Beat by Beat	Ventricular ectopic beat	91.21%	90.37%
Run by Run	Ventricular couplet	92.28%	83.40%

Based on the database such as Minnesota code, AHA, MIT-BIH, ESC, NST, CU, Ohio ECG/Diabetes database, and DIANO.

Wearable ECG devices have demonstrated their non-inferiority in detecting arrhythmia when compared to the current standard of care.¹

¹ Kamga P, Mostafa R, Zafar S. The Use of Wearable ECG Devices in the Clinical Setting: a Review. *Curr Emerg Hosp Med Rep*. 2022;10(3):67-72. doi: 10.1007/s40138-022-00248-Epub 2022 Jun 25. PMID: 35789964; PMCID: PMC9244148

Product specification

Product name	HiCardi+® SmartPatch™
Type	Reusable smart patch
HR range	0, 15-300 beats per minutes
HR accuracy	±2bpm or ±2% whichever is greater
Temperature	32-43°C (±0.3%)
Respiration	0, 5-60 or 120 (±2bpm or ±2 %)
Battery time	72 hours (1-2 hours charging)
Water protection	IP67
Memory	Up to 7 days (optional)
Weight	Less than 17g (0.6oz)

Certification

HiCardi+® is a medical device intended for use by qualified healthcare professionals for the assessment of arrhythmias using ECG data in subjects of neonates, infants, pediatric, and over 18 years of age depending on country of sales. Medical Device Class II certified by MFDS in Korea. Class IIa in Europe (CE2265) in compliance with the Medical Device Directive (MDD 93/42/EEC amended by 2007/47/EC). 510K with Class II in the USA is currently being cleared.

Slim and lightweight design of HiCardi+® resolves the inconvenience of patient wearing a conventional MCT, while accurate diagnosis is secured with advanced anti-motion filtering technology, reducing artifacts.