Miniature Wireless Cardiac Monitor

Matthew Tarler, Ph.D., Don Adams, John Pao, Jay Eiger

Cleveland Medical Devices Inc, Cleveland, OH

CleveMed
Cleveland Medical Devices Inc.

877-CLEVEMED
WWW.CLEVEMED.COM

Specific Aim

The specific goal of the proposed program was to develop the Heart Doc™, a miniature, wireless, ECG (electrocardiogram) monitoring system. This Heart Doc system, self-dubbed the "next generation of holter monitors", consists of three primary components: the Heart Doc monitoring unit, the Heart Doc docking station, and the Cardiac Patch. The Heart Doc monitoring unit mounts directly to the custom Cardiac Patch for acquiring the ECG signal and is placed in the Heart Doc docking station for downloading the data and recharging the battery. The Heart Doc monitoring unit also has Bluetooth™ capability built-in for sending event data through a Bluetooth enabled cell phone, streaming real-time data to a computer unit, and downloading the data if a docking station is not available.

Hardware

Heart Doc
- Size: 1.5" x 2.5" x 0.7"
- Weight: <40 grams
- Channels: 2 differential
- Sampling Rate: 1,000 S/s each channel
- Resolution: 12 bit
- Two-axis accelerometer
- Batt. Life: 48 hrs typical (min 36 hrs)
- Mem. Life: 48 hrs typical (min 36 hrs)
- Bluetooth module for wireless data link

Patch
- Size: 7.5" x 5.25" x 0.06"
- Number of Electrodes: 4 (min 2)
- Self Adhesive
- Defib Tested
- Typ. Wear Time: 24 hrs (72 hrs tested)

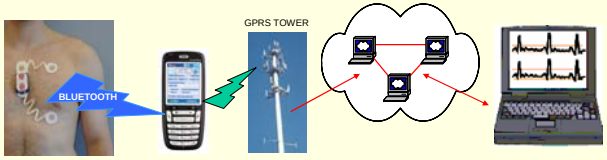
Docking Station
- Size: 7.5" x 5.25" x 0.06"
- USB
- Downloads Data
- Recharges Battery

Cell Phone w/Windows Mobile (Audiovox SMT 5600)
- Size: 4.24" x 1.82" x 0.69"
- Weight: 3.6 oz
- Battery: 1050 mAh LiIon
  - Standby: 6 days - Talk: 4 hrs.
- Built-in Bluetooth
- Mini SD Card (1GB added)

Modes of Usage (Tested and Validated)

Heart Doc Patch → docking station → PC

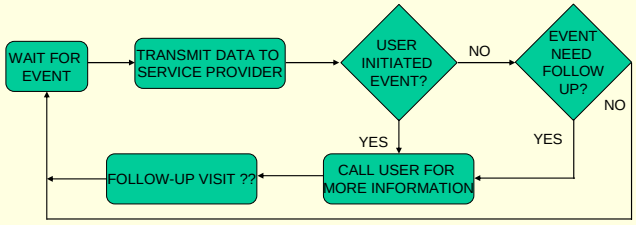
Heart Doc Patch → Trigger* → BlueTooth → PC (near real-time)



Heart Doc Patch → Trigger* → BlueTooth → Phone → GPRS tower → Internet → Server

* Trigger ('Automated' or 'Manual') transfer preset amount of data (programmable) starting a pretrigger amount of time before the event (also programmable).

Remote Patient Monitoring



DISADVANTAGE: Auto trigger results in more data/calls into the service center

ADVANTAGE: The user is not aware of calls and therefore less data and less time is needed.

Clinical Data

Automated Event Trigger

Clinical Performance (Tested against MIT Arrhythmia and Atrial Fibullation databases)

Atrial Fibrillation Detection
- Sensitivity: 87.07%
- Positive Predictivity: 32.39%
- Beat to Beat: > 93%

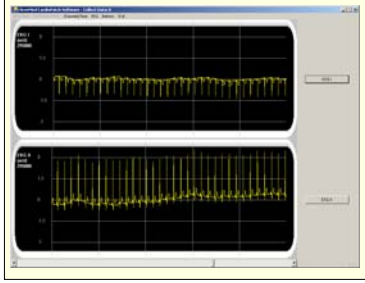
Arrhythmia Detection
- PVCs: 97.35%
- (plus detection of Bradycardia/ Tachycardia/Asystole)

Hardware Performance

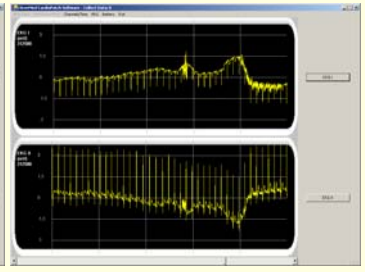
Size: 40 KB (AFIB, PVC, Brady, Tachy, Asys)
27 KB (AFIB only)
Time: 6 sec per 30 seconds of data
Algorithm – 1.9 sec
RAM access – 4 sec

ECG Data

Example of typical ECG data.



Example of typical ECG data with movement artifact



Conclusions

We have developed this miniature wireless cardiac monitor that has Bluetooth capability and the arrhythmia detection algorithms. We have successfully tested and demonstrated the system in many paradigms. The system is capable of storing data for USB download or Bluetooth data transfer for back-up or real-time monitoring. The arrhythmia algorithms were tested on a companion computer both off-line (during data transfer) and during real-time. The Heart Doc system was also tested on multiple volunteers with excellent results. The ECG signals were not found to be any different than recordings made from standard holter monitoring equipment. The ECG analysis was also found to be significantly better than the methods used by standard holter monitors when tested on the data from the MIT arrhythmia database. We will continue the testing of the Heart Doc system, especially testing the arrhythmia detection algorithms on actual subjects with cardio-vascular disease, and finish some of the final packaging of all of the advanced features.

Acknowledgments

This work was supported by NIH SBIR Grant No. 5R44HL65024-02