

Multi-Parameter Vital Signs Monitor

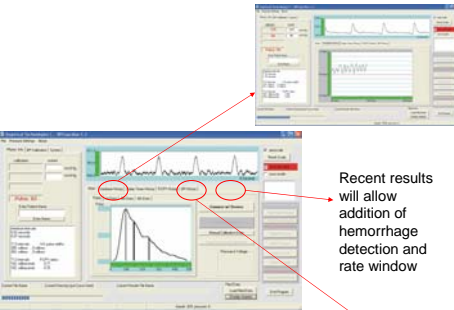
WITH A SIMPLE DEVICE: CareTaker™
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 Empirical Technologies Corporation

CARETAKER SYSTEM



Present System Future System*

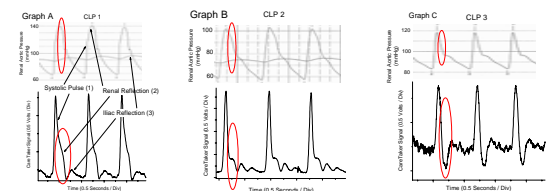
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|--------------|------------------------|-----------|
| •Lightweight | 5 ounces | <3 |
| •Long life | 12 hours | 100 |
| •Small | xx inches ³ | 3 |
| •Radio | Bluetooth | Bluetooth |
| •Range | 100m Line of sight | 100 |



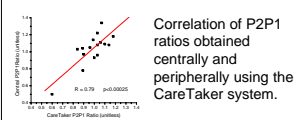
*CareTaker later this year

- Palm sized system with finger cuff about 2" diameter and 1/2" in height
- On board analysis and data storage
- LCD for radio free use
- Virtual charts and notes for uploading to PC, PDA, smart cell phones
- Plug and play oximeter
- Provides warnings of out-of-range parameters such as tachycardia
- Provides inputs to infusion systems

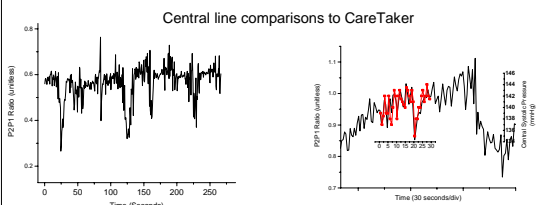
BEAT-BY-BEAT Tracking of Central Systolic and Diastolic BLOOD PRESSURE But, without hoses and a heavy battery



Comparisons of pulse line shapes obtained with a central line catheter (top charts) with simultaneously obtained CareTaker derivative pulse line shapes. Of particular interest is the size of the renal reflection (red circles). The relative amplitudes of systolic peak and renal reflection obtained centrally match those obtained peripherally.



P2P1
 P2P1 is the ratio between the amplitude of the primary systolic peak, P1, and the second systolic peak (the first reflection), P2.

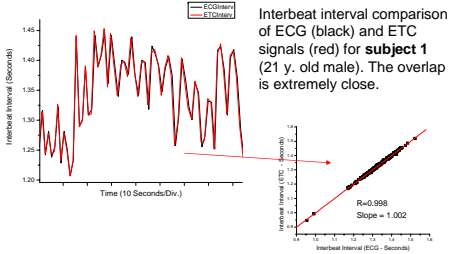


In more than half the patients there were periodic significant variations in systolic blood pressure as measured by CareTaker. Shown above is a data stream extending four minutes showing a series of these drops, some lasting more than half a minute and extending over 20 or so heartbeats. The majority of these decreases were missed by the catheter observation time window because the protocol only allowed 18 seconds of quiet observation at the renal artery region.

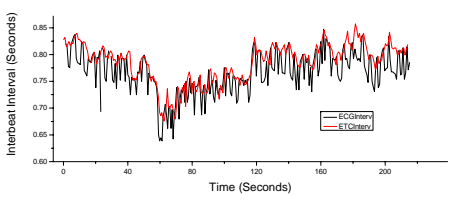
Shown above is an overlay of CareTaker's P2P1 signal (black) with the overlap of the catheter derived aortic systolic blood pressure signal (red dots) during the allowed 18-second observation window (red trace). An event, as described on the left panel, is simultaneously recorded and verified to be real. Another similar event was verified among 23 trials and in both standing and sleeping subjects.

Verifications also include the first two hours of dialysis for 43 patients, Valsalva, and cold pressor experiments. Simultaneous data has been obtained with finapres, Finometer, Colin Pilot, and numerous blood pressure cuffs systems, auscultatory and oscillometric. Recent tests on patients with confirmed aneurysms, showed that CareTaker was able to detect and locate them.

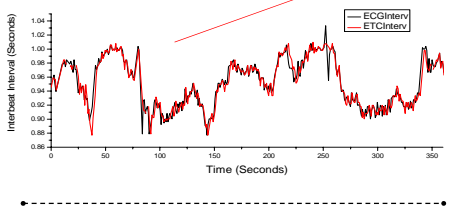
HEART RATE as accurate as an ECG But without the wires



Interbeat interval comparison of ECG (black) and ETC signals (red) for **subject 3** (65 male with right side bundle branch block). While the trend in both signals is the same, the detailed overlap is very poor.



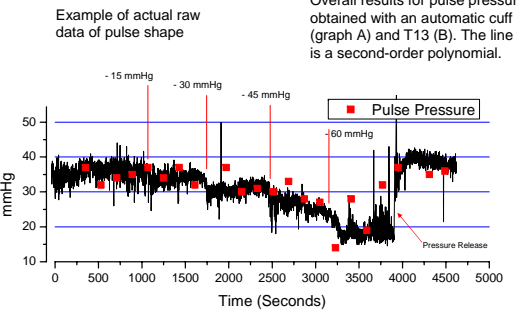
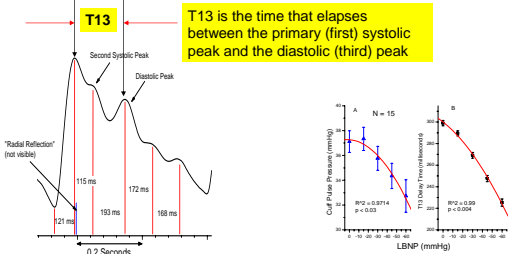
Overlap of interbeat intervals obtained with ECG (black) and ETC sensor (red) for **subject 4**, a 70 y. male with a pacemaker. Again, the trends are identical in both traces.



Subject 2, is a 47 year old male. The linear regression results are $R = 0.996$ and the standard deviation is 6.54 milliseconds

The First Portable Device for Monitoring and Tracking HEMORRHAGE

CareTaker measures T13 for each detected pulse. T13 is normally about 300 msec for healthy adults. Under simulated hemorrhaging using a lower body negative pressure chamber (LBNP), T13 decreases, nearly linearly, to about 200 msec for a hemorrhage volume of about one liter.



PLANNED TESTING PROGRAM

- Observe T13 for 50 volunteers at a blood donation clinic during the removal of one pint of blood.
- Observe the T13 and P2P1 parameters of 50 patients in a medical intensive care unit that have catheters. Many of these will experience abdominal bleeding and others will be recovering from very invasive surgery.

Acknowledgements

ONR SBIR Phase II with options, N0001404C0204, *Anti-Terrorism-Consequence Management and Recovery*, for a first responder health protection system

NHLBI SBIR Phase I, *Continuous BP Monitor for dialysis applications*, 1R43HL087476-01A1; 80 patients undergoing dialysis and 20 patients with arterial and aortic catheters

OTCC/CAT at California State University, San Bernardino, building of multiple CareTaker prototypes and marketing studies

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