

**Horizon Scan Report 0001****28 January 2009****Diagnostic Technology:**

Handheld HeartScan ECG monitor for detecting Atrial Fibrillation in Primary Care

**Clinical Question:** In community-based settings, do handheld ECG monitors accurately diagnose patients with atrial fibrillation compared to routine practice.

**Device:** Omron HeartScan HCG-801

**Advantages over Existing Technology:**

The Omron HeartScan HCG-801 is a portable, compact, cordless, single-channel ECG which connects to a PC to provide instant rhythm interpretation. It can be used instead of 12 lead ECG recordings for assessment of basic arrhythmias. In addition the HeartScan offers the possibility of long-term rhythm monitoring in contrast to 24-hour Holter systems which record actual events. Continuous measurement devices also require discipline and inconvenient electrodes and wires for the patient. Implanted reveal devices are also available, but require a minor invasive procedure and are therefore more expensive and less appealing for patients.

**Details of Technology:**

The HeartScan has a finger electrode and a chest electrode and is held against the chest during measurements. The device can record about 30 seconds of heart rhythm and waveform each time it is activated. After recording, the automatic evaluation software will check the collected data. Directly after completing the measurement the recorded rhythm strip can be reviewed on the LCD screen. For further detailed evaluation the data can be transferred to a PC screen with the ECG-viewer software. The SD memory card can store up to 300 recordings offering sufficient space for long-term monitoring.

**Patient Group and Use:**

- Patients exhibiting symptoms with a strong suspicion of an arrhythmic cause, but who are a diagnostic challenge
- Prognosis using arrhythmia detection or measurement of heart rate variability in patients with no symptoms
- Assessing efficacy of antiarrhythmic therapy
- Assessing pacemaker and implantable cardioverter-defibrillator function
- Detecting myocardial ischemia

**Importance:**

Atrial fibrillation (AF) is a major risk factor for stroke and the prevalence in patients  $\geq 75$  years in primary care is 10%. Widespread use of anticoagulants in these patients could greatly reduce the incidence of stroke but many patients are untreated. Diagnosis for patients who present with AF in primary care is done by detection of an irregular pulse. The sensitivity of pulse palpation is over 90% in all groups, but the specificity of this method falls to 71% in the elderly. Due to the low specificity current detection requires a 12 lead ECG, this often requires an additional appointment in the GP surgery or in the hospital (many GP surgeries do not do routine ECGs). Rapid, accurate point of care diagnosis of AF would be a benefit to both patient and the GP and a portable device could facilitate immediate diagnosis both in surgery and during home visits. Active screening for atrial fibrillation detects additional cases over current practice. The preferred method of screening in patients aged 65 or over in primary care is opportunistic pulse taking with follow-up ECG. Atrial fibrillation or flutter fulfils most of the criteria set out by Cuckle and Wald for a worthwhile screening programme (5).

**Previous Research:**

1. A prospective validation of the OMRON HeartScan ECG monitor for the detection of arrhythmias showed the OMRON HeartScan ECG monitor had a sensitivity of 99% and specificity of 96% for detection of atrial fibrillation (6).
2. Prospective comparison of the diagnostic utility of a standard event monitor versus the OMRON HeartScan portable ECG monitor in the evaluation of 18 patients with palpitations showed that all 18 individuals were compliant with the

OMRON monitor for the 30-day period while only 14 (78%) patients were compliant with the standard event monitor ( $p=0.10$ ). During a combined monitoring period of 563 days, 159 symptomatic episodes were recorded with the OMRON ECG monitor ( $8.8\pm 9.7$  per patient, range 1–35) and 169 symptomatic episodes were recorded with the event monitor ( $12\pm 8.3$  per patient, range 1–33) ( $p=NS$ ). The OMRON monitor recorded arrhythmias in 13 of 18 patients (72%) and the standard event monitor recorded arrhythmias in 8 of 14 patients (57%) ( $p=NS$ ). The OMRON monitor was associated with high patient compliance and resulted in high quality ECG (7).

Buyers' Guide, NHS Purchasing and Supplies agency: Patient-activated ECG event recorders. CEP09007. April 2009.

### Research Questions:

To test the feasibility of screening for AF using the OMRON HeartScan ECG monitor in Primary Care

### Suggested next step:

- 1) Cross sectional study of accuracy in primary care
- 2) Multi-centre cluster randomised controlled trial

### Expected outcomes:

Single-lead patient-activated ECG systems are easy to use and have a high diagnostic accuracy for the detection of atrial fibrillation and other arrhythmias. Single-lead ECG systems may also help to improve rapid and accurate diagnosis of transient ECG changes, e.g. in patients with palpitations, syncope, or other unexplained transient cardiac symptoms.

### Policy Context Comments:

This technology is relevant to the supplementary chapter on 'Arrhythmias and Sudden Cardiac Death' added into the CHD NSF in 2005 and, more recently, to the National Stroke Strategy (2007). For NHS commissioners the technology also links to the 18-week commissioning pathway for palpitations. The patients attending for screening as a result of the DH Vascular Programme represent a population to which this technology could be easily be applied – perhaps after triage using the recently developed risk score for atrial fibrillation (Lancet, February 28th, 2009) and in conjunction with Ankle-Brachial blood pressure assessment.

### Other Devices on the market:

DailyCare BioMedical (ScanMed Medical) Readmyheart handheld ECG monitor (CE Marked; Validation not found)  
Card Guard 1-Lead ECG Event Recorder CG-2206 (Validation not found)

### References:

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3. Fitzmaurice DA, Hobbs FD, Jowett S, Mant J, Murray ET, Holder R, Raftery JP, Bryan S, Davies M, Lip GY, Allan TF. 2007. Screening versus routine practice in detection of atrial fibrillation in patients aged 65 or over: cluster randomised controlled trial. *BMJ*. 335(7616):383.
4. Sudlow M, Rodgers H, Kenny RA, Thomson R. 1998. Identification of patients with atrial fibrillation in general practice: a study of screening methods. *BMJ*. 317:327-8.
5. Cuckle HS, Wald NJ, Lindenbaum RH. 1984. Maternal serum alpha fetoprotein measurement: A screening test for Down syndrome. *Lancet*. i:926-9.
6. Kaleschke G, Willems S, Naebauer M, Goette A, Meinertz T, Steinbeck G, Breithardt G, Kirchhof P. 2008. Prospective, multi-centre validation of a simple, patient-operated ECG system for the detection of arrhythmias and ECG changes. ESC Poster AFNET OMRON Kaleschke
7. Scherr D, Dalal D, Henrikson CA, Spragg DD, Berger RD, Calkins H, Cheng A. 2008. Prospective comparison of the diagnostic utility of a standard event monitor versus a "leadless" portable ECG monitor in the evaluation of patients with palpitations. *J Interv Card Electrophysiol*. 22(1):39-44.

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