This technology summary is based on information available at the time of research and a limited literature search. It is not intended to be a definitive statement on the safety, efficacy or effectiveness of the health technology covered and should not be used for commercial purposes.

The National Horizon Scanning Centre Research Programme is part of the National Institute for Health Research Technology for patient group
HeartSmart® for cardiac dynamic monitoring

Target group
- Patients requiring cardiac dynamic monitoring in:
  - General intensive care units
  - Neuro-intensive care units
  - Open heart surgery or corrective open heart surgery
  - Sepsis and or shock, or other post operative or medical complications and entering into general intensive care units
  - Major general surgery or medical procedures
  - Assessment of pulmonary artery pressures prior to operations on the liver.

Technology description
HeartSmart is a new technology using empirical physiological algorithms embedded into a software program designed to perform cardiac dynamic monitoring in real time. Encoded within HeartSmart are algorithms which define relationships between all key blood flow variables. The external physiological parameters required by HeartSmart are: heart rate, central venous pressure, blood pressure, and core body temperature. These parameters are measured by standard pre-existing hospital equipment such as the central venous catheter (CVC) inserted into the vena cava. Readings are inputted into HeartSmart manually as existing monitoring systems have unique and secure computer coded outputs which cannot be read by third-party monitoring systems.

HeartSmart provides information on absolute or index values, cardiac index, pulmonary and systemic vascular resistance indexes with mean pulmonary artery and mean pulmonary artery occlusion (wedge) pressures, and all haemodynamic variables. Optimisation of patient blood flow and fluid management is achieved by adjustments of cardiac preload, afterload, and contractility to balance oxygen delivery with oxygen demand (goal directed therapy$^1$).

In addition to HeartSmart software, the company plans to develop and market HeartSmart hardware (HeartSmart algorithms embedded into a microchip, and HeartSmart dedicated haemodynamic monitor) which could allow true continuous cardiac dynamic monitoring.

Innovation and/or advantages
- Cardiac dynamic monitoring using HeartSmart is less invasive than alternatives such as pulmonary artery catheter thermodilution (PACTD).
- Effects of changes in management can be seen immediately.
- Pre-operative optimisation of oxygen delivery and cardiac output in major elective surgery could lead to a significant and cost effective improvement in perioperative care$^{2,3}$.

Developer
HeartSmart Limited
Place of use

- Home care e.g. home dialysis
- Community or residential care e.g. district nurses, physio
- Secondary care e.g. general, non-specialist hospital
- Tertiary care e.g. highly specialist services or hospital
- Primary care e.g. used by GPs or practice nurses
- General public e.g. over the counter
- Other:

Availability, launch or marketing dates, and licensing plans:
CE marked and available in the UK from APC Cardiovascular Limited

NHS or Government priority area:
This technology could be relevant to numerous National Service Frameworks and government priority areas, including cardiovascular disease and cancer.

Relevant guidance
NICE technology appraisal

Clinical need and burden of disease
Given that no routine data are collected, it is difficult to estimate how many catheters are placed each year. According to one report, it is estimated that approximately 200,000 central venous access procedures are performed each year in the NHS; however the company believes that this figure is much higher.

Existing comparators and treatments
- Pulmonary artery catheter thermodilution (PACTD): considered as a reference standard in cardiac haemodynamic monitoring. This involves invasive temperature measurements made from the tip of a catheter inserted into the pulmonary artery. This technique can be problematic and sometimes fatal, and is associated with increased risk of arrhythmias during insertion, infections, thrombotic complications, and occasionally pulmonary artery rupture. A systematic review of the literature found that there is no evidence of benefit or harm from the use of a pulmonary artery catheter.
-Indicator dilution techniques: transpulmonary thermodilution (PiCCO, Pulsion), transpulmonary lithium dilution method (LiDCO), pulmonary artery catheter based continuous thermodilution (Vigilance, Baxter; Opti-Q, Abbott; and TruCCOMs, Aortech).
- Echo-Doppler ultrasound: measures blood flow through the aorta, making assumptions to blood flow through the heart chambers and valves.
- Impedance cardiology (ICG): an electrical current is transmitted through the chest and seeks the path of least resistance through the blood filled aorta. ICG measures the baseline impedance and subsequent impedance changes after each heart beat. Changes in impedance are used with an ECG to provide haemodynamic data.
- Fick principle: the NICO (Novametrix) system applies Fick’s principle using CO₂ as the substrate instead of oxygen:
  \[
  \text{Cardiac Output} = \frac{\text{oxygen consumption}}{\text{arteriovenous oxygen content difference}}
  \]
This is a non-invasive method used to determine cardiac output requiring airway gas measurements only.
- Arterial pulse contour analysis: PiCCO (Pulsion), PulseCO (LiDCO) and Modelflow (TNO/BMI). Cardiac output is estimated by relating an arterial pressure or pressure
difference to flow or volume change. Each method requires specific calibration and uses an invasively measured arterial blood pressure.

Most of the above require the patient to be under general anaesthetic. None of the above cardiac output techniques provide all desirable parameters: accuracy, reproducibility (precision), fast response time, operator independency, ease of use, continuous use, cost effectiveness, and no increased mortality or morbidity.

**Efficacy and safety**

There are numerous trials ongoing or planned comparing HeartSmart with current technologies in: general intensive care; burns units; bariatric surgery; neurosurgery; obstetrics; organ donor patients; paediatric transoesophageal monitoring.

**Estimated cost and cost impact**

A single set of HeartSmart measurement costs approximately £10-£15 depending on the type and volume of the purchased licence. The licence is delivered electronically from the HeartSmart centre to the clients HeartSmart program enabling the desired number of measurements to be used. HeartSmart costs around £400 for installation and set-up, not including ongoing site maintenance.

The company estimate that for every 1,000 major surgical procedures performed, about a quarter of the patients may require central venous pressure monitoring with each patient requiring 3 to 4 HeartSmart measurements.

HeartSmart has no capital equipment or disposable consumable costs, has no maintenance requirements, and free on site training is provided.

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<th><strong>Existing comparator costs</strong></th>
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<td><strong>Current technology</strong></td>
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<tr>
<td>PACTD</td>
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<td>Central venous catheter</td>
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**Potential or intended impact – speculative**

**Patients**

✔ Reduced morbidity 
✔ Reduced mortality or increased survival 
☐ Improved quality of life for patients and/or carers 
☐ Non identified 

☐ More accurate monitoring of patient condition 

**Services**

☐ Increased use 
☐ Service reorganisation required 
✔ Staff or training required 
☐ Other: 
☐ Non identified 

☐ Decreased use 
☐ Other: 
☐ Non identified
Costs

- Increased unit cost compared to alternative
- New costs
- Increased costs: more patients coming for treatment
- Savings: reduced stay in ITU
- Increased costs: capital investment needed
- Other: Length of stay reduced in non-critically ill patients.

References


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