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CardioQ-ODM oesoph ageal doppler monitor

NICE medical technology guidance 3
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CardioQ-ODM oesophageal doppler monitor

You can download the following documents from http://www.nice.org.uk/guidance/MTG3

- The NICE guidance (this document).
- A lay summary of the guidance for patients and carers
- Details of all the evidence that was looked at and other background information.

This guidance represents the view of NICE, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

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NICE medical technology guidance addresses specific technologies notified to NICE by manufacturers. The ‘case for adoption’ is based on the claimed advantages of introducing the specific technology compared with current management of the condition. This ‘case’ is reviewed against the evidence submitted and expert advice. If the case for adopting the technology is supported, then the technology has been found to offer advantages to patients and the NHS. The specific recommendations on individual technologies are not intended to limit use of other relevant technologies which may offer similar advantages.

1 Recommendations

1.1 The case for adopting the CardioQ-ODM in the NHS, when used as described in 1.2, is supported by the evidence. There is a reduction in post-operative complications, use of central venous catheters and in-hospital stay (with no increase in the rate of re-admission or repeat surgery) compared with conventional clinical assessment with or without invasive cardiovascular monitoring. The cost saving per patient, when the CardioQ-ODM is used instead of a central venous catheter in the peri-operative period, is about £1100 based on a 7.5-day hospital stay.

1.2 The CardioQ-ODM should be considered for use in patients undergoing major or high-risk surgery or other surgical patients in whom a clinician would consider using invasive cardiovascular monitoring.

2 The technology

Description of the technology

2.1 The CardioQ-ODM (Deltex Medical) is an oesophageal doppler monitor that assesses cardiac output and intravascular fluid status.
2.2 Oesophageal doppler monitoring is undertaken with a single-use probe, which is placed in the oesophagus via the mouth or nose. The device generates a low-frequency ultrasound signal, which is reflected by red blood cells travelling down the aorta. By applying the doppler principle, the reflected signal can be used to determine flow velocity. A validated nomogram is used to derive volumetric data such as stroke volume and cardiac output. Fluid management during surgery is guided by the use of the CardioQ-ODM to monitor changes in stroke volume following repeated fluid challenges. This approach can correct functional hypovolaemia, which is often present before surgery, and can optimise intravascular volume.

2.3 The cost of the CardioQ-ODM is approximately £11,000. The cost of probes varies depending on the intended length of use. The average cost of a probe is approximately £67 for patients undergoing surgery and approximately £118 for patients in the critical care unit. The cost of the CardioQ-ODM and probes may vary because of differences in purchasing contracts.

**Current management**

2.4 Optimising intravascular volume and cardiac output is essential to ensure adequate organ perfusion in patients who are undergoing major surgery or who are critically ill.

2.5 Cardiac output is monitored using a variety of techniques, such as inserting a pulmonary artery catheter or using systems based on pulse contour analysis and dye dilution. Less invasive methods include trans-oesophageal echocardiography and measuring thoracic electrical bioimpedance. These techniques are combined with conventional clinical assessment. In some cases a central venous catheter is inserted to measure cardiac pre-load.
3 Clinical evidence

3.1 Clinical outcomes relevant to the use of the CardioQ-ODM are mortality, peri-operative complications, reductions in the use of central venous catheters, length of critical care and in-hospital stay and re-admission rates. Full details of all clinical outcomes considered by the Committee are available in the assessment report at http://guidance.nice.org.uk/MT/80

Patients undergoing surgery

3.2 Wakeling et al. (2005) reported a trial of 124 patients undergoing bowel surgery, which found that the median hospital stay after surgery was 10 days when the CardioQ-ODM was combined with central venous pressure monitoring compared with 11.5 days in the control group who had central venous pressure monitoring alone (p = 0.031). The median difference in time to fitness for discharge was 1.5 days in favour of the CardioQ-ODM (p = 0.012). Noblett et al. (2006) reported a study of 108 patients undergoing bowel surgery and found the median post-operative stay was 7 days when the CardioQ-ODM was combined with central venous pressure monitoring compared with 9 days in the control group who had central venous pressure monitoring alone (p = 0.003). The median time to fitness for discharge was 6 days for the CardioQ-ODM monitoring compared with 9 days for the control group (p = 0.003).

3.3 Mythen et al. (1995) reported a trial of 60 patients undergoing cardiac surgery, which found that the mean length of hospital stay was 6.4 days when the CardioQ-ODM was combined with central venous pressure monitoring compared with 10.1 days in the control group who had central venous pressure monitoring alone (p = 0.011). The mean length of stay in the critical care unit was also reduced by 0.7 days (1 day versus 1.7 days, p = 0.023).
3.4 Gan et al. (2002) reported a trial of 100 patients undergoing gynaecological or urological surgery, which found the median hospital stay was 6 days when the CardioQ-ODM was combined with central venous pressure monitoring compared with 7 days in the group with central venous pressure monitoring alone (p = 0.03). The difference in mean length of hospital stay was 2 days.

3.5 Venn et al. (2002) reported a three-arm trial of 90 patients undergoing surgery for fractured neck of femur, which compared CardioQ-ODM monitoring with central venous pressure monitoring and with conventional assessment. The mean time to fitness for discharge was 7.7 days (95% confidence interval [CI] 5.9 to 12.3 days) in the CardioQ-ODM group, 10 days (95% CI 8.1 to 12.0 days) in the central venous pressure group, and 13.9 days (95% CI 11.9 to 16.9 days) in the conventional assessment group (p = 0.035). The mean length of hospital stay was 13.5 days (95% CI 10.9 to 17.5 days) in the CardioQ-ODM group, 13.3 days (95% CI 10.3 to 19.2 days) in the central venous pressure group and 17.5 days (95% CI 13.9 to 24.4 days) in the conventional assessment group (p = 0.27). Sinclair et al. (1997) reported a study of 40 older adults undergoing surgery for fractured neck of femur, which found that mean acute hospital bed stay was 10 days in the group who had CardioQ-ODM monitoring compared with 17 days in a group who had conventional assessment (p < 0.05). A 6-day reduction in mean time to fitness for discharge (9 days versus 15 days, p < 0.05) and a 9-day reduction in mean length of hospital stay (11 days versus 20 days, p < 0.05) were also reported.

3.6 Senagore et al. (2009) reported a three-arm trial in which CardioQ-ODM monitoring with colloid fluid administration and CardioQ-ODM monitoring with crystalloid fluid administration were compared with standard fluid management in patients undergoing laparoscopic bowel surgery. The length of hospital stay was shortest with
standard fluid management: 64.9 hours (21 patients) compared with 75.5 hours for CardioQ-ODM-guided colloid fluid management (22 patients) and 71.8 hours for CardioQ-ODM-guided crystalloid fluid management (21 patients, p < 0.05). The difference in hospital stay was small and the paper did not report whether hospital stay was a mean or median value. This trial included patients having lower risk surgery and used an atypical CardioQ-ODM-guided protocol for fluid management. The External Assessment Centre considered this study and concluded that, because of the differences in design, these results have little effect on the body of evidence, which largely supports monitoring with CardioQ-ODM compared with standard fluid management.

3.7 Wakeling et al. (2005) reported a study of 124 patients undergoing bowel surgery and found total complications were reduced in the group who had CardioQ-ODM monitoring combined with central venous pressure monitoring compared with the group who had central venous pressure monitoring alone (38% [24/67] versus 59% [38/67], p = 0.013). Gastrointestinal complications were also reduced in the group who had CardioQ-ODM monitoring (14% [9/67] versus 45% [29/67], p = 0.001). Other indicators of enhanced recovery from surgery favoured CardioQ-ODM monitoring over central venous pressure monitoring alone, namely the return of flatus (median 3 days versus 4 days, p = 0.085), bowel movement (median 4 days versus 5 days, p = 0.014) and the adoption of a full diet (median 6 days versus 7 days, p = 0.001). Noblett et al. (2006) reported a study of 108 patients undergoing bowel surgery, which found that intermediate or major complications were lower in a group who had CardioQ-ODM monitoring and central venous pressure monitoring compared with a group who had central venous pressure monitoring alone (2% [1/54] versus 15% [8/54], p = 0.043). Patients who had CardioQ-ODM monitoring tolerated food sooner (median 2 days versus 4 days, p value not provided),
but there was no difference in the return of flatus (median 2 days versus 2 days, p = 0.9) or bowel movement (median 3 days versus 4 days, p = 0.7).

3.8 Mythen et al. (1995) reported a study of 60 patients undergoing cardiac surgery, which found that gut hypoperfusion at the end of surgery and major complications after surgery were lower with the CardioQ-ODM and central venous pressure monitoring than with central venous pressure monitoring alone (gut hypoperfusion: 7% [2/30] versus 56% [17/30], p < 0.001; major complications: 0% [0/30] versus 20% [6/30], p = 0.01).

3.9 Gan et al. (2002) reported a study of 100 patients undergoing urological or gynaecological surgery, which found that 7 patients needed antiemetic drugs after surgery when CardioQ-ODM monitoring was combined with central venous pressure monitoring compared with 18 patients who had central venous pressure monitoring alone (p < 0.05).

3.10 The NHS Technology Adoption Centre reported audit data following the adoption of intra-operative oesophageal doppler-guided fluid management in three hospitals in England. CardioQ-ODM was used for intra-operative oesophageal doppler-guided fluid management in a total of 626 patients undergoing major intra-abdominal or orthopaedic surgery. Results from these patients were compared with an historical control group of 621 patients who received standard care. The results confirmed the potential benefit of oesophageal doppler monitoring, with reduction in mean length of hospital stay of 3 days, reduction in hospital stay after surgery of 4 days, and 23% fewer surgical patients requiring a central venous catheter to be inserted.

3.11 Evidence from a number of systematic reviews of oesophageal doppler monitoring was also considered. The most recent major
review was a Health Technology Assessment performed by the UK National Institute for Health Research. The Health Technology Assessment considered ten clinical trials that included a total of 959 patients. Eight of these trials used the CardioQ-ODM (accounting for 77% of the total number of patients), whereas the other two studies used other oesophageal doppler monitoring devices. Furthermore, eight of these studies were of patients undergoing surgery whereas two investigated the impact of oesophageal doppler monitoring on patients in a critical care setting. The review reported that generic oesophageal doppler monitoring reduced the length of stay by on average 2 days, and by up to 6 days. The review also reported that complications were reduced by more than 50% when oesophageal doppler monitoring was used either during surgery or after surgery in the critical care unit. In a subgroup analysis that assumed that central venous pressure monitoring was used in both study arms, the odds ratio of complications was 0.43 for oesophageal doppler monitoring during surgery and 0.49 for oesophageal doppler monitoring after surgery in the critical care unit.

*Patients in the critical care unit*

3.12 McKendry et al. (2004) reported a study of 174 patients in a critical care unit after cardiac surgery, which found no statistically significant difference in mean hospital stay between patients who had CardioQ-ODM monitoring combined with central venous pressure monitoring and patients who had central venous pressure monitoring alone; although the median hospital stay was reduced to 7 days in the group who had CardioQ-ODM monitoring compared with 9 days in the group with central venous pressure monitoring alone (p = 0.02).
Committee considerations

3.13 The Committee considered that the available evidence supported a reduction in peri-operative complications and length of in-hospital stay in patients undergoing surgery when the CardioQ-ODM was used compared to outcomes for patients with central venous pressure monitoring alone. It observed that these benefits were achieved without an increase in rates of repeat surgery or re-admission.

3.14 The Committee concluded that patients most likely to benefit from the use of the CardioQ-ODM are those in whom the clinician would consider using invasive cardiovascular monitoring (such as central venous pressure or pulmonary artery catheter monitoring). This will include patients undergoing major or high-risk surgery or high-risk patients undergoing intermediate-risk surgery.

3.15 The Committee noted that although evidence of benefit with the CardioQ-ODM was particularly convincing for patients undergoing gastrointestinal surgery, benefit was also observed in patients undergoing other types of surgery.

3.16 The Committee was advised that the CardioQ-ODM cannot usually be used in patients undergoing head and neck, oesophageal or aortic surgery and is poorly tolerated by conscious patients after surgery.

3.17 The Committee received expert advice that the CardioQ-ODM may sometimes be used with, rather than as an alternative to, central venous pressure monitoring in patients undergoing surgery. It noted that this is most likely to be the case when clinicians are gaining experience with the new technology. Central venous catheters will still be needed in some cases for central venous access and for administering inotropic drugs.
3.18 The Committee recognised that monitoring cardiac output is helpful in a critical care environment. However, it concluded that there is insufficient evidence to recommend CardioQ-ODM monitoring in preference to other techniques for monitoring cardiac output in critical care.

3.19 The Committee considered that further research would be helpful to compare the CardioQ-ODM with other techniques for monitoring cardiac output, particularly in patients in the critical care environment.

3.20 The Committee recognised that trials using the CardioQ-ODM are currently ongoing in the UK and internationally. The Committee was advised on the relevance and impact of ongoing and recently published trials (such as the OPTIMISE trial and the COMPETE C study) and concluded that the available evidence supported the benefits of CardioQ-ODM.

3.21 The Committee considered that there is no evidence of adverse events which suggests that the use of the CardioQ-ODM is harmful to patients.

4 NHS considerations

System impact

4.1 Cost savings associated with the use of the CardioQ-ODM in patients undergoing major or high-risk surgery are largely derived from a reduction in the length of critical care and in-hospital stay. Additional savings will result from a reduction in post-operative complications.

4.2 A report from the NHS Technology Adoption Centre considered the potential economic impact of the widespread adoption of the CardioQ-ODM across five surgical specialties in the NHS. This
The Committee was advised that the use of the CardioQ-ODM in a peri-operative setting or critical care environment requires a trained clinician or nurse to re-adjust the device and interpret the readings.

**Committee considerations**

The Committee was informed that the CardioQ-ODM has been available to the NHS for a number of years but, although used routinely in some hospitals, could be adopted more widely. The Committee was advised that current barriers to wider adoption include financial, training and motivational issues.

## 5 Cost considerations

**Cost impact evidence**

The economic evidence comprises a cost analysis submitted by the manufacturer, data from a National Institute for Health Research’s Health Technology Assessment and economic results from the NHS Technology Adoption Centre’s project on intra-operative oesophageal doppler-guided fluid management.

The manufacturer’s cost analysis was undertaken from the perspective of the NHS. The model evaluated separately the cost impact of using the CardioQ-ODM in patients undergoing surgery and in a critical care environment. Both arms of the model used the same comparators. The CardioQ-ODM plus conventional clinical assessment was compared with:

- conventional clinical assessment alone
- central venous pressure monitoring plus conventional clinical assessment
- pulse pressure waveform analysis plus conventional clinical assessment
• central venous pressure monitoring plus pulse pressure waveform analysis plus conventional clinical assessment
• central venous pressure monitoring plus the CardioQ-ODM plus conventional clinical assessment.

The key outcome in the cost analysis was length of in-hospital stay, with adverse events and complications captured through their impact on length of stay. The time horizon chosen for the model was the period of in-hospital care.

5.3 In the cost model for patients undergoing surgery, the baseline length of hospital stay was 7.52 days (0.16 days in the critical care unit, 0.58 days in the high-dependency unit and 6.78 days in a general ward). The baseline length of stay is the stay associated with patients whose fluid status is monitored using conventional clinical assessment alone. The base-case analysis assumed that monitoring with the CardioQ-ODM was associated with a reduction in length of stay of 50% in the critical care unit, and 25% in both the high-dependency unit and the general ward, resulting in a total reduction in length of stay of 1.92 days. The External Assessment Centre considered that a 35% reduction in length of stay in the critical care unit was more appropriate for monitoring with the CardioQ-ODM, based on the evidence from randomised controlled trials. Central venous pressure monitoring was assumed to have no impact on length of stay in any setting. Some data used to populate the manufacturer’s cost model were considered by the External Assessment Centre to be inaccurate and the Centre updated the model with more accurate data relating to the costs of nurse time and bed-days in the high-dependency unit. The base-case analysis reported that the costs associated with CardioQ-ODM monitoring in patients undergoing surgery were lower than for any of the comparators. The corrected incremental cost for the most relevant comparator, namely central venous pressure monitoring, was
£1062 in favour of the CardioQ-ODM based on a 7.5-day hospital stay.

5.4 Deterministic sensitivity analyses were undertaken for a range of parameter values, including reduction in length of stay in the critical care unit, high-dependency unit and general ward, baseline length of stay, device use, general ward cost, and purchase and maintenance costs for comparator devices. The main factors affecting cost were changes in the length of stay parameters. The sensitivity analyses showed CardioQ-ODM to be cost saving in all cases, except when it is assumed that central venous pressure monitoring reduces the length of stay in the general ward by 30%.

5.5 In the cost model exploring the use of the CardioQ-ODM in patients on a critical care unit, the baseline length of stay was 36 days. This was subdivided into 12 days on the critical care unit and 24 days on the general ward. Data for reduction in length of stay relating to CardioQ-ODM monitoring were derived from the only relevant randomised controlled trial available. The base-case analysis assumed a 20% reduction in length of stay on both the critical care unit and the general ward for patients who had CardioQ-ODM monitoring. In the same analysis, the comparator, pulse pressure waveform analysis, was assumed to lead to no reduction in length of stay on the critical care unit, and a 10% reduction in length of stay on the general ward. Some data used to populate the manufacturer’s cost model were considered inaccurate by the External Assessment Centre who updated the model with more appropriate data relating to the cost of nurse time, bed-day costs in the high-dependency unit and for three incorrect values that were typographical errors. Additional calculations were carried out by the External Assessment Centre on the impact of pulse pressure waveform analysis on the length of stay in the critical care unit and the subsequent length of stay on the general ward. In the revised
calculation, a reduction of length of stay on the general ward of 41% rather than 10% was applied on the basis of the results of Pearse et al. (2005), and the incremental cost saving with the CardioQ-ODM was £1285 compared with £3064 as cited in the manufacturer’s submission.

**Committee considerations**

5.6 The Committee heard from the experts that when clinicians start to use the CardioQ-ODM, they are initially reluctant to stop using central venous pressure monitoring until their confidence with the new technology grows. The Committee noted that the cost model showed a marginal reduction in incremental cost to £1022 when central venous pressure monitoring was compared with the combination of central venous pressure and CardioQ-ODM monitoring, from the £1062 when central venous pressure monitoring was compared with CardioQ-ODM monitoring alone.

5.7 The Committee noted that the cost savings associated with the use of the CardioQ-ODM for patients undergoing surgery were similar in the manufacturer’s cost analysis and in the NHS Technology Adoption Centre’s report.

5.8 The Committee concluded that the lack of convincing evidence of benefit when the CardioQ-ODM was used in patients on the critical care unit who have not had surgery means that there is considerable uncertainty about potential cost savings in this clinical setting.

**6 Conclusions**

6.1 The Committee concluded that the available data support a clinical benefit and a cost saving when the CardioQ-ODM is used in patients undergoing major or high-risk surgery or other surgical
patients in whom a clinician would consider using invasive cardiac monitoring.

6.2 The Committee considered that further research would be helpful to compare the CardioQ-ODM with other techniques for monitoring cardiac output, particularly in patients in the critical care environment.

7 Implementation

7.1 NICE has developed tools to help organisations put this guidance into practice (listed below). These are available on our website (www.nice.org.uk/guidance/MTG3).

- Slide set highlighting key messages for local discussion.
- Costing template and report to estimate the national and local savings and costs associated with implementation.
- A podcast with Dr Daniel Conway (Clinical Expert for the lead team of the Medical Technologies Advisory Committee) and Katie Worrall (NICE implementation adviser).

8 Related NICE guidance

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Chief Executive
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Appendix A. Committee members and NICE lead team

A Medical Technologies Advisory Committee members

The Medical Technologies Advisory Committee is a standing advisory committee of NICE. A list of the Committee members who took part in the discussions for this guidance appears below.

Committee members are asked to declare any interests in the technology to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each Medical Technologies Advisory Committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Professor Bruce Campbell (Chair)
Consultant Vascular Surgeon, Exeter

Dr Dilly Anumba
Senior Clinical Lecturer/Honorary Consultant Obstetrician and Gynaecologist, University of Sheffield

Susan Bennett
Lay member

Professor Bipin Bhakta
Charterhouse Professor in rehabilitation Medicine and NHS Consultant Physician, University of Leeds

Dr Keith Blanshard
Consultant Radiologist, Leicester Royal Infirmary

Dr (Robert) Martyn Bracewell
Senior Lecturer in Neurology and Neuroscience, Bangor University
Dr Daniel Clark  
Head of Clinical Engineering, Nottingham University Hospitals NHS Trust

Professor Karl Claxton  
Professor of Economics, University of York

Mrs Gail Coster  
Radiography Manager, Strategy, Planning and Governance, Yorkshire NHS Trust

Dr Craig Dobson  
General Practitioner and Senior Lecturer in Medical Education and General Practice, Hull York Medical School

Dr Alex Faulkner  
Senior Research Fellow, Centre for Biomedicine & Society, King’s College London

Professor Tony Freemont  
Professor of Osteoarticular Pathology, University of Manchester

Professor Peter Gaines  
Consultant Interventional Radiologist, Sheffield, Vascular Institute and Sheffield Hallam University

Mr Harry Golby  
Head of Commissioning, Acute, Access and Diagnostics, Salford NHS

Dr Peter Groves  
Consultant Cardiologist, Cardiff and Vale NHS Trust

Matthew Hill  
Lay member

Dr Paul Knox  
Reader in Vision Science, University of Liverpool
Mrs Catherine Leonard
Reimbursement Manager, Medtronic UK

Dr Susanne Ludgate
Clinical Director, Devices Medicines & Healthcare Products Regulatory Agency

Professor Christopher McCabe
Professor of Health Economics, Institute of Health Sciences, University of Leeds

Mrs Jacqui Nettleton
Programme Director, Long Term Conditions, West Sussex PCT

Professor Sharon Peacock
Professor of Clinical Microbiology, University of Cambridge

Dr Allan Swift
Director of Quality and Regulatory Affairs, Gen-Probe Life Sciences

Professor Stephen Westaby
Consultant Cardiac Surgeon, John Radcliffe Hospital, Oxford

Dr Janelle York
Lecturer & Researcher in Nursing, University of Salford
**B NICE lead team**

Each medical technology assessment is assigned a lead team of a NICE technical analyst and technical adviser, a clinical expert, a representative of the External Assessment Centre, and a non-expert member of the Medical Technologies Advisory Committee.

**Bernice Dillon**
Technical analyst

**Professor Karl Claxton**
Medical Technologies Advisory Committee (non-expert member)

**Dr Stuart Gold**
Clinical expert

**Dr Daniel Conway**
Clinical expert

**Mr Andrew Cleves**
External Assessment Centre representative

**Lizzy Latimer**
Technical adviser
Appendix B. Sources of evidence considered by the Medical Technologies Advisory Committee

A The External Assessment Centre report for this assessment was prepared by Cedar, Cardiff and Vale University Health Board with support from the Support Unit for Research Evidence, Cardiff University:


B Submissions from the following manufacturer/sponsors:

- Deltex Medical Group

C The following people gave their expert personal view on the CardioQ-ODM oesophageal doppler monitor by providing their expert comments on the draft scope, assessment report and medical technologies consultation document.

- Daniel Conway, nominated by the Royal College of Anaesthetists
- Stuart Gold, nominated by the Royal College of Anaesthetists
- Martin Kuper, nominated by the Royal College of Anaesthetists

The following individuals gave their expert personal view on the CardioQ-ODM oesophageal doppler monitor in writing by completing a patient questionnaire or expert adviser questionnaire provided to the Committee.

- Daniel Conway, nominated by the Royal College of Anaesthetists
- Stuart Gold, nominated by the Royal College of Anaesthetists
- Max Jonas nominated by the Intensive Care Society
- Martin Kuper, nominated by the Royal College of Anaesthetists
- Susanne Price nominated by the British Society of Echocardiography
• Howard Wakeling nominated by the Association of Anaesthetists of Great Britain and Ireland