Costing update report of MTG8: MiraQ for assessing graft flow during coronary artery bypass graft surgery

This medical technology guidance was published in November 2011 and updated in February 2018.

All medical technology guidance is reviewed 3 years after publication according to the process described in the MTEP Interim addendum on guidance reviews.

This report is part of the information considered in the guidance review. It describes an update of the cost model so that it reflects any new relevant information including revising the cost and resource parameters to current values. The results from the updated cost model are used to estimate the current savings associated with the use of the technology.

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1. Background

The company (Medistim) developed the original *de novo* cost calculator for MiraQ systems (previously called VeriQ; MTG8, 2011). The time horizon of the company model was not explicitly specified (data was used from Becit *et al.* 2007 and Kieser *et al.* 2010 which did not define the observational period), but the company stated in their submission of evidence that the model represented costs within one to three years after coronary artery bypass graft (CABG). The base-case economic model was updated by King's Technology Evaluation Centre EAC (KiTEC) in 2017 and included the basic version of the MiraQ Cardiac system (which measures transit time flow measurement [TTFM] and allows accurate measurement of blood flow through a blood vessel), as part of the guidance review process. MiraQ Cardiac remained cost saving of £141 in the base-case and throughout sensitivity analysis (with the exception of one scenario where no difference in the risk of needing an intra-aortic balloon pump [IABP] insertion with or without TTFM was assumed, which resulted in MiraQ Cardiac being cost incurring by £13.43).

The objective of this report is to produce a cost model update for the MiraQ Cardiac device. In order to achieve this objective, the EAC has reviewed the model and updated parameters affected by revised costs only. For the purposes of these costing updates, no review of clinical effectiveness has taken place.

2. Current validity of model

Collated Expert Advice Questionnaires sent from NICE, summarising responses from two experts, confirms that the care and clinical pathway have not substantially changed since the original assessment. One expert stated that intra-operative flowmetry is standard of care within their department due to complications associated with early graft occlusion. However, one expert stated that due to budget constraints funding the maintenance and replacement of non-essential equipment is difficult.

The two experts were not aware of other products with the same purpose as MiraQ.

One new clinical study was identified by the experts:

- Taggart *et al*. Intraoperative transit-time flow measurement and high-frequency ultrasound assessment in coronary artery bypass grafting. J Thorac Cardiovasc Surg 2020

The company provided a spreadsheet containing references of 161 articles which report the use of MiraQ or VeriQ which have been published between

2016 and mid-September 2021 (including 105 clinical studies, 29 meta-analyses or reviews, 6 guidelines, expert opinions or editorials, 17 case reports and 4 miscellaneous or other publication types). The company sent an additional systematic review (Gaudino *et al.* 2021) on 06/10/2021. The EAC has not reviewed these articles within this costing update.

The two experts were unaware of newer versions of the technology. The company confirmed that the technology has not changed since 2011.

3. Updated input parameters

The cost parameters were updated in the economic model (see Table 1) to include the following:

- Change in device, maintenance, and probe prices (from company correspondence).

- Change in staff costs (using costs from Personal Social Services Research Unit [PSSRU] Unit Costs of Health & Social Care 2019/20). Note that PSSRU no longer report costs per patient contact hour (for the staff included in this costing update) meaning the EAC is unable to replicate the sensitivity analysis conducted by KiTEC in their update report from 2017. Therefore, the staff costs listed in Table 1 represent the cost per working hour. Additionally, physician assistant costs were included in sensitivity analysis of the original company model and costing update conducted by KiTEC, however the source of this cost was undefined, and therefore the EAC has assumed this is the same cost as a Band 6 nurse.

- All additional costs not readily available were taken from the KiTEC costing update report (2017) and inflated to 2020 prices using Consumer Price Index (Office for National Statistics [ONS] – Table 9 L528 Health; published online 17/09/2021, next update due 20/10/2021).

Sensitivity analysis on the base case included:

- Increasing the number of times each MiraQ Cardiac system would be used each year, from 1 patient per day for 220 days in the base case to 4 patients per day, that is, 880 uses per year (raised in the committee considerations in MTG8);
- Decreasing the number of uses per probe during its lifetime from 50 (in the base case) to 25 (reliability of the probe up to 50 uses was queried by both clinical experts);

- Applying the worse case scenario in sensitivity analysis (varying parameters to the upper range applied in previous costing update conducted by KiTEC EAC, 2017).

Table 1: Updated cost parameters

Cost parameter	Unit cost (Original model)	Unit costs (Updated 2017)	Unit costs (Updated 2021)	Source (Updated 2021)
Purchase costs of MiraQ Cardiac	£32,000	£34,000	£35,955	Assumes 10-year lifespan, used in surgery of 220 patients per year.
Service costs, annual	£1,800.00	£1,800.00	£1369.80	Total lifetime maintenance cost of £13,698 provided by manufacturer, with assumed ten year lifespan
Probe costs	£1,582	£1,481 (£50.35 per patient)	£1720 (£58.48 per patient)	Assumes lifespan of 50 uses, requirement of mean 1.7 probes per patient scanned.
Total cost per patient scanned	Not reported	£75.25	£85.62	Combining system, service and probe costs per patient, including discounting.
Actual or suspected Myocardial Infarction (MI)	£1,415.20	£1,773.29	£1,597.07	NHS Reference costs 2019/20 (using weighted average of total activity from EB10A, EB10B, EB10C, EB10D, EB10E: Actual or Suspected Myocardial Infarction – all CC scores)
Rehab for acute MI and other cardiac disorders	£251.76	£257.78	£378.02	NHS Reference costs (VC38Z: Rehabilitation for Acute Myocardial Infarction or Other Cardiac Disorders)
Deep sternal infection, intermediate without clinical complications	£860.55	£1,119.98	£988.25	NHS Reference costs (WH07G: Infections or Other Complications of Procedures, without Interventions, with CC Score 0-1)
Proxy for IABP	£2,657.37	£2,574.38	£1,709.69	NHS Reference costs (using weighted average of total activity from EC20A, EC20B: Diagnostic Percutaneous Intervention for Congenital Heart

				Disease with any CC score)
Re-operative procedure costs	£180.41	£180.41	£194.02	Source undetermined (numerical value in excel model with no formulae to track source), inflated using ONS Consumer price inflation tables (112.6/104.7)
Cardiac surgeon, per hour	£68.54	£138.00	£114.00	PSSRU 2019/20 (hospital based surgical consultant)
Anaesthetist	£41.90	£128.00	£117.00	PSSRU 2019/20 (associate specialist)
Cardiac nurse (and anaesthetist nurse included in sensitivity analysis)	£23.37	£51.00	£50.00	PSSRU 2019/20 (hospital based nurse band 6). Note that costs per hour for a nurse with qualifications is no longer reported by PSSRU.
Cardiac perfusionist	£24.17	£60.00	£60.00	PSSRU 2019/20 (hospital based nurse band 7). Note that costs per hour for a nurse with qualifications is no longer reported by PSSRU.
Physician assistant (included in sensitivity analysis only)	£21.35 (source not reported in original company submission)	£21.35	£50.00	PSSRU 2019/20 (assume same as hospital based nurse band 6).

4. Results from updated model

Results from the updated model (compared with update conducted by KiTEC EAC in 2017, and the original model submitted by the company) are summarised in Table 2. The updated cost model shows a cost saving for MiraQ of £80.27, when compared with clinical assessment.

Results from sensitivity analysis are summarised in Table 3 (note that the EAC identified and corrected two errors in the summary table of sensitivity analysis for mean number of probes used in procedure, and MI rates that was in the original economic model and in the 2017 update). Both experts raised concerns of the probe reliability, stating that 50 uses per probe was unlikely. The EAC conducted threshold analysis and found that the MiraQ Cardiac system remains cost saving even when the lifespan of the probe is assumed to be 25 uses. Additional threshold analysis finds that the MiraQ Cardiac system is cost incurring at 21 uses (£234.63 vs. £234.14, incurring £0.49 cost). Two experts confirmed that each probe would likely exceed this use (one commenting that this was dependent upon the probe expiry date).

The only scenarios which resulted in the MiraQ Cardiac arm being cost incurring were those which assumed that the rate of MI and IABP was the same in intervention and comparator arms, which the EAC considers unlikely. From additional threshold analysis conducted by the EAC, if the proportion requiring intra-aortic balloon pump insertion in the comparator arm was 7.0%, the MiraQ Cardiac system becomes cost incurring if the proportion requiring IABP insertion was 5.7% or higher. If the proportion suffering MI in the comparator arm was 5.0%, the MiraQ Cardiac system becomes cost incurring if the proportion suffering MI was 4.1% or higher. One expert has confirmed that these thresholds for MI and IABP are unlikely clinically, however another expert stated that if MI and IABP rates were low then it would be very difficult to show benefit of MiraQ Cardiac system (Appendix 1).

Table 2: Results from updated cost model.

	Unit cost (Original model)		Unit costs (Updated 2017)		Unit costs (Updated 2021)	
	MiraQ Cardiac	Clinical assessment	MiraQ Cardiac	Clinical assessment	MiraQ Cardiac	Clinical assessment
Graft assessment	£121.73	£0.00	£114.98	£0.00	£121.07	£0.00
Operative issues	£40.59	£283.38	£42.36	£298.37	£32.80	£234.14
Total cost per patient	£162.32	£283.38	£157.34	£298.37	£153.87	£234.14
Cost difference (MiraQ-clinical assessment)		**-£121.06**		**-£141.03**		**-£80.27**

Table 3: Sensitivity analysis

Parameter	Base-case value	Updated value	MiraQ Cardiac	Clinical assessment	Cost difference (MiraQ Cardiac – Clinical assessment)
Base case scenario	N/A	N/A	£153.87	£234.14	**-£80.27**
Device uses per year	220	440*	£140.30	£234.14	**-£93.84**
Device uses per year	220	660*	£135.78	£234.14	**-£98.36**
Device uses per year	220	880*	£133.52	£234.14	**-£100.62**
Duration of TTFM, minutes	2.35	5.0	£176.17	£234.14	**-£57.96**
Probes per procedure	1.7	2.0	£164.19	£234.14	**-£69.95**
Probe life span, uses	50	25	£212.35	£234.14	**-£21.79**
Patients with revisions, %	6.58	14.60	£172.95	£234.14	**-£61.18**
Minor revision duration, minutes	2.5	5.0	£154.35	£234.14	**-£79.79**
Mean duration of major revision (on and off pump), minutes	42	57	£159.30	£234.14	**-£74.84**
Minor revision rate (given revision), %	34.7	50.0	£150.53	£234.14	**-£83.61**

Cost of re-operative procedure, £	194.02	291.03†	£156.78	£237.05	**-£80.27**
Cost of re-operative procedure, £	194.02	353.50ǂ	£158.65	£238.92	**-£80.27**
Cost of IABP, £	1709.69	2564.54†	£162.42	£293.98	**-£131.56**
Cost of MI, £	1975.09 (1597.07+378.02)	2962.64†	£153.87	£283.51	**-£129.64**
Cost of deep sternal infection, £	988.25	1482.38†	£158.81	£239.08	**-£80.27**
Re-exploration for bleeding	TTFM: 3.0% No TTFM: 3.0%	TTFM: 8.5% No TTFM: 0.6%	£164.54	£229.48	**-£64.94**
Re-exploration for bleeding	TTFM: 3% No TTFM: 3%	TTFM: 6% No TTFM: 3%	£159.69	£234.14	**-£74.45**
Deep sternal infection	TTFM: 1.0% No TTFM: 1.0%	TTFM: 5.5% No TTFM: 0.0%	£198.34	£224.25	**-£25.91**
Deep sternal infection	TTFM: 1% No TTFM: 1%	TTFM: 2% No TTFM: 1%	£163.75	£234.14	**-£70.38**
IABP	TTFM: 1.0% No TTFM: 7.0%	TTFM: 3.5% No TTFM: 3.5%	£196.61	£174.30	**+£22.32**

IABP	TTFM: 1% No TTFM: 7%	TTFM: 7% No TTFM: 7%	£256.45	£234.14	**+£22.32**
MI	TTFM: 0.0% No TTFM: 5.0%	TTFM: 2.5% No TTFM: 2.5%	£252.62	£234.14	**+£18.49**
MI	TTFM: 0% No TTFM: 5%	TTFM: 5% No TTFM: 5%	£252.62	£234.14	**+£18.49**
CABG team composition	2 surgeons, 1 anaesthetist, 1 perfusionist, 2 cardiac nurses	2 surgeons, 1 anaesthetist, 1 perfusionist, 2 cardiac nurses, 1 nurse anaesthetist, 2 physician assistants	£164.40	£234.14	**-£69.74**

Abbreviations: CABG, coronary artery bypass graft; IABP, intra-aortic balloon pump; MI, myocardial infarction; TTFM transit time flow measurement.

*original company model assumed device was used 220 time in a year (by 1 patient per working weekday). Sensitivity analysis increased this to 440, 660 and 880 uses per year to model device being used by 2, 3 and 4 patients respectively.

†50% increase

ǂ based on formulae [(duration in minutes of major revision on-pump*rate of on-pump CABG) + (duration in minutes of major revision off-pump*rate of off-pump CABG)] x aggregated staff costs per minute.

5. Conclusion

The update of cost parameters has not changed the direction of cost saving; MiraQ Cardiac results in a cost saving of £80.27 per patient scanned over a one year time horizon. Sensitivity analysis, addressing concerns of committee and clinical experts, still demonstrates MiraQ to be cost saving when compared against clinical assessment. The only scenarios which result in cost expenditure are those which consider the rate of IABP insertion and MI to be equivalent across MiraQ and clinical assessment arms, which the EAC considers unlikely. Additional threshold analysis confirms that MiraQ only becomes cost incurring if the lifespan of the probe drops to 21 uses, if the difference in rate of MI (between MiraQ and clinical assessment) is 0.9% or lower, and if the difference in rate of IABP insertion (between MiraQ and clinical assessment) was 1.3% or lower. Two clinical experts agreed that the thresholds for probe use were clinically unlikely. One expert stated that using data from large observational studies that the thresholds for MI and IABP were unlikely, another expert advised that MI and IABP rates were low in their Trust and therefore demonstrating an absolute difference in MI and IABP of 0.9% and 1.3% respectively with MiraQ would be difficult.

The EAC advises that no update to guidance, based on economic evidence alone, is required. However, the company has shared a substantial list of references as additional clinical evidence. Furthermore, the adverse event rates could be updated in both arms (including MI and IABP rates), to determine impact on costs.

6. References

Becit N, Erkut B, Ceviz M, Unlu Y, Colak A, Koack H. The impact of intraoperative transit time flow measurement on the results of on-pump coronary surgery. Eur J Cardiothorac Surg. 2007; 32: 313-8

Gaudino M, Sandner S, Di Giammarco G, Di Franco A, Arai H, Asai T *et al*. The use of intraoperative transit time flow measurement for coronary arty bypass surgery: systematic review of the evidence and expert opinion statements. Circulation. 2021; 144(14): 1160-71

Kieser TM, Rose S, Kowalewski R, Belenkie I. Transit-time flow predicts outcomes in coronary bypass graft patients: a series of 1000 consecutive arterial grafts. Eur J Cardiothorac Surg. 2010; 38: 155-62.

Taggart DP, Thuijs DJFM, Giammarco GD, Puskas JD, Wendt D, Trachiotis GD *et al*. Intraoperative transit-time flow measurement and high-frequency ultrasound assessment in coronary artery bypass grafting. J Thorac Cardiovasc Surg. 2020;159:1283-92.

Appendix 1: Communication with experts

Question sent to experts (14/10/2021):

The EAC is conducting a costing update related to the MiraQ cardiac device. Sensitivity analysis has been conducted, and the only scenarios in which MiraQ is cost incurring is when:
a) the life span of the probe drops to 21 uses
b) if the difference in rate of MI (between MiraQ and clinical assessment) is 0.9% or lower (i.e. MiraQ reduces MIs by 0.9% or less)
c) if the difference in rate of IABP insertion (between MiraQ and clinical assessment) is 1.3% or lower (i.e. MiraQ reduces IABP insertion by 1.3% or less)

Please can you comment on each of the above scenarios (a,b,c) to advise NICE on whether these are clinically likely or unlikely?

Expert	Response
#1	a) the life span of the probe drops to 21 uses The probes are guaranteed for 50 sterilisation cycles according to the product brochure. We have seen less reliable results as the probes near end-of-life but the lifespan is still between 40-50 cycles. This scenario is unlikely. b) if the difference in rate of MI (between MiraQ and clinical assessment) is 0.9% or lower (i.e. MiraQ reduces MIs by 0.9% or less) The other queries are harder to answer because of a lack of evidence. There is only one small RCT studying patients undergoing CABG with or without transit-time flowmetry (J Thorac Cardiovasc Surg 2010;139:294-301) that found no differences in the rates of MI or IABP insertion. However, there are larger observational studies that report admirably low rates of peri-op MI (e.g. Eur J Cardiothorac Surg 2010;38:155–62 and J Thorac Cardiovasc Surg 2020;159:1283-92) and these suggest that it is likely that MiraQ would lead to a ≥ 0.9% absolute reduction in MIs c) if the difference in rate of IABP insertion (between MiraQ and clinical assessment) is 1.3% or lower (i.e. MiraQ reduces IABP insertion by 1.3% or less) There is only one other study that reports IABP insertion rates (Eur J Cardiothorac Surg 2007;32:313–18) with a marked reduction in IABP insertion in the TTFM cohort. This scenario appears unlikely based on this limited evidence.

#2	a) This is possible/likely if the opportunity to use the probe is limited by an expiry date. If the probes have no expiry date and the hospital/ cardiac surgical group is enthusiastic in using them it is likely that each probe will exceed 21 cases. b) Diagnosis of peri-operative MI in units is not straightforward. Some units routinely measure cardiac enzymes immediately post op to see if there is evidence of issues with myocardial protection or a cardiac event has occurred perioperatively. In our unit this is not routine as cardiac enzymes are not always diagnostic of a clinically significant event. In my unit I would say that a clear diagnosis of a post-operative MI in the immediate post-operative period is very low, probably less than 1%. In the first 12 months post-surgery again the rate is already very low so the chances of reliably measuring a reduction in MI by 0.9% could be challenging as the numbers required could be very large. c) Post-operative IABP insertion for CABG patients is more related to pre-operative ventricular function and demonstration of viability in regions of ischaemic heart muscle. Again a very large number of patients would need to be studied to discern a statistically reliable reduction in requirement of IABP. In addition, threshold for use of an IABP varies from surgeon to surgeon and there could be multiple confounding factors.

Appendix 2. Background documents for this review

Hyperlinks for the background documents for this review report:

1. Medical technologies guidance document
2. Assessment report

   Additional work: January 2018 review decision, January 2018 review report
3. Scope of assessment
4. A copy of the company information request regarding the technology
5. A list of expert advisers and their completed questionnaires on the MTG review
6. Executable cost model which aligns with the base case described in the MTG documents
7. If there is new evidence which is relevant to any of the clinical parameters in the model, the analyst should send the updated values.
8. Any relevant other documents which are not available on the NICE website.