

Computed tomography (CT) scanners for cardiac imaging (10/107/01) - Additional studies submitted by manufacturers (08/08/2011)

Siemens

Top 50 – Selected Scientific Papers, Somatom Definition FLASH April 2011:

This document provides a further list of publications from Siemens, rather than specific publications which they believe have been missed by the EAG (as agreed at the DAC meeting). Lists of this type should be submitted at the beginning of the assessment process, as indicated in the timelines for the project (in this case 04/04/2011). However, we have checked those publications which could not be immediately excluded from title screening and all were identified by our original searches (i.e. they have already been assessed and excluded).

The latest scientific publications with the SOMATOM Definition Flash – CT imaging of the heart and thorax:

This document provides a list of publications which post-date the searches undertaken for the assessment. We would not normally re-visit searches at this stage of the assessment process. However, we have screened those publications that appeared (from the titles) to possibly meet the inclusion criteria of the assessment:

Achenbach S, Goroll T, Seltmann M, Pflederer T, Anders K, Ropers D, Daniel WG, Uder M, Lell M, Marwan M. Detection of coronary artery stenoses by low-dose, prospectively ECG-triggered, high-pitch spiral coronary CT angiography. *JACC Cardiovasc Imaging*. 2011 Apr;4(4):328-37. – **no separate data for difficult to image patients.**

Moscariello A, Takx RA, Schoepf UJ, Renker M, Zwerner PL, O'Brien TX, Allmendinger T, Vogt S, Schmidt B, Savino G, Fink C, Bonomo L, Henzler T. Coronary CT angiography: image quality, diagnostic accuracy, and potential for radiation dose reduction using a novel iterative image reconstruction technique-comparison with traditional filtered back projection. *Eur Radiol*. 2011 May 25. [Epub ahead of print] – **only viewable as an abstract, but no indication of separate data for difficult to image patients.**

Achenbach S. Multicenter Evaluation of Dual Source Coronary CT Angiography in Patients with Intermediate Likelihood of Coronary Artery Disease (MEDIC). Preliminary Report 2011. – **no separate data for difficult to image patients.**

GE

The publications provided by GE are for a 64-slice instrument (GE Lightspeed VCT (64-slice)), which was outside the scope of the assessment; as such, they were not identified by our searches.

Whether or not this technology should, retrospectively, be considered part of the assessment is a

decision for NICE and would require expert input from radiology expert members of the committee. However, as 64-slice instruments were specifically excluded from the scope (both as index tests and comparators) and manufacturers were asked, during the scoping phase, to identify any technologies that they considered relevant, we do not believe that post-hoc changes to scope can now be justified. Regarding the individual studies:

Andreini D, Pontone G, Bartorelli AL, et al. High diagnostic accuracy of prospective ECG-gating 64-slice computed tomography coronary angiography for the detection of in-stent restenosis. In-stent restenosis assessment by low-dose MDCT. 2011. *European Radiology*. - **Provides per stent data on accuracy for the detection of in-stent restenosis. However, publication post-dates the searches undertaken for this assessment (i.e. regardless of any extension to the scope, this publication would not have been identified for inclusion in the assessment).**

Budoff MJ, Dowe D, Jollis JG, et al. Diagnostic Performance of 64-Multidetector Row Coronary Computed Tomographic Angiography for Evaluation of Coronary Artery Stenosis in Individuals Without Known Coronary Artery Disease: Results from the Prospective Multicenter ACCURACY (Assessment by Coronary Computed Tomographic Angiography of Individuals Undergoing Invasive Coronary Angiography) Trial. *J. American College of Cardiology*. 2008 – **Provides sensitivity and specificity data for obese patients, patients with coronary calcium scores >400 and patients with heart rates >65 bpm. However, insufficient data are reported to allow the derivation of 2x2 tables (numbers of true positive, false negative, false positive and true negative test results (i.e. regardless of any extension to the scope, this study would fail the inclusion criteria for the assessment)).**

Romagnoli A, Patrei A, Mancini A, et al. Diagnostic accuracy of 64-slice CT in evaluating coronary artery bypass grafts and of the native coronary arteries. *Radiol. Med*. 2010;115:1167-1178. – **Provides data on diagnostic accuracy in patients with previous bypass graft.**

We do not believe that data reported in any of the studies submitted would substantively add to the findings of our report.