

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

GUIDANCE EXECUTIVE (GE)

Review of Diagnostics Guidance 3: New generation cardiac CT scanners (Aquilion ONE, Brilliance iCT, Discovery CT750 HD and Somatom Definition Flash) for cardiac imaging in people with suspected or known coronary artery disease in whom imaging is difficult with earlier generation CT scanners

Final recommendation post consultation

A technical supplement should be produced and the guidance should be transferred to the 'static guidance list'.

1. Background

This guidance was issued in January 2012.

At the GE meeting of 3 March 2015 it was agreed that we would consult on the recommendations made in the GE proposal paper. A four week consultation has been conducted and the responses are presented below.

2. Proposal put to stakeholders

A technical supplement should be produced and the guidance should be transferred to the 'static guidance list'.

3. Rationale for selecting this proposal

Changes in clinical practice, technology costs or evidence that would lead to a change in the recommendations of the original guidance have not been identified. However, all CT scanners included in the original guidance have been upgraded with new features or replaced with newer models. It is therefore proposed that a technical supplement describing these newer versions is produced, and that the guidance is placed on the static list.

4. Summary of consultation comments

Comments received during consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The published comments are a record of the comments received, and are not endorsed by NICE, its officers or advisory committees.

<p>Respondent: GE Healthcare</p> <p>Response to proposal:</p> <p>GE Healthcare agrees with the recommendations of the review proposal and the decision to produce a technical supplement to the guidance. GE Healthcare welcomes the opportunity to provide information on its products to contribute to develop the technical supplement.</p> <p><u>Section 6.1.4</u></p> <p>GE Healthcare requests that this section, describing updates to the technologies, is amended to read as follows:</p> <p>“6.1.4 Discovery CT750 HD (GE Healthcare)</p> <p>The GE Discovery CT750 HD scanner model is no longer marketed. It has been replaced by the Revolution GSI and Revolution HD scanner models.</p> <p>Inheriting the Gemstone technology from the Discovery CT750 HD, the Revolution HD provides high definition images due to higher spatial resolution. In addition the Revolution GSI has spectral imaging capabilities.</p> <p>Both products feature new workflow, dose and image quality capabilities such as:</p> <ul style="list-style-type: none">• A touch-screen interface included in the scanner gantry for improved patient workflow.• New software which corrects for motion and is useful for imaging patients with high heart rates.• New software for automatic selection of x-ray tube potential for optimisation of image quality at reduced radiation dose.”	<p>Comments from the Diagnostics Assessment Programme</p> <p>Thank you for your comments, which have been considered by NICE.</p> <p>Changes have been made to section 6.1.4 of the review proposal to reflect your comments on factual accuracy.</p>
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Section 6.1.5

Revolution CT does have dual energy scanning capability. The report is incorrect to state “the Revolution CT model does not have dual energy scanning.”

GE Healthcare requests that this section, describing the new technology, is amended to read as follows:

“Revolution CT (GE Healthcare)

Compared to the Revolution GSI, the Revolution CT delivers the following:

- Increased coverage – 16cm per rotation which enables scanning of the heart in one rotation.
- Faster rotation speed (0.28 second) when combined with intelligent motion correction gives an effective temporal resolution of 24 ms.
- A wider 80cm bore for improved patient access.”

Section 6.3.3

GE Healthcare provided additional information and details of new evidence in its manufacturer submission to NICE on 6 January 2015. This document highlighted a number of studies supporting the diagnostic accuracy of Discovery CT750HD in patients with high heart rates using the motion correction technology of SnapShot™ Freeze. We would request that the following references are considered for inclusion in the review proposal evidence summary as they provide support for improvements in outcomes from new technologies:

Carrascosa, Patricia, Alejandro Deviggiano, Carlos Capunay, Macarena C. De Zan, Alejandro Goldsmit, and Gaston A. Rodriguez-Granillo. "Effect of Intracycle Motion Correction Algorithm on Image Quality and Diagnostic Performance of Computed Tomography Coronary Angiography in Patients with Suspected Coronary Artery Disease." *Acad Radiol* 2015; 22:81–86

Haruhiko Machida MD et al, "Influence of a Novel Motion Correction Algorithm on Quality and Interpretability of Images of 64-detector Coronary CT Angiography among Patients Grouped by Heart Rate", RSNA 2014 proceedings - SSC02-04

Gianluca Pontone MD et al. "Impact of Intra-cycle Motion Correction Algorithm on Overall Evaluability and Accuracy in 160 Not-evaluable Consecutive Patients Studied by Computed Tomography Coronary Angiography for Suspected CAD ", RSNA 2014 proceedings - SSK03-05

Changes have been made to section 6.1.5 of the review proposal to reflect your comments on factual accuracy.

Thank you for highlighting these additional studies which were not included in the review proposal.

NICE considers updating published diagnostics guidance if the evidence base or clinical environment has changed to an extent that is likely to have a material effect on the recommendations in the existing guidance.

The current guidance makes positive recommendations on the use of CT scanners. New evidence which provides further support for improvements in outcomes is unlikely to have a material effect on these positive recommendations.

<p>Leipsic, Jonathon, Troy M. Labounty, Cameron J. Hague, G. B. Mancini, Julie M. O'Brien, David A. Wood, Carolyn M. Taylor et al. "Effect of a novel vendor-specific motion-correction algorithm on image quality and diagnostic accuracy in persons undergoing coronary CT angiography without rate-control medications." Journal of Cardiovascular Computed Tomography (2012) 6, 164–171</p> <p>Section 6.3 GE Healthcare provided additional information and details of new evidence in its manufacturer submission to NICE on 6 January 2015. This document highlighted a number of studies supporting the diagnostic accuracy of Discovery CT750HD in patients with dense vessel calcification. We would request that the following reference is considered for inclusion in the review proposal evidence summary to update the guidance as it provides support for improvements in outcomes from new technologies:</p> <p>Yasutoshi Ohta MD et al., "The Diagnostic Performance of Calcification Suppressed Coronary CT Angiography Using Rapid kV Switching Dual Energy CT", RSNA 2014 proceedings - SSQ02-02</p>	<p>Thank you for highlighting this additional study which was not included in the review proposal.</p>
<p>Respondent: Siemens Healthcare Diagnostics</p> <p>Response to proposal:</p> <p>Section 6.1.1 In the introduction, we would recommend adding a statement, that the SOMATOM Definition Flash is still the only dual-source CT scanner considered in this assessment.</p> <p>We recommend adding the clinical benefits of the Stellar detector, the lowest possible radiation dose for special populations with a high prevalence of coronary heart disease, and obese patients.</p> <p>Section 6.1.4 To avoid confusion, it might be beneficial to clarify that the dual energy scanning of the GE Revolution GSI results out of a single source scanner.</p> <p>Section 6.1.5 We recommend to add to “reduced gantry rotation time and therefore reducing the intrinsic</p>	<p>Comment from the Diagnostics Assessment Programme</p> <p>Thank you for your comments, which have been considered by NICE.</p> <p>Changes have been made to section 6.1.1, 6.1.4 and 6.1.5 of the review proposal to reflect your comments on factual accuracy.</p>

temporal resolution to 66 ms”

Section 6.3.4

We feel that some relevant information is missing, showing both the efficacy and benefits of the 2nd generation Dual-Source Scanner in patients with high-grade arrhythmia:

Lee AM, Engel LC, Shah B, Liew G, Sidhu MS, Kalra M, Abbara S, Brady TJ, Hoffmann U, Ghoshhajra BB. Coronary computed tomography angiography during arrhythmia: Radiation dose reduction with prospectively ECG-triggered axial and retrospectively ECG-gated helical 128-slice dual-source CT. *J Cardiovasc Comput Tomogr*. 2012 May-Jun;6(3):172-183.e2.

Srichai MB, Barreto M, Lim RP, Donnino R, Babb JS, Jacobs JE. Prospective-triggered sequential dual-source end-systolic coronary CT angiography for patients with atrial fibrillation: a feasibility study. *J Cardiovasc Comput Tomogr*. 2013 Mar-Apr;7(2):102-9.

Lee AM, Beaudoin J, Engel LC, Sidhu MS, Abbara S, Brady TJ, Hoffmann U, Ghoshhajra BB. Assessment of image quality and radiation dose of prospectively ECG-triggered adaptive dual-source coronary computed tomography angiography (cCTA) with arrhythmia rejection algorithm in systole versus diastole: a retrospective cohort study. *Int J Cardiovasc Imaging*. 2013 Aug;29(6):1361-70.

Section 7

If the diagnostic assessment program is interested in adding some information and impact beyond CT Angiography – which actually has the impact to change the treatment pathway, we would be happy to support you. For your information please find some of the most relevant publications:

Srichai MB, Chandarana H, Donnino R, Lim II, Leidecker C, Babb J, Jacobs JE. Diagnostic accuracy of cardiac computed tomography angiography for myocardial infarction. *World J Radiol*. 2013 Aug 28;5(8):295-303.

Rossi A, Dharampal A, Wragg A, Davies LC, van Geuns RJ, Anagnostopoulos C, Klotz E, Kitslaar P, Broersen A, Mathur A, Nieman K, Hunink MG, de Feyter PJ, Petersen SE, Pugliese F. Diagnostic performance of hyperaemic myocardial blood flow index obtained by dynamic computed tomography: does it predict functionally significant coronary lesions? *Eur Heart J Cardiovasc Imaging*. 2014 Jan;15(1):85-94.

Thank you for highlighting these additional studies which were not included in the review proposal.

NICE considers updating published diagnostics guidance if the evidence base or clinical environment has changed to an extent that is likely to have a material effect on the recommendations in the existing guidance.

The current guidance makes positive recommendations on the use of CT scanners. New evidence which provides further support for improvements in outcomes is unlikely to have a material effect on these positive recommendations.

Thank you for highlighting these additional studies which were not included in the review proposal.

The original assessment focused on CT angiography in difficult to image patients with a comparator of invasive coronary angiography. When guidance is updated it would not normally be expanded to include new patient populations or subgroups, or a different disease severity or aetiology.

These studies on cardiac CT for

<p>Bamberg F, Marcus RP, Becker A, Hildebrandt K, Bauner K, Schwarz F, Greif M, von Ziegler F, Bischoff B, Becker HC, Johnson TR, Reiser MF, Nikolaou K, Theisen D. Dynamic myocardial CT perfusion imaging for evaluation of myocardial ischemia as determined by MR imaging. JACC Cardiovasc Imaging. 2014 Mar;7(3):267-77.</p> <p>Kono AK, Coenen A, Lubbers M, Kurata A, Rossi A, Dharampal A, Dijkshoorn M, van Geuns RJ, Krestin GP, Nieman K. Relative myocardial blood flow by dynamic computed tomographic perfusion imaging predicts hemodynamic significance of coronary stenosis better than absolute blood flow. Invest Radiol. 2014 Dec;49(12):801-7.</p> <p>Wang Z, Chen Y, Wang Y, Xue H, Jin Z, Kong L, Cao J, Li S. Feasibility of low-dose contrast medium high pitch CT angiography for the combined evaluation of coronary, head and neck arteries. PLoS One. 2014 Mar 3;9(3):e90268.</p> <p>Meinel FG, Ebersberger U, Schoepf UJ, Lo GG, Choe YH, Wang Y, Maivelett JA, Krazinski AW, Marcus RP, Bamberg F, De Cecco CN. Global quantification of left ventricular myocardial perfusion at dynamic CT: feasibility in a multicenter patient population. AJR Am J Roentgenol. 2014 Aug;203(2):W174-80.</p> <p>Li W, Zhu X, Li J, Peng C, Chen N, Qi Z, Yang Q, Gao Y, Zhao Y, Sun K, Li K. Comparison of the sensitivity and specificity of 5 image sets of dual-energy computed tomography for detecting first-pass myocardial perfusion defects compared with positron emission tomography. Medicine (Baltimore). 2014 Dec;93(28):e329.</p> <p>Ho KT, Ong HY, Tan G, Yong QW. Dynamic CT myocardial perfusion measurements of resting and hyperaemic blood flow in low-risk subjects with 128-slice dual-source CT. Eur Heart J Cardiovasc Imaging. 2014 Nov 6. pii: jeu200. [Epub ahead of print]</p>	<p>functional imaging and other uses are interesting but this evidence does not fit the scope of the original assessment.</p> <p>If you would like NICE to consider assessing CT scanners for other uses, we encourage you to contact the Medical Technologies team at MedTech@nice.org.uk. Further information can be found on the NICE website: NICE medical technologies programme.</p>
<p>Respondent: Toshiba Medical</p> <p>Response to proposal:</p> <p><u>Section 6.1.5</u></p> <p>Toshiba Medical would like the Aquilion PRIME to be included with in this document. - Following a review of the document, it is clear that other vendors have kept their 4cm detector products in this document. (This was not challenged during the setting up of the original guidance as it was their highest level of system). Now that they have higher systems to compete with the Flash and the ONE we expected these would be removed. Based on the fact that they remain we would like the Aquilion PRIME included as it is a competitors in this product range.</p> <p>Product description for the above.</p>	<p>Comment from the Diagnostics Assessment Programme</p> <p>Thank you for your comments, which have been considered by NICE.</p> <p>NICE considers updating published diagnostics guidance if the evidence base or clinical environment has changed to an extent that is likely to have a material effect on the recommendations in the existing guidance. If changes in these areas are</p>

<p>The Aquilion PRIME is a 160 slice system, with a 4cm PUREViSION detector comprising of 80 rows and 0.5mm elements. Using SURECardio Prospective (Toshiba’s unique helical prospective Cardiac Acquisition package) the Aquilion PRIME utilises in combination with the PUREViSION detector - AIDR3D Enhanced, automated kV selection, automated mA modulation, to achieve low dose acquisitions (sub millisvert) in 4-5 consecutive beats. Much of this information can be seen on the Aquilion PRIME website www.aquilionprime.com</p> <p><u>Section 6.1.2</u> Dependent on the display of information. The Aquilion ONE ViSION is a new system. The Aquilion ONE is still a product sharing the same name (but much like a BMW 5 series of today) it is a very different scanner to the system referred to in the original guidance. AIDR3D Toshiba’s advanced iterative reconstruction has been through a number of development steps to reach its latest level of AIDR3D Enhanced visually improved with a finer grain size, PUREViSION detector. SURE kV – automated kV selection, SUREXposure – automated mA selection based on patient size, Coronary SURESubtraction – subtracting calcification and stents to see true vessel lumen, AMC automated motion correction – this software package is able to review movement unsharpness in an image and reviews the temporal data to correct for this movement. Much of this information can be seen on the Aquilion ONE website www.aquilionvision.com</p>	<p>identified and an update is recommended, newer technologies or newer versions of technologies can be considered for inclusion in the updated guidance.</p> <p>Changes in clinical practice, technology costs or evidence that would lead to a change in the recommendations of the original guidance have not been identified. However, all CT scanners included in the original guidance have been upgraded with new features or replaced with newer models. It is therefore proposed that a technical supplement describing these newer versions is produced, and that the guidance is placed on the static list.</p> <p>Changes have been made to section 6.1.2 of the review proposal to reflect your comments on factual accuracy.</p>
<p>Respondent: Department of Health Response to proposal: The Department of Health has no substantive comments to make, regarding this consultation.</p>	<p>Comment from the Diagnostics Assessment Programme Thank you for your comment.</p>

Respondent: Lay person

Response to proposal:

When the original assessment was published I thought it inappropriate that the title of the document should specify machines rather than the generic technology; this appeared to preclude the entry of any unlisted manufacturer, and a listed manufacturer's new machines, into this field of diagnostic devices. To be precise, I felt that the part in parentheses of the title should be deleted. I would like to see this precept implemented in any future publication.

Comment from the Diagnostics Assessment Programme

Thank you for your comment, which has been considered by NICE.

The Diagnostics assessment programme focusses on the assessment of specific, innovative systems where a well-defined value position in the care pathway can be identified. Different systems, as a result of their particular specifications, have different outcomes and costs. Other systems not included in the assessment could have different specifications, associated outcomes and costs to those included. Therefore, for precision, the assessed technologies are included in the title of the guidance.

Changes in clinical practice, technology costs or evidence that would lead to a change in the recommendations of the original guidance have not been identified. However, all CT scanners included in the original guidance have been upgraded with new features or replaced with newer models. It is therefore proposed that a technical supplement describing these newer versions is produced, and that the

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Paper signed off by:

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