

Aquilion PRIME CT scanner for imaging coronary artery disease in adults in whom imaging is difficult

Medtech innovation briefing

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Summary

The Aquilion PRIME is a CT scanner that can be used for computed tomography coronary angiography (CTCA), to diagnose or evaluate coronary artery disease non-invasively in people with conditions that make it difficult to obtain good-quality CTCA images. The Aquilion PRIME has technical features that are recognised to address clinical challenges in patients who have coronary artery disease that is difficult to image, but there is no published evidence on the safety or effectiveness for this indication. It can also be used for other clinical imaging applications in adults and children. The Aquilion PRIME typically costs between £350,000 and £500,000, excluding VAT, depending on the configuration.

During the review process for diagnostics guidance on [new generation cardiac CT](#)

scanners, NICE became aware of the Aquilion PRIME CT scanner, which has similar technical specifications to those recommended in the guidance. NICE has also published a medtech innovation briefing on the Somatom Definition Edge CT scanner.

Product summary and likely place in therapy	Effectiveness and safety
<ul style="list-style-type: none">• The Aquilion PRIME CT scanner can be used to perform computed tomography coronary angiography (CTCA) to diagnose or evaluate coronary artery disease non-invasively.• It would be used in adults with suspected or known coronary artery disease in whom:<ul style="list-style-type: none">– revascularisation is being considered and– imaging with earlier generation CT is difficult. <p>This includes people with obesity, high levels of coronary calcium, arrhythmias, high heart rates, stents or bypass grafts.</p> <ul style="list-style-type: none">• It can also be used for other clinical imaging applications in adults and children.	<ul style="list-style-type: none">• There is no published evidence on the safety or effectiveness of the Aquilion PRIME scanner in people with difficult-to-image coronary artery disease. There is little evidence available on many CT scanner models in difficult-to-image subgroups because of the relatively rapid evolution of CT technology, particularly software enhancements.

Technical and patient factors	Cost and resource use
<ul style="list-style-type: none">• The Aquilion PRIME is a single-source, dual-energy helical CT scanner with 80 detector rows and is available in 80- or 160-slice models.• The scanner is suitable for all people in whom CT imaging is recommended, including adults (aged 18 years and over) with suspected or known coronary artery disease.• The scanner is intended for use in secondary care settings, specifically by trained radiographers who have the expertise to perform CTCA. Images are interpreted by radiologists or cardiologists.	<ul style="list-style-type: none">• The Aquilion PRIME typically costs between £350,000 and £500,000 excluding VAT, depending on the configuration.• No published evidence on cost effectiveness or resource use was available for this scanner.

Introduction

Coronary artery disease (CAD) is a condition in which an atherosclerotic plaque, made up of fat, cholesterol, calcium and other substances found in the blood, builds up inside the coronary arteries (NHS Choices 2014). Over time, the plaque hardens and narrows the coronary arteries, restricting the flow of oxygen-rich blood to the heart (ischaemia). Sometimes, an area of the plaque can rupture, causing a blood clot to form on the surface of the plaque. If the clot becomes large enough, it can largely or completely block blood flow through a coronary artery. The most common symptoms of CAD are shortness of breath and chest pain or discomfort. Chest pain caused by CAD is called angina, which is broadly divided into 2 categories:

- Stable angina: when the pain is caused by anticipated factors (triggers), such as physical exercise, and usually resolves with rest or medication.
- Unstable angina: when the pain occurs unpredictably, without triggers. This may be a sign that the function of the heart has rapidly deteriorated and should be managed as a form of acute coronary syndrome, similar to a heart attack (myocardial infarction).

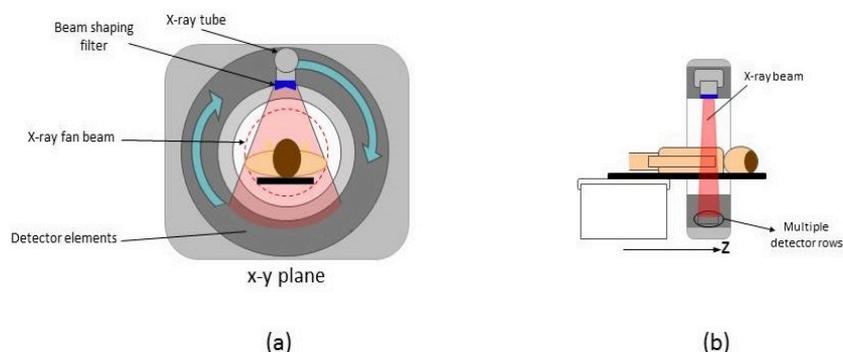
If left untreated, CAD can lead to myocardial infarction and death. In the UK, an estimated 2.3 million people are living with CAD and an estimated 74,000 deaths were caused by CAD in 2012 (Townsend et al. 2014).

When a person presents with acute chest pain the NICE clinical guideline on the [assessment and diagnosis of chest pain of recent onset](#), before the 2016 update, recommended that if acute coronary syndrome is not suspected, but CAD (stable angina) cannot be ruled out after clinical assessment, the person's estimated likelihood of having CAD should be determined. This is calculated on the basis of symptoms, age, sex and risk factors. The guideline recommended that computed tomography coronary angiography (CTCA) should be offered if the estimated likelihood of CAD is 10–29% and that people in this category should be offered calcium scoring (a measure of atherosclerotic plaque burden), followed by CTCA if the calcium score is between 1 and 400. CTCA, therefore, would rule out a diagnosis of CAD, rather than confirm it (British Heart Foundation 2015). A calcium score above 400 indicates that imaging using earlier generation CT scanners would be difficult, and the guideline recommended invasive coronary angiography (ICA), the gold standard for evaluating coronary anatomy in these cases, if this was considered clinically appropriate.

NICE diagnostics guidance on [new generation cardiac CT scanners](#) also recommends CTCA as an option for first-line evaluation of disease progression to establish the need for revascularisation, in people with known CAD in whom imaging with earlier generation CT scanners is difficult. Furthermore, according to the NICE guideline on [stable angina](#), CTCA should also be offered to people with stable angina whose symptoms are not satisfactorily controlled with medical treatment.

CTCA involves combining multiple X-rays into cross-sectional images (slices) of the heart to assess potential coronary artery narrowing or occlusion, as well as coronary plaque morphology and density. A standard intravenous cannula is inserted into a suitable vein in the arm. A contrast medium is injected and the CT image is acquired as the person moves through the gantry (the doughnut-shaped opening containing the X-ray source and detectors; [see figure 1](#)). The blood vessels containing the contrast medium are visible on the CT scan and any narrowed or blocked vessels can be seen (NHS Choices 2013).

Figure 1 Schematic of CT scanner main components (a) in x-y plane and (b) in z-axis direction.



In some patient populations, it is difficult to get good-quality CTCA images unless the CT scanners have particular technical specifications. The following common conditions can make CTCA difficult:

- A high heart rate that cannot be lowered with drugs. The movement associated with a high heart rate creates blurring in the scan (motion artefact).
- An irregular heart beat (arrhythmia), which causes artefacts (distortions unrelated to the subject being scanned) in the resulting image. More than 2 million people a year experience arrhythmias (NHS Choices 2015).
- Excessive coronary calcium. Calcified plaques appear proportionally larger on the CT scan than they actually are, and can obscure the lumen of the blood vessel (blooming artefact). According to NICE diagnostics guidance on [new generation cardiac CT scanners](#) a calcium score above 400 suggests imaging using earlier generation CT scanners would be difficult.
- Obesity. CT images of patients with obesity may be poor quality because of increased image noise, making it difficult to distinguish different structures (due to poorer contrast resolution). According to the Health Survey for England, 67% of men and 57% of women were overweight (with a BMI between 25 kg/m² and 30 kg/m²) or obese (with a BMI over 30 kg/m²; Health & Social Care Information Centre 2012). A higher BMI increases the risk of CAD, so a significant proportion of people who could benefit from cardiac CT imaging may be overweight or obese.

- Cardiac stents. Stents can cause image artefacts (blooming; Mahnken 2015) and therefore may not be well defined in CT images. Over 71,500 percutaneous coronary intervention procedures, in which stents are commonly inserted to widen coronary arteries, were carried out in the UK in 2014 (Health & Social Care Information Centre 2015).
- Previous coronary artery bypass grafts. These surgical procedures are carried out in people with severe CAD who will have narrowed and calcified coronary arteries, which are difficult to image. Over 16,000 coronary artery bypass grafts were conducted in the UK in 2012 (Townsend et al. 2014).

The NICE clinical guideline on the [assessment and diagnosis of chest pain of recent onset](#) recommends using 64-slice (or above) CT scanners, which are the most commonly used scanners in the NHS (Clinical Imaging Board 2015). NICE diagnostics guidance on [new generation cardiac CT scanners](#) recommends 4 specific scanners (Aquilion ONE, Brilliance iCT, Discovery CT750 HD and Somatom Definition Flash), all of which have technical enhancements that can improve CTCA image acquisition in people with suspected or known coronary artery disease in whom imaging is difficult with earlier generation CT scanners.

The following technical performance parameters are helpful when performing CTCA where imaging is difficult (also [see figure 2](#)):

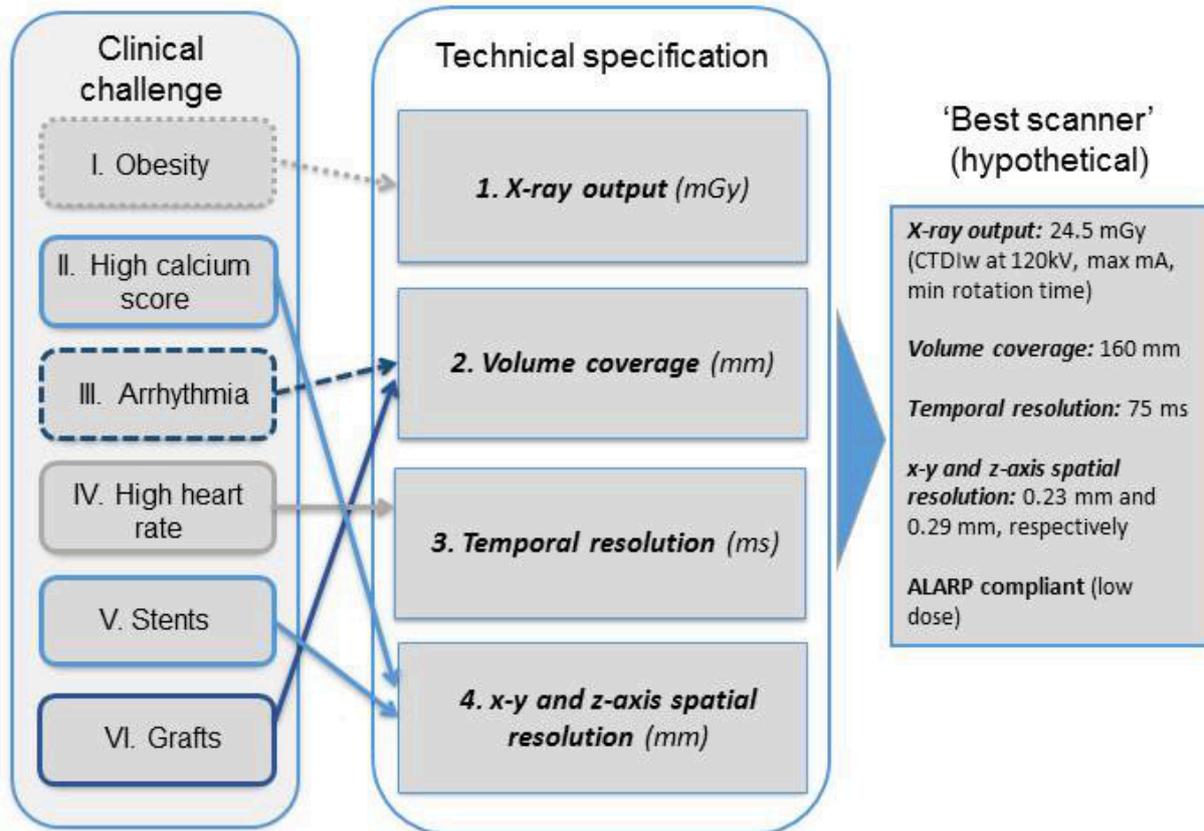
- X-ray output: a measure of the intensity of the X-ray beam produced by a scanner. This must be at a level which is sufficient to provide images that distinguish between different tissues. It can be expressed as CT dose index weighted (CTDI_w).
 - Higher CTDI_w values will result in lower image noise and improved contrast resolution.
 - Maintaining image quality with increased X-ray intensity can be difficult when scanning people with obesity.
- Volume coverage: the length of anatomy in the z-axis (that is, head to toe) that can be scanned in 1 axial rotation of the scanner.
 - With a large volume coverage, the cardiac volume can be acquired in a smaller number of heartbeats (ideally a single heartbeat), reducing image artefacts. Fast volume coverage can improve imaging for people with arrhythmia or grafts.

- Temporal resolution: the period of time over which images are reconstructed.
 - The intrinsic temporal resolution is defined as the time taken to acquire 180° of data, the minimum usually necessary for image reconstruction. The effective temporal resolution is the time taken when various methods for improving the intrinsic temporal resolution (for example, motion correction algorithms, multi-segment reconstruction) are applied.
 - A high temporal resolution (lower values represent better resolution) is important for acquiring CTCA images that are free from blurring in people with a high heart rate.
- Spatial resolution: the ability of the imaging system to depict small anatomical features in an image. It is defined as the minimum distance (mm) between 2 small, high-contrast objects that allows both structures to be seen in the image.
 - Spatial resolution in the x-y plane (across the body) and on the z-axis (down the body) often differ. Several algorithms used to reconstruct the images have been developed by different CT scanner manufacturers. These provide different effective spatial resolution in the x-y plane for general CTCA scans and improved high-contrast resolution for CTCA in people with stents or high calcium scores. High spatial resolution (lower values represent better resolution) can reduce the amount of blooming from stents or high calcium levels.

There is no single scanner on the market that optimally addresses all clinical challenges for all patient subgroups. NICE diagnostics guidance on [new generation cardiac CT scanners](#) recommends a range of CT scanners as a first-line option for people in whom cardiac imaging is difficult, because they have advanced features to produce better images at lower radiation doses, and avoid blooming or motion (blurring) artefacts. The Aquilion PRIME was not covered by the NICE guidance but also has some of these features. Figure 2 highlights the clinical challenge for each patient group in whom imaging is difficult and matches this to the key technical feature of scanners designed to improve the image quality for that group. The highest specification commercially available for each technical feature is used to 'create' a hypothetical scanner.

Figure 2 Clinical challenges for each subgroup of patients in whom imaging is difficult, matched to key technical features of CT scanners intended to

improve the image quality for each subpopulation. The optimal specification for each technical feature is used to 'create' a hypothetical scanner



Abbreviations: ALARP, as low as reasonably practicable; CTDIw, CT dose index weighted (the average absorbed dose across the field of view in a standard phantom); kV, kilovolt; mA, milliamp; mGy, milligray; mm, millimetre; ms, millisecond.

Technology overview

This briefing describes the regulated use of the technology for the indication specified, in the setting described, and with any other specific equipment referred to. It is the responsibility of healthcare professionals to check the regulatory status of any intended use of the technology in other indications and settings.

About the technology

CE marking

The Aquilion PRIME (Toshiba Medical Systems) was originally launched in the UK in 2011. It has a CE marking as a class IIb device under the Medical Devices Directive 1993/42/EEC. This was renewed on 26 February 2015 after a hardware modification.

Description

The Aquilion PRIME (Toshiba Medical Systems) is a helical (rotating with a constant radius) CT scanner with the following main features and specifications:

- Single-source: a single X-ray source within the scanner gantry.
- Multi-slice: capable of imaging multiple parallel, cross-sectional slices in a single rotation.
- Dual-energy: images are acquired at 2 different energies to allow differentiation between tissues.
- 78 cm bore (aperture diameter) with a couch that can be driven low to the ground, a table weight limit of 300 kg and lateral movement capability, which allows the patient to be positioned accurately.

Table 1 Technical specifications

Technical specification	Aquilion PRIME
1. X-ray output	
a. X-ray generator power	72 kW
b. Tube potential of 100 kV	
i. Maximum tube current	600 mA
ii. CTDI _w /100 mA	13.9 mGy
c. Tube potential of 120 kV	
i. Maximum tube current	600 mA

ii. CTDI _w /100 mA	22.5 mGy
2. Volume coverage	
a. Detector rows	80 proprietary PUREVISION scintillator array)
b. Detector row size	0.5 mm
c. z-axis length	40 mm
d. Number of slices per rotation	80 (160 slices can be generated with a reconstruction algorithm)
3. Temporal resolution	
a. Minimum gantry rotation time	350 ms
b. Intrinsic temporal resolution	175 ms
c. Effective temporal resolution	35–175 ms
4. Spatial resolution	
a. Detectors per row	896
b. x-y plane spatial resolution (standard mode)	0.45 mm
c. x-y plane spatial resolution (high resolution mode)	0.39 mm
d. z-width of detector row	0.5 mm
e. z-spatial resolution	0.45 mm
Abbreviations: CTDI _w , CT dose index weighted (the average absorbed dose across the field of view in a standard phantom); kV, kilovolt; kW; kilowatt; mA, milliamp; mGy, milligray; mm, millimetre; ms, millisecond.	

According to the manufacturer, the Aquilion PRIME includes the following software and capabilities, which are claimed to improve cardiac CT scanning in people in whom imaging is difficult:

- Dose reduction and image quality
 - Adaptive Iterative Dose Reduction (AIDR 3D): noise reduction technology, enabling a lower radiation dose and less contrast medium to be used, while improving image detail. AIDR 3D is also designed to minimise artefacts to improve image quality in computed tomography coronary angiography (CTCA) for people with grafts or obesity.
 - ^{SURE}Exposure 3D: adjusts exposure in the x, y and z directions in response to a person's shape and size, thus reducing radiation exposure. The algorithm calculates the amount of tube current needed to achieve the target image quality specified by the user. This may be particularly beneficial for people with obesity.
 - ^{SURE}kV: automatically sets the tube potential (the energy and intensity of the X-ray beam) based on the person's size, ^{SURE}Exposure settings and generator capacity. Lowering the kV optimises the contrast within the image, thereby reducing the amount of additional contrast medium needed. This feature intends to standardise image quality for people of varying size and may be particularly beneficial in people with obesity. It could also reduce the risk of contrast-related adverse events.
- Gating functionality (selective imaging at specific points in the cardiac cycle)
 - ^{SURE}Cardio: prospective software which rapidly pulses the X-rays on and off, so the person is only exposed to radiation during the cardiac phase or the phases needed for the diagnostic procedure. If an irregular heart rhythm is detected, the software will automatically set optimal scanning conditions to ensure good image acquisition. This may be beneficial for people with high heart rates or arrhythmia.
 - Cardiac retrospective scanning: helical scanning of the heart over a number of cardiac cycles to allow retrospective reconstruction of the different phases, using a larger dose of radiation when compared to prospective gating. This is beneficial for people with high heart rates or arrhythmia.

Setting and intended use

The Aquilion PRIME is intended for use in secondary care settings, specifically by staff with expertise in conducting and interpreting cardiac CT imaging. Additionally, the hospital must comply with radiological protection standards, including basic standards for protection against the dangers inherent in exposure to ionising radiation. The test would

be requested by a clinician involved in managing coronary artery disease, normally a cardiologist. A radiographer would carry out the scan and a radiologist or cardiologist would interpret the results.

Current NHS options

The NICE guideline on chest pain of recent onset (currently being updated) recommends CTCA for people with a low estimated likelihood (10–29%) of CAD and a calcium score of 1–400.

NICE diagnostics guidance on new generation cardiac CT scanners recommends 4 specific scanners (Aquilion ONE, Brilliance iCT, Discovery CT750 HD and Somatom Definition Flash), all of which have technical enhancements that can improve CTCA image acquisition, to be used to perform CTCA in the following groups:

- people with chest pain who have an estimated likelihood of CAD of 10–29% and are difficult to image
- people with known CAD in whom imaging is difficult with earlier generation CT scanners and for whom revascularisation is being considered.

NICE is aware of the following CE-marked single-source CT scanners that appear to fulfil a similar function to the Aquilion PRIME.

- Aquilion ONE (Toshiba)
- Aquilion ONE Vision (Toshiba)
- Optima 660 (GE Healthcare)
- Revolution GSI/HD (Discovery CT750 HD; GE Healthcare)
- Revolution CT (GE Healthcare)
- Brilliance iCT (first launch; Philips Healthcare)
- iCT Elite (new generation; Philips Healthcare)
- Ingenuity (Philips Healthcare)
- IQon Spectral CT (Philips Healthcare)

- Somatom Definition AS+ (Siemens)
- Somatom Definition Edge (Siemens)
- Somatom Definition Flash (Siemens)
- Somatom Force (Siemens).

NICE has produced a medtech innovation briefing on the [Somatom Definition Edge CT scanner](#). NICE has produced a technical supplement to the diagnostics guidance on [new generation cardiac CT scanners](#) to describe the newer versions of the scanners included in the guidance.

Costs and use of the technology

According to the manufacturer, the Aquilion PRIME typically costs between £350,000 and £500,000, excluding VAT, depending on the options added to the core system at the time of purchase or added any time thereafter. The lifespan of a CT scanner is 7–10 years (Clinical Imaging Board 2015). Irrespective of the capital cost, the nationally representative unit cost for a cardiac CT scan including labour time, overheads and consumables is £259 (Department of Health 2014, code RA68Z).

Training to use the Aquilion PRIME system is provided free of charge by the manufacturer.

Other diagnostic procedures used in the chest pain pathway include invasive coronary angiography (ICA), magnetic resonance imaging (MRI), single photon computed emission tomography (SPECT) and stress echocardiography (ECHO). The ICA procedure has a unit cost of £1,241 (NHS 2014/15 National tariff payment system, code EA36A). An outpatient cardiac MRI scan inclusive of contrast medium costs £527 (Department of Health 2014, code RA66Z). The unit cost for SPECT is £220 (NHS 2014/15 National tariff payment system, code RA37Z). The unit cost for stress ECHO is £74 (NHS 2014/15 National tariff payment system, code RA60Z).

CT scanner technologies need specific infrastructure and equipment, as well as suitably trained radiographic and radiological staff. There are no particular practical difficulties in using or adopting the Aquilion PRIME.

Likely place in therapy

The Aquilion PRIME would be used to perform cardiac CT imaging in adults (aged 18 years and over) with suspected CAD in whom imaging with earlier generation CT is difficult and who have an estimated likelihood of CAD of 10–29%, or known CAD in whom imaging with earlier generation CT is difficult and for whom revascularisation is being considered. The scanner may also be used to perform CTCA in people with stable angina whose symptoms are not satisfactorily controlled with medical treatment.

The Aquilion PRIME can also be used for other clinical imaging applications in adults and children.

Specialist commentator comments

One commentator stated that although CTCA is predominantly used to rule out CAD in people with an estimated likelihood of 10–29% of having the disease, it can also be used as a rule-in test to confirm CAD in people at moderate risk (30–60%). The commentator said that, in practice, people at low, moderate and intermediate risk (10–90%) of CAD have CTCA. People at moderate risk with no sign of disease on CTCA do not have further investigations, whereas people with signs of disease are assessed further using functional imaging, the choice of which will depend on their individual circumstances. The NICE clinical guideline on the [assessment and diagnosis of chest pain of recent onset](#) recommended other forms of imaging such as SPECT, ECHO or MRI, or ICA for higher-risk groups.

Two specialist commentators emphasised the capability of the Aquilion PRIME to scan people with obesity. One stated that the scanner has a larger bore than previous models and has the option of a bariatric table that can support a larger person. Both commentators noted that larger people need higher volumes of contrast medium or higher injection rates. One specialist commentator added that this must be balanced with the advantage of better contrast that can be obtained at lower kV levels, because lowering the kV for people with obesity can result in added image noise and affects the quality of the images. The commentator believed that the ^{SURE}kV software had the potential to automatically standardise 1 of the imaging parameters based on patient size. Another commentator noted that the automated software tends to use higher kV in people with larger body masses. One commentator did not consider that AIDR 3D iterative reconstruction could reduce the amount of contrast medium or minimise artefacts for people with obesity or grafts.

One specialist commentator stated that the Aquilion PRIME does not have specific features that address the problems posed by people with high coronary calcium.

Because of the range of available CT scanners that are capable of assessing people with bypass grafts, 1 commentator did not believe people with previous bypass grafts were difficult to image. A second commentator noted that non-invasive imaging of the grafts is often desirable before ICA, because ICA can be challenging in this group.

One specialist commentator said that the arrhythmia detection employed by the Aquilion PRIME, including ^{SURE}Cardio software, is useful for people with ectopic beats (extra heartbeats) but does not address the difficulties of scanning people with atrial fibrillation. More advanced CT scanners, such as the Toshiba Aquilion ONE (which only needs a single heartbeat for image acquisition), are preferable for obtaining clear images of people with atrial fibrillation. The commentator also noted that the Aquilion PRIME does not have as high an intrinsic temporal resolution as dual-source CT scanners or other scanners with higher tube rotation times. They noted that the retrospectively gated mode with segmented reconstruction can be used for high (regular) heart rates, but that the use of beta blockers to lower and control heart rate remains essential for best-quality images at the lowest radiation doses, as with most coronary CT. They also noted that the optimal temporal resolution is only possible with retrospective ECG-gating and multi-segment reconstructions with a higher dose, increasing the possibility of movement artefacts. Finally, the commentator stated that stent visualisation is better in scanners that are more advanced than Aquilion PRIME, particularly where multiple stents may cross acquisition boundaries in prospective scanning. Another specialist commentator noted that using medication to lower heart rate has implications for people who are unable to take or tolerate beta-blockers.

According to 1 specialist commentator, a scanner lifespan of 7 years is a long time given the rapid rate of technology evolution. The commentator also said that the nationally representative unit cost (which does not account for capital cost) underestimates the cost of advanced cardiac CT scanning in complex cases, which need more advanced (and expensive) hardware.

One specialist commentator noted that the NICE clinical guideline on the assessment and diagnosis of chest pain of recent onset was under review at the time they provided their comments, and that the NICE diagnostics guidance on new generation cardiac CT scanners is out of date because several of the models from the guidance have been superseded and are no longer available.

Two specialist commentators noted that there are currently more advanced scanners on the market that can address clinical challenges for all subgroups of people who are difficult to image. These include the Toshiba Aquilion ONE Vision, Siemens Somatom Force, Philips IQon and the GE Revolution. One of the commentators explained that Aquilion PRIME is a mid-range scanner, similar to Siemens Definition AS+ and GE Revolution GSI/HD. The same commentator noted that dual-source scanners have different technological solutions but are not necessarily superior to single-source scanners for all applications. They stated that their overall impression is that the Toshiba Aquilion PRIME is an excellent general CT scanner that can produce high-quality cardiac/coronary images, especially in people with low steady heart rates and good breath-hold capability. It has advantages over previous generation scanners in its ability to scan people with obesity, better image quality and a significant reduction in radiation doses with the advanced iterative reconstruction. However, they added that if the purpose of buying a CT scanner is to scan people who are difficult to image (including those with arrhythmia, poor breath-hold ability and coronary stents), it would be advisable to buy a more advanced CT scanner that significantly simplifies the scanning procedure and is more robust and 'future-proof'. The commentator suggested that this might include those with broad detector arrays (16 cm) such as the Toshiba Aquilion ONE series or GE Revolution. This point was reiterated by another specialist commentator, who stated that, in practice, the latest CT technology would offer more image improvement and dose-saving capability, and thus be suitable for use in everyone, including those in whom imaging is difficult.

Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance, NICE aims to comply fully with all legal obligations to:

- promote race and disability equality and equality of opportunity between men and women
- eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

People with diabetes or obesity may be considered to be disabled under the Equality Act if these conditions have a substantial and long-term adverse effect on their ability to carry

out normal day-to-day activities. Disability is a protected characteristic defined in the Equality Act 2010.

Evidence review

Clinical and technical evidence

Regulatory bodies

A search of the Medicines and Healthcare Products Regulatory Agency website revealed 2 manufacturer field safety notices (FSNs) published in 2015 regarding software issues. The first FSN states that certain operations in multi-phase scanning do not save the acquired data. The second notice explains that if specific scans are executed consecutively, image reconstruction may not be performed correctly or the couch position may not be displayed correctly. No MHRA Medical Device Alerts were found for this device and no reports of adverse events were identified from a search of the US Food and Drug Administration (FDA) Manufacturer and User Device Facility Experience (MAUDE) database.

Clinical evidence

Two searches were performed to find publications relevant to Aquilion PRIME in people who are difficult to image (see appendix for [search strategies](#)). No relevant publications were found. There is little evidence available on the effectiveness and safety of particular CT scanner models in diagnosing CAD in difficult-to-image subgroups because of the relatively rapid evolution of CT technology, particularly software enhancements. The available general evidence points to the key technical parameters of a scanner that determine suitability in this application: temporal resolution, spatial resolution and acquisition time.

Recent and ongoing studies

No ongoing or in-development trials on the Aquilion PRIME for cardiac patients were identified.

Costs and resource consequences

It was not possible to estimate the future NHS usage of the Aquilion PRIME for the relevant population. In NICE diagnostics guidance on [new generation cardiac CT scanners](#), it is estimated that the number of people in England in whom imaging is difficult with earlier generation CT scanners may range from 10 million to 18 million. This may be indicative of future NHS usage.

According to the manufacturer, the device is being used at 33 NHS centres.

There will be no need to change the way in which current services are organised or delivered. No other additional facilities or technologies are needed alongside the technology.

No published evidence on resource consequences was identified in the systematic review. However, an economic evaluation by Westwood et al. (2013) contains a model assessing the cost-effectiveness of invasive coronary angiography (ICA) alone, ICA following a positive CT scan using a new-generation CT scanner, and new-generation CT scanning alone in difficult-to-image subgroups with suspected or known CAD. Westwood et al. (2013) do not mention the Aquilion PRIME, but include high-end scanners from the NICE diagnostics guidance on [new generation cardiac CT scanners](#). They report that in patients with suspected CAD, the 'CT scanner only' strategy is the most cost-effective approach compared with the other strategies.

Relevance to NICE guidance programmes

NICE has issued the following guidance:

- [Chest pain of recent onset: assessment and diagnosis](#) (2010) NICE guideline CG95. Date for review: November 2018.
- [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](#) (2012) NICE diagnostics guidance DG3.
- [Stable angina: management](#) (2011) NICE guideline CG126.

- [Unstable angina and NSTEMI: early management](#) (2010) NICE guideline CG94.

References

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Mahnken AH (2012) [CT imaging of coronary stents: past, present, and future](#). International Scholarly Research Notices Cardiology 139823

NHS Choices (2013) [Coronary angiography – clinical trial details](#) [online; accessed 12 December 2015]

NHS Choices (2014) [Coronary heart disease](#) [online; accessed 27 October 2015]

NHS Choices (2015) [Arrhythmia](#) [online; accessed 30 October 2015]

NHS England (2013) 2014/15 [National tariff payment system](#) [online; accessed 2 November 2015]

Townsend N, Williams J, Bhatnagar P et al. (2014) [Cardiovascular disease statistics, 2014](#). British Heart Foundation [online; accessed 27 October 2015]

Westwood M, Al M, Burgers L et al. (2013) [A systematic review and economic evaluation of new-generation computed tomography scanners for imaging in coronary artery disease and congenital heart disease: Somatom Definition Flash, Aquilion ONE, Brilliance iCT and](#)

Appendix: search strategy and evidence selection

Search strategy

For the clinical evidence

Embase 1980 to 2015 October 22, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) 1946 to Present; searched 22 October 2015

Search strategy 1: Device and Coronary Artery Disease

1. CT.mp.
2. computed tomography.mp.
3. Coronary Artery Disease.mp. or Coronary Artery Disease/
4. Coronary Artery Disease/ or Coronary Disease/ or Coronary Angiography/
5. CAD.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
6. myocardial infarction.mp. or Myocardial Infarction/
7. myocardial ischemia.mp. or Myocardial Ischemia/
8. Aquilion.mp.
9. Prime.mp.
10. Toshiba.mp.
11. 1 or 2

12. 3 or 4 or 5 or 6 or 7

13. 8 or 9 or 10

14. 11 and 12 and 13

15. limit 14 to yr="2012 - current"

16. limit 15 to english language

Search strategy 2: Population and CT

1. CT.tw.

2. computed tomography.tw.

3. Coronary Artery Disease.tw. or Coronary Artery Disease/

4. Coronary Artery Disease/ or Coronary Disease/ or Coronary Angiography/

5. (coronary adj2 disease).tw.

6. CAD.tw.

7. myocardial infarction.tw. or Myocardial Infarction/

8. myocardial ischemia.tw. or Myocardial Ischemia/

9. high heart rate.tw.

10. arrhythmia.tw.

11. (tachycardia or tachyarrhythmia).tw.

12. (obesity or obese).tw.

13. stents.tw.

14. bypass grafts.tw.

15. calcium score.tw.

16. 1 or 2

17. 3 or 4 or 5 or 6

18. 7 or 8 or 9 or 11 or 12 or 13 or 14 or 15

19. 16 and 17 and 18

20. 19 not (perfusion or gene or neuro* or immuno* or simulat* or child* or youth or baby or infant).tw.

21. limit 20 to english language

22. limit 21 to yr="2012-current"

For the economic evidence

Embase 1974 to 2015 October 28, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) 1946 to Present; Searched on 29 October 2015

1. CT.mp.

2. computed tomography.mp.

3. Coronary Artery Disease.mp. or Coronary Artery Disease/

4. Coronary Artery Disease/ or Coronary Disease/ or Coronary Angiography/

5. CAD.mp.

6. myocardial infarction.mp. or Myocardial Infarction/

7. myocardial ischemia.mp. or Myocardial Ischemia/

8. Aquilion.mp.

9. Prime.mp.

10. Toshiba.mp.

11. 1 or 2

12. 3 or 4 or 5 or 6 or 7

13. 8 or 9 or 10

14. 11 and 12 and 13

15. cost*.mp.

16. economic*.mp.

17. 15 or 16

18. 14 and 17

19. limit 18 to english language

20. limit 19 to yr="2012 -Current"

Cochrane Database of Systematic Reviews: Issue 10 of 12, October 2015

Cochrane Central Register of Controlled Trials: Issue 9 of 12, September 2015

Database of Abstracts of Reviews of Effect: Issue 2 of 4, April 2015

Cochrane Methodology Register: Issue 3 of 4, July 2012

Health Technology Assessment Database: Issue 3 of 4, July 2015

NHS Economic Evaluation Database: Issue 2 of 4, April 2015

1. CT
2. computed tomography
3. Coronary Artery Disease
4. Coronary Disease or Coronary Angiography
5. CAD
6. myocardial infarction
7. myocardial ischemia
8. Aquilion
9. Prime
10. Toshiba
11. #1 or #2
12. #3 or #4 or #5 or #6 or #7
13. #8 or #9 or #10
14. #11 and #12 and #13
15. cost*
16. economic*
17. #15 or #16
18. #14 and #17 Publication Year from 2012 to 2015

Evidence selection

Evidence was selected based on the following criteria:

- Population: patients with suspected or known CAD with 1 of the following conditions:
 - obesity
 - high levels of coronary calcium (greater than 400 Agatston units [AU])
 - high heart rates (more than 65 beats per minute) that cannot be lowered with drugs
 - arrhythmias (irregular heart rhythm)
 - stents
 - previous bypass grafts.
- Intervention: Toshiba Aquilion PRIME.
- Comparator: ICA, cardiac MRI, SPECT, ECHO.
- Outcomes: diagnostic test accuracy, indeterminacy, radiation exposure and clinical outcomes including side effects associated with the use of contrast medium, major adverse cardiac events, or mortality.
- Exclusion criteria: case studies, editorials, letters, reviews, conference proceedings/ abstracts, animal studies, non-English language studies, studies not using the Aquilion PRIME.

For the clinical evidence

- Total number of publications reviewed: 1972
- Total number of publications considered relevant: 0
- Total number of publications selected for inclusion in this briefing: 0

For the economic evidence

- Total abstracts: 21
- Duplicates: 1
- Abstracts reviewed: 20
- Full papers reviewed: 0

- Studies for review: 0

About this briefing

Medtech innovation briefings summarise the published evidence and information available for individual medical technologies. The briefings provide information to aid local decision-making by clinicians, managers and procurement professionals.

Medtech innovation briefings aim to present information and critically review the strengths and weaknesses of the relevant evidence, but contain no recommendations and **are not formal NICE guidance**.

Development of this briefing

This briefing was developed for NICE by King's Technology Evaluation Centre (KiTEC). The [interim process and methods statement](#) sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

Project team

King's Technology Evaluation Centre (KiTEC)

Medical Technologies Evaluation Programme, NICE

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Specialist commentators

The following specialist commentators provided comments on a draft of this briefing:

- Bobby Agarwal, Consultant Cardiothoracic Radiologist, Papworth Hospital NHS Foundation Trust
- Madava Djearaman, Consultant Cardiothoracic Radiologist, Heart of England NHS Foundation Trust
- Mark Kon, Consultant Thoracic Radiologist, Bradford Teaching Hospitals NHS Foundation Trust
- Arjun Nair, Consultant Radiologist, Guy's and St Thomas' NHS Foundation Trust
- Giles Roditi, Consultant Cardiovascular Radiologist, Glasgow Royal Infirmary

Declarations of interest

- Mark Kon has given oral presentations at several symposia and conferences for Toshiba UK, Toshiba Europe (pre-RSNA launch meeting 2014, RSNA guest event 2013) and Toshiba Canada (CT symposium 2014). He has received honoraria up to 750 euro per international presentation as well as expenses. His hospital has been the Global Reference Centre for a Toshiba CT scanner and he expects to continue this relationship with Toshiba.
- No other relevant interests were declared.

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