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## CADTH Horizon Scan

# Photon-Counting CT: High Resolution, Less Radiation

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Emerging Health Technologies

# Key Messages

## Why Is This an Important Area of Interest?

- CT scanners play an essential role as medical imaging devices for screening, diagnosis, and monitoring of various health conditions. Photon-counting CT (PCCT) is an emerging medical technology that can improve image quality with less radiation exposure.
- Although Health Canada has licensed certain PCCT scanners for use, it remains unclear whether PCCT currently has a place in care.

## What Is the Technology?

- PCCT uses a semiconductor material to directly convert each incident photon into an electrical signal. The detector can quickly read out and "count" each individual photon. By directly detecting each X-ray photon and its energy level, PCCT scans can provide a clearer image.

## What Is the Potential Impact?

- PCCT is intended to function like conventional CT (i.e., scanning various anatomical structures for the purpose of screening, diagnosing, and monitoring health conditions). Any person requiring a CT scan could potentially be eligible for a PCCT scan.
- PCCT requires less time to complete a scan versus a conventional system. This could increase the number of CT scans a health care organization can conduct per day, if there are resources available to operationalize the additional capacity (e.g., health care personnel).
- We identified evidence that suggests, with a few exceptions, PCCT can provide similar or improved image quality and reduced image noise with often reduced radiation doses compared to conventional CT. It remains unclear whether this results in improvements in key health outcomes. The increased image quality may also increase incidental findings (e.g., incidentalomas), most of which are not clinically relevant.
- Compared to conventional CT, trends indicate higher or similar diagnostic confidence among clinicians and improved comfort for patients with PCCT. Trends also suggest PCCT may be valuable at improving the ability to diagnose or detect key markers of certain health conditions or diseases, especially for lung conditions.
- PCCT may offer particular benefits to children, people who require frequent CT scans, and people living with overweight or obesity.

# Key Messages

## What Else Do We Need to Know?

- PCCT scanners cost 3 to 5 times more than conventional CT scanners. Additional clinical trials to investigate whether the higher resolution and lower radiation doses result in downstream improvements in key health outcomes are imperative to determine if the additional cost of PCCT scanners is justified.
- To comprehensively assess whether PCCT should be implemented for clinical use in Canada, additional information on certain implementation factors — such as training requirements and implications of dual-machine exposure, user perceptions, accessibility, and its overall place in care — is needed.

## Purpose and Scope

This Horizon Scan aims to provide health care knowledge users with an overview of information regarding the use of photon-counting CT (PCCT) scanners for people requiring CT imaging to support decision-makers in making informed decisions about its suitability for implementation and use in Canada.

This report is not a systematic review and does not involve critical appraisal or include a detailed summary of study findings. It is not intended to provide recommendations for or against the use of the technology.

## The Innovation of Photon-Counting CT Could Be a New Era for CT Imaging

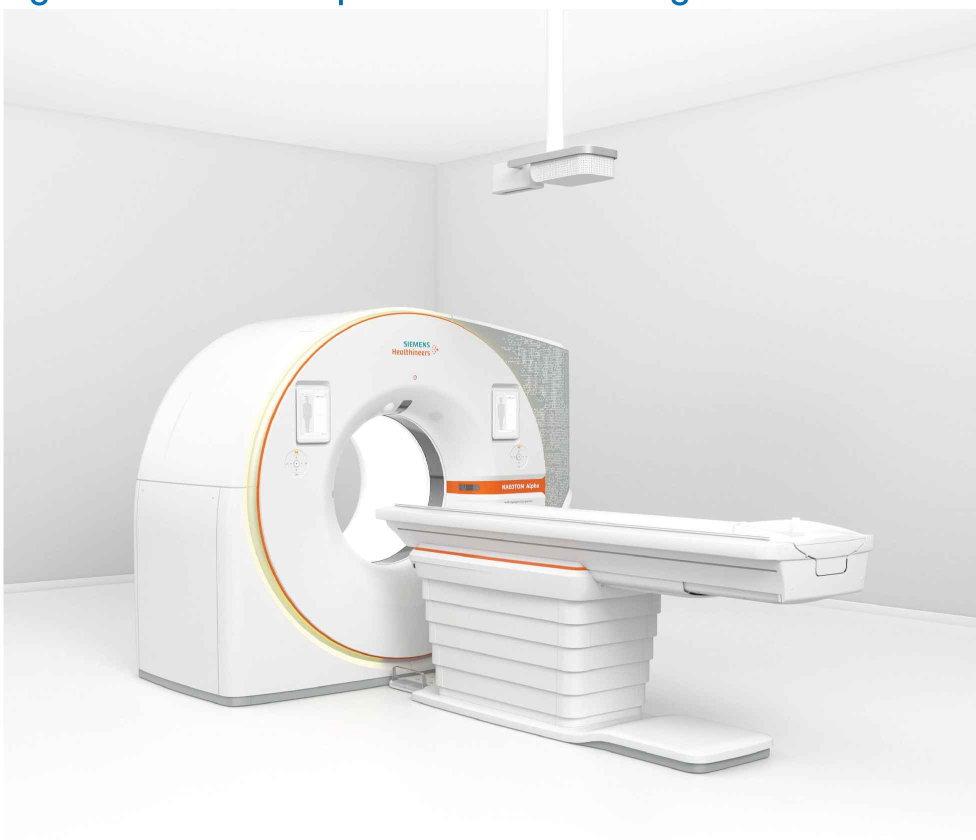
CT scanners are an established tool for the diagnosis and monitoring of a wide range of health conditions as well as interventional and research use.[1] CT scanners provide health care practitioners with detailed, cross-sectional views of the human body. Since their development in the 1970s, CT scanners have undergone numerous technological advancements, including improved image resolution, faster scan times, and the ability to create noncontrast images.[1-3] CADTH's Canadian Medical Imaging Inventory documents current practices and developments in the supply, distribution, technical operations, and general clinical and research use of advanced imaging equipment, including CT, across Canada.[4] From currently available data, CT scanners are the most common imaging modality in Canada: Canada has 544 CT units unevenly distributed across each province and territory.[4] Over the past decade, the volume of CT scans conducted increased by 47.7% (approximately 6.5 million in 2022–2023 compared with 4.4 million exams in 2012) and the CT exams per 1,000 population increased by 28.9% (162.0 in 2022–2023 compared with 125.7 in 2012).[4] We are also aware that Canada's imaging equipment is aging: a 2022–2023 survey found one-third of CT units are at least 10 years old. This signals the need to replace many CT units over the next 5 years; the Canadian Association of Radiology recommends the maximum life expectancy and clinical relevance for any imaging equipment to not exceed 15 years.[4] Despite advances to CT technology, conventional CT scanners have limitations, including image artifacts that can limit diagnostic accuracy for people who have medical implants (metal objects can absorb or scatter X-rays that cause shadows or streaks on the scan).[3]

PCCT, an emerging imaging modality, is described as an innovative advancement in the field of medical imaging (an example of a PCCT scanner is shown in Figure 1).

> **Compared to conventional CT, PCCT is intended to provide a higher resolution image with a lower radiation dose and improve tissue differentiation at a greater speed with less electronic noise.[2,3]**

PCCT scanners directly respond to the ALARA ("as low as reasonably achievable") guiding principle of radiation safety as well as the goals of campaigns such as Choosing Wisely and Image Wisely.[6-8] These campaigns emphasize the appropriate use of CT and optimizing studies to obtain the best image quality with the lowest radiation dose, especially for higher risk individuals (e.g., children are more sensitive to radiation).[6,7,9,10] It is unclear, however, if PCCT addresses a specific unmet need in health care systems in Canada. PCCT needs further exploration to see if its improvements result in better diagnostic capabilities to justify its implementation and use.

### Figure 1: NAEOTOM Alpha Photon-Counting CT Scanner

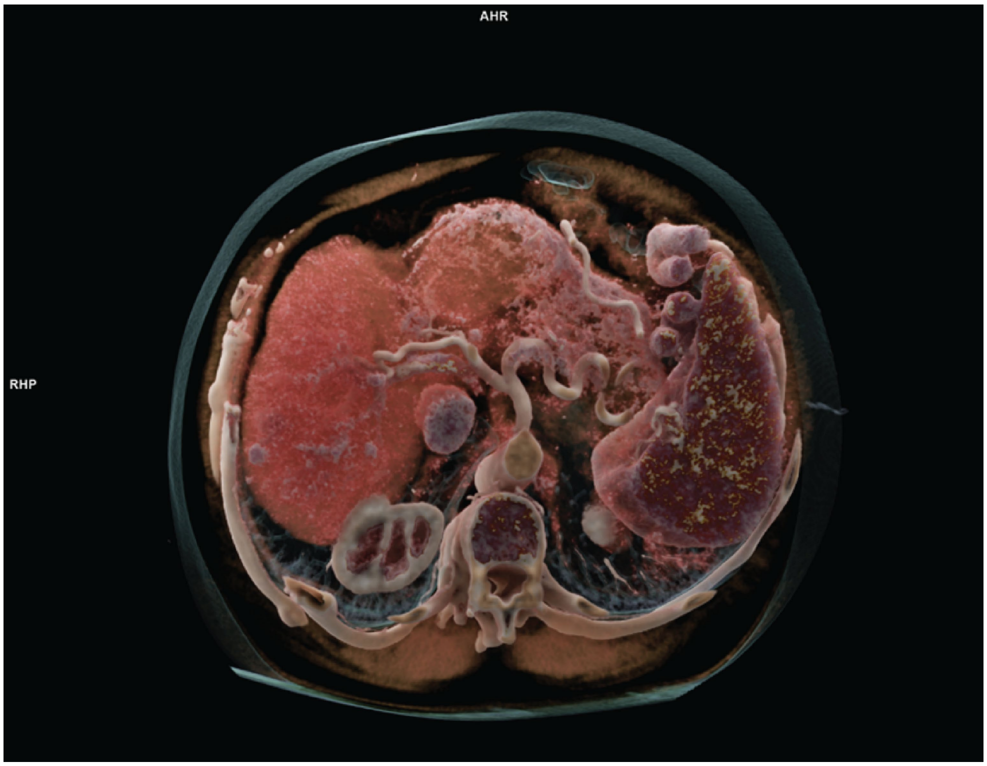


Source: Siemens Healthineers.

## How It Works

The main components of a CT scanner are an X-ray tube, a gantry (i.e., scanning unit that includes detectors), and a computer.[11] Conventional CTs use energy-integrating detectors (EIDs) that rely on scintillators to convert X-ray photons to visible light, and the integrated photon energies are then recorded as electric signals.[12] PCCT scanners, also referred to as spectral PCCT, use a novel approach in the way CT systems detect X-rays. PCCT uses a semiconductor material (e.g., cadmium zinc telluride,[13,14] silicon[15]) to directly convert each incident photon into an electrical signal that can be read quickly by the detector circuity to “count” each individual photon.[13] When an incident photon strikes the detector, it creates an electric charge cloud in the detector material that is directly proportional to the energy of the incident photon.[12,13,16] Based on the measured energy, the counted photons are sorted into energy bins that are used to generate optimal image quality with inherent spectral information using advanced reconstruction techniques, ultimately providing more usable data (Figure 2).[3,12,13] Examples of PCCT scanners are presented in Table 1.

## Figure 2: Cross-Sectional Output Image From the NAEOTOM Alpha Photon-Counting CT Scanner




Source: Erasmus Medical Center, Rotterdam, NL. Siemens Healthineers.

## Table 1: Examples of Photon-Counting CT Scanners

| Company name | Device name | Health Canada approval | Included studies | Brief description |
|---|---|---|---|---|
| Canon Medical[13] | Canon Photon Counting Scanner | No | None; only studies using phantoms[a] identified. | Canon is developing a PCCT scanner in partnership with Redlen Technologies Inc.[13] The detector is constructed using cadmium zinc telluride. The read out circuitry is designed to maximize the detector's active area to achieve geometric dose efficiency.[13] A clinical trial is under way (JPRN-jRCTs032220618).[17] |
| GE Healthcare[15] | Deep Silicon PCCT | No | None; only studies using phantoms[a] identified. | GE Healthcare describes this PCCT scanner as it may enable a significant increase in imaging performance for oncology, cardiology, neurology, and other clinical CT applications.[15] This scanner uses Deep Silicon as the semiconductor material |

| Company name | Device name | Health Canada approval | Included studies | Brief description |
|---|---|---|---|---|
| | | | | for its intended PCCT to help clinicians realize the full potential of spectral CT (e.g., purity, abundance, length, broad manufacturing). GE Healthcare calls it "Deep Silicon" because the effective depth of the detector is determined by the length of the silicon (not by the thickness), allowing the detector to have as long an absorption length, as necessary.[15] Human participant research is under way.[17] |
| MARS[18] | MARS Microlab 5X120 | No | None | MARS describes this scanner as able to simultaneously measure up to 8 energy windows per bin at very high spatial resolution (50 μm to 200 μm) and with low noise.[18] This technology enables identification and quantification of various components of bones, cartilage, soft tissues, and exogenously administered contrast agents and pharmaceuticals in a single scan (up to 6 different materials simultaneously). MARS described this system as directly translatable to clinical human imaging (i.e., same software, hardware, and visualization tools are used). No human participant research is under way (i.e., preclinical phase).[18] |
| NeuroLogica[16] | OmniTom Elite Photon Counting Detector | No | None; only studies using phantoms[a] identified. | NeuroLogica describes this scanner as the first to combine 2 key technologies: portability and photon counting.[16] This scanner is designed to bring medical imaging closer to the bedside, which may help to reduce the risks with transporting people who are critically ill to the CT suite.[16] |
| Philips Healthcare[14] | Whole-body spectral photon counting | No | Yes, 2 comparative clinical studies identified.[19,20] | Philips Healthcare describes their PCCT scanner as a scanner that uses spectral photon-counting detectors that are made of cadmium zinc telluride semiconductors.[14] Philips' clinical prototype is the first full-field-of-view spectral PCCT system. This prototype has been installed at Lyon University Hospital, France. Human participant research has been published and is ongoing.[14] |
| Siemens Healthineers[21] | NAEOTOM Alpha | Yes | Yes, 31 comparative clinical studies identified.[22-52] | Siemens described their PCCT scanner as the first PCCT scanner.[21] It has a QuantaMax detector which is intended to offer high-resolution images at minimal radiation dose, improved contrast at lower noise, and spectral information in every scan. Human participant research has been published and is ongoing.[21] |
| **Siemens Healthineers[53]** | Somatom Count Plus | No | Yes, 5 comparative clinical studies identified.[37,53-56] | An investigational, single-source PCCT system. |

PCCT = photon-counting CT.

[a]Phantoms are objects used as stand-ins for human tissues to ensure that systems and methods for imaging the human body are operating correctly.[5]

## Regulatory Status and Use in Canada

In April 2023, Health Canada granted approval of NAEOTOM Alpha (Siemens Healthineers, Erlangen, Germany) for clinical use in Canada.[57,58] We did not identify any NAEOTOM Alpha units implemented for clinical use in Canada.

In November 2021, NAEOTOM Alpha was cleared for clinical use in the US and Europe.[59] At that time, more than 20 NAEOTOM Alpha units were already installed for use.[59] From published research and press release articles, we are aware that NAEOTOM Alpha PCCT units have been installed and used in, at minimum, the following countries: Australia, Austria, Belgium, Germany, Singapore, Switzerland, the UK, and the US.[23,27,45,46,52,60-62]

In February 2022, the OmniTom Elite (NeuroLogica Corporation, a subsidiary of Samsung Electronics, Danvers, US), a single-source PCCT scanner with a single detector, received Food and Drug Administration (FDA) 510(k) clearance for use in the US.[63,64]

We did not find other vendor's PCCT scanners approved for clinical use in Canada.

## Cost

The initial cost of a PCCT scanner is approximately US$5 million (NAEOTOM Alpha, Siemens Healthineers; i.e., the hardware)[65,66] plus the expected yearly service and subscription (i.e., software) fees. In comparison, the cost of a conventional CT scanner ranges between US$1.0 million to US$1.5 million for 64 slices (Somatom Definition AS64, Siemens Healthineers) and US$1.7 million for 128 slices (Somatom Definition AS+, Siemens Healthineers). The cost of PCCT systems may reduce as the technology becomes more widespread.[65] It is not clear what training requirements are needed for clinicians to interpret scans from this novel technology (an additional operational cost) nor the training required for maintenance and operating staff.

## Who Might Benefit?

The PCCT scanner aims to function as:

- a conventional scanner that can scan various body parts and tissues for the diagnosis and monitoring of a wide range of health conditions
- a research tool for preclinical (e.g., studies using animals, phantoms, cadavers) and clinical studies (i.e., studies that look for treatment outcomes in humans).

Thus, if PCCT is implemented in Canada, it has the potential to affect many people requiring CT imaging. PCCT could change care if it is effective from a clinical perspective. If PCCT images provide enhanced image quality, clinicians might diagnose certain conditions with greater accuracy and confidence and observe more incidental findings (e.g., incidentalomas), thereby impacting the management plan for patients.

> **There are certain populations that may benefit from PCCT versus conventional CT scanners.**

PCCT scanners, particularly the NAEOTOM Alpha PCCT scanner, has a higher table load capacity than conventional CT scanners; therefore, more people (i.e., those with a higher body weight that exceeded previous CT scanner limits) will be eligible for CT scans when they are required.[66] For instance, the NAEOTOM Alpha PCCT scanner has a maximum capacity of 307 kg without restrictions, whereas the conventional Somatom Definition AS+ and Somatom Definition AS64 CT scanners has a maximum capacity of 227 kg without restrictions.[66] Because PCCT scans may require less radiation than conventional CT scans, their use could benefit those individuals who require CT scans on a more frequent basis, especially on radiation-sensitive tissues (e.g., breasts, lungs, thyroid, and bone marrow are more vulnerable due to rapid cell division; the brain is less vulnerable because its cells do not divide as quickly).[9] In addition, PCCT may benefit children who require CT procedures because they have longer life expectancies and are more sensitive to radiation.[9,10]

## What Is the Evidence?

### Clinical Studies

We identified 37 primary studies that examined the use of PCCT by human participants compared with other imaging modalities.[19,20,22-56] Most studies focused on adults,[19,20,22-44,47-56] 2 studies included children,[45,46] and 3 studies discussed adults living with overweight or obesity.[31-33] The identified studies investigated CT scans of the abdomen, bone, chest, heart, and whole body. **Unless otherwise reported, the clinical evidence compares the NAEOTOM Alpha PCCT scanner (intervention) to a conventional EID CT scanner (comparator).** Numerous brands of EID CT scanners were used, including:

- Brilliance iCT256 by Philips Healthcare
- GoldSeal Discovery CT750 HD by GE Healthcare
- Revolution Apex Platform by GE Healthcare
- Somatom series by Siemens Healthineers, including Definition AS, Definition Edge, Definition Flash, Drive, Force, go.Top, and Sensation 64 (this series was the most common comparator).

#### Image Quality

One of the major draws of PCCT scanners is their ability to achieve higher spatial resolution in the resulting images.

##### *Children*

We identified 2 studies that compared the image quality of chest and heart CT scans between PCCT and EID CT scanners when imaging children.

- **Chest CT:** In 1 study, the study authors did not find any statistically significant differences for objective or subjective image quality ratings when comparing PCCT with EID CT of the chest.[46] This finding is clinically important considering the differences in radiation dose levels, as described in the radiation dose subsection.[46]

- **Heart CT:** One study, which focused on children with suspected congenital heart defects, found PCCT images of the heart and thoracic aorta received higher overall image ratings by experienced clinicians compared to EID CT images.[45]

*Adults*

We identified 32 studies that compared the image quality of CT scans (i.e., abdomen, bone, chest, heart, and whole body) between PCCT and EID CT scanners when imaging adults.

- **Abdominal CT:** Study authors reported significantly better or similar ratings for subjective and objective image quality of PCCT compared to EID CT images for abdominal scans.[31,39-41,47,48]
- **Bone CT:** When assessing bone CT, image quality and visualization of osseous structures for the PCCT scans scored higher than the EID CT scans for the temporal bone (Somatom Count Plus 1 study,[55] NAEOTOM Alpha 1 study),[38] spine,[36] hip,[34] pelvis (Somatom Count Plus),[54] shoulders (Somatom Count Plus),[54] and wrist (Somatom Count Plus).[53]
- **Chest CT:** Compared to EID CT, PCCT demonstrated similar or better image quality for chest CT scans used in the screening or monitoring of lung conditions (e.g., lung cancer screening, monitoring progression of interstitial lung disease).[22,24,25,27,42-44,52] For example, 1 study found more precise imaging of interstitial lung disease features, such as visualizing more distal bronchial divisions and improved sharpness of bronchial walls.[24] When comparing chest CT scans from the Somatom Count Plus PCCT scanner with a conventional EID CT scan, PCCT scans had higher scores in overall image quality (e.g., reticulation, ground glass opacity, mosaic pattern).[37] Similarly, another study found PCCT (Somatom Count) increased radiologists' ability to visualize higher order bronchi and bronchial walls without compromising nodule evaluation compared to EID CT.[56]
- **Heart CT:** When conducting CT angiography of the aorta, 3 studies did not find significant differences in image quality for PCCT compared with EID CT systems.[32,49,50] Two studies found image quality improved with PCCT compared to EID CT[33] or invasive coronary angiography[28] for CT angiography. Two studies comparing whole-body spectral photon counting CT (Philips Healthcare) with conventional EID CT found improved objective and subjective image quality with PCCT for coronary CT angiography for people with confirmed or suspected coronary artery disease.[19,20]
- **Whole-body CT:** Three studies examined PCCT versus EID CT for whole-body CT scans for people with multiple myeloma. The findings from these studies differed regarding reported image quality: 2 studies reported PCCT provides higher subjective and objective image quality (e.g., edge sharpness, lesion conspicuity),[35,51] whereas 1 study did not find any statistically significant differences between the PCCT and CT systems.[29]

### Image Noise

PCCT systems are designed with the intention of reducing image noise and artifacts that have been a limitation of conventional EID CTs. Common measures of noise are signal-to-noise ratio (SNR) and contrast-to-noise ratio (CNR); an increase in these ratios suggests a cleaner and more accurate CT image. These improvements may lead to more accurate diagnoses.

### *Children*

We identified 1 study investigating pediatric **CT scans of the heart and thoracic aorta**, which found PCCT provided a higher SNR and CNR (i.e., better cardiovascular imaging) than EID CT.[45]

### *Adults*

We identified 22 studies that included an outcome related to image noise, such as SNR and CNR.

- **Abdominal CT:** For all abdominal CT studies, better scores were reported for PCCT systems. Image noise outcomes (i.e., SNR[40,41,47] and CNR[31,39,40,48]) were significantly higher for PCCT compared to conventional EID CT.
- **Bone CT:** Study authors found PCCT had either lower image noise (hip,[34] spine[36]) or no significant differences in image noise (Somatom Count Plus; shoulder,[54] pelvis,[54] wrist[53]) and artifacts (hip[34]) compared with EID CT.
- **Chest CT:** Study authors reported variable findings for outcome related to image noise. Studies reported less noise in some cases,[42,43] more noise in others,[24,26,37] or no statistically significant differences[44] when comparing PCCT with EID CT. Although some studies reported increased noise for PCCT systems, this did not appear to affect diagnostic quality compared to EID CT at lower radiation doses because of its improved image resolution.[24,26,37]
- **Heart CT:** For all studies, the authors reported PCCT systems had better scores on image noise outcomes (i.e., studies reported significantly higher SNR[49] and CNR[32,33,49,50] for PCCT compared to EID CT).
- **Whole-body CT:** For people with multiple myeloma, whole-body scans using PCCT resulted in better scores for image noise in some cases[35] or there were no significant differences (i.e., CNRs and SNRs were similar)[29] in image noise between modalities compared to EID CT.

## Radiation Dose

Another promoted feature of PCCT scanners is their ability to operate at lower radiation doses while maintaining image quality.[2,3] This is particularly beneficial for children and those requiring frequent CT scans. The following is a summary of the evidence we found about radiation and PCCT.

### *Children*

We identified 2 studies that examined radiation dose outcomes for children. One study reported mean effective radiation doses were similar for PCCT and EID CT for **CT scans of the heart and thoracic aorta.**[45] In the second study, PCCT significantly reduced dose levels without a significant difference in image quality of **chest PCCT scans** compared with EID CT scans.[46]

### *Adults*

- **Abdominal CT:** Most studies described PCCT as operating with a significantly reduced radiation dose (e.g., lower mean CT dose index and effective dose) while maintaining similar image quality to EID CT.[31,39,40] However, 1 study reported significantly higher dose exposure for PCCT versus EID CT.[41]
- **Bone CT:** Study authors found PCCT systems (NAEOTOM Alpha,[34,36,38] Somatom Count Plus[53,54]) could operate at lower radiation doses compared to EID CT.
- **Chest CT:** Compared to EID CT, study authors found PCCT systems could operate at lower radiation doses.[22-26,42-44] For example, mean CT dose index was 2.0 times higher in EID CT scans of the chest compared with PCCT scans.[44] In another study, PCCT afforded a reduction in **contrast medium** and radiation dose for the diagnosis of acute pulmonary embolism, while maintaining good to excellent image quality compared to EID CT.[22]
- **Heart CT:** Study authors found PCCT (whole-body spectral photon counting CT by Philips Healthcare) could operate at lower radiation doses compared with EID CT.[20]
- **Whole-body CT:** Two studies reported significantly lower radiation doses for PCCT compared to EID CT.[29,35]

## Diagnostic Confidence

The implementation of this emerging technology can impact the level of confidence a clinician has with their diagnosis of various health conditions.

### *Children*

No evidence identified.

### *Adults*

We identified 7 studies that measured diagnostic confidence among clinicians when reviewing adult CT scans from a PCCT device.[19,27,29,34-37] Among these, 4 studies reported that clinicians rated their diagnostic confidence significantly higher for CT scans obtained with a PCCT scanner (NAEOTOM Alpha[34-36] and whole-body spectral photon counting CT by Philips Heatlhcare[19]) compared to a conventional EID CT scanner. These improvements were noted in various diagnostic scenarios, including **whole-body CT** scans for people with multiple myeloma,[35] **pelvis CT** scans for people living with or suspected femoroacetabular impingement syndrome,[34] **spine CT** scans for evaluating surgical outcomes after people had spinal interventions,[36] and **coronary CT angiography** for people with coronary artery disease.[19] Conversely, 3 studies did not report statistically significant differences in clinicians' diagnostic confidence when comparing PCCT and EID CT scanners for the diagnostic interpretation of the tested lung structures (**chest CT**),[27] interstitial pneumonia (**chest CT**),[37] and the detection of osteolytic lesions that can be observed in people with multiple myeloma (**whole-body CT**).[29]

## Clinical Outcomes

Although image quality, noise and radiation reduction, and diagnostic confidence are important outcomes, PCCT scanners should demonstrate improvements in clinical outcomes to warrant widespread adoption of PCCT scanners in Canada. We identified 10 studies that considered at least 1 health outcome.

### *Children*

No evidence identified.

### *Adults*

- **Abdominal CT:** One study compared PCCT with EID CT for the detection and characterization of kidney stones in people with known kidney stones. Study authors found PCCT was not significantly different in detecting kidney stones compared to EID CT but found PCCT to be better able to characterize (i.e., uric acid or non–uric acid stones) small kidney stones,[30] which can impact clinical decisions about the most appropriate treatment plan. For example, the treatment plan for patients with uric acid stones is usually less invasive and expensive (e.g., urinary alkalinization can be prescribed to dissolve uric acid stones versus interventional urinary procedures or external shock wave lithotripsy).[67]
- **Chest CT:** PCCT may be valuable for detecting lung conditions. PCCT allows for spectral assessment of lung vasculature at a high scan speed, benefiting people with suspected pulmonary embolism who often experience shortness of breath.[22] Compared with EID CT, another study reported PCCT conserves high diagnostic accuracy for the detection of interstitial lung disease, with a radiation dose reduction of 66%.[23] Moreover, for people with interstitial lung disease, the improved visualization of CT features with PCCT led to the reclassification of type of lung disease in 4 people (i.e., from nonfibrotic to fibrotic interstitial lung disease; study included 112 patients).[24] Another study found PCCT improved the ability to detect emphysema and lung nodule borders compared to EID CT.[25] Coinciding with higher scores in image quality, PCCT (Somatom Count Plus) demonstrated a decreased number of indeterminate ground glass opacities, an increased number of unlikely ground glass opacities, and an increased number of likely reticulations relative to EID CT.[37] PCCT offered equivalent or better diagnostic quality compared to EID at lower radiation doses, due to its improved resolution.[26] However, 1 study could not demonstrate a perceived difference in diagnostic interpretation for certain lung structures and abnormalities.[27]
- **Heart CT:** Compared with invasive coronary angiography, PCCT provided accurate diagnosis of coronary artery disease for people at high risk, including people with severe coronary calcification or prior stent placement.[28]
- **Whole-body CT:** We identified 1 study that reported PCCT helped identify more lesions in people with multiple myeloma than EID CT.[29]

## Other: Body Size

### *Children*

No evidence identified.

### *Adults*

PCCT scanners, such as NAEOTOM Alpha, have a higher table load capacity than conventional CT scanners. This may enable more people (i.e., those with a higher body weight that exceeded previous limits) to be eligible for CT scans when they are required. It is also important to determine if body size has an impact on relevant outcomes when comparing PCCT with EID CT.

We found 3 studies that investigated how PCCT impacts people living with overweight or obesity. One study compared PCCT to EID CT for people living with overweight, based on body mass index as the marker, and determined PCCT can provide similar or improved image quality with abdominal CT with less radiation.[31] Compared to EID CT, coronary artery CNR values from PCCT were significantly higher (i.e., better), with greater differences for people living with obesity.[33] This study suggests that PCCT may provide better visualization of the coronary arteries, especially for people living with obesity.[33] Similarly, the third study found the CNR gain of PCCT increased in people living with overweight.[32]

### Patient Perspectives and Experiences

Acknowledging that patient perspectives and experiences are important to explore for any emerging technology, 1 study evaluated patient comfort during PCCT scans.[68] This study evaluated the comfort of adults undergoing a chest and/or abdomen CT scan using a PCCT device (NAEOTOM Alpha). Compared to conventional CT, patients rated PCCT significantly better for the speed and comfort of the CT table and the ease of holding their breath during the scan. No statistically significant differences were found for all other outcomes, such as claustrophobia, the effort to lie down and to get up from the CT table, and communication during the examination.[68]

## Additional Considerations

### Implementation and Uptake

If senior health care decision-makers determine that PCCT is appropriate for implementation in Canada, there will be certain factors that they will need to consider. For example:

- **Cost:** The cost is a substantial factor that may prevent the widespread use of the technology. PCCT scanners are 3 to 5 times more expensive than conventional CT scanners.[65,66] This does not consider the training requirements that may also be needed for clinicians as well as operating and maintenance staff. This difference in cost may narrow over time as more health care organizations implement this emerging technology. A senior health care decision-maker may perceive it to be more valuable to have 3 EID CTs instead of 1 PCCT to conduct more CT scans per day. However, this does not factor in other important considerations, such as additional infrastructure required (e.g., staff, power consumption for multiple units, physical space). Another consideration may be whether other tools (e.g., clinical decision support tools; artificial intelligence, such as reconstruction algorithms and software) may be more cost-effective than implementing PCCT.
- **Substitutive versus additive intervention:** Will the PCCT system replace an older system (e.g., EID CT, MRI) or will it be an additional CT system within the health care organization? This will help clarify what additional resources may be needed (e.g., staff, computing power, storage, physical space).[60] Either option can have health system implications: PCCT devices may increase the number of CT

scans a health care organization can conduct per day if PCCT scanners require less time to complete a scan versus a conventional system.[60]

- **Essential versus discretionary intervention:** Senior health care decision-makers may want to consider if the existing CT technology is effective enough at making clinical decisions. This factor should lean on the available and upcoming clinical evidence along with other important considerations such as cost and perceptions from patients and clinicians who have used PCCT.

#### *Jurisdictional Interest*

We asked jurisdictional representatives from all provinces and territories regarding whether they are considering purchasing PCCT. We received responses from 6 provinces:

- 1 province is considering the purchase of PCCT scanner(s) within 1 to 2 years
- 2 provinces are considering the purchase of PCCT scanner(s) within 2 to 5 years
- 2 provinces are not considering the purchase of PCCT scanner(s) within the next 5 years
- 1 province mentioned it is not known if there is interest in the purchase of PCCT scanner(s) at the facility level.

Responses from these jurisdictions further emphasized the cost of PCCT as prohibitive to purchase.

### Provider Training

The training requirements for health care staff to conduct and interpret scans from this novel technology are unclear. One PCCT manufacturer claims that the workflow is “nearly identical for hospital staff”[14] but they do not provide specific details regarding the differences. It is unclear whether radiologists will have challenges when reviewing CT from 2 distinct types of scanners (i.e., PCCT and EID) if both are used at their health care organization. It will be important to understand the potential implications of clinicians being exposed to 2 unique CT scanners, and whether this may reduce their diagnostic accuracy when interpreting CT scans from EIDs with lower image quality.

### Accessibility

For the PCCT scanners with approval for clinical use, they have primarily been installed in densely populated areas within an academic centre. If health systems in Canada decide to implement PCCT scanners for research and/or clinical use, it is likely they will be installed in these same types of areas (e.g., urban, academic centres versus rural, community centres), potentially leading to unequal access for people living in Canada.

## Future Developments

The body of evidence will continue to expand as more people undergo CT scans using PCCT and as additional brands of PCCT scans are cleared for use in clinical settings. As of September 2023, we identified 15 ongoing clinical trials investigating PCCT with human participants, with a limited number of ongoing randomized studies (refer to Table 2). These studies are continuing to assess the diagnostic accuracy, clinical benefits, and clinical harms of PCCT for different populations (e.g., people with lived experience or suspected cardiovascular disease, arthritis, cancer [head and neck, lung, breast], bone fractures). In addition, we identified 4 systematic review protocols that are registered in PROSPERO that will further our understanding of PCCT.[69-72]

## Final Remarks

PCCT scanners represent an emerging health technology that advances the field of medical imaging, although there are some important caveats. PCCT scanners cost 3 to 5 times more than conventional CT scanners and this additional cost must be justified by improved clinical benefits or reduced clinical harms. We identified trends indicating that PCCT may hold value in diagnosing health conditions in specific areas, such as respiratory medicine. Additional clinical research is needed to fill in the evidence gaps and determine the clinical implications of PCCT across various health care domains. For example, more research is needed that focuses on pediatric populations, considering their increased sensitivity to radiation exposure. Ongoing comparative studies will continue to provide new information about this emerging technology, covering areas not detailed in this report (e.g., people with lived experience with or suspected atherosclerosis, diabetes, stroke, adrenal gland lesions, and breast cancer). Notwithstanding clinical benefits, there is a need for a greater understanding of the factors affecting implementation, such as training requirements, user perceptions, accessibility, and its overall place in care. Moreover, the cost of PCCT is an important barrier to implementing PCCT, further emphasized by jurisdictional representatives, which may limit access and widespread adoption of this technology. Thus, the results from future and ongoing clinical trials is imperative to determine if the additional cost of PCCT scanners is justified. Further understanding of these factors will aid senior health care decision-makers to make informed decisions regarding its use in Canada.

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# Appendix 1: Methods

Note that this appendix has not been copy-edited.

## Literature Search Strategy

An information specialist conducted a literature search on key resources including MEDLINE, the Cochrane Database of Systematic Reviews, the International HTA Database, the websites of Canadian and major international health technology agencies, as well as a focused internet search. The following clinical trials registries were searched: the US National Institutes of Health's clinicaltrials.gov, WHO's International Clinical Trials Registry Platform (ICTRP) search portal, Health Canada's Clinical Trials Database, the European Union Clinical Trials Register, and the European Union Clinical Trials Information System (CTIS). The search approach was customized to retrieve a limited set of results, balancing comprehensiveness with relevancy. The search strategy comprised both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. Search concepts were developed based on the elements of the research questions and selection criteria. The main search concepts were photon-counting and CT. The search was completed on September 21, 2023, and limited to English-language documents published since January 1, 2018.

## Study Selection

One author screened the literature search results and reviewed the full text of all potentially relevant studies. The author considered studies for inclusion if the intervention was photon counting CT. The author excluded studies when they did not include human participants (i.e., studies using phantoms or simulation studies, studies that used animals or cadavers).

# Appendix 2: Ongoing Clinical Trials

## Table 2: Ongoing Clinical Trials With Photon-Counting CT

| Study name, trial registration number, location | Intervention, index test, comparator, reference standard | Study type, study time frame | Participants | Study aims | Study outcomes |
|---|---|---|---|---|---|
| **Comparison of Spectral PCCT With DECT and MRI for Plaque and Lumen Carotid Arteries Evaluation CAPL**<br>NCT04466787<br>**France** | Intervention: Spectral PCCT (IQon, Philips, Amsterdam, The Netherlands)<br>Comparator: DECT | Randomized, parallel assignment<br>June 2019 to June 2024 | People 18 years of age or older with known or suspected supra-aortic arterial disease, referred for evaluation of any supra-aortic vessel, follow-up for a stent in a supra-aortic vessel, prior imaging ultrasounds showing 50% or more stenosis of a supra-aortic vessel segment, or undergoing surgery within 1 month of carotid plaque evaluation.<br>N = 40 (targeted) | To determine the efficiency of a spectral PCCT at characterizing vulnerable plaques and luminal stenosis in carotid atherosclerosis compared to current practice (i.e., DECT, MRI). | Lipid necrotic core, intraplaque hemorrhage, fibrous cap ulceration (primary outcomes).<br>Number of irregularities, number of ulcerations, assessable vascular segments with lack of image artifacts, radiation dose, tolerance to device (secondary outcomes). |
| **On Dose Efficiency of Modern CT-scanners in Chest Scans**<br>NCT04996693<br>**Germany** | Intervention: PCCT: NAEOTOM Alpha (Siemens Healthineers)<br>Comparator: EID CT (128-slice) or EID CT (20-slice) | Randomized, parallel assignment<br>October 2021 to October 2024 | People 18 years of age or older referred for an unenhanced CT or contrast-enhanced CT of the chest/thorax confirmed by a board-certified radiologist.<br>N = 2400 (targeted) | To measure and compare dose efficiency of modern CT scanners for unenhanced and contrast-enhanced scan protocols of the chest/thorax. | Parameters of objective image quality and radiation dose (primary outcomes).<br>Subjective image quality evaluation (secondary outcome). |
| **Comparison of Imaging Quality Between Spectral PCCT and DECT** | Index test: Spectral PCCT (IQon, Philips, Amsterdam, The Netherlands)<br>Reference standard: DECT | Diagnostic, single group assignment (crossover study)<br>January 2021 to January 2024 | People 18 years and older presenting with 1 of the following conditions: asymptomatic type 1 or 2 diabetes as regard to | To determine to which extent spectral PCCT allows obtaining images with improved quality and diagnostic | Quality of images (primary outcome)<br>Diagnostic confidence, subjective image quality, CT dose index volumic, dose |

| Study name, trial registration number, location | Intervention, index test, comparator, reference standard | Study type, study time frame | Participants | Study aims | Study outcomes |
|---|---|---|---|---|---|
| NCT04328181<br>**France** | | | cardiovascular risks, diabetic foot ulcer, adrenal gland lesions, urinary stone(s), known coronary artery disease.<br>N = 316 (targeted) | confidence vs. standard DECT, both with and without contrast agent injection. | length product, equivalent dose, quantitatively image quality (i.e., noise, density, contrast-to-noise ratio), depiction of anatomic structures of interest, radiation dose (secondary outcomes). |
| **Clinical value of PCCT technology in routine clinical care**<br>DRKS00030591<br>**Germany** | Intervention: PCCT<br>Comparator: Unclear | Diagnostic, single group assignment<br>October 2021 to not specified (i.e., not reported) | People 18 years of age or older with regular clinical CT examination indicated by the expert radiologist in cooperation with the clinical partner.<br>N = 200 (targeted) | To assess the clinical value of PCCT technology in routine clinical care. | Image quality, level of detail of tissue resolution (primary outcome)<br>Radiation dose measures (secondary outcomes) |
| **Image Quality and Radiation Dose Associated With Cardiac Scans in Modern CT Scanners**<br>NCT05245149<br>**Germany** | Index Test: Cardiac CT angiography on a PCCT<br>Reference Standard: Cardiac CT angiography on a regular CT with EID | Prospective cohort and a matched retrospective cohort<br>February 2022 to August 2024 | People 18 years of age or older with a clinical indication for a coronary CT angiography scan.<br>N = 200 (targeted) | To evaluate the dose efficiency of coronary CT angiography using a PCCT with the dose efficiency of coronary CT angiography of prior CT generations. | Intraluminal enhancement of coronary arteries, image noise, overall subjective image quality, dose length product (primary outcomes).<br>Diagnostic accuracy of coronary artery stenosis assessment (secondary outcome). |
| **Clinical Impact of Cardiac Photon Counting CT**<br>NCT05240807<br>**US** | Intervention: contrast-enhanced coronary CT angiogram using PCCT<br>Comparator: conventional CT, MRI, or nuclear medicine imaging systems | Diagnostic, parallel assignment.<br>August 2022 to June 2024 | People 18 years of age or older referred for coronary artery cardiac CT imaging or nuclear medicine or MRI cardiac perfusion.<br>N = 450 (targeted) | To determine whether images taken using a PCCT after the person has received a drug that makes the heart work harder provide clinically important information about the severity of suspected | Change in disease status or postexam recommendations (primary outcome) |

| Study name, trial registration number, location | Intervention, index test, comparator, reference standard | Study type, study time frame | Participants | Study aims | Study outcomes |
|---|---|---|---|---|---|
| | | | | coronary artery disease compared to CT imaging performed without using the drug that causes the heart to work harder. | |
| **Novel Complex Radiodiagnostics of Peripheral Arthropathies**<br>NCT05657847<br>**Hungary** | Intervention: PCCT<br>Comparator: MRI and conventional radiography | Prospective, cohort<br>March 2022 to February 2027 | People 18 years of age or older with rheumatoid arthritis, psoriatic arthritis, or crystal arthropathies<br>N = 500 (targeted) | To assess the role of PCCT in the diagnostics of peripheral arthropathies.<br>To compare the role of PCCT in the detection of arthritis-related pathologies with other imaging modalities like MRI and conventional radiography. | Bone erosions, bone marrow edema and periarticular soft tissue involvement, crystal deposit characterization (primary outcomes).<br>Performance in the detection of active arthritis-related imaging findings and structural damages (secondary outcome). |
| **Value of PCCT for Breast Diagnosis**<br>DRKS00028997<br>**Germany** | Index test: PCCT<br>Reference standard: mammography | Diagnostic, parallel assignment.<br>July 2022 to not specified (i.e., not reported) | People (45 to 75 years of age) with confirmed breast carcinoma and current mammography/ tomosynthesis or clinical indication for mammography/ tomosynthesis and clinical indication for CT thorax with contrast medium and people without breast carcinoma with current mammography/ tomosynthesis or clinical indication for mammography/ tomosynthesis and clinical | To assess the value of PCCT for breast cancer diagnosis. | Evaluation of the presence of breast cancer on PCCT for each breast by breast radiologists blinded to patient data (sensitivity, specificity of PCCT; primary outcome).<br>Size of breast cancer in PCCT (maximal diameter and volumetry), spread of breast cancer in PCCT (single, multicentric or multifocal) evaluated for each breast by breast radiologists blinded for patient data; positive margin |

| Study name, trial registration number, location | Intervention, index test, comparator, reference standard | Study type, study time frame | Participants | Study aims | Study outcomes |
|---|---|---|---|---|---|
| | | | indication for CT thorax with contrast medium due to other diseases.<br>N = 110 (targeted) | | resection rate (secondary outcomes). |
| **CT in Calcified Coronary Arteries With Photon Counting Detector (CCT-PCD-1)**<br>NCT05551351<br>**Sweden** | Index test: PCCT<br>Reference standard: Conventional coronary angiography | Prospective, cohort<br>February 2023 to December 2024 | People 65 years of age or older referred for cardiac CT and conventional coronary angiography as part of routine preoperative evaluation.<br>N = 75 (targeted) | To examine diagnostic accuracy of PCCT regarding coronary artery stenosis for preoperative patients. | Diagnostic accuracy of CT concerning coronary stenosis (primary outcome)<br>Image quality (secondary outcome) |
| **Evaluation of PCCT Based Image Parameters in the Assessment and Quantification of Coronary Artery Disease (EPIPHANY))**<br>NCT05877768<br>**Germany** | Intervention: Coronary CT Angiography on the PCCT (NAEOTOM Alpha, Siemens Healthineers)<br>Comparator: N/A | Prospective, cohort<br>June 2023 to June 2033 | People referred for coronary CT angiography for suspected coronary artery disease and those with known coronary artery disease or the suspicion of progressive disease.<br>N = 3,000 (targeted) | To determine image quality; accuracy of image measurements; if there is a relationship between images and the management of disease (e.g., new medication or additional investigations, results of follow-up investigations and/or patient outcomes. | Major adverse cardiac events (primary outcome).<br>> 30 secondary outcomes listed. |
| **Exploratory study on clinical applications of PCCT**<br>JPRN-jRCTs032220618<br>**Japan** | Intervention: Canon PCCT<br>Comparator: N/A | Diagnostic, single group assignment.<br>August 2023 to not specified (i.e., not reported) | People 20 years and older with suspected or diagnosed solid tumour (head, neck, lung).<br>N = 360 (targeted) | To explore clinical applications of PCCT. | Specificity, image quality (primary outcomes)<br>Sensitivity, positive predictive value, negative predictive value, image quality score, SNR, contrast noise ratio, CT dose index-volume, dose length product, adverse event rate, renal function tests and change |

| Study name, trial registration number, location | Intervention, index test, comparator, reference standard | Study type, study time frame | Participants | Study aims | Study outcomes |
|---|---|---|---|---|---|
| | | | | | ratio of the renal function test between the pre- and post-protocol tests |
| **Detecting and Assessing Leg and Foot Stress Fractures Using PCCT (FootPCCT)**<br>NCT06024798<br>**Switzerland** | Intervention: PCCT<br>Comparator: N/A | Prospective, case study<br>September 2023 to May 2024 | People 16 years and older with clinically suspected stress or insufficiency fracture of the lower extremity.<br>N = 50 (targeted) | To investigate the diagnostic accuracy of PCCT in lower extremity stress fractures as a dose-saving technology, guaranteeing an examination according to the ALARA-principle (as low as reasonably achievable). | Presence of a fracture (primary outcome)<br>Presence of bone edema or soft tissue edema (secondary outcomes) |
| **Clinical Feasibility and Evaluation of Silicon Photon Counting CT**<br>NCT05838482<br>**US** | Intervention: PCCT<br>Comparator: N/A | Diagnostic, single group assignment<br>September 2023 to November 2024 | People 18 years and older who have in the past 120 days or will in the future 30 days undergo a clinically indicated CT exam of the head, neck, heart, chest, abdomen, pelvis, or extremities where images are available for this prior scheduled exam.<br>N = 100 (targeted) | To collect data to evaluate utility of the using photon-counting CT in a clinical setting. | Number of Participants with raw investigational PCCT scan data along with prior standard of care diagnostic CT exam data/images (primary outcome)<br>Image quality, feedback on performance and images generated on the PCCT (secondary outcomes) |
| **CT Evaluation of Carotid Plaque Components**<br>NCT05764772<br>**US** | Index Test: Spectral PCCT<br>Reference standard: MRI/semiautomated segmentation software and histology | Prospective, cohort<br>September 2023 to December 2028 | People 18 years of age or older with acute stroke or transient ischemic attacks and stenosis of the ipsilateral carotid artery.<br>N = 70 (targeted) | To validate the diagnostic performance of PCCT to distinguish tissue components in ischemic stroke. | Diagnostic performance, including:<br>- presence or absence of calcium, hemorrhage, and lipid plaque components as determined on CT will be confirmed with carotid MRI, segmentation quantitative |

| Study name, trial registration number, location | Intervention, index test, comparator, reference standard | Study type, study time frame | Participants | Study aims | Study outcomes |
|---|---|---|---|---|---|
| | | | | | (e.g., volume) output from segmentation software, or histologic staining (primary outcome).<br>- volumes of hemorrhage, lipid, and calcium components will be measured to determine plaque phenotype and correlated with ipsilateral intracranial stroke burden (secondary outcome) |
| **Clinical Data Collection On Advanced CT System**<br>NCT05835284<br>**Sweden** | Intervention: Investigational Edge-on Silicon PCCT device<br>Comparator: NA | Diagnostic, single group assignment<br>April 2024 to January 2025 | Adults (25 years of age or older) that have undergone a clinically indicated CT exam of the head, neck, chest, abdomen, pelvis, or extremities where images are available within 90 days of investigational scanning.<br>N = 120 (targeted) | To evaluate the investigational Edge-on Silicon PCCT device in a clinical setting. | Data collection (i.e., raw investigational CT scan data along with standard of care raw CT data/images; primary outcome).<br>Safety (i.e., type and number of serious adverse events and adverse events) and image quality (secondary outcomes). |

DECT = dual energy computed tomography; EID = energy-integrating detector; N/A = not applicable; PCCT = photon-counting computed tomography.

Note that this table has not been copy-edited.

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