Technical Brief Series

Considerations when Purchasing a Point-of-Care CT System

Introduction

Point-of-care CT (POC-CT) scanning devices can deliver powerful benefits, but choosing the right vendor requires careful consideration. Price is only one of many important purchase considerations – practices should also look for experienced vendors who produce reliable POC-CTs, are experienced in supporting otolaryngology and allergy practices, and who can provide quality customer support over the life of the CT scanner.

The following purchasing considerations will be covered:

- Image quality and radiation dose
- Equipment design and usability
- CT accreditation support
- DICOM and image-guided surgery integration
- Image storage and viewing
- Sales, installation, training and technical support
- Total cost of ownership and return on investment
- Vendor financial stability and commitment

Image Quality and Radiation Dose

Image Quality and Fields of View

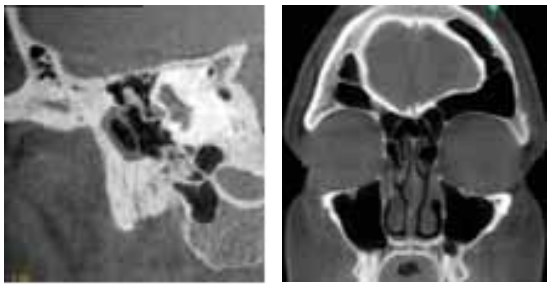
Point-of-care CT systems using cone-beam technology vary in the number of fields of view and spatial resolution options. POC-CTs with a broad range of fields of view can deliver isotropic, sub-millimeter spatial resolution that results in good visualization of sinus structures; sub-millimeter structures at air-bone interfaces; and middle ear and inner components and interfaces such as the tympanic membrane, ossicles, semicircular canals, mastoid air cells and cochlea.[1]

Cone-beam CT technology is also useful for applications requiring reduced metal artifacts, such as cochlear implant imaging, and those requiring visualization of the ossicular chain, bony labyrinth of the inner ear, internal cochlear anatomy and the facial nerve.[2]

Radiation Dose

Minimizing radiation dose is important, especially in children and adults who require multiple CT scans. In fact, a recent retrospective cohort study reported that cumulative CT doses of 50-60 mGy in children may increase the relative risk of developing leukemia and brain tumors.[3]

Figure 1. Temporal bone (0.09 mm slice thickness) and sinus (0.3 mm slice thickness) images from Carestream CS 9300 system



POC-CTs, particularly those with a broad range of fields of view, deliver a much lower dose than conventional multi-detector CT (MDCT) systems. For example, Carestream's CS 9300 POC-CT delivers adult effective and absolute dose levels as low as 0.04 mSv and 2.9 mGy, respectively.[1] Conversely, the effective dose of sinus and temporal bone exams performed with MDCTs using standard protocols generally range from 0.8 mSv to 2.0 mSv, with mean absolute doses of 44 mGy to 52 mGy.[4,5,6,7]

Table 1. Effective dose of Carestream CS 9300 scan protocols

Scan Protocol and Field of View	Effective Dose (mSv)[1]
Sinus 17x13.5 cm	0.19
Sinus 17x11 cm HC	0.14
Sinus 17x11 cm Fast	0.09
Temporal 17x6 cm HC	0.07
Temporal 8x8 cm HC	0.08
Temporal 5x5 cm HC	0.07
Temporal 5x5 cm Fast	0.04

Half-scan acquisition protocols offered in some POC-CTs can result in considerable dose sparing of the anterior region, including the eyes, as compared with full-scan protocols used in conventional MDCT and other POC-CTs.[1]

Equipment Design and Usability

Physical Design

The size and design of a POC-CT should be considered in the purchasing decision. The larger the POC-CT scanning device, the more physical space necessary to house and operate the device. This may require remodeling or even dedicating an entire room to the POC-CT, both of which add to the total cost of ownership.

Patient and Staff Comfort and Safety

POC-CTs vary in their ability to comfortably accommodate patients of different sizes. Some POC-CTs cannot be used for very large patients, while others require the transfer of patients in wheelchairs to the unit, which takes time and increases the risk of staff or patient injury. Patient comfort is important to avoid retakes due to patient movement.

Usability and Learning Curve

In many practices, the physician, nurse or other staff member that will operate the equipment may have never operated a POC-CT previously. Therefore it is important to ensure that the equipment and software are easy to learn and operate. During the purchase process, it is often helpful to involve the staff members who will ultimately operate the POC-CT equipment.

Additionally, for high volume practices, it is important to ask vendors about minimum wait times between scans to ensure no disruptions to practice workflow. Minimal wait times can vary from 2-3 minutes to more than 10 minutes.

CT Accreditation Support

Prompt CT accreditation is important to ensure maximum reimbursement and an attractive return on investment. As of January 2012, the Centers for Medicare & Medicaid Services (CMS) requires that all non-hospital practices using POC-CTs obtain accreditation in order to be eligible for reimbursement by CMS. Some private insurers have also begun to mandate accreditation. Most POC-CT vendors provide accreditation support, but it can be difficult to assess the amount and quality of the support that will be provided.

Accreditation Specialist Experience

A skilled accreditation specialist can help attain swift accreditation and thus faster reimbursement. Practices should ask how many sites the specialist has assisted with CT accreditation and the average length of the process. Contacting other practices the accreditation specialist has supported may also be helpful.

Type of Accreditation Support Provided

Details should be provided by the vendor outlining what accreditation support will be provided, whether the total hours of support are limited or unlimited, and how the specialist will provide the support (e.g., phone, email, onsite visit). Complete accreditation support generally consists of in-depth help with the accreditation application, policies and procedures, QC testing and case studies, plus the final review of accreditation application materials.

Visit www.carestream.com/ent-allergy for a white paper entitled "Obtaining Accreditation for CT Scanning Devices."

DICOM and Image-Guided Surgery Integration

DICOM Compliance

DICOM (Digital Imaging and Communications in Medicine) compliance is a critical element for successfully implementing POC-CT in private practices, as it enables compatibility with image-guided surgery systems, third-party viewing software, PACS and electronic health record (EHR/EMR) systems. DICOM compliance also enables practices to share images with radiologists and other healthcare providers.

DICOM compliance can be complex, so practices should seek vendors with significant DICOM experience. POC-CT vendors with a large radiology customer base will likely have stronger DICOM expertise than those primarily serving other clinical specialties.

Visit www.carestream.com/ent-allergy for a white paper entitled "DICOM Standards and Point-of-Care Imaging."

Image-Guided Surgery Compatibility

Practices that offer image-guided surgery (IGS) should request IGS-formatted images from prospective POC-CT vendors and confirm compatibility prior to purchase. Additionally, practices should request their POC-CT vendor to validate that the entire workflow – everything from capturing the image to performing surgery – is working seamlessly prior to completing the installation.

Because many IGS systems were designed for conventional MDCT's with larger fields of view, proper positioning of the patient in the POC-CT is critical. Practices should ensure that their staff is trained and comfortable capturing IGS scans. Selecting a POC-CT vendor with IGS integration experience is thus strongly recommended.

Image Storage and Viewing

Image Storage Requirements

Practices are required to comply with federal, state and local healthcare information standards and security/privacy regulations such as HIPAA. For example, images must be stored securely outside the practice to protect against disasters or other events such as power outages. A POC-CT vendor should be acutely familiar with these requirements and provide a failsafe solution. POC-CT systems should include local image storage as well as the ability to save images on a CD and USB drive.

Cloud-Based Remote Image Viewing

Many medical imaging providers are choosing third-party cloud-based services to prevent data security issues, optimize workflow and minimize cost. Cloud-based services also make it easy for a practice to share images with other physicians, an important consideration for practices who anticipate utilizing radiologists to over-read some or all of their scans.

The following questions should be asked of potential cloud-based storage vendors:

- How many medical images do they store, who are their customers, and how long have they been providing image storage and viewing services?
- What technologies, infrastructure and processes do they have in place to ensure data security and health information protection? Is their data monitored 24/7 and managed by IT professionals?
- Are images stored in DICOM file formats? Can a practice easily obtain their images and move them to another vendor, if desired?

Practices may be more comfortable with vendors with many years of data security experience, vendors storing a high volume (millions) of medical images and vendors trusted by large medical imaging providers, such as hospitals and imaging centers.

Visit www.carestream.com/ent-allergy for a white paper entitled "Cloud-Based Security for Physician Practices."

Data Security Requirements

When evaluating data security capabilities, there are four primary components to be considered.

- Availability ensures continuous access to data even in the event of a disaster or power outage.
- Integrity ensures that the data is maintained in its original state and has not been intentionally or accidentally altered.
- Confidentiality means information is available or disclosed only to authorized individuals, entities or IT processes.
- Traceability is the ability to verify the history, location or application of an item by means of records.

Sales, Installation, Training and Technical Support

As many practices have never purchased or operated a radiation-emitting imaging device, it is critical that practices seek vendors that offer comprehensive support.

Sales Support

A knowledgeable, experienced sales representative can provide valuable advice, such as where to place the POC-CT for optimized workflow. A sales representative can also help the practice analyze whether the POC-CT will result in a good return on investment.

Installation Preparation

A "full-service" installation approach can dramatically simplify the process of getting a new POC-CT system up and running. Critical components of installation include: developing a shielding plan with a medical physicist, performing any needed room modifications, state registration and completion of the appropriate documents, installation acceptance testing, and radiation protection programs. Selecting a vendor experienced in installing POC-CTs in physicians' offices is advisable.

User Training

Practices are wise to seek a vendor with significant experience training users of POC-CT systems in otolaryngology and allergy practices. Repetition is essential. Adequate operator training, both onsite and remotely, is also critical. Typically two days of onsite training are needed to successfully train staff members. POC-CT training should include basic equipment and software operation, patient positioning and rudimentary troubleshooting. Also, practices should confirm that ongoing remote

training is available to refresh operator knowledge and train new staff members.

Technical Support

Remote System Monitoring. Once a POC-CT device is installed, it should reliably provide quality images. Some vendors remotely monitor equipment initially to ensure it is working properly.

Trained Support Specialists. Even with thorough training, questions about different functions are likely to arise. And phone and onsite support may be needed over the life of the equipment. Practices should make sure a vendor has an adequate number of trained phone support specialists to promptly handle phone calls.

Number and Location of Field Engineers. POC-CT vendors with a large number of certified field engineers located throughout the US are more likely to provide prompt onsite service than those with a small team located in a few locations. A prompt response is important because downtime can negatively impact practice workflow and revenue.

Ongoing Product Improvements

A POC-CT is a major financial investment, so it is wise to seek a vendor with a history of continued product improvements, such as software upgrades. Asking the vendor for a list of recent product enhancements may provide insights as to whether it is investing in product improvements.

Total Cost of Ownership and Return on Investment

Practices should evaluate the total cost of POC-CT ownership, not just the initial purchase price. Costs of ownership which may be overlooked include associated equipment, practice remodeling, remote image storage, accreditation support, software upgrades, medical physics services, preventative maintenance, training and service costs.

The good news for practices is that the purchase price of a POC-CT has declined in recent years. The breakeven scan volume for some POC-CTs is as low as 20 scans per month. This means that most practices can generate an attractive return on investment.

Vendor Financial Stability and Commitment

Practices are prudent to select a vendor who can meet their needs today and over the life of their POC-CT. It can be difficult to assess the financial stability of a vendor, but doing a background check including a credit report may be helpful.

Also, asking the following questions may provide insights:

- Does the vendor have a diversified product portfolio, or is it dependent on one product or market segment?
- Does the vendor have a stable management team and workforce?
- Does the vendor have a large US installed base of the POC-CT model being considered?
- Does the vendor have longevity in diagnostic imaging? Has it survived several economic cycles?

Conclusion

The factors that should be evaluated when considering a point-of-care CT system go beyond price. Because a POC-CT is a major long-term capital investment, practices should choose a vendor who can not only meet immediate needs but support a POC-CT device throughout its lifetime.

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