Computed Tomography (CT)

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**Description**

Figure 1: Drawing of CT fan beam (left) and patient in a CT imaging system

Computed tomography (CT), sometimes called "computerized tomography" or "computed axial tomography" (CAT), is a noninvasive medical examination or procedure that uses specialized X-ray ([http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MedicalX-Rays/default.htm](http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MedicalX-Rays/default.htm)) equipment to produce cross-sectional images of the body. Each cross-sectional image represents a "slice" of the person being imaged, like the slices in a loaf of bread. These cross-sectional images are used for a variety of diagnostic and therapeutic purposes.
CT scans can be performed on every region of the body for a variety of reasons (e.g., diagnostic, treatment planning, interventional, or screening). Most CT scans are performed as outpatient procedures.

How a CT system works:

- A motorized table moves the patient through a circular opening in the CT imaging system.
- While the patient is inside the opening, an X-ray source and a detector assembly within the system rotate around the patient. A single rotation typically takes a second or less. During rotation the X-ray source produces a narrow, fan-shaped beam of X-rays that passes through a section of the patient's body.
- Detectors in rows opposite the X-ray source register the X-rays that pass through the patient's body as a snapshot in the process of creating an image. Many different "snapshots" (at many angles through the patient) are collected during one complete rotation.
- For each rotation of the X-ray source and detector assembly, the image data are sent to a computer to reconstruct all of the individual "snapshots" into one or multiple cross-sectional images (slices) of the internal organs and tissues.

Figure 2: The red lines on the patient's body are light from a laser alignment system

CT images of internal organs, bones, soft tissue, and blood vessels provide greater clarity and more details than conventional X-ray images, such as a chest X-Ray (see Figures 3 and 4).

Uses

CT is a valuable medical tool that can help a physician:

- Diagnose disease, trauma or abnormality
- Plan and guide interventional or therapeutic procedures
- Monitor the effectiveness of therapy (e.g., cancer treatment)
When used appropriately, the benefits of a CT scan far exceed the risks. CT scans can provide detailed information to diagnose, plan treatment for, and evaluate many conditions in adults and children. Additionally, the detailed images provided by CT scans may eliminate the need for exploratory surgery.

Concerns about CT scans include the risks from exposure to ionizing radiation and possible reactions to the intravenous contrast agent, or dye, which may be used to improve visualization. The exposure to ionizing radiation may cause a small increase in a person’s lifetime risk of developing cancer. Exposure to ionizing radiation is of particular concern in pediatric patients because the cancer risk per unit dose of ionizing radiation is higher for younger patients than adults, and younger patients have a longer lifetime for the effects of radiation exposure to manifest as cancer.

However, in children and adults, the risk from a medically necessary imaging exam is quite small when compared to the benefit of accurate diagnosis or intervention. It is especially important to make sure that CT scans in children are performed with appropriate exposure factors, as use of exposure settings designed for adults can result in a larger radiation dose than necessary to produce a useful image for a pediatric patient.

Additional information on benefits and risks of X-ray imaging, including CT are found on the Medical X-Ray Imaging web page (http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MedicalX-Rays/default.htm).
If a physician recommends a CT scan for you or your child, the FDA encourages you to discuss the benefits and risks of the CT scan, as well as any past X-ray procedures you or your child have had, with your physician. A CT scan should always be performed if it is medically necessary and other exams using no or less radiation are unsuitable. At this time, the FDA does not see a benefit to whole-body scanning of individuals without symptoms.

More resources on CT exams:

- FDA: [Pediatric X-Ray Imaging](http://www.fda.gov/Radiation EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/ucm298899.htm)
- Alliance for Radiation Safety in Pediatric Imaging: [Image Gently Campaign](http://www.pedrad.org/associations/5364/ig/?page=591)
- FDA: [Full-Body CT Scans - What You Need to Know](http://www.fda.gov/Radiation EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MedicalXRays/ucm115340.htm)
- Radiology Info: [Computed Tomography (CT or CAT Scan)](http://www.radiologyinfo.org/en/sitemap/modal-alias.cfm?modal=CT)
- National Cancer Institute (NCI): [Computed Tomography (CT) Questions and Answers](http://www.cancer.gov/cancertopics/factsheet/detection/CT)
The FDA has regulations covering the safety and effectiveness and radiation control of all X-ray imaging devices, including CT. Individual states and other federal agencies regulate the use of CT devices through recommendations and requirements for personnel qualifications, quality assurance and quality control programs, and facility accreditation.

**Exam justification: CT screening guidelines and incidental findings**

The individual risk from a necessary imaging exam is quite small when compared to the benefit of aiding accurate diagnosis or intervention. However, the FDA recommends that health care professionals and hospital administrators work to reduce radiation exposure to patients by following these steps:

- Discuss the rationale for the examination with the patient and/or parent to make sure there is a clear understanding of benefits and risks.
- Justify CT exams by:
  - making sure the CT exam is necessary to answer a clinical question,
  - considering other examinations that use less or no radiation exposure, such as ultrasound or MRI, if appropriate, and,
  - checking the patient's medical imaging history to avoid duplicate examinations.

These precautions are especially important with pediatric patients, since children are more susceptible to radiation effects than adults.

In addition to referral (also called "appropriate use") criteria, screening guidelines are an important tool available to the referring physician to determine if a certain CT examination is justified.

**Optimization: facility quality assurance (QA) and personnel training**

The imaging team (e.g., physician, radiologic technologist, and medical physicist) should use techniques and protocols that administer the lowest radiation dose that will yield an image quality adequate for diagnosis and intervention.

Additional resources specific to radiation management in CT include:

- **Image Wisely:** [http://www.imagewisely.org/](http://www.imagewisely.org/)
- **Radiation Safety in Adult Medical Imaging**
m) Alternatives to CT and Dose-Saving Modifications to CT Technique.

- American Association of Physicists in Medicine
  - CT Scan Protocols (http://www.aapm.org/pubs/CTProtocols/) (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm) (AAPM 2011)
  - Size-Specific Dose Estimates (SSDE) in Pediatric and Adult Body CT Examinations (http://www.aapm.org/pubs/reports/RPT_204.pdf) (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm) (AAPM report 204, 2011).


Information for Industry: CT Manufacturers and Assemblers


CT devices are classified under [21 CFR 892.1750](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfdocs/cfcdfr/CFindex.cfm?fr=892.1750). The EPRC requirements and guidance specific to CT devices include:

- **1020.33 - Computed Tomography (CT) equipment**

- **Diagnostic X-Ray CT Products Radiation Safety Report (PDF - 477KB)**
  ([/downloads/AboutFDA/ReportsManualsForms/Forms/UCM081569.pdf](/downloads/AboutFDA/ReportsManualsForms/Forms/UCM081569.pdf))

- **Provision for Alternate Measure of the Computed Tomography Dose Index (CTDI) to Assure Compliance with the Dose Information Requirements of the Federal Performance Standard for Computed Tomography**
  ([/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094379.htm](/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094379.htm))
For more information on EPRC and medical device regulations and guidance for CT and other X-ray equipment, please see the Medical X-Ray Imaging webpage (http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MedicalX-Rays/default.htm).

Reporting Problems to FDA

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with the product. We encourage health care providers and patients who suspect a problem with a medical imaging device to file a voluntary report through MedWatch: The FDA Safety Information and Adverse Event Reporting Program (/Safety/MedWatch/ucm2005699.htm).

Health care personnel employed by facilities that are subject to Reporting Adverse Events (Medical Devices) (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm) should follow the reporting procedures established by their facilities.

Medical device manufacturers, distributors, importers, and device user facilities (which include many health care facilities) must comply with the Reporting Adverse Events (Medical Devices) (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm).

In addition to following the general recommendations (for manufacturers, facilities, and any member of the public) for reporting problems for adverse events associated with CT overexposure, the following information should be included in reports, if available:

- the protocol you were following during the event;
- the CT conditions of operation (i.e. technical parameters including kVp, mA, time per rotation, mAs, mode, etc.); and
- the dose-index values displayed (CTDI_{vol}, DLP).
Resource Box

- FDA: Dental Cone-beam Computed Tomography (/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MedicalX-Rays/ucm315011.htm)
- FDA: "What are the Radiation Risks from CT?" (/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MedicalX-Rays/ucm115329.htm)
- FDA: Pediatric X-Ray Imaging (/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/ucm298899.htm)
- FDA: Other Information Resources Related to Whole-Body CT Screening (/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MedicalX-Rays/ucm115332.htm)
- U.S. Preventive Services Task Force: Screening for Coronary Heart Disease With Electrocardiography (2012) (http://www.uspreventiveservicestaskforce.org/uspstf/uspsacad.htm) (/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)
- U.S. Preventive Services Task Force: Screening for Colorectal Cancer (2008) (http://www.uspreventiveservicestaskforce.org/uspstf08/colocancer/colors.htm) (/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)

More in Medical X-ray Imaging (/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MedicalX-Rays/default.htm)

Radiography (/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MedicalX-Rays/ucm175028.htm)

Computed Tomography (CT) (/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MedicalX-Rays/ucm115317.htm)
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