

[Home](#) > [Radiation-Emitting Products](#) > [Radiation-Emitting Products and Procedures](#) > [Medical Imaging](#)

Radiation-Emitting Products

Computed Tomography (CT)

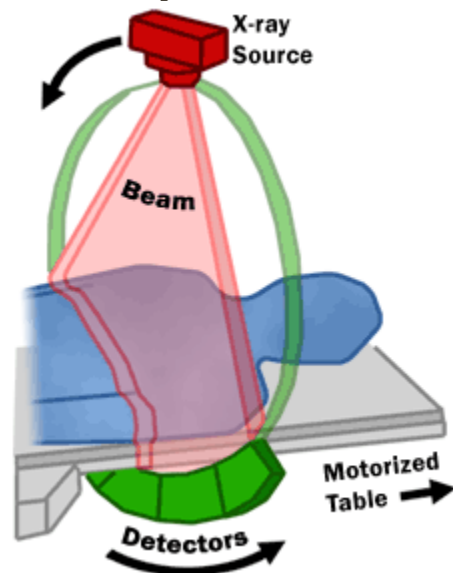
- [Description](#)
- [Uses](#)
- [Risks/Benefits](#)
- [Information for Patients](#)
- [Information for Professionals](#)
- [Laws, Regulations & Performance Standards](#)
- [Industry Guidance](#)
- [Other Resources](#)

Description

Computed tomography (CT) scanning, also called computerized axial tomography (CAT) scanning, is a medical imaging procedure that uses x-rays to show cross-sectional images of the body.

A CT imaging system produces cross-sectional images or "slices" of areas of the body, like the slices in a loaf of bread. These cross-sectional images are used for a variety of diagnostic and therapeutic purposes.

How a CT system works:



1. A motorized table moves the patient through a circular opening in the CT imaging system.
2. While the patient is inside the opening of the CT imaging system, an x-ray source and detector within the housing rotate around the patient. A single rotation takes about 1 second. The x-ray source produces a narrow, fan-shaped beam of x-rays that passes through a section of the patient's body.
3. A detector opposite from the x-ray source records the x-rays passing through the patient's body as a "snapshot" image. Many different "snapshots" (at many angles through the patient) are collected during one complete rotation.
4. For each rotation of the x-ray source and detector, 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.

Uses

CT can help diagnose or rule out a disease or condition. CT has become recognized as a valuable medical tool, for:

- Diagnosis of disease, trauma, or abnormality
- Planning, guiding, and monitoring therapy

Risks/Benefits

As in many aspects of medicine, there are risks associated with the use of CT. The main risks associated with CT are:

- An increased lifetime risk of cancer due to x-ray radiation exposure.
- Possible allergic reactions or kidney failure due to contrast agent, or "dye" that may be used in some cases to improve visualization.
- The need for additional follow-up tests after receiving abnormal test results or to monitor the effect of a treatment on disease, such as to monitor a tumor after surgical removal. Some of these tests may be invasive and present additional risks.

Under some rare circumstances of prolonged, high-dose exposure, x-rays can cause other adverse health effects, such as skin reddening (erythema), skin tissue injury, hair loss, cataracts, and potentially, birth defects (if scanning is done during pregnancy).

Radiation exposure is a concern in both adults and children. However, these concerns are greater for children because they are more sensitive to radiation and have a longer life expectancy than adults. As a result, accumulated exposures over a child's lifetime are more likely to result in an adverse health effect. A child's smaller size also has an impact on the radiation dose they receive. For example, if a CT scan is performed on a child using the same parameters as those used on an adult, an unnecessarily large dose will be delivered to the child. CT equipment settings (exposure parameters such as, x-ray tube current, slice thickness, or pitch) can be adjusted to reduce dose significantly while maintaining diagnostic image quality.

Information for Patients

- [Full-Body CT Scans - What You Need to Know](#)¹
- [FDA's Radiation-Emitting Products](#)²
- [Safety Investigation of CT Brain Perfusion Scans: Update 12/8/2009](#)³
- [Reducing Radiation from Medical X-rays](#)⁴
- [Reducing Radiation from Medical X-rays \(video\)](#)⁵
- [FDA Public Health Notification: Reducing Radiation Risk from Computed Tomography for Pediatric and Small Adult Patients](#)⁶
- [RadiologyInfo, a Radiology Information Resource for Patients](#)^{7,8}

Information for Professionals

- [Radiation Dose Quality Assurance: Questions and Answers](#)⁹
- [FDA Public Health Notification: Reducing Radiation Risk from Computed Tomography for Pediatric and Small Adult Patients](#)¹⁰
- [Radiation Risks and Pediatric Computed Tomography: A Guide for Health Care Providers](#)^{11,12}
- [Computed Tomography \(CT\) – An Increasing Source of Radiation Exposure, New England Journal of Medicine, Nov., 29, 2007](#)^{13,14}
- [National Council on Radiation Protection and Measurements](#)^{15,16}
- [Nationwide Evaluation of X-Ray Trends \(NEXT\) - Tabulation and Graphical Summary of 2000 Survey of Computed Tomography](#)^{17,18}

Laws, Regulations & Performance Standards

Manufacturers of electronic radiation emitting products sold in the United States are responsible for compliance with the [Federal Food, Drug and Cosmetic Act \(FDCA\), Chapter V, Subchapter C - Electronic Product Radiation Control](#)¹⁹.

Manufacturers of CT products are responsible for compliance with all applicable requirements of Title 21 Code of Federal Regulations (Subchapter J, Radiological Health) Parts 1000 through 1005:

[1000 - General](#)²⁰

[1002 - Records and Reports](#)²¹

[1003 - Notification of defects or failure to comply](#)²²

[1004 - Repurchase, repairs, or replacement of electronic products](#)²³

[1005 - Importation of electronic products](#)²⁴

In addition, CT products must comply with radiation safety performance standards in Title 21 Code of Federal Regulations (Subchapter J, Radiological Health) Parts 1010 and 1020:

[1010 - Performance standards for electronic products: general](#)²⁵

[1020.30 - Diagnostic x-ray systems and their major components](#)²⁶

Industry Guidance

- [Inspection of Domestic and Foreign Manufacturers of Diagnostic X Ray Equipment](#)²⁷ (May 15, 2008)
- [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](#)²⁸ (October 20, 2006)
- [FDA Issues Amendments to the Federal Radiation Safety Performance Standard for Diagnostic X-Ray Systems](#)²⁹ (June 2005)
- [Information Disclosure by Manufacturers to Assemblers for Diagnostic X-ray Systems; Final Guidance for Industry & FDA](#)³⁰ (September 5, 2003)

Other Resources

- [Device Advice: Does the Product Emit Radiation?](#)³¹ (July 28, 2006)
- [Frequently Asked Questions for Manufacturers of Electronic Products that Emit Radiation](#)³² (April 25, 2006)
- [Regulated Industry: Reports and Recordkeeping](#)³³
- [FDA eSubmitter](#)³⁴
- [Regulated Industry: Imports & Exports](#)³⁵
- [Guidance for FDA Staff - Compliance Program Guidance Manual: Field Compliance Testing of Diagnostic \(Medical\) X-ray Equipment](#)³⁶
- [CDRH Organ Dose handbooks containing reference values of radiation doses absorbed in tissues of patients undergoing representative procedures](#)³⁷

Links on this page:

1. <http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MedicalX-Rays/ucm115340.htm>
2. <http://www.fda.gov/Radiation-EmittingProducts/default.htm>
3. <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm185898.htm>
4. <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm095505.htm>

5. <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm186377.htm>
6. <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm062185.htm>
7. <http://www.radiologyinfo.org>
8. <http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm>
9. <http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/RadiationDoseReduction/ucm232550.htm>
10. <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm062185.htm>
11. <http://www.cancer.gov/cancertopics/causes/radiation-risks-pediatric-CT>
12. <http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm>
13. <http://content.nejm.org/cgi/content/full/357/22/2277>
14. <http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm>
15. <http://www.ncrponline.org/>
16. <http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm>
17. http://www.crcpd.org/Pubs/NEXT_docs/NEXT2000-CT.pdf
18. <http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm>
19. <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAAct/FDCAActChapterVDrugsandDevices/ucm110337.htm>
20. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1000>
21. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1002>
22. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1003>
23. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1004>
24. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1005>
25. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1010>
26. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/showCFR.cfm?FR=1020.30>
27. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm113216.htm>
28. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094379.htm>
29. <http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MedicalX-Rays/ucm135573.htm>
30. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089799.htm>
31. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089799.htm>
32. <http://www.fda.gov/Radiation-EmittingProducts/ElectronicProductRadiationControlProgram/GettingaProducttoMarket/default.htm>
33. <http://www.fda.gov/Radiation-EmittingProducts/ElectronicProductRadiationControlProgram/GettingaProducttoMarket/RecordsandReporting/default.htm>
34. <http://www.fda.gov/ForIndustry/FDAeSubmitter/default.htm>
35. <http://www.fda.gov/Radiation-EmittingProducts/ElectronicProductRadiationControlProgram/GettingaProducttoMarket/ImportingandExportingElectronicProducts/default.htm>

36. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm106198.htm>
37. <http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MedicalX-Rays/ucm117898.htm>