

Multi-Detector Computed Tomography (CT)

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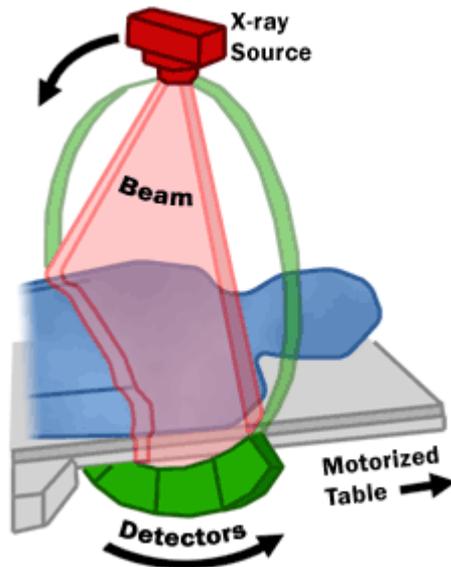
Product Overview

CT is a medical imaging technique using X-rays to produce cross-sectional images (slices) of the body.

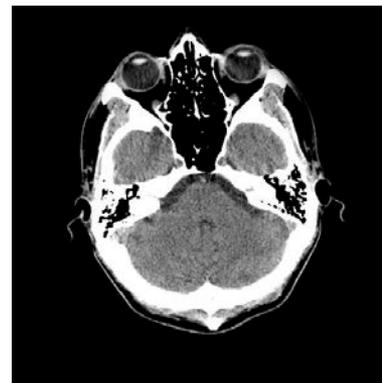
CT scans are used for a variety of diagnostic and interventional purposes.



Source: [Wikipedia](#)

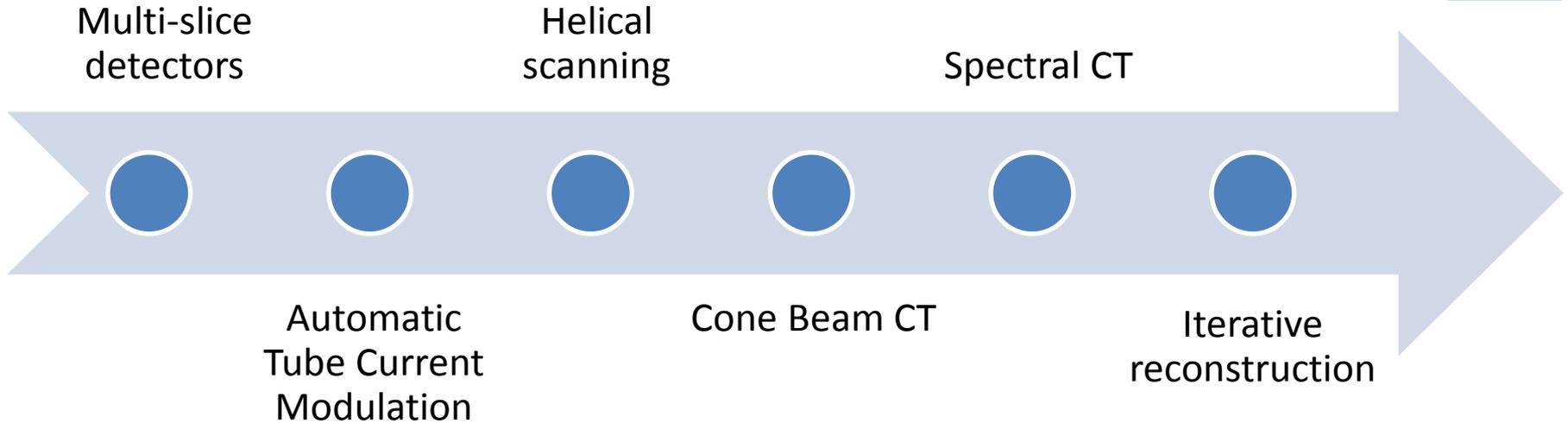


Source: fda.gov



Source: [Wikipedia](#)

Advances in CT technology since 1985



Increased CT use

1980: 3 million CT scans performed in US [1].

2006: 62 million CT scans performed per year [2], with 4-7 million performed on pediatric patients [2].

1. Boodman, Sandra G. (2016, January 4). Should you worry about the radiation from CT scans? *The Washington Post*. Retrieved from <http://www.washingtonpost.com>

2. Mettler FA, Thomadsen BR, Bhargavan M, et al. Medical radiation exposure in the U.S. in 2006: preliminary results. *Health Phys* 2008; 95:502–507

3. Strauss KJ, Goske MJ, Kaste SC, et al. Image Gently: ten steps you can take to optimize image quality and lower CT dose for pediatric patients. *AJR* 2010; 194:868–873

History of Performance Standards

- FDA's Performance Standards for X-ray Computed Tomography (21 CFR 1020.33) were published in 1985, and have not been updated since.
- The increased use of CT, and new technology, create safety concerns that could not have been predicted in 1985.

Safety Concerns

- Increased use of CT means increased radiation dose to US population. CT contributes ~50% of US collective dose from medical radiation.
 - Ionizing radiation exposure may slightly increase a person's lifetime risk of cancer.
 - For pediatric patients, cancer risk per unit radiation dose is higher, and their longer lifetimes give more time for potential long-term effects to occur.
- Harmful over-exposure can occur when operators don't have access to safety features and dose information.



FDA Proposal

- FDA wants to ensure that appropriate safety features and user safety information are available for all CT devices.
- We propose updated device performance standards and adoption of international consensus standards.
- Our proposals are based on public comments from a 2010 public meeting and recommendations from national and international organizations.

Examples of safety features not in FDA performance standards

- Automatic Exposure Control (IEC 60601-2-44)
- Radiation Dose Structured Report (IEC 60601-2-44)
- Access controls (NEMA XR-26)
- Dose Check (NEMA XR-25; IEC 60601-2-44)
- Improved dose-related user information (NEMA XR-28)
- Size-specific dose estimates (IEC standard in development)

FDA's proposal will help...

Reduce unnecessary radiation exposure to patients of all ages

- Image Gently recommends that pediatric CT be performed only when medically necessary, using only the exposure levels necessary to provide diagnostic quality images.
- Implementation requires accurate size-scaled dose estimates, detailed dose reporting, and safety features.

Avoid CT misuse and unintentional overexposure

Questions for TEPRSSC

- How should FDA approach safety features and requirements which are contained in voluntary consensus standards, but not included in an FDA performance standard?
- What about features that are not yet in FDA or voluntary standards?

Questions for TEPRSSC

- Other than SSDE, does TEPRSSC have specific recommendations to address pediatric safety concerns for multidetector CT systems?