

Full-Body CT Scans



U.S. Department of Health
and Human Services



U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

www.fda.gov

DHHS Publication No. (FDA) 03-0001
March 2003



What You Need to Know

Using a technology that “takes a look” at people’s insides and promises early warnings of cancer, cardiac disease, and other abnormalities, clinics and medical imaging facilities nationwide are touting a new service for health-conscious people: “Whole-body CT screening.” This typically involves scanning the body from the chin to below the hips with a form of X-ray imaging that produces cross-sectional images.



The technology used is called “X-ray computed tomography” (CT), sometimes referred to as “computerized axial tomography” (CAT). A number of different types of X-ray CT systems are being promoted for various types of screening. For example, “multi-slice” CT (MSCT) and “electron beam” CT (EBCT)—also called “electron beam tomography” (EBT)—are X-ray CT systems that produce images rapidly and are often promoted for screening the buildup of calcium in arteries of the heart.

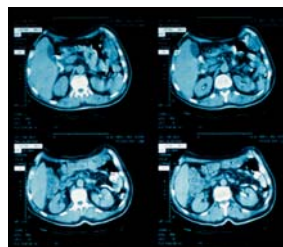
CT, MSCT and EBCT all use X-rays to produce images representing “slices” of the body—like the slices of a loaf of bread. Each image slice corresponds to a wafer-thin section which can be viewed to reveal body structures in great detail.

CT is recognized as an invaluable medical tool for the diagnosis of disease, trauma, or abnormality in patients with signs or symptoms of disease. It’s also used for planning, guiding, and monitoring therapy. What’s new is that CT is being marketed as a preventive or proactive

health care measure to healthy individuals who have no symptoms of disease.

No Proven Benefits for Healthy People

Taking preventive action, finding unsuspected disease, uncovering problems while they are treatable—these all sound great, almost too good to be true! In fact, at this time the Food and Drug Administration (FDA) knows of no scientific evidence demonstrating that whole-body scanning of individuals without symptoms provides more benefit than harm to people being screened. The FDA is responsible for assuring the safety and effectiveness of such medical devices, and it prohibits manufacturers of CT systems to promote their use for whole-body screening of asymptomatic people. The FDA, however, does not regulate practitioners and they may choose to use a device for any use they deem appropriate.



Compared to most other diagnostic X-ray procedures, CT scans result in relatively high radiation exposure. The risks associated with such exposure are greatly outweighed by the benefits of diagnostic and therapeutic CT. However, for whole-body CT screening of asymptomatic people, the benefits are questionable:

- Can it effectively differentiate between healthy people and those who have a hidden disease?
- Do suspicious findings lead to additional invasive testing or treatments that produce additional risk with little benefit?
- Does a “normal” finding guarantee good health? Many people don’t realize that getting a whole-

body CT screening exam won’t necessarily give them the “peace of mind” they are hoping for, or the information that would allow them to prevent a health problem. An abnormal finding, for example, may not be a serious one, and a normal finding may be inaccurate. CT scans, like other medical procedures, will miss some conditions, and “false” leads can prompt further, unnecessary testing.



Points to consider if you are thinking of having a whole-body screening:

- CT screening has not been demonstrated to meet generally accepted criteria for an effective screening procedure.
- Medical professional societies have not endorsed CT scanning for individuals without symptoms.
- CT screening of high-risk individuals for specific diseases such as lung cancer or colon cancer is currently being studied, but results are not yet available.
- The radiation from a CT scan may be associated with a very small increase in the possibility of developing cancer later in a person’s life.
- The FDA provides additional information regarding whole-body CT screening on its Web site at: www.fda.gov/cdrh/ct.

FDA’s Recommendation:

Before having a CT screening procedure, carefully investigate and consider the potential risks and benefits and discuss them with your physician.