

Thermographic Imaging Systems for Breast Cancer Screening: FDA Safety Communication

U.S. Food & Drug Administration

ISSUE: FDA notified consumers, women who participate in breast cancer screening and healthcare professionals that thermography is not a replacement for screening mammography and should not be used by itself to diagnose breast cancer. Thermographic systems use an infrared camera to produce images (thermograms) that show the patterns of heat and blood flow on or near the surface of the body. The FDA is not aware of any valid scientific data to show that thermographic devices, when used on their own, are an effective screening tool for any medical condition including the early detection of breast cancer or other breast disease. The FDA is concerned that women will believe these misleading claims about thermography and not receive needed mammograms.

BACKGROUND: Certain facilities, websites, and mobile units are promoting the use of thermography as a stand-alone evaluation tool for screening and diagnosing breast cancer, claiming that is a substitute for or superior to mammography. They also claim that thermography can detect pre-cancerous abnormalities and diagnose breast cancer long before mammography and that compressing the breast during mammography will cause or spread cancer by pushing cancer cells into additional locations in the body.

RECOMMENDATION: Woman should have regular mammograms according to screening guidelines or as recommended by a health care provider. Patients should follow a health care provider's recommendations for additional breast diagnostic procedure which could include thermography, clinical breast exam, breast ultrasound, MRI or biopsy.

Healthcare professionals and patients are encouraged to report adverse events, side effects, or product quality problems related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm [1]
- [Download form](#) [2] or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[06/02/2011 - [Safety Communication](#) [3] - FDA]

[06/02/2011 - [News Release](#) [4] - FDA]

[06/02/2011 - [Consumer Update - Thermogram No Substitute for Mammogram](#) [5] - FDA]

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[03/09/2010 - [National Cancer Institute - Breast Cancer Screening](#) [6] - NIH]  [7]

[06/02/2011 - [Women's Health Topics: Mammography](#) [8] - FDA]

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<http://www.mdtmag.com/news/2011/06/thermographic-imaging-systems-breast-cancer-screening-fda-safety-communication>

Links:

[1] <http://www.fda.gov/MedWatch/report.htm>

[2] <http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm>

[3] <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm257259.htm>

[4]

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm257633.htm>

[5] <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm257499.htm>

[6] <http://www.cancer.gov/cancertopics/pdq/screening/breast/Patient>

[7] <http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm>

[8] <http://www.fda.gov/ForConsumers/ByAudience/ForWomen/WomensHealthTopics/ucm117967.htm>

[9] <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm257707.htm>