

FDA Warns Thermography Should Not Be Used in Place of Mammography to Detect, Diagnose, or Screen for Breast Cancer: FDA Safety Communication

Date Issued

February 25, 2019

Audience

- Women
- People recommended for breast cancer screening
- Health care providers
- Cancer treatment advocacy organizations

Medical Specialties

Radiology, Pathology, Internal Medicine, Obstetrics/Gynecology, Oncology, Nursing, General Practice, Breast Surgery, Acupuncture, Osteopathy, Chiropractic, Naturopath

Product

Thermography is a noninvasive tool that uses an infrared camera to produce images (thermograms) that show the patterns of heat and blood flow on or near the surface of the body. Thermography devices, also known as digital infrared imaging devices, have been cleared for marketing by the FDA only for use with another screening or diagnostic test like mammography, not for use as a standalone diagnostic tool.

Purpose

The FDA is alerting women, health care providers, and people getting breast cancer screening, that thermography is not an effective alternative to mammography and should not be used in place of mammography for breast cancer screening or diagnosis.

There is no valid scientific data to demonstrate that thermography devices, when used on their own or with another diagnostic test, are an effective screening tool for any medical condition including the early detection of breast cancer or other diseases and health conditions.

Mammography (taking X-ray pictures of the breasts) is the most effective breast cancer screening method and the only method proven to increase the chance of survival through earlier detection. (<https://www.sbi-online.org/Portals/0/Position%20Statements/2018/nov0818-mammography-primary-factor-in-reduced-breast-cancer-deaths.pdf>)

Summary of Problem and Scope

The FDA is aware that health spas, homeopathic clinics, mobile health units, and other health care facilities are using thermography inappropriately as a standalone tool for breast cancer screening or diagnosis.

The FDA has received reports that these types of facilities provide false information that can mislead patients into believing that thermography is an alternative or better option than mammography. Some facilities make inaccurate, unsupported, and misleading claims, such as thermography can find breast cancer years before it would be detected through other methods or thermography improves detection of cancer in dense breasts.

None of these claims are true or have any valid scientific evidence to support them. In addition, the **Society for Breast Imaging (https://www.sbi-online.org/RESOURCES/PolicyPositionStatements/Breast_Thermography.aspx)** notes a lack of evidence that thermography has any effective role in breast cancer screening. Mammography is the most safe and effective tool for screening and diagnosis of breast cancer, and the only method proven to increase the chance of survival through earlier detection.

The FDA is concerned that people will believe the misleading claims about thermography and not get mammograms to screen for breast cancer. People who choose thermography instead of mammograms may miss the chance to detect cancer at its earliest and most treatable stages. The agency is taking steps to stop the false advertising of thermography—see the **FDA Actions section** below for more information.

Recommendations for People Getting Breast Cancer Screening

- Be aware that thermography is not a substitute for regular mammograms and should not be used in place of mammography for breast cancer screening or diagnosis.
- Have regular mammograms according to screening guidelines or as recommended by your health care provider.
 - You can learn more about what to expect during a mammogram on the **FDA's Mammograms webpage (<https://www.fda.gov/ForConsumers/ByAudience/ForWomen/ucm118546.htm>)**.
- Follow your health care provider's recommendations for additional steps to diagnose breast cancer such as a clinical breast exam, other breast imaging (for example, breast ultrasound or MRI), or breast tissue biopsy.

Recommendations for Health Care Providers

- Educate patients about the limitations of thermography. For example, the high false negative and false positive rates of thermography can provide misleading information that could result in a delayed diagnosis or unnecessary medical follow up.
- Discourage the use of thermography to diagnose or screen for breast cancer.

- Talk to patients or caregivers about safe and effective ways to screen for breast cancer including the benefits and risks of available testing options.

FDA Actions

On February 22, 2019, the FDA issued a **Warning Letter (/ICECI/EnforcementActions/WarningLetters/ucm631593.htm)** to Total Thermal Imaging, Inc., in La Mesa, California, for marketing and promoting thermography devices for uses that have not received marketing clearance or approval.

The FDA has also issued Warning Letters to the following facilities:

- **Warning Letter to Thermogram Assessment Services (November 10, 2016) (<https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm540528.htm>)**
- **Warning Letter to Nature's Treasures (April 17, 2017) (<https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm553688.htm>)**
- **Warning Letter to Meditherm, Inc (April 4, 2011) (<https://wayback.archive-it.org/7993/20170112094003/http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2011/ucm249863.htm>)**
- **Warning Letter to Dr. Joseph Mercola, Dr. Mercola's Natural Health Center (March 22, 2011) (<https://web.archive.org/web/20111208202236/http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2011/ucm250701.htm>)**
- **Warning Letter to Central Coast Thermography (January 6, 2011) (<https://web.archive.org/web/20111208202237/http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2011/ucm245253.htm>)**

In these Warning Letters, the FDA instructed the providers to immediately stop making inappropriate claims about thermography devices.

The FDA is closely monitoring adverse event reports associated with thermography and will take additional steps necessary to address the risks associated with use of these products. We are committed to protecting and promoting access to safe and effective breast screening devices.

Reporting Problems to the FDA

If you experience an injury or adverse event with thermography, the FDA encourages you to file a voluntary report by phone at 1-800-FDA-1088 or online at **MedWatch, the FDA Safety Information and Adverse Event Reporting program (<https://www.fda.gov/Safety/MedWatch/HowToReport/default.htm>)**. Please include the following information in your reports:

- Device Name (Brand Name)
- Manufacturer's Name
- Details of Adverse Event and Medical and/or Surgical Interventions (if applicable)

Prompt reporting of adverse events can help the FDA identify and better understand the risks related to the use of medical devices.

Additional Resources

- **FDA Consumer Update: Breast Cancer Screening: Thermogram No Substitute for Mammogram (<https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm257499.htm#top>)**
- **FDA issues warning letter to clinic illegally marketing unapproved thermography device, warns consumers to avoid using thermography devices to detect breast cancer (<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm631957.htm>)**
- **FDA Mammography Information (<https://www.fda.gov/ForConsumers/ByAudience/ForWomen/WomensHealthTopics/ucm117967.htm>)**
- **FDA Consumer Update: Mammography: What You Need to Know (<https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm420463.htm>)**
- **Centers for Disease Control and Prevention (CDC) Breast Cancer Screening Information (https://www.cdc.gov/cancer/breast/basic_info/screening.htm)**
- **American College of Radiology - New Study Cements Fact That Mammography is a Primary Factor in Reduced Breast Cancer Deaths (<https://www.acr.org/Media-Center/ACR-News-Releases/2018/New-Study-Cements-Fact-That-Mammography-is-a-Primary-Factor-in-Reduced-Breast-Cancer-Deaths>)**
- **National Cancer Institute - Breast Cancer Screening (<https://www.cancer.gov/types/breast/patient/breast-screening-pdq>)**
- **American Cancer Society Breast Cancer Screening Guideline (<https://www.cancer.org/latest-news/special-coverage/american-cancer-society-breast-cancer-screening-guidelines.html>)**

Contact Information

If you have questions about this communication, please contact the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV (<mailto:DICE@FDA.HHS.GOV>), 800-638-2041 or 301-796-7100.

More in Safety Communications
[\(/MedicalDevices/Safety/AlertsandNotices/default.htm\)](/MedicalDevices/Safety/AlertsandNotices/default.htm)

2019 Safety Communications (</MedicalDevices/Safety/AlertsandNotices/ucm630141.htm>)

2018 Safety Communications (</MedicalDevices/Safety/AlertsandNotices/ucm592582.htm>)

2017 Safety Communications (</MedicalDevices/Safety/AlertsandNotices/ucm553873.htm>)