



Health  
Canada

Santé  
Canada

Health Products  
and Food Branch

Direction générale des produits  
de santé et des aliments

Health Products and Food Branch  
Inspectorate  
Graham Spry Building, 3<sup>rd</sup> Floor  
250 Lanark Avenue  
Address Locator # 2003C  
Ottawa, Ontario  
K1A 0K9

November 29, 2012

To: Canadian Association of Radiologists (CAR)

**Subject:** Thermography Machines are not Authorized to Screen for Breast Cancer

Health Canada has become aware that thermography (thermal imaging) machines are being used to screen for breast cancer in various health clinics throughout Canada. Please be advised that no thermography machines have been approved to screen for breast cancer in Canada. Therefore, clinics should not be promoting or using thermography machines to screen for breast cancer.

Health Canada is not aware of any clinical evidence that thermography can be used effectively as a screening technique for the early detection of breast cancer. Thermography machines are not a replacement for routine monitoring and screening for breast cancer. As such, they present a potential health risk to women who may have relied on the results.

I am writing to ensure your Association is aware of this issue, and to encourage your Association to share this information with your membership. I would also encourage your Association to post this letter on your website.

The safety of medical devices in Canada is a shared responsibility. The federal government is responsible for the regulatory framework, such as authorising medical devices, while the provinces and territories are responsible for delivery of health care services, such as the use of medical devices. Associations such as yours play a key role in sharing health and safety information.

Health Canada has issued the attached risk communication [also available at [http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/\\_2012/2012\\_178-eng.php](http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/_2012/2012_178-eng.php)] to inform Canadians and Canadian health care practitioners of this issue. It is our hope that patients who have relied on the results of these machines will contact their physicians for appropriate follow-up and testing.

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The Department is also following-up with the manufacturers of these devices to help ensure they are aware that it is illegal to advertise or sell these types of machines to screen for breast cancer in Canada. This could result in a stop sale of any unlicensed product. Health Canada is also working with the Canada Border Services Agency to stop any unlicensed devices from entering Canada.

Health Canada has also written to the Provincial/Territorial Ministries of Health to recommend that, if not already done so, these ministries contact clinics to request that they cease and desist the use of thermography machines for the detection of breast cancer or other breast disorders, and that they inform any past patients of this issue.

For further information, or to report thermography machines being used in the screening of breast cancer, please contact the Health Products and Food Branch Inspectorate by calling the toll-free hotline at 1-800-267-9675, or by writing to:

Health Products and Food Branch Inspectorate  
Health Canada  
Address Locator: 2003D  
Ottawa, Ontario K1A 0K9

Your truly,

A handwritten signature in black ink, appearing to read 'Diana Dowthwaite', with a horizontal line extending from the end of the signature.

Diana Dowthwaite  
Director General

Attachment: Information Update



Home > About Health Canada > Media Room > Advisories and Warnings

## About Health Canada

### Thermography Machines not Authorized to Screen for Breast Cancer

#### Information Update

2012-178

November 28, 2012

For immediate release

**OTTAWA** – Health Canada is advising Canadians and health care practitioners that no thermography (thermal imaging) machines have been approved to screen for breast cancer in Canada.

Health Canada is not aware of any clinical evidence that thermography can be used effectively as a screening technique for the early detection of breast cancer. As such, it may present a potential risk to women relying on the results.

Health Canada would also like to remind consumers that thermography machines are not a replacement for routine monitoring and screening for breast cancer. Patients who have relied on these types of machines for breast cancer screening should contact their physician for appropriate follow-up and testing.

The Department is following-up with the manufacturers of these devices to help ensure they are aware that it is illegal to advertise or sell these types of machines to screen for breast cancer in Canada. This could result in a stop sale of any unlicensed product. Health Canada is also working with the Canada Border Services Agency to stop any unlicensed devices from entering Canada.

Health Canada will be communicating with the provincial and territorial ministries of health to advise them that clinics falling under their responsibility should not be promoting or using these devices to screen for breast cancer.

There is more information on breast cancer, available through the [Public Health Agency of Canada](http://www.phac-aspc.gc.ca/cd-mc/cancer/breast_cancer-cancer_du_sein-eng.php) at [http://www.phac-aspc.gc.ca/cd-mc/cancer/breast\\_cancer-cancer\\_du\\_sein-eng.php](http://www.phac-aspc.gc.ca/cd-mc/cancer/breast_cancer-cancer_du_sein-eng.php). To confirm whether a device is licensed in Canada, please refer to the [Medical Devices Active Licence Listing](http://www.mdall.ca) at [www.mdall.ca](http://www.mdall.ca).

Complaints involving thermography machines used in the screening of breast cancer can be reported to the Health Products and Food Branch Inspectorate by calling the toll-free hotline at 1-800-267-9675, or by writing to:

Health Products and Food Branch Inspectorate  
Health Canada  
Address Locator: 2003D  
Ottawa, Ontario K1A 0K9

Consumers requiring more information about this advisory can contact Health Canada's public enquiries line at (613) 957-2991, or toll free at 1-866-225-0709.

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#### Media Enquiries:

Health Canada  
613-957-2983

**Public Enquiries:**

613-957-2991

1-866-225-0709

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Date Modified: 2012-11-28