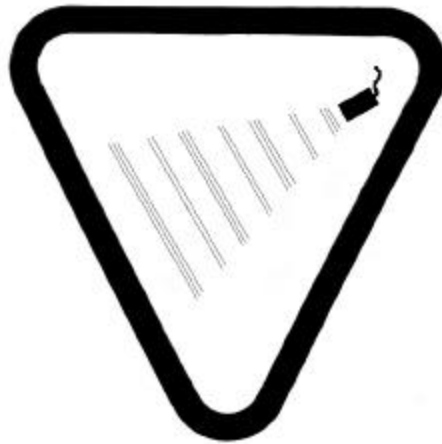


SELLING ULTRASOUND THERAPY DEVICES IN CANADA ?

WHAT YOU NEED TO KNOW



Radiation Protection Bureau
Environmental Health Directorate

Health Protection Branch
Health Canada

1999

Do you wish to sell ultrasound therapy devices in Canada?

If you do, then you need to know that sale, importation and advertisement of ultrasound therapy devices are regulated by the Radiation Emitting Devices Act and its Regulations, and by the Food and Drugs Act and its Medical Devices Regulations.

COMMON QUESTIONS

What do I have to do to comply with the Medical Devices Regulations?

- A manufacturer of ultrasound therapy devices must obtain a Medical Device Licence before selling, importing or advertising an ultrasound therapy device in Canada. Information on obtaining a Medical Device Licence is provided in the document, titled "Guidance on How to Complete the Application for a New Medical Device Licence. This and other guidance documents are available via the Internet (www.hc-sc.gc.ca/hpb-dgpps/therapeut). For further assistance, please contact the Medical Devices Bureau at (613)957-7285.
- An importer or distributor of ultrasound therapy devices is required to obtain an Establishment Licence. For information on how to obtain an Establishment Licence, please contact the Bureau of Compliance and Enforcement at (613)952-3828.

What do I need to know about the Radiation Emitting Devices Act ?

Radiation safety of ultrasound therapy devices is governed by the Radiation Emitting Devices Act (RED Act) and its Regulations. This legislation covers both electromagnetic and acoustical radiation. Ultrasound is an example of acoustical radiation.

- ! The RED Act and its regulations are intended to protect the public from health risks and fraudulent claims regarding the emission of radiation from devices.
- ! Ultrasound therapy devices cannot be legally sold in Canada unless they comply with the Ultrasound Therapy Devices Standard, a regulation under the RED Act.
- ! The Radiation Protection Bureau of Health Canada enforces the RED Act and its regulations and can assist manufacturers, importers and distributors trying to achieve compliance.

What do I have to do to comply with the RED Act and its Regulations?

The Radiation Protection Bureau of Health Canada has developed a form and guidelines that will help you determine whether the device you wish to sell complies with Canadian radiation safety legislation and standards. The guidelines on the next few pages will help you:

- ! understand the requirements of the legislation and standards that pertain to the radiation safety of ultrasound therapy devices
- ! verify that the performance of your device complies with these standards
- ! measure the exposure parameters required for the labelling of your device
- ! answer the questions contained in our Submission of Information form

Do I have to complete the Submission of Information form?

No, completion of the form is entirely voluntary. However, doing so may help you save the time, money and inconvenience involved in having to correct a non-compliant device after it has been placed on the market.

What are the benefits of submitting this form?

The Radiation Protection Bureau helps manufacturers meet the requirements of the RED Act and the Ultrasound Therapy Devices Standard. Once we receive your form, staff will evaluate whether there is any reason to consider that the sale of the device might be prohibited in Canada under Section 4 of the RED Act.

We will inform you if we have identified any areas of concern regarding the compliance of the device you wish to sell. If there are, we can give you expert advice on what you need to do to help ensure compliance.

Specifically, we can advise you on the way the standard is interpreted, measurement methods, lot sampling procedures and how to correct violations. If necessary, we can also conduct inspections and measurements on your device to help you achieve compliance.

What do I do first?

First, read the background information on the next few pages. This will give you an overview of the RED Act and its regulations. It will also give you a convenient summary of the requirements your device has to meet under the Ultrasound Therapy Devices

Standard. Then you can proceed to fill out the form. We have included a detailed set of notes on most sections to assist you in answering the questions.

What if I make several different products with the same ultrasound design and performance specifications?

These products can be included in a single report. Each product or model that shares the same ultrasound components should be identified. In general, you should submit a new report if a modification to a product results in a change in performance specifications, or if a change in the labelling of the product is considered to affect radiation safety. Other changes to a product, such as cosmetic ones, need not be reported.

Who should I call if I have questions about the form or the legislation?

At the Radiation Protection Bureau, we strive to maintain open lines of communication with manufacturers at all times. We encourage you to contact us with your questions and concerns.

Radiation Protection Bureau,
Acoustics Unit, Rm: 237
775 Brookfield Rd.
Ottawa, Ontario, Canada, K1A 1C1
Postal Locator 6301B

Physicist, Dr. S.H.P. Bly (613) 954-0308, sbly@hc-sc.gc.ca
Inspector, Mr. R.G. Hussey (613) 954-0313, Robert_Hussey@hc-sc.gc.ca

FAX: 941-1734

BASIC FACTS ON THE RADIATION EMITTING DEVICES ACT AND REGULATIONS

- ! It is illegal to sell or import a radiation emitting device that is not in compliance with the RED Act and any prescribed standard.
- ! The device must not create a radiation health risk by failing to perform according to the claimed performance characteristics, or by failing to accomplish its claimed purpose, or by emitting unnecessary radiation.
- ! It is illegal to label or advertise a device in a way that is false or misleading regarding design, performance, or safety relating to the emission of radiation.
- ! The prescribed standard is the Ultrasound Therapy Devices Standard (see Part XIII of Schedule II of the Regulations). This standard regulates the design, construction and functioning of ultrasound therapy devices sold in Canada. This standard specifies requirements for labelling and performance.
- ! Manufacturers and importers must notify the Minister if they become aware, after a device has left their premises, that the sale was illegal under the Act.
- ! The Minister may require that manufacturers notify concerned persons of a device's defect or failure to comply with the law. Such notification may also be required if the Minister's own research, inspection or testing determines that the sale of a device was illegal under the Act.
- ! The rules for enforcement of the Act, disposition of devices, and terms of offence and punishment are given in Sections 7 to 15 of the RED Act.

SUMMARY OF THE REQUIREMENTS OF THE ULTRASOUND THERAPY DEVICES STANDARD

This brief summary is for guidance purposes only, the Regulation should be consulted directly in order determine device compliance.

Labelling requirements

Generator housing label

The ultrasonic therapy device must bear a clearly visible label on the external surface of its housing. This label must state:

- ! the name and address of the manufacturer and distributor
- ! the month and year of manufacture
- ! the device identification by type, model and serial number
- ! the operating ultrasonic frequency (with an accuracy of $\pm 5\%$)
- ! the type of output (continuous or amplitude modulated [pulsed])
- ! when the amplitude modulated (pulsed) mode is available, the label must include:
 - the pulse duration and repetition rate,
 - an illustration of the wave form,
 - the ratio of the temporal maximum effective ultrasonic intensity, to the temporal average effective ultrasonic intensity
- ! the voltage used for normal operation
- ! the ultrasound radiation warning sign



This labelling may take the form of an actual label or may consist of lettering on the front, sides or rear of the housing. You should avoid placing labels on the bottom surfaces.

Applicator label

Each ultrasound therapy applicator, whether sold individually or as part of an ultrasound therapy device, must bear a label identifying:

- ! the type and model of ultrasound therapy device for which it is designed
- ! a unique serial number
- ! the effective radiating area (with an accuracy of $\pm 20\%$)

Performance requirements

Indicated ultrasonic output

- ! The radiated ultrasonic power and intensity must be indicated with an accuracy of $\pm 20\%$ when the output is greater than 10% of maximum.
- ! If the device operates in the continuous mode, the time average ultrasonic power and effective ultrasonic intensity must be indicated.
- ! If the device operates in the amplitude modulated wave (pulse mode), temporal **maximum** ultrasonic power and temporal **maximum** effective ultrasonic intensity must be indicated.

Timer

- ! The ultrasonic output must be controlled by a timer. The timer must not allow the generation of ultrasound with the timer set to zero. The timer must terminate the generation of ultrasound after a preset time period and return to zero.
- ! The timer must also be accurate within ± 30 seconds for settings less than 5 minutes, $\pm 10\%$ for settings between from 5 to 10 minutes and ± 1 minute for settings greater than 1 minute.

Energized sound head indication

- ! The user must be provided with a visual indication when electrical energy is applied to the sound head.

Output stability

- ! The ultrasonic power output must be stable within $\pm 20\%$ of its initial value over one hour of continuous operation at maximum output.

Output limits

- ! The maximum value of the **temporal average effective ultrasonic intensity must not exceed 3 W/cm^2 .**

REPORTING FORM

Manufacturer / Importer Identification and Address:

Manufacturer corporate headquarters: _____ _____ _____ _____ _____	Place of manufacture, same [] or: _____ _____ _____
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Device Identification:

Report Covers: [] Complete unit [] Generator only [] Applicator only
Indicate, model number, brand name, or other designation of the product
_____ _____ _____

Importer: _____ _____ _____

Name, signature, title, and address of the person submitting the report:	
Name: _____	Signature: _____
Title: _____	Telephone: _____
Address: _____	Date of Submission: _____
_____	(dd/mm/yy)

Reporting of Labelling Requirements

The information reported in this section will be used to determine whether the product complies with the requirements set forth in paragraphs 2(2)(a) - 2(3) of the Standard for Ultrasound Therapy Devices Part XIII, Schedule II of the Radiation Emitting Devices Regulations.

Generator labels:

Inspect the external surface of the generator housing and indicate below with a check mark the compliance of your product with the standard.

Regulatory Reference

- 2(2)(a) All marks, labels and signs are permanently affixed and clearly visible. []
- (b) All user controls and meters lights are clearly visible, readily discernible and clearly labelled to indicate their function. []
- 2(3)(a) The following information is labelled
- (i) Name and address of manufacturer []
 - (ii) Name and address of distributor []
 - (iii) Type and model designation []
 - (iv) Serial number []
 - (v) Month and year of manufacture []
 - (vi) Ultrasonic frequencies in kHz or MHz []
 - (vii) Indication whether the wave is continuous or amplitude modulated []
 - (viii) (A)(B) If modulated
 - pulse repetition rate _____ []
 - pulse duration _____ []
 - ratio of temporal maximum to temporal average _____ []
 - description of wave shape []
 - (ix) Line voltage for normal operation - volts []
 - (x) Ultrasound radiation warning sign, in two contrasting colours, clearly visible and identifiable from a distance of 1 meter (see sample diagram). []



Applicator labels

Inspect the external surface of each applicator and indicate below with a check mark the compliance of your product with the standard.

Regulatory Reference

2(3)(b) (i)	Applicator	type and model of ultrasound therapy device	[]
(ii)		if focussed - focal length - cm _____	[]
		focal area - cm ² _____	[]
(iii)		serial number	[]
(iv)		effective radiating area in cm ² _____	[]

Attach samples of the generator and applicator labels to the space below; if labels are unavailable at the time of reporting, attach a facsimile in the space provided, or provide a specification control drawing.

Reporting of Design and Construction Requirements

Inspect the functional performance of your ultrasound device and then indicate below with a check mark that your product complies with the standard. All user controls, meters, lights or other indicators must be clearly visible and labelled in a way that identifies the function controlled. The units of measure must be clearly labelled. If a separate control and indicator are associated with the same function, it is necessary to label the units of measure for the indicator. It is not necessary to do so for the control.

Regulatory Reference

- | | | |
|-------------|--|-----|
| 2(4)(a) (i) | Indicator shows whether the line voltage is ON or OFF | [] |
| (ii) | Indicator shows when ultrasonic power is applied to applicator | [] |
| 2(4)(b) (i) | For continuous wave mode, an indicator shows, by direct reading, the levels of:
- temporal average ultrasonic power | [] |
| | - temporal average effective ultrasonic intensity | [] |
| (ii) | For amplitude modulated wave mode, an indicator shows, by direct reading, the levels of:
-temporal maximum ultrasonic power | [] |
| | -temporal maximum effective ultrasonic intensity | [] |
| 2(4)(c) | Indicator of the range used on the ultrasonic power indicator if two or more ranges are used | [] |
| 2(4)(d) (i) | Timer: - terminates generation of ultrasound after a preset time interval and returns to zero | [] |
| (ii) | - does not allow generation of ultrasound with timer set at zero | [] |
| (iii) | - is adjustable to settings in increments not greater than one minute | [] |
| 2(5)(a) | If there is an ultrasound power control, it allows the adjustment of ultrasonic power | [] |
| 2(5)(b) | The ultrasound power control has a minimum and maximum adjustment that relates to the ultrasonic power level indicator | [] |

Standards of Functioning

The information reported in this section will be used as an aid in determining whether your devices are in compliance with the standards of functioning as set out in paragraphs 3(1) to 3(7) of the ultrasound Therapy Devices Standard.

On the following pages, indicate with a check mark that your product complies with the standard. To complete our evaluation, we will also need a description of the tests that convinced you that compliance was achieved for all of your units. (Refer also to the next section on Measurement Guidance).

Please describe fully all the tests performed on the product during or after production. The description of each test should:

- ! Identify all instruments that are used for the test.
- ! State the sources of error and estimate the uncertainty in the measured result. Where applicable, this should include instrument calibration.
- ! Indicate traceability of the calibration.
- ! State whether performed on a 100% or sampling basis. If tested on a sampling basis, include lot size, proportion of total production tested, method of sample selection to ensure randomness, and the rationale for choosing to sample rather than testing on a 100% basis. (While the Bureau has no objection to sampling per se, it should be clearly demonstrated that such a program would provide reasonable proof of compliance.)
- ! Describe the test procedure in detail, including any assumptions and calculations that are made in obtaining the results.
- ! Describe the corrective action taken following unit or lot rejection (i.e., increase sampling, test 100%, and so forth).

Attach this documentation to the form, clearly identifying the applicable regulatory reference. If some documentation applies to more than one regulatory reference, please ensure that this is indicated.

**Regulatory
Reference**

3(1) Maximum temporal average spatial average effective ultrasonic intensity does not exceed 3 W/cm². []

What is the maximum temporal average effective ultrasonic intensity? _____W/cm².

3(3) Power indicator shows the ultrasonic power with an accuracy of ± 20% when the output is more than 10% of maximum. []

State the typical accuracy of the ultrasonic power shown by the indicator of paragraph 2(4)(b) of the Standard for

(a) Temporal average ultrasonic power ± _____%

(b) Temporal maximum ultrasonic power ± _____%

Is a radiation force balance used to measure temporal average ultrasonic power?
Yes [] No []

For the test for accuracy of indicated power, state the:

- ! specific power levels at which the measurement is made
- ! the percentage accuracy of the indicated power at each point
(100% x (Indicated - Measured)/Measured)
- ! the range over which the specified tolerance is assumed to hold

This should be done in two parts:

- ! Describe test results for temporal average ultrasonic power.
- ! Describe test results for temporal maximum ultrasonic power.

The presentation of results for temporal maximum ultrasonic power will depend on the method used. However, in either case, a description of the hydrophone (or other method) used to measure the ultrasonic waveforms should be provided.

In addition, where needed, include samples of properly labelled photographs or plots of the pulsed waveforms as supporting test evidence. Clearly indicate that this information pertains to paragraph 3(3) of the standard.

3(4) Timer is accurate to ± 30 seconds for settings less than 5 minutes, $\pm 10\%$ for settings 5 to 10 minutes, ± 1 minute for settings greater than 10 minutes. []

What is the timer accuracy for settings less than 5 minutes? _____ seconds.

What is the timer accuracy for settings between 5 and 10 minutes? \pm _____ %.

What is the timer accuracy for settings greater than 10 minutes? \pm _____ seconds.

Clearly indicate that any supporting documentation is pertinent to paragraph 3(4) of the standard.

3(5) The ultrasonic power remains constant within $\pm 20\%$ of the initial value during one hour of continuous operation, at maximum output and at rated supply line voltage, in water at a temperature of $22^{\circ}\text{C} \pm 3^{\circ}\text{C}$. []

How constant is the ultrasonic power during one hour of continuous operation at rated supply line voltage in water at $22 \pm 3^{\circ}\text{C}$?

Within \pm _____ % of the initial value.

Clearly indicate that any supporting documentation is pertinent to paragraph 3(5) of the standard.

3(6) Ultrasonic frequency of the device does not differ more than $\pm 5\%$ from the nominal frequency. []

What is the rated value? _____ MHZ.

What is the typical measured value? _____ MHZ.

Clearly indicate that supporting documentation pertain to paragraph 3(6) of the standard.

3(7) The effective radiating area is within $\pm 20\%$ of the rated value. []
What is the typical difference between the measured value and rated value ? ___% of the rated value.

A description of the hydrophone and scanning apparatus used to measure the effective radiating area is needed as supporting documentation. Please ensure that this includes the dimensions of the active element of the hydrophone.

Clearly indicate that supporting documentation pertains to paragraph 3(7) of the standard.

MEASUREMENT GUIDANCE

It is recommended that measurements of **temporal average** ultrasonic power be made according to IEC standard 61161: 1992-07 "Ultrasonic power measurement in liquids in the frequency range 0.5 MHz to 25 MHz". Some introductory guidance to ultrasonic power measurements is also provided below.

Determinations of the **temporal maximum** ultrasonic power and the effective radiating area should be made using the guidance provided below.

IEC standard 61102: 1991-11 "Measurement and characterization of ultrasonic fields using hydrophones in the frequency range 0.5 MHz to 15 MHz can also be of help in making the hydrophone measurements required to achieve compliance with the Ultrasound Therapy Devices Standard.

Measurement conditions

All ultrasound measurements should be made in water at room temperature ($22 \pm 3^{\circ}\text{C}$).

Unwanted reflections of the ultrasound beam need to be minimized to ensure that they do not lead to unacceptable measurement uncertainties. This can be achieved by using a suitable combination of baffles, lining materials, and size and shape of tank. Also, to minimize reflections in effective radiating area measurements, a probe hydrophone is required with the active element sufficiently far from other structures to avoid significant reflections.

There should be no bubbles visible anywhere in the radiation force balance or hydrophone measurement tank. Even very small bubbles create unacceptable uncertainties in the measurement of ultrasound. The formation of bubbles by ultrasound (cavitation) can be avoided in effective radiating area measurements simply by operating at the lowest effective intensities which can reasonably be achieved. The reasonableness is determined by whether the measurement can be made with the required accuracy. For ultrasonic power measurements, you can only avoid cavitation if degassed water is used.

You can degas water by boiling for 15 minutes at atmospheric pressure, or by subjecting it to a reduced pressure of not more than 30 mm of mercury for 3 hours. Degassing should be carried out before each set of measurements unless special storage methods are used. Care should be taken throughout all procedures to minimize re-solution of air in the water. The amount of dissolved oxygen in the water is a good indicator of gas levels in the water. Oxygen levels must be less than 4 ppm. in order to avoid cavitation. The dissolved oxygen levels are easily monitored during measurements with an inexpensive test kit. The degassed water in a balance radiometer will have a typical working time of 3 or 4 hours (if it was degassed initially to less than 2 ppm. oxygen).

Hydrophone measurements of effective radiating area of ultrasound therapy applicators

You can measure the effective radiating area by using a small piezoelectric probe, or hydrophone, which can be accurately positioned at any point in the field radiated by the transducer. The voltage output of the hydrophone will be proportional to the ultrasonic pressure at that point. It is sufficient to make effective radiating area tests on a sampling basis, rather than on total production. For this test, a manufacturer may hire another firm or institution, already equipped to make such measurements,

For a typical planar disc applicator, the most straightforward and accurate method of determining the effective radiating area is to scan the hydrophone in a rectangular grid (raster scan) 5 millimetres from the applicator face. The grid should be somewhat larger than the applicator face. In the least sophisticated system, this would require point-by-point measurement of the hydrophone output over the entire grid, with a distance between points of less than a wavelength. For measurement purposes, the intensity is approximated as being proportional to the square of the voltage output of the hydrophone. Also, each point would be associated with an incremental area defined by the distances between points. At one of the measured points, the intensity would have a maximum value; all other points for which the intensity was 5% or more of this maximum would contribute to the effective radiating area, i.e., the total area would consist of the sum of all the incremental areas associated with the contributing points.

Whatever the nature of the circuitry that processes the hydrophone output, (peak detector, true RMS voltmeter, etc.), the response and decay times of this circuitry, along with the spatial variations in the ultrasonic beam being measured, will determine the maximum speed at which the hydrophone can be scanned. These factors also determine scan speed and the spacing between scan points when the scan is being made on a point-by-point basis.

In measurements performed at the Bureau, we found that the most reproducible results were obtained when the intensity maximum was located with very fine step sizes (approximately 0.2 mm). Once the maximum was found, coarser steps could be used for the entire scan. However, due to the rapid spatial variations in the near field of ultrasonic sources, the distance between lines or points in the raster scan (for a typical ultrasonic therapy applicator) should not exceed one wavelength or 1 mm, whichever is less.

It has also been found that non-linearity of the circuitry processing the hydrophone output can be an important source of error. Ideally, the non-linearity should be determined and a correction applied to the scans where required. Failure to do so, increases the uncertainty in the effective radiating error.

Measurement of temporal maximum ultrasonic power

For the purposes of the Ultrasound Therapy Devices Standard, ultrasonic power is defined specifically as the ultrasonic energy emitted per unit time, **averaged over each cycle of the ultrasonic carrier wave**. The maximum value of this quantity is the temporal maximum ultrasonic power. It is not directly measured, but it can be derived from a measurement of the temporal average ultrasonic power and hydrophone measurements of the temporal behaviour of the ultrasonic pressure waveform.

The temporal average ultrasonic power is identical to the ultrasonic power measured with either a radiation force balance or calorimeter. The uncertainties in the derivation of the temporal maximum ultrasonic power will depend on three factors:

- C The accuracy of the power measurement system.
- C The accuracy of the voltage measurement instrumentation.
- C The precision with which the controls (power, and pulsed output) can be re-set after transferring from the radiation force balance (or calorimeter) to the hydrophone measurement.

The temporal maximum ultrasonic power can be derived from the ratio of the temporal maximum effective ultrasonic intensity to the temporal average effective ultrasonic intensity (R). At the desired calibration point the device is measured in the amplitude modulated wave (pulsed) mode. The temporal average ultrasonic power, P_A is measured (typically on a radiation force balance). At the same control settings, the temporal peak voltage, and the root mean square (rms) voltage from the hydrophone is measured.

The value of R is given by:

$$R = \frac{1}{2} \left(\frac{V_P}{V_{rms}} \right)^2$$

(Note that the factor $\frac{1}{2}$ arises because the ultrasonic power is a quantity which is averaged over each cycle of the carrier wave.)

The temporal maximum ultrasonic power is given by:

$$P_M = P_A \times R$$

To obtain the hydrophone voltages for the derivation of the temporal maximum ultrasonic power, the hydrophone's active element should be positioned on the axis of the ultrasound beam and at a distance greater than: a^2 divided by the ultrasonic wavelength, where a is the geometrical radius of the transducer element.