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FORM FDA 3644 (09/20)

Guide for Preparing Product Reports for Ultrasonic Therapy Products

This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

More industry guidance and assistance can be found at the FDA homepage, see: http://www.fda.gov/Radiation-EmittingProducts/ .

Send your completed report to:

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
DOCUMENT MAIL CENTER – WO66-G609
ATTN: ELECTRONIC PRODUCT REPORTS
10903 NEW HAMPSHIRE AVENUE
SILVER SPRING, MD 20993-0002

Questions about reporting and suggestions for changes to this guide may be sent to the above address or may be discussed by calling 1-800-638-2041.

GUIDE FOR PREPARING PRODUCT REPORTS FOR ULTRASONIC THERAPY PRODUCTS

August 1996

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Devices and Radiological Health
Silver Spring, MD 20993

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Foreword

The Office of Compliance, Center for Devices and Radiological Health (CDRH) developed this guide. This guide will assist manufacturers[1] of electronic products which emit radiation in providing adequate reporting of radiation safety testing and compliance with federal performance standards. Title 21 of the Code of Federal Regulations (CFR), Parts 1002 and 1003 specify Reporting and Notification requirements[2,3].

Reports submitted on radiation safety of electronic products must follow the appropriate guide (21 CFR 1002.7). If the report does not follow an applicable guide it must contain a sufficient justification for any deviations. The submitter of the report will receive an acknowledgment letter with the accession number we assign to the report. Please reference this accession number in the future when providing additional information about this model family in either a supplement or the annual report. If a report is incomplete or inadequate CDRH may reject it and return it for completion. CDRH will not enter a rejected report into our database. Also, a rejected report will not receive an accession number.

WE DO NOT APPROVE THESE REPORTS OR THE PRODUCTS BEING REPORTED. It is the manufacturer's responsibility to certify that their products comply with all applicable standards (21 CFR 1010 - 1050), based on a testing program in accordance with good manufacturing practices. Prior to the shipment of products in interstate commerce 21 CFR 1002 requires the manufacturer to submit the report and to comply with all applicable importation requirements (21 CFR 1005). If there are deficiencies, we may disapprove the firm's quality control and testing program, determine that the product contains a radiation defect, or determine that the product fails to comply with a standard. We will notify the manufacturer if we make such a determination. CDRH may require the manufacturer to cease introduction into U.S. commerce until deficiencies are corrected, and to initiate a corrective action program (21 CFR 1003 - 1004) for products already introduced into commerce.

Please mail your reports to the address below (FDA can not process electronic submissions at this time). Provide the original report with appropriate signature(s) (no facsimiles, please). Provide extra copies only if this guide specifically requires them. Submit the report written in the English language. Translate any text that appears in a language other than English into English in a complete and accurate manner. Keep a copy of the completed reports in your records.

We are making our reporting guides and other regulatory information available on the Internet under http://www.fda.gov/Radiation-EmittingProducts/. No copyright exists for these guides. Reproduce these guides as needed. If you would like to comment on the reporting guides, web site, or future electronic submissions, you may direct the comments to the address below. If you need additional regulations for electronic products or medical devices, you should contact the Division of Small Manufacturers, International and Consumer Assistance by telephone at 1-800-638-2041 or by facsimile at 301-847-8149.

Sincerely yours,

Lillian J. Gill
Director
Office of Compliance

E-MAIL ADDRESS: dsmica@fda.hhs.gov

MAILING ADDRESS (see 21 CFR 1002.7 for further information):

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
DOCUMENT MAIL CENTER – WO66-G609
ATTN: ELECTRONIC PRODUCT REPORTS
10903 NEW HAMPSHIRE AVENUE
SILVER SPRING, MD 20993-0002

[1] **Manufacturer** (see 21 CFR § 1000.3 (n)) means any person engaged in the business of manufacturing, assembling, or importing electronic products.

[2] **Accidental Radiation Occurrences:** 21 CFR 1002.20 requires manufacturers to immediately report accidental radiation occurrences (see 21 CFR 1000.3(a) for the definition).

[3] **Notification:** Title 21 CFR Part 1003 requires manufacturers to provide Notification of Defects or Failure to Comply. Send these notifications to the above address.

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ULTRASONIC THERAPY REPORTING GUIDE

INTRODUCTION

This document is to be used by manufacturers of ultrasonic therapy devices in the preparation of product reports, as required by the Code of Federal Regulations, Title 21 (21 CFR), parts 1002.10 and 1002.11. In sections 1.0 through 3.4 of this guide, the requested information should be given in the spaces provided. These pages should then be removed from the guide and combined with the information requested in sections 3.5 through 5.4 to form the completed report. Please be sure that all information supplied as sections 3.5 through 5.4 is clearly identified. Part 1002.7(b) of 21 CFR requires that reports be filed using this guide, unless otherwise specified. Maintain a blank copy of this guide for future use, and maintain a copy of each completed report for your records.

These reports will be used by the Center for Devices and Radiological Health (CDRH) staff as an aid in determining whether the product complies with the requirements set forth in the performance standard for ultrasonic therapy products, 21 CFR 1050.10. It is hoped that open lines of communication will be maintained at all times between CDRH and all manufacturers; any questions regarding this guide or compliance programs in general should be directed to the Office of Compliance.

Part 1050.10(b)(25) of 21 CFR defines an ultrasonic therapy product to be any device intended to generate and emit ultrasonic radiation for therapeutic purposes, or any generator or applicator designed or specifically designated for use in such a device. Any generator or applicator that is sold as an individual unit is therefore subject to all the requirements of 1050.10 and must be reported in a product report. Products covered by this reporting guide include, but should not be limited to:

- ultrasonic diathermy equipment
- therapeutic massagers
- ultrasound and muscle stimulation equipment
- therapeutic vibrators

GENERAL INSTRUCTIONS

Model Families: In order to reduce the number of reports that a manufacturer must file, CDRH categorizes products that are of the same basic design into model families. For therapy ultrasound devices, a model family may consist of all units that have the same ultrasound performance specifications; i.e., frequency, maximum radiated power, pulse duration. For example, if a manufacturer makes several physical therapy products that differ in the types of modalities provided but have the same ultrasound performance specifications, those products would all belong to the same model family and would be covered by a single report.

For product lines consisting of applicators only, a model family would consist of all applicators having the same crystal configuration. For example, a line of applicators using a single crystal of the same material but of different sizes would constitute a model family and would be covered in a single report, whereas applicators using multiple crystal configurations would constitute a different model family and would require a different report.

If there are questions as to whether a particular product should be included as part of a model family, a manufacturer should consult with the Office of Compliance.

Product Reports: A product report is required for each family of ultrasonic therapy products prior to introduction into commerce by a manufacturer. When submitting a product report, all sections of this guide must be completed in detail.

Upon receipt of a product report, CDRH will assign the report a seven-digit accession number, which locates the report in the CDRH file system. All future correspondence concerning the report should reference this accession number.

Report Supplements: Once a product report has been filed for a model family, any product modifications that affect its radiation safety performance must be reported as a report supplement. When a supplement report is submitted, all items in section 1.0 of this guide must be completed. For those items in sections 2.0 through 5.0 for which the response is identical to that given in the original report, a reference to the original report is sufficient. Items that have been changed must be reported in detail.

Changes to testing programs for previously reported products must also be reported in a report supplement. In either case, the accession number of the report being supplemented must be provided in section 1.4.

Changes to testing programs for previously reported products must also be reported in a report supplement. In either case, the accession number of the report being supplemented must be provided in section 1.4.

In general, any modification to the product that results in a change in any of the performance specifications in section 2.0, or any changes in the labeling of the product, is considered to affect the radiation safety performance. Cosmetic changes, etc., need not be reported. If there are questions as to the applicability of a report supplement, a manufacturer should consult with the Office of Compliance.

Report Addressee: All reports and report supplements should be addressed to:

Center for Devices and Radiological Health
Document Mail Center – W066-G609
ATTN: Electronic Product Reports
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

1.0 Report and Model Identification

1.1 Name and address of the corporate headquarters of the manufacturer

_____

_____

Email address: _____

1.2 Address of the place of manufacture if other than above

_____

_____

Email address: _____

1.3 Name and address of the importer, if the product is imported

_____

_____

Email address: _____

1.4 Type of report and date

☐ Product report Date of submission: _____

☐ Report supplement (give CDRH accession number)

1.5 Product classification

Indicate below the type of product or family of products covered by this report. When reporting on generators or applicators only, respond to those items which are inappropriate for the product by writing "N/A".

This report covers:

☐ Generator only ☐ Applicator(s) only ☐ Complete unit

1.6 Model number and brand name of the product

Report the model number, brand name, or other designation of the product. If reporting a model family, provide the model designation of each model and clearly describe the differences between models. Clearly identify this information as section 1.6.

1.7 Name, title, address and signature of the person submitting the report:

Name: _____

Title: _____

Address: _____

Email address: _____

Signature:

2.0 Performance Specifications

The information reported in this section will be used to determine whether the product complies with the requirements set forth in 21 CFR 1050.10(c). Several items must be reported in terms of definitions that are provided by the standard; please refer to 21 CFR Part 1050.10 for these definitions.

2.1 Frequency(ies) of operation

☐ Fixed at _____ MHz

☐ Variable, from _____ MHz to _____ MHz

☐ Multiple fixed at _____ MHz, _____ MHz, _____ MHz

Operating frequency(ies) are indicated to the user by:

_____

_____

2.2 Output parameters for continuous-wave units

2.2.1 Temporal-average ultrasonic power

- variable, from _____ watts to _____ watts

- indicated to the user by _____

2.2.2 Temporal-average effective intensity

- variable, from _____ W/cm^2 to _____ W/cm^2

- indicated to the user by _____

2.3 Output parameters for amplitude-modulated units

2.3.1 Temporal-maximum ultrasonic power

- variable, from _____ watts to _____ watts

- indicated to the user by _____

2.3.2 Temporal-maximum effective intensity

- variable, from _____ W/cm^2 to _____ W/cm^2

- indicated to the user by _____

2.3.3 Output pulse width

☐ Fixed at _____ milliseconds

☐ Variable, from _____ milliseconds to _____ milliseconds

- indicated to the user by _____

2.3.4 Output pulse repetition rate

☐ Fixed at _____ pulses/second

☐ User selected from the available settings (list all available settings):

_____

☐ Variable, from _____ to _____ pulses/second

- indicated to the user by _____

2.4 Timer specifications

2.4.1 Timer accuracy for settings of:

- Less than 5 minutes: ± _____ minutes

- Between 5 and 10 minutes: ± _____ percent

- Greater than 10 minutes: ± _____ minutes

2.4.2 Maximum timer setting: _____ minutes

2.4.3 How does ultrasonic emission automatically terminate at the end of preset time?

_____

_____

2.4.4 How can ultrasonic emission be terminated prior to the end of the preset time?

_____

_____

2.4.5 How is radiation emission routinely terminated?

_____

_____

2.5 Applicators

2.5.1 Type of applicators

☐ Collimating, with an effective radiating area (ERA) of cm^2

☐ Diverging, with an effective radiating area (ERA) of cm^2

☐ Focusing, with a focal area of _____ cm^2 and a focal length of _____ cm

2.5.2 Transducer configuration

☐ Single crystal (specify material)

_____

_____

☐ Multiple element - describe each element, the manner in which connected and the resulting effect on the radiated field:

_____

_____

_____

_____

2.6 Cables

2.6.1 How is application of electrical power to the transducer indicated to the user?

_____

_____

2.6.2 How is a broken cable or open connection indicated to the user?

_____

_____

3.0 Labeling Requirements

The information reported in this section will be used to determine whether the product complies with the requirements set forth in 21 CFR Parts 801, 1010.2, 1010.3 and 1050.10(d). Most of the items below require that a copy of the label be attached; if labels are unavailable at the time of reporting, please provide a specification control drawing.

3.1 Certification

Part 1010.2 of 21 CFR requires that the product (generator and applicator, if detachable) bear a permanently affixed tag or label certifying that it complies with the provisions of Part 1050.10. Provide the following information concerning the certification label:

3.1.1 The manner in which the label is attached:

_____

_____

3.1.2 The location of the label:

_____

_____

3.1.3 Attach a sample of the label.

3.2 Identification

Part 1010.3 of 21 CFR requires that the product (generator and applicator, if detachable) bear a permanently affixed tag or label giving the following information:

(a) The name and address of the manufacturer. (Where the product is sold under a name other than that of the manufacturer, the name and address of the individual or company under whose name the product is sold may be given on the label, provided that such individual or company has previously supplied the CDRH with the name and address of the manufacturer.)

(b) The place, month, and year of manufacture. (The place of manufacture may appear in coded form if the manufacturer has previously supplied the CDRH with the codes and their meaning.) The month and year of manufacture must be given without abbreviation and with the year as a four-digit number (for example: Manufactured: SEPTEMBER 1978).

Provide the following information concerning the identification label:

3.2.1 The manner in which the label is attached:

_____

_____

3.2.2 The location of the label:

_____

_____

3.2.3 Attach a sample of the label.

3.3 Prescription

Part 801 of CFR 21 requires that the product (generator and applicator, if detachable) bear permanently affixed labels in accordance with Part 801.109(b) through 801.109(e), inclusive.

Provide the following information concerning the identification label:

3.3.1 The manner in which the label is attached:

_____

_____

3.3.2 The location of the label:

_____

_____

3.3.3 Attach a sample of the label.

3.4 Generator labels

Part 1050.10(d)(3) of 21 CFR requires that each ultrasonic therapy generator bear a label giving the following information:

(a) The brand name, model designation, and serial number of the generator.

(b) The ultrasonic frequency (unless variable, and indicated on the controls).

(c) The type of waveform (continuous wave or amplitude modulated).

In addition to the above, generators employing amplitude modulated waveforms are required to bear additional labeling giving the following information:

(a) Pulse duration and repetition rate (unless variable, and indicated on the controls).

(b) An illustration of the waveform.

(c) The ratio of the temporal-maximum effective intensity to the temporal-average effective intensity. If this ratio is a function of any operation control setting, then the range of the ratio shall be given, and the waveform illustration shall be for the maximum value of this ratio.

Provide the following information concerning the generator label:

3.4.1 The manner in which the label is attached:

_____

_____

3.4.2 The location of the label:

_____

_____

3.4.3 Attach a sample of the label.

3.5 Applicator labels

Part 1050.10(d)(4) of 21 CFR requires that each ultrasonic therapy applicator bear a label giving the following information:

(a) The brand name, model designation, and serial number of the applicator.

(b) The designation of the generator for which the applicator is intended.

(c) The ultrasonic frequency, effective radiating area, maximum beam nonuniformity ratio, type of applicator (focusing, collimating, diverging) and, for focusing applicators, the focal length and focal area.

Provide the following information concerning the applicator label:

3.5.1 The manner in which the label is attached:

_____

_____

3.5.2 Attach a sample of the label.

3.6 Operation controls

Part 1050.10(d)(1) of 21 CFR requires that each operation control be clearly labeled, identifying the function controlled and, where appropriate, the units of measure of that function. If a separate control and indicator are associated with the same function, labeling the units of measure of that function is required for the indicator but not for the control. Provide drawings, photographs, or other documents, clearly identified as section 3.6, which show clearly the location and labeling of all such controls.

3.7 Service controls

Part 1050.10(d)(2) of 21 CFR requires that each service control that is accessible without displacement or removal of any part of the product be clearly labeled, identifying the function controlled and including the phrase for service adjustment only. Provide drawings, photographs, or other documents, clearly identified as section 3.7, which show clearly the location and labeling of all such controls.

4.0 Information Requirements

4.1 Servicing information

Part 1050.10(f)(1) of 21 CFR requires a manufacturer to provide to servicing dealers and distributors adequate instructions for operation, service, and calibration of the product. This must include:

(a) A description of those controls and procedures that could be used to increase radiation emission levels.

(b) A schedule of maintenance necessary to keep the product in compliance with 21 CFR 1050.10.

(c) Any safety precautions that may be necessary regarding ultrasonic exposure.

Attach a copy of the servicing information to the preceding sections, clearly identified as section 4.1.

4.2 User information

Part 1050.10(f)(2) of 21 CFR requires a manufacturer to provide users with adequate instructions for assembly, operation, and safe use of the product. This must include:

(a) A discussion of all operation controls and a description of the effect of each control.

(b) A schedule of maintenance necessary to keep the product in compliance with 21 CFR 1050.10.

(c) Any safety precautions that may be necessary regarding ultrasound exposure.

(d) A description (including textual discussion and diagrams, plots or photographs) of the spatial distribution of the radiated field. The description must include the statement that it applies for the radiation emitted into the equivalent of an infinite medium of distilled, degassed water at 30 °C and with line voltage variations in the range of ± 10 percent, or the rated value.

(e) The uncertainties in magnitude, expressed in percentage error, of the ultrasonic frequency, effective radiating area, and (when applicable) the ratio of the temporal-maximum to temporal-average effective intensity, pulse duration, pulse repetition rate, focal area, and focal length.

(f) The error in indication of radiated power and intensity.

(g) The error in indication of preset treatment time.

(h) A listing of all controls, adjustments, and procedures for operation and maintenance, including the warning "Caution--use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous exposure to ultrasonic energy."

Attach a copy of the user information to the preceding sections, clearly identified as section 4.2.

4.3 Product description

In order to adequately review a manufacturer's product, CDRH requires that a product report provide a thorough physical description of the product. Such a description must include:

(a) Photographs or drawings or the generator and applicator.

(b) A complete schematic diagram of the product.

If this information has been provided in sections 3.6, 3.7, 4.1, or 4.2, then no further description is necessary. If not, attach the necessary document to the preceding sections, clearly identified as section 4.3.

5.0 Testing Programs

The information reported in this section will be used to determine whether the manufacturer's testing programs are adequate for certification (21 CFR 1010.2) and that the products are in compliance with the performance standard. Each item in this section must be addressed individually and in detail. The responses to all items should be attached to the preceding sections, clearly identified as section 5.0.

5.1 Incoming component testing

Fully describe all tests that are performed on components whose performance can affect compliance with this standard. This description should include, but is not limited to:

(a) Identify the component tested and its function.

(b) State whether the component is tested on a 100 percent or sampling basis. If tested on a sampling basis, provide all sampling parameters and the basis for selecting the Acceptable Quality Level.

(c) Describe the corrective action taken following unit or lot rejection (i.e., return component to manufacturer, test 100 percent of components, increase sampling level). If the sampling level is increased, provide the complete rationale for this procedure, and any revised acceptance criteria.

Provide the above information as a subsection of section 5.1 for each tested component. For example, if transducer crystals and timers are among the components tested, present the description of the testing of crystals as section 5.1.1, the description of the testing of timers as 5.1.2, and so forth.

5.2 Calibration of test instruments

Fully describe the instruments used in any test conducted to ensure compliance with this standard. This should include, but is not limited to, the following:

5.2.1 The manufacturer, model number, type (e.g., radiation force), accuracy, and resolution of the instrument used to measure ultrasonic power.

5.2.2 The procedure by which the above instrument is calibrated. Include a description of any calibrated source used, stating the accuracy and by whom calibrated.

5.2.3 The manufacturer, model number, and complete specifications of the hydrophone used to measure ultrasonic intensity.

5.2.4 A description of the scanning apparatus used to measure the spatial distribution of the radiated field.

5.2.5 A description of, and calibration procedures for, any other instrument used for compliance testing.

5.3 Production testing

Fully describe all tests that are performed on the product during or after production to ensure compliance with this standard. The description of each test must include, but is not limited to, items (a) through (e) below. Note that part 1050.10(e) of 21 CFR requires that measurements of ultrasonic radiation be made with the radiation emitted into the equivalent of an infinite medium of distilled, degassed water at 30 °C, and with line voltage variations in the range of ± 10 percent of the rated value.

(a) Identify all instruments reported in section 5.2 that are used for the test.

(b) State the sources and magnitudes of uncertainty in the test.

(c) State whether the component or parameter is tested on a 100 percent 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 sampling rather than testing on a 100 percent basis. It must be clearly demonstrated that such a sampling program will ensure compliance of all certified products.

(d) Describe the test procedure in detail, including any assumptions that are taken from the results. For example, in the description of the test for accuracy of indicated power, state the specific power levels at which the measurement is made, the error in indicated power at each point, and the range over which the average error is assumed to hold.

(e) Describe the corrective action taken following unit or lot rejection (i.e., increase sampling, test 100 percent).

Provide the above information as a subsection of 5.3 for each parameter tested. For example, present the description of the test for error in indicated power as section 5.3.1. The parameters tested during production should include, but are not limited to:

(a) Error in indication of the temporal-average ultrasonic power (CW units).

(b) Error in indication of the temporal-maximum ultrasonic power (pulsed units).

(c) Error in measured value of effective radiating area.

(d) Error in the determination of the ratio of the temporal-maximum effective intensity to the temporal-average effective intensity.

(e) Error in indication of preset treatment time.

(f) Proper operation of manual and automatic treatment termination devices.

(g) Proper operation of visual "ultrasound on" indicator.

(h) Proper operation of indicators of pulse duration, pulse repetition rate, and ultrasonic frequency (where applicable).

5.4 Life testing

Fully describe all tests that are performed on the product to ensure that it is capable of complying with the standard throughout its life. This should include, but is not limited to:

5.4.1 Sample size, frequency of sampling, and selection criteria.

5.4.2 Description of the test, including the sources and magnitudes of error, parameters measured or monitored, instruments used, and length of test or equivalent length of test.