Summary of the Ultrasonic Therapy Performance Standard Requirements

A. Performance Requirements

1. OUTPUT INDICATION: Each ultrasound therapy generator must provide an indication of the radiated ultrasonic power and intensity, and this indication (usually a meter) must be accurate within certain limits. If the generator operates in the continuous mode, the average power and intensity must be indicated; if the generator operates in the pulsed mode, the peak power and intensity must be indicated. Generators which operate in the pulsed mode may also provide an indication of the average power and intensity if the manufacturer so desires, but this is not required by the standard. An alternative to providing a meter as an indication would be to label the positions of the output control with the appropriate values.

2. TIMER: Each ultrasound therapy generator must provide a means by which the treatment time can be preset, and this mechanism must also be accurate within certain limits.

3. PULSE DURATION AND REPETITION RATE INDICATIONS: Generators which operate in the pulsed mode and have controls to vary the pulse width and/or repetition rate must provide the user with an indication of the magnitude of these quantities. This indication might be provided by a meter or by markings on the control itself.

4. FREQUENCY INDICATION: Generators for which the ultrasonic frequency is variable must provide the user with an indication of the magnitude of this quantity.

5. ENERGIZED SOUNDHEAD INDICATION: All generators must provide the user with some visual indication when electrical energy is being applied to the soundhead. If an output meter is used to satisfy the requirements outlined in 1., the meter itself satisfies this requirement. If no output meter is used, this requirement could be satisfied by an indicator light.

B. Labeling Requirements

1. CERTIFICATION AND IDENTIFICATION: All ultrasonic therapy generators and applicators must bear a label stating that the product complies with the standard and identifying the manufacturer by name and address. The month and year of manufacture must also be given. This labeling may take the form of an actual label or may consist of lettering on the front, sides or rear of the unit. The wording of the certification statement may be quite general, e.g., "complies with applicable DHHS regulations", or quite specific, e.g. "complies with 21 CFR 1050.10". When a generator and applicator are sold as a complete unit, as is usually the case, the certification and

identification labeling on the generator will apply to the applicator as well. When an applicator is sold individually, it must bear its own label; these might take the form of actual labels or might consist of documents accompanying the applicator.

2. GENERATOR LABEL: In addition to the certification and identification labels described above, each generator must bear a label identifying the generator by model number and serial number and giving certain technical information about the generator. This includes the operating frequency and type of output (continuous or pulsed); if the generator is pulsed, the label must specify the pulse width and repetition rate (unless variable), provide an illustration of the waveform, and give the ratio of the temporal-maximum intensity to the temporal-average intensity. The terms temporal-maximum and temporal-average refer to the maximum intensity during the pulse and the average intensity over the pulse period, respectively. This ratio can be used to determine the temporal-average power radiated at a given setting of the (indicated) temporal-maximum power.

3. APPLICATOR LABEL: Each ultrasound therapy applicator, whether sold individually or as a part of a generator/applicator unit, must bear a label identifying the applicator by brand name, model number, and serial number, and giving certain technical information about the applicator. This includes the operating frequency, radiating area, beam nonuniformity ratio, and type of applicator, i.e. whether focusing, collimating, or diverging. If the applicator is of the focusing type, the focal length and focal area must be specified. The beam non-uniformity ratio is the ratio of the spatial-maximum intensity to the spatial-average intensity, i.e., the ratio of the maximum intensity at any point in the radiated field to the average intensity for any setting of the intensity control. It is thus a measure of the spatial "nonuniformity" of the beam, and has a function similar to that of the temporal-peak to temporal-average ratio described above. For example, suppose that the applicator is in use with a generator whose output is set at 2.0 Watts/cm^2. If the beam nonuniformity ratio is 5:1, the user knows that at some point in the beam, the intensity is 10.0 Watts/cm^2.

Since ultrasound therapy applicators have a minimum amount of available label space, the Center allows the manufacturer to use certain specific abbreviations on this label; however, when the abbreviations are used, the manufacturer is required to provide an explanation of them as part of the user information.

C. Information Requirements

1. SERVICE INFORMATION: The manufacturer is required to supply to dealers who are qualified to service the products, adequate

instructions for the operation, service, and calibration of the product.

2. USER INFORMATION: The manufacturer is also required to supply the user of the product with adequate instructions for the safe use of the product, including a description of all controls and a schedule of maintenance necessary to keep the product in compliance with the standard. The user information must also include a description of the uncertainties in magnitude, expressed as a percentage error, of the ultrasonic frequency, effective radiating area, and pulse parameters if the generator is pulsed. Finally, the user information must include a description of the spatial distribution of energy in the radiated field, i.e., an explanation (including graphs or photographs) of how the ultrasonic intensity varies in some specified plane.

The above is a summary of the basic requirements of the standard. A few minor details have been omitted for purposes of clarity; however, all of the requirements are stated in full detail in the enclosed 21 CFR, Parts 800-1299.

DEPARTMENT OF HEALTH. EDUCATION. AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE. MARYLAND 20857

DEC 0 6 1978

To: All Manufacturers and Potential Manufacturers of Ultrasonic
         Therapy Products

Subject: Interpretation of the Performance Standard for Ultrasonic
         Therapy Products

The Bureau of Radiological Health has received several requests for
interpretation of the requirements of 21 CFR 1050.10. This document
outlines the particular requirements under scrutiny and states the
position of the Bureau on each.

1. Type and Location of Applicator Labels

    BACKGROUND: 21 CFR 1050.10(d)(4) requires that each ultrasound
    therapy applicator bear a label that provides certain identifying
    and technical information. However, the specific type of
    label and location are not specified and several manufacturers
    have asked for clarification of these issues, e.g., are tag
    labels acceptable, may the label be located at the connector
    end of the cable, etc.

    POLICY: Ultrasonic therapy applicators are manufactured in a
    wide range of sizes and configurations. It is the Bureau's
    position that any policy which attempted to dictate the exact
    nature or location of an applicator label would eventually prove
    to be too restrictive. These issues must therefore be determined
    on an individual case basis. In general, applicator labels
    should not interfere with the use of the applicator, nor
    should they be removable under normal use conditions. The
    Bureau will give due consideration to any form of applicator
    labeling that meets these general guidelines. Manufacturers
    may submit sketches, facsimiles, or samples of their proposed
    applicator label to the Director, Division of Compliance, for
    evaluation. The description should include the proposed lo-
    cation of the label and the means by which it will be attached.

2. Abbreviation of Applicator Label Information

    BACKGROUND: Some manufacturers have expressed concern about the
    amount of information required to be contained on the ultrasound
    therapy applicator label (21 CFR 1050.10(d)(4)) and have asked
    if abbreviations could be used to reduce the size of the label.

POLICY: The Bureau recognizes that it will be necessary to
abbreviate the information given on the applicator label. The
intent of the applicator labeling requirements will best be
realized if all manufacturers use the same notation for the
various parameters. Toward this end, the Bureau requests that
when abbreviations are used, manufacturers use the abbreviations
listed below to specify the required information, with a blank
space separating the abbreviation from the actual value of the
parameter. However, when the abbreviated form is used, an
explanation of each abbreviation must be provided as part of
the user information required by 21 CFR 1050.10(f)(2).

a. Generator designation: The abbreviation GEN should
be used for generator. If an applicator is intended for
use with specific generators, the model designation of
those generators must be given. If it is intended for
use with all generators made by the manufacturer, the
label may read GEN: ALL.

b. The ultrasonic frequency should be designated by a
lower case f, e.g., f: 1.0 MHz.

c. The effective radiating area should be designated by
the word AREA, e.g., AREA: 10 cm^2.

d. The beam nonuniformity ratio should be designated by
the letters BNR, e.g., BNR: 4:1

e. The type of applicator (focusing, collimating, diverging)
should be designated by the word TYPE and may be abbreviated
to FOC, COLL, or DIV, e.g., TYPE: COLL. For focusing
applicators, the focal length and focal area should be
designated by the letter FL and FA repectively, e.g.,
TYPE: FOC
FL: 5 cm
FA: 6 cm^2

3. Scanning Measurements

BACKGROUND: Several parts of the standard require measurements
that can only be made by use of a small piezoelectric probe, or
hydrophone, which can be accurately positioned at any point in
the field radiated by the transducer. For example, the applicator

labeling requirements in 21 CFR 1050.10(d)(4)(iii) require
that the maximum value of the beam nonuniformity ratio be
specified for each applicator. Other such measurements are
that of effective radiating area and the determination of
whether a given applicator is collimating, diverging, or
focusing. The Bureau expects that it will be sufficient to
make such tests on a sampling basis, rather than on total
production. Some manufacturers have asked whether the Bureau
will accept measurements made by someone other than the man-
ufacturer, e.g., whether a manufacturer may hire another firm
or institution, already equipped to make such measurements, to
perform this part of their testing program.

POLICY: The Bureau has no objection per se to measurements
made on a contractual basis. However, manufacturers must be
aware that they alone are ultimately responsible for all aspects
of their compliance testing program and for the certification of
their products. When establishing such a contract, manufacturers
must be sure that the details of the tests, including a descrip-
tion of any test apparatus, used will be available to them for
reporting purposes. They should also be aware that the contractor
is subject to the inspection authority of Section 360A of the
Radiation Control for Health and Safety Act of 1968.

4. Servicing Information

BACKGROUND: 21 CFR 1050.10(f)(1) requires an ultrasound
therapy product manufacturer to supply adequate instructions
for servicing and calibration of the product. The intent of
this requirement is to minimize the threat to public health
posed by the use of improperly serviced equipment. Several
manufacturers have argued that they are best qualified to
service their own products and have expressed a reluctance to
supply all or part of the service instructions to others.

POLICY: The Bureau agrees that in many cases it will be in
the best interest of the public health for certain critical
functions of ultrasonic therapy products to be serviced and
calibrated only by the manufacturer. In lieu of providing
specific servicing and calibration information a manufacturer
may instruct users, dealers, and distributors to return products
to the factory for all (if all are deemed critical) or specific
types of service or for calibration. When return to the
factory is recommended only for specific types of service,
adequate instruction must be provided for all other types of

service. Also, under the provisions of 21 CFR 1050.10(f)(1),
servicing information must be provided when specifically
requested.

5.   Labeling of Meter Scales

BACKGROUND: 21 CFR 1050.10(c)(1) requires that units operating
in the continuous-wave mode provide an indication of the
temporal-average ultrasonic power and intensity, and that
units operating in the amplitude-modulated (pulsed) mode provide
an indication of the temporal-maximum power and intensity.
The Bureau has been asked whether pulsed units may instead
provide an indication of temporal-average power and the conversion
factor necessary to obtain the temporal-maximum power.

POLICY: One of the primary purposes of the performance standard
is to ensure that users of amplitude-modulated ultrasound therapy
equipment have a direct indication of the radiated temporal-
maximum intensity. The need for this is established by various
studies of non-thermal biological effects. Consequently, the
proposal to provide an indication of temporal-average intensity
along with a conversion factor for calculating the temporal-
maximum intensity is not acceptable. A manufacturer may, at his
option, provide the user with the conversion factor necessary
to calculate the temporal-average from the indicated temporal-
maximum intensity, or he may provide an additional scale to
directly indicate the temporal-average intensity. However, a
direct indication of the radiated temporal-maximum intensity
must be provided.

6.   Visual Indicator Requirements

BACKGROUND: 21 CFR 1050.10(c)(5) requires that an ultra-
sound therapy generator provide a clear visual indication of the
application of electrical power, at the appropriate ultrasonic
frequency, to the soundhead. Interpreted literally, this could
require that the visual indicator respond only to electrical
energy at the desired ultrasonic frequency, i.e., such a device
would have to include a frequency discriminating circuit. Several
manufacturers have asked if this is in fact necessary and appropriaı

POLICY: The intent of the standard is to ensure that the user
of an ultrasound therapy device will have some easily understood
indication of an energized soundhead. For generators which
have an output meter, the meter itself satisfies the intent of
this requirement. While it is true that a typical meter
circuit would respond even if the generator were operating at

the wrong frequency, the resulting radiated field would be lower
in intensity than the field radiated by the transducer at its
resonant frequency. Therefore the visual indicator, whether a
meter or some other device, need not be frequency selective in
order to comply with 21 CFR 1050.10(c)(5).

7. Interrupted Continuous-Wave Operation

BACKGROUND: Several manufacturers currently make ultrasound
therapy generators which can be operated in either a
"continuous" or "interrupted" mode. When the continuous mode
is selected, the ultrasound is on for the duration of the
preset time; when the interrupted mode is selected, the appli-
cation of electrical power to the soundhead is electronically
or electromechanically switched on and off for short (e.g., two
seconds) intervals. On at least one such device, the ultrasonic
field radiated by the soundhead, when it is energized, is classified
as amplitude-modulated by the provisions of 21 CFR 1050.10(b)(1);
the question thus arises of whether the on/off switching
should be considered an additional form of amplitude modulation,
since this bears directly on the indication provided by the
output meter.

POLICY: The interrupted mode of operation will be considered to be
a form of amplitude modulation only when the duration of the "on"
period is less than one second. The meter on a generator operating
in this way would therefore be required to indicate the temporal-
maximum radiated power and intensity even during the "off" period.
If the duration of the "on" time is one second or greater and (a)
the radiated field is amplitude-modulated according to the
definition in 21 CFR 1050.10(b)(1), then the meter must indicate
the temporal-maximum intensity and power during the "on"
interval; if (b) the radiated field meets the definition of
continuous-wave (21 CFR 1050.10 (b)(7)), then the meter must
indicate the temporal-average intensity and power. In either
case, if the "on" time is one second or greater, the meter should
return to zero during the "off" intervals. Meter response
time should be adequate to provide a true reading of the ap-
propriate output intensity.

8. Display of Pulse Duration and Repetition Rate

BACKGROUND: 21 CFR 1050.10(c)(3) requires that an
amplitude-modulated ultrasonic therapy generator incorporate
a means of indicating the magnitudes of the pulse duration and
the pulse repetition rate, if these quantities are variable.

One manufacturer has asked if it will be acceptable to display the period of the amplitude-modulated waveform, rather than the repetition rate, and include on the front panel a legend indicating that the repetition rate is equal to the reciprocal of the period.
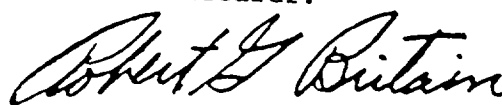
POLICY: The Bureau finds this to be an acceptable means of indicating the pulse repetition rate, since the relationship between period and repetition rate is well known. Furthermore, displaying the repetition rate in this manner does not deprive the user of any information necessary for the safe use of the product, since in any case an indication of the temporal-maximum power and intensity must be provided.

9. Certification of Applicators

BACKGROUND: All electronic products that are subject to a radiation safety performance standard are required to bear labels (a) certifying that the product complies with the applicable standard, (21 CFR 1010.2) and (b) identifying the manufacturer and the date and place of manufacture (21 CFR 1010.3). One manufacturer has asked whether certification and identification labels will be required on applicators that are manufactured specifically to be sold as replacement units.

POLICY: 21 CFR 1050.10(b)(25)(ii) specifically defines an applicator as an ultrasonic therapy product. Any applicator manufactured on or after February 17, 1979, whether sold individually or with a generator, must therefore comply with the requirements of 1050.10 and must be certified to be in compliance with the standard. When an applicator is sold as part of a generator/applicator combination, it will be sufficient for the certification and identification labels to appear on the generator; when an applicator is sold individually, it will be required to bear its own certification and identification labels.

Manufacturers should note that in the case of products for which it is not feasible to affix certification or identification labels, 21 CFR 1010.2 and 1010.3 allow for alternate means of labeling. Approval of such alternate means may be granted by the Director, Bureau of Radiological Health, upon written application by a manufacturer.

Robert G. Britain

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20857

JUN 2 7 1980

To: All Manufacturers and Potential Manufacturers of Ultrasonic
       Therapy Products

Subject: Accuracy requirements for Indication of Temporal-Maximum
            Ultrasonic Power and Intensity, 21 CFR 1050.10 (c)(1)(ii).

BACKGROUND: The subject paragraph of the Ultrasonic Therapy Performance
Standard requires that units having an amplitude-modulated (pulsed)
output waveform provide an indication of the temporal-maximum ultrasonic
power and intensity. The requirement also states that the sum of the
errors in the indications of temporal-maximum ultrasonic power and
ratio of the temporal-maximum to temporal-average intensities may not
exceed $\pm$ 20 percent for all emissions greater than 10 percent of the
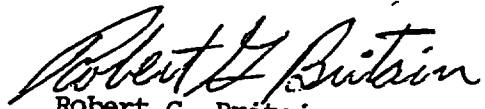maximum emission.

This accuracy requirement was specified in this way, i.e., as a sum of
errors, in order to relate the error in the indication to the uncertainty
in measurement of the temporal-average power. In the current state-of-
the-art, the measurement of temporal-average power can be made with
greater accuracy (e.g., by radiation force techniques) than the measure-
ment of temporal-maximum power, which currently must rely on hydrophone
measurements. Furthermore, many ultrasonic therapy devices are capable
of operating in either the pulsed or continuous mode; since the production
testing of such devices would include measurement of the temporal-
average power (to calibrate the continuous mode), it is logical to relate
the calibration of the pulsed mode to the same measurement.

The actual wording of this section of the standard has caused some
confusion among users and manufacturers. The Bureau intends to formally
amend the standard so that the requirement will be stated more clearly.
The amendment process requires a certain amount of time; for the interim
period, the Bureau policy regarding the calibration of the pulsed mode
will be as specified below.

POLICY: The Bureau's intent regarding the calibration of the pulsed
mode can be stated as follows: The temporal-maximum power and intensity
must be indicated, and the ratio of temporal-peak to temporal-average
intensities must be specified. For a given setting of the output control,
the indicated temporal-maximum power divided by the ratio of intensities
will yield a value for temporal-average power. This calculated value

must agree with the measured value of the temporal-average power, for the same setting of the output control, to within $\pm$ 20 percent. This policy will guide the Bureau's compliance testing, and should guide manufacturers in production testing. Manufacturers and interested parties will be notified when the proposed amendment is published for comment and when the formal amendment process has been completed.

Robert G. Britain
Director
Division of Compliance
Bureau of Radiological Health

HYDROPHONE MEASUREMENTS OF EFFECTIVE
RADIATING AREA AND BEAM NONUNIFORMITY
RATIO OF ULTRASOUND THERAPY APPLICATORS

I. <u>Effective Radiating Area</u>: The Ultrasound Therapy Performance Standard defines the effective radiating surface to be the surface consisting of all points 5 millimeters from the applicator face. The effective radiating area is then defined as the sum of all points of the effective radiating surface at which the intensity is 5 percent or more of the maximum intensity at the effective radiating surface. For a typical plane-wave type applicator, the most straightforward and accurate method of determining this is to scan the hydrophone in a rectangular grid slightly 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. The intensity at each point would then be associated with the 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 percent 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 those points.

This procedure can be made simpler by the use of an x-y or strip chart recorder connected so that the output of the hydrophone is plotted as a function of distance across the beam. The hydrophone is then driven (by hand or by motor) from one side of the beam to the opposite side, starting and ending at positions where the intensity is negligible. After each scan made in this way, the hydrophone is "stepped" an incremental distance in a direction normal to the direction of the scan. Thus, the next scan will parallel the preceeding ones. The first scan should be made along a line slightly outside the beam, and the series of parallel scans continued until the hydrophone is totally outside the beam on the opposite side. On one of the scans thus produced, the hydrophone output will have a maximum value; on that scan and on all others, the portion of the scan that contributes to the effective radiating area is that portion for which the intensity is 5 percent or more of this maximum. The length of that portion, multiplied by the distance between scans, yields an incremental strip (or strips) of area; the effective radiating area is the sum of these incremental areas for all scans. Several points which should be emphasized are as follows:

1. The voltage output of the hydrophone is related to the acoustic pressure, not intensity. Since the intensity is proportional to the square of the pressure, a graph of intensity vs. hydrophone position can be obtained only if the hydrophone output is squared before being fed to the y-axis of the recorder. One would then take the contributing portion of each scan to be that portion for which

the hydrophone output is 5 percent of the maximum. If the hydrophone output is fed directly to the recorder without being squared, the resulting plot will be of acoustic pressure vs. position. Since the pressure is related to the square root of the intensity, and the square root of .05 is .224, the contributing portion of each scan will be that portion for which the hydrophone output is 22.4 percent of the maximum.

2. Whatever the nature of the circuitry that processes the hydrophone output, (peak detector, true RMS voltmeter, etc.), it must produce a d.c. voltage proportional to the amplitude of the ultrasonic wave in order to accurately drive a chart recorder. Also, it should be kept in mind that 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.

3. Due to the nature of near-field behavior, the distance between scans (for a typical ultrasonic therapy applicator) should not exceed .050 inches. Of course, when actually calculating the area, all distances must be converted to centimeters.

II. <u>Beam Nonuniformity Ratio</u>: As mentioned previously, the ultrasonic intensity is related to the square of the hydrophone output voltage, i.e.,

$$I = kV^2 \qquad (1)$$

Measurement of the beam nonuniformity ratio is simplified a great deal by knowing the hydrophone calibration factor k; therefore, we first describe a technique for determining this parameter.

As noted previously, the intensity at an arbitrary point in the ultrasonic field can be associated with an incremental area. The magnitude of this area is simply the product of the distance between adjacent points on the scan and the distance between scans. Since, in general, ultrasonic power is the product of intensity and area, each measured intensity and its associated area may be thought of as an incremental "element" of ultrasonic power. The total power is then equal to the sum of all these individual contributors, i.e.,

$$P = \sum_{i=1}^{N} I_i \cdot A_i \qquad (2)$$

If the distances between points are the same for all measured intensities, the area will be the same for each measured intensity, or

$$P = A \sum_{i=1}^{N} I_i \qquad (3)$$

Recalling equation (1), this becomes

$$P = A \sum_{i=1}^{N} kV_i^2 = kA \sum_{i=1}^{N} V_i^2 \qquad (4)$$

Solving for k, we obtain

$$k = P/A \sum_{i=1}^{N} V_i^2 \qquad (5)$$

Here N denotes the total number of voltage measurements made with the hydrophone. Thus, the procedure for determining k is as follows:

1. Set the ultrasonic power output to some accurately known value (P).

2. With the hydrophone positioned at a sufficient distance from the applicator to be in the far field, measure the hydrophone output voltage at each point in a grid sufficiently large to include the entire ultrasonic beam. For typical ultrasonic therapy applicators, it is sufficient to have a distance between points and between scans of .100 inches when measuring in the far field.

3. Sum the squares of the voltages thus obtained and multiply the result by the incremental area A in cm^2.

4. Divide the ultrasonic power P by the result obtained in step 3. This yields the hydrophone calibration constant k in watts/cm^2/$volt^2$.

Having determined k, we may now proceed to measure the beam nonuniformity ratio (BNR). By definition, this is the ratio of the spatial-maximum to spatial-average intensities, i.e.,

$$BNR = I_{SP}/I_{SA} \qquad (6)$$

The spatial-average intensity is just the ultrasonic power P divided by the effective radiating area (ERA), as determined by the procedures described above. The spatial-maximum intensity is related to the maximum voltage measured by the hydrophone in the usual way, i.e.,

$$I_{SP} = kV_{SP}^2 \qquad (7)$$

Thus equation (6) becomes

$$BNR = I_{SP}/I_{SA} = kV_{SP}^2 /(P/ERA)$$

$$= kV_{SP}^2 \cdot ERA/P \qquad (8)$$

Thus the procedure for determining the beam nonuniformity ratio, once the calibration constant k is known, is to locate the point where the hydrophone voltage is a maximum, square this voltage, and calculate the ratio using equation (8).

For typical ultrasonic therapy applicators, i.e., single-crystal, plane, circular piston radiators, the spatial-maximum intensity may be expected to occur on or near the axis of the beam. A detailed description of the behavior of the axial intensity for such a source may be found in Handbook of Physical Medicine and Rehabilitation, F.H. Krusen, ed., p. 271 ff, W.B. Saunders Co., 1965. In general, the intensity along the axis will fluctuate through several maxima and minima as the hydrophone is scanned away from the applicator face. Since it is expected that the point of maximum intensity will lie very close to one of these relative maxima, the hydrophone output should be observed throughout a small area surrounding each of these relative maxima. The maximum voltage thus observed can be taken as the spatial maximum voltage specified in equations (7) and (8).

The above procedures for measuring the effective radiating area and beam nonuniformity ratio and for calibrating the hydrophone are basically the procedures that will be used by BRH for compliance testing. Note that scanning a plane in the far field is required only when calibrating the hydrophone, and is not required each time an applicator is measured for beam nonuniformity ratio. It is conceivable that the hydrophone calibration could change over extended periods, and the calibration should therefore be checked periodically. If and when changes to these procedures are developed by BRH, the changes will be communicated to the industry.

JUN 3 1981

.TO: ALL ULTRASOUND THERAPY MANUFACTURERS

SUBJECT: ERA and BNR Testing

Many manufacturers of ultrasound therapy devices are currently performing final testing on a preset percentage of production units that includes measurements of the effective radiating area (ERA) and beam nonuniformity (BNR). This practice has been endorsed by the Bureau as a necessary part of the required quality control and testing program for radiation safety, and is in keeping with the good manufacturing practices regulation for medical device manufacturers.

The Bureau has reevaluated the need for ERA and BNR measurements on production units of established models. A review of these test results during compliance inspections has revealed an industry-wide history of stable manufacturing procedures and consistent test results. It appears that continued production testing of single crystal, flat faced applicator ultrasound therapy devices is not necessary, as long as the testing program includes measurements of ERA and BNR on preproduction units and on a statistically valid sample of early production (2-3 months) units. However, the ERA and BNR measurements need to continue being made as part of an adequate testing program on production units with other types of applicators. The selection of units for these measurements should be based on 100% testing or on a statistically valid sampling plan.

The Bureau requests that a measurement of BNR and ERA be conducted periodically (i.e. quarterly) on a production unit of each applicator model no longer subject to routine tests of these parameters. This will continue to provide assurance of acceptable products and manufacturing control. A review of this measurement program should be included in in your audit procedures to verify compliance with the GMP quality assurance program.

Any changes made in a manufacturer's quality control and testing program should be submitted as a report supplement. Any questions regarding this notice should be directed to the Microwave/Acoustic Products Section at (301) 443-6540.

Walter E. Gundaker
Acting Director
Division of Compliance
Bureau of Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 2 5 1988

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

TO: ALL MANUFACTURERS AND IMPORTERS OF ULTRASONIC THERAPY EQUIPMENT

SUBJECT: CORRECT CALCULATION OF THE R_{tpa} FOR PULSED OR AMPLITUDE-MODULATED WAVEFORM PRODUCING ULTRASONIC THERAPY EQUIPMENT

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (Center) is aware that confusion exists within the ultrasonic therapy industry concerning the computation of the ratio of temporal-maximum to temporal-average effective intensity (R_{tpa}). The Federal performance standard for ultrasonic therapy equipment requires that the R_{tpa} be computed and clearly labeled on all equipment which produces pulsed or amplitude-modulated waveforms (21 CFR 1050.10 (c)(1)(ii)). This ratio is needed to calculate the temporal average intensity and power from the peak values indicated for the product. The average intensity and power calculated must be accurate to within +/- 20 percent. Failure to provide the R_{tpa}, or providing an incorrect R_{tpa}, on the equipment label constitutes a noncompliance with the standard.

The Center is concerned by the magnitude and extent of the confusion and is initiating a program to inform manufacturers of the correct measurement and calculation procedures for computing the R_{tpa}. The first step in this program is to determine which practices are currently in use and where the most common errors are occurring. Once this information is gathered, appropriate literature and assistance will be provided by the Center to enable manufacturers to remedy any difficulties they might have. This will be followed by further investigation and assistance, if necessary, to ensure that the industry is in proper compliance with this aspect of the standard.

The Center is therefore now requesting that you submit detailed information explaining the method used by your company to derive the R_{tpa} for your products. This information should be submitted as a supplement to Part 5.3(d) of the initial report for each model family currently in production, and should be included in the initial reports for any new products which you manufacture in the future. The supplement for each model family should:

(a) Identify all instruments and the quantities they are used to measure. Include instrument settings used, placement of the hydrophone, and any other information relevant to the functioning of the equipment and the outcome of the measurement.

(b) Describe the measurement and calculation procedures in detail. Include the explicit formula and measured quantities used for calculation.

(c) Explain any assumptions that are made in taking measurements or making calculations. Specifically, this applies to the treatment of RC

"spikes" and any other electronic artifacts that occur in the waveform.
(d) Identify all sources and magnitudes of inaccuracy in the measurements and perpetuated in the calculation of the Rtpa.
(e) State whether the Rtpa is determined on a 100 percent or a sampling basis. If the Rtpa is determined on a sampling basis, state the lot size, proportion of total production tested, the 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 program ensures compliance of all certified products.

An explanation of the Rtpa determination procedure used by the Winchester Engineering and Analytical Center (WEAC) is enclosed. Please direct any questions concerning our requests or your responsibilities to:

Mr. George Kraus
Microwave/Acoustic Products Section
Office of Compliance (HFZ-312)
Center for Devices and Radiological Health
8757 Georgia Avenue
Silver Spring, MD 20910
(301) 427-7187

We hope that the information you provide will enable us to assist you in bringing your procedures up to standard and eliminating future confusion.
Thank you for your cooperation.

Sincerely,

Joanne Barron, Chief
Microwave/Acoustic Products Section
Division of Radiological Products
Office of Compliance
Center for Devices and
    Radiological Health

II. PERFORMANCE TESTS

A. WAVEFORM (CONTINUOUS OR AMPLITUDE-MODULATED)

Determine the type of waveform the therapy unit produces by performing the following steps:

1. Position the therapy transducer in the scan tank (See Appendix C)
2. Position the hydrophone to obtain a viewable signal on the oscilloscope. Move the hydrophone to a point on the beam axis in the far field of the beam. (For a typical 10 cm^2 applicator, the transition from near field to far field theoretically occurs at about 22 cm--about 8.5 inches--from the applicator face.) Adjust the signal gain in order to obtain an undistorted waveform with a peak to peak excursion of about five divisions on the oscilloscope.
3. If the observed waveform is a pulsed wave then identify the waveform as such and skip steps 4 through 6.
4. At this point in the ultrasonic field measure the peak voltage (Vp) of the observed waveform.
5. At this same point measure the RMS voltage (Vrms) of the observed waveform.
6. Calculate the following relationship:

$$Vr = \frac{Vp}{Vrms} \times \frac{\sqrt{2}}{2}$$

Where Vp and Vrms are the peak and RMS values of the hydrophone output voltages, respectively.

This assumes the waveform is sinusoidal in nature, if it is not, consult Supervisor.

If Vr $\leq$ 1.05 then the wave form is defined as being continuous.

If Vr > 1.05 then it is defined as being amplitude-modulated.

B. TEMPORAL PEAK TO AVERAGE RATIO (Rtpa)

This portion of the testing only applies to non-continuous waves (ie. pulsed or amplitude-modulated waveforms). Determine the

temporal peak to average ratio (Rtpa) by performing
the following steps:

1. Perform steps II. A. 1 and 2 above.
2. The temporal peak to average ratio is defined as:

$$Rtpa = \frac{1}{2}\left[\frac{PEAK\ INTENSITY}{RMS\ INTENSITY}\right]$$

The hydrophone output voltage is directly proportional
to the acoustic pressure. The acoustic pressure is
directly proportional to the square root of the
intensity. Therefore the temporal peak to average
ratio can be calculated by the following relationship:

$$Rtpa = \frac{1}{2}\left[\frac{Vp}{Vrms}\right]^2$$

Where Vp and Vrms are the peak
and RMS values of the
hydrophone output voltages,
respectively.

C. PULSE DURATION, PULSE REPETITION RATE, AND DUTY FACTOR

This portion of the testing only applies to pulsed
waveforms. Determine the pulse parameters by
performing the following steps:

1. Perform steps II. A. 1 and 2 above.
2. On the oscilloscope, measure the pulse
   duration. The pulse duration is equal to the
   time between the points on the leading and
   trailing edges of the pulse where the pulse
   amplitude equals 10% of the peak pulse
   amplitude.
3. On the oscilloscope, measure the pulse
   repetition rate. The pulse. repetition rate
   is equal to the reciprocal of the time
   between similar points between two adjacent
   pulses, eg: leading edge of pulse where pulse
   amplitude reaches 10% of peak pulse
   amplitude.
4. The duty cycle can be determined by
   calculating the following relationship:

   DUTY CYCLE = PULSE DURATION X PULSE
                      REPETITION RATE

DATE: _____

WAVEFORM

V_p = _____ volts

V_{rms} = _____ volts

$V_r = \dfrac{V_p}{V_{rms}} \times \dfrac{\sqrt{2}}{2}$ = _____ (use only for a sine wave type signal)

Type of Waveform _____

TEMPORAL PEAK TO AVERAGE RATIO (R_{tpa})

Do not fill in for continuous wave type waveform

$R_{tpa} = 1/2 \left[\dfrac{V_p}{V_{rms}}\right]^2$ = _____

FREQUENCY

Frequency = _____ MHz

APPENDIX C

TEST PROCEDURES FOR SCANNING OF ULTRASONIC THERAPY DEVICES

I. GENERAL INSTRUCTIONS

    A. A test tank of sufficient dimensions is needed to allow scanning of the full cross section of the ultrasonic beam from the therapy transducer anywhere from 5mm to about 40cm from the face of the transducer. The tank should have adequate absorbers to prevent standing wave interference. It should be filled with distilled water to a sufficient depth to allow immersion of the therapy transducer to a depth that will minimize the effects of reflections from the water/air interface. Distilled water, rather than degassed water, can be used because the dissolved O_2 level will have negligible effects at the ultrasonic power levels being used for measurement in the scan tank.

    B. An appropriate hydrophone is necessary for receiving the ultrasonic signal for processing. The frequency response of the hydrophone must encompass the frequency output of the therapy transducer. The output voltage of the hydrophone must be directly proportional to the acoustic pressure of the received signal. The diameter of the hydrophone crystal must be less than one wavelength of the received signal. (Wavelength for 1MH ultrasonic signal in water at $25\,^{\circ}C \approx 1.48mm \approx .058in$)

II. SCANNING TECHNIQUES

    A. For typical ultrasonic therapy applicators, ie., single-crystal, plane circular piston radiators, the spatial-maximum intensity may be expected to occur on or near the axis of the beam. In general, the intensity along the axis will fluctuate through several maxima and minima as the hydrophone is scanned away from the applicator face. Since it is expected that the point of maximum intensity will lie very close to one of these relative maxima, the hydrophone output should be observed in a small area surrounding each of these relative maxima.

    B. All scans should be done in a beam cross section which is perpendicular to the beam axis. To insure that a perpendicular cross section will be scanned, perform the following steps:

        1. Position the therapy transducer underwater (see Part I.A. of this Appendix) so its face is perpendicular

to the long axis of the scan tank.

2. Position the scanning hydrophone so it is pointing approximately at the center of the face of the transducer, parallel with the ultrasonic beam axis, and about 22cm (about 8.5 inches) away from the transducer.

3. In the vicinity of the beam axis, find the local maximum in this cross section by moving the hydrophone in this cross section.

4. Once the local maximum is found, move the hydrophone away from the transducer along the beam axis until it is about 35cm (about 14 inches) away from the transducer.

5. Scan the area of the new cross section in the vicinity of the beam axis trying to find a value higher than the point in this beam cross section which was on the scanned axis.

6. If the point of maximum intensity is not on the scanned axis then adjust the position of the therapy transducer and repeat steps 2 through 6. If the point of maximum intensity in this new cross section is on the scanned axis, then the cross sectional scans will be perpendicular to the beam axis.

NOTE: The distances at which the alignment is performed are not critical; however, it is important that all alignment takes place in the far field. For a typical 10 cm^2 applicator, the transition from near field to far field occurs (theoretically) at about eight inches away from the applicator face.

It may be advisable to move the hydrophone to another cross sectional area and repeat steps 5 and 6 to assure that you are on the beam axis.

C. All cross sectional scans should encompass the entire ultrasonic beam. Once it is assured, by step B. that the cross section to be scanned is perpendicular to the beam axis, move the hydrophone to the cross section to be scanned. Move the hydrophone in a direction perpendicular to the beam axis until the amplified hydrophone output reaches approximately zero. This distance should be less than one half the dimension of the square scan size.

D. Whatever the nature of the ciruitry that processes the hydrophone output, ie., peak detector, true RMS voltmeter, etc., it must produce a DC voltage proportional to the amplitude of the ultrasonic wave in order to provide a wave suitable for accurate representation of the beam cross section. Also, it should be kept in mind that 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.

E. All scans should be performed using CW power, otherwise the spatial characteristics of the ultrasonic beam (such as the ERA, the BNR, and applicator type) may not be properly represented by the test data. Follow the procedure outlined below for all units.

1. Measure the frequency of the waveform. (See Part II. D. of the Test Procedures).

2. Disconnect the therapy transducer from the generator, if possible, and drive it with a CW wave of the same frequency. While this is not the waveform generated by the generator, it will allow better characterization of the spatial characteristics of the ultrasonic beam.