OUTPUT LEVELS FROM

MEDICAL DIAGNOSTIC ULTRASOUND DEVICES

SOLD IN CANADA

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ABSTRACT

Health and Welfare Canada, the World Health
Organization and the National Council on Radiation
Protection and Measurements and other health
organizations have recommended that information on
acoustic output levels from diagnostic ultrasound
devices be made available to the user to minimize
unnecessary exposure to ultrasound. To help achieve
this, a survey of output levels from all diagnostic
ultrasound devices sold in Canada was conducted in the
spring of 1985. Statistical results of this survey are
presented here. The results showed a wide spread in
output levels for devices with the same claimed purpose.
Comparison of the output level data to biological
effects data indicated that, for many devices, a small
but significant risk, due to unnecessary ultrasound
exposure, cannot be ruled out.

RÉSUMÉ

Santé et Bien-être social Canada, l'Organisation
modiale de la Santé, le National Council on Radiation
Protection and Measurements ainsi que d'autres
organisations sanitaires ont recommandé que des
renseignements sur les niveaux d'intensité sonore
provenant des instruments de diagnostic par ultrasons
soient mis à la disposition de l'usager afin de
minimiser l'exposition inutile aux ultrasons. À cette
fin, une étude de tous les instruments de diagnostic par
ultrasons vendus au Canada a été effectuée au cours du
printemps de 1985. Le rapport présente les résultats
statistiques de cette étude, lesquels font état d'un
important écart entre les niveaux sonores d'instruments
ayant le même but. Selon une comparaison établie entre
les données sur le débit sonore et celles sur les effets
biologiques, on ne peut écarter la possibilité d'un
risque minime mais néanmoins significatif d'une
exposition aux ultrasons.

I. INTRODUCTION

Over the past decade there has been a considerable national (and international) effort dedicated to the safety of diagnostic ultrasound, particularly for obstetrical applications. There are several reasons for this. First, it has been estimated that 80% of all newborn Canadians are now exposed to ultrasound at least once prior to birth (1). In addition, the developing human fetus is generally considered more sensitive to damage than the adult human. Furthermore, biological effects of ultrasound both in vivo and in vitro have been observed, though usually at output levels higher than those produced by diagnostic equipment (2).

A number of guidelines for the safe use of diagnostic ultrasound have been established over the past decade (2-6). Common to all of them is the recommendation that information on output levels from diagnostic ultrasound devices be made conveniently available to the user. In this way unnecessary acoustical exposure can be minimized through the informed purchase and use of these devices. Furthermore, output level information is needed for updating assessments of safety and for traceability of patients in the event that a health hazard be discovered for high output levels. However, at present only seven manufacturers of obstetrical devices sold in Canada receive AIUM commendations (7) for making this data public.

In order to get a more complete set of output levels, a survey was conducted in 1985 by the Bureau of Radiation and Medical Devices to obtain information on output levels from all known manufacturers of diagnostic ultrasound devices sold in Canada. The results of this survey are presented here.

A detailed statistical analysis was performed on 120 devices (excluding fetal heart monitors and detectors) with the claimed purpose of use in obstetrics.

The results of this analysis were consistent with other published surveys (2,4,6,8,9). There continues to be a wide spread of output levels for devices with the same claimed purpose, which suggests that unnecessary ultrasound exposure could occur during clinical examinations. Furthermore, comparison of the output levels to biological effects data indicates that for some devices, a small but significant risk, due to unnecessary ultrasound exposure, cannot be ruled out.

II. METHOD

A questionnaire was sent to all manufacturers believed to be selling diagnostic ultrasound equipment in Canada. A total of 48 companies received the questionnaire. All data presented here were received between November 1984 and September 1985. Since the information was not required by law, further contact with the companies was needed to maximize response. The questionnaire was designed to provide information on the type of scan, the transducer assembly, the scan method, the intended use and the absolute maximum output levels from each transducer assembly in each scan mode (as indicated by the AIUM/NEMA Safety Standard (4) and Canadian Guidelines (Safety Code 23) (3)). Similar information is requested for new devices, by law, by the U.S. Food and Drug Administration in their 510(k) reporting guide (10).

III. RESULTS

1.0 General Information

There were 25 replies. Eighteen of the respondents were selling devices in Canada. All but one gave the information requested. It is known that at least three other companies, which did not reply, sold (and still sell) devices in Canada. It was found that there were at least 150 devices on the market for three major applications of ultrasound: obstetrics, abdominal and cardiography.

The most common devices sold were those which provided real time imaging. Very few manual scanning systems are now being sold. Most of the imaging devices also had an M-mode option which provides a picture of motion at a single location. In addition some pulsed Doppler devices were being sold for the purpose of measuring fetal blood flow.

The majority of transducers were found to be mechanical auto-scanning devices with an M-mode option. This was mainly due to a preponderance of such devices sold by one manufacturer. Amongst the other manufacturers there was approximately an even split between linear arrays (electronic scanning) and mechanical scanners.

For obstetrical use, most transducers operate nominally at 3.5 and 5 MHz with a much smaller number at 2.25 and 7.5 MHz. Generally, as the frequency increases, the depth of penetration decreases but resolution increases. This probably accounts for the wide use of 3.5 and 5 MHz as a compromise between these two desired properties.

2.0 Output Levels

For devices with the claimed purpose of use in obstetrics, statistical analysis was done for two reported output levels (i) I(SPTA), the spatial peak, time average intensity and (ii) I(SPPA), the spatial peak pulse average intensity. These quantites are the largest values of time average and pulse average intensity found in the free field ultrasound beam measured in room temperature water. The instantaneous intensity, I(t), is approximated as

$$I(t) \ = \ p^2(t)/\rho c \qquad\qquad\qquad (1)$$

where p(t) is the acoustic pressure (measured with a calibrated hydrophone), ρ is the density of room temperature water and c is the speed of sound in room temperature water. The quantities I(SPTA) and I(SPPA) are then determined by integrating I(t) over the entire pulse. The integrated quantity, called the pulse intensity integral, is then divided by the pulse repetition period (time between pulses) to obtain I(SPTA). The pulse intensity integral is divided by the pulse duration (length of the pulse) to yield I(SPPA). Precise definitions of pulse duration, I(SPTA) and I(SPPA) can be found in the AIUM/NEMA safety standard (4). All the devices analyzed, operated in the pulsed mode with pulse durations on the order of a microsecond and pulse repetition periods on the order of a millisecond.

The output level data was broken down into four groups: (i) I(SPTA) for auto-scanning (real time imaging) transducer assemblies where the ultrasound beam is constantly moving, (ii) I(SPTA) for static transducer assemblies (manual scanning or M-mode) where the beam is stationary, (iii) I(SPPA) which includes auto-scanning, manual scanning and M-mode and (iv) I(SPTA) for pulsed Doppler mode. Detailed histograms are shown for the first three groups.

There were insufficient numbers for a histogram of pulsed Doppler devices with claimed obstetrical use. However, it still appeared that there was a wide spread in the output levels. These devices were found to have a mean I(SPTA) value of 463 mW/cm^2 with a standard deviation of 226 mW/cm^2. The largest value reported was 874 mW/cm^2.

The histogram of Figure 1 indicates a wide spread in I(SPTA) for auto scanning devices but a very low mean of only 19 mW/cm^2. By far the majority of devices are below 20 mW/cm^2. The wide spread of output levels shown in Figure 1A is due to the inclusion of mixed M-mode and real time imaging scanners. With the mixed mode scanners, the ultrasound beam spends more time at one position than with the purely real time imaging mode. This leads to larger I(SPTA) values. Figure 1B indicates that there is a wide spread in output levels even at the low I(SPTA) values found with the purely real time imaging devices.

The histogram for static devices is shown in Figure 2. The mean I(SPTA) value is 74 mW/cm^2. As expected, this is substantially larger than for auto-scanning devices because the ultrasound beam remains at a fixed position. About 20% of the devices have values above 100 mW/cm^2 as shown in Figure 2. Again there is a very wide spread in I(SPTA). The wide spread in I(SPTA) could be due to a wide spread in the ratio of pulse duration to pulse repetition period as well as in I(SPPA) for the various transducer assemblies.
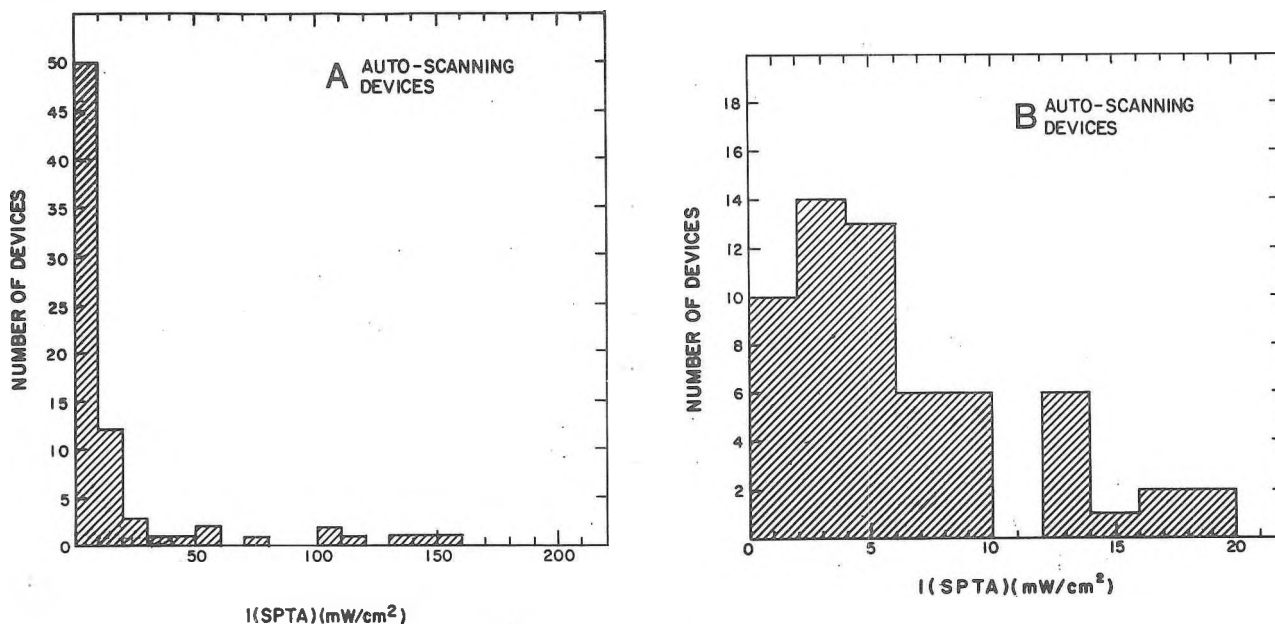

Figure 1.

Histogram of number of auto-scanning devices as a function of spatial peak, temporal average intensity I(SPTA) in mW/cm^2. Figure 1B is an expansion of the first two sample intervals of Figure 1A.
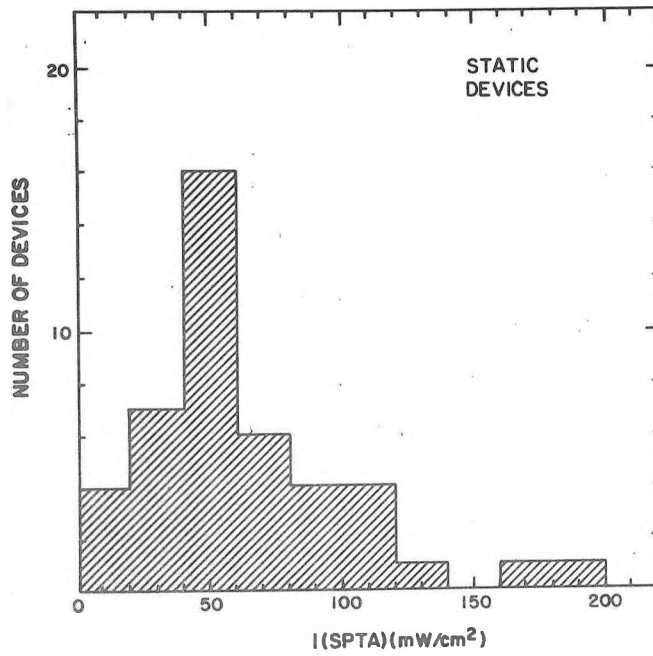
Figure 2.

Histogram of number of static devices as a function of spatial peak, temporal average intensity, I(SPTA) in mW/cm^2.
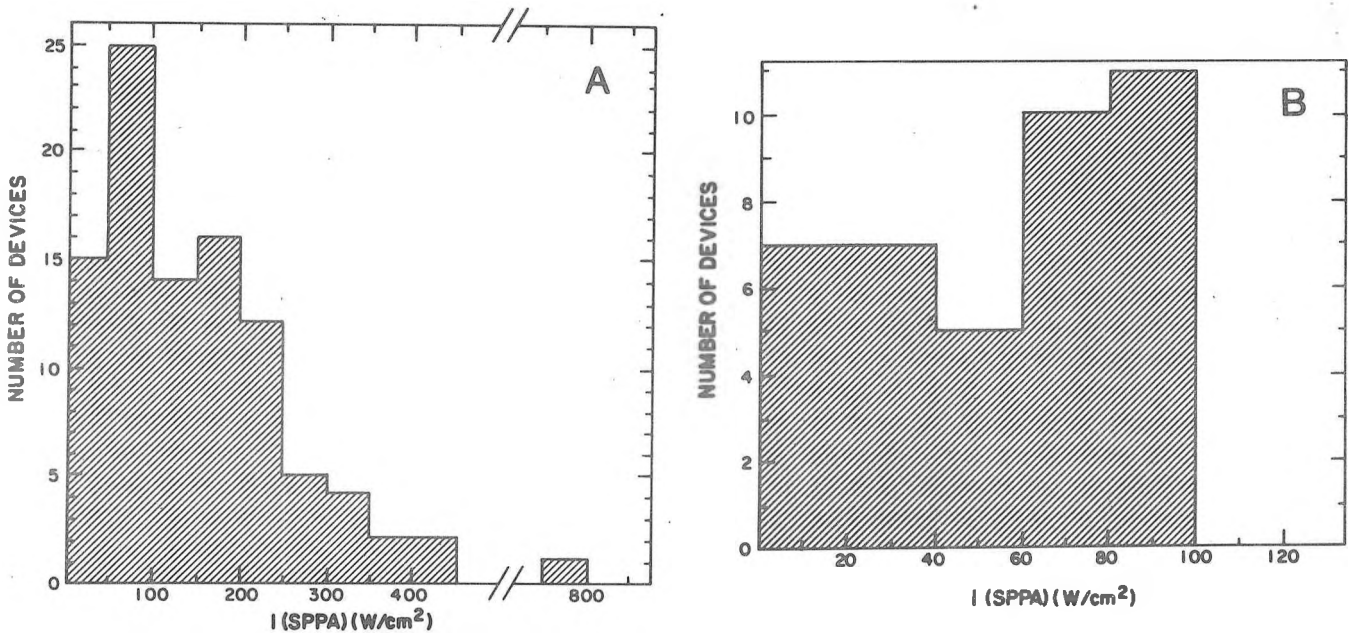
Figure 3.

Histogram of number of devices as a function of spatial peak, pulse average intensity, I(SPPA) in W/cm^2. Figure 3B is an expansion of the first two sample intervals of Figure 3A.

The histogram of Figure 3 indicates that there is a wide spread in I(SPPA) with a mean of 156 W/cm^2. Remarkably, the lowest I(SPPA) value was only 0.1 W/cm^2 and the highest value was 750 W/cm^2. Most values were greater than 100 W/cm^2.

Generally, there is a wide spread in output levels for all the quantities analyzed. Most devices fall in a range covering 1-2 orders of magnitude for each of the histograms of Figures 1-3, with the occasional device extending the full range even further. Even allowing for the possibility of measurement error this must be considered a large variance for equipment with the same claimed purpose. This strongly suggests that, based on present device design, the potential exists for unnecessary exposure to ultrasound during obstetrical examinations.

3.0 Comparison to Biological Effects Data

The maximum available value for I(SPPA) in the histogram of Figure 3 is well above the threshold for which transient cavitation (the violent and biologically damaging collapse of a microbubble) has been predicted in a low viscosity, aqueous medium with stabilized cavitation nuclei (11). In addition, it is well above the observed threshold for transient cavitation observed in insect larvae (12). However these systems may not be suitable models for human tissue and extrapolation from these biological effects to a hazard to human health is not possible. Nonetheless, from the above studies, it is clear that a biologically damaging effect can occur at output levels from many currently available diagnostic ultrasound devices. Therefore, at present we cannot rule out the potential for transient cavitation to cause a small but significant risk from some current imaging devices.

For dwell times (the dwell time is the amount of time the applicator remains in one place) of more than ten minutes, no biological effects in mammals have been observed below I(SPTA) values of 100 mW/cm^2 (2). Nor are any effects expected at these low output levels based on the heating of tissue via the absorption of ultrasound. By extrapolation from the animal model (2), below 100 mW/cm^2, significant heating of the fetus is extremely unlikely. In our survey, both the Doppler and M-mode equipment yield I(SPTA) values above 100 mW/cm^2. Only the mixed M and B-mode auto-scanning devices yielded I(SPTA) values above 100 mW/cm^2. Most auto-scanning devices yielded I(SPTA) values less than 20 mW/cm^2. Hence, purely real time imaging devices almost certainly will not heat the fetus in a damaging way. Typical dwell times for M-mode examinations are less than 5 minutes. Hence, heating should still be very unlikely with this mode. The question of heating with fetal pulsed Doppler devices needs to be addressed. The dwell times and I(SPTA) values of some of these devices fall into the regime where significant in vivo mammalian biological effects have been observed.

A number of epidemiological studies have found no significant adverse health effect due to fetal exposure to diagnostic ultrasound (2). Only one study (13) has stated the maximum output levels for the exposures. Based on the output levels reported by Stark et al (13), it was estimated that, in their study, the maximum I(SPPA) and I(SPTA) values were 30 W/cm^2

30 mW/cm^2, respectively. It is uncertain whether the assumption of safety, based on epidemiological studies done at allegedly low output levels, can be extrapolated to the higher output levels from the devices presently sold in Canada.

IV. CONCLUSIONS

Based on the above results and discussion, it appears that at present there exists the potential for a small risk to human health due to unnecessary exposure to ultrasound during obstetrical ultrasound examinations. It is not known whether this risk is significant or entirely negligible. Furthermore, it is not known how long it will take for a reliable risk assessment. If the risk is truly due to unnecessary radiation, as suggested by the results of this survey, then it is sensible to initiate, prior to a more definitive risk assessment, attempts to minimize this radiation. This can be done with both accurate labelling of output levels and calibrated output level controls to allow the user to get useful diagnostic information with the minimum required acoustical exposure. To help achieve this the Acoustics Unit at the Bureau of Radiation and Medical Devices is developing a measurement apparatus to monitor the accuracy of output levels specified by the manufacturer.

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