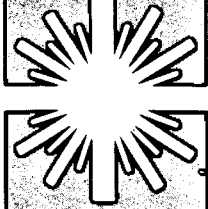
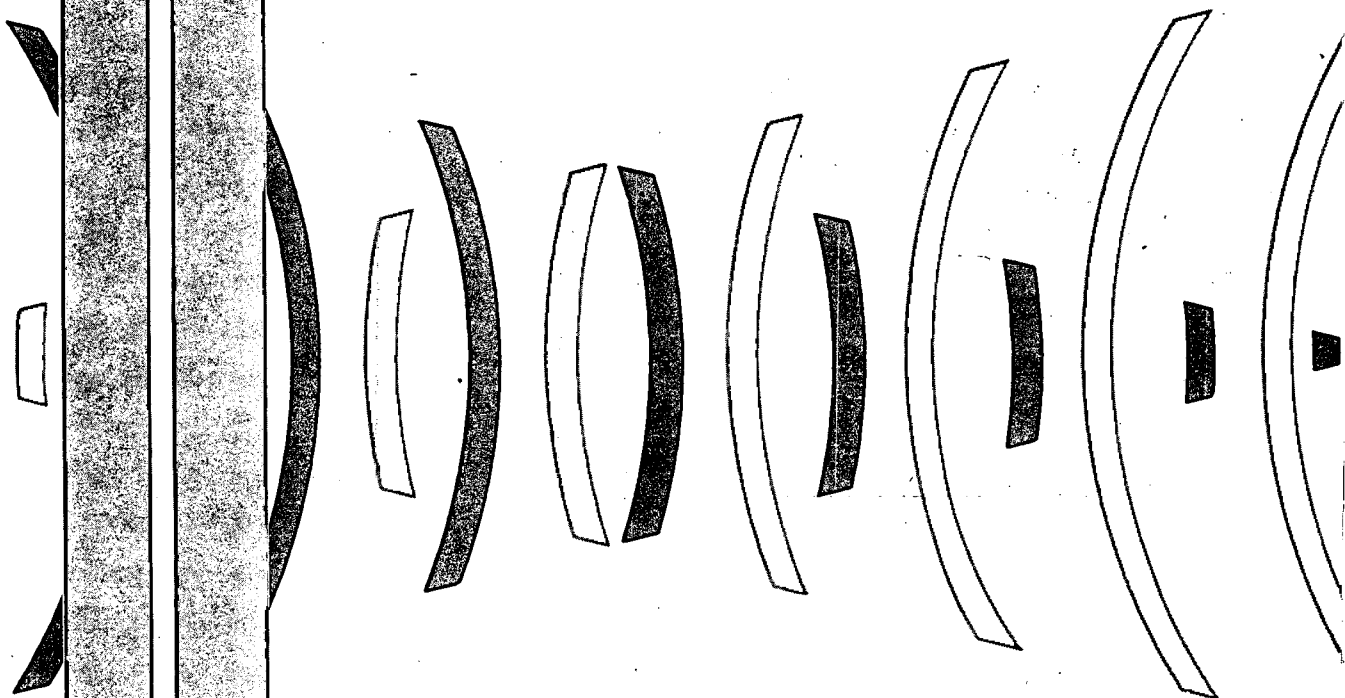


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A LIMITED MICROWAVE DIATHERMY FIELD SURVEY



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A LIMITED MICROWAVE DIATHERMY FIELD SURVEY

*[results of a study of
the performance characteristics
and use conditions of
diathermy in five
treatment facilities
and one education-
al institution;
includes section
on users
"awareness of
hazards"]*

↓
Gideon Kantor, Ph.D.
Paul S. Ruggera

Division of Electronic Products *Rept.*

December 1974

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
FOOD AND DRUG ADMINISTRATION
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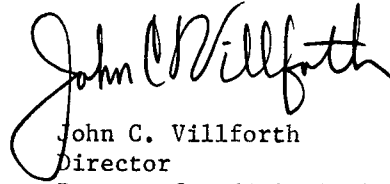
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John C. Villforth
Director
Bureau of Radiological Health

PREFACE

One of the requirements of the Radiation Control for Health and Safety Act of 1968, which was enacted to protect the public from exposure to radiation from electronic products, is that programs shall be carried out to study and evaluate emissions of and conditions of exposure to electronic product radiations. In the implementation of this requirement, a study has been made of the performance characteristics and use conditions of microwave diathermy machines in five treatment facilities and one educational institution.

This report details the results of this study as well as the methodology and instrumentation used for the survey.



Roger H. Schneider
Director
Division of Electronic Products
Bureau of Radiological Health

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ABSTRACT

During February and March 1974, the Division of Electronic Products designed and executed a field survey to study the performance characteristics and use conditions of microwave diathermy machines. This report details the results of the study which was conducted in five treatment facilities and one educational institution. It also details the methodology and instrumentation used for the survey.

A LIMITED MICROWAVE DIATHERMY FIELD SURVEY

1. INTRODUCTION

It is well known that high-level microwave exposure can have deleterious biological effects.¹ Since microwave diathermy results in high exposure levels, it is important to obtain current information on this electronic product and its use. Although reports of previous surveys of microwave diathermy exist,^{2,3} newly developed instrumentation and lack of information on technique indicated that a new, limited survey was warranted. The purpose of this particular survey was twofold: first, to provide a means for determining the uniformity, or consistency of operation between the various machines; and second, to obtain a better understanding of the use and methods employed for actual treatment.

The survey team observed the local environment and the operator's routine. They discussed the frequency of the use of microwave treatments, the source of instructions, and details of specific treatments. Performance tests were made to obtain field pattern measurements and data on exposure termination and leakage. The therapists were asked what performance characteristics they desired and what safety precautions they followed to protect both patient and operator.

This report details the results of the field survey conducted during February 1974. Five treatment facilities and one educational institution were visited. Field patterns were obtained from seven machines using a total of 20 applicators. These patterns were compared with those generated in the Electromagnetics Branch laboratory under anechoic conditions. During the survey six physiotherapists, one physiotherapist assistant, and two instructors, both of whom had previous clinical experience, were interviewed.

2. SURVEY RESULTS

2.1 GENERAL INFORMATION

2.1.1 Local Environment

In the treatment facilities visited, the physical therapy departments were located in remote areas of the building and not near any sensitive areas, such

¹Safety Level of Electromagnetic Radiation with Respect to Personnel. United States of America Standards Institute, USAS C95.1, 1966.

²Survey of Diathermy Equipment Use in Pinellas County, Florida. Report BRH/NERHL 71-1.

³Diathermy Survey by Massachusetts Department of Public Health, New England Journal of Medicine, May 11, 1972.

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as operating rooms, intensive care units, or cardiac care areas. Of the staff of institutions visited, no one had ever given a microwave diathermy treatment in any area other than a physical therapy department.

The number of treatment "areas" ranged from about four to eight. They are separated from one another by a curtain suspended from the ceiling. When not in use, the curtains are usually against the wall, revealing a large room with treatment tables and associated equipment. In many instances these cubicles were used to "store" equipment not in use at the time. Several users indicated that if a piece of machinery, such as an ultrasonic therapy unit was in the cubicle and its presence did not obstruct the setting up of a microwave treatment, it would not be moved. (One improvement suggestion received was that the microwave unit be reduced in size to facilitate the practice.) In some instances exercise equipment was located near the cubicles.

In all of the treatment facilities and the one educational institution visited, the treatment tables were made of a nonconducting material. During the diathermy treatment the patient is either lying on a treatment table or sitting in a chair. Some metal-rimmed chairs were in the vicinity; however, in no instance did a therapist indicate during questioning that anything other than a wooden chair was used for treatment.

2.1.2 Operator Routine

The survey indicated that the operator's routine in administering a diathermy treatment appears to be quite standardized. The patient enters the cubicle and removes all clothing and metal objects in the area to be treated. He is then positioned in such a way as to direct the microwave energy to the area of treatment with minimal physical discomfort. (This is desirable since the treatment time during which the patient should not move is about 20 minutes.)

The applicator that will treat the specified area most effectively is then selected. In this survey the applicator favored seemed to be the type B in the older units and the type E in the newer units. (The newer units come with the type E as original equipment.) Once the applicator is attached, it is positioned over the area of treatment and, through use of a spacer on the applicator, the distance is fixed. The determination of the proper spacing and appropriate power level setting seemed to be the most uncertain factors in the entire treatment process. While all operators said they followed the manufacturer's charts (Burdick applicators usually state the power level that should be used for a given distance), it became evident during the course of the interviews that previous "successful treatment routine" was the primary factor in determining spacing and power level. (From the therapists visited, it was ascertained that the basis for "successful treatment routine" was the number of patient visits necessary to eliminate the symptoms for which diathermy was prescribed. The fewer the visits, the better the routine.) One perceived that the distance usually was not varied and the recommended power range probably was not exceeded. In most instances only one applicator was used for all treatments.

Once the applicator was positioned over the patient, the machine was activated and the power was increased to the determined value. The timer was set on the machine to the standard 20 minutes, and in some institutions an independent timer was also used. This setup procedure takes an average of 2 to 3 minutes, after which the therapist leaves the cubicle. Most of the interviewees indicated that they would check back on the patient once or twice during the 20-minute treatment. This check back usually consisted of glancing at the patient

while walking past the cubicle. In all locations the patients are instructed to ring a bell or verbally indicate excessive heat; however, none of the units surveyed had a "patient-activated turn-off" capability. (A patient turn-off through use of a string attached to the main power switch was observed in one institution on a shortwave diathermy machine. The switches on the microwave units have the same capability, a hole through which a string could be attached.) In no instance had any of the therapists contacted ever terminated a microwave diathermy treatment because of patient complaint of excessive heating, nor had they observed any redness of the skin after treatment. As a result of this, the therapist is almost totally dependent on the meter and lights for an indication that the unit is operating. (Interviewees stated that in the case of shortwave diathermy the patient can feel the heat more readily, and reddening of the skin has been observed when the levels were too high.)

2.1.3. Frequency of Use

Of the five physical therapy departments contacted during the survey, the frequency of use of microwave diathermy varied. In one department the unit had not been used since the person interviewed had been there--a period of 6 months. In another institution the estimate was three times a year. The third reported less than one patient per week. The fourth reported two to three treatments per month, and the fifth, which had specific figures, reported 60 in 1972 and 75 in 1973. When the microwave diathermy was used, it was always for only one or two specific ailments. The specific ailments for which microwave diathermy was found more useful than other modalities will be discussed later. The specific ailments treated were not necessarily common to all institutions.

2.2 EQUIPMENT DESCRIPTION AND MAINTENANCE

Table 1 shows the type of equipment encountered in this survey. Note that two facilities had the latest models (Burdick MW-225); one also had an old model (Burdick MW-1); two facilities had an older model (Burdick MW-200); and two facilities had very old models (Raytheon-Microtherm CMD-5 and CMD-10). The list of applicators is as follows:

- Four type A: 4 inch (10.16 cm) hemisphere
- Six type B: 6 inch (15.24 cm) hemisphere
- Five type C: 5 inch (12.7 cm) by 4-1/2 inch (11.43 cm) corner reflector
- Two type D: 22 inch (55.88 cm) by 5 inch (12.7 cm) corner reflector
- Three type E: 6-3/4 inch (17.15 cm) by 5-1/2 inch (13.97 cm) corner reflector

Only one facility had quarterly service checks by general maintenance personnel. Others indicated they called either the local general appliance repair shop or relied on their in-house capability for repair as needed.

There were two instances where a general service contract could have easily prevented deterioration of equipment. In one case, a power cord connected to a plug was not properly insulated, causing a safety hazard. In the other case, the inner conductor pin of a coaxial connector of a Type B applicator was bent, possibly causing significant reflections. In each case the facility involved was informed of the condition.

Table 1. List of Microwave Diathermy Machines with Applicators at Each Facility

	Facility	Type of unit (year manufactured)	Applicator type	Number of applicators
1	Research Hospital California	Raytheon-Microtherm CMD-5 (1947)	A	1
			B	2
			C	1
2	Military Hospital Maryland	Burdick MW-200 (1966)	A	1
			B	1
			C	1
			E	1
3	PHS Outpatient Clinic Washington, D.C.	Burdick MW-1 (1961)	A	1
			B	1
			C	1
			D	1
		Burdick MW-225 (1972)	E	1
4	PHS Hospital Maryland	Burdick MW-200 (1966)	B	1
			C	1
5	PHS Research Hospital Maryland	Raytheon-Microtherm CMD-10 (1957)	A	1
			B	1
			C	1
			D	1
6	Community College Virginia	Burdick MW-225 (1972)	B	1
			E	1
7	BRH Test Facility Maryland	Burdick MW-1 (1961)	A	1
			B	1
			C	1
			D	1
		Burdick MW-225 (1972)	E	1

2.3 RESULTS OF PERFORMANCE TESTS

2.3.1 Generator-Module

The safety controls of the generator-module were tested at the five facilities surveyed in the Washington area. The meter readings were recorded with the power control knob set to zero and the timer turned on. One machine gave readings under these conditions of 3 watts with a Type B applicator and 5 watts with a Type E applicator. This occurred on a unit manufactured in 1972. The other units that were tested in this manner showed meter readings of not more than 2 watts. A unit manufactured in 1966 indicated a serious malfunction in its power control reset. With the timer set to zero from a particular time setting and with the power control knob on "reset," it was possible to set the power knob to any desired output level.

The more recent output models have power cut-off functions. At a value above the maximum of the scale, the output power is cut off and the meter needle returns to its zero position. No malfunction was noted in this case.

The safety control of the old Burdick machines that automatically turns the microwave power off when the applicator is disconnected was checked out and found to be operating properly.

2.3.2 Leakage

The leakage from the generator-module was measured with the Narda 8300 electromagnetic radiation survey meter. The power output was set to a maximum and the output was terminated in a high-power coaxial load. The leakage from the generator-module in all cases was less than 0.5 mW/cm^2 . The maximum occurred when the probe was positioned at the air vents of the generator-module.

2.3.3 Applicators

2.3.3.1 Pattern Measurements

Figure 1 shows the test setup for measuring the applicator patterns at the six surveyed facilities. It was also used in the EMB test facility with one modification: absorbing material was used to minimize reflection from the laboratory environment for purpose of comparison. A grid was constructed using a low dielectric constant material. The grid contained five locating holes for a Narda 8300 probe. One location was at the center, and the other four were symmetrically placed about the center. The spacing between the circular holes to position the sphere of the probe, as well as the diameter of each circular hole, is given to scale in figures 2 through 6. The same probe orientation was maintained for each reading.

A summary of the variation of pattern measurements of each type of applicator is given for the four outer locations in figures 2 through 6. The probe readings are normalized to a power density of 1 mW/cm^2 at the center location. Two numbers are shown at each of the four outer locations; one is the maximum and one is the minimum of the normalized data, in mW/cm^2 , of this normalized data. Table 2 gives the extremes and average values of the grid center data taken at the surveyed facilities and the corresponding values obtained at the Electromagnetics Branch laboratory. (Note that the power output was initially set to 10 watts or to the 10 percent level, depending on the unit tested.)

The measurement techniques used in this survey were selected to obtain meaningful results without unduly disturbing hospital routine. There are several factors that can account for the variation of the results, such as the actual power output for the same knob setting on different machines, the relative positioning of applicator, radiation grid, and probe, as well as the possibility of hot spots or electromagnetic interference in the hospital environment.

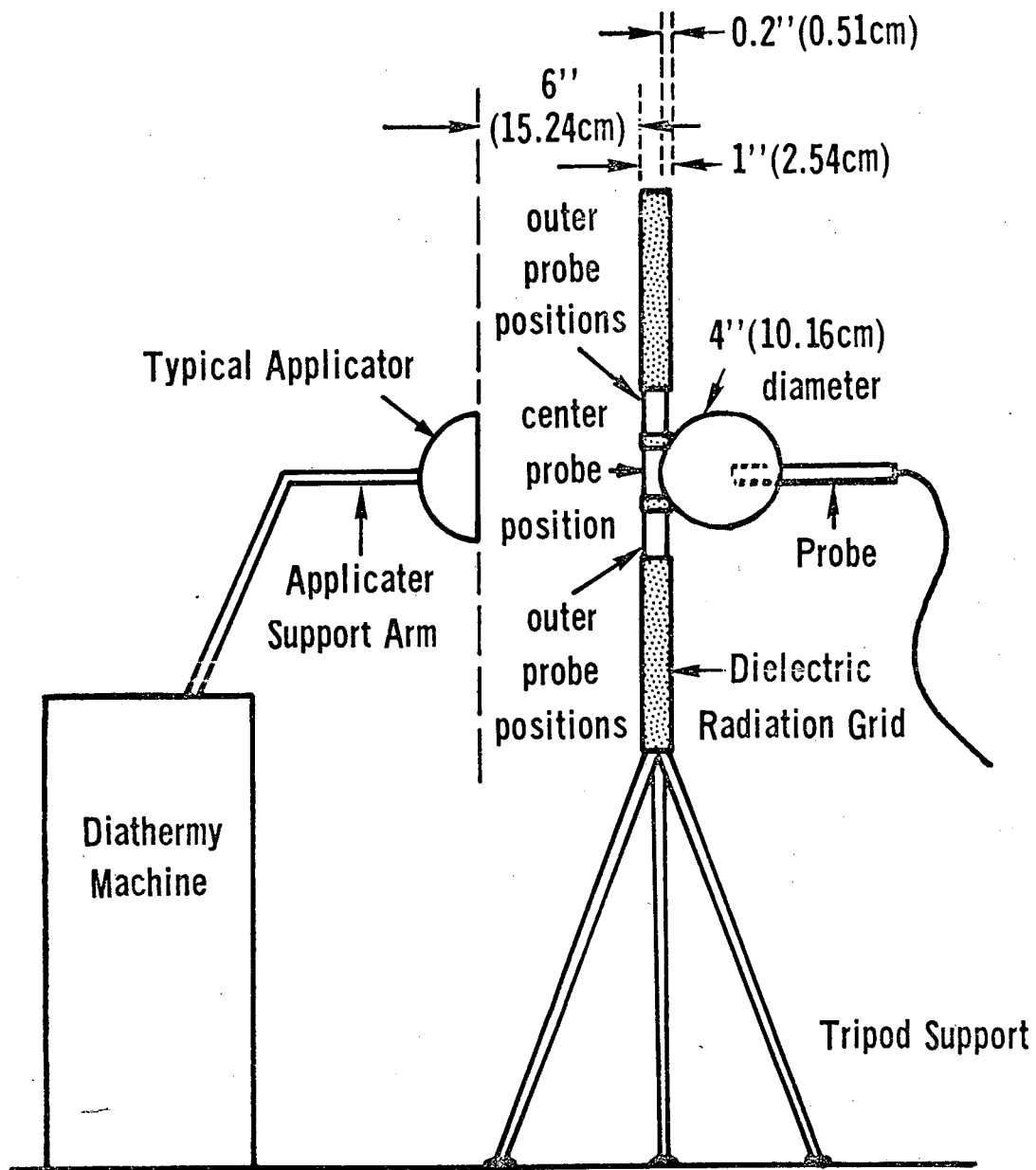
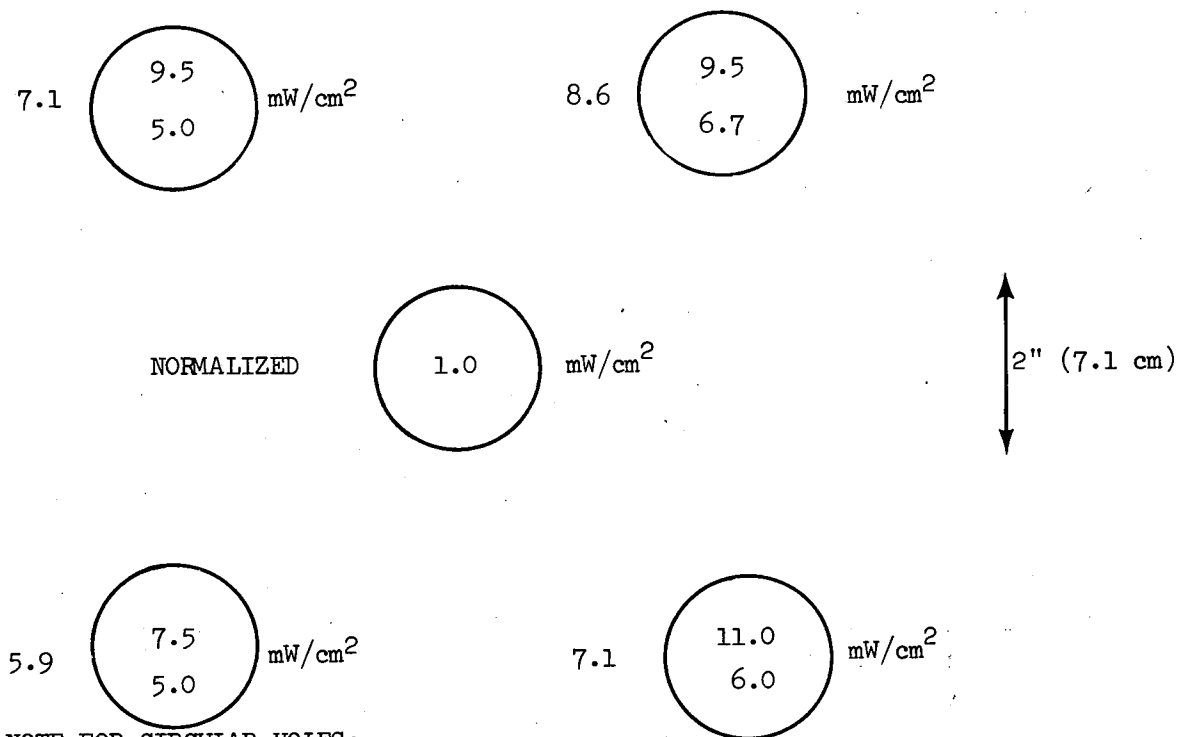


Figure 1. Sketch of Radiation Measurement Setup



NOTE FOR CIRCULAR HOLES:
 Inside Values: Normalized Maxima & Minima
 Values to Left: Normalized Average
 For Details, See Text

Figure 2. Applicator "A" Pattern Using 6" Spaced Radiation Grid

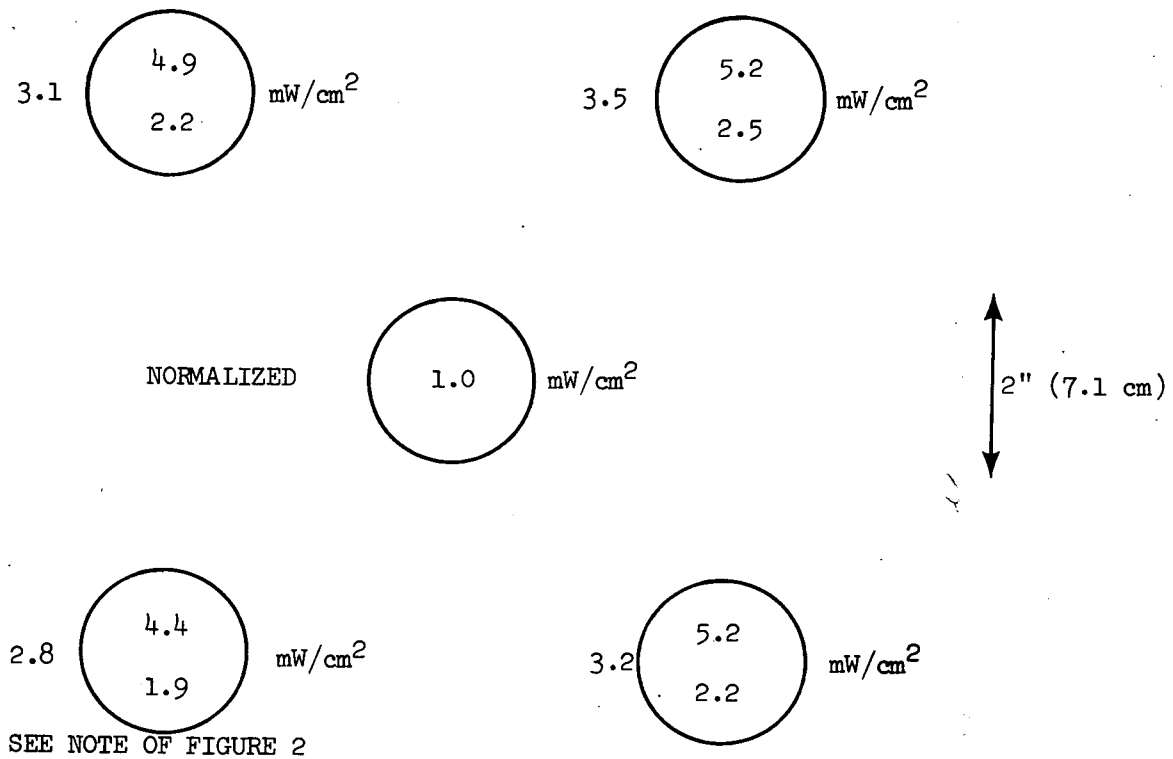
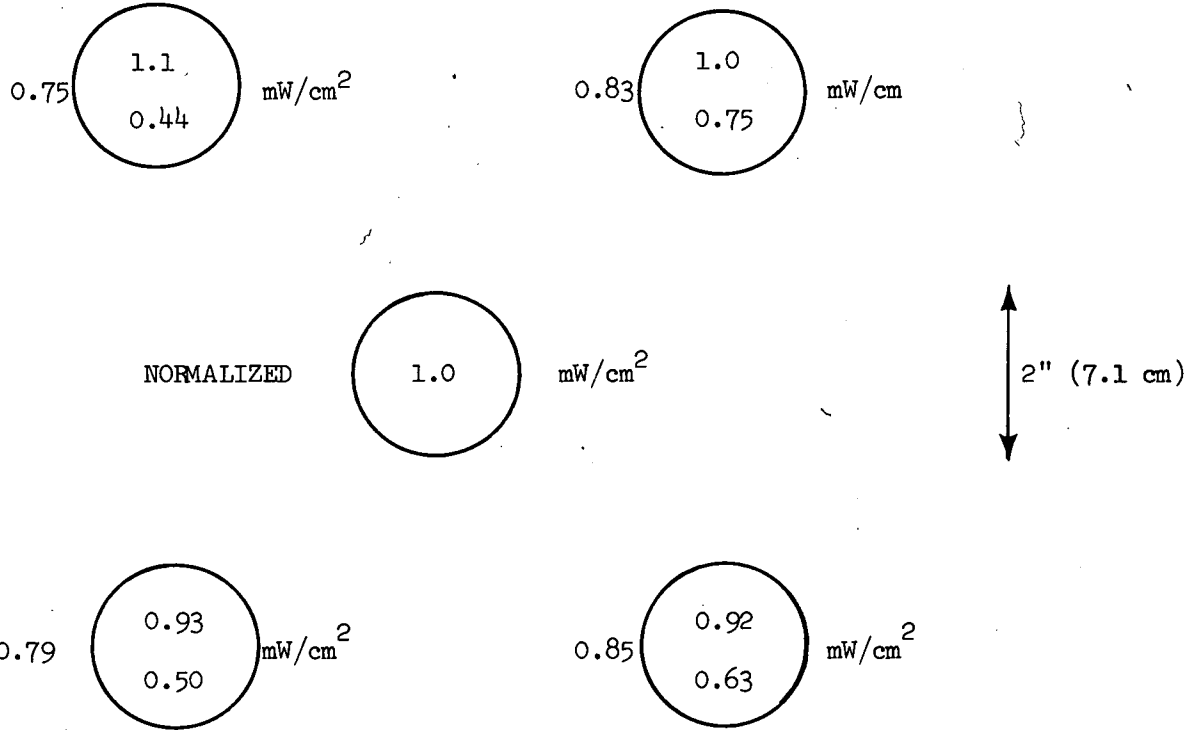
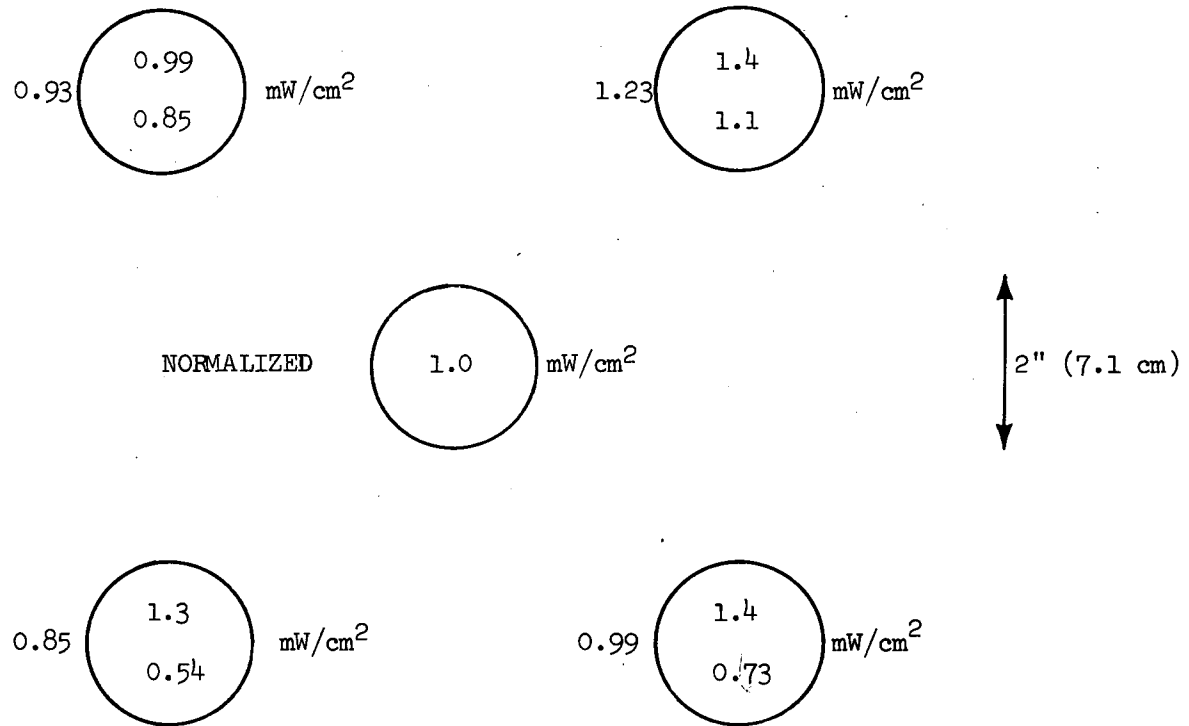


Figure 3. Applicator "B" Pattern Using 6" Spaced Radiation Grid



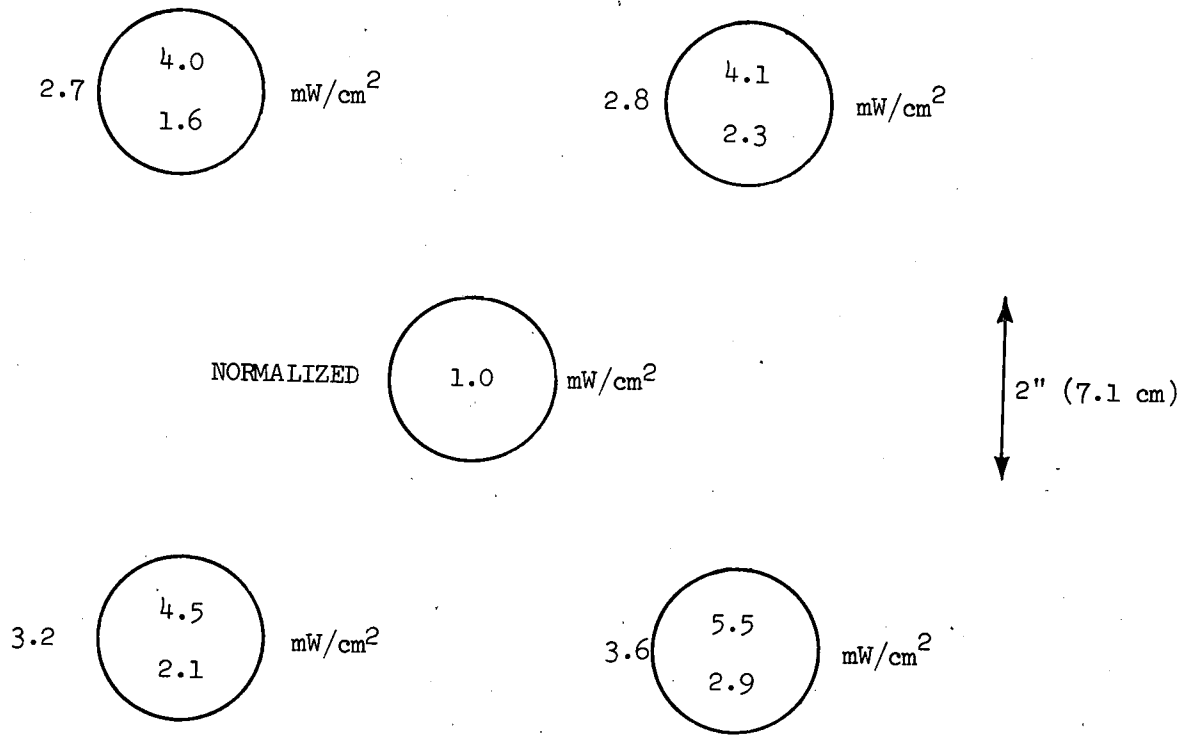
SEE NOTE OF FIGURE 2

Figure 4. Applicator "C" Pattern Using 6" Spaced Radiation Grid



SEE NOTE OF FIGURE 2

Figure 5. Applicator "D" Pattern Using 6" Spaced Radiation Grid



SEE NOTE OF FIGURE 2

Figure 6. Applicator "E" Pattern Using 6" Spaced Radiation Grid

Table 2. Measurements at Grid Center

Applicator	Measurements at surveyed facilities (mW/cm ²)	Measurements at EMB (mW/cm ²)
Type A	Max: 0.3 Av: 0.2 Min: 0.2	0.2
Type B	Max: 3.0 Av: 2.0 Min: 1.0	1.2
Type C	Max: 10.5 Av: 7.4 Min: 5.6	6.5
Type D	Max: 8.9 Av: 8.4 Min: 8.0	8.1
Type E	Max: 2.4 Av: 1.9 Min: 1.2	1.0

2.3.3.2 Aperture Leakage

Leakage from the apertures was measured for the previously discussed case in which the power control knob was set at zero and the timer was turned on. For a power output of 3 watts with a Type B applicator and 5 watts with a Type E applicator (see 2.3.1), the radiated leakage at the aperture surfaces, measured with the Narda 8300 probe, was 2.5 mW/cm² and 3.2 mW/cm², respectively. The other diathermy units were also tested to determine leakage radiation; values of less than 0.5 mW/cm² were obtained.

2.4 TREATMENT CONSIDERATIONS

2.4.1 Procedure

2.4.1.1 Origin and Types of Instructions

There are two primary factors that determine the type of treatment given to a patient. The first is the physician's prescription; the second is the physical therapist's past experience in treating different ailments. All diathermy treatments are initiated through a physician's prescription. The extent and details of this prescription determine the amount of variability allowed the physical therapist. A few physicians apparently are very specific and prescribe microwave diathermy. In general, the instruction will be less specific, prescribing "deep heat" or "diathermy" only.

In the first instance, if the physical therapist believes, through past experience, that another modality or treatment is more successful, he will call the physician and obtain permission to change the treatment. In the second instance, the therapist determines, again primarily through experience, what

modality is likely to be most successful. This was evident from the number of patients treated in various institutions (see 2.1.3).

When questioned concerning the type of instructions that are available, the most often quoted references were the "Burdick Syllabus, A Compendium on Electromedical Therapy," as well as "Suggested Technique for Microwave Diathermy Therapy," a chart also published by the Burdick Corporation. Formal training, in varying degrees, was received by all persons contacted by the survey team.

2.4.1.2 Discussion of Specific Treatments

When discussing the frequency of use earlier in this report, it was pointed out that only certain specific conditions (ailments) were treated using microwave diathermy. It was also indicated that there were some differences between the conditions physiotherapists chose to treat with microwave diathermy.

An example of this variance in treatment is that only one institution contacted uses this modality to treat pelvic inflammatory disease--and they do not use microwave diathermy for any other condition. The treatment was administered with a Type B applicator at 100 percent power; spaced 3 inches from the abdomen; for a duration of 20 minutes; three times per week for 2 weeks. (In this case the pelvic inflammatory disease was specifically inflammation of the uterus.) Although this treatment is listed as a suggested technique in the Burdick manual, no other person contacted had used it.

At three of the five clinical institutions visited, microwave diathermy was used for inflammation of the lateral epicondyle (tennis elbow). The applicator was Type B, C, or E; spacing was 2 to 4 inches; power was 60 to 80 percent; duration was 20 minutes; number of treatments was 6 to 12; and treatments were administered three times per week. Additional conditions treated and data pertinent to the treatments are as follows:

- | | |
|-----------------|---|
| Bursitis: | Type B applicator; 2-inch spacing; 50 percent power; 20-minute duration; 10 to 12 treatments; three treatments per week. |
| Tendonitis: | Type B applicator; 4-inch spacing; 80 to 100 percent power; 20-minute duration; 10 to 15 treatments; one treatment per day. |
| Muscle Strains: | Type B applicator; 5-inch spacing; 75 percent power; 20-minute duration; 5 to 6 treatments; one treatment per day. |
| Arthritis: | Type C applicator; 4-inch spacing; 70 to 80 percent power; 20-minute duration; if improvement seen after a few treatments, then approximately 20 treatments will be given; one treatment per day. |

2.4.2 User's Desired Performance Characteristics

2.4.2.1 Dose Distribution

Only a few comments were obtained on dose distribution. This was not unexpected since readily available information on this subject is rather sparse. The therapists had different opinions on the extent of the penetration depth. Some stated that microwave diathermy is useful for shallow heating, and others suggested using it for deep heating of small, prescribed tissue areas. This is the reason that one practitioner chose tennis elbow and another chose pelvic inflammatory disease when citing examples of treatments using microwave diathermy.

2.4.2.2 Other Characteristics

Only a few general comments on performance characteristics were received. One comment suggested that the instruction manual should specify the illuminated area of the prescribed tissue for each applicator and each spacing, similar to the Burdick instructions for ultraviolet treatments. Another therapist suggested improvement of the design of the applicator arm to permit easier positioning of microwave units, and manufacturing small generator units (see 2.1.1).

One instructor, who was employed as a physiotherapist before entering the teaching profession, preferred microwave diathermy over shortwave when treating acute tendonitis from a performance standpoint. The physical reason is that the microwave applicator did not come in contact with the patient and therefore added no additional weight which would cause increased pain.

2.4.3 Awareness of Hazards

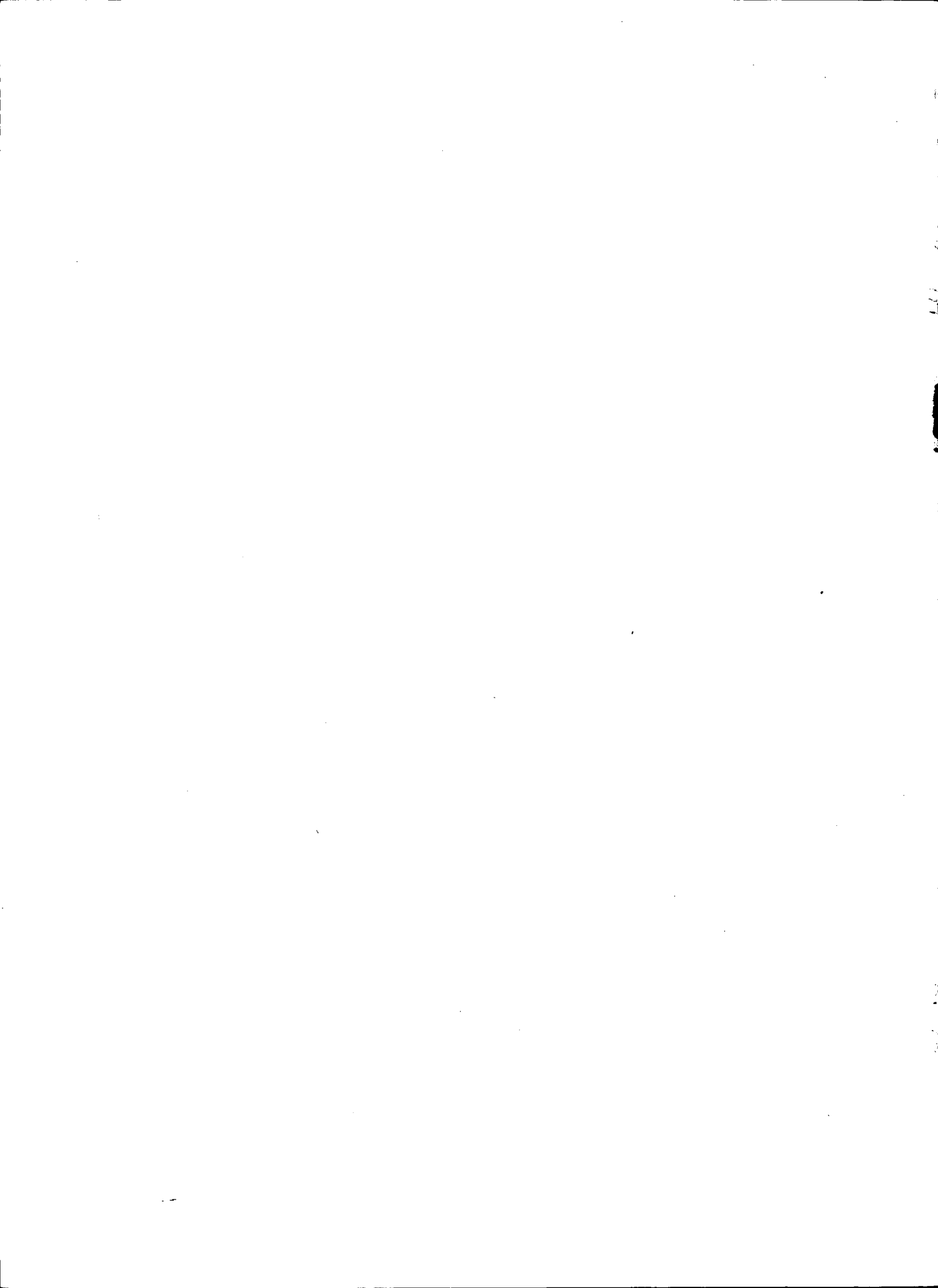
During the course of the survey there was time to discuss the hazards in the use of microwave diathermy as viewed by the therapists contacted. All of the people contacted, and this may not represent the situation nationwide, were aware of some adverse interaction if the microwaves were allowed to impinge on metal objects. They all stressed the use of wood treatment tables and removal of metal objects from the patient before treatment. They were not as cognizant about removing metal machines or chairs that might be in or near the cubicle. One therapist said that he looks for scars which could be indications of metal implants, such as pins in joints. (Apparently, people who had such implants have been treated and experienced pain.) They all conceded that pacemaker wearers should not be treated; however, it may have been a loaded question from their point of view--no one volunteered that information. Another therapist has the patient turn his head away from the applicator and places a dry towel over the patient's face when treating the shoulder area. He does this to shield the eyes from the microwaves. None of the therapists interviewed seemed to fear the unit. In one facility visited, however, a therapist who was pregnant would leave the room when any diathermy unit (shortwave, microwave, or ultrasound) was turned on.

3. FINAL COMMENTS

The survey suggests that the users interviewed are aware that high-level microwave exposure can have harmful effects; however, their understanding of electromagnetic radiation is rather limited. For example, one instructor, while observing the technique used by the survey team to measure the radiation output from an applicator, was startled to learn that at the test distance, which was in the far field, the power density at the center point was actually lower than it was in areas closer to the periphery. (The team explained that at treatment distances the tissue would most likely be in the near field, a condition which results in the high power density--and subsequent heating--in the center.) Unaware of this pattern variability due to distance, the operator could easily expose unprescribed areas. Serious inadvertent exposure to the therapist is less likely since he spends very little time in the applicator vicinity during treatment (see 2.1.2).

Enough facilities were surveyed to suggest that malfunctioning equipment, which could result in overexposure, does exist. An example is the previously mentioned case in which the timer did not function properly. It is possible that the operator could assume that the microwave radiation is turned off, as it should be, because the timer is on zero even though the power knob is set for treatment. A resulting high value of output power could inadvertently result in overexposure of the patient or operator.

As a result of the clinical contacts and a visit to an instructional institution, it appears as though the main guide for use of microwave diathermy is the manufacturer's recommendations contained in the manuals. As stated previously, some therapists deviate from published instructions according to past successful experience in treating a given condition.



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Gideon Kantor, Ph.D., and Paul S. Ruggera. A LIMITED MICROWAVE DIATHERMY FIELD SURVEY.

Accession No.

U.S. Department of Health, Education, and Welfare, PHS, Food and Drug Administration, Bureau of Radiological Health. DHEW Publication (FDA) 75-8018 (December 1974) 15 pp.

ABSTRACT: During February and March 1974, the Division of Electronic Products designed and executed a field survey to study the performance characteristics and use conditions of microwave diathermy machines. This report details the results of the study which was conducted in five treatment facilities and one educational institution. It also details the methodology and instrumentation used for the survey.

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