Electric Field Intensity Emitted from Medical Devices and Its Potential Electromotive Force According to the Quality of Grounding

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Abstract—*If an electric product is used with improper grounding, excessive electrical energy will remain on the metal parts of the product. If the charge reaches a certain limit, the collected energy will be emitted as an electromagnetic field, which could cause an electric current to flow through the body if touched. When this current exceeds a critical value, ventricular fibrillation can occur. If a radiated electric field is observed around an electronic device, the grounding of the device must be inappropriate. We used a power supply with variable resistance to measure the electric field intensity emitted from medical pumps. Also, we determined the relationship between the radiated electric field and electromotive force (EMF). The results showed that medical devices and the metal surrounding them collect an electric charge when grounding is improper. Also, the electromagnetic field emitted was shown to increase as the condition of the grounding worsened.*

Keywords: *Medical devices, Electric power supply facility, Grounding, Electric field, EMF*

I Introduction

The increasing use in hospitals of electronic medical devices driven by electrical power has increased the importance of carefully installing electric power supply facilities and insuring proper maintenance. In Japan, there are domestic standards for electric outlet sockets (JIS–Japan Industrial Standard) C8303 [1]) and "medical grade" outlet sockets (JIS T1021 [2]). The first version of JIS C8303 was enacted in 1950 and JIS T1021 was enacted in 1982. In addition to JIS T1021, which specifies only outlet sockets with grounding pins (hereafter, "3P outlet"), the JIS C8303 specifications include outlet sockets without grounding pins (hereafter, "2P outlet"). Because JIS T1021 is much newer than JIS C8303, many 2P outlets can be seen in homes and even in older hospitals. Other reasons for the existence of hospital 2P outlets are that some hospital construction companies do not understand JIS T1021 and that "medical grade" outlets and plugs are quite expensive. Also, unfortunately, the maintenance of electric grounding (earth) tends to be ignored after the system is installed. Cases in which the existing grounding has been cut when a hospital is remodeled or a new addition has been added have been reported [3].

When electricity is supplied to a tabular or cylindrical metal object, an electric charge will collect on it. The same occurs to the metal in a medical device. Because the human body is electrically conductive, if a person touches the electrically charged metal, there is the possibility that an electric current will flow through the body. If this current exceeds a critical value (in the tens of micro amperes), ventricular fibrillation can occur [4, 5]. Such a state is called "shock" (a micro or a macro shock). The standards for grounding as a preventive measure against "shock" in Japanese hospitals are described in JIS T1022 [6]. This is also included in international standard IEC 60601-1 [7].

Earth grounding should be done to reduce the possibility of excessive electric charges, which occur on the surface or inside of a product to which electric power is supplied. Therefore, the resistance of the grounding line needs to be very low. If an electric product is used with improper grounding, i.e., grounding with high resistance or not equipotential, excessive electrical energy (mainly noise) generated in the power source supply unit, for example, will remain on the metal parts of the product. If the condition of the grounding improves, the charge will instantly go to the earth. However if the remaining charge exceeds the limit, the collected energy will be emitted from metal as an electromagnetic field because the metal part has a higher potential: If a radiated electric field is observed around an electronic device, the grounding of the device must be inappropriate.

Herein, we have used a power supply with variable resistance to measure the electric field intensity emitted from medical pumps in order to determine the relationship between the quality of the grounding and the electric field intensity. Also, we determined the relationship between the radiated electric field and electromotive force (EMF).

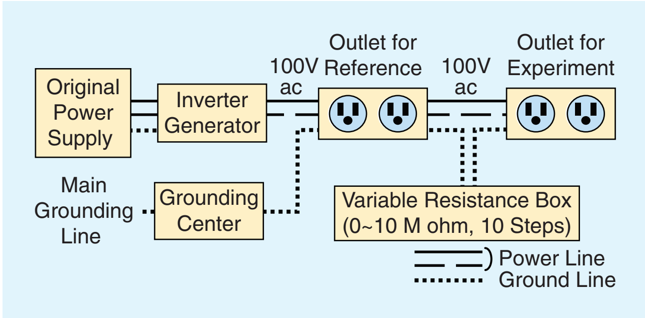

Fig. 1. Configuration of the experimental circuit.

Fig. 2. Measurement setting (a variable resistance box, front, and an antenna, the white box in back).

II Method

Measurement of the Electric Field Intensity Emitted from Medical Devices

We made an experimental circuit that included stable output inverter power (single-phase AC 100 V, 60 Hz) and "Type C" grounding [8] (grounding using a metal wire with a resistance of 10 ohms or less and 0.39 or more kN of pull strength or a metal wire not less than 1.6 mm in diameter), as shown in Fig. 1. The resistance of the grounding in the experimental circuit was 4.21 ohms. Also, the resistance of the circuit was able to be set to ten levels, 300 ohms, 1 kilo ohm, 3 kilo ohms, 10 kilo ohms, 30 kilo ohms, 100 kilo ohms, 300 kilo ohms, 1 mega ohm, 3 mega ohms, and 10 mega ohms. The variance of resistance was ±0.5%.

Using this circuit to supply the medical pumps, we measured the electric field intensity when a probe that included a flat antenna was placed 10 cm from the pump surface. The probe was placed in a straight line from the center of the case front (direction was done with a control panel), and the probe direction was set parallel to the case front. The number of pumps tested was eight, and each pump was switched on during measurement. The specifications of each pump are shown in Table 1. The measurement situation is shown in Fig. 2, and a diagram of the measurement is shown in Fig. 3. The receiving antenna used in this measurement consists of two copper plates. If the two plates are in an alternative electric field, a voltage difference is produced between them. Electric field intensity is

TABLE 1. SPECIFICATIONS OF SUBJECT PUMPS.

Pump name	Pump classification	Casing size (Front panel side) (mm × mm)	Year of Manufacture (M)/Purchased (P)
A	Infusion pump	170 × 210	2002 (M)
B	Infusion pump	85 × 225	2004 (M)
C	Enteric nutrition pump	110 × 145	2005 (M)
D	Infusion pump	130 × 135	2003 (P)
E	Infusion pump	100 × 200	1989 (M)
F	Transfusion pump	130 × 200	1988 (P)
G	Syringe pump	125 × 325	1996 (P)
H	Syringe pump	125 × 325	2005 (P)

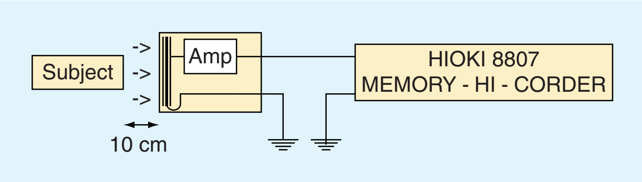

Fig. 3. Configuration of the measurement circuit.

defined by voltage per meter (V/m); the voltage difference between two points 1 m apart. By measuring the voltage between two plates located at a fixed distance, the electric field intensity can be calculated. For this measurement, the distance between the two plates was set in such a way that the electric field intensity could be calculated as 1,000 times the voltage gap. Thus, the value measured was voltage produced in the receiving antenna as potential difference. The electric field intensity was then computed from the measured voltage.

Measurement of EMF by a Radiated Field

When a metal tray is placed near a television that is switched on, EMF is generated to the metal tray. Therefore, we measured EMF (potential voltage) using a television and a metal tray. The EMF on the metal tray was measured when the tray was placed at point where the specific electric field intensity could be measured.

A 14 and a 30-inch television with cathode-ray tubes (CRT) were used. Neither of the power plugs was grounded. Many 14-inch CRT televisions are used for patient amusement in Japanese hospital rooms. The metal tray used in this measurement was 2 mm thick, 170 mm by 210 mm, and made of 18-8 stainless steel.

The televisions were in the standby state (the power plug was in the power outlet and the standby current was flowing) at the time of measurement. For the 14-inch television, measurement was also done with a program playing. A block diagram of the experiment is shown in Fig. 4.

III Results

The electric field intensities induced by the electromagnetic fields emitted by each pump are shown in Fig. 5. Examples of the observed voltage waveform are shown in Fig. 6. When the grounding resistance became larger, as was seen with almost all pumps, a stronger electric field was observed, Fig. 5. However, the point at which the intensity began to rise differed for each pump. Also, the intensity at lower resistance differed for each pump. A strong electric field was observed for pump C at all resistance values.

EMF by the electromagnetic field emitted by the televisions is shown in Fig. 7. The relation between electric field intensity and the distance from the screen surface of the 14-inch television in a standby mode is shown in Table 2. The EMF generated when a metal tray was put on the top of the 30-inch television in standby mode was 661.12 mV, and it was 2962.2 mV when the metal tray was touching the CRT surface. EMF by the 14-inch television while a program was being broadcast caused a change in the brightness of the screen. The value was about 60 mV at a distance of 72 cm and about 140 mV at a distance of 24.5 cm.

TABLE 2. INTENSITY AND DISTANCE FROM THE SURFACE OF A 14-INCH TELEVISION.

Electric field intensity (V/m)	Distance from screen surface (cm)
10	72
20	47.5
50	24.5
100	12.5

IV Discussion

For all of the tested pumps, except one, the electric field intensity became larger when the resistance increased. For Pump C, it may be that there was no grounding inside the apparatus, which may be related to the high field intensity measured, irrespective of grounding resistance. This pump does not meet the guidelines of JIS T 0601-1 [9] or IEC 60601-1 [7] that regulate medical equipment safety. Therefore, we have eliminated this pump from the analysis.

The graph in Fig. 5 shows that for three pumps (B, D, and H) the point at which the field intensity begins to rise is earlier than for the others. These three are newer products than the others, and when the resistance is more than 10 kilo ohms, almost the same distortion was observed, as shown in the lower

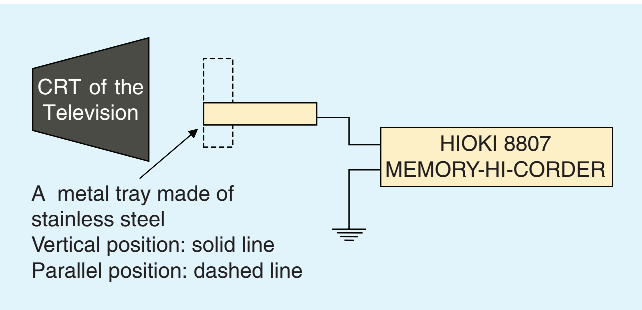

Fig. 4. Block diagram of the EMF measurement.

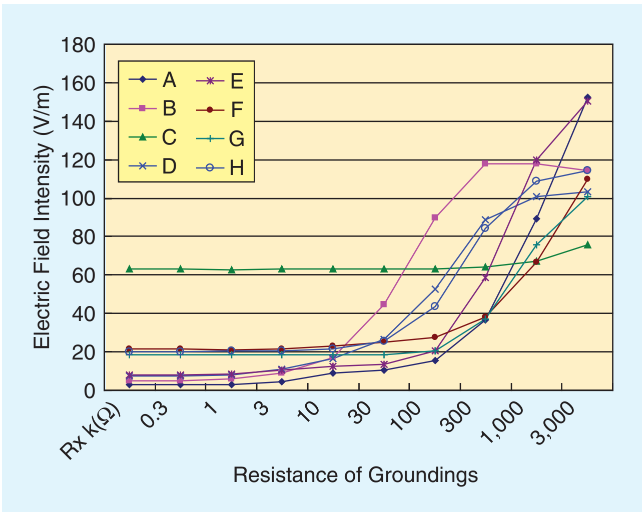

Fig. 5. Grounding resistance and electric field intensity for each pump.

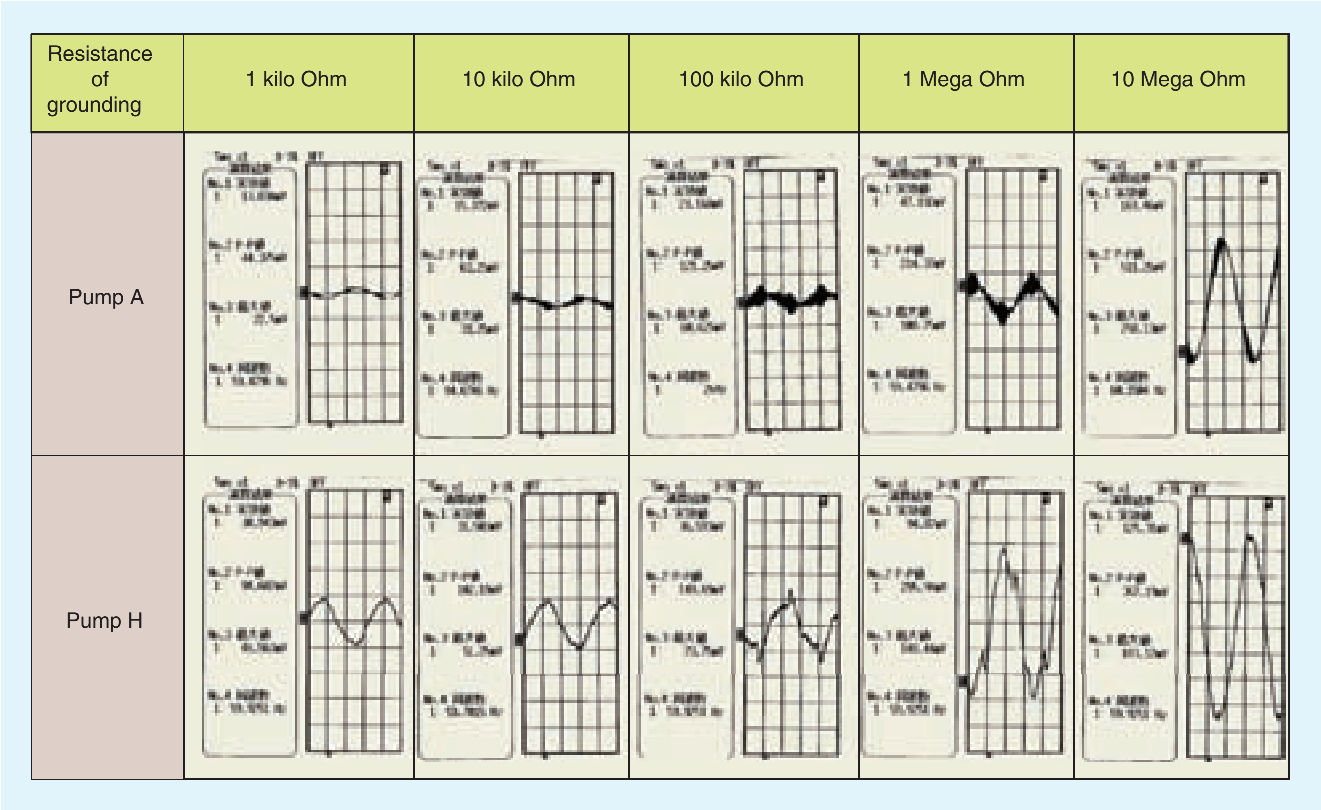

Fig. 6. Observed voltage distortion waveform at each setting of resistance (Subtraction of 60 kHz sine wave from observed voltage waveform).

line of Fig. 6. It is obvious that these distortions are not superposition of a mere high frequency component. A difference in structure or a difference of an element used in the power supply circuit, which is the main source of noise, would be possible causes of the difference in distortion. On the other hand, the field intensity when the resistance was low also differed. Three pumps (F, G, and H) showed high values, whereas the others were low. With the pumps for which the field intensity was high, it is possible that less metal is used than in the others: Less metal means less electric charge. Also, as Fig. 5 shows, even though resistance increased to over the threshold value, the electric field intensity of some pumps did not increase (B, D, etc.). The maximum electric field of these pumps was larger when the front surface of the case was larger. When considering the directivity of the antenna used in this measurement, these phenomena would seem to be related to the influence of the area of the surface of the front of the pump case. However, because none of the pumps could be disassembled, these factors are speculation. These measurement results show that an excessive electric charge, which should have been brought to ground, was collected on the metal parts of the medical devices because of increased resistance of the groundings. At the same time, it was shown that there is a limit to the quantity of electric charge that it can accept.

The EMF generated by the televisions in the standby mode seems to have resulted from the collection of an electric charge on the bottom of the metal tray, which acted as an antenna. Considering the characteristics of flat antennas, this phenomenon can be proven because the EMF observed when the bottom of the metal tray is parallel to the TV CRT is larger than that when the tray is vertical and at every location. Because the

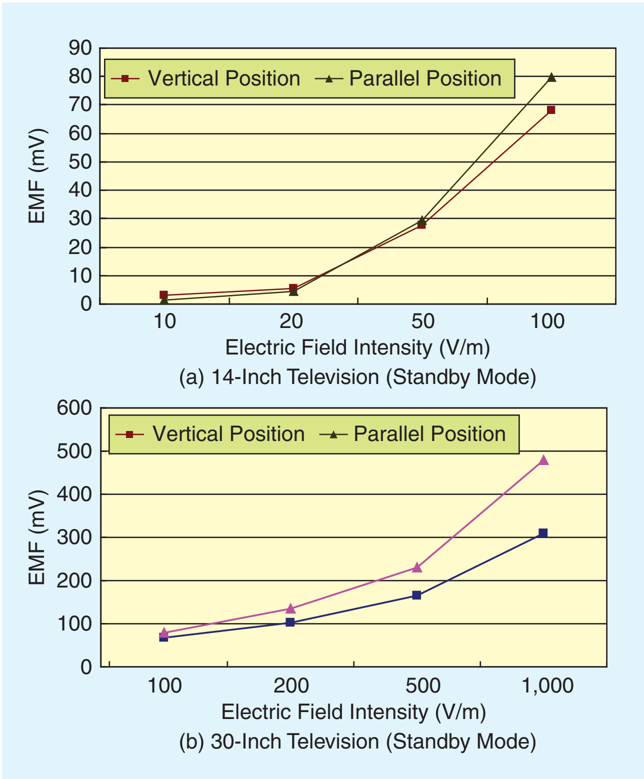

Fig. 7. Electric field intensity and generated EMF (a) 14-inch television (standby mode) (b) 30-inch television (standby mode).

resistance of a human body is considered to be 1 kilo ohm in JIS T1022 [6], the observed EMF means that a maximum current of tens of micro amperes might flow into a person, a value sufficient to cause "shock". The value will become higher if 0.5 kilo ohm is used as a measure of the resistance of human body tissue [10]. The observed EMF induced by an electric field intensity exceeding 150 V/m, as emitted by an incorrectly grounded infusion pump, may also generate a shock when a person touches the neighboring metal.

Grounding is indispensable for the proper use of electric products. However, electric power has long been supplied through a 2P outlet in almost all Japanese houses, except for washing machines and refrigerators. This is also true of hospitals built over 20 years ago. Even though the plug and electric outlet for medical devices are specified in JIS (T 1021) [2], medical device suppliers seem to take insufficient consideration of grounding, for example by attaching or selling a 3P plug conversion adapter for earth grounding. Many medical devices are being used with a power supply that uses a conversion adapter for a 2P outlet, even devices with built-in batteries [3].

If an electric product containing metal is used without grounding, an electric charge will be collected and an electromagnetic field will be emitted. The electromagnetic field emitted is caught by the surrounding metal, which causes the device to collect an electric charge. However, most medical staff members are unaware of this fact. Medical staff members, except for clinical engineers, usually do not have an opportunity to study about the electromagnetic environment surrounding medical devices. The hospital staff, especially any person dealing with medical devices, must consider proper grounding. Grounding should be done for all medical devices used around patients and for any fixtures containing metal that are near a medical device. When two or more groundings are done in the same room, a difference in the collected potentials may arise between the devices and fixtures. Therefore, it is important to install grounding with potential equalization (equipotential grounding) in every hospital room [6]. From our results, the grounding condition of the electric power supply can be estimated by simply measuring electric field intensity at the commercial frequency. In future study we intend to study real grounding conditions to confirm the findings of this study.

V Conclusion

Our experiments showed that medical devices and metal around them collect an electric charge if proper grounding is not done. Also, the electromagnetic field emitted was shown to increase as the state of the grounding worsened. Furthermore, we found that the induced electromagnetic field might induce a micro or macro shock. With these results, it becomes possible to determine the suitability of grounding using a simple field intensity meter.

However, because the inside of the medical devices was not possible to observe, our investigation is not conclusive. Future research into the relationship between grounding and radiated electric fields in the clinical setting with the cooperation of a number of hospitals is necessary.

As far as clinical safety is concerned, the importance of grounding has been known for several decades [5]; however, the importance has been focused on areas such as operating rooms in recent years [4]. It is our hope that clinical safety throughout the hospital can be improved through proper grounding.

Acknowledgement

Part of this research was done in the Shimane University Collaboration Center. It was done in cooperation with ACTIVE MEDICAL Co., Ltd., and Takenaka Corp. It was partially supported by a grant-in-aid from the Japan Society for the Promotion of Science (No.20390151).

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Biographies

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