

Electromagnetic Interferences of Electric Medical Equipment from hand-held radiocommunication Equipment

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Abstract: Electromagnetic interferences (EMI) by cellular phones and PHS terminals were examined in 366 current electric medical equipment (EME) at EMC test sites and 108 units in hospitals.

Cellular phones caused EMI in 66% of EME and PHS terminal caused only 8% of EME. The maximum EMI distance was 400 cm in cellular phones and 65 cm in PHS terminals. The level of interferences were also categorized into six grades from the view point of clinical risks. These experimental results suggested the user's rule of cellular phones and PHS terminals in medical facilities.

1. INTRODUCTION

A report of electromagnetic interference (EMI) between European cellular phones and an electric shaver pump suggested that various electric medical equipments (EME) in hospital might be also interfered from the cellular phone in Japan. We examined the EMI on EME from hand-held radiocommunication, supported by Japanese government. This EMI tests was cooperated with the Japan Federation of Medical Device Associations (JFMDA), NTT Mobile Communication Industry Association of Japan.

2. METHOD AND MATERIALS

(1) The Experiments at EMC test sites

The total number of tested EME was 366 current models. Cellular phones and PHS terminals were the following list.

- (a) Digital cellular phone terminal PDC
800-MHz band 0.8W
- (b) Digital cellular phone terminal PDC
1.5-GHz band 0.8W
- (c) Analog cellular phone terminal NTT
800-MHz band 0.6W

- (d) PHS terminal PHS
1.9-GHz band 80mW

The tests were carried out in anechoic chamber test sites to exclude EMI effects from other RF sources and from public telecommunication systems.

The test procedures were as follows:

a) an electrocardiograph (ECG) and ECG monitor were connected to a patient simulator (battery type) to simulate normal use. Tabletop devices were placed on a wooden table about 80 cm above the floor, and floor-standing devices were placed on the floor.

b) One investigator operated the R-F transmitter, which was controlled to maintain the maximum power output, while another investigator monitored the medical device.

c) The transmitter was gradually brought closer and closer to the medical device. If performance degradation occurred, the transmitter was turned off to check if the performance degradation ceased, and to check whether the degradation was reversible or irreversible.

d) Then, the transmitter was turned on to see if the performance degradation recurred. If it was reproduced, the transmitter was moved away from the medical device until the performance degradation ceased.

e) The effect on the medical device, reversible or irreversible, and the distances were recorded.

f) A cellular phone was switched on and off to produce a transient effect on the medical device at almost the same distances as in the above procedures. If performance degradation occurred, the transmitter was moved away from the medical device until the degradation ceased. Then the effect,

reversible or irreversible, and the distances were recorded.

g) The same procedure as in a-f was repeated with different types of cellular phones and medical devices.

(2) The Experiments in Hospitals

The objective of the tests was to study EMI from radiocommunication equipment on medical devices in the hospital environment. and, to study EMI on older EMI compared to newly developed EME in hospitals.

We performed the same EMC test on 108 models in 4 hospitals.

We checked before the tests to make sure no medical device was being used in adjacent rooms, including the upper and lower floor rooms.

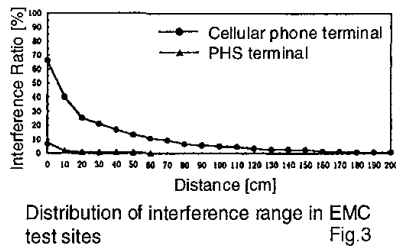
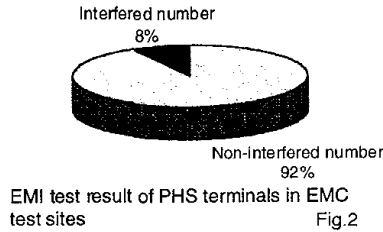
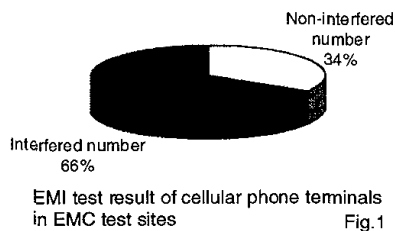
3. RESULTS

(1) Results at EMC test sites

a) Cellular phones with maximum output power from 0.6W to 0.8W caused EMI in 66% of EME. Ninety percent of EME were within a 1-m distance from the cellular phones. (Fig.1 and 3)

b) PHS terminals with a burst output power of 0.08W affected only 8% of EME. Ninety percent of the affected devices were located at a distance of less than 20 cm. (Fig.2 and 3)

c) The performance degradation depends on the nature of the medical device and was both reversible and irreversible.



Typical degradation occurred in the tests as follows:

1) Artifact in images of diagnostic imaging equipment such as ultrasound, X-ray, CT.

2) Noise on the waveform of physiological signals from such devices as an ECG and the patient monitor, and error in the displayed numerical value of the heart rate.

3) Sensor malfunction, alarm activation and cessation of function in such devices as infusion pumps, syringe pumps, ventilators, IABP and dialysis equipment.

4) Change in the operating mode of devices such as external pacemakers, from asynchronous to fixed rate.

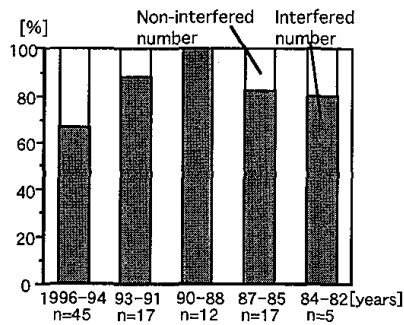
(2) Results in hospitals

a) 53 % (57 of 108) of the medical devices experienced interference from cellular phones. but interference from PHS terminals was only 4 % (4 of 108).

b) The distance range for irreversible interference was within 20 cm for cellular phones and the maximum distance for reversible interference was 150 cm for cellular phones and 60 cm for PHS terminals.

c) The interference ratio (>80%) of old-type medical equipment manufactured before 1993 was rather higher than the ratio

(67%) of equipment manufactured after 1994, as shown in Fig 4. The results show that the immunity level for EMI is being gradually improved by the manufacturers.



EMI occurrence of old medical electric Equipments in hospitals Fig.4

(3) Typical cases

Case 1: ECG in the defibrillator showed a large noise baseline drift, and the ECG monitor showed a noisy signal, indicating an unstable electrode condition.

Case 2: Anesthetic equipment showed a wrong value on the control panel when the cellular phone was moved very close, but the display became normal when the phone was moved away.

Case 3: A ventilator gave off an alarm when the cellular phone was moved near the heating and humidifier system. This alarm system could not be returned to normal until the staff had checked and reset the equipment. However, a patient would normally be safe if the condition did not continue for an extended period.

Case 4: An external cardiac pacemaker did not produce the stimulating pulse when the cellular phone was moved close. This phenomenon was reversible when the cellular phone was moved away.

Case 5: Some syringe pumps were stopped by the alarm when the cellular phone was brought near the syringe holder. This abnormal condition could not be reversed until staff members had reset the equipment. A similar phenomenon occurred in some infusion pumps.

4. DISCUSSION

The number of EMI-tested devices was 474, which was approximately half of the number of newly-approved medical devices per year in Japan. This data quantity seems to correspond to only a small percentage of all the types of medical devices actually used in hospitals. Simultaneously, in our experience, the different EMI hazards were observed in two identical types of equipment that were manufactured in different years. This EMI difference was considered to be caused by the different EMC immunity levels employed by the manufacturer or differences in the maintenance conditions in the hospital.

Because of these differences in EMI, we should understand that the number of our EMI tests was not adequate to completely explain the EMI condition caused by cellular phones, or PHS terminals, in medical devices. This data quantity shall be considered to make a due guideline for the use of cellular phones or PHS terminals in medical facilities.

(1) Categorization of EMI effects and Risk Analysis

Our experimental EMI data included various types of hazard phenomena which could result in various clinical problems. We felt that it was necessary to categorize the clinical problems caused by EMI in medical devices.

From the clinical point of view, the following six categories in table 1 may be considered.

Clinical Risk Level Categories Based on EMI Effects	
	Problem Levels
Table 1	
Category 6	The electronic medical equipment problem is irreversible, and could lead to fatality unless emergency actions are taken.
Category 5	The electronic medical equipment problem is reversible, but could lead to fatality if it continues.
Category 4	The electronic medical equipment problem is irreversible, and leading to wrong diagnosis or treatment. Emergency actions should be taken.
Category 3	The electronic medical equipment problem is reversible, and leading to wrong diagnosis or treatment. Or, in other cases, the problem is irreversible and could cause wrong diagnosis.
Category 2	The electronic medical equipment problem is reversible, and could cause wrong diagnosis.
Category 1	No problem occurs.

Based on the above general concepts of medical device problems and clinical hazards, EMI effects from cellular phones and PHS terminals are classified into the six categories of clinical risk level in Table 1. According to the categorization in Table 1, our experimental case 1, mentioned above, is a typical example of category 2, case 2 is in category 3; case 3 is in category 4, case 4 is in category 5, and case 5 is in category 6. For example, the implant cardiac pacemaker reported by D. L. Hayes, was affected by EMI in a similar way as that in our category 5.

(2) Safe Separation Distance and Limitation of areas of use for cellular phones

From the results of this study, existence of the risk zone within which a cellular phone cannot be used alongside medical devices, as well as the EMI range, have been ascertained. However, considering the clinical risk analysis based on the EMI categorization; the different mechanisms of EMI in individual medical devices; and the limit in the number of tested medical devices (that does not cover all the types of medical devices being used in medical facilities); and the different refraction characteristics of radio waves in each room, we think it is still too early to define the safe operating distance from cellular phones for each type of medical equipment.

On the other hand, it is much more practical to establish limited areas in medical facilities for use of cellular phones, and easier to manage the limited areas compared with setting a safe separation distance for each medical device.

(3) Regarding the use of PHS terminals in medical facilities

Compared with cellular phones of output power 0.6 W to 0.8 W, the possibility of interference by PHS terminals is extremely low, but since the appearance of the current PHS terminals are similar to cellular phones, the public cannot distinguish between PHS terminals and cellular phones; therefore, it is still necessary to limit the use of PHS terminals to avoid unnecessary confusion

within medical facilities.

In the future, if PHS terminals can be more easily distinguished from cellular phones with, for example, special labeling, then they can be used within restricted areas.

5. CONCLUSION

Medical devices are allocated in a hospital, according to the clinical requirement. The allocation places are classified into three areas.

Area A. Operation Rooms, ICUs and CCUs

Area B. Examination rooms and inpatient rooms

Area C. Lobby and Inpatient Rooms

Based upon this allocation of medical devices, the following is the conclusion on the use of cellular phones and PHS terminals in medical facilities.

(1) The use of cellular phones

- a) They must not be brought to the area A.
- b) They must be switched off in and around the area B.
- c) The use of cellular phones may be permitted in area C designated by the medical institution.

(2) The use of PHS terminals

- a) PHS base station to be installed in hospital should have an average output power of less than 160 mW, and the restricted areas should be designated by the medical institution.
- b) PHS terminals of 80 mW burst output power, which are permissible, should be administrated and clearly distinguished from cellular phones and other hand-held radiocommunication equipment by identification stickers, labels, etc.

6. REFERENCE

- 1) I. Baba, H. Furuhashi et al. Experimental study of electromagnetic interference from cellular phones with electronic medical equipment. *Journal of Clinical Engineering*. March/April:122-134, 1998
- 2) D. L. Hayes, P. J. Wang et al. Interference with cardiac pacemakers by cellular telephones. *New England Journal of Medicine*, Vol.336, No.21:1473-79, 1997