IEEE Access
Multidisciplinary ⋮ Rapid Review ⋮ Open Access Journal

Received 12 January 2024, accepted 24 January 2024, date of publication 1 February 2024, date of current version 13 February 2024.

Digital Object Identifier 10.1109/ACCESS.2024.3361028

RESEARCH ARTICLE

Dependency of Waveforms in Intermittent Transmission at Mobile Phone Frequencies on Electromagnetic Interference With Medical Devices

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ABSTRACT This study focuses on the effect of waveforms, i.e., signal length and period in intermittent transmission, on electromagnetic interference (EMI) with medical devices. It was already shown that intermittent transmission with the period of 1 s (500 ms: ON and 500 ms: OFF) tends to cause EMI on medical devices compared to continuous transmission. To evaluate the impact of waveforms on EMI with medical devices, we conducted an experiment at 837.5 MHz and 1950 MHz using five medical devices that yielded the following results. For EMI dissipation, the input power of an antenna simulating mobile phones increased and the separation distance between the antenna and medical device decreased as the signal length became shorter in the case of a signal length of less than 10 ms. On the other hand, the signal period exhibited no specific tendency regarding such power and distance. We confirmed that previous EMI tests, in which we used a radio signal with the length and period of 100 ms in intermittent transmission, were conservative from the viewpoint of waveforms. Results of this investigation indicate that the influence of EMI on medical devices does not depend on the average power but on the burst power. Based on this, EMI characteristics with medical devices for a certain radio system could be estimated based on previous EMI test results for other radio systems if their frequencies are close to each other and their signal specifications are clearly determined.

INDEX TERMS Electromagnetic interference (EMI), medical devices, mobile phones.

I. INTRODUCTION

As mobile communication devices including mobile phones have become widely available in recent years, addressing electromagnetic interference (EMI) issues has become increasingly important. Especially in the medical field, to manage the risk of EMI with medical devices is a requirement for safety. Since the 1990s, EMI with medical devices regarding mobile communications has drawn attention, and has continuously been investigated as mobile phone systems have evolved [1], [2], [3], [4], [5], [6], [7]. Based on such investigations, the immunity of medical devices to electromagnetic waves has gradually improved, and mobile phones can be used under certain conditions in hospitals and medical institutions. Several years ago, Mariappan et al. pointed out that the risk of problems is clearly very low in

The associate editor coordinating the review of this manuscript and approving it for publication was Mehmet Alper Uslu.

a review regarding such EMI based on 2nd/3rd/4th Generation (2G/3G/4G) mobile phones [8], and Wiinberg et al. reported that such risk is lower than generally feared based on a questionnaire to Swedish hospitals [9]. However, it has also been shown in such papers that the EMI with medical devices might occur if mobile phones and medical devices are very close to each other. This is because the electric field strength in the vicinity of the mobile phone might be greater than the immunity electric field strength required by the EMI standards applied to medical devices, for example the latest edition of the International Electrotechnical Commission (IEC) 60601-1-2 [10]. In addition, a recommended practice by American National Standards Institute (ANSI) to provide an ad hoc test method to estimate the electromagnetic immunity of medical devices determined a minimum separation distance of approximately 25 cm [11]. However, mobile phones could get closer to medical devices than such distance. Mobile communications will be used more often in healthcare environments for not only voice and video calls on mobile phones but also for applications such as telemedicine, home medical care, remote surgery. In addition, the number of mobile phone contracts in 2022 was approximately 11 times what it was in 2000 according to the World Bank statistics [12]. Considering such situations, the probability of mobile communication devices used in close proximity to medical devices will increase and investigations on EMI with medical devices regarding mobile communication devices remain extremely important.

Our research group has investigated such EMI regarding radio waves transmitted from mobile phones including Wideband Code Division Multiple Access (W-CDMA), High Speed Uplink Packet Access (HSUPA), and Long-Term Evolution (LTE) with multiple frequency bands [13], [14]. New Radio access technology (NR), which is used in the 5th Generation (5G) mobile phones, and Wireless Local Area Networks (WLANs) were also included in such radio waves, and in total 116 medical devices have been investigated using at least one type of radio wave described above. One feature in these studies was that the transmission of radio waves was not only continuous but also intermittent with the period of 1 s (500 ms: ON and 500 ms: OFF). In preceding research, compared to continuous transmission, intermittent transmission caused higher levels of EMI [15], and this finding was reproduced in subsequent studies [13], [14]. According to [13], 32 medical devices were used in EMI tests, of which the number of units with EMI and the maximum separation distances for EMI dissipation were 7 cm and 28 cm in continuous transmission, respectively. On the other hand, in intermittent transmission, they were 12 cm and 80 cm, respectively. This means that the EMI with medical devices occurs even with continuous transmission, and intermittent transmission has an additional impact on EMI through a specific mechanism. Modern radio systems represented by mobile phone systems transmit radio waves intermittently, and the latest edition of IEC 60601-1-2 [10] includes EMI tests with a signal modulated using a 50 % duty cycle square wave between 710 MHz and 5.785 GHz considering such technological advancement. Additional findings in [13] were that the difference in the peak-to-average power ratio (PAPR) did not have a significant effect and that the EMI strongly depended on the transmission power.

This paper focuses on the waveform of radio waves suitable for such EMI evaluation in intermittent transmission to predict EMI and reduce the waveform parameters. For example, studies with a similar purpose were conducted using avionic systems [16], [17]. A recent Food and Drug Administration (FDA) guidance expressed concerns due to the risk from EMI based on commonly available radio communication system specifications [18], and this investigation will address such concerns. Among the waveform parameters, we specifically focused on the time profile for transmission because periodic repetition in transmission may increase the impact of EMI on medical devices as described above. From another viewpoint, previous studies have assumed a situation in which the maximum amounts of time and frequency resources were allocated to one mobile phone. However, in a real environment, not all resources are necessarily allocated in this way. As part of simulating various ways of transmitting radio waves from mobile phones, the signal length and period of the waveform are varied over 500 ms. By addressing this issue, we can approach the optimal waveform for EMI tests on medical devices and confirm whether the results of our previous EMI tests were conservative or not. We focused on the 800-MHz and 2-GHz bands because such frequencies will continue to be used for mobile phone systems to provide sufficient coverage. In addition, since a great deal of reference data for such frequencies has been published, it is possible to increase the reliability of comparisons and discussions with the present results in this paper.

II. MATERIALS AND METHODS

A. TESTED MEDICAL DEVICES

Based on the results in [13] and [14] that EMI occurred in 12 of 32 medical devices in intermittent transmission, we selected medical devices from those previously tested and confirmed EMI results with clinically important interference, or the successors to such medical devices. The devices were an electrocardiograph, a nerve stimulator, a flowmeter, and two extracorporeal cardiac pacemakers (labeled A to E, respectively), which were different types of medical devices. They conformed to electromagnetic compatibility (EMC) standard IEC 60601-1-2: 2001 [19] or later. Therefore, the immunity level in electric field strength was approximately 10 V/m to 30 V/m. On the other hand, the near field strength of mobile phones could exceed 100 V/m when the transmission power is at maximum, and such conditions were simulated in our previous studies. Therefore, the EMI with medical devices was quite reasonable. The medical devices under test were set under normal operating conditions with appropriate simulators, if necessary.

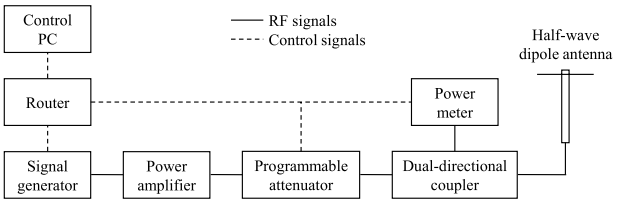

FIGURE 1. Block diagram of EMI evaluation system.

TABLE 1. Parameters of signals used in EMI tests.

	800 MHz band	2 GHz band
Center frequency	837.5 MHz	1950 MHz
Bandwidth	15 MHz	20 MHz
Radio access method	Single Carrier Frequency Division Multiple Access (SC-FDMA)	
Duplexing	Frequency Division Duplex (FDD)	
Modulation	64QAM	

B. TEST PROCEDURE

In the EMI evaluation on medical devices from radio waves transmitted from mobile phones, it is important to consider that the electric circuits of the medical devices and mobile phone antennas can become directly coupled in a near electromagnetic field. Therefore, the test procedure in this study refers to two near-field evaluation methods. One is the method used by the Electromagnetic Compatibility Conference Japan [20] and the Ministry of Internal Affairs and Communication in Japan [21], and the other method is determined by ANSI [11].

EMI tests were conducted in a shield tent in which radio wave absorbers were placed on each side and the ceiling. The space for testing was at least 2 m in length, width, and height. Fig. 1 illustrates a schematic diagram of the employed EMI evaluation system. LTE signals with adjusted signal length and signal period, which are described later, were generated using a signal generator (N5172B, Keysight Technologies) and amplified using a power amplifier (AMP2098, Exodus Advanced Communications) to an arbitrary power level. A programmable attenuator (J7211B, Keysight Technologies) was used to achieve intermittent transmission with a period of 1 s (500 ms: ON and 500 ms: OFF). Center frequencies for such signals were 837.5 MHz and 1950 MHz. Table 1 summarizes the signal parameters in detail. Half-wave dipole antennas (MA5612 series, Anritsu) adjusted for the test frequency were used to scan on each surface of the medical device. While scanning, the direction of the antenna element was set both perpendicular and parallel to the long side of each face of the medical device. Transmission power was monitored using a dual-directional coupler (Model 500520020, Krytar) and a power meter (NRP2, Rohde&Schwarz) during the EMI tests. When EMI appeared with the maximum burst transmission power, i.e., 23 dBm for the antenna input power, the following two kinds of evaluations were conducted. Fig. 2 illustrates the procedure for the EMI test on the medical devices.

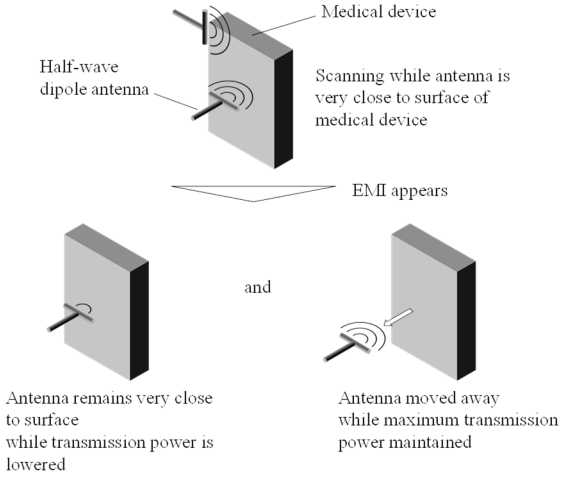

FIGURE 2. Procedure of EMI test on medical devices.

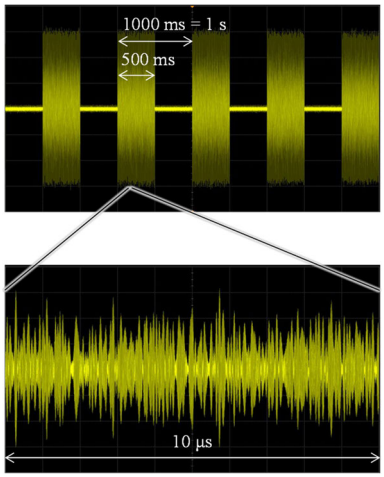

FIGURE 3. Example of measured waveforms of intermittent transmission for LTE at 1950 MHz.

- Transmission power for EMI dissipation: The transmission power was lowered step by step until the EMI dissipated while the antenna was still very close (less than 5 mm) to the surface of the medical device.
- Separation distance for EMI dissipation: The antenna was moved away from the surface of the medical device to clarify the antenna separation distance at which the EMI dissipated while the burst transmission power remained at maximum, i.e., 23 dBm.

If EMI evaluations associated with new radio technology for medical devices are conducted, the measuring instruments described above should be replaced appropriately.

C. TRANSMISSION WAVEFORMS

Fig. 3 shows an example of the measured waveform of intermittent transmission for LTE at 1950 MHz. From a macro perspective, it appears as a square wave with a frequency of 1 Hz. On the other hand, it is purely an LTE uplink signal with a frequency of 1950 MHz in 500-ms bursts from a micro

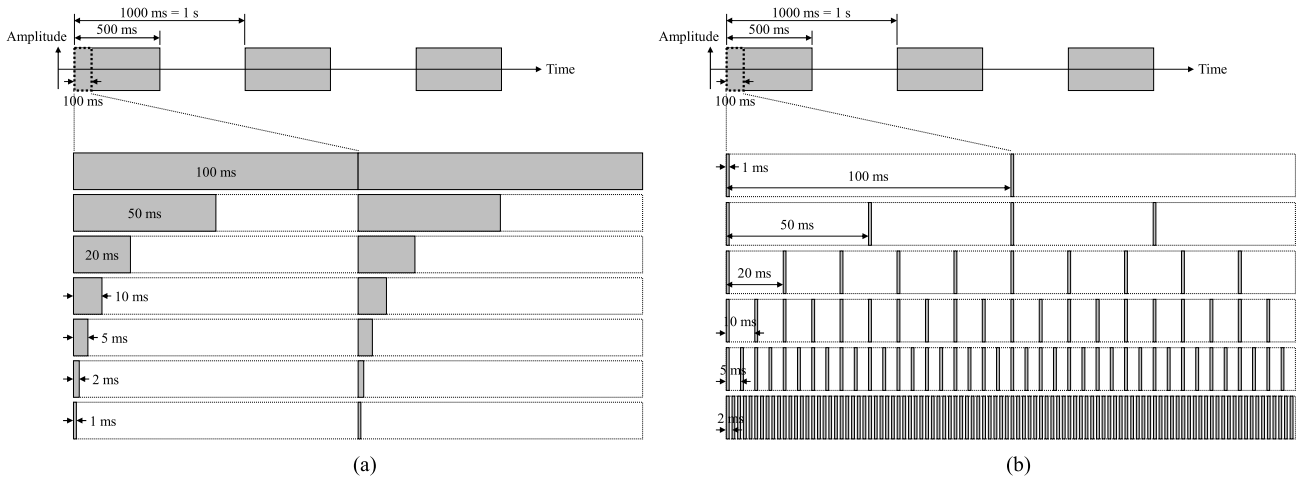

FIGURE 4. Waveforms used for EMI tests: (a) Varied signal length, (b) Varied signal period.

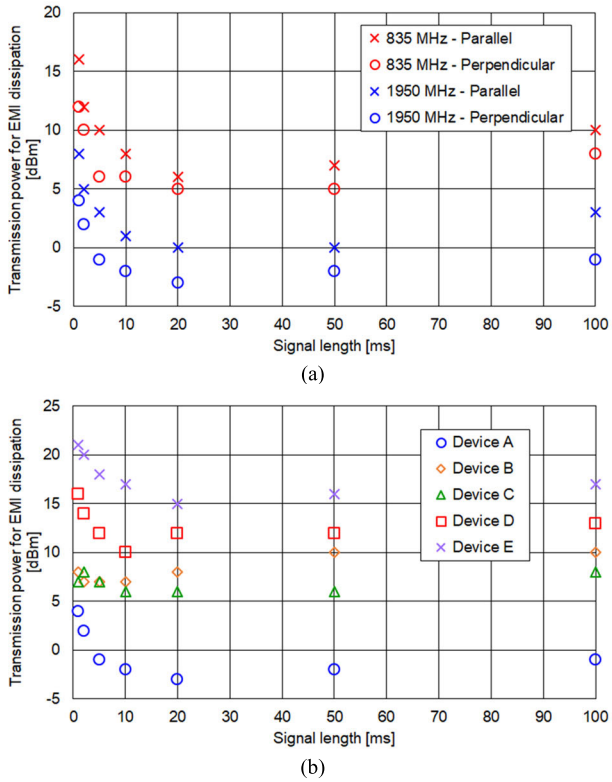

FIGURE 5. Transmission power characteristics for EMI dissipation as a function of signal length: (a) Medical device A, (b) Five medical devices.

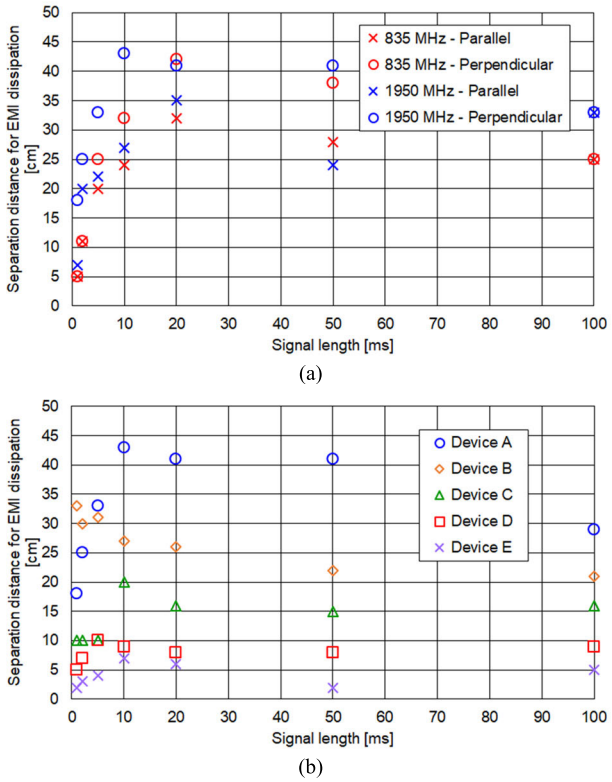

FIGURE 6. Separation distance characteristics for EMI dissipation as a function of signal length: (a) Medical device A, (b) Five medical devices.

perspective. In this study, the signal length and period were varied during such 500-ms bursts. They can be actualized by properly specifying the parameters of the resource blocks in LTE signals using the signal generator described above and dedicated software (Signal Studio, Keysight Technologies).

1) SIGNAL LENGTH

During a 500-ms burst, the signal length was varied from 100 ms to 1 ms, which correspond to 10 times and one-tenth of the LTE radio frame length of 10 ms, respectively, while the period was fixed to 100 ms. Fig. 4(a) illustrates the time profile regarding the signal length.

2) SIGNAL PERIOD

During a 500-ms burst, the signal period was varied from 100 ms to 2 ms while the signal length was fixed to 1 ms, which corresponds to the length of the LTE subframe.

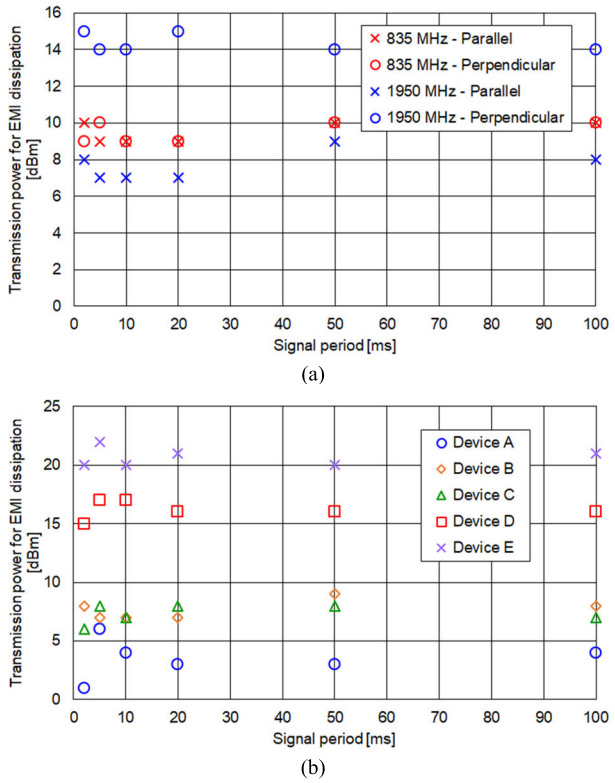

FIGURE 7. Transmission power characteristics for EMI dissipation as a function of signal period: (a) Medical device B, (b) Five medical devices.

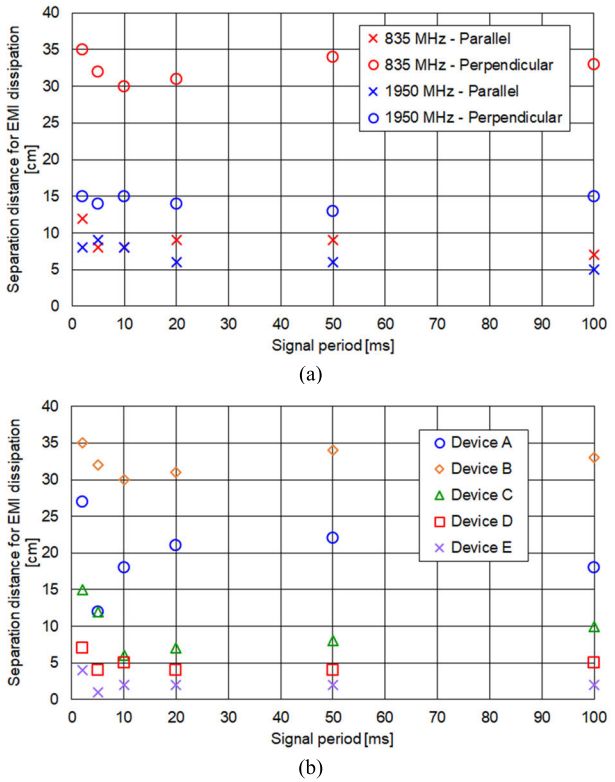

FIGURE 8. Separation distance characteristics for EMI dissipation as a function of signal period: (a) Medical device B, (b) Five medical devices.

Fig. 4(b) illustrates the time profile regarding the signal period.

D. ASSESSMENT OF EMI

When EMI appeared on the medical device, clinical engineers at the Kanazawa University Hospital confirmed the type of interference such as waveform distortion and change in displayed value. They also estimated the impact of such interference on medical interventions.

III. RESULTS

A. SIGNAL LENGTH

Fig. 5(a) shows the transmission power characteristics for EMI dissipation as a function of the signal length for medical device A at 837.5 MHz and 1950 MHz while the antenna was still very close (less than 5 mm) to the surface of the medical device and the antenna orientation was changed. Focusing on the signal length, no significant difference was observed in the transmission power for EMI dissipation from 100 ms to 20 ms for the same frequency and antenna orientation. However, in the case of a signal length of less than 10 ms, the power increased as the signal length became shorter. For five medical devices, such characteristics are summarized in Fig. 5(b). In this figure, for each medical device, the frequency and antenna orientation are selected in which the minimum transmission power for EMI dissipation was obtained. A tendency similar to that described above can also be seen in Fig. 5(b).

Fig. 6(a) shows the separation distance characteristics for EMI dissipation as a function of the signal length for medical device A at 837.5 MHz and 1950 MHz while the transmission power was set to the maximum and the antenna orientation was changed. Focusing on the signal period, no significant difference was observed in the separation distance for EMI dissipation from 100 ms to 20 ms for the same frequency and antenna orientation. However, in the case of a signal length of less than 10 ms, the distance decreased as the signal period became shorter. For five medical devices, such characteristics are summarized in Fig. 6(b). In this figure, for each medical device, the frequency and antenna orientation are selected in which the maximum separation distance for EMI dissipation was obtained. A tendency similar to that described above can also be seen for four medical devices in Fig. 6(b). Medical device B has an opposite tendency, and the reason for this is assumed to be the difference in the coupling between the antenna and medical device.

B. SIGNAL PERIOD

Fig. 7(a) shows the transmission power characteristics for EMI dissipation as a function of the signal period for medical device B at 837.5 MHz and 1950 MHz while the antenna was still very close (less than 5 mm) to the surface of the medical device and the antenna orientation was changed. Focusing on the signal period, the transmission power for EMI dissipation exhibited no remarkable tendency from 100 ms to 2 ms for

TABLE 2. Details of EMI with medical devices and conditions of the frequency and antenna orientation when EMI to medical devices occurred with the minimum transmission power for EMI dissipation.

Medical device	EMI details	Frequency and antenna orientation in figures.	
		Figs. 5(b), 7(b)	Figs. 6(b), 8(b)
(A) Electrocardiograph	Waveform distortion, Change in displayed value	1950 MHz Perpendicular	1950 MHz Perpendicular
(B) Nerve stimulator	Waveform distortion	1950 MHz Parallel	835 MHz Perpendicular
(C) Flowmeter	Change in displayed value	1950 MHz Parallel	835 MHz Perpendicular
(D) Extracorporeal cardiac pacemaker 1	Pacing pulse disabled (Oversensing)	1950 MHz Perpendicular	1950 MHz Perpendicular
(E) Extracorporeal cardiac pacemaker 2	Pacing pulse disabled (Oversensing)	835 MHz Parallel	835 MHz Parallel

the same frequency and antenna orientation. For five medical devices, such characteristics are summarized in Fig. 7(b). In this figure, for each medical device, the frequency and antenna orientation are selected in which the minimum transmission power for EMI dissipation was obtained. Although the characteristics are different for each medical device, no remarkable tendency is observed in Fig. 7(b).

Fig. 8(a) shows the separation distance characteristics for EMI dissipation as a function of the signal period for medical device B at 837.5 MHz and 1950 MHz while the transmission power was set to the maximum and the antenna orientation was changed. Focusing on the signal period, the separation distance for EMI dissipation exhibited no remarkable tendency from 100 ms to 2 ms for the same frequency and antenna orientation. For five medical devices, such characteristics are summarized in Fig. 8(b). In this figure, for each medical device, the frequency and antenna orientation are selected in which the maximum separation distance for EMI dissipation was obtained. Although the characteristics are different for each medical device, no remarkable tendency is observed in Fig. 8(b).

The specific details of EMI with medical devices are given in Table 2. Regardless of the signal length and signal period, no difference emerged in the EMI details for each medical device. Table 2 also summarizes the conditions of the frequency and antenna orientation when EMI with medical devices occurred with the minimum transmission power for EMI dissipation, i.e., conditions for each plot in Figs. 5(b) and 6(b). These conditions are also common to each plot in Figs. 7(b) and 8(b), respectively. Because of the inconsistency in such conditions, it can be concluded that there is no specific tendency for EMI to occur more easily at which frequency or which antenna orientation.

IV. DISCUSSION

Previous research indicates that sensors attached to medical devices seem to be susceptible to EMI and it is recommended that such parts be included in the EMI tests [11]. To amplify weak vital signals obtained using such sensors, op-amps are commonly employed. In the case that a radiofrequency (RF) signal has a frequency spectrum outside the operating band of the op-amp, the direct current (DC) input offset voltage can fluctuate and rectification characteristics of diodes in the op-amp could be responsible for this phenomenon. Capacitance and conductance of the assumed distributed parameter line are not negligible, and they could work as a low pass filter.

Apart from such circuit characteristics, the RF signal waveform must be considered when burst signals are periodically transmitted. For example, mobile phones of the Global System for Mobile Communications (GSM), which is a mobile phone system based on Time Division Multiple Access (TDMA) with a typical signal period of 4.6 ms, cause magnetic fields at 217 Hz (= 1/4.6 ms) [22], [23]. To investigate the frequency components and their amplitude in this study, the Fourier transformation was applied to the waveforms used in the EMI tests. The following techniques and interpretations are commonly applicable regardless of waveform and frequency.

Fig. 9(a) shows the results of the Fourier transformation applied to three signals used for the signal length test up to 500 Hz. In a 500-ms burst, the signal lengths were 100 ms, 10 ms, and 1 ms while the period was fixed to 100 ms. The amplitudes were normalized to the maximum value when the signal length and period were both 100 ms. For the signal length of 100 ms, i.e., the signal was continuous in the 500-ms burst, frequency components were distributed in the lowest frequency range. For the signal length of 1 ms, there were no dominant frequency components, and the components were distributed over a wide frequency range. Fig. 9(b) shows the cumulative ratios of the frequency components. They are normalized so that the cumulative ratio at 500 Hz is 1 for the signal length and period of 100 ms and 10 ms, respectively. Such a cumulative ratio is used, for example, in [24], and the number of components that pass through the filter can be easily understood. The cumulative ratios for the signal lengths of 100 ms and 10 ms are approximately 2 to 7 times higher than that for the signal length of 1 ms up to 500 Hz. Assuming that some parts of the electric circuits in medical devices work if it were low-pass filters with a cut-off frequency of approximately 100 Hz, over 60 % of the components remain when the signal length is 100 ms and 10 ms. However, for the signal length of 1 ms, only 10 % of the components remain. This is a reasonable explanation why the transmission power and separation distance for EMI dissipation are respectively increased and decreased for a signal length of less than 10 ms. It is known that the main frequencies of electromyograms and electroencephalograms are at most a few hundred and a few dozen hertz, respectively, and the assumption of a cut-off frequency of approximately 100 Hz seems quite reasonable.

The results of Fourier transformation and the cumulative ratio of the three signals used for the signal period test up

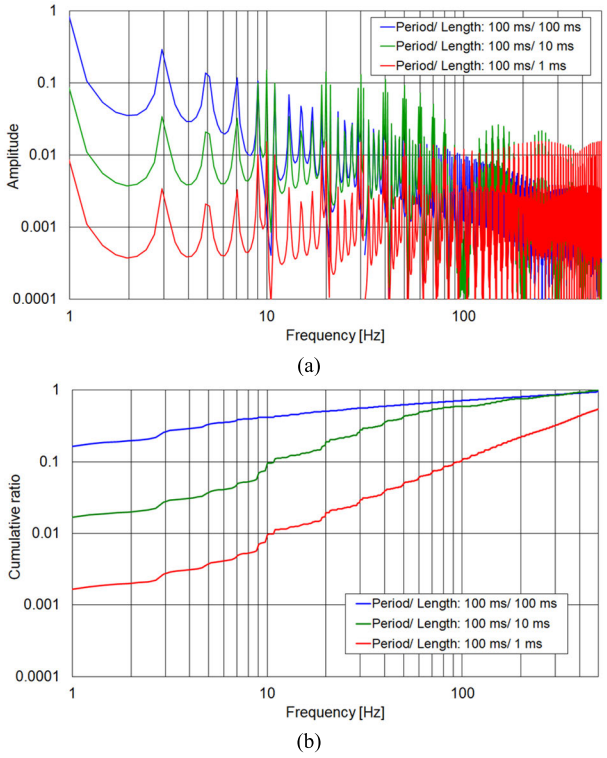

FIGURE 9. Frequency characteristics of waveforms used in EMI tests after Fourier transformation when the signal length is varied: (a) Spectrum (amplitude is normalized to the maximum value when the signal length and period are 100 ms), (b) Cumulative (ratio is normalized to the maximum value when the signal length and period are respectively 100 ms and 10 ms).

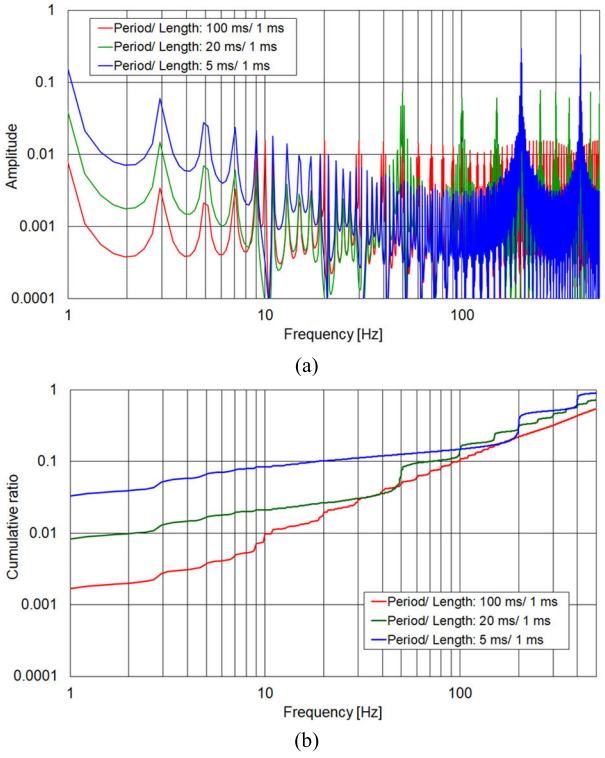

FIGURE 10. Frequency characteristics of waveforms used in EMI tests after Fourier transformation when the signal period is varied: (a) Spectrum (amplitude is normalized to the maximum value when the signal length and period are 100 ms), (b) Cumulative (ratio is normalized to the maximum value when the signal length and period are respectively 100 ms and 10 ms).

to 500 Hz are shown in Figs. 10(a) and 10(b), respectively. In a 500-ms burst, the signal periods were 100 ms, 20 ms, and 5 ms while the length was fixed to 1 ms. The amplitudes were normalized to the maximum value when the signal length and period were both 100 ms, and the cumulative ratios were normalized to the case that the signal length and period were 100 ms and 10 ms, respectively. In all cases, there were no dominant frequency components and the components distributed over a wide frequency range. Assuming that some parts of the electric circuits in medical devices work as they were low-pass filters with a cut-off frequency of approximately 100 Hz, 10% to 15% of the components remain. This is a reasonable explanation why the transmission power and separation distance for EMI dissipation are almost unchanged for the signal period.

In this investigation, there was a 50-fold difference in average power when the signal period was varied from 100 ms to 2 ms. However, the EMI with medical devices was almost equivalent regardless of the average power. Therefore, the burst power is the dominant factor rather than the average power. Here, it is required that low frequency components such as 100 Hz or less are so small that they can be ignored. Based on this, EMI characteristics on medical devices for a certain radio system could be estimated based on previous EMI test results for other radio systems if their frequencies are close to each other and the signal specifications are clearly determined. This concept can be explained using the Personal Handy-phone System (PHS), a 1.9 GHz-band TDMA-based radio system, as an example [25]. There is a national consensus in Japan that PHS has negligible EMI impact on medical devices and the use of PHS is safe because of its low power. PHS has often been used within medical facilities without any concern or report raised from healthcare facilities for more than 10 years in Japan. Based on this fact, we used PHS as a reference safe radio system for medical devices in a healthcare setting. PHS terminals transmit radio waves in bursts with a signal period of 5 ms and a signal length of 0.625 ms, in which the peak radiated power is 80 mW. This period produces a frequency component of 200 Hz (= 1/5 ms). Assuming that some parts of the electric circuits in medical devices work as if they were low-pass filters as described above, such frequency component is negligible, and we can focus solely on the burst power. Therefore, EMI effects on medical devices by PHS terminals are comparable to those by mobile phones for LTE if the output power is limited to 80 mW by some means. Takao et al. [26] showed data supporting this consideration. According to Figs. 3 and 4 in [26], PHS terminals tend to cause less EMI compared to LTE, HSUPA, and W-CDMA mobile phones in the 2-GHz band with the fixed radiated power of 200 mW or 250 mW. However, compared to such mobile phones with the fixed radiated power of 10 mW, PHS terminals tend to cause

more EMI. Therefore, there is no contradiction in presuming that EMI on medical devices caused by LTE, HSUPA, and W-CDMA mobile phones with the fixed radiated power of 80 mW and PHS terminals are comparable. Under such a power limitation on LTE mobile phones in the 2-GHz band, EMI test data for PHS terminals, which are described in [27] for example, can be used to predict EMI with medical devices.

V. CONCLUSION

Focusing on the effect of waveforms in intermittent transmission used for EMI tests on medical devices, we investigated the transmission power and the separation distance for EMI dissipation regarding medical devices while the signal length and period are varied. For a signal length of less than 10 ms, the power increased and distance decreased as the signal length became shorter. However, the signal period exhibited no specific tendency regarding the power and distance. We confirmed that our previous EMI tests, in which we used a radio signal with the length and period of 100 ms, were conservative from the viewpoint of waveforms.

In addition, the results of EMI evaluation on medical devices we tested showed that the EMI effect did not depend on the average power but on the burst power. Based on this, EMI characteristics with medical devices for a certain radio system could be estimated based on previous EMI test results for other radio systems if their frequencies are close to each other and the signal specifications are clearly determined.

Future work includes analysis of detailed mechanisms of EMI with medical devices.

ACKNOWLEDGMENT

The authors greatly appreciate the help and support in preparing the medical devices and determining the occurrence of EMI provided by the clinical engineers at Kanazawa University Hospital.

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