Research on Key Projects of Electromagnetic Compatibility Field Testing for Large Medical Robot

Mingjian Zhu[1,2], Chengke Zhu[1,2], Qingyu Li[1,2], Shu Yang[1,2], Shuyi Zhang[1,2], Mei Wang[1,2], Deyu Li[1,2], Meili Liu[1,2], Meng Liu[1,2*]

[1] Shandong Institute of Medical Device and Pharmaceutical Packaging Inspection, Jinan 250101, Shandong, China

[2] NMPA Key Laboratory for Quality Evaluation of Medical Materials and Biological Protective Devices, Jinan 250101, Shandong, China

[*] Corresponding author

DOI: 10.32629/jcmr.v5i3.2634

Abstract: The present study aims to investigate the electromagnetic compatibility testing method for large medical robots. This paper explores the operational mode and fundamental performance of large medical robots in electromagnetic compatibility testing, based on the working principle and structural composition of a sampling robot. Furthermore, it focuses on analyzing the field detection methods for radiation emission test and radiation immunity test of large medical robots. Ultimately, this research provides valuable insights for conducting electromagnetic compatibility field tests on large medical robots.

***Keywords*:** large medical robot, electromagnetic compatibility, field test, radiated emission test , radiated RF electromagnetic field immunity test

1. Introduction

In recent years, with the rapid advancement of artificial intelligence and the deepening application in various fields, the medical industry has also witnessed significant attention towards its development[1-3]. As a result, related industries and clusters have experienced rapid growth, leading to a substantial increase in research and development as well as listing of numerous medical robots[4-7]. Currently, these medical robots can be categorized into four main types: surgical robots, rehabilitation robots, auxiliary robots, and medical service robots. Due to variations in their intended functions, mechanical structures, and electrical components; their corresponding electromagnetic compatibility requirements also differ accordingly[8]. For certain high-demanding installation conditions or situations where additional auxiliary devices are necessary for operation or when standard laboratory sites fail to meet the bearing and movement requirements; field tests should be considered during electromagnetic compatibility testing.

2. Operating mode and essential performance

The operating mode of a medical robot is divided into launch test and immunity test. For the launch test, the medical robot should be tested within the range of normal parameters required by the manufacturer's specifications to generate maximum disturbance[9]. It is generally necessary to consider testing under maximum stroke and power conditions, meaning continuous motion at maximum speed according to the designed maximum stroke or path, while also taking into account the impact of load state on test results[10]. For immunity testing, based on the operation mode used in the launch test, it is also necessary to consider potential unexpected actions of the medical robot due to interference signals in static states. Additionally, custom modes need to be developed for different types of medical robots. For example, if a medical robot operates using batteries, tests should be conducted with independent battery power supply as well as during battery charging mode. Medical robots equipped with data transmission capabilities or clinical functions such as diagnosis and treatment, rehabilitation, nursing etc., their specific clinical functions should have taken into consideration during testing whenever possible.

Regarding essential performance evaluation for medical robots, manufacturers typically obtain this information through risk analysis based on specific characteristics including process design, materials, mechanics, electronics etc., related to each individual robot model developed and produced. When conducting electromagnetic compatibility tests related to basic performance evaluation, it is important to consider these aspects under conditions that eliminate single faults. Taking a sampling robot as an example, its structure consists of a collaborative robot (including force control module and vision module), opening and closing cover module, swab unpacking module, swab cutting module, negative pressure module, disinfection module and management software. The structure diagram is shown in Figure 1. Combined with the intended

use and structure of the product, the essential performance should focus on the smooth completion of the sampling action.

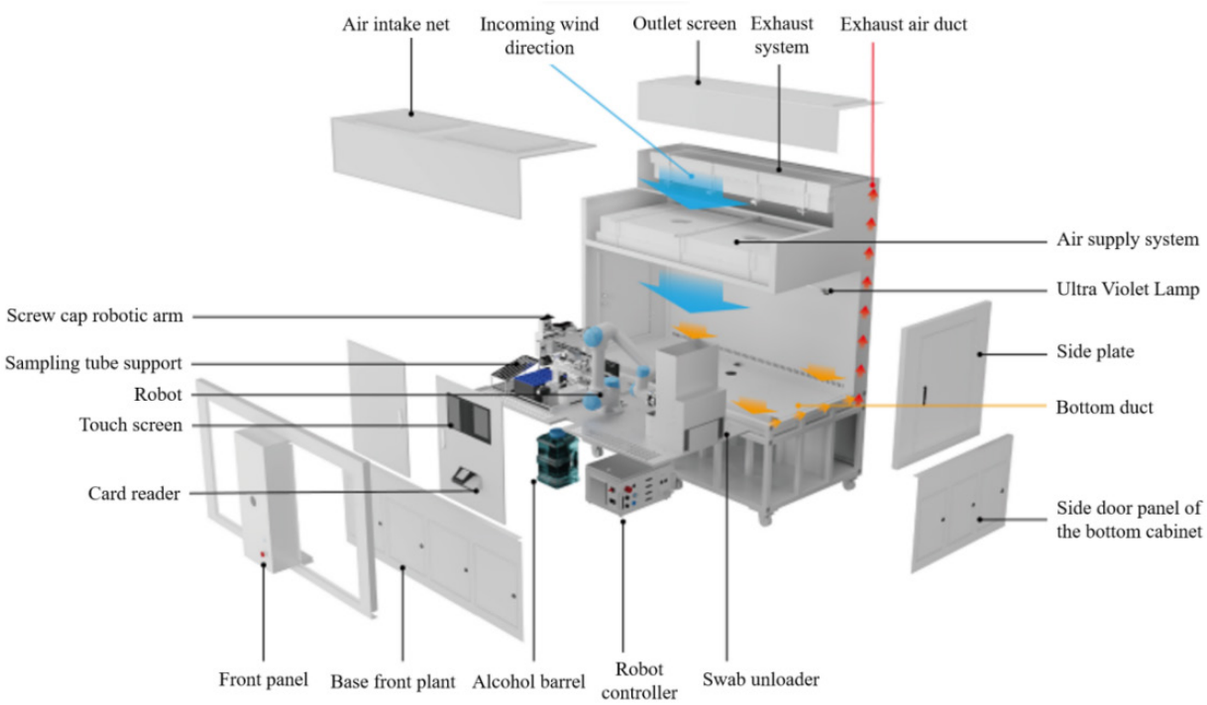

Figure 1. Product structure diagram of a sampling robot

3. Test site

In compliance with the requirements of IEC60601-1-2, type tests for medical electrical equipment or medical electrical systems that cannot be accommodated within a 2m × 2m × 2.5m space (excluding cables but including distributed ME systems) may be conducted at test sites conforming to CISPR11 standards, located at the typical responsible party and operator's premises. These sites are typically categorized as either manufacturer-designated installation locations such as workshops or inside plants, or final equipment installation sites like hospitals or nursing homes. Figure 1 illustrates an example of a robot test site. Unlike standard test environments such as open fields and an-echoic chambers, these sites significantly influence the test results due to factors like background noise, ground impedance, and metal reflections. Therefore, it is essential to mitigate these specific influencing factors during testing in order to enhance accuracy.

Figure 2. Test site of a sampling robot

4. Radiated emission test

For the radiated emission test, due to the non-standard testing sites, the measuring equipment such as test antennas and receivers directly receive disturbance signals generated by transmitters, communication equipment, and power systems surrounding the test site. This leads to a significantly high and uncontrolled ambient noise level during the overall test. Additionally, according to CISPR11 standard's field test method, the measurement distance is set at 30m from external buildings. The corresponding group A limit requirements are 30dBμV and 37dBμV at a boundary frequency point of 230MHz. The main challenge posed by this testing method is that due to the long measurement distance, it becomes difficult to distinguish between the disturbance signal emitted by the medical robot itself after spatial attenuation and shielding of buildings from background noise. Consequently, this poses difficulties in accurately interpreting the test results. To mitigate unexpected signals' impact on test results during actual testing processes, certain measures can be implemented for suppressing or screening disturbance signals of medical robots.

4.1 Utilize CMAD (Common Mode Absorption Device)

For no more than three cables leaving the test area, employ one CMAD for each cable (including power cables, signal cables, and communication cables) that exits the testing area. This helps reduce external cable interference on radiation emission measurements.

4.2 Utilize a near-field probe with a 3-meter range to analyze the disturbance signal

The near-field probe can be employed to scan the medical robot's shell (focusing on gaps, metal protrusions, cables, and interfaces), comparing the disturbance levels when it is turned on and off. It records the frequency center or frequency band of high emission levels emitted by the medical robot itself and their corresponding emission directions. A linear polarized antenna is used for far-field scanning of the medical robot at a test distance of 3 meters. By moving the antenna, full coverage of its 3dB lobe angle is achieved. The scanning process with the near-field probe focuses on sensitive frequencies and radiation directions to obtain both disturbance frequency bands and emission directions corresponding to higher emission levels in the far-field emissions from the medical robot at a distance of 3 meters. Finally, during the 30-meter far-field test, screening of signals from within a tested spectrum can be conducted after testing in maximum emission direction obtained at a 3-meter test distance. This allows for comparison with standard limit values to ensure no omissions in test results while greatly reducing workload associated with useful signal screening due to complex environmental noise.

4.3 Antenna pitch mode is employed to ensure complete coverage of the antenna lobe

Given that the equipment is installed in non-standard test sites like hospitals and factories, where the installation floor may vary, it becomes necessary to consider adjusting the antenna pitch for medical robots with elevated installation floors during a 30-meter radiation emission test. This adjustment ensures that the 3dB lobe angle of the antenna adequately covers the entire machine being tested.

4.4 Broadcast communication signal screening

By conducting a thorough search of the test site and referring to regulatory documents from organizations such as the International Telecommunication Union (ITU) and radio spectrum division guidelines, combined with utilizing modulation and demodulation functions on a test receiver, it becomes possible to screen and record local broadcast communication signals, mobile phone communication signals, radio service signals, satellite communication signals, etc., at the test site. These recorded signals are then treated as environmental noise levels. If these levels exceed standard limits, they are not considered acceptable.

4.5 Staggered time for testing

In situations where environmental noise is complex or high in level or when there is frequency band overlap with normal transmission frequencies used by medical robots, error time testing can be selected. This means conducting tests during periods when surrounding factories are not operational or when transmitters are silent. Such measures aim to enhance accuracy during testing procedures.

Through the aforementioned measures, the impact of environmental noise levels can be mitigated or useful signals can be filtered out, thereby enabling the acquisition of final test results for medical robot radiation emission field tests through spectrum comparison in both operational and shutdown states. As depicted in Figure 3, far-field testing of radiation emission from a sampling robot is conducted during nighttime to minimize the influence of environmental noise.

Figure 3. Far-field test of sampling robot radiation emission test

5. Radiated RF electromagnetic field immunity test

When conducting field tests for Radiated RF electromagnetic field immunity test, it is also difficult to form a specified level of test field strength required in the standard test plane, due to the lack of absorbing materials in the standard site. Therefore, it can be considered to conduct type tests using radio frequency sources (such as telephones, walkie-talkies and other legitimate transmitters) in typical medical monitoring environments, the frequencies of ITU designated engineering medical equipment in the frequency range of 80MHz~6GHz, combined with actual modulation and suitable test distances to simulate actual interference, as depicted in Figure 4. This is a field test of radiated RF electromagnetic fields for a sampling robot.

Figure 4. Field test of radiated RF electromagnetic field immunity test for a sampling robot

For the RF source that simulates a typical medical monitoring environment on site, two ways can be realized. The corresponding transmitter was used directly to emit disturbance signals actually, while the deviation of basic safety and essential performance of medical robots was monitored, The test results of the test was obtained. The test method is simple and easy to operate. However, transmitters with more standards and operating frequencies are needed to meet the test requirements of different frequency bands and different modulation, such as mobile phones with different standards 2G, 3G, 4G and 5G, Bluetooth modules and WLAN routers, amateur radio stations and devices intended to transmit in the medical frequency band of engineering, etc. They are difficult for general laboratories to configure fully, and due to differences in transmission power and test distance, the final test results will also have a large difference. The other way is a wide-band antenna was used; the signal source, power amplifier analog modulation output were used to meet the needs of the actual test; table A.3 requirements of standard IEC60601-1-2 were used for testing, as depicted in Table 1.

Table 1. Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Banda) (MHz)	Servicea)	Maximum power (W)	IMMUNITY TESTLEVEL (V/m)
385	380-390	TETRA 400	1,8	27
450	430-470	GMRS 460, FRS 460	2	28
710 745 780	704-787	LTE Band 13, 17	0.2	9
810 870 930	800-960	GSM 800/900,TETRA 800,iDEN 820,CDMA 850,LTE Band5	2	28
1720 1845 1970	1700-1990	GSM 1800;CDMA 1900;GSM 1900;DECT;LTE Band1,3,4,25;UMTS	2	28
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450,LTE Band 7	2	28
5240 5500 5785	5100-5800	WLAN 802.11a/n	0.2	9

[a)] For some services, only the uplink frequencies are included.

The modulation frequencies and standards in Table 1 are only for reference and not suitable for used directly. Because of differences in regulations, countries are not the same in the division of spectrum and the choice of communication frequency bands. Therefore, it is necessary to first confirm the country or region where the medical robot is expected to be used, to confirm whether the frequency bandwidth corresponding to the service type in the table meets the requirements of local regulatory. For example, an operating frequency of 800MHz in TETRA was required in China. There are also many differences of the bands of LTE in different countries, so it is necessary to combine ITU and national regulations to confirm the actual test frequency, so that such a test has practical significance.

For the radiation disturbance caused by engineering medical equipment designated by ITU in the frequency range of 80MHz~6GHz, it is also subject to the requirements of ITU and local regulations, such as 433.05MHz~434.79MHz (center frequency 433.92MHz) band is the frequency band designated for ISM application by some European countries in ITU Region I. However, most ITU Region 3 countries do not specify a frequency band for ISM applications in the 100MHz~1GHz band.

6. Summary

The large medical robots can not be tested in the laboratory due to its own characteristics and installation requirements, they were only tested in the field. Since the requirements and test methods of other immunity tests in the field test are basically the same as those of the type test, this paper focuses on the analysis and discussion of the radiated emissions and the radiated RF electromagnetic fields in the field test, and a sampling robot was took as an example to give a specific explanation. Due to the complex and changeable field test environment, the next step will be to study the field test specifications and the improvement of the accuracy of the test results, to improve the effectiveness and safety of large medical devices.

Acknowledgments

This paper was supported by the following fund projects: Innovation Ability Improvement Project of Science and Technology SMEs in Shandong Province (2023TSGC0711); Internal research project of Shandong Institute of Medical Device and Pharmaceutical Packaging Inspection (NB202301).

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Author Bio

Author Introduction: Mingjian Zhu (1987 -), female, postgraduate, master, engineer, medical device inspector, mainly engaged in electromagnetic compatibility testing of active medical device, E-mail: zhumingjian_emc@163.com.

Corresponding author Introduction: Meng Liu (1989 -), male, Deputy Director of Electromagnetic Compatibility Laboratory, mainly engaged in the research work of active medical device testing and evaluation, E-mail: lmlzcl@163.com.