A Case Study on Post-Market Safety Verification of Electromedical Equipment: Evaluating ABNT NBR IEC 62353 Standard Testing in Real-World and Lab Settings

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Abstract. This preliminary study investigates the role of testing environments in the post-market safety verification of electromedical devices, particularly electrocardiographs, using the ABNT NBR IEC 62353 Standard. Electrical tests were conducted in two distinct scenarios: a well-controlled laboratory and a typical hospital environment, focusing on two tests, insulation resistance and leakage current evaluations. Some variations were observed in the insulation resistance test outcomes within the hospital setting, specifically on accessible parts and applied parts, potentially reflecting the inherent complexities of real-world testing environments. Nevertheless, all tests confirmed the compliance of the equipment with the ABNT NBR IEC 62353 Standard requirements. These findings underscore the importance of robust testing protocols that account for environmental factors, ensuring the reliable and comprehensive safety assessment of electromedical devices across diverse real-world healthcare settings.

Keywords: medical devices, ABNT NBR IEC 62353, insulation resistance, leakage current.

1. INTRODUCTION

Patient and operator safety is paramount in a healthcare setting, and a significant aspect of this involves the electrical safety of medical equipment. The ABNT NBR IEC 62353 Standard is a critical benchmark in the field of medical equipment safety and performance. This Standard ensures the continued safety and effectiveness of medical devices in the post-market phase, encompassing initial acceptance testing, routine verification, and testing after repairs [1, 2].

The ABNT NBR IEC 62353 includes functional, visual, and electrical inspections of electromedical devices. The electrical inspections encompass protective earth resistance (item 5.3.2), insulation resistance (item 5.3.3), and leakage current (item 5.3.4) evaluations. Each of these tests plays a crucial role in identifying potential electrical hazards and ensuring the safe operation of electromedical devices during routine use.

Leakage current tests aim to detect any undesirable current that may be leaking out of the circuit, potentially posing a risk to the user or patient. Since leakage current can be influenced by various factors and can manifest in different ways, the Standard specifies three methods for leakage current measurement: the alternative method, the direct method, and the differential current method. Some failures must be simulated during the tests, such as inverted polarity and exclusion of earth protection.

Insulation resistance tests aim to identify insulation faults caused by dust, wetness, or pollution. The Standard states that insulation resistance evaluation is optional and specifies minimum limits of 2 MΩ for Class I protection, 7 MΩ for Class II protection, and 70 MΩ for Cardiac Floating (CF) applied parts.

As the execution of the tests proposed by the ABNT NBR IEC 62353 Standard will generally be carried out outside the controlled environment of a test laboratory, the aim of this article is to propose an initial debate on the possible challenges of conducting some of these tests in a hospital setting. For this purpose, we evaluated a electromedical device in two different scenarios: in a laboratory designed for electromedical testing and in a hospital environment.

2. MATERIALS AND METHODS

Tests were performed on a Class I (equipment that has protection against electric shocks based on a protective earth connection, in addition to basic insulation and CF-type applied parts that have greater protection against electric shock) electrocardiograph [3] manufactured in 2018 and in use at the Biomedical Engineering Laboratory of the University of São Paulo (LEB/USP), referred to in this study as Local A. The tests on Local A were conducted in a controlled laboratory environment at the LEB/USP, while the tests on Local B were performed at the University Hospital of the University of São Paulo (HU-USP), in the sector specialized to maintenance and evaluation of medical equipment. All electrical measurements were performed using an electrical safety analyzer (AS1000 A Series, R&D Mediq, Brazil) with valid calibration certificate issued by a laboratory enrolled in the Rede Brasileira de Calibração (RBC). The tests were conducted by technicians with extensive metrological experience in performing tests on electromedical devices.

Insulation resistance measurements were executed following figure 1. Five configurations were tested: L/N to protective earth terminal (figure 1(a)); protective earth terminal to applied parts (figure 1(b)); L/N to accessible conductive part (figure 1(c)); L/N to applied parts (figure 1(d)) and accessible conductive part to applied parts (figure 1(e)). The safety analyzer was set to apply 500 Vdc with a stress duration of 30 seconds in the insulation resistance test.

Five measurement rounds were performed in each configuration for all electrical tests. The mean, and standard deviation of the results were obtained. The combined uncertainty u(y) was calculated by the square root of the sum of the squares of all uncertainty contributions (Type A and Type B). Expanded uncertainty was computed using k factor considering confidence interval of approximately 95,45% [4].

Wilcoxon Rank-Sum statistical tests were carried out for each measurement to ascertain the differences in results between the environments of Local A and Local B. The test was performed using a two-tailed approach. Differences were considered statistically significant at a p-value less than 0.05.

After completing the electrical safety tests outlined in this methodology, we performed functional tests on both devices to assess the performance of the electrocardiogram function. These tests used the ECG simulator built into the electrical safety analyzer itself, ensuring the devices were functioning optimally before returning them to their respective clinical departments in the hospital.

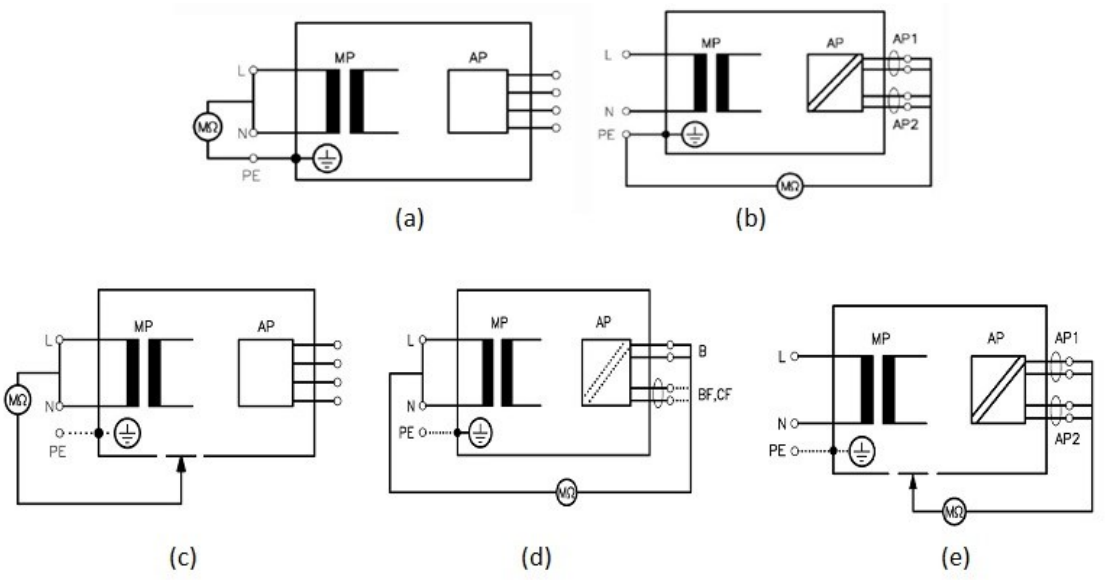

Figure 1. Measurement configurations for insulation resistance test in Class I electromedical equipment. L: live conductor; N: neutral conductor; PE: protective earth; MP: mains part that will be connected into power line; AP: applied parts; MΩ: measuring instrument. Figure adapted from [1].

Leakage current measurements were performed following figure 2 configurations, executing only the alternative and direct method in this case study. All measurements were executed with ECG applied parts connected to a single terminal of the safety analyzer.

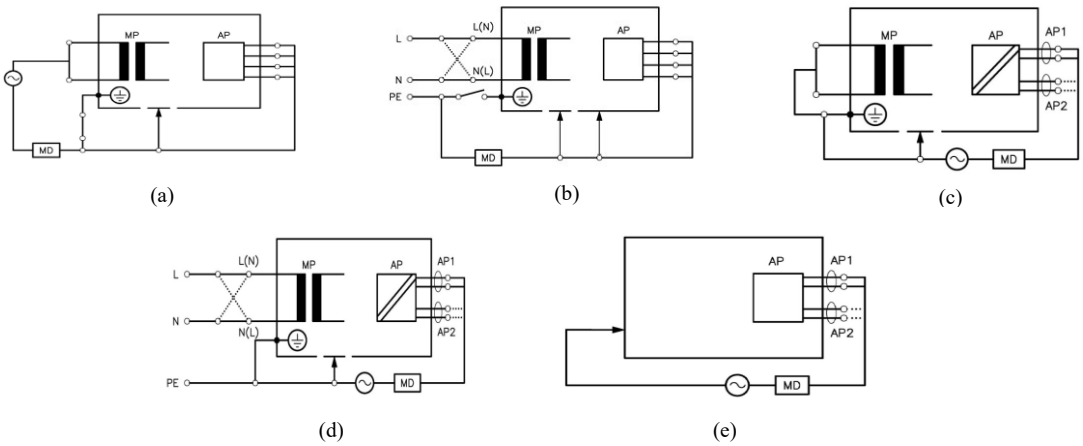

Figure 2. Connections configurations for leakage current measurements in Class I electromedical equipment. MD: measuring device; other symbols follow figure 1. Circuits: (a) Alternative method for equipment leakage current. (b) Direct method for equipment leakage current, inverting the conductors. (c) Alternative method for type F applied part. (d) Direct method for power line voltage on type F applied part. (e) Direct method for equipment with internal electrical power supply. Figure adapted from [1].

3. RESULTS

Table 1 shows the measurements obtained for the insulation resistance test, while other tables show the measurements obtained for the leakage current in different parts of the electromedical device.

Table 1. Measurements for insulation resistance test.

Insulation resistance (MΩ)	Local A		Local B		U Wilcoxon Rank-Sum	P Wilcoxon Rank-Sum
	Mean ± Uncertainty	k factor	Mean ± Uncertainty	k factor		
L/N to Earth	159.04 ± 5.01	2.03	105.66 ± 6.23	2.32	25	< 0.05
L/N and Accessible Parts	70.58 ± 3.26	2.17	53.48 ± 1.71	2.03	25	< 0.05
L/N to Accessible Parts (F)	162.32 ± 13.91	2.52	80.60 ± 2.70	2.03	25	< 0.05
Accessible Parts (F) to Earth	182.16 ± 16.92	2.65	119.88 ± 4.58	2.08	25	< 0.05
Applied Parts (F) and Accessible Parts	245.10 ± 18.47	2.52	107.56 ± 9.02	2.52	25	< 0.05

Tables 2 and 3 describe the results for the leakage currents tests. Some failure conditions were Not Applicable (NA) according to the measurement method. Comparatively conditions occurred in tables 4 and 5, as it was connected in a single terminal of safety analyzer.

Table 2. Results of the measurements for leakage current tests using the configuration circuit shown in figure 2(a).

Equipment leakage current (µA)	Alternative Method					
	Local A		Local B		U Wilcoxon Rank-Sum	P Wilcoxon Rank-Sum
	Mean ± Uncertainty	k factor	Mean ± Uncertainty	k factor		
Normal condition	63.06 ± 0.65	2.87	78.86 ± 0.30	2.65	0	< 0.05
Failure 1: N open	NA	NA	NA	NA	NA	NA
Failure 2: Inverted polarity	NA	NA	NA	NA	NA	NA
Failure 3: Inverted polarity with N open	NA	NA	NA	NA	NA	NA
Failure 4: no Applied Parts connected	NA	NA	NA	NA	NA	NA
Failure 5: Inverted polarity without Applied Parts	NA	NA	NA	NA	NA	NA

Table 3. Results of the measurements for leakage current tests using the configuration circuit shown in figure 2(b).

Equipment leakage current (µA)	Direct Method					
	Local A		Local B		U Wilcoxon Rank-Sum	P Wilcoxon Rank-Sum
	Mean ± Uncertainty	k factor	Mean ± Uncertainty	k factor		
Normal condition	167.22 ± 0.87	2.87	169.04 ± 0.31	2.65	0	< 0.05
Failure 1: N open	169.18 ± 0.58	2.87	170.52 ± 0.36	2.65	0	< 0.05
Failure 2: Inverted polarity	166.88 ± 0.69	2.87	168.80 ± 0.44	2.65	0	< 0.05
Failure 3: Inverted polarity with N open	168.00 ± 0.49	2.87	168.70 ± 0.54	2.87	0	< 0.05
Failure 4: no Applied Parts connected	167.02 ± 0.34	2.65	169.06 ± 0.45	2.87	0	< 0.05
Failure 5: Inverted polarity without Applied Parts	167.06 ± 0.43	2.87	168.88 ± 0.40	2.87	0	< 0.05

Table 4. Results of the measurements for leakage current tests using the configuration circuit shown in figure 2(c).

Applied Parts leakage current (µA)	Alternative Method					
	Local A		Local B		U Wilcoxon Rank-Sum	P Wilcoxon Rank-Sum
	Mean ± Uncertainty	k factor	Mean ± Uncertainty	k factor		
Normal condition	34.30 ± 0.52	2.87	37.32 ± 0.15	2.21	0	< 0.05
Failure 1: N open	NA	NA	NA	NA	NA	NA

Table 5. Results of the measurements for leakage current tests using the configuration circuit shown in figure 2(d).

Applied Parts leakage current (µA)	Direct Method					
	Local A		Local B		U Wilcoxon Rank-Sum	P Wilcoxon Rank-Sum
	Mean ± Uncertainty	k factor	Mean ± Uncertainty	k factor		
Normal condition	33.76 ± 0.33	2.65	33.78 ± 1.12	2.87	10	0.67
Failure 1: N open	33.90 ± 0.49	2.87	33.92 ± 1.02	2.87	12.5	1.00

Table 6. Results of the measurements for leakage current tests using the configuration circuit shown in figure 2(e).

Equipment leakage current deriving from the power supply (µA)	Alternative Method					
	Local A		Local B		U Wilcoxon Rank-Sum	P Wilcoxon Rank-Sum
	Mean ± Uncertainty	k factor	Mean ± Uncertainty	k factor		
Normal condition	33.48 ± 0.52	2.87	33.48 ± 0.95	2.87	12.5	1.00

4. DISCUSSIONS

The ABNT NBR IEC 60601 [5] and ABNT NBR IEC 62353 Standard play a critical role in the testing of electromedical devices, but they vary significantly in terms of their testing objectives. The ABNT NBR IEC 60601 Series specifies pre-market testing procedures conducted in highly regulated laboratory settings to verify the safety and essential performance of electromedical devices. The controlled conditions include specific parameters for temperature, humidity, earthing, power supply quality, and electromagnetic interference. These factors are all critical in ensuring the reliability and accuracy of the test results. On the other hand, the ABNT NBR IEC 62353 Standard provides guidelines for testing electromedical devices in real-world environments, such as hospitals. Unlike the laboratory settings required by ABNT NBR IEC 60601, these environments are not as strictly controlled and may present unique challenges such as unstable power line quality, suboptimal grounding conditions, and higher degrees of electromagnetic interference. These differences highlight the need for discussions and awareness of the potential influence of environmental factors on post-market testing performed in uncontrolled environments.

The results underscore the significant challenges associated with post-market testing when performed across diverse environments. This distinction is made evident by the marked statistical differences observed in most of the results ($p < 0.05$). Two potential factors that might explain these disparities are the differential electromagnetic environments and variations in mains power supply

quality between the laboratory and the hospital. These are speculative considerations, and although they may have influenced the accuracy and performance of the measurement instruments employed, it's essential to interpret them with caution. To determine the precise and quantitative causes of these differences, more rigorous tests and research are deemed essential in future investigations. While the results highlighted notable differences between the conditions, it's crucial to emphasize that the equipment tested adhered to the limits established by ABNT NBR IEC 62353 in both scenarios.

In this study case, we have observed some factors that require special attention when choosing the location for the tests within a hospital environment. The site must ensure minimal conditions of temperature regulation, adequate quality of the electrical network, grounding, and lighting. These conditions can be ensured by adopting protocols for regular verification of these aspects. A schedule can be adopted in which the electrical grounding of the site, the quality of the electrical network, the correct maintenance of the air conditioning and lighting equipment of the environment are inspected.

5. CONCLUSION

This preliminary study underscores the distinctive challenges and parameters associated with the ABNT NBR IEC 62353 Standard testing of electromedical devices in real-world hospital environments. Despite the unique conditions, including possible variable electromagnetic influences, the tested device met the ABNT NBR IEC 62353 Standard requirements. These results are initial, and there is a need for further comprehensive research. We intend to extend this exploration, focusing on comparative testing across multiple environments.

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