Measurement of creepage distance and air clearance: differences between different professionals

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Abstract: The standard IEC/ISO 60601-1:2005 specifies general requirements for measuring creepage distance and air clearance for medical electrical equipment. Four experienced professionals were asked to measure creepage distances and air clearance in three different segments of an acrylic body of proof. The results were compared and the found differences were discussed in order to discover the misinterpretations of the standard requirements. After a final consensus between the professionals, the distances were measured again to obtain the final results.

Keywords: creepage distances; air clearances; measuring; IEC/ISO 60601-1:2005;

1. INTRODUCTION

The IEC/ISO 60601 series specifies requirements for basic safety and essential performance applicable to medical electrical equipment. The item 8.9 prescribes measurement tests of creepage distance and air clearance. The main purpose of this test is to verify the insulation between electrical parts of the equipment as a mean of operator and patient protection.

The standard IEC/ISO 60601-1:2005 defines creepage distance as ‘the shortest distance along the surface of the insulating material between two conductive parts’ and air clearance as ‘the shortest path in air between two conductive parts’.

2. OBJECTIVE

The main objective of this article is to show the misinterpretations of the standard requirements during the measurement of creepage distances and air clearance comparing the results obtained by four different experienced professionals.

3. MATERIALS AND METHODS

The measurements were performed on an acrylic body of proof provided by an independent organization (Qualabor, Brazil). Its diagram is shown in figure 1.

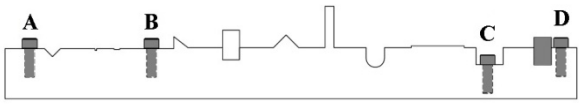

Figure 1. Body of proof. Gray parts are metal parts.

This bar has several grooves and some metal parts. There are four screws fixed in the bar determining the points A, B, C and D.

The measurements were made between points A-B (figure 2), B-C (figure 3) and C-D (figure 4). Every distance has a particular characteristic and format.

Figure 2. Diagram of the segment between points A and B.

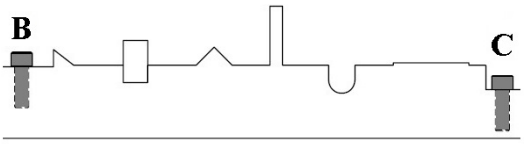

Figure 3. Diagram of the segment between points B and C.

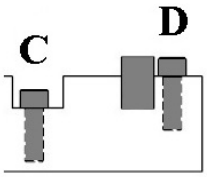

Figure 4. Diagram of the segment between points C and D.

The distances were measured with the same caliper rule (330-114, Mitutoyo Corporation, Japan) (Calibration certificate traceable by International System valid until 12/3/2016).

Four experienced professional (I, II, II, and IV) were asked to perform measurements.

During the tests, all professionals consulted the standard IEC/ISO 60601-1:2005 to remind the concepts.

After all measurements have been made, the results were compared and the problems were identified in a consensual way by the professionals. After a final consensus, the distances were measured again to obtain the final results.

3.1 SOME APPLIED STANDARDIZATION CONCEPTS

The method used to measure distances is based on IEC/ISO 60601-1:2005 illustrative figures as showed in figures 5, 6, 7 and 8, where the dashed line represents air clearance and the shaded bar representes creepage distance.

Illustrative figures can lead sometimes to misinterpretations depending on the reader. Therefore, it is very helpful to understand the reasons of some misinterpretations in order to prevent the occurrence of this kind of mistakes.

Figure 5 shows that both distances have to be measured directly across the groove if its distance is lower than 1 mm.

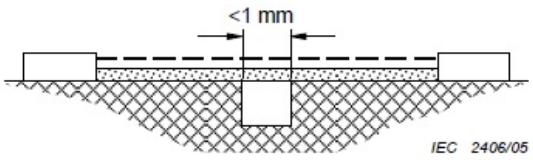

Figure 5. IEC/ISO 60601-1:2005 (Figure 23)

Figure 6 shows that if the groove is longer than 1 mm, creepage distance path follow the contour of the groove.

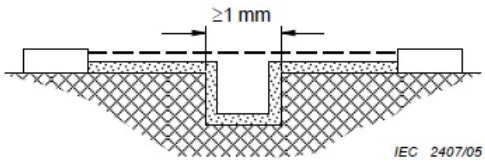

Figure 6. IEC/ISO 60601-1:2005 (Figure 24)

Figure 7 shows that creepage distance path follows the contour of the rib and air clearance is the shortest direct air path over the top.

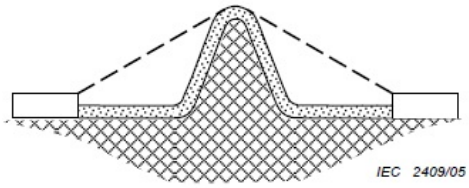

Figure 7. IEC/ISO 60601-1:2005 (Figure 26)

Figure 8 shows that when the gap between the head of the screw and the wall of recess is wide enough to be taken into account so the air clearance is the shortest distance to any point on the head of the screw and creepage distance path follows the surface [1].

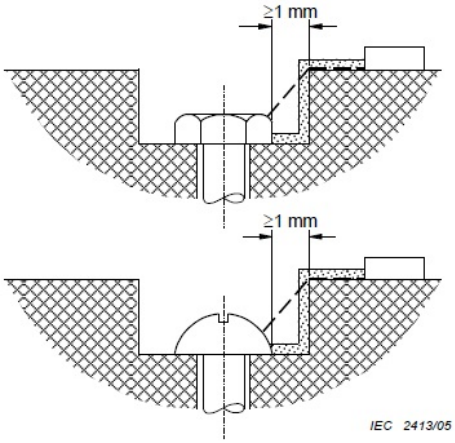

Figure 8. IEC/ISO 60601-1:2005 (Figure 30)

4. RESULTS

The measurements of all professionals were compared for each segment.

The table 1 presents the measurements of air clearance.

The table 2 presents the measurements of creepage distance.

Table 1. Measurements for air clearance.

Air Clearance	A-B (mm)	B-C (mm)	C-D (mm)
I	54.1	200.6	29.3
II	53.9	200.9	27.4
III	54.0	201.5	27.5
IV	54.1	200.5	29.1
Average	54.0	200.9	28.3
Standard deviation	0.1	0.5	1.0
Maximum error	0.1	0.6	1.0
Maximum Error/Average (%)	0.2	0.3	3.5

Table 2. Measurements for creepage distance.

Creepage Distance	A-B (mm)	B-C (mm)	C-D (mm)
I	58.3	302.8	36.8
II	60.8	306.4	36.8
III	58.8	302.3	37.2
IV	58.3	302.8	36.8
Average	59.1	303.6	36.9
Standard deviation	1.2	1.9	0.2
Maximum error	1.8	2.8	0.3
Maximum Error/Average (%)	3.0	0.9	0.8

The table 3 presents final results.

Table 3. Final results (mean ± standard deviation).

Final results	A-B (mm)	B-C (mm)	C-D (mm)
Air Clearance	54.2±0.1	200.4±0.4	29.1±0.4
Creepage Distance	58.7±1.3	302.5±1.6	36.8±1.9

4. DISCUSSIONS

After analysis of table 1 (air clearance distance) the group could conclude that for distance A-B, the measurements were very close. The standard deviation between these points was small (0.1 mm) and the maximum error relating to

average was 0.2%. For the distance B-C, the standard deviation was a little higher than the others (0.5 mm) and the maximum error relating to average was 0.3%. These first two results was considered acceptable by the group. For distance C-D**,** the standard deviation was 1.0 mm and the maximum error relating to average was considered high (3.5%). Professionals II and III had a misunderstanding of the concept. They used the distance of the base of chamfer instead of the method presented in figure 8.

After analysis of table 2 (creepage distance) the group could conclude that for distance A-B, the standard deviation was 1.2 mm and the maximum error relating to average was considered high (3.0%). Professional II measured the entire pathway, having a misunderstanding of the concept presented in figure 6. There was a groove smaller than 1 mm in this interval of the bar and all its surfaces were measured by professional II.

For distance B-C, the standard deviation was 1.9 mm and the maximum error relating to average was 0.9%. The measurement between these points was the most difficult one, due to the sample format. The number of parts to measure was higher, about 25. The maximum error was 2.8 mm, considered high (Professional II). The most complicated measurement was the one presented in figure 9. Basically, each professional measured in a different way once the standard IEC/ISO 60601-1 does not exemplify this case. Professionals I and IV considered the perimeter of the semi circle and professionals II and III imaginatively drew a square to make the measurements. After analysis, the professionals considered right the measurement of the semi circle.

Figure 9. Semi circle

For distance C-D, the standard deviation was 0.2 mm and the maximum error relating to average was (0.8%), considered acceptable by the group.

Measurement of creepage distance is more complex than air clearance as presented by results. The first one has a higher number of measurements and some of them are difficult due to sample format.

The final measurements were performed after the comparisons and discussions as showed in table 3.

The standard IEC/ISO 60601-1:2005 already has an amendment 1:2012 but it was not published in Brazil yet. This amendment changes the value presented in figures 5, 6, 7 and 8. Now this value is according to the micro-environment pollution degree.

5. CONCLUSION

Although the measurements of creepage distance and air clearance look straightforward, some rules and concepts have to be known by the professionals because misunderstandings of the standard directions based on illustrative figures can easily happen.

6. REFERENCES

[1] ABNT NBR ISO/IEC 17025:2005 - Requisitos gerais para a competência de laboratórios de ensaio e calibração.

[2] NIT-DICLA-026 rev08 – Requisitos sobre a participação dos laboratórios de ensaio e de calibração em atividades de ensaio de proficiência.

[3] IEC/ISO 60601-1:2005 – Medical electrical equipment. Part 1: general requirements for basic safety and essential performance.

[4] IEC/ISO 60601-1:2005 + Amendment 1:2012 – Medical electrical equipment. Part 1: general requirements for basic safety and essential performance.