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METROLOGICAL RELIABILITY OF HIGH FREQUENCY SURGICAL EQUIPMENT

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Abstract: The metrological reliability of high frequency surgical equipment in use at three (3) hospitals in Rio de Janeiro, Brazil was evaluated. The units tested did not satisfy safety and performance requirements, indicating that (post-sale) periodic verifications are essential, and that crest factor analysis should be included in technical standards.

Keywords: legal metrology, metrological reliability, medical electrical equipment, high frequency surgical equipment, electrosurgical unit.

1. INTRODUCTION

Despite the fact that (pre-sale) type approval and (post-sale) periodic verifications are routinely used in legal metrology for the metrological control of measuring instruments, medical electrical equipment are usually only required to go through type approval. Type approval for medical electrical equipment usually involves compliance with the IEC 60601 series and/or national deviations that apply [1-3].

Particularly, for high frequency surgical equipment, also known as electrosurgical unit (ESU), type approval involves compliance with safety standards: **a.** IEC 60601-1 (*Medical Electrical Equipment – Part 1: General Requirements for Safety*), **b.** the particular standard IEC 60601-2-2 (*Medical electrical equipment – Part 2: Particular requirements for the safety of high frequency surgical equipment*), and/or **c.** national standards [4-5]. However, after the ESUs are sold, there are no compulsory initial or periodic verifications to access neither safety nor performance [6].

In order to access the need for periodic verifications, the metrological reliability of ESUs in use at hospitals, clinics and other healthcare establishments should be evaluated. With this purpose, fourteen (14) ESUs used at three (3) hospitals in Rio de Janeiro, Brazil, one (1) private and two (2) public, were tested for some of the relevant safety and performance parameters. The results, reported and discussed in this paper, indicate a need for standards requiring mandatory periodic verifications. In addition, the results indicate that measurements of a new parameter (crest factor), not included in the current particular safety standard, should be included.

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2. PRINCIPLES OF ELECTROSURGERY AND TISSUE EFFECT

In electrosurgery, the voltage applied creates a high frequency (radiofrequency) current used to heat the tissue. The complete circuit consists of the voltage source, an active electrode, the patient, and the neutral electrode (also know as plate, plate electrode, passive, return or dispersive electrode).

The active electrode, which applies current to the tissue, is located at the surgical site. In the monopolar method, the neutral electrode is in contact somewhere else with the patient's body, and the current passes through other tissues to reach it. In the bipolar method, the neutral electrode is located at the surgical site, and the current passes only through the tissue grasped between both electrodes [4-5, 7].

Varying the electrical waveform will result in different tissue effects: cutting, coagulation, fulguration, or desiccation [7].

The waveform for cutting is constant (non-modulated). Tissue division is obtained by holding the active electrode slightly away from the tissue, which will result in electrical sparks. This will produce intense heat, which, in turn, vaporizes or cuts the tissue [7].

Coagulation, which reduces or terminates undesired bleeding, is obtained by producing less heat by means of an intermittent (modulated) waveform with short duty cycle ("on time" of approximately 6% and "off time" of approximately 94%) [4-5, 7].

Fulguration, also known as spray or non-contact coagulation, is a form of coagulation using long electrical sparks (0.5 mm or more) in order to avoid contact between the active electrode and the tissue [4-5, 7].

Desiccation can be obtained with any waveform by holding the active electrode in direct contact with the tissue. Best results are obtained with the constant (non-modulated) cutting waveform. Contact between the tissue and the electrode will produce less heat, and the cells will dry out and form a coagulum, instead of vaporizing and exploding [7].

In addition to the cutting and coagulation operating modes, some electrosurgical units (ESUs) have one or more blend modes that can be used to obtain cutting with coagulation. Blend modes, considered cutting modes, also use intermittent (modulated) waveforms, but with longer duty cycles. For example, the waveform for blend 1 (cutting with minimum coagulation) could have “on time” of approximately 50% and “off time” of approximately 50%, the waveform for blend 2 could have “on time” of approximately 40% and “off time” of approximately 60%, and the waveform for blend 3 (cutting with maximum coagulation) could have “on time” of approximately 25% and “off time” of approximately 75% [4-5, 7].

3. PARAMETERS FOR MEASUREMENT

There are several parameters that impact the performance of ESUs. The desired effects will be obtained only if the patient is part of the electrosurgical circuit, and if the current flows through the target tissue. Additionally, the result will depend on: waveform; output power setting; electrode size and geometry; activation time; orientation of the electrode; and tissue impedance [7].

Ideally, all relevant safety and performance parameters should have been evaluated in all ESUs tested; however, since there was a high demand for the ESUs at the hospitals, the time available with each unit was limited, therefore limiting the number of tests performed.

According to the particular safety standard for high frequency surgical equipment (IEC 60601-2-2), the frequency of the output current should be between 0.3 MHz and 5 MHz. Lower frequencies cause undesired nerve and muscular stimulation, while higher frequencies cause leakage currents that may cause burning [4-5, 7]. In order to investigate if the ESUs complied with this safety requirement, frequency measurements were performed in ten (10) of the ESUs tested.

Additionally, according to the particular safety standard 60601-2-2, each operating mode (monopolar: cut, coagulation and blend; and bipolar) has an appropriate output power range that should be specified in the technical manual and should be within acceptable limits [4-5]. In order to test if the output power of the ESUs was close to its nominal value within acceptable limits, output power measurements for different operating modes were performed. Since these tests were time consuming and there was a high demand for the ESUs at the hospitals, it was not possible to test all output power values for all operating modes in all ESUs.

Two (2) other important tests, for which there are no requirements in the particular safety standard, were also performed: visual inspection of the waveform and quantitative analysis of its crest factor. The importance of these parameters is discussed below.

As mentioned earlier, each operating mode (cut, coagulation and blend) has a typical waveform shape. Waveforms with shorter duty cycles (“on time”) have higher coagulating capacity. A qualitative evaluation of this waveform can be performed by visual inspection. Visual inspections of the waveforms were performed in ten (10) of the ESUs tested.

The crest factor - maximum output voltage divided by the root mean square (r.m.s.) voltage - is a quantitative evaluation of the waveform that can be used to measure its coagulating quality. Waveforms with higher crest factors have higher coagulating capacity, whereas cutting waveforms have crest factors close to one (1). Usually, typical acceptable ranges for each operating mode function can be found in the manufacture’s operation manual. In order to investigate if the crest factor of the ESUs was within acceptable limits, crest factor measurements for different modes were performed, according to the availability of the ESUs.

Several of the safety qualitative tests recommended in the general standard for medical electrical equipment (IEC 60601-1) were performed in all electrosurgical units (ESUs).

4. MATERIALS AND METHODS

As mentioned earlier, since all ESUs analyzed were used regularly at the hospitals, the tests were subject to the availability of the units. For this reason, it was not possible to test all ESUs belonging to each hospital. As can be seen in Table 1, a total of fourteen (14) units, three (3) different brands and five (5) different models, were tested.

Table 1. Electrosurgical units classified by hospital, brand and model.

Hospital	Electrosurgical Unit	Brand	Model
Hospital 1 (private)	B1	Brand 1	Model 1.1
Hospital 1 (private)	B2	Brand 1	Model 1.1
Hospital 2 (public)	B3	Brand 2	Model 2.1
Hospital 2 (public)	B4	Brand 2	Model 2.1
Hospital 2 (public)	B5	Brand 2	Model 2.2
Hospital 3 (public)	B6	Brand 2	Model 2.2
Hospital 3 (public)	B7	Brand 2	Model 2.3
Hospital 3 (public)	B8	Brand 2	Model 2.3
Hospital 3 (public)	B9	Brand 3	Model 3.1
Hospital 3 (public)	B10	Brand 3	Model 3.1
Hospital 3 (public)	B11	Brand 3	Model 3.1
Hospital 3 (public)	B12	Brand 3	Model 3.1
Hospital 3 (public)	B13	Brand 3	Model 3.1
Hospital 3 (public)	B14	Brand 3	Model 3.1

The history of each unit was not informed by the hospitals; however, they reported that none of the units analyzed had been acquired recently.

The setups used for the measurements in the monopolar and bipolar modes were the ones suggested in the particular safety standard IEC 60601-2-2 [4-5].

A Tektronix oscilloscope (TDS 210) was used to visually inspect the waveforms and measure their frequencies. Output powers and crest factors were measured with a WEM electrosurgical analyzer (model 454 A).

Output power verifications were made for the operating modes tested by performing a number of measurements for different output power settings. The cut and blend modes in units B1 and B2 were tested by performing five (5) measurements at each of five (5) different output power settings. The cut, blend, coagulation and bipolar modes in units B3 through B8 were tested by performing ten (10) measurements at each of five (5) different output power settings (the bipolar mode was not tested in units B7 and B8). The cut, coagulation and bipolar modes in units B9

Table 2. Power (P), crest factor (C) and frequency analysis for the 14 ESUs evaluated.

		B1	B2	B3	B4	B5	B6	B7	B8	B9	B10	B11	B12	B13	B14
Cut	P	√	√	√	**	**	*	√	*	***	****	**	***	ESU malfunction during analysis	
	C	**	**	√	√	√	*	√	√	**	**	**	**		
Blend 1	P	√	**	*	**	**	*	√	√	NA	NA	NA	NA		
	C	**	**	*	*	√	√	√	√						
Blend 2	P	NP	NP	*	**	**	*	√	√	NA	NA	NA	NA		
	C			*	√	√	√	√	√						
Blend 3	P	NP	NP	√	**	**	**	√	√	NA	NA	NA	NA		
	C			√	*	√	√	√	√						
Coagulation	P	NP	NP	*	**	**	**	√	**	***	****	**	**		
	C			√	√	√	√	***	***	***	***	***	***		
Bipolar	P	NP	NP	√	*	√	*	NP	NP	****	***	NP	****		
Frequency (kHz)		NP	NP	NP	NP	500 to 510	481	478 to 481	478 to 481	490	490	391	400	500 to 510	481

Power (P) Error:
√ less than 10%
* 10% - 15%
** 16% - 40%
*** 41% - 70%
**** above 30%

Crest Factor (C) Error:
√ within specified range
* less than 10%
** 10% - 30%
*** above 30%

NA - Not Applicable

NP - Not Performed

through B12 were tested by performing ten (10) measurements at each of five (5) different output power settings (the bipolar mode was not tested in unit B11). Output power measurements could not be completed for units B13 and B14 due to their malfunction soon after the frequency and waveform analysis.

Type A evaluation of uncertainty in measurement was performed for all output power measurements.

5. RESULTS AND DISCUSSION

Frequency analysis performed for units B5 to B14 yielded results between 391 kHz and 510 kHz (Table2), within the recommended values according to the particular safety standard 60601-2-2.

For the power analysis (**P** in Table 2), only two units (B1 and B7) delivered acceptable output values; however, results for one of them (B1) were not considered conclusive, since, due to availability for testing, only two (2) of its seven (7) modes were analyzed. The uncertainties in the output power measurements were low.

Visual inspection of the waveforms showed that they seemed to have the shape expected; however, quantitative analysis of the waveforms (crest factor) showed that this was not true. Crest factor analysis (**C** in Table 2) was performed for twelve (12) ESUs (B1 to B12). Except for unit B5, crest factors were outside the manufacturer's specified range for at least one of the operating modes. It is important to note that even unit B7, the only unit that passed completely the output power test, did not pass the crest factor test. In fact, all ESUs in which the quantitative analysis for output power and crest factor was performed failed in at least one parameter studied, i. e. no ESUs was approved in all tests.

These results also showed that visual inspection of the waveform is not sufficient to evaluate its quality, and that crest factor analysis should be performed.

Despite being an important parameter to assure the electrosurgical effect desired, crest factor analysis is not included in the requirements of the particular safety standard IEC 60601-2-2. Therefore, unit B7 would have been considered in compliance with the standard, even though the crest factor results show it is not reliable.

Finally, the qualitative tests, recommended in the general safety standard for medical electrical equipment (IEC 60601-1), also exposed irregularities in all ESUs evaluated.

6. CONCLUSION

The present study evaluated ESUs in use in healthcare establishments, showing that the units tested did not satisfy safety and performance requirements. These results indicate that safety and performance (post-sale) periodic verifications are essential. In addition, crest factor measurements, not included in the current particular safety standard, showed that most units had the crest factor outside the manufacturer's specified range for at least one of the operating modes.

These results indicate a need for new regulations requiring mandatory safety and performance (post-sale) periodic verifications. In addition, a new measurement (crest factor) should be included in the current (pre-sale) particular standard (IEC 60601-2-2) used for type testing, as well as in the new regulation requiring periodic verifications.

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REFERENCES

[1] Eisner, L., Brown, R. M., and Modi, D. A Primer for IEC 60601-1. **Medical Device & Diagnostic Industry**, Regulatory Outlook, Los Angeles, September 2003. http://www.devicelink.com/mddi/archive/03/09/015.html

[2] International Electrotechnical Commission. **IEC 60601-1**: Medical electrical equipment—Part 1: General requirements for safety. Ed. 3. Geneva, 2005.

[3] Associação Brasileira de Normas Técnicas. **NBR IEC 60601-1**: Equipamento eletromédico – Parte 1: Prescrições gerais para segurança. Rio de Janeiro, 1997.

[4] International Electrotechnical Commission. **IEC 60601-2-2**: Medical electrical equipment – Part 2: Particular requirements for the safety of high frequency surgical equipment. Ed. 3. Geneva, 1998.

[5] Associação Brasileira de Normas Técnicas. **NBR IEC 60601-2-2**: Equipamento eletromédico – Parte 2: Prescrições particulares de segurança para equipamento cirúrgico de alta freqüência. Rio de Janeiro, 2001.

[6] Costa Monteiro, E., Lessa, M.L. A Metrologia na área da Saúde: Garantia da Segurança e da Qualidade dos Equipamentos Eletromédicos. Accepted for publication by Engevista, 2006

[7] Valleylab, Principles of Electrosurgery ONLINE, Educational booklet on electrosurgery, 2000. http://www.valleylab.com/education/poes/index.html