

A Study on Performance and Safety Tests of Electrosurgical Equipment

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ABSTRACT

Introduction: Modern medicine employs a wide variety of instruments with different physiological effects and measurements. Periodic verifications are routinely used in legal metrology for industrial measuring instruments. The correct operation of electrosurgical generators is essential to ensure patient's safety and management of the risks associated with the use of high and low frequency electrical currents on human body.

Material and Methods: The metrological reliability of 20 electrosurgical equipment in six hospitals (3 private and 3 public) was evaluated in one of the provinces of Iran according to international and national standards.

Results: The achieved results show that HF leakage current of ground-referenced generators are more than isolated generators and the power analysis of only eight units delivered acceptable output values and the precision in the output power measurements was low.

Conclusion: Results indicate a need for new and severe regulations on periodic performance verifications and medical equipment quality control program especially in high risk instruments. It is also necessary to provide training courses for operating staff in the field of meterology in medicine to be acquainted with critical parameters to get accuracy results with operation room equipment.

Keywords

Meterology, Electrosurgical Equipmen, High Frequency, Patient Safety, Medical Electrical Equipment

Introduction

Today, Electrosurgical devices are frequently used in hospital operating rooms. The principle of electrosurgery is heat generating by high frequency electrical current for coagulation, cutting, desiccation and fulguration of biological tissues developed by Bovie. The correct operation of electrosurgical generators is essential to ensure patient's safety and to manage the risks associated with the use of high and low frequency electrical current on human body. Manufacturers of electrosurgical generators must follow the strict design criteria of IEC 60601-2-2, which stipulates the specific requirements in order to provide a controlled approach to patient's safety when using electrosurgical devices.

A complete understanding of each energy modality, waveform and tissue effect is critical in reducing potential complications and hazards while the performance and safety of these electrosurgical devices must be regularly verified at least annually using electrosurgical analyzer by

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experts. Particularly, for electrosurgical equipment type approval involves compliance with these standards, a) IEC 60601-1 (Medical Electrical Equipment – Part1: General requirements for safety), b) The particular standard IEC 60601-2-2 (Medical Electrical Equipment – Part2: Particular requirements for the safety of high frequency surgical equipment) and c) national standards [1, 2].

In order to meet the requirements for periodic verifications, the metrological reliability of ESUs which are in use at hospitals, clinics and other medical or healthcare centers should be evaluated. For this purpose in this research, twenty (20) ESUs were used at six hospitals; three publics and three privates, and clinics in one of Iran's province. They were tested under some relevant safety and performance parameters.

Technical Background

Principles of Electrosurgery and Tissue Effect

The concept of using heat as a form of therapy and treatment to stop bleeding has been used for centuries. This was initially known as thermalcautery where tissues were burnt by thermal heat. Electrocautery was developed in the 19th century as a means of destroying tissue by using electrical currents to heat intensely an instrument. Further advancement in electrical technology was developed into modern-day electrosurgery beginning at the turn of the century when a French physicist, Alex d'Arsonval, demonstrated that radio-frequency currents could heat living tissue without muscle or nerve stimulation. Because nerve and muscle stimulations are ceased at 100 KHz, electrosurgical generator takes 60 cycle currents and increases the frequency to over 200 KHz. At this frequency, electrosurgical energy can pass through the patient with minimal neuromuscular stimulation and no risk of electrocution.

Electrosurgery uses high voltage and high

frequency AC current and the electrosurgical circuit is composed of an electrical generator or ESU, an active electrode, the patient and a return electrode. Current enters body because it is included in the circuit and biological tissue provides impedance which results in heat production as electrons try to overcome this resistance [1].

Electrosurgery generator units are a crucial piece of equipment in the majority of operative settings and the most useful and common instruments used by surgeons today. This technique allows the high frequency current to cut or coagulate the tissue, minimizing blood loss and shortening operating time. The principle of heat production via current passing into tissue can be adjusted to produce a variety of tissue effects such as coagulation, cutting, desiccation and fulguration.

Modes of Operation

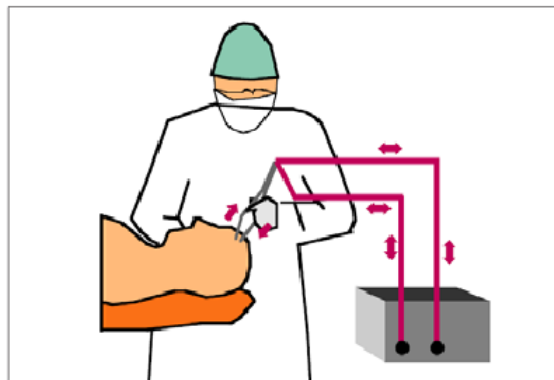
There are two electrosurgical delivery techniques: Monopolar and Bipolar.

Monopolar

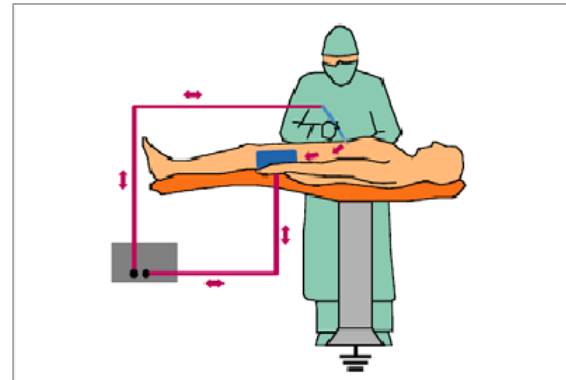
Monopolar mode of electrosurgery is the most commonly used mode in surgery which is an active electrode located at the surgical site. In monopolar mode, the electrical current flows from the active electrode through the patient's body, to the patient return electrode placed under the patient and back to the generator, see Figure 1.

Bipolar

In bipolar mode, the active and return electrodes are both located at the site of surgery as a general within the instrument tip which is usually forceps, see Figure 1. Most bipolar units use a lower voltage waveform in operation to achieve less hemostasis and avoid collateral tissue damage. Bipolar mode has a more limited area of thermal spread as compared with that of monopolar mode. Disadvantages of bipolar versus monopolar mode include the increased time due to a low power setting needed for coagulation and tissue adherence with incidental tearing of adjacent blood vessels [2].



Electrosurgery – Bipolar Mode



Electrosurgery – Monopolar Mode

Figure 1: Electrosurgery: Bipolar Mode versus Monopolar Mode

Electrosurgical Waveforms

Electrosurgical generators depending on their functionality are able to produce a variety of electric waveforms. As waveforms change, so will the corresponding tissue effects. Several parameters have influence on the tissue effect associated with different electrosurgical current waveforms as the size and shape of the electrode and output modes of the generator change. There are three types of current waveforms: cutting, coagulation and blended currents. See Figure 2, [1, 2].

Cutting Currents

Cutting currents is continues without any interrupted sinusoidal waveform with high aver-

age power and high current density, Figure 2.

Coagulation currents

Coagulation currents are characterized by high voltage, relatively low current intermittent bursts of dampened sine waves which drive the current through a tissue, Figure 2.

Desiccation is a direct contact form of coagulation where 100% of the electrical energy is converted into heat within a tissue, not seen with other current waveforms. It uses low current density over a broad area which causes dehydration of cells without the need for an electrical spark.

Fulguration is a non-contact form of coagulation producing a spark gap and electric

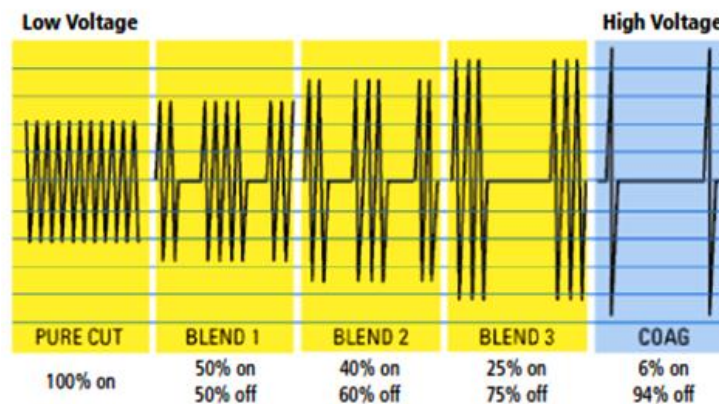


Figure 2: Different types of Current Waveforms: Cutting, Coagulation and Blended Currents

discharge arc to mediate the tissue as the air between the probe and tissue ionizes. A spray effect at various regions causes shallow tissue destruction.

Blended Currents

A blended current is a modification mode operating at voltages between those of cutting and coagulation. Blended currents allow for tissue division whilst maintaining a variable degree of hemostasis which is defined by off-period. Three blends are shown in Figure 2.

Electrosurgical Units

ESU Generator Technology

Today electrosurgical units were revolutionized by isolated generator technology. This technology eliminates many hazards inherent in grounded systems, most importantly, current division and alternate site burns. As this view, there are two types of electrosurgical units.

Ground-referenced Generators

Originally, ESUs were ground-referenced where the electrical current passed through the patient's body and returned to ground, Figure 3. However, electrical currents seek to travel down the pathway of least resistance and therefore current can travel through any conductive grounding object which is in contact with the patient as a method of ground return such as; ECG electrodes or tables and operat-

ing staff.

Isolated Generators

Isolated generator systems were developed in the early 1970's to overcome the risk of alternative site burns due to grounded systems. The current still passes through the patient and must return through the patient return electrode which leads to the negative side of an isolation transformer located within the generator. The return electrode is not connected or referenced to ground and therefore alternate pathways are avoided. If the current does not find its way to the patient return electrode, then the ESU will stop delivering energy current as there must be an alternative grounding path of less resistance than the return electrode, Figure 3, [3,4].

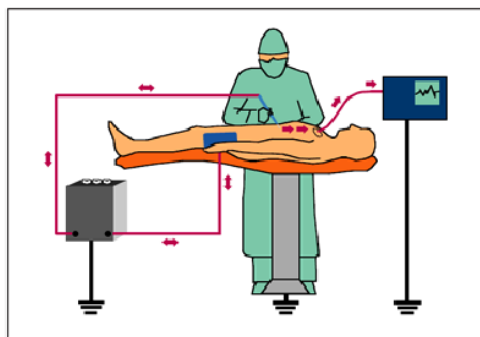
Electrodes

Active Electrode

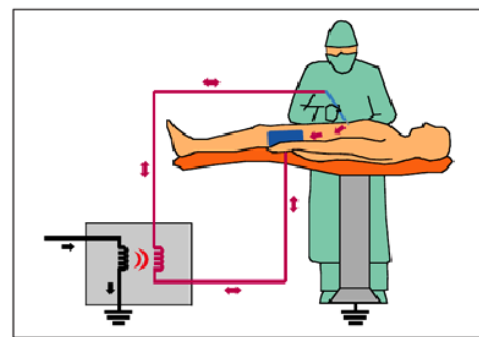
They are also called "Electrode Tips", the active electrode delivers the energy as high frequency AC current from the ESU to surgical site. The current density varies depending on the type, size and shape of a tip. There is a wide variety of sizes and shapes suited to specific clinical indications such as; bipolar forceps for desiccation, needle electrodes for precise cut and coagulation, blade electrodes for faster cut and coagulation and ball tips for broad coagulation, Figure 4.

Patient Return Electrode

The primary function of patient return elec-



Ground-Referenced Electrosurgical Generator



Isolated Output Electrosurgical Generator

Figure 3: Ground-referenced and Isolated Generator

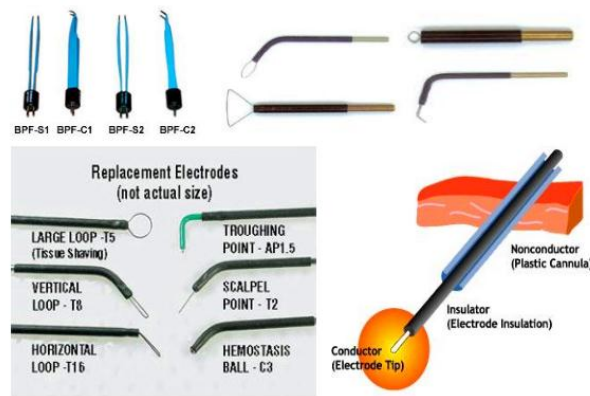


Figure 4: Some example of Electrode Size and Shape

trode or neutral electrode is to collect the high frequency current delivered to the patient during electrosurgery and to remove it from the patient safely back to ESU. The size of return electrode should be proportional to the energy and the time that ESU is used. Large electrode area and small contact impedance reduce the current density of the energy dispersing from patient to levels where tissue heating is minimal thus preventing skin burns [3, 4].

Material and Methods

In this study, twenty ESUs, four (4) different brands and three (3) different models were used at six (6) hospitals, three publics and three privates were tested. The technical history of each unit was not informed or not completed by these hospitals; however, they announced that none of the units' analyses had been acquired recently.

The setup used for the measurements in different modes was designed in accordance with the particular safety standard IEC 60601-2-2. Output power and HF leakage currents were measured by a Fluke biomedical analyzer (PRF 303) and a Fluke electrical safety analyzer (ESA 620) used for general electrical safety evaluations for measuring the patient's leakage current.

Output power verifications were made for three operating modes: Cut, Couagulation and blend by performing a number of measure-

ments or high output power setting at least three different modes [5, 6].

Performance Parameters

There are several parameters that impact the performance of ESUs. Some of these parameters are demonstrated in Table 1, [6].

Ideally, all safety and performance parameters should have been evaluated in ESU tests; however, since there was a working load on this equipment in operating room, the time needed for testing was limited; therefore, the number of performed tests was limited and only the critical parameters have been considered.

Based on 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 within acceptable limits. In order to test if the output power of ESUs was close to its nominal value within acceptable limits, output power measurements for different operating modes were performed. The test was performed for each mode in three different loads at its maximum output setting. Nominal load was selected as one of them according to manufacturer's instructions.

In order to prevent unintended thermal burns, HF leakage currents were tested from active and neutral electrodes with HF patient

Table 1: Performance Parameters of Electrosurgical Units

Qualitative Tasks	Quantitative Tasks
Chassis/Housing	RF Output Power
Strain Reliefs	RF Output Isolation
Cables	HF Leakage Currents
Fitting/Connectors	Cross-Coupling between different HF Patient Circuits
Controls/Switches	
Indicators/Displays	Dispersive Cable Continuity Monitor
Dispersive Electrodes	Performs Return Electrode Monitoring
Audible Signals	
Footswitch/Accessories	Electrical Safety Tests

activated circuits and shall comply with the standard requirements.

Several safety tests, according to general standard for medical electrical equipment (IEC 60601-1) especially patient leakage current, were performed in all electrosurgical units, [5, 6].

Results and Discussion

The performance and safety testing of high frequency surgical equipment in use at six hospitals were evaluated. Table 2 shows a brief history of achieved results.

Quantitative analysis of HF leakage current measurements showed the amount of obtained results in many units are critical and have high value over the standard limitations especially in ground-referenced generators. HF leakage currents of electrosurgical equipment are dependent on the amount of earthing resistance of hospital or medical centers. High earth resistance causes high HF leakage current. Therefore, the quality of earth system of hospital has a key role in safety performance of an electrosurgical unit as well as patient's safety. As a result prior to conducting any test on the unit, it is necessary to evaluate the quality of earth system of the hospital.

Achieved results show that HF leakage cur-

rent of ground-referenced generators are more than isolated generators. Therefore, it is suggested to use medical centers isolated generators in order to reach a high level of patients' safety.

For the power analysis (P in table 2), only eight units delivered acceptable output values and the precision in the output power measurements were low.

Conclusion

The use of electrosurgical generators has led to more effective surgical treatments and improved patient's safety through better control and management of complications during surgery.

Optimal performance and safety tests of these high frequency generators can lead to further improvement of patient's safety by ensuring the safety features of each generator which remains intact and the performance accuracy is guaranteed.

Results indicate a need for new and severe regulations on periodic performance verifications and medical equipment quality control program especially in high-risk instruments. It is also necessary to provide training courses for operating staff in the field of metrology in medicine and to equip them with critical

Table 2: A brief Summary of Evaluated Technical Result for each Unit

Items	U1	U2	U3	U4	U5	U6	U7	U8	U9	U10	U11	U12	U13	U14	U15	U16	U17	U18	U19	U20	
P(M)	Cut	*	*	*	**	**	*	***	**	*	**	**	*	**	**	***	**	**	**	***	
	Coagulation	*	*	*	**	*	*	**	**	*	**	**	*	**	*	**	**	**	**	**	
	Blend	*	*	**	**	*	*	**	**	*	**	**	*	**	*	**	**	*	**	**	
	Cut	NP	*	*	**	*	*	NP	**	*	**	**	NP	NP	*	NP	*	**	*	**	
P(B)	Coagulation	NP	*	*	**	*	NP	**	**	*	**	**	NP	NP	*	NP	*	*	*	**	
	Blend	NP	*	**	**	*	NP	**	**	*	**	**	NP	NP	*	NP	*	*	*	**	
	Ground Ref:	NA	√	NA	x	√	NA	x	NA	√	NA	NA	x	x	NA	x	x	x	x	x	
HF	Isolated	√	NA	√	NA	NA	√	NA	√	NA	√	√	NA	NA	√	NA	NA	NA	NA	NA	
	Patient Leakage Current	√	√	√	x	√	√	x	√	√	√	√	√	x	√	√	x	√	√	x	
		* 10-20%																			
		** 20-30%																			
		*** Above 30%																			
NP: Not Performed	P(B): Power Analysis of Bipolar	(According to the manufacturer disclosure)										(According to the manufacturer disclosure)									
		Patient Leakage Current										Patient Leakage Current									
		Normal Condition										Fault Condition									
NA: Not Applicable	P(M): Power Analysis of Monopolar	Patient Leakage Current										Patient Leakage Current									
		Normal Condition										Fault Condition									
		√ - In Standard Limitation										√ - In Standard Limitation									
		HF: HF Leakage Currents; (Max: 150 mA)																			
		CF Type: 10 μA										CF Type: 50 μA									
		BF Type: 100 μA										BF Type: 500 μA									
		x - Out of Standard Limitation																			

parameters for eliciting accurate results with operation room equipment.

Conflict of Interest

None

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