

プラズマ技術を用いた医用電気機器の国際標準化研究  
**Characteristics of the medical electrical equipment using plasma technologies**

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Medical Plasma Equipment for Blood Coagulation は、「発生させたプラズマを照射することにより、血液凝固を生じさせ出血の制御を可能とさせる」医用電子機器である。2013 年 4 月に上海で行われた International Electronics Commission (IEC) TC62-SC62D 総会において、同装置には、IEC の定める止血装置の国際標準 IEC60601-2 「high Frequency Electrosurgery equipment」でカバーされない項目が存在することが確認され、これに対応する New Working Item Proposal (NWIP)提案の必要性が確認された。そして、Japanese Industrial Standards Committee (JISC)が、NWIP の提案を行うとして承認された。Table 1 は、capillaries に対して実用化されている止血装置と低温プラズマに関して、出力計測などに関する規格の有無についてまとめたものである。

現在、将来的な新規 IEC 60601-2-xx 規格を目指して、NWIP の策定を現在行っているところである。図 1 に規格検討例を示す。講演では、電気的安全性に関する規格項目例と評価例について発表をする予定である。

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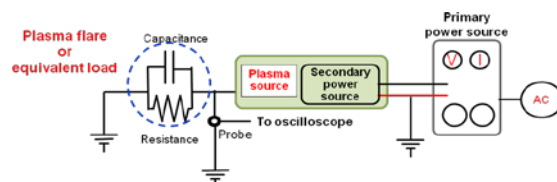


Fig. 1. An example of a measurement system.

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Table. Equipments for controlling bleeding from small and capillary vessels.

	Without cauterization		Cauterization generally occurs		
	Low-temperature plasma	High-temperature plasma (ex., APC)	Laser	Ultrasonic wave equipment	High-frequency electrical coagulator
Operating points for hemostasis	Acceleration of blood coagulation process	Heat to destruct small blood vessel	Heat to destruct small blood vessel	ultrasonic vibration and the heat to destruct small blood vessel	High frequent current heating to destruct small blood vessel
Adaptation for bleeding control	Capillaries, small vessels, and veins	Capillaries, small vessels, and veins	Capillaries, small vessels, and veins	Capillaries, small vessels, and veins	Capillaries, small vessels, and veins
Measurement of output power	Not defined	Not defined	○	○	○