Standardization of a Low Energy Ionized Gas Haemostasis Equipment in International Electrotechnical Commission

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High frequency surgical equipment which is defined in IEC 60601-2-2 has been effectively used for the blood coagulation from capillaries and small vessels. However, high-frequency current induces a thermal effect, e.g. to control or prevent bleeding, induce tissue destruction, or induce tissue shrinkage. Then, the equipment that do not induce the burn injury is desired for the stop bleeding of capillaries. While, low temperature plasma directly accelerates the blood coagulation process [1,2]. Moreover, it was reported that low temperature plasma treatment can reduce invasiveness under hemostasis, and reduce risk of postoperative disorders [3,4]. It was confirmed that medical plasma equipment using low temperature plasma for blood coagulation is not fully covered by the document of IEC60601-1, IEC60601-2-2 and the related international standard documents, at Shanghai, 2013, in general meeting of Technical Committee 62, Sub-committee 62D plenary session, International Electrotechnical Commission (IEC). Then, new working group was established, and discussed basic safety and essential performance. Especially in the document, intended use of the equipment is defined, and possible hazards to the patients and medical doctors were considered as the basic safety. Measurement methods of hazards were defined, and upper limit values of each output were shown as a guideline from a safety point of view. Finally, new document of IEC 60601-2-76 on “low energy ionized gas haemostasis equipment” was published in 10th April 2018. / This work had been conducted with Prof. Y. Ikehara at AIST, and Chiba Univ. I thank all of IEC working group 34 members, especially, Dr. T. Shimizu, Mr. M. Schmidt’s, Mr. J. Eggleston, and Dr. V. Antoni. I thank Prof. Y. Seto at the Univ. Tokyo Hospital, Prof. N. Shimizu at SANNO Hospital, Dr. T. Arikado at Tokyo Electron Device LTD, Prof. M. Ichinose and Dr. T. Niwa at Wakayama Medical Univ., T. Kaneko at Tohoku Univ., K. Kurihara at Toshiba Corporation, Prof. S. Hamaguchi and Prof. E. Morii at Osaka Univ., Mr. O. Shimoda, Mr. M. Hamatani, Dr. S. Makinouchi, Mr. M. Fujino, Dr. S. Watanabe at Nikon Corporation, Dr. S. Hamada at Otsu Municipal hospital, Prof. H. Hayashi at Chiba Univ., Prof. M. Hori and Dr. Y. Kodera at Nagoya Univ., Dr. H. Nakanishi at Aichi Cancer Center Research Institute, Dr. M. Natsui at Nerima-Hikarigaoka Hospital, Mr. K. Toda at Muranaka Medical Instruments Co. LTD, E. Uchimura at The Osaka Chamber of Commerce and Industry, Prof. N. Yahagi at Keio Univ., Prof. M. Zuka at Kanazawa Univ., Mr. M. Naito, Dr. S. Kiyama, Dr. S. Ikehara, Dr. J. Kim, and Ms. R. Okuma at AIST, and Mr. H. Yamada at Univ. Tsukuba. This study was financially supported by Strategic International Standardization Acceleration Projects from the Ministry of Economy, Trade and Industry of Japan, and in part by JSPS KAKENHI Grants-in-Aid for Scientific Research on Priority Area (24108006).

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