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Safety Requirements and Test Methods of a Radiofrequency Stimulator

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Abstract

In this study, we investigate the safety requirements and test methods of a radiofrequency stimulator. The main test items include controls of a minimum output, accommodation range, and output parameters that have been known as the safety requirements in conformity with international standards. As the test criteria for controlling the minimum output, an increase or decrease in a unit of 1 mA or 1 V or less was applied to the output amplitude regulator for both continuous and discontinuous control, and the output at the minimum setting was manipulated to not exceed 2% of the maximum setting. For controlling the output parameters, one of the representative test criteria states that the current limit of 250 mA should be equal to or less than 1,500 Hz. Consequently, when applying the radiofrequency stimulator on the human body, we need to ensure that the safety requirements conform to the international standards.

Index Terms: Output parameter, Radiofrequency, Stimulator

I. INTRODUCTION

The principle of radiofrequency (RF) currents is that on being applied through an electrode in the vicinity of the target neural structure, they release energy to the surrounding tissues and raise the temperatures as they pass by. During the RF thermal lesioning, the electrode itself is only passively heated. Temperatures above 45℃ are known to be neurodestructive [1].

RF is an innovative therapeutic method including several latent applications to relieve pain. A number of investigators have studied pain treatment using RF energy. In 1976, Sweet [2] reported the results of a retrogasserian differential lidocaine blocking process used for assisting in the selection of patients for a differential thermal lesion in the trigeminal ganglion and the rootlets. This process repeated the condition of analgesia where one can withstand RF heating without using anesthesia. In 1997, Uematsu [3] induced a large lesion by using a large gauge electrode with a tip temperature of 75℃. As a result, dorsal root ganglia were severely damaged, and many after effects of deafferentation were caused. At the end of this era, the use of RF for pain treatment by most of the neurosurgeons decreased gradually. However, RF was continuously developed. Stimulation for a study on RF appeared in Australian society in 1995. Sluijter [4] reported additional clinical effects from exposure to a magnetic field other than tissue damage from RF.

The central idea of discussions developed in Sluijter et al. [5] later on is that RF was capable of delivering RF energy adequate to modulate the electrical field but inadequate to cause tissue thermocoagulation. Several months after the embryonic conference, an electronics engineer developed a

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prototype RF generator. In early 1996, Sluijter et al. used this equipment for managing preparatory clinical trials and wrote the first-ever report on the clinical effects of RF on dorsal root ganglia in 1998 [5]. Mathematical calculations were included in the first publication on RF to show the fact that high-density electrical currents are generated at the tips of an electrode that can stress the cellular membranes and cause altered cell functions and injury. However, investigators insisted on a combination of electrical and thermal tissue abrasion from RF application later [6, 7]. Recently, Barbieri and Bellini [8] reported the benefit of RF pain-soothing processes without any side effects.

Electrodes of an RF stimulator are mainly divided into two types: monopolar and bipolar. In theoretical terms, a bipolar current source and the tissue should have good contact, and electrocoagulation should occur irrespective of the surrounding fluid medium. The area of tissue damage is expected to be confined to the point of application of a bipolar electrode because the production of thermal energy does not depend on the conduction of currents between active and indifferent electrodes. Monopolar diathermy turns the whole patient into electrolyte solutions where currents between two electrodes can flow. However, the danger of applying monopolar diathermy to structures on pedicles is well recognized [9].

Fig. 1 shows a monopolar electrode. A conductive area where electric current flows, is shaped like a disk, and there is a nonconductive type that does not allow the flow of electric current. Fig. 2 shows a bipolar electrode that is composed of a catheter with two polarities (+, −); the contacting surfaces of handpieces reciprocally cross each other.

There are no international standards or applicable study standards for an RF stimulator, and International Electrotechnical Commission (IEC) Standard 60601-2-10 is being applied as the relevant standard. The IEC 60601-2-10 standard is applied to all devices that allow electric current through a directly contacting electrode for the treatment and diagnosis of neuromuscular diseases. However, problems related to the following two categories from IEC 60601-2-10 have occurred.

Even a slight increase in the output amplitude of Test 1 can stimulate subjects asymmetrically. Therefore, controlling the output amplitude smoothly or to a lower level is an important safety characteristic. Limiting an output to the minimum level of the output control may increase the output amplitude from the lower level. However, if the RF output is lowered to 1 mA or 1 V, step by step, it has to go through many steps to reach the maximum output. The acceptable limit of electric current defined in the Limit of Output Parameter section in Test 2 should not exceed 100 mA. However, there are problems in applying the IEC 60601-2-10 standard when considering the effects of its use in accordance with the characteristics of RF stimulators because the limit of electric current defined in the standard is remarkably lower than the output of the RF stimulators. Therefore, a testing standard applicable to RF stimulators needs to be established on the basis of the characteristics of the relevant product, and accordingly, data on safety and efficacy are required. Thus, we are reporting the safety requirements and testing methods in accordance with the characteristics of RF energy.

Fig. 1. Monopolar electrode.

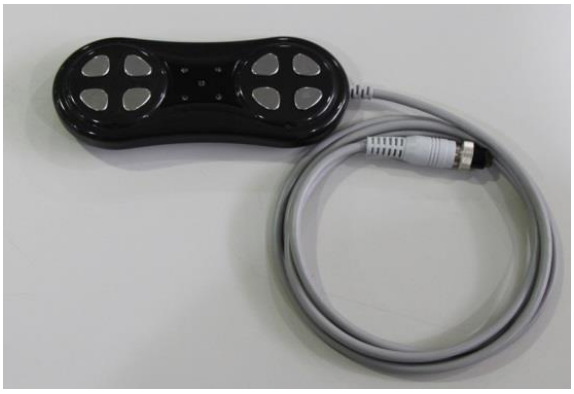

Fig. 2. Bipolar electrode.

II. METHODS

A 64-MXs-B digital oscilloscope by Lecroy was used for measuring voltage, pulse width, frequency, etc., and an ADP30X differential probe by Lecroy was used for measuring voltage and other parameters. An SP-9100A automatic voltage regulator by Samsung Power System Ltd, 10-kVA single-phase voltage slidacs with a 300-V capacity by Daekwang Tech. Ltd, 10-kVA single-phase isolated transformer by C. A. Korea, and a WT210 digital power meter by Yokogawa Electric Corporation were used.

Table 1. Testing conditions

Output method	Output frequency	Output power	Output current (based on 500-Ω resistance)	Output intensity control
Monopolar Mode 1	300 kHz	Maximum of 150 W	Maximum of 460 mA ± 20%	Level 10
Monopolar Mode 2	500 kHz	Maximum of 150 W	Maximum of 460 mA ± 20%	Level 10
Monopolar Mode 3	500 kHz	Maximum of 150 W	Maximum of 460 mA ± 20%	Level 10
Bipolar Mode 1	1 MHz	Maximum of 150 W	Maximum of 460 mA ± 20%	Level 10
Bipolar Mode 2	0.5 MHz	Maximum of 150 W	Maximum of 460 mA ± 20%	Level 10
Bipolar Mode 3	1 MHz	Maximum of 150 W	Maximum of 460 mA ± 20%	Level 10

Table 2. IEC 60601-2-10:2012 (third edition)

Test category	Requirements
Test 1. Output Amplitude	There should be a method to control the output of a stimulator continuously from the minimum to the maximum, or to lower the output to 1 mA or 1 V, step by step. The output from the minimum setting should not exceed 2% of the output from the maximum setting.
Test 2. Limit of Output Parameter	(a) Medical equipment (hereinafter, ME) device for treatment: The output current should not exceed the following limits when loaded with 500 Ω of load resistance. If an output has alternating current and direct current, these should be measured separately and compared with acceptable limits.

Pulse frequency	Limit current
Direct current	80 mA
≤400 Hz	50 mA
>400 Hz and ≤1,500 Hz	80 mA
>1,500 Hz	>100 mA

(b) ME device for a diagnosis purpose: If an ME device is used for dental medicine or ophthalmology, direct current with 2,000 Ω of load resistance should not exceed 10 mA.

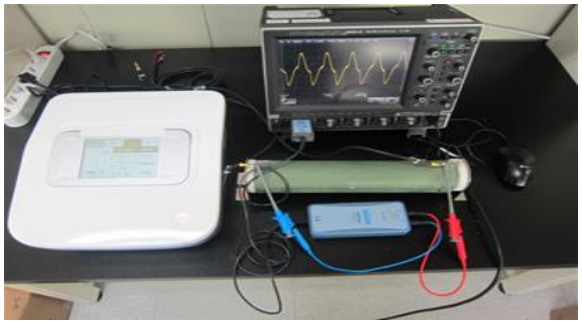

Fig. 3. Test: Limit of minimum output and control range.

Fig. 4. Test: Limit of output parameter.

A. Testing Method

1) Test on the Limit of Minimum Output and a Control Range

As shown in Table 1, the testing sample is provided with the rated voltage and frequency. After connecting the sample with 500 Ω of non-inductive resistance as shown in Fig. 3, we carried out the measurement with an oscilloscope and compared the output voltage.

2) Limit of Output Parameter

The output current at a load resistance of 500 Ω should not exceed the limits of Test 2, as listed in Table 2. In the case of an output that has alternating current (AC) and DC components, individual components were separately measured and compared with each acceptable limit.

A testing method is used for supplying the rated voltage and frequency to the testing sample as shown in Table 1. After connecting a non-inductive resistance of 500 Ω to the sample, the output was measured with an oscilloscope and the effective value of the output current was measured by connecting a thermoammeter in series to the testing circuit.

III. RESULTS AND DISCUSSIONS

In Food and Drug Administration (FDA) guidance documents, stimulators are classified depending on the purpose of use: transcutaneous electrical nerve stimulator, electrical stimulator for rehabilitation therapy, and transcutaneous electrical stimulator for cosmetic uses. These three types of stimulators are specified as stimulators with an output limit and the stimulators without an output limit. In general, the documents require manufacturers to provide requirements for the applicable range of each item according to the classification, protection against harm, characteristics of performance, and data on the safety and efficacy of devices. In particular, the documents limit devices with an output limit that meets the limit of a maximum electric current of 100 mA. Further, they are mostly composed of the status of output limits, type and classification of devices, etc., and they require a sufficient amount of source data, data related to a clinical field, data on output variables, and an analysis of these data for protection from and alleviation of the electrical and mechanical harm that can occur in ordinary situations. One of the test items, the limit of the minimum output and a range of control, was investigated as a required item irrespective of the type, classification, and purpose of the product by IEC 60601-2-10 and the FDA guidance. Further, some requirements of IEC 60601-2-10, such as stability of output control, change in voltage for power supply, protection of output, etc., can be found in the FDA guidance documents. On the basis of these pieces of information, it is certain that the application of the IEC 60601-2-10 standard to RF stimulators is not wrong. When applying the guidance to "test for the limit of the output parameter," it was clear that the output limitation was classified depending on the purpose of the devices. However, there is a limit to elicit the output limit grounds from the FDA guidance. It should be determined that the electric current limit standards for a test for output parameter limits should be provided on the basis of the clinical data for the purpose of the manufacturer of an RF stimulator or the data that can verify the safety and efficacy of the product [10].

We have performed the test on the minimum output limit and the control range and the test on the output parameter limit, and then investigated the details. The tests on the minimum output limit and the control range were conducted under six different conditions. The first test was conducted in Monopolar Mode 1, which includes a deep capacity electric transfer (CET) and 300 kHz. The output level was divided into 10 levels with a load resistance of 500 Ω. Fig. 5 shows the output level (intensity)–output voltage graph with deep CET and 300 kHz as the conditions of Monopolar Mode 1. The red line denotes the actual voltage V_{rms} of the output voltage. The blue line indicates a regression line.

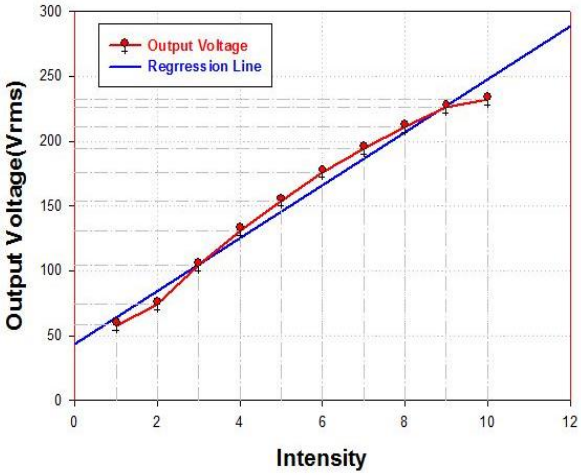

Fig. 5. Output level–output voltage graph: result of measurement of output voltage of Monopolar Mode 1 (deep CET, 300 kHz).

Fig. 6. Result of the waveform in intensity (1–10) of the output voltage of Monopolar Mode 2 (CET, 500 kHz).

Table 3. Result of the measurement of output voltage of Monopolar Mode 2 (CET, 500 kHz)

Output level (intensity)	Output voltage (V_{rms})	Load resistance (Ω)
1–10	33	500

A linear increase can be observed from the output voltage–intensity curve.

When determined on the basis of Test 1. Limit of minimum output and range of control of IEC 60601-2-10 as a testing standard, the control range of Monopolar Mode 1, as shown in Fig. 5, fluctuated with a difference of approximately 20 V, and 25% of the maximum output voltage was measured as the minimum output.

The second test was conducted in Monopolar Mode 2, which included CET, and the frequency was set to 500 kHz. The output level was divided into 10 levels. The output voltage was estimated to be 33 V (Table 3). Fig. 6 shows the measured value of the output voltage per output level with

deep CET and 300 kHz as Monopolar Mode 1.

The third test was conducted in Monopolar Mode 3 (resistive electric transfer [RET]), and the frequency was set to 500 kHz. The output level was divided into 10 levels. The output voltage was estimated to be 24 V (Table 4). Fig. 7 shows the measured value of the output voltage per output level with deep RET and 500 kHz as in the case of Monopolar Mode 1.

Fig. 7. Result of the waveform for the intensity (1–10) of the output voltage of Monopolar Mode 3 (RET, 500 kHz).

Table 4. Result of the measurement of output voltage of Monopolar Mode 3 (RET, 500 kHz)

Output level (intensity)	Output voltage (V_{rms})	Load resistance (Ω)
1–10	24	500

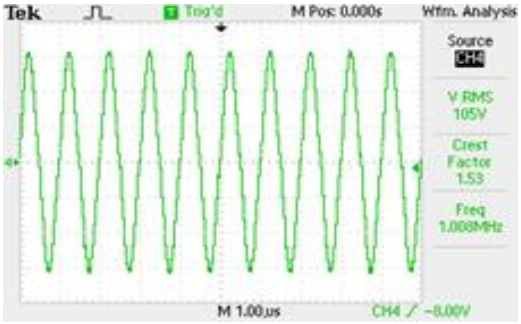

Fig. 8. Result of the waveform of the intensity (1–10) of the output voltage of Bipolar Mode 1 (RET, 1 MHz).

Table 5. Result of the measurement of the output voltage of Bipolar Mode 1 (RET, 1 MHz)

Output level (intensity)	Output voltage (V_{rms})	Load resistance (Ω)
1–10	105	500

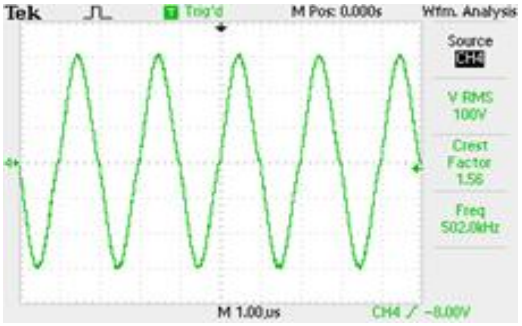

Fig. 9. Result of the waveform of the intensity (1–10) of the output voltage of Bipolar Mode 2 (0.5 MHz).

Table 6. Result of the measurement of the output voltage of Bipolar Mode 2 (0.5 MHz)

Output level (intensity)	Output voltage (V_{rms})	Load resistance (Ω)
1–10	100	500

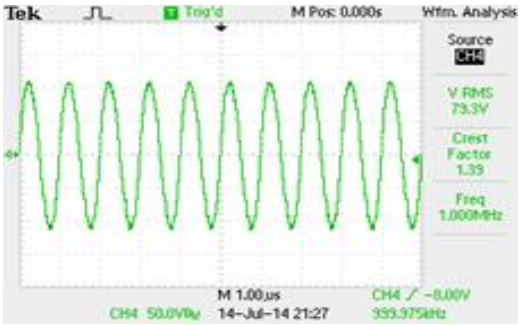

Fig. 10. Result of the waveform for the intensity (1–10) of the output voltage of Bipolar Mode 3 (1 MHz).

Table 7. Result of the measurement of the output voltage of Bipolar Mode 3 (1 MHz)

Output level (intensity)	Output voltage (V_{rms})	Load resistance (Ω)
1–10	79	500

The fourth test was conducted in Bipolar Mode 1, and the frequency was set to 1 MHz. The output level was divided into 10 levels. The output voltage was estimated to be 105 V (Table 5). Fig. 8 shows the measured value of the output voltage per output level with deep RET and 1,000 kHz as in the case of Monopolar Mode 1.

The fifth test was conducted in Bipolar Mode 2, and the frequency was set to 0.5 MHz. The output level was divided into 10 levels. The output voltage was estimated to be 100 V

(Table 6). Fig. 9 shows the measured value of the output voltage per output level with 0.5 MHz as Bipolar Mode 2.

The sixth test was conducted in Bipolar Mode 3, and the frequency was set to 1 MHz. The output level was divided into 10 levels, and the output voltage was estimated to be 79 V (Table 7). Fig. 10 shows the measured value of the output voltage per output level with 1 MHz as in the case of Bipolar Mode 3.

As a result of the test conducted using a sample of the relevant product, we confirmed that various results from each of the monopolar and bipolar modes were obtained. In the graph shown in Fig. 6, the x-axis denotes the time domain and the y-axis, the voltage domain. The effective values of the voltage from intensity 1 to 10 are 33 V_{rms}.

Further, we confirmed from monopolar and bipolar electrodes (Figs. 7–10) that the output voltage results were the same depending on the intensity of the output. Even in this situation, it did not meet the standard for the limits of the minimum output and the control range. As a result, we could draw a conclusion that a test for determining the limits of the minimum output and the control range for the IEC 60601-2-10 standard is not suitable for RF stimulators. However, according to the FDA guidance, the output of any type of stimulator should be increased gradually and the same requirement is stated in IEC 60601-2-10. Therefore, the same testing standard and the same testing method should be applied to this test category [11, 12]. However, with respect to the intended uses confirmed by this study, it is inadequate to draw a conclusion with a load resistance of only 500 Ω, which is used for testing. If an electrical surgical instrument has a small application range for its intended use, bipolar electrodes should be tested for various outputs ranging from 10 to 1,000 Ω, and monopolar electrodes should be tested for those ranging from 100 to 2,000 Ω. Similarly, item 201.12.1.10 in IEC 60601-2-2:2011, which is a standard for RF stimulators, requires output measurements for at least five different load resistances and rated loads, including 100–2,000 Ω for monopolar electrodes and 10–1,000 Ω for bipolar electrodes, as functions for the output control setting, and the application of these testing methods is considered desirable for RF stimulators. In other words, there should be a guideline for selecting the load resistance considering the manufacturer's intended use (points of application to the human body) by classifying the load resistance standard of 500 Ω for RF stimulators, which is a testing method required by the IEC 60601-2-10 standard during the test for the limits of the minimum output and the control range, into the bipolar type and the monopolar type. Similar to the test for the limits of the minimum output and the control range, the test for the limit of the output parameter was performed by dividing it into six different types. The load resistance was 500 Ω, and the output level was divided into 10 levels.

The first test was conducted in Monopolar Mode 1, which included a deep CET, and the frequency was set to 300 kHz. Fig. 11 shows the output level (intensity)–output current graph for Monopolar Mode 1 (deep CET, 300 kHz). The red line denotes the output current, and the blue line indicates a regression line. A linear increase can be observed from the output current–intensity curve.

When determined on the basis of the testing standard for the limits of the output parameter from IEC 60601-2-10, the maximum output current in the case of Monopolar Mode 1 (deep CET, 300 kHz), as shown in Fig. 11, was measured as 460 mA. In this test, it was difficult to consider the maximum output current as an output limit because the maximum output current was very high.

The second test was conducted in Monopolar Mode 2, which was CET, and the frequency was set to 500 kHz.

Table 8 presents the output currents depending on the changes in the output level. Despite the changes in the output level, the output currents were all 70 mA.

The third test was conducted in Monopolar Mode 3, which was RET, and the frequency was set to 500 kHz.

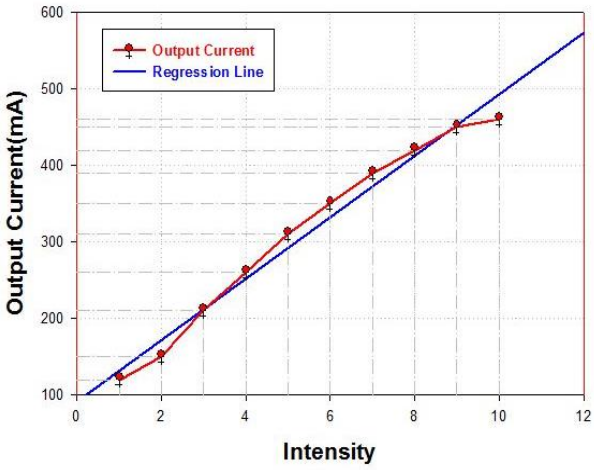

Fig. 11. Output level–output current graph: result of the measurement of the output current of Monopolar Mode 1 (deep CET, 300 kHz).

Table 8. Result of the measurement of the output current of Monopolar Mode 2 (CET, 500 kHz)

Output level (intensity)	Output current (mA)	Load resistance (Ω)
1–10	70	500

Table 9. Result of the measurement of the output current of Monopolar Mode 3 (RET, 500 kHz)

Output level (intensity)	Output current (mA)	Load resistance (Ω)
1–10	50	500

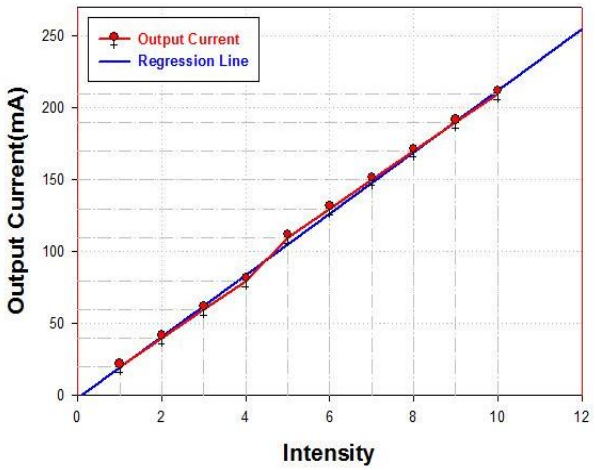

Fig. 12. Output level–output voltage graph: result of the measurement of the output current of Bipolar Mode 1 (1 MHz).

Table 9 shows the output currents depending on the changes in the output level. Despite the changes in the output level, the output currents were all 50 mA.

The fourth test was conducted in Bipolar Mode 1, and the frequency was set to 500 kHz. Fig. 12 shows the output level–output voltage graph for the case of Bipolar Mode 1 (1 MHz). The red line denotes the output currents, and the blue line indicates a regression line. A linear increase can be observed from the output current–intensity curve.

As shown in Fig. 12, the maximum output current was measured to be 210 mA, and the value greater than 200 mA was obtained as a limit.

The fifth test was conducted in Bipolar Mode 2, and the frequency was set to 0.5 MHz. Table 10 presents the output currents depending on the changes in the output level. Despite the changes in the output level, the output currents were all 20 mA.

The sixth test was conducted in Bipolar Mode 3, and the frequency was set to 1 MHz. Table 11 presents the output currents depending on the changes in the output level. Despite the changes in the output level, the output currents were all 20 mA.

For the output values per monopolar and bipolar electrode and mode, as presented in Tables 8–11, the same output current values were measured depending on the intensity of the output, and they were lower than the limit of 100 mA. However, a standard for the limit of the output parameter for low-frequency stimulators was not met because values higher than 100 mA were measured in some modes. Since the highest maximum output excluding that shown in Fig. 11 was 210 mA, the maximum output was set to 250 mA considering an allowable error of 10%. Thus, we concluded that a test for the limit of the output parameter in the IEC 60601-2-10 standards is not suitable for RF stimulators when considering the test results.

Table 10. Result of the measurement of the output current of Bipolar Mode 2 (0.5 MHz)

Output level (intensity)	Output current (mA)	Load resistance (Ω)
1–10	20	500

Table 11. Result of the measurement of the output current of Bipolar Mode 3 (1 MHz)

Output level (intensity)	Output current (mA)	Load resistance (Ω)
1–10	20	500

However, if a basis is provided that an output of more than 100 mA can secure the safety and efficacy while maintaining the intended use and clinical effect, a testing standard provided by the manufacturer should be applied in accordance with the method provided by the FDA guidance. However, the output current was selected on the basis of the highest output current from the approved products that we investigated. Further, there should be a guideline for selecting the load resistance considering the manufacturer's intended use (points of application to the human body) by classifying a load resistance of 500 Ω defined by the "output parameter test" into the bipolar type and the monopolar type as mentioned in the test for "the limits of the minimum output and the control range." The testing standards selected through the abovementioned tests are as follows: Table 12 shows the testing methods and specifications on the minimum output limit and the control range.

In the case of the test for the limit of the minimum output and the control range, instead of limiting the load resistance of the testing method required by the IEC 60601-2-10 standard to 500 Ω, it was set for measurement by dividing the load resistance considering the manufacturer's intended use (points of application to the human body). A discontinuous regulator should be increased and decreased in the units of 1 mA or 1 V or less, and the output at the minimum

setting should not exceed 2% of the maximum setting, which can be adjusted with the regulator. Therefore, the ratio between the minimum setting and the maximum setting was calculated and set to be appropriate for the standard.

Table 13 presents the limits of the output parameter. As a testing standard, the output parameter was limited by setting the limit of the output current at the manufacturer-set load resistance to 250 mA. Further, stability was obtained by considering the manufacturer's intended use (points of application to the human body) and setting the load resistance.

Table 12. Limits of minimum output and control range

Category	Test standard	Testing method
Limits of minimum output and range of control	An output amplitude regulator should be continuously regulating or a discontinuous regulator should be increased and decreased in units of 1 mA or 1 V or less.	1) If an output amplitude regulator is a continuous regulator: Connect both ends of an output section to a specific value of the load resistance set by the manufacturer in parallel, and operate the continuous regulator of a stimulator to check whether the output increases or decreases continuously. 2) If an output amplitude regulator is a discontinuous regulator: Connect both ends of an output section to a specific value of the load resistance set by the manufacturer in parallel after the output amplitude regulator of a stimulator is set to the minimum setting. If the level of the output voltage is being measured, connect an oscilloscope to the load resistance set by the manufacturer in parallel. If the output current is being measured, connect an ampere meter to a specific value of the load resistance set by the manufacturer in series. Measure the increase in the amplitude by increasing the output amplitude regulator of a stimulator gradually.
	The output at the minimum setting should not exceed 2% of the maximum setting, which can be adjusted with the regulator.	Set up a discontinuous regulator in the same way as described in item 1) above and measure the output at the minimum setting by using an oscilloscope or an ampere meter. Then, measure the output at the maximum setting by using an oscilloscope or an ampere meter. Measure the ratio of each measured value.

Table 13. Limit of output parameter

Category	Test standard	Testing method
Limits of output parameter	The output current from the load resistance set by the manufacturer should not exceed the limits specified in the table below.	1) Connect both ends of an output section to a specific value of the load resistance set by the manufacturer in parallel. 2) If an ampere meter is being used: After connecting an ampere meter to a specific value of the load resistance set by the manufacturer in series, set the output of a stimulator to the maximum and operate it. The effective value (rms) of the output current is then measured. If an oscilloscope is being used: After connecting an oscilloscope to a specific value of the load resistance set by the manufacturer in parallel, set the output of a stimulator to the maximum and operate it. Measure the effective value (rms) of the output current, and calculate the output current by using the formula I = V/R. In this formula, V denotes the effective value (rms) of the voltage (V_{rms}) and R indicates the load resistance (Ω) set by the manufacturer. In the case of an output that has AC and DC components, each component should be separately measured and compared with each acceptable limit.

Frequency	Limit current
Direct current	80 mA
≤400 Hz	50 mA
>400 Hz and ≤1,500 Hz	80 mA
>1,500 Hz	250 mA

IV. CONCLUSIONS

RF stimulators do not have individual standards or medical device standards for IEC 60601-1, and hence, there are difficulties in testing for the relevant items. In this study, a testing standard and method were established through various reference documents for conducting tests for the various categories of an RF stimulator performance evaluation and the analysis of the relevant standards. Reliability was verified through an analysis of the conducted tests. The information necessary for the safety and performance of RF stimulators was thus obtained in this study. In addition, we believe that the effectiveness of the considered product will increase during its development by medical device manufacturers and the license application process for certification and evaluation by a licensing body.

Thus, RF stimulators will contribute to the improvement of national health.

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