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Measurement of the output power of electrosurgical high-frequency equipment when simulating single fault conditions

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Abstract

The issues of determining the output power of high-frequency electrosurgical equipment by simulation of single fault conditions in accordance with the particular standard DSTU EN 60601-2-2:2015 are considered. It is noted that modern high-frequency equipment is equipped with measuring units to control output current and voltage in order to ensure control of output power. A method for monitoring the performance of built-in protection systems of modern HF equipment is proposed if the output power exceeds the limits of allowable values under single fault conditions. This method is common for most operating modes of HF equipment. Practical examples of such tests are given.

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1. Introduction

Today, the solution to the problem of health protection and ensuring the population's safety during medical services largely depends on the quality, efficiency, and safety of medical devices that enter our domestic market and are used for their intended purpose. Safety of medical products during their use, according to [1-4], means the exclusion of unacceptable potential risks that could result in harm to the health of patients and medical personnel, both «direct» and «indirect» risks due to malfunction of medical equipment or its improper use. Depending on the potential risk of their use, medical devices are divided into four classes: I, IIa, IIb, III. Of course, the most stringent controls were carried out on products of classes IIb (increased risk) and III (high risk). Electrosurgical high-frequency equipment belongs to risk group IIb, which is due to their functional purpose and conditions of use. Such equipment provides cutting and coagulation of the biological tissues of patients. This is due to the heat that created in the biological tissues during the passage through them of high-frequency currents (at least 200 kHz). The maximum tempera-

Measurements infrastructure Vol. 4 (2022) MI_016_021121 https://doi.org/10.33955/v4(2022)-016

ture in biological tissue achieved during normal use is proportional to the electrical power supplied to it and the duration of action [5-8]. The less this power, the less probability of temperature increase above the allowable level, which can lead to a probable burn.

2. Actuality and purpose of the publication

The main consideration when setting the maximum allowable output power values of HF equipment is the maximum possible safety of the patient and medical personnel. Particular standard DSTU EN 60601-2-2:2015 set allowable output power values for both the normal condition of the product (not more than 400 W) and for single fault conditions according to subclause 201.12.4.4.101 of this standard [9]. These allowable output power values for single fault conditions are shown in Table 1. Note that the maximum allowable output power under single fault conditions shall be calculated separately for each patient circuit and mode of operation. Measurements of the essential performance of HF equipment (and, first of all, the output power and HF leakage currents) for the normal condition of the product are described in [10].

This article considers the normalization and measurement of the output power of high-frequency electrosurgical equipment under simulated single fault conditions.

3. Main body

Modern HF equipment, as a rule, has an integrated protection system, which carries out:

- monitoring of output power dosage with its shutdown in case of a single fault conditions;
- automatic limitation of the maximum duration of the output power switching on;
- monitoring of a neutral electrode with one or two contact surfaces to control the presence of electrical connection between the device and the neutral electrode, and also the correct application of the neutral electrode on the patient's body (for example, devices from ERBE Elektromedizin GmbH have the NESSY system for this, devices by BOWA-electronic GmbH – EASY system).
- an internal self-test that detects and signals both functional errors and operator errors.

To ensure the control of the output power, measuring units are introduced into the circuits of modern HF equipment to control the output current and voltage, which make it possible to determine the output power. The principle of construction of protection systems against overpowering output power beyond the allowable values is based on the fact that the output power has a maximum at an optimal load resistance. For other load resistance in the range specified in the standard DSTU EN 60601-2-2:2015, the output power decreases. If the HF equipment meets the requirements for the allowable output power at the optimal resistance (corresponds to the allowable limits according to Table 1), then it will automatically comply with these requirements even at other resistances from the specified range. Therefore, it is enough to ensure the functioning of the protection

Setting (range in % of rated output power)	Maximum allowed output power in single fault conditions
Less than 10	20 % of rated output power
10 to 25	Setting x 2
Greater than 25 and up to 80	Setting + 25 % rated output power
Greater than 80 and up to 100	Setting + 30 % rated output power

Table 1. *Maximum output powers in single fault conditions*

system and check its operability at the optimal load resistance of the HF equipment. There are a large number of elements in the product, the malfunction of which can lead to a significant increase in the output power. Item-by-item checks are irrational. The number of inspections is increasing substantially, and it is practically impossible to carry out a technical check of the product's performance. Therefore, to control the serviceability of the built-in protection system of modern HF equipment, the following method is proposed. It is common for most modes of operation of such devices, except for some of their special modes, in which the output voltage of large amplitude with a significant duty is formed (for example, pulse cutting with coagulation and non-contact coagulation, which are used in the HF apparatus ECONT-0201.3). The output power of the product set by the reference voltage of the built-in stabilizer. When checking, the output of this stabilizer was turned off and an external regulated voltage source was connected instead. By changing the voltage of this source, it is necessary to set such an output power of the HF equipment, which will lead to the operation of its protection system. In this case, the real output power P (1) is indirectly determined by the measuring device from the result of measuring the U_{rms} voltage value at the optimal load resistance.

$$P = U^2_{rms} / R_l, \quad (1)$$

where:

U_{rms}, V – readings of the measuring device; R_l, Ohm – active load resistance, which is connected between the electrodes (for example, low-inductive resistors of the C5-40V type for 500 W with nominal resistances from 51 to 2000 Ohm with tolerances of ± 10 %).

Let us give examples of various versions used to determine the output power of HF equipment when simulating single fault conditions, leading to the operation of the protection system. The measurements were carried out using an Agilent DSO3102A oscilloscope in the normal sweep mode. If necessary, including increased accuracy, the voltage value was recorded no more than three times.

Operating mode		Rated power P, W	Rated load R_l, Ohm	Set point (range in % of rated power)	Installed power, W	Limiting power, W	
						Calculated value	Measured value
Monopolar							
1	Universal cutting 3	300	400	< 10	15	60	27
				10…25	60	120	108
				26…80	90	165	161
				81…100	255	345	340
2	Universal coagulation 3	150	300	< 10	10	30	15
				10…25	30	60	30
				26…80	45	82,5	55
				81…100	130	175	145
Bipolar							
3	Forced coagulation	150	50	< 10	10	30	21
				10…25	30	60	32
				26…80	45	82,5	65
				81…100	125	170	159
4	Cutting BI-TUR	300	100	< 10	10	60	17
				10…25	30	60	58
				26…80	80	155	148
				81…100	250	340	332

Table 2. *Maximum output power of single fault conditions for some operating modes of HF apparatus* ECONT-0201.3

Measurements infrastructure Vol. 4 (2022) MI_016_021121

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Examples of using the suggested method for measuring the output power of HF equipment during modeling of single fault conditions

Example 1.

Let us consider the tests of the domestic HF apparatus ECONT-0201.3 manufactured by «Contact Co., Ltd», Kyiv. The product, as indicated above, uses measuring units for monitoring current and voltage, information from which is sent to a microprocessor that determines and controls the output power. The results of determining the output power of this HF device when simulating single fault conditions for some of its operating modes are presented in Table 2. They were carried out at the KNT3.558.023 stand (Fig. 1), developed by the specialists of the same company.

To control the output power using the stand, instead of the reference voltage of the built-in stabilizer, connect the external power supply of the A1 stand and the required load resistance of its block A7. Then set the mode and power of the apparatus according to check Table 2 and gradually increase the voltage using the A2 autotransformer with the built-in digital voltmeter until the device protection circuit is triggered; the last maximum value of the U_{rms} voltage on the measuring device is recorded, and the output power is determined.

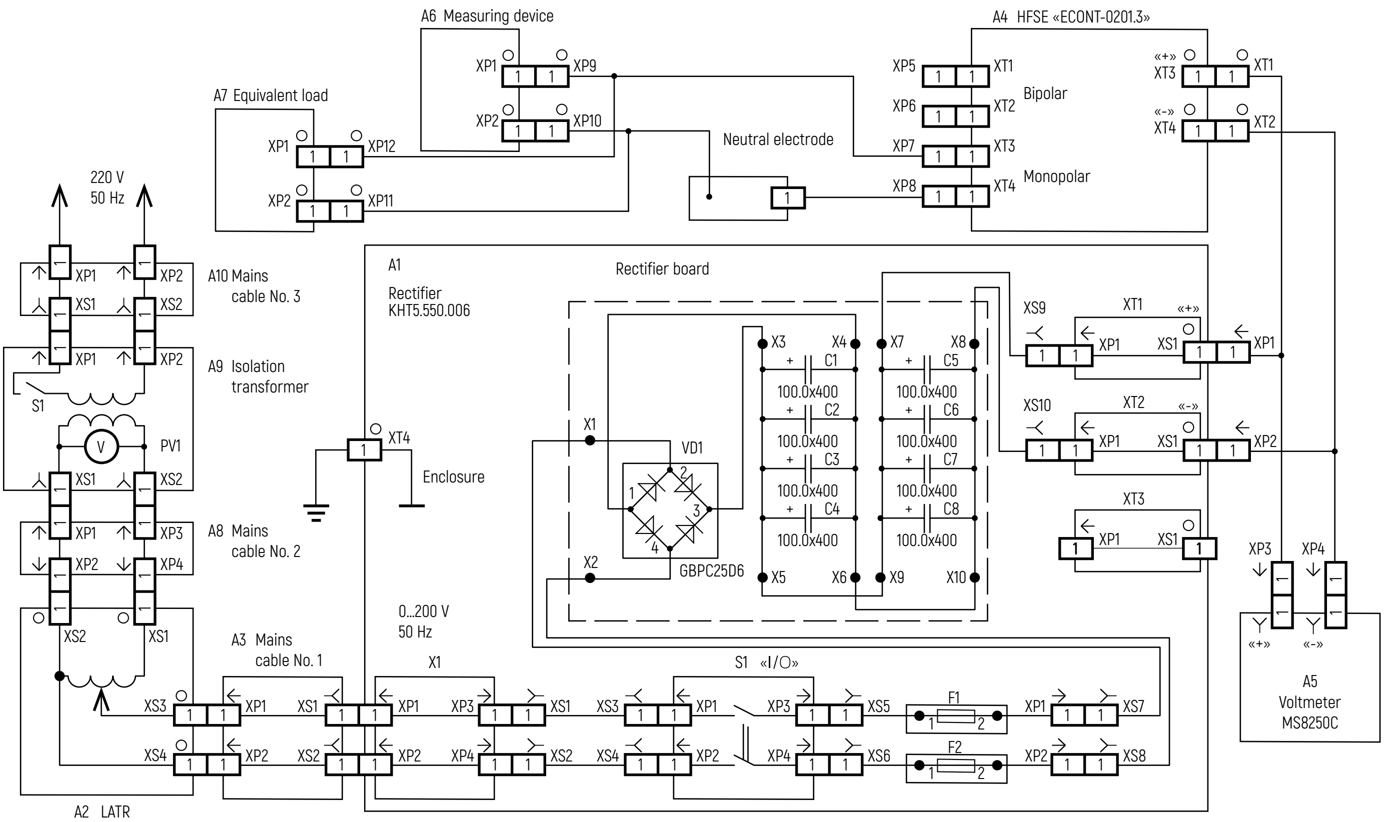

Fig. 1. *Structural scheme of the stand KHT3.558.023 for determining the HF output power of the apparatus ECONT-0201.3 by simulation of single fault conditions*

Example 2.

Consider the tests of domestic devices of the electrosurgical high frequency (ESHF) equipment series «Nadiya-4» (models 120, 200, 300) manufactured by TOV «MNVK «NDI PE», Kyiv. The microprocessor of this device measures the output current and voltage and transmits the data via the RS232 interface to a personal computer on which a monitor software is installed, which is specially designed to determine the output power of the product. For each rated value of the output power of the

Measurements infrastructure Vol. 4 (2022) MI_016_021121 https://doi.org/10.33955/v4(2022)-016

product, certain codes for the power of its allowable exceeding are in Table 3. During the tests, at each value of the set rated power, the voltage of the regulated external source was gradually increased until the power code displayed on the monitor software reached the set-point value, and the product protection circuit was triggered. The output voltage was fixed by the Run/Stop button of the oscilloscope, and its U_{rms} value was determined using cursor measurements.

The results of calculating the output power of the apparatus ESHF-120 «Nadiya-4» when simulating single fault conditions are presented in Table 4. Note that a power source was used as an external power source DC Keysight E3631A with adjustable output voltage 0-25 V with 10 mV resolution. As a load resistance for 10, 20, 50, 100, 200, 500, 1000, 2000 Ohm, they used a series of resistors type of the MOR300S from HITANO (Fig. 2), developed by specialists of TOV «MNVK «NDI PE» for testing HF equipment.

Uncertainty of measuring the output power of ESHF equipment series «Nadiya-4» (models 120, 200, 300) when simulating single fault conditions

«Cutting»

P_{max}=	120
R_n=	502
K_r=	3,906
Error	7 %

Limits						Measurements						Codes			Verification			Installation		
$P_{Indic.}$	P %	P-20%	P+20%	$P_{allow\ properties}$	$P_{lim.}$ W	U_{trms} V	P_{out} W	Code		Limits				Code MCS	U_{out} V	P_{out} W	Code	U_{out} V	P_{out} W	$P_{lim.}$ W
								K_p=1	$N_{corr.}$	-20%	20%	$N_{lim.1}$	$N_{lim.\ -5\%}$							
5	4,2	4	6	$P_{ind}\cdot 2$	10	13,2	5,3	500	470	376	564	1280	1190	1190	17,4	9,2	1200	18,1	10	10
10	8,3	8	12	$P_{ind}\cdot 2$	20	18,4	10,3	1320	1280	1024	1536	3280	3050	3050	24,4	18,1	3100			
15	12,5	12	18	$P_{ind}\cdot 2$	30	22,5	15,4	2280	2220	1776	2664	5760	5357	5360	30,3	27,9	5400			
20	16,7	16	24	$P_{ind}\cdot 2$	40	25,7	20,1	3300	3280	2624	3936	8440	7849	7850	35,1	37,4	7900			
25	20,8	20	30	$P_{ind}\cdot 2$	50	28,6	24,9	4550	4570	3656	5484	11130	10351	10350	39,5	47,4	10400			
30	25	24	36	$P_{ind}\cdot 2$	60	31,5	30,2	5800	5760	4608	6912	14020	13039	13040	43,2	56,7	13100			
35	29,2	28	42	P_{ind}+25	65	33,8	34,7	7000	7060	5648	8472	15350	14276	14280	44,8	61	14300	46,2	64,9	65
40	33,3	32	48	P_{ind}+25	70	36,2	39,8	8400	8440	6752	10128	16860	15680	15680	46,6	66	15700			
45	37,5	36	54	P_{ind}+25	75	38,4	44,8	9750	9790	7832	11748	18260	16982	16980	48,3	70,9	17000			
50	41,7	40	60	P_{ind}+25	80	40,3	49,4	11000	11130	8904	13356	19900	18507	18510	50,2	76,6	18500			
55	45,8	44	66	P_{ind}+25	85	42,5	54,9	12500	12520	10016	15024	21400	19902	19900	51,6	80,9	19900			
60	50	48	72	P_{ind}+25	90	44,4	59,9	14000	14020	11216	16824	22850	21251	21250	53,1	85,7	21300			
65	54,2	52	78	P_{ind}+25	95	46,3	65,2	15400	15350	12280	18420	24670	22943	22940	55,1	92,3	23000			
70	58,3	56	84	P_{ind}+25	100	48,2	70,6	17000	16860	13488	20232	26220	24385	24390	56,6	97,4	24400			
75	62,5	60	90	P_{ind}+25	105	50	76	18500	18260	14608	21912	27400	25482	25480	57,7	101,2	25500			
80	66,7	64	96	P_{ind}+25	110	51,6	80,9	20125	19900	15920	23880	28550	26552	26550	58,7	104,7	26600			
85	70,8	68	102	P_{ind}+25	115	53	85,4	21500	21400	17120	25680	30100	27993	27990	60,4	110,9	28000			
90	75	72	108	P_{ind}+25	120	54,6	90,6	23000	22850	18280	27420	32030	29788	29790	61,4	114,6	29800			
95	79,2	76	114	P_{ind}+25	125	56	95,3	24750	24670	19736	29604	33365	31029	31030	62,6	119,1	31100			
100	83,3	80	120	P_{ind}+30	136	57,4	100,1	26250	26220	20976	31464	36301	33760	34560	65,2	129,2	34600	66,9	136	136
105	87,5	84	126	P_{ind}+30	141	58,9	105,4	27500	27400	21920	32880	37635	35001	35963	66,2	133,2	36000			
110	91,7	88	132	P_{ind}+30	146	60,1	109,8	28500	28550	22840	34260	38970	36242	37347	67,5	138,5	37400			
115	95,8	92	138	P_{ind}+30	151	61,4	114,6	30000	30100	24080	36120	40304	37483	38976	68,6	143	39000			
120	100	96	144	P_{ind}+30	156	62,7	119,5	31900	32030	25624	38436	41639	38724	40838	69,6	147,2	40900	71,7	156,2	156

Table 3. *Verification data of the apparatus ESHF-120 «Nadiya-4» with the requirements subclause 201.12.4.4.101 of the standard DSTU EN 60601-2-2:2015*

Operating mode		Rated power P, W	Rated load R_l, Ohm	Set point (range in % of rated power)	Installed power, W	Limiting power, W	
						Calculated value	Measured value
Monopolar							
1	Cutting 1	120	500	<10	5	24	9,2
				10…25	20	40	37,4
				26…80	60	90	85,7
				81…100	100	136	129,2
2	Cutting 2	120	200	<10	5	24	9,7
				10…25	20	40	36,6
				26…80	60	90	85,9
				81…100	100	136	130,6
3	Coagulation-M	120	100	<10	5	24	8,3
				10…25	20	40	38,5
				26…80	60	90	87,3
				81…100	100	136	126,0
Bipolar							
4	Coagulation -B	120	100	<10	5	24	9,7
				10…25	20	40	39,4
				26…80	60	90	85,8
				81…100	100	136	129,6

Table 4. *Maximum output power for operating modes of the apparatus ESHF-120 «Nadiya-4» in single fault conditions*

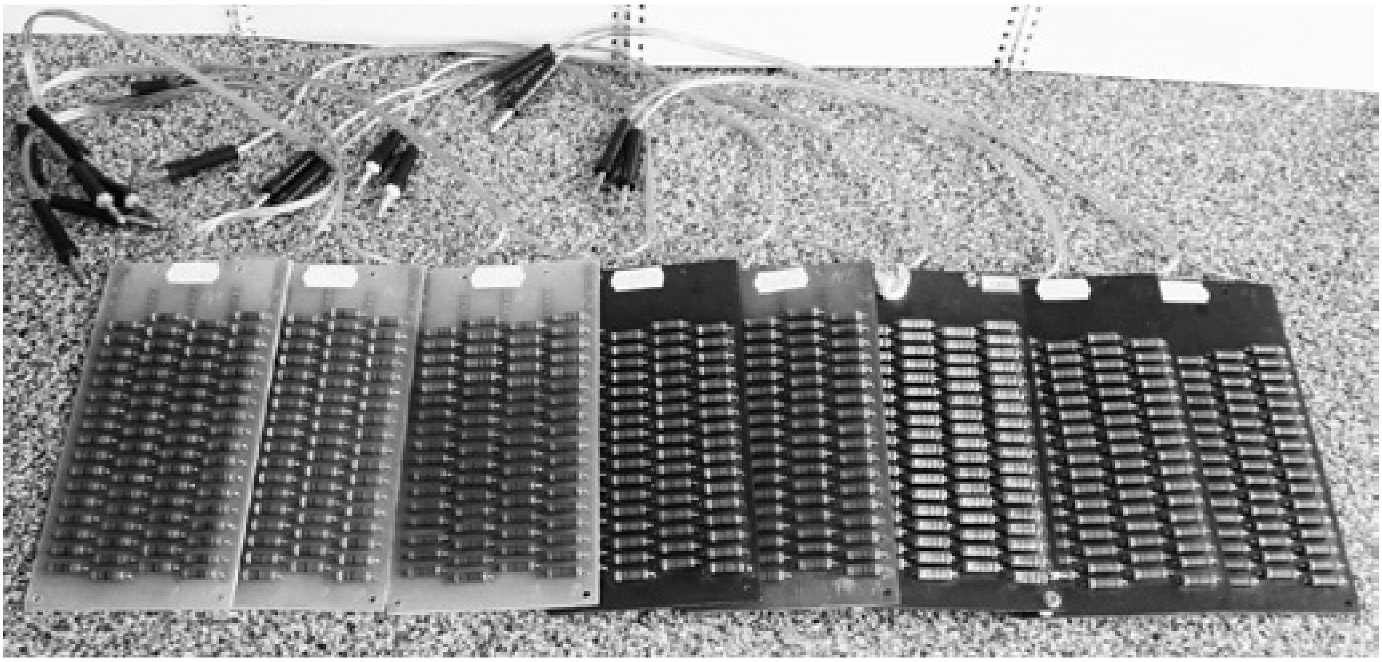

Fig. 2. *Load resistances kit for testing ESHF equipment series «Nadiya-4» based on MOR300S type*

Let us estimate the error of indirect measurement of the output power using measuring instruments, using formula (1), and bearing in mind that their input resistance is much higher than the load resistance. Of course, the best way to measure the U_{rms} value of the signal voltage is to use a modern digital storage oscilloscope (for example, Agilent DSO3000 series or Tektronix TDS2000C series, etc.).

Measurements infrastructure Vol. 4 (2022) MI_016_021121 https://doi.org/10.33955/v4(2022)-016

The limiting values of the basic relative error of power measurement are calculated as (2):

$$\delta = \pm\sqrt{4(\Delta U_{rms}/U_{rms})^2 + (\Delta R_l/R_l)^2 + (\Delta U_p/U_p)^2}, \quad (2)$$

where

$\Delta U_{rms} / U_{rms}$ – the main maximum relative oscilloscope error (for an Agilent DSO3102A oscilloscope with 1:10, 1:100, 1:1000 probes, it is not more than 2,2 %);

$\Delta R_l / R_l = 0{,}066$ % – relative measurement error of resistance R_l when using an Agilent 34405A multimeter;

$\Delta U_p / U_p = 0{,}117$ % – DC power supply relative error.

Component of the error $\Delta R_l / R_l$ and $\Delta U_p / U_p$ can be ignored due to its smallness compared to the relative error $\Delta U_{rms} / U_{rms}$.

Then we can write (3):

$$\delta \approx \pm\sqrt{4(\Delta U_{rms} / U_{rms})^2}\,. \quad (3)$$

Let us determine the uncertainty of the output power measurements result, taking into account the fact that, as a rule, single measurements are carried out using measuring equipment, the error limits of which are determined during verification or are indicated in the metrological documentation [11].

The total standard uncertainty of the output power measurement in relative form when using the Agilent DSO3102A oscilloscope is (4):

$$u_c(P) \approx \delta / \sqrt{3} \approx \pm\, 0{,}025\ \%. \quad (4)$$

The expanded uncertainty in measuring the output power at a confidence level of 0,95 and a coverage factor k = 2 (taking into account the assumption of the normality of the distribution law of the measurement result) in relative form is equal to (5):

$$U = k \cdot u_c(P) \approx \pm\, 0{,}05\ \%. \quad (5)$$

This indicates an acceptable quality of the measurement results and measuring instruments used.

4. Conclusions

1. Compliance of the output power of HF equipment with the established regulatory requirements both for normal conditions and for single fault conditions guarantees their safe and high-quality operation.

2. The method of monitoring the serviceability of built-in protection systems of modern HF devices, if the output power under single fault conditions exceeds allowable values defined in particular standard DSTU EN 60601-2-2:2015, is proposed. This method is common for most modes of operation of such devices, except for some of their special modes.

3. The assessment of the uncertainty of the results of measurements of the output power of the RF devices under single fault conditions, which were obtained using the proposed method, indicates the expediency of its use during such measurements.

4. We hope that the article will be useful to everyone involved in the production and operation of high-frequency electrosurgical equipment, as well as for employees of testing laboratories and accredited service centers for the maintenance of such products.

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