Testing of Medical Electrical Equipment–Ultrasonic Therapy Equipment (Case Study)

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Abstract: *We have tested the output intensity of 9 ultrasonic therapeutic devices according to the safety requirements stated in the relevant international and at the national standard. Our results show that nearly 40% of transducer heads are not operating properly and another 46% should be recalibrated. Through this example we would like to point out the need for regular preventive maintenance of all electromedical equipment by professional engineering staff – clinical engineers. Preventive maintenance is the first and irreplacable step in safety assurance.*

INTRODUCTION

Preventive maintenance increases the realibility of electromedical equipment, reduces the likelihood of major faults and extends its lifetime. This was recognised in clinical environment three decades ago and solved through introduction of clinical engineers and clinical engineering departments. In some less developed and undeveloped countries the health care authorities still have not recognized the importance of preventive maintenance and clinical engineering, considering it to be only a cost [1]. The case study presented in this paper shows the consequences of such an attitude. Through this example we would like to initiate a discussion which should bring to a proposal for an optimal solution for safety assurance and regular preventive maintenance of electromedical equipment in small countries like Croatia and Slovenia.

THERAPEUTIC USE OF ULTRASOUND

Ultrasound has been used in medical treatment for several decades. The first ultrasonic therapeutic device was constructed in 1938 by Pohlman and successfully applied by Richter and Parow (800 kHz at 5W/cm^2) for neuralgia of the solar plexus and sciatica in the following year [2]. After the post-war period when ultrasonic therapy was overvaluated, it become the most frequently used therapuetic modality in rehabilitation and sports medicine, having the effect of selective heating of the underlaying tissue.

The limitations for safe use of ultrasonic therapy were adopted in 1984, when the International Electrotechnical Commission (IEC) accepted the standard defining particular requirements for the safety of ultrasonic therapy equipment [3]. In clinical practice, the safety can be achieved only through regular safety check-up and maintenance.

Safety of medical equipment includes implicitly safety (no risk for health or life) of patients and medical staff but the correct operation of the equipment as well. Even in developed countries, periodic check-ups often found that the output power or intensity of ultrasonic therapeutic equipment exceeds the permitted limits (± 30% of the set value or 3 W/cm^2) [4, 5, 6]. Two studies performed in Croatia in mid 80's and mid 90's showed significant deviations of the output ultrasonic intensity from the declared [7].

MATERIALS AND METHODS

We measured the output power of 9 ultrasonic therapeutic devices, i.e. 13 different transducer probes from 5 health care institutions from Zagreb (Table I). The ultrasonic devices were tested in all modes of operation (continous mode, modulation, etc.). The following companies manufactured the tested devices: Bosch, Cosmagama, Erbe, Iskra Medical and Siemens. We found three additional pieces of ultrasonic therapy equipment, but they were out of order. In one institution, the devices were not available for testing, but we were ensured that they are regularly checked up and calibrated.

For measurement of the output power of the transducer probes we used the ultrasound wattmeter UW-3 (BIO-TEK Instruments, Inc.) that measures the average power with resolution of 0,1 W and accuracy of reading ± 10% from 0 – 30 W. In order to obtain the value of the ultrasound intensity, the measured value was divided by the declared effective area of the transducer head. We have measured the output power for the following values of intensity, set at the display of the tested device: 0,5 W/cm^2, 1 W/cm^2, 2 W/cm^2 and 3 W/cm^2.

RESULTS

We checked the output intensity of different transducer probes (only) according to the safety requirements (limits) stated in the standard IEC 60601-2-5, section 8, chapters 50.1 and 51.2. The results of our measurement are shown in Table I. We have grouped the devices into three groups:

- Accurate (A), if all measured values were within the stated limits,
- Partially faulty (PF), if only one measured value, usually the one obtained at the lowest output intensity, was out of the limits,
- Faulty (F), if the majority of the curve(s) lay outside the limits.

Table I. Results of the output intensity test for ultrasonic therapy equipment (number of pieces of equipment /percentage; A – accurate, PF – partially faulty, F – faulty).

	A	PF	F	Total
Devices	2/22%	6/67%	1/11%	9
Transducer heads	2/15%	6/46%	5/39%	13

Table II shows the fault pattern of the faulty and partially faulty treatment heads. We classified the faulty heads into three groups: those having the output intensity higher than specified in standard (>+30%), those having the output intensity less than –30% and those that under different modes of operation have either higher or smaller output than allowed.

Table II. Fault pattern of treatment probes.

	> +30%	> -30%	Spread	Total
Faulty	1	4	-	5
Partially faulty	2	2	2	6

In Figures 1a-b, particular results for four transducer probes are shown. The measured results for modulated output power are normalized to continous power output in order to present the graphs in the same scale. The transducer probe No. 1 is faulty and produces output power that is 100% smaller than the set value in continous mode and 200% smaller in modulated modes of operation (Fig 1a). The transducer probe No. 2 is faulty as well and produces practically no output power (Fig. 1a). The transducer probe No 3. shows an interesting pattern: in continous mode, the output power is smaller than the set value, for two types of modulation the probe is within the required accuracy and for one type of operation it produces the output power higher than allowed by safety requirements (Fig 1b).

DISCUSSION

The results in Table I. show that the majority of tested ultrasonic therapy equipment is not working properly. The equipment that produces higher output than allowed by safety requirements should immediately be excluded from clinical practice and should undergo a service and recalibration.

The most common faulty condition is too small an output intensity. From the point of view of safety, too small output intensity is not a risk for health of the patients. However, the efficiency of the ultrasonic therapy is questionable. How is it possible that the medical staff does not recognise smaller efficiency of ultrasonic therapy? Most probably because the treatment usually consists of several therapeutic modalities, so patient gain from other treatment modalities. But, from the aspect of patients, who undergo an inefficient treatment it is a waste of time and money, just the same as for the health care authorities who (in social states, like Croatia) pay to the health care providers for the treatment.

Though ultrasonic therapy equipment was chosen as a case study and the number of tested devices/treatment heads is statistically not significant, the results are significant because the condition of the equipment is not satisfactory. On the basis of these results, one cannot conclude on the general safety conditions of all electromedical diagnostic and therapy devices and equipment in Croatia, but certainly can have doubts on how safe and how efficient they are.

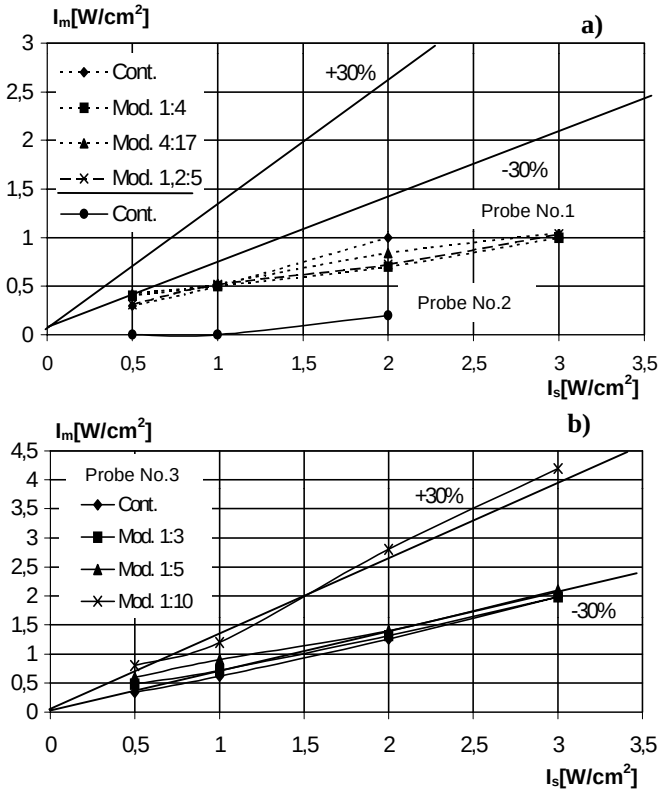

Figure 1: Results of testing of the treatment heads a) No. 1 and 2, and b) No. 3. I_s – the set value of intensity, I_m – the measured value of intensity.

CONCLUSION

The results of this case study imply that the ultrasonic therapy equipment is not maintained properly and therefore either not safe for use or not efficient. It suggests that similar situation may be expected for many other types of electromedical equipment. In our opinion, only systematic and regular maintenance guarantees safe use of electromedical equipment. Therefore, organization of clinical engineering support should be one of the major interests of health care authorities and health care providers.

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