



Risk assessment of EMF exposure in the operating room: a new paradigm

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Abstract

Physicians who perform electrosurgical unit (ESU) procedures are exposed to an electromagnetic field (EMF), the waveform of which is generally complex. This requires performing the exposure assessment under unperturbed field conditions and using the weighted peak (WP) method, according to international ICNIRP guidelines and the European Union Directive.

It is not uncommon to measure electric field (EF) values on the order of hundreds of V/m at a few tens of centimeters away from the handpiece. Therefore, it is reasonable to assume, upon contact with the handpiece, the Action Levels (ALs) defined by current legislation for worker health protection will be exceeded. However, only the assessment of ALs for sensory effects can be considered, since the electrosurgical unit never emits EMF for six minutes and therefore the assessment of ALs for thermal effects is not applicable.

Due to the close distance between the source and the exposed subject, dosimetric evaluation becomes the only reasonably usable method of analysis (as suggested by ICNIRP guidelines). This is further confirmed by the fact that the EF measurement in contact with the ESU handpiece is perturbed, making EF measurements metrologically incorrect, and thus confirming the importance of the dosimetric evaluation methods.

Assuming that the ALs for sensory effects may be exceeded, the question has been raised as to why symptoms in surgeons are not reported in the literature. The evaluation of induced currents in the limbs of surgeons could help to assess the potential effects that the physicians might undergo.

This work presents the results of a measurement campaign regarding the evaluations of induced currents in the limbs of operators using such electromedical equipment.

The values obtained were compared with the reference levels (RLs) reported in the last ICNIRP guidelines and with the exposure reference levels (ERLs) reported in the last IEEE standard, and considerations were made regarding the lack of evidence in the literature concerning stimulation effects in the limbs of surgeons.

1. Introduction

The effects on the human body related to exposure to EMFs are documented, and European Directive 2013/35/EU [1] imposes an obligation on employers to assess the specific risk of exposure to such physical agents.

Several studies [2-5] have investigated the emission levels of different equipment, including ESU, which is particularly relevant due to their widespread use in healthcare. These devices expose workers to highly localized intense EFs, yet measurement methods [4] lack in standardization. In such cases, the electrical component prevails over the magnetic field in intensity, making its evaluation more crucial for safety purposes.

Although exposure assessments have been performed through EF measurements at the operator's position, the variety of dummies used in these studies has led to inconsistencies and a lack of reproducibility in measurements [2, 5, 6], raising metrological concerns that will be further discussed.

Such measurements have shown EF values exceeding hundreds of V/m within a few centimeters of the handpiece, direct contact with the electrode could lead to an exceeding of the ALs established by European Directive 2013/35/EU [1].

Before continuing, it should be specified that Exposure Limit Values (ELVs) are determined on the basis of biophysical and biological considerations established for the protection of scientifically established acute effects and that they are not measurable quantities in the exposure environment. Therefore, compliance with ELVs, the direct determination of which, especially in the case of time-varying fields, would require dosimetric simulations using complex software, is ensured by compliance with ALs.

ALs are thus operational values expressed in terms of physical quantities (electric, magnetic and electromagnetic fields) that can be measured in the exposure scenario and established in order to simplify the process of demonstrating compliance with the relevant ELVs during experimental testing.

This two-level approach adopted by European Directive 2013/35/EU [1] and derives from the ICNIRP guidelines [7-9] in which a distinction is made between basic restrictions and reference levels. Similarly, the 2019 IEEE

standard [10], introduces the concept of dosimetric reference limits (DRLs) and exposure reference levels (ERLs). In the case of ESUs, which operate at frequencies between 300 kHz and 1 MHz, the applicable ALs for EF exposure assessment are specified in Table B1 – Part II of the Decree (Non-Thermal Effects).

Table 1 - ALs for ambient EF for the frequency range from 3 kHz to 10 MHz [1].

Frequency range	Lower ALs for E (RMS, V/m)	Higher ALs for E (RMS, V/m)
$3 \text{ kHz} \leq f \leq 10 \text{ MHz}$	1.7×10^2	6.1×10^2

Not exceeding both “lower ALs” and “higher AsL” ensures compliance with the corresponding ELVs. If in the former case these values prevent the generation of electrical discharges, in the latter specific protective measures must be taken. Under standard working conditions, it is advisable to refer to the lower ALs (170 V/m).

Limitations on EMF exposure are based mainly on the prevention of the following phenomena:

- the stimulation of nerves of the central and peripheral nervous system - the stimulation of muscle tissue
- the induction of a type of visual phenomenon known as “phosphenes” - possible disturbance of brain function
- increased body temperature

Relative to ESUs, the increase in body temperature can be excluded, since a continuous exposure of 6 minutes or more is considered for the occurrence of thermal effects to account for physiological responses to the stimulus. ALs for such an effect are then defined as RMS values to be averaged over 6 minutes. Usually, the radiofrequency emission for cutting or clotting commanded by the surgeon is repeated intervals of a few seconds and never continuous. While a possible exceedance of the lower ALs for EF can be estimated from measurements and the literature data [2, 6, 11], one may wonder why there is no evidence in the literature of symptoms associated with surgeons' use of this equipment.

The current method of risk assessment for EF is outlined within the Non-binding Guide to Good Practice for implementing Directive 2013/35/EU Electromagnetic Fields, which also refers to the ICNIRP guidelines. EF measurements should be made under unperturbed field conditions. This requires the absence of the operator or any objects that might disturb the field.

In addition, choosing the appropriate instrument for the measurement may not be simple. If the signal is sinusoidal, a broadband instrument is sufficient. In case of a complex waveform (as for the ESU case), the recommendation of ICNIRP and current regulations is to use an instrument capable of analyzing the signal by the WP method, but not many instruments are capable of performing this analysis in real time for frequencies emitted by ESUs. More complex simulation methodologies using specific software are not always functional for risk assessment in the hospital environment, as they are not readily available and usable.

Therefore, a methodologically correct EF measurement following current standards can be problematic.

The European Directive 2013/35/EU [1] and the 2010 ICNIRP guidelines [8] both state that dosimetric assessments should be carried out in the case of a very localized source, a few centimeters away from the body. This is the case with ESUs.

It was therefore decided to approach the problem of risk assessment from EF exposure by measuring induced currents in the limbs of operators. These measurements are unaffected by any perturbation and are easy to perform.

To carry out this analysis we referred to two international documents: the ICNIRP 2020 guidelines [9] and the IEEE 2019 standard [10]. The reference values are the same in both cases and are given in Table 2, although the terminology is different.

Table 2 - Reference levels for induced currents in each limb for the frequency range of 100 kHz to 110 MHz [9, 10].

Exposure scenario	Induced Current (mA)
Occupational	100
Population	45

Induced current values are related to thermal effects. The values refer to the average over 6 minutes of exposure.

Instead, in the IEEE, induced current values are also covered for neuromuscular electrostimulation effects (see Table 3). It is however specified that, for operating frequencies above 100 kHz, the measured current needs to be lower than those given in Table 2 (thermal effects), because in the range of 100 kHz to 5 MHz both electrostimulation and thermal effects may be present. However, the values in Table 3 apply only to sinusoidal waveforms.

Table 3 - Reference levels for induced currents in each limb for frequency range of 3 kHz to 5 MHz [9,10].

Exposure condition	Induced current value in single foot (mA)
Free environment	$0.45 f$
Confined environment	$1.00 f$

The results of a measurement campaign assessing EF exposure from a sample of ESUs in a hospital setting are now presented, highlighting critical issues and how they were addressed. The adopted method for the measured induced currents in the arms and ankles will be described.

2. Materials and methods

2.1 Electrosurgical Unit

Electrosurgical scalpels cut and coagulate tissue by heat, generated by the Joule effect, from currents flowing through the tissue. They consist of a radiofrequency current generator and electrodes, and can be used in bipolar or monopolar mode. The latter is more commonly used in

clinical practice, generating a more intense EF. In this mode, there are two electrodes: the neutral one, consisting of a disposable adhesive plate to be placed on the patient's skin, and the active one, consisting of a metal tip placed at the end of a handpiece. On the handpiece are buttons related to the modes of use: shear and clot. Hybrid modes perform combined effects, such as blend cuts. In addition to the buttons on the handpiece, a foot pedal can also be used depending on the surgeon's needs.

2.2 Measuring Instruments

The instruments used for the EF evaluation (Figure 1) are a Field Analyzer Narda EHP-200 (measurement range 9 kHz to 30 MHz) and a Field Meter Narda 8053-2004/04 with probe EP-330 (measurement range 100 kHz to 3 GHz). A Holaday HI-3702 was used for induced current measurements. The system is based on a toroidal geometry probe, placed around the operator's limbs and connected via optical fiber to a LCD monitor readout system (Figure 1). Operating frequency ranges from 9 kHz to 70 MHz.

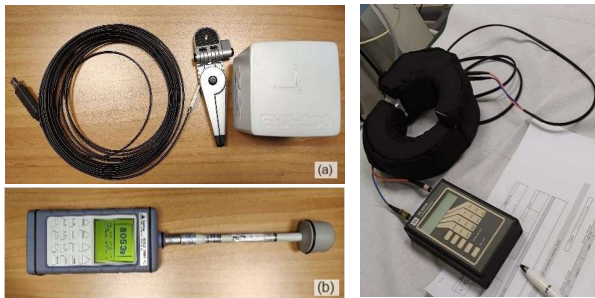


Figure 1. EHP-200 Field Analyzer (a) and Narda 8053-2004/04 Field Meter with the EP-330 probe (b) on the left. On the right, Holaday HI-3702 for induced limb current measurements.

2.3 Measurement Method

To simulate the surgeon's EF exposure in the presence of the patient, a phantom consisting of a plastic tank filled with saline (simulating conductivity and resistivity of the human body) was used, placing the neutral ESU electrode consisting of a disposable adhesive plate at the bottom.

EF was measured in two ways: using the Field Meter 8053 and the Field Analyzer EHP200. In the first case, the probe was placed at various distances from the handpiece and measured values were recorded. In the second case, spectra were acquired by placing the probe about 10 cm from the handpiece.

Since the unperturbed field condition was not met, it was decided to make some measurements without the operator near the equipment. In this setup, the use of the ESU was made possible by employing the appropriate foot pedal, placed about 2 m away.

Induced currents were measured using the toroidal probe placed around the operator's arm and ankle. Three positions (wrist, forearm, and arm) were chosen for the arm ipsilateral to the handpiece, the wrist of the contralateral arm, and finally the right ankle.

3. Results

Three different ESU have been analyzed. The EF values for ESU No. 1 and No. 2 were measured with the Field Meter 8053, while only the EHP-200 was used for ESU No. 3. The second instrument differs from the first in the linear response for the frequency range of interest.

The 8053 Field Meter is a broadband instrument and does not provide information on signal shape or frequencies components. Furthermore, the calibration coefficients, obtained as the ratio of the detected field to the sample field, are defined for individual frequencies and are significantly below 1 within the relevant range. Specifically, the coefficients are 0.30 at 100 kHz, 0.45 at 300 kHz, and up to 0.79 at 3 MHz.

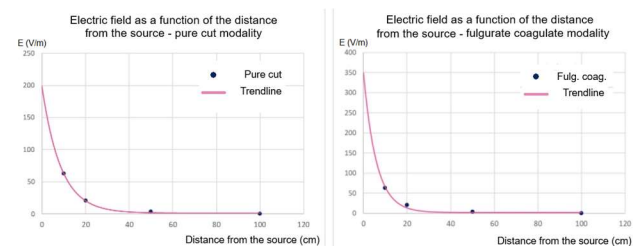
Therefore, the measured EF values do not represent the actual field emitted in the room, as individual frequency components cannot be identified, and an appropriate calibration coefficient cannot be applied.

Consequently, all measured values are reported without correction for the calibration coefficient. Most ESUs did not emit only at the fundamental frequency but also generated harmonics or complex signals, particularly during the “clot” mode (data not shown).

Since the EF values were measured from a distance of 10 cm from the active electrode, in order to estimate how much the EF could be in contact with the operator's hand, an interpolation was used, according to what is indicated in [11] for SAR calculation. In addition, the same approach is used and reported in the WebNIR platform (available at <https://webnir.eu>) developed by CNR-IFAC.

Therefore, fits of the measured points were performed with an exponential curve.

Figure 2. EF trend as a function of distance from the source for two modes of ESU No.3 use.



The interpolation results show that relative to ESU No. 3, the ALs of 170 V/m at contact is exceeded for both modes of use (Figure 2), pure cut (199 V/m at 0 cm distance from the source) and fulgurate coagulate (349 V/m at 0 cm distance from the source).

Measurements of the EF emitted by ESU No. 3 were also made when the operator was away from the equipment. The comparison between measurements shows that the results are almost the same, with the exception of two operation modes: cut low (58 V/m vs 137 V/m, with and without an operator, respectively) and desiccated clot (67 V/m vs 121 V/m).

Therefore, EF measurements performed by this method cannot be considered reliable for risk assessment, due to

the variability of data depending on the environmental conditions.

4. Discussion

According to our results, the exposures remain below the ALs defined for non-thermal effects, except in the case of ESU No. 3, with values above 170 V/m.

European guidelines state that assessment of EF in working environment should be carried out under unperturbed field conditions and, in the case of complex waveforms, instruments capable of performing signal analysis using the WP method should be used. Regarding the first condition, its complexity has already been discussed, as the operator or the instrumentation used can often influence the measurement. Therefore, it would at least be advisable to make measurements while maintaining a certain distance from the source, although this is not always possible and depends on the type of equipment, instrument, and probe used. Regarding the WP, measurement instruments appropriate for the signals of the most common ESUs have only recently come onto the market, but as they were not available for the present study, they were not used.

It is important to consider calibration coefficients when using broadband instruments, as there can be significant discrepancies between the instrument and the actual value. Even in this case, the methodology may not be adequate because the EF is unlikely to exhibit a single frequency. Using a broadband instrument, individual components of the signal at different frequencies cannot be identified a priori, and therefore adequate calibration factors cannot be applied.

Analysis of induced currents may provide a solution to these problems, as it is a relatively simple and reliable method of measurement. The current European directive was issued in 2013, and in the last 10 years new ICNIRP guidelines [9] and IEEE standards [10] have been published, updating some aspects related to induced currents. There is a significant difference between the two, as the IEEE establishes AVs for currents to avoid neuromuscular stimulation, while the ICNIRP only considers thermal effects. As a result, the ICNIRP tables require averaging of currents over a 6-minute period, while the IEEE tables for stimulation effects require averaging over 0.2 seconds - namely instantaneous values.

The analysis of induced currents may also explain why no cases have been reported in the literature of surgeons or health care workers experiencing symptoms related to the use of ESUs, such as tingling, pain, or muscle spasms. Although in some cases the EFs were found to be above the ALs of 170 V/m, the values of the induced currents always remained below the respective reference levels, with a maximum of 5.5 mA in the case of ESU No. 2.

5. Conclusions

In this study, critical issues related to the current approach of assessing the risk of exposure to EFs were highlighted. The measurement results presented, particularly those

obtained with the broadband field meter, may not be reliable.

An overcoming of the EF measurement problems could be achieved by focusing on the assessment of induced currents in the limbs of healthcare workers using radiofrequency medical equipment. These evaluations have proven to be simple and effective, revealing that the values of induced currents turn out to be one or two orders of magnitude lower than the limits.

In light of these results and considering the absence of reports of symptoms among surgeons using ESUs, it is possible that the current AVs for EF are more conservative than necessary.

6. Acknowledgements

This work benefited from the financial support provided by INAIL within the framework of the Bric-2022 project.

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