Protocol for measurements on monopolar electrosurgical units v1.3

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Foreword

When assessing the emissions of electrosurgical units for the subjects present in the environment of use, we are always in a field region very close to the source, so the electric field and the magnetic field must be assessed separately. For this type of medical electrical equipment the electric field is the relevant quantity from the protection point of view; moreover, the sources of the emissions are both the handpiece and the outgoing and return cables towards the generator. Consequently, both the arrangement of the cables and the objects present in the exposure scenario can affect the extent of the emissions, even significantly.

However, what interests us at this stage is to estimate a clearance distance for the purpose of zoning the areas, with a known uncertainty that need not be pushed to extremes. Just to draw a comparison with other situations, the considerations on the clearance distances to be derived from the measurements are more similar to those made in the computation of shielding and worker protection in radiation protection than to those made in the computation of doses in radiotherapy. For this reason we are content to know whether the clearance distance for a given limit is 30 cm or 1.5 m, but we can neglect the fact that it is 1.5 m or 1.3 m (provided we take it as 1.5 m and not 1.3 m).

If an exposure situation had to be assessed that required greater precision, then one would have to go into the details of how much the various parameters affect the results and outline a much more rigorous measurement protocol, which however would also have to be followed by an equally rigorous and controlled protocol of use.

Measurement geometry

The electric field is the relevant quantity from the protection point of view; consequently, to perform the measurements the machine is placed on a wooden table (any screws or the like do not matter), in order to minimise the influence of the environment on the measured value. Alternatively, the same support used in clinical practice (for example the operating table) could be used, so as to reproduce a similar electromagnetic environment.

The cables are the sources of the stray field, and it is not always easy to understand how they will be arranged during operations. In any case, to increase the reproducibility of the measurements and in view of possible modelling, the outgoing cable is laid out for a length of at least 1 metre and the sensor is placed on the axis of the cable at a minimum distance of about 30 centimetres. At this point the measurements can be performed under the worst-case conditions, which correspond to keeping the return cable as far as possible from the outgoing one. In some hospitals, also with a view to containing the exposure to electromagnetic fields, in clinical practice the generator is positioned at the patient's feet and the outgoing and return cables are kept close together, alongside the patient's legs. Using this configuration prevents the cables from having to pass at close range to the body of some operator. To simulate such a situation, the measurements can be performed by arranging them 5-10 cm from each other, a configuration that also has the advantage of cutting down the dispersion of the fields owing to the proximity of the two sources of opposite field.

According to what is required by ICNIRP, in order to avoid possible perturbations, the electromagnetic field measurements should be made in the positions occupied by the operators, in their absence. However, this is not always possible during field measurements. In the case of assessment of low-frequency magnetic field emissions this precaution is not critical, the influence of the operator being negligible. Instead, the emissions of the electrosurgical unit are mainly of medium-frequency electric field, and the presence of the operator affects the result of the measurement. Should measurements have to be performed in the presence of the operator, some tests carried out show that by placing the probe between source and operator the measured level is about 30% higher than the one that would be obtained in the absence of the operator; whereas by placing the probe behind the operator a shielding effect occurs which decreases the measured field by the same amount. Obviously, in order to be more precautionary, it is preferable to always keep the probe between operator and source.

Again in order to have a higher reproducibility of the results, during the assessment of the emissions in the closed-circuit configuration the electrosurgical unit is connected to the tester device normally used by clinical engineering to perform the electrical checks. Normally, different load values can be set on the tester. The lower the selected load, the higher the delivered current, hence the higher the magnetic field, while the electric field tends to decrease. For example, to place oneself in the worst-case conditions for the magnetic field, measurements can be performed with a 50 ohm load; in any case this quantity has always turned out to be negligible for protection purposes. A load of 300-500 ohm can instead be set to measure the electric field.

The delivery of energy by an electrosurgical unit should always take place with the handpiece in the working position, so that current flows immediately. However, talking with physicians and maintenance technicians, we were told that sometimes the physician tests the electrosurgical unit in the air before use, or activates it when it is not yet exactly in position. Under these conditions there is no current flow, so the intensity of the dispersed electric field is at its maximum. For this reason, measurements are also performed with the handpiece supplied with the electrosurgical unit held in the air, without closing the circuit (open circuit).

Acquisition settings

To measure electrosurgical units, up to the time of writing of this protocol, we have always used the Narda EHP200 instrument. It is a spectrum analyser that performs scans of the field sequentially on the 3 axes so as to compute: the value of the selected field (electric or magnetic) in broadband, its spectral distribution, and, if selected, the exposure indices for stimulation and thermal effects. These indices are the result of the measurements and are used to assess the exposure of the operators. Note that the index for thermal effects must be evaluated over a 6-minute time average. In practice, a measurement is made to assess its value during power delivery, and the 6-minute time average is computed afterwards as envisaged by the regulations in force, considering the times used in clinical practice. Owing to the brevity of the operations performed with electrosurgical units, the thermal index does not normally turn out to be the most significant one.

Since the acquisition of the signals is sequential in frequency and along the 3 axes, a compromise must be found between the parameters of spectral resolution and acquired frequency range on one side and the overheating of the medical device on the other. In fact, a scan with a high resolution (i.e. a small RBW, for example 3 kHz or 10 kHz) covering a frequency range of a few MHz can last several tens of seconds, putting the cooling system of the electrosurgical unit to a severe test. On the other hand, by decreasing the resolution (i.e. increasing the RBW), especially in the case of the "coagulation" emission mode, one risks substantially underestimating the exposure index. For this reason it is important to manage to obtain a spectrum made up of peaks separated from one another, so as to obtain a stable index value that no longer increases as the resolution is increased further. As an example, Figure 1 shows the result of the index measurement obtained with 3 different spectral resolutions. With each spectral resolution the instrument associated a markedly different index, expressed as a percentage: 150% with a resolution of 3 kHz (blue spectrum); 128% at 10 kHz (red spectrum) and 75% at 30 kHz (green spectrum).

To acquire a frequency range that includes all the relevant emission, the spectrum can be divided into 2 or 3 consecutive, non-overlapping intervals, acquiring one spectral interval at a time and letting the electrosurgical unit "rest" between one measurement and the next. Since both the index for stimulation effects and the one for thermal effects are additive in frequency, their total value will be obtained by summing the indices computed in the frequency sub-intervals. In this way it could happen that emissions located at the final frequency of one interval and the initial frequency of the next are summed twice, but observing the number of contributions normally found when measuring electrosurgical units, this fact should lead to a negligible overestimation of the final index value.

The quantity to be set for the computation of the index will almost always be the electric field, although a measurement to verify that the magnetic field is negligible should always be made.

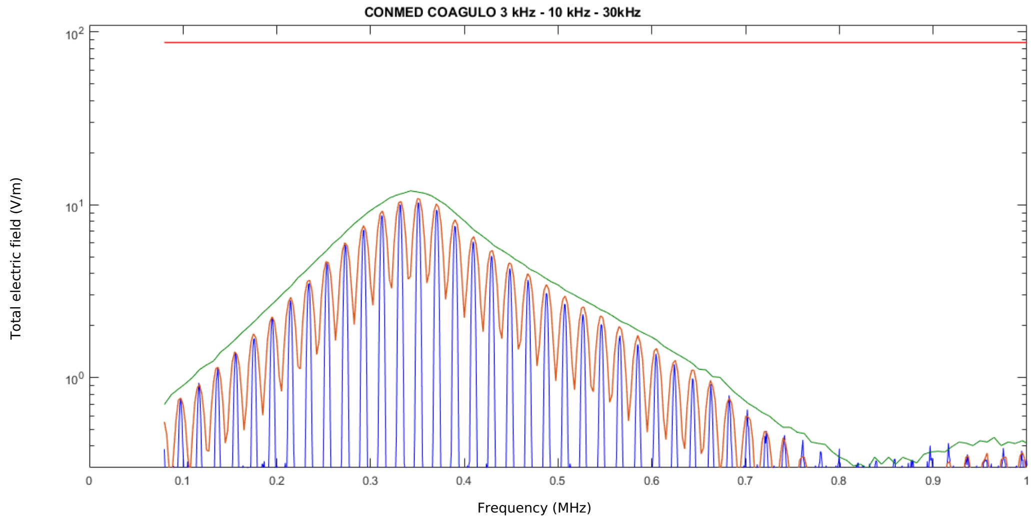

Figure 1. *Electric field emission spectra from an electrosurgical unit in coagulation mode, measured by the EHP200 instrument. The spectra are acquired with different resolutions.*

Measurements for zoning

With the electrosurgical unit set to the maximum power (or to the maximum power used), both the coagulation mode and the cutting mode are assessed, performing measurements at open circuit as well.

Measurements are performed moving the probe progressively away from the source, so as to find the clearance distance for the different limits to be considered in the assessment, i.e. the distances at which the exposure index, expressed as a percentage, equals 100%. Certainly the first is the reference value for the general public (European Recommendation 1999/519, transposed in Italy by Law No. 36 of 22 February 2001). Once this is done, the clearance distance for the action values for workers is found (Legislative Decree 81/08 as amended, Title VIII Chapter IV). Especially as regards the clearance distance for the reference levels for the general public, since in some configurations it can even reach a few metres, it could also be extrapolated from measurements performed at shorter distances. On the other hand, the probe being rather large, it should never be brought closer than 25-30 cm to the cable.

The coagulation mode at open circuit is normally the one corresponding to the largest clearance distances and has the richest spectrum, hence the most difficult to measure.