Towards the definition of a shared procedure for the assessment of occupational exposure to the electric and magnetic fields generated by electrosurgical units[1]

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Introduction

Legislative Decree 81/2008 [1] made explicit, within the more general obligation for employers to assess all risks to the health and safety of their workers, the specific obligation concerning the assessment of the risk connected with exposure to electromagnetic fields (EMF). The entry into force of the decree consequently brought to light the instrumental and methodological shortcomings that in many situations (and particularly in healthcare facilities) put in difficulty the personnel in charge of EMF risk assessment. The case of electrosurgical units is one of the most evident examples in this respect.

The electrosurgical unit

"High-frequency electrosurgery devices", or electrosurgical units (ESUs), are devices by now present in all operating theatres; thanks to their flexibility and ease of use, the fields of surgery in which they are employed are indeed constantly expanding.

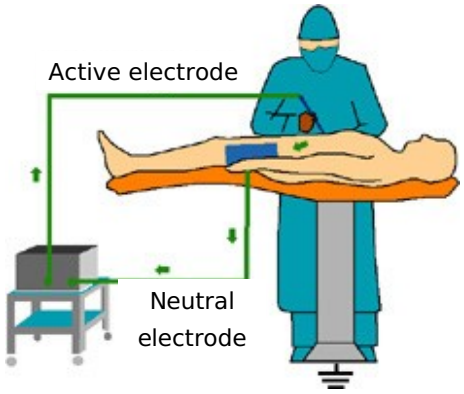

Figure 1. *Diagram of an electrosurgical unit in monopolar configuration.*

Electrosurgical units offer a series of functionalities made possible by the flow of an intense high-frequency current through the tissues undergoing surgery. Two types of apparatus exist: electrosurgical units properly so called, which use currents with frequencies of the order of a few hundred kilohertz, and radiosurgical units (which we shall not deal with in this work), which operate instead at frequencies of at least a few megahertz.

The electrosurgical unit is used by means of a handpiece made of insulating material, held by the surgeon. The handpiece ends with a metal electrode of various shapes, called the blade, connected by a long lead to the radiofrequency generator. Two different connection configurations are possible: monopolar and bipolar.

In the monopolar configuration, the connecting lead carries only the active conductor (also called the hot conductor), connected to the blade, while the neutral (or cold) conductor is connected, with an independent lead, to a large-surface electrode called the return plate, placed in contact with the patient in an area different from the surgical field; the working current therefore flows from the blade to the tissues to be treated and then passes through part of the

patient's body to reach the return plate. The monopolar configuration is illustrated in Figure 1 (source: http://ilcatalogomedicale.wordpress.com/2011/10/19/come-funzione-unelettrobisutri-monopolare/).

In the bipolar configuration, the connecting lead carries both the active conductor and the neutral conductor, connected to the two distinct and closely spaced electrodes of which, in this case, the blade is made; there is no return plate and the working current flows only between the two electrodes of the blade and the patient tissue with which they are in contact. This configuration has a narrower range of use than the monopolar configuration: for this reason too, but above all because of its lower radiation protection relevance, we shall not deal with bipolar configurations in this work.

All electrosurgical units make two basic operating modes available to the surgeon: cutting and coagulation. These are often flanked by a series of accessory modes (for example "fulgurate", "blend", "spray") that modify one of the two basic modes or constitute a mixture of them. In the cutting mode, the waveform of the working current is approximately sinusoidal (with frequency of the order of hundreds of kilohertz) and stationary; the contact between the handpiece blade and the tissue is fairly good and therefore this mode corresponds to an electrical situation in which, compared with the coagulation mode, the voltage applied to the handpiece is lower (but still generally between 0.5 and 2 kV peak, and in some models even 3 kV peak) and the current is higher (up to one or a few amperes). In the coagulation mode, the waveform is more complex and consists of pulses or trains of damped sinusoids (with a frequency similar to that of the cutting mode) of limited duration (a few tens of microseconds), repeated at a regular rate of the order of a few tens of kilohertz (we shall see an example in Figure 8, referring to a measurement campaign that will be discussed later); this mode corresponds to the situation in which the voltage applied to the blade is at its maximum (up to values even beyond 5 kV peak in some models).

The electrosurgical unit as a source of EMF exposure

The electrosurgical unit, being a device operating with radiofrequency currents of considerable power, is a relevant source of electromagnetic fields. In particular, the handpiece with its blade and the conductors connecting it to the generator are the main elements dispersing EMF into the surrounding environment; the generator too, if not well shielded or earthed, can represent a significant source, which however we shall not deal with in this work. Figure 2 [taken from the EMF-NET document that also hosts ref. 7] qualitatively illustrates the distribution of the intensity of the electric and magnetic fields dispersed by an electrosurgical unit.

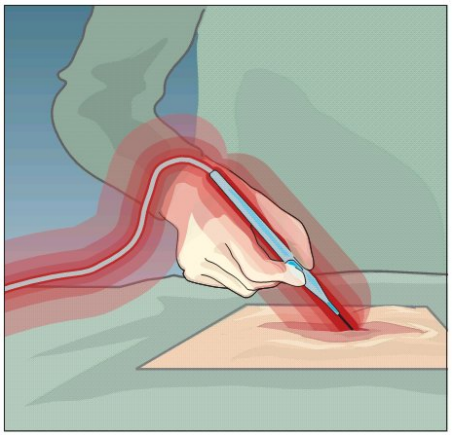

Figure 2. *Qualitative representation of the distribution of the intensity of the fields dispersed by an electrosurgical unit.*

Considering the frequency involved, the emitted electromagnetic field has quasi-static characteristics at all distances of interest: the electric field and the magnetic field can thus be considered distinct and independent physical agents, the former related to the electric potential reached, during power delivery, by the handpiece and its connecting conductor, the latter related to the current flowing through them. This is the reason why the bipolar configuration has a lower radiation protection relevance: the contiguity between the hot conductor (at high potential) and the cold conductor (at zero potential) produces a shielding effect on the dispersed electric field, while the proximity of the outgoing current to the return current leads to a significant mitigation of the magnetic field. Again because of the quasi-static nature of the field, the electric component of the dispersed field is at its maximum in the modes in which the generator delivers the maximum voltage (i.e. in the coagulation and similar modes), while the magnetic component is at its maximum in the cutting mode, in which the current circulating in the handpiece connecting conductors is at its maximum.

Electrosurgical units and the SITES-P2 project

Electrosurgical units constitute a category of EMF sources of considerable relevance, considering their widespread diffusion in hospital facilities, the intensity of the dispersed field and the potentially large number of exposed subjects for each application. Nevertheless, although a fair amount of scientific literature is available on the subject [2,3,4,5,6], no methods consolidated at national level exist to date that allow the control bodies to manage risk assessment in a standardised way; a general document, produced within the European EMF-NET project [7], is still very preliminary as regards the aspects related to electrosurgical units.

Within the Strategic Programme "Safety and Healthcare Technologies" (SITES) of the Ministry of Health — and in particular within Project 2 (P2) devoted to the risks from exposure to electromagnetic fields — an in-depth study was therefore undertaken, still in progress, aimed at developing a procedure for the assessment of the exposure of healthcare workers to the

electromagnetic fields emitted by electrosurgical units, shared among the various parties collaborating in the project. This work describes the issues addressed and the conclusions reached, and gives an account of problems still open.

A large part of the considerations developed emerged or were put to the test on the occasion of a dedicated measurement campaign carried out by the SITES-P2 working group at a laboratory of the Istituto Superiore di Sanità (Italian National Institute of Health) during the month of October 2012. In that campaign, the apparatus under examination was a Valleylab Force FX-8C electrosurgical unit. The experience on which this work is based was then enriched by subsequent measurements, performed by individual members of the group in different contexts [see for example ref. 8; other campaigns have not been published for the time being].

The definition of the regulatory context

It was first of all necessary to address a general issue, concerning the definition of the pertinent regulatory context, also in view of the recent developments at European level; these, in fact, will extend for a further three years the current situation in which employers are under no obligation to comply with any occupational limit for exposure to electromagnetic fields. Indeed, the final deadline for the transposition of the very recent European Directive 2013/35 [9] has been postponed to 1 July 2016; this directive, at the end of the long process of updating the previous Directive 2004/40 [10], redefines the regulatory framework for the protection of workers.

Besides the directives in question, other regulatory documents to be kept in mind are the ICNIRP guidelines of 1998 [11] and 2010 [12], European Recommendation 1999/519 for the protection of the general public [13] and the national consolidated act on the protection of workers [1]. The latter, which originally referred to the now repealed Directive 2004/40, will have to be amended to transpose the new European directive, to which it is therefore considered advisable to refer from now on. Finally, we recall the existence of a CEI standard specific to electrosurgical units [14], which however does not actually address the problem of human exposure to electromagnetic fields.

For the definition of the radiometric limits (called "action levels"), Directive 2013/35 draws on the ICNIRP-1998 reference levels as regards the prevention of thermal effects (see [9], Annex III, table B1) and on the ICNIRP-2010 levels for nerve stimulation effects (referred to as non-thermal effects, see [9], Annex II, tables B1 and B2). However, in the latter case the new directive introduced an additional and less precautionary level of protection with respect to the ICNIRP limits, where it distinguishes between "low" action levels (corresponding to the ICNIRP-2010 reference levels) and "high" action levels (decoupled from the ICNIRP guidelines). This distinction, for the magnetic flux density, exists only for frequencies from 1 to 300 Hz, since for higher frequencies the low and high levels coincide; for the electric field, instead, it exists in the band from 25 Hz to 10 MHz. Moreover, for the magnetic flux density, the directive also provides

specific action levels for the exposure of the limbs alone to a localised magnetic field; these are defined over the whole frequency band in which the limits for non-thermal effects are applicable (between 1 Hz and 10 MHz) and are higher in value even than the high action levels.

For electrosurgical units, which have a working frequency above 100 kHz and below 10 MHz, compliance must be verified both with the action levels for the prevention of thermal effects and with those for non-thermal effects. It should be said, however, that considering the intermittent mode of use typical of these devices, the provision of averaging the exposure over 6 minutes reduces the risk of exceeding the thermal limits.

Ultimately, if the objective is the protection of workers, the limits with which — looking ahead — one must comply are first of all the action levels specified by the recent European directive for the prevention of the non-thermal effects of electric and magnetic fields with frequency between 3 kHz and 10 MHz. These limits, which do not depend on frequency, are summarised for convenience in Table 1; for comparison purposes, the table also reports the action levels for protection against thermal effects in the range between 100 kHz and 1 MHz and in particular at the frequency of 400 kHz; as can be seen, the only situation in which thermal effects are of concern is in relation to the magnetic field, in case there may be a 6-minute interval within which the electrosurgical unit is activated for more than 1/20 of the time, i.e. for at least 18 seconds (at 400 kHz).

Table 1. *Action levels specified by European Directive 2013/35 [9, Annexes II and III] for the prevention of the non-thermal effects of electric and magnetic fields with frequency between 3 kHz and 10 MHz, and of the thermal effects for frequencies between 100 kHz and 1 MHz and in particular at the frequency of 400 kHz.*

		Electric field (V/m, RMS)	Magnetic flux density (μT, RMS)
Action levels for protection against non-thermal effects between 3 kHz and 10 MHz	low	170	100
	high	610	100
	limbs exposed to a localised magnetic field	N/A	300
Action levels for protection against thermal effects	100 kHz - 1 MHz	610	20 - 2
	@ 400 kHz	610	5

Classification of the exposed subjects

An important aspect, on the regulatory level, concerns the identification and classification of the exposed subjects, who can be traced back to four categories.

The patient, to whom no radiation protection regulation applies, since the advisability of allowing the exposure must be established on the basis of risk-benefit considerations.

The surgeon, i.e. the subject who personally uses the electrosurgical unit and thus holds its handpiece. Their exposure is to be classified as occupational; however, since the subject holds the source in their hand, the exposure itself cannot be assessed with radiometric methods (i.e. with measurements of the electric and magnetic fields in the environment), and it is instead necessary to resort to dosimetric methods (i.e. to the numerical computation of the electric field induced inside the tissues) based on a specific modelling of the exposure scenario. This concept is expressed in the ICNIRP-2010 guidelines [12, p. 827], where one reads "for a very localized source with a distance of a few centimeters from the body, the only realistic option for the exposure assessment is to determine dosimetrically the induced electric field, case by case", and is also reiterated in the new European directive [9, notes B1-3 p. 14, B2-3 p. 15 and B1-3 p. 17]. Dosimetric methods, however, are rather onerous, both in the preparation phase (since a complex exposure scenario must be modelled) and in the execution phase (since substantial computing resources may be needed). Dosimetric investigations may therefore be set up for research or illustrative purposes in some typical cases, but they fall outside a risk assessment procedure suited to standardised and widespread interventions. The surgeon must in any case be informed of the exposure received and placed under adequate health surveillance.

The auxiliary personnel, consisting of the subjects who take part in the operation assisting the surgeon and who are therefore exposed to varying degrees to the electric and magnetic fields emitted by the electrosurgical unit. This too is occupational exposure which, however, unlike the previous case, can be assessed through radiometric investigations, taking as reference the action levels for workers summarised in Table 1. This category of exposed subjects represents the main addressee of the considerations developed in this document.

The accidentally exposed, i.e. the individuals who happen to pass by or linger near an operating electrosurgical unit, without however being involved in the surgical operation for which it is used. This (presumably small) category falls within the general public, for which the risk assessment must take as reference the limit values indicated in European Recommendation 1999/519 [13]. Note that this recommendation still incorporates, also for non-thermal effects, the ICNIRP-1998 reference levels [11].

Standardised approach to the radiometric assessment

Among the aspects most directly connected with the specific case, it was deemed necessary to consider the definition of a standardised scenario for carrying out the radiometric measurements and their subsequent interpretation; this includes the discussion on the device with which to simulate the patient's body, the question of the most appropriate assessment metric, and the choice of suitable instrumentation.

In view of what was said in the previous section, it is believed that the purpose of a standard measurement procedure should be first of all to provide the auxiliary personnel and the accidentally exposed with indications regarding the minimum distance from the conductors and from the handpiece of an electrosurgical unit, to be respected so as not to be exposed to EMF levels higher, respectively, than the occupational action levels or the reference levels for the

general public. Figure 3 schematically illustrates a measurement configuration that makes it possible to select a section of conductor in order to assess its emission at various distances, moving the rest of the source away from the field sensor.

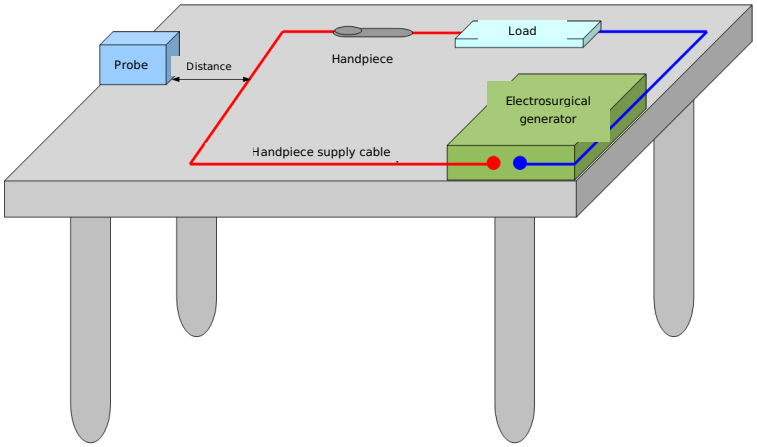

Figure 3. *Diagram of the measurement configuration.*

The load simulator

One of the aspects discussed in greatest depth within the SITES-P2 working group concerns the device with which to simulate, in the measurement configuration, the patient's body and the tissues on which the electrosurgical unit acts. The main conclusions reached are summarised below.

- The inadvisability of resorting to fanciful solutions, based on bars of soap, steaks [as in ref. 6] and the like, which do not allow a well-characterised and reproducible measurement configuration to be defined, was acknowledged.
- The possibility of using a liquid or semi-solid phantom with electromagnetic characteristics similar to human muscle tissue was studied; dedicated numerical simulations made it possible to characterise the behaviour of the phantom and to highlight some interesting aspects, including the following:
  - it is possible to size the phantom without particular problems, since the impedance seen by the generator depends on the contact area between the handpiece blade and the surface of the phantom, and not on the dimensions of the latter;
  - when the handpiece blade is in contact with the phantom, the generator sees a resistive and capacitive impedance whose time constant depends on the dielectric properties of the material constituting the phantom itself, and not on the geometry of the blade or of the container;
  - when, instead, the blade is not in contact with the phantom, the impedance seen by the generator does not depend on the dielectric properties of the material, since the whole potential difference tends to drop between the blade and the surface of the phantom, while the latter remains, to a good approximation, at zero potential;
  - the external magnetic field is scarcely affected by the path of the currents inside the phantom;

- as regards the external electric field, the phantom behaves in effect like a perfectly conducting, hence equipotential, object.

- The hypothesis of using a liquid phantom (Figure 4), i.e. a container filled with a standardised saline solution as in [3], was considered but eventually discarded, because it does not allow simulating the operating mode of the electrosurgical unit in which an electric arc forms between the handpiece blade and the tissue simulator.

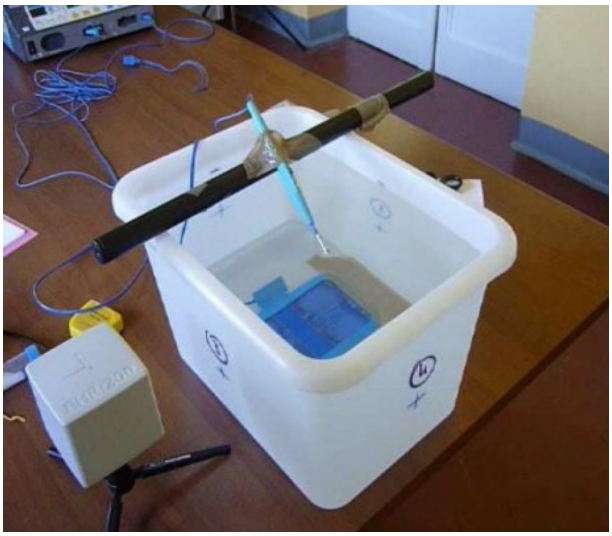

Figure 4. *Phantom made with saline solution.*

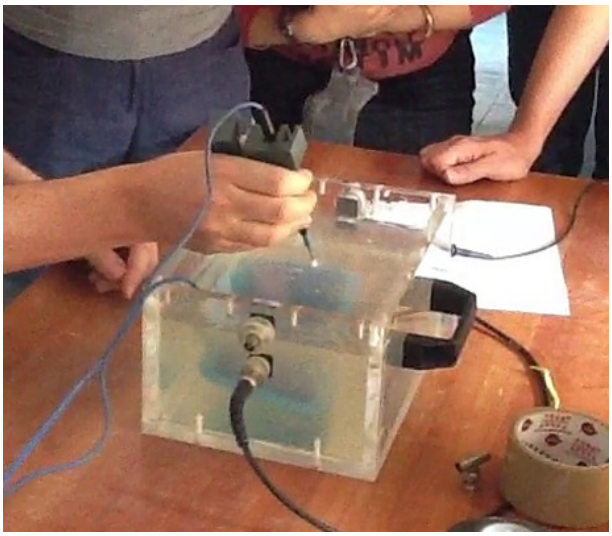

Figure 5. *Semi-solid phantom, arc mode.*

- During the measurement campaign at the ISS (October 2012), a phantom made of semi-solid material was built and used, which presents numerous advantages: in particular, it is sufficiently stable and reproducible and allows the electric arc to be activated (Figure 5); however, the construction of a phantom of this type does not seem within the reach of all the services dealing with protection from electromagnetic fields in healthcare environments.

- The semi-solid phantom of Figure 5 consists of a plexiglas container (dimensions about 28 cm × 20 cm × 26 cm) filled with a solution of sodium chloride in water with conductivity 0.3 S/m, equal to the weighted average of the tissues of the human trunk at the frequency of 400 kHz; the solution was then thickened by adding hydroxyethyl cellulose in an amount equal to 4% by weight.
- The use of the semi-solid phantom showed that operation under "arc" conditions closely resembles an alternation of "open-circuit" operation and operation under "good electrical contact" conditions (i.e. with low impedance between handpiece and tissues). Open-circuit operation corresponds to the maximum voltage on the active electrode and hence to the maximum dispersed electric field.
- An easily practicable alternative consists in using, as a load for the electrosurgical unit, a bank of resistors connected in series and/or parallel, so as to obtain the desired resistance value (a few hundred ohms) and an adequate power handling level.
- The use of dedicated commercial equipment for the testing of electrosurgical units (which also provides a load resistance of adjustable value) is conceptually equivalent to the previous case and perhaps preferable from the standpoint of standardisation.

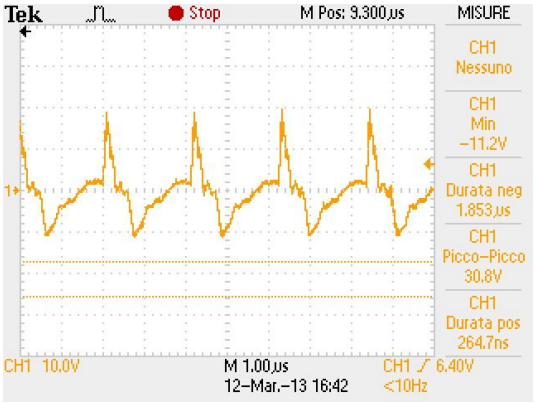

Figure 6. *Alsa Excell MCDS electrosurgical unit, cutting mode, voltage waveform on a commonly used 500 Ω load resistance.*

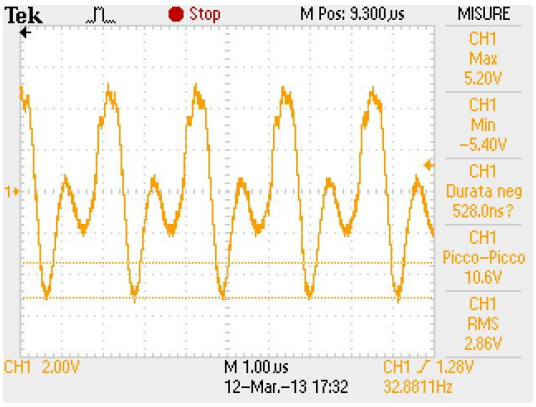

Figure 7. *Alsa Excell MCDS electrosurgical unit, cutting mode, voltage waveform on an anti-inductive load resistance of a few tens of ohms.*

- A problem common to all types of load lies in the impossibility of guaranteeing that the impedance offered to the generator is such, in amplitude and phase, as to give rise to voltage and current waveforms equal to those occurring under real operating conditions; this fact is relevant since, as will be said in the next section, the waveform has a precise radiation protection significance. The problem is greater with resistor banks (see Figure 6 and Figure 7, relating to a measurement campaign carried out by some of the authors but not published) because they exhibit an inductive reactance, whereas tissues and liquid and semi-solid phantoms exhibit a capacitive reactance. Pending the identification of an optimal solution to this problem, it is nevertheless believed that the best choice for carrying out the measurements in a risk assessment context is to operate at open circuit for the detection of the electric field, and to use electrosurgical-unit testing equipment, set to the minimum resistance envisaged by the apparatus under test (typically 100-200 Ω), for the detection of the magnetic field; it is reasonable to expect that such a low resistance value minimises any distortion due to the reactive part of the impedance. In any case, the measurements performed will then have to be scaled proportionally, on the basis of the maximum voltage and maximum current the apparatus can deliver (data obtainable from the documentation), in relation to the voltage applied and the current circulating at the time of the measurement.

The assessment metric

The assessment metric makes it possible to determine, starting from the measured values, the radiometric datum to be compared with the regulatory limits. This operation is immediate in the case of sinusoidal waveforms (as is, to a first approximation, the waveform generated by many electrosurgical units in cutting mode), since any instrument provides the RMS value to be compared (possibly averaging it over 6 minutes) with the pertinent action level.

The problem becomes more complicated when dealing with complex waveforms, such as those produced by an electrosurgical unit in coagulation mode: Figure 8 shows, by way of example, the waveform of the voltage produced by the Valleylab Force FX-8C apparatus operating on a semi-solid phantom in coagulation mode; the waveform was acquired during the above-mentioned measurement campaign at the ISS (October 2012). For the prevention of thermal

effects, it is necessary to use a probe able to determine the RMS values of the individual spectral components of the waveform, which must then be combined, frequency by frequency, with the respective action levels according to the algorithm indicated in [11, eqs. (9) and (10)]. To verify compliance with the limits concerning non-thermal effects (which, according to the measurements performed so far, seem to be the most relevant aspect of the exposure caused by an electrosurgical unit), Directive 2013/35 recommends applying the weighted-peak method with filtering in the time domain [9, Annex II]; this method, at the frequencies involved, is not supported by any probe currently on the market. The problem can be circumvented by performing voltage and current measurements with a digital sampling chain, but this approach (mentioned in the following section) is within the reach of specialised laboratories only. A simplification, in the case at hand, derives from the invariability of the non-thermal action levels envisaged by the directive in the frequency range between 3 kHz and 10 MHz (see Table 1); this circumstance makes it possible to determine the weighted-peak index by taking the ratio between the peak value of the quantity of interest and the corresponding action level (the latter multiplied by the square root of two, to convert it from an RMS value to a peak value). Despite the undoubted simplification, the difficulties remain nonetheless, since no commercial instrumentation exists that can provide the instantaneous peak value of the electric or magnetic field dispersed by an electrosurgical unit. However, on the occasion of the measurement campaign at the ISS, it was possible to verify the validity of this approach, as shown in Figure 9; it reports the comparison between the weighted-peak index and the ratio between the instantaneous peak value and the (peak) action level; the index and the instantaneous peak value were determined starting from the voltage delivered by the electrosurgical unit, acquired by means of a LeCroy WP7300 digital sampling oscilloscope; they were then related to the low action levels for the electric field: for this reason, the scales on the two axes are arbitrary and have therefore been omitted.

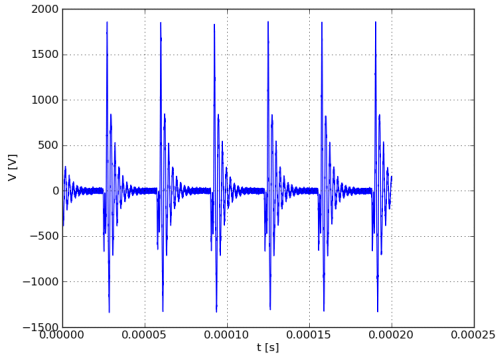

Figure 8. *Valleylab Force FX-8C electrosurgical unit, coagulation mode, voltage waveform on a semi-solid phantom.*

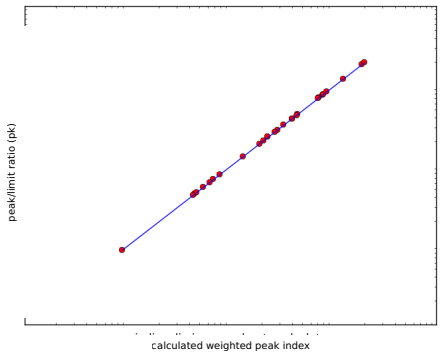

Figure 9. *Valleylab Force FX-8C electrosurgical unit, comparison between the weighted-peak index and the peak/limit ratio (see text).*

The instrumentation

Carrying out a measurement campaign on an electrosurgical apparatus requires a probe (or a set of probes) able to detect both the electric field and the magnetic field, in a frequency range spanning at least from 200 kHz to 5 MHz, and able to determine:

- the RMS value of the field intensities, separately for each spectral component, possibly performing the 6-minute average automatically;
- the weighted-peak index evaluated on the field amplitudes with reference to the action levels of the European directive; alternatively, the instantaneous peak value of the amplitudes themselves.

Such an instrument is not commercially available to date.

For all the measurements performed so far, both within the SITES-P2 working group and in other contexts, a Narda-PMM EHP-200A probe has always been used. This probe makes it possible to detect the electric field and the magnetic field isotropically in the frequency band from 9 kHz to 30 MHz, to determine their spectrum and to report to the user the RMS intensity of each spectral component; the probe does not allow computing the weighted-peak index, but makes it possible to determine the standard index adopted by the ICNIRP-1998 guidelines [11, eqs. (7) and (8)] and accepted also by the 2010 guidelines [12, eqs. (4) and (5)]. The standard index does not take into account the phases of the spectral components and therefore provides an unjustifiably more precautionary assessment than the weighted-peak index, but one that is nevertheless useful for a first-instance approach. For the determination of this index to be valid, it is necessary (especially in coagulation mode) to use a resolution bandwidth smaller than 10 kHz: the high resolution, together with the wide frequency range to be analysed, extends the duration of each measurement in a way that is often impracticable.

To overcome this difficulty, an attempt is being made within the working group to develop a different approach, which integrates the electric and magnetic field measurements performed with the EHP-200A with the numerical analysis of the voltage and current waveforms delivered by the electrosurgical unit, acquired with a sampling device (such as the digital oscilloscope already mentioned) and processed in the time domain. To this end it is necessary, once the

working configuration is fixed, to determine the coefficients relating the voltage to the electric field and the current to the magnetic field at each measurement point, through suitable coupled measurements performed in a predetermined operating mode (for example in cutting mode); these ratios can then be used to work back from the voltage and current measurements performed in a different mode to the field values expected at each point, for that mode.

Conclusions and open problems

Within the SITES-P2 working group, some practical and methodological aspects were addressed with the objective of arriving at the proposal of a standardised radiometric procedure for the assessment of the risk from exposure to the electric and magnetic fields emitted by electrosurgical devices, having as its objective the protection of the auxiliary personnel of the operating theatre and of any accidentally exposed individuals. It was indeed agreed that the exposure of the surgeon cannot be assessed with radiometric methods, while the patient falls outside the application of radiation protection regulations.

Among the results already achieved, we can cite the study and prototype implementation of a measurement configuration reproducible in the laboratory, based on an arrangement of the various parts (generator, conductors, handpiece, phantom) that is as standardised as possible and aimed at determining the clearance distances from the handpiece conductor beyond which the regulatory limits are complied with. The issue concerning the "phantom", i.e. the dummy load to be used in place of the patient's body, was addressed in depth, reaching the conclusion that the electric field measurements can conveniently be performed "at open circuit" (i.e. with the handpiece of the electrosurgical unit not in contact with the simulator of the patient's body), since in that case the electric field is at its maximum; the open-circuit condition is not merely academic, because it corresponds to operating situations that can occur in actual use. The magnetic field, on the other hand, must be measured with the electrosurgical unit closed on a standard resistive load of low value (100-200 Ω), preferably obtained using commercial equipment for the testing of electrosurgical units.

The detected field values must be compared with the action levels envisaged for the prevention of both thermal and non-thermal effects. In the latter case, when dealing with complex waveforms, the appropriate metric consists in the determination of the weighted-peak index, which requires at the very least the availability of the instantaneous peak value of the amplitudes of the measured fields.

The first measurements highlighted the prevalence, from the radiation protection point of view, of the electric field over the magnetic field and of the limits for the prevention of non-thermal effects over the thermal ones: in particular, the electric field is greater in the coagulation modes, in which the highest peak voltages are applied to the handpiece. For the magnetic field, the prevalence of non-thermal effects must be verified in the light of a better characterisation of the duty cycle of the electrosurgical unit in surgical practice.

Among the other aspects still under discussion, it remains to be established how to apply the weighted-peak method most effectively, since no adequate instrumentation is commercially available. It is also necessary to further investigate the problem of the waveform distortion due to the reactance of the dummy load used, and to assess its actual impact. Finally, work has also begun on the dosimetric problem (i.e. the assessment of compliance with the "exposure limit values" indicated in Directive 2013/35). An attempt is being made to outline an adequate approach that allows the problems of exposure to the electric field of electrosurgical units to be addressed while reaching an optimal compromise between the level of detail of the modelling and the computational resources it requires.

References

[1] Legislative Decree 9 April 2008, No. 81: "Attuazione dell'articolo 1 della legge 3 agosto 2007, n. 123, in materia di tutela della salute e della sicurezza nei luoghi di lavoro" ("Implementation of Article 1 of Law No. 123 of 3 August 2007 on the protection of health and safety in the workplace"). Gazzetta Ufficiale della Repubblica Italiana, No. 101, 30-4-2008, ordinary supplement No. 108.

[2] J.D. Paz, R. Milliken, W.T. Ingram, A. Frank and A. Atkin: "Potential ocular damage from microwave exposure during electrosurgery: dosimetric survey". Journal of Occupational Medicine, Vol. 29, N. 7, July 1987, pp. 580–583.

[3] E. Tzima and C.J. Martin: "An evaluation of safe practices to restrict exposure to electric and magnetic fields from therapeutic and surgical diathermy equipment". Physiological Measurement, Vol. 15, N. 2, May 1994, pp. 201–216.

[4] B. Liljestrand, M. Sandström and K. Hansson Mild: "RF exposure during use of electrosurgical units". Electromagnetic Biology and Medicine, Vol. 22, N. 2-3, 2003, pp. 127–132.

[5] M. De Marco and S. Maggi: "Evaluation of stray radiofrequency radiation emitted by electrosurgical devices". Physics in Medicine and Biology, Vol. 51, N. 14, July 2006, pp. 3347–3358.

[6] J. Wilen: "Exposure assessment of electromagnetic fields near electrosurgical units". Bioelectromagnetics, Vol. 31, N. 7, October 2010, pp. 513–518.

[7] K. Gryz and J. Karpowicz: "Electrosurgery. Occupational exposure to electromagnetic fields – assessment in practice". EMF-NET Project no. SSPE-CT-2004-502173 "Effects of the exposure to electromagnetic fields: from science to public health and safer workplace", Deliverable D49 – Fact Sheet, April 2008. Available online (21/08/2013) at: http://ihcp.jrc.ec.europa.eu/our_activities/public-health/exposure_health_impact_met/emf-net/docs/reports/Final%20technical%20report_D49_FactSheet.pdf

[8] A. Merlino, G. Quadrio, D. Andreuccetti, N. Zoppetti, A. Bogi, I. Pinto, L. Diamanti, N. Pasqualini and P. Zani: "Misure di campo elettromagnetico in ambito sanitario" ("Electromagnetic field measurements in the healthcare sector"). Proceedings (on electronic media) of the XXXV AIRP National Radiation Protection Congress, Venice, 17-19 October 2012, pp. 72–81.

[9] Directive 2013/35/EU of the European Parliament and of the Council of 26 June 2013 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields). Official Journal of the European Union, L 179/1, 29.6.2013.

[10] Directive 2004/40/EC of the European Parliament and of the Council of 29 April 2004 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields). Official Journal of the European Union, L 184/1, 24.5.2004.

[11] ICNIRP: "Guidelines for limiting exposure to time-varying electric, magnetic, and electromagnetic fields (up to 300 GHz)". Health Physics, Vol. 74, N. 4, April 1998, pp. 494–522.

[12] ICNIRP: "Guidelines for limiting exposure to time-varying electric and magnetic fields (1 Hz to 100 kHz)". Health Physics, Vol. 99, N. 6, December 2010, pp. 818–836.

[13] Council Recommendation 1999/519/EC of 12 July 1999 on the limitation of exposure of the general public to electromagnetic fields (0 Hz to 300 GHz). Official Journal of the European Communities, L 199/59, 30.7.1999.

[14] CEI (Italian Electrotechnical Committee): "Apparecchi elettromedicali – Parte 2: Prescrizioni particolari relative alla sicurezza fondamentale e alle prestazioni essenziali degli apparecchi ed accessori per elettrochirurgia ad alta frequenza" (Medical electrical equipment – Part 2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories). Standard CEI EN 60601-2-2, March 2011.