RF leakage current in electrosurgical units: Influence of the layout in taking measurements

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Abstract. The RF leakage current in electrosurgical units is a critical parameter to measure, because it may cause accidental burns in patients. The particular standard for electrosurgical units IEC 60601-2-2 indicates the maximum RF leakage levels and defines the elements and their layout to do these measurements. On this paper we show the RF leakage current values of 6 electrosurgical units. We did these measurements in two different ways: in the first one we measured in normal conditions of use in the operating rooms and in the second we followed the mentioned Standard. The results shows differences between one group and the other, observing higher RF leakage current values in the measurements that we did without following the standard’s layout.

1. Introduction

The radiofrequency (RF) leakage current in electrosurgical units (ESU) is a critical parameter because it involves patients safety. This current flows from active and return electrodes to ground and may cause accidental patient burns. The standard IEC 60601-2-2 [1], particular requirements for the safety of high frequency surgical equipment, limits this parameter to a maximum of 4.5 W measured on a 200 Ω non inductive resistor for monopolar applications.

RF leakage current measurement is one of the periodical inspections to do in ESU’s [3], [4], because it will indicate a dielectric loss at the power output of these devices. On the other hand, measuring this parameter depends on many factors, such us the device and instrument layout, cables length, height respect to ground and so on.

The IEC 60601-2-2 standard sets the instruments and ESU layout to do the RF leakage current measurement, as we show in Figure 1. The goal of setting this layout is to standardize the measurements and ensure repeatability.

During functional inspections of ESUs its quite difficult to set the layout of the standard, because the measurements are usually done in the operating rooms where this devices operate. In this situation the ESU lays on a cart at a height different to the suggested by the Standard to do these measurements, and also the lay out of the instrument and the cables is random.

In this work we try to quantify the effect of layout modifications when taking RF leakage current measurements, to determine if we must follow exactly the IEC 60601-2-2 layout or if we can directly take the measurements in the operating rooms without following a specific layout.

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2. Methods and Materials

For the achievement of the measurements we have used an ESU analyzer, model RF-302, manufactured from Biotek. We analyzed six Valleylab devices: three of them were Force FX model, and three Force 2. All the devices measured are showed in table 1, and their output features are showed in chart 2 y 3, for Force FX and Force 2 respectively. Leakage current measurements have made in two stages. First, we analyzed each ESU in the normal situation, inside an operation room, with the elements layout like it showed in figure 2. Then, in the second stage, we have made the measurements with the devices placed in a test table, like IEC 60601-2-2 suggest. The elements layout are showed in figure 1.

Main differences between measurements in stage 1 and stage 2 are: height ESU to the floor, distance between wires and use of return electrode

2.1. Stage 1

In a normal situation of use inside the operating room in I.C.Y.C.C., we found each device on a stainless steel transport table at a height of 20 cm from the floor. In Each measurement, the RF-302 analyzer stayed on floor and connected to ESU using test wires and an active electrode Conmed™,
like figure 2 shows. The location of wires was randomly, using another test wire to connect RF-302 to the ground connector placed on the wall. Return electrode to ground and active electrode to ground leakage RF Power was measured from monopolar output using a footswitch. The value was registered using all the available waveforms with the maximum power setup. This measure was called “out of norm/rule measurements”, because we don’t respect the device height, distance between wires and the use of return electrode.

| Name  | Trademark  | Model | Serial number |
|-------|------------|-------|---------------|
| ESU 1 | Valleylab  | Force FX | F5J42368A |
| ESU 2 | Valleylab  | Force FX | F5J42380A |
| ESU 3 | Valleylab  | Force FX | F5J42389A |
| ESU 4 | Valleylab  | Force 2 | F2C17574T |
| ESU 5 | Valleylab  | Force 2 | F7C31701T |
| ESU 6 | Valleylab  | Force 2 | F7132747T |

Table 2. Waveforms, maximum power output and voltage values for Valleylab Force FX.

| Mode | Waveform  | Max.Power @300Ω | Max. voltage |
|------|-----------|-----------------|--------------|
| Cut  | Low       | 300 W           | 1350 Vpp     |
| Cut  | Pure      | 300 W           | 2300 Vpp     |
| Cut  | Blend     | 200 W           | 3300 Vpp     |
| Coag. | Dessicate | 120 W           | 3500 Vpp     |
| Coag. | Fulgurate | 120 W           | 8500 Vpp     |
| Coag. | Spray     | 120 W           | 9000 Vpp     |

2.2. Stage 2

In the second stage we measured each device on a test table like IEC60601-2-2 suggests. Fig.1 shows the location of the elements. For connections between ESU and analyzer we used test wires with 4mm plug and croc clips to connect the return electrode. The return electrode used was a disposable split electrode, 3M model 9160F.

The measurement instrument (RF-302) used was the same for both stages.
3. Results

Comparing the measurements done in stages 1 and 2 for return and active electrodes RF leakage current, we can see differences between them. The average and standard deviation are (stage 1 and 2, in this order):

Return leakage current [W]: 7.333 ± 1.514; 2.875 ±1.242

Active leakage current [W]: 3.166 ± 0.970; 2.333 ±0.996

We have done a statistic analysis with the T Student test [5] in which we saw a significative difference (p<0.05) between the measurements done in stages Nº1 and Nº2 for return electrode leakage current.

For the active electrode leakage current measurements to ground, although the average value is greater in the measurements taking out of norm, there isn’t enough statistics evidence to confirm that this difference is significant (p<0.05)

In figure 3 and figure 4 we show the highest values measured in both conditions for each 6 ESUs, for return and active leakage current.

4. Discussion

The measurement’s results show a significant difference between the values when modifying the ESU’s height respect to ground, the cable’s length and their layout. In all the cases we measure a higher RF leakage current when taking them in the operating room conditions.

In the RF return leakage current measures without following the Standard’s conditions, the values we obtained were higher than the maximum allowed by the IEC 60601-2-2 Standard, which is 4.5 watts. On the other hand, when we repeated the measurements following the Standard’s layout of the elements involved (ESU, measuring instrument and cables) we obtained all of the values in the allowed range regardless one of the unit (ESU 6), in which the leakage current measured following the Standard is quite higher than the maximum allowed level. (5 watts).
When we analyzed the facts of the active electrode’s measurements leakage current, we observed that measuring with the IEC layout, the devices have a RF leakage below the maximum level. Measuring with a different layout (stage 1, called “out of norm”), we observed that the leakage levels increased in all cases, like it happened measuring from return electrode.

Table 3. Waveforms, maximum power output and voltage values for Valleylab Force 2.

| Mode     | Waveform | Max. Power @300Ω | Max. voltage |
|----------|----------|------------------|--------------|
| Cut      | Pure cut | 300 W            | 3500 Vpp     |
| Cut      | Blend 1  | 250 W            | 3800 Vpp     |
| Cut      | Blend 2  | 200 W            | 4000 Vpp     |
| Cut      | Blend 3  | 200 W            | 4000 Vpp     |
| Coagulation | Coag. | 120 W            | 7000 Vpp     |

5. Conclusions

RF leakage current measurement in this kind of devices is an important parameter that gives information about its safety.

We can see an important difference in the measurements according to the layout of the different elements involved.

It is necessary to count with a standard procedure to do these measurements, in which the effects of the layout be constant and don’t interfere with the desired measuring parameter.

Based on the results of this work, measuring RF leakage power in normal conditions of use, will give higher values. Doing this we may consider that an ESU is out of the highest allowed RF leakage because we are doing a wrong procedure.

We recommend that to do this kind of measurements you must follow the layout suggested by the IEC 60601-2-2 standard.

6. Appendix

We will next describe the elements of figure 1:

1. Main supply
2. Isolated table
3. ESU
4. Active electrode
5. Neutral or return electrode
6. Measuring resistor, 200Ω
7. RF meter
8. Conductive surface connected to ground
7. References

[1] International Standard IEC 60601-2-2. Medical electrical equipment. Particular requirements for the safety of high frequency surgical equipment. Fourth edition 2006

[2] Bio-tek electrosurgery analyzer RF 302. User’s guide. 1991

[3] Valleylab Force FX-C, electrosurgical generator. Service manual. 1999

[4] Valleylab Force 2, electrosurgical generator. Service manual. 1991

[5] Montgomery D and Runger C, *Applied statistics and probability for engineers*, Third edition 2003