ENCISION®

AEM® SAFETY – PERFORMANCE – VALUE

Quantifying the Risk of Burning Patients during Laparoscopy:
AEM® vs. non-AEM Monopolar Instruments

Patient Burns from Stray Energy; Cause and Implications

Coupling of energy through the outer insulation of conventional non-AEM monopolar laparoscopic instruments has been a problem since the inception of minimally invasive surgery (MIS). The issue is an inherent design flaw in non-AEM instruments; the instruments must transmit high frequency electrosurgical energy down the laparoscopic instrument's shaft, but lack the ability to contain this energy. This leads to stray energy "escaping" non-AEM instruments along the length of the instrument shaft through coupling. This stray energy may be coupled through an insulation failure or through intact insulation by capacitive coupling, both of which can burn a patient intraoperatively (figure 1).

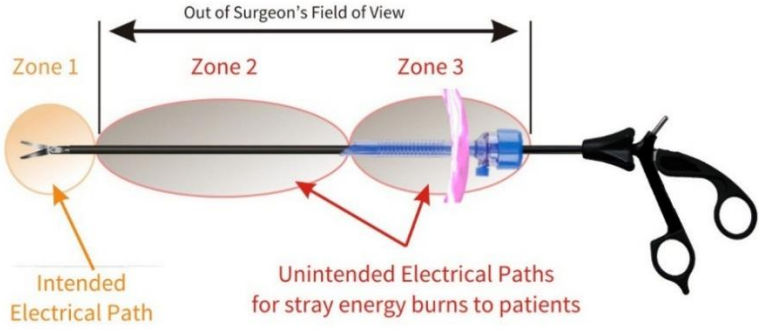


Figure 1: Conventional non-AEM Instrument

Insulation failure occurs when the outer insulation of the laparoscopic instrument is compromised. These holes in the outer insulation may be microscopic (not visible with the naked eye) and deliver the full power of the electrosurgical generator (ESU) to the patient at a location other than the operative site (i.e. through the side of the instrument shaft). During insulation failure a spark discharge, very similar to the effect at the active tip of the instrument, occurs when the shaft of the instrument comes close to the patient's tissue (figure 2). These stray energy burns can be catastrophic to patients.

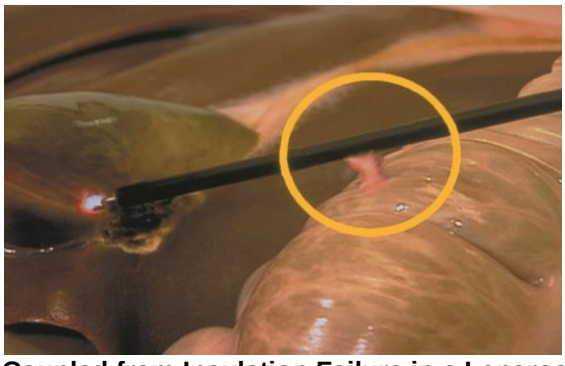


Figure 2: Energy Coupled from Insulation Failure in a Laparoscopic Monopolar Instrument to the Patient's Bowel, Causing Burns and Intestinal Perforation

Capacitive coupling occurs during MIS when current flows from the instrument to the patient. Even with intact insulation, charge may collect on the outside of an instrument and transfer to sensitive vascular or organ tissue (figure 3). This condition is inherent in every non-AEM laparoscopic surgical procedure, as a capacitor is created between the instrument and the patient's body. A capacitor is defined as two conductors separated by an insulator, where the instrument and the patient's body are conductors and the outer insulation of the instrument is the insulator. When the laparoscopic instrument is activated, the electrosurgical energy from the ESU is coupled to the patient's tissue; non-AEM instruments are not able to always prevent this stray energy and therefore may burn patients. This process can produce heating of the tissue, leading to 3rd degree burns and irreversible damage. A power level as low as 3.1 watts (W) will cause 3rd degree burns to tissue within 2 seconds[1]. A power level as low as 1.3 W will cause a 3rd degree burn to tissue within 5 seconds[1]. Therefore 1 watt of coupled power is considered to be the power level at which there begins to be concern.

Figure 3: Energy Capacitively Coupled from Laparoscopic Monopolar Instrument to Patient's Bowel, Causing Burns and Intestinal Perforation

Comparative Study for Preventing Patient Burns;
AEM vs. non-AEM Monopolar Laparoscopic Instruments

With the electrosurgical generators (ESUs) available today both the voltage and frequency vary among models. Some of the newer ESU technologies allude to a reduction in the level of capacitively coupled energy, when used in specialized modes and low power settings; however the level of reduction in capacitively coupled energy is not readily defined and none of these ESUs claim to prevent patient burns from insulation failure.

In contrast to these ESU technologies, AEM technology eliminates stray energy burns to patients, from insulation failure and capacitive coupling, while using AEM monopolar energy during laparoscopy.

Therefore a study was implemented to assess the relationship among several generators with respect to the power coupled through the insulation of a typical instrument, using typical generator settings for capacitive coupling and insulation failure. The test was run by Encision in a controlled laboratory environment, using calibrated test equipment, and setup conditions that closely mimic conditions found during monopolar laparoscopy. The study compared the "safest" modes of the various ESUs, using a standard 5mm Covidien laparoscopic scissor, and a relatively low power setting vs. the same ESU, mode, and power setting using AEM monitoring technology and instrumentation (see appendix A for test method and equipment).

Insulation Failure Results (figure 4): All non-AEM test setups were found to couple the same power from a hole in the side of the instrument (which may lead to a stray energy burn to a patient) as the active tip of the instrument; essentially an insulation failure in a non-AEM instrument is equivalent to having a second active tip. All setups using AEM technology were found to couple less than 0.2% of the

set power; this level of power is within the range of measurement error; essentially an insulation failure on an AEM instrument has no clinical effect and poses no risk to a patient.

Capacitive Coupling Results (figure 5): All non-AEM test setups were found to transmit 35% to 60% of the power emitted from the tip of the instrument, via capacitive coupling through the side of the instrument shaft (with intact insulation); all of these test results were in the power range capable of causing patient burns. All setups using AEM technology were found to couple less than 0.2% of the set power; this level of power is within the range of measurement error; essentially AEM instruments do not have any clinical effect from capacitively coupled energy and pose no risk to a patient.

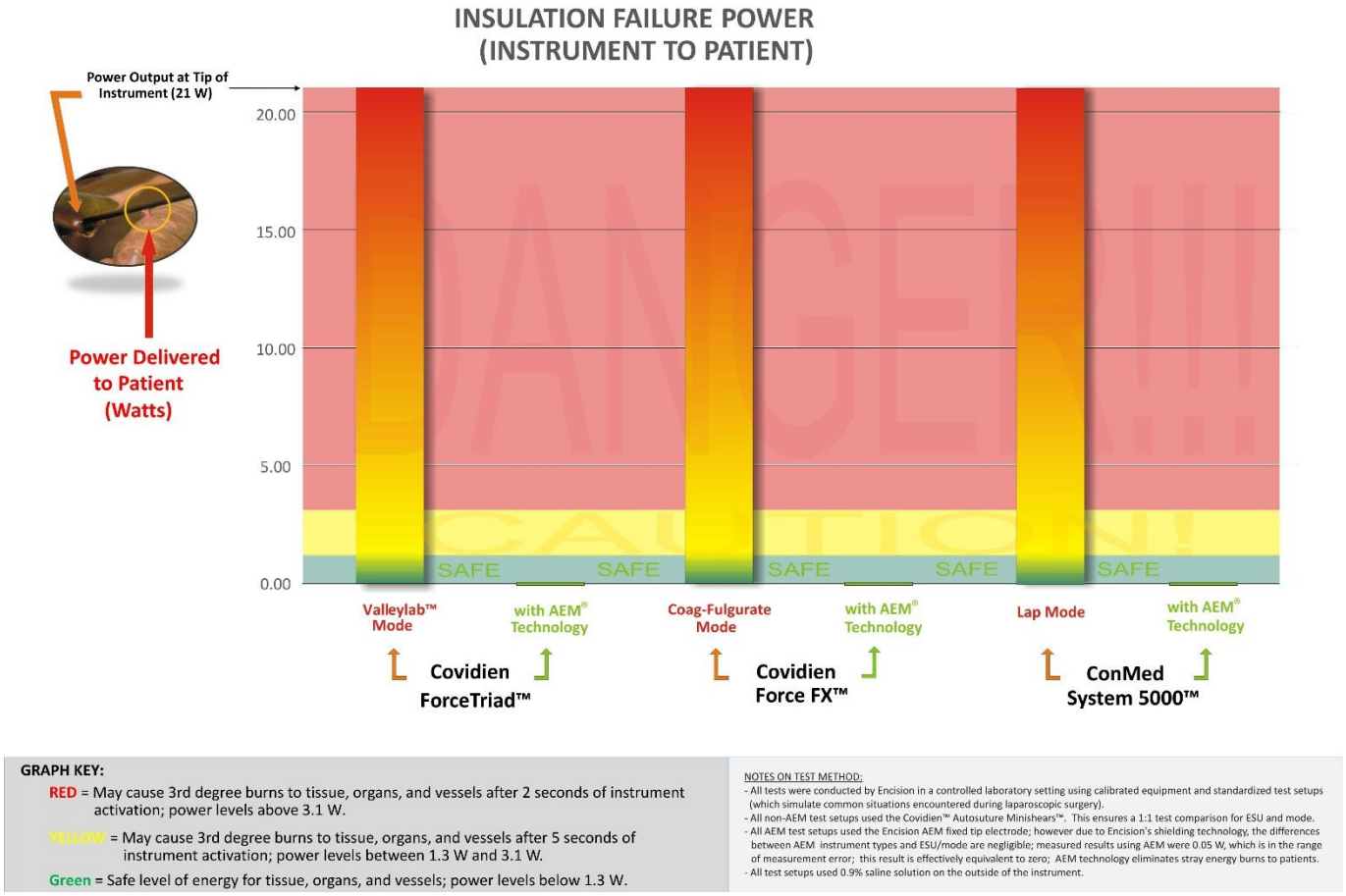
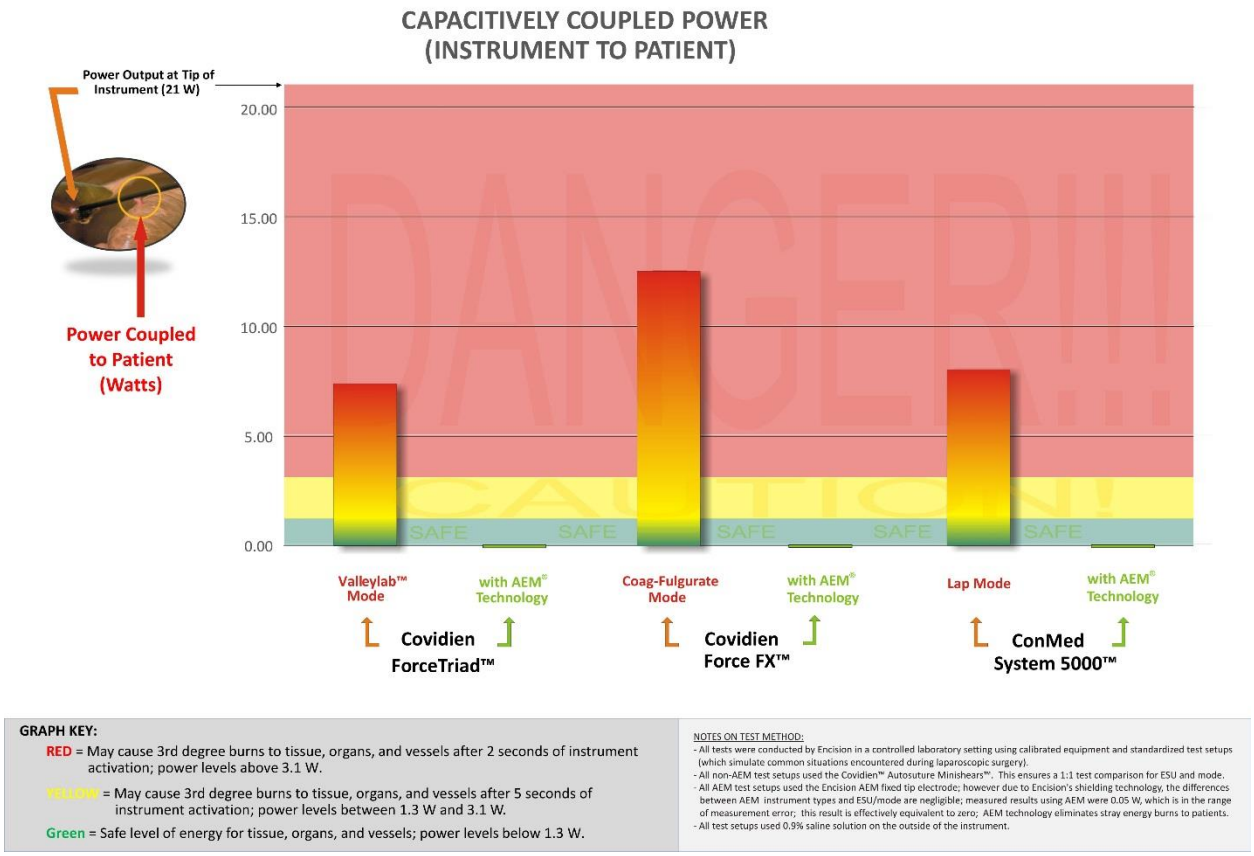


Figure 4: Insulation Failure Test Results
AEM vs. non-AEM Monopolar Laparoscopic Instruments



GRAPH KEY:

RED = May cause 3rd degree burns to tissue, organs, and vessels after 2 seconds of instrument activation; power levels above 3.1 W.

YELLOW = May cause 3rd degree burns to tissue, organs, and vessels after 5 seconds of instrument activation; power levels between 1.3 W and 3.1 W.

Green = Safe level of energy for tissue, organs, and vessels; power levels below 1.3 W.

NOTES ON TEST METHOD:

- All tests were conducted by Encision in a controlled laboratory setting using calibrated equipment and standardized test setups (which simulate common situations encountered during laparoscopic surgery).
- All non-AEM test setups used the Covidien™ Autosuture Minishears™. This ensures a 1:1 test comparison for ESU and mode.
- All AEM test setups used the Encision AEM fixed tip electrode; however due to Encision's shielding technology, the differences between AEM instrument types and ESU/mode are negligible; measured results using AEM were 0.05 W, which is in the range of measurement error; this result is effectively equivalent to zero; AEM technology eliminates stray energy burns to patients.
- All test setups used 0.9% saline solution on the outside of the instrument.

Figure 5: Capacitively Coupled Energy Test Results
AEM vs. non-AEM Monopolar Laparoscopic Instruments

Eliminating Patient Burns:

Encision's AEM technology eliminates the chance of stray energy burns to patients during laparoscopy by electrically shielding and monitoring the AEM instruments. Every AEM instrument has a protective shield that is actively monitored by the AEM system throughout a procedure (figure 8). This protective shield eliminates the risk of capacitive coupling to the patient by draining the energy away from the patient to the AEM monitor. If an insulation failure occurs, the AEM system actively drains the electrosurgical energy away from the patient through this protective shield. In addition the AEM system immediately shuts down the instrument power, similar to a circuit breaker (GFCI) in the electrical wiring of a house.

Figure 8: AEM Instrument Design

In every AEM instrument, the active electrode is surrounded by the primary insulation layer. The primary insulation layer withstands the high voltages of electrosurgery, ensuring effective use of the active electrode. The protective shield is a conductive tube that surrounds the primary insulation layer and active electrode, in zones 2 and 3 of the instrument (i.e. the entire length of the instrument shaft excluding zone 1, the active tip). The shield conducts stray energy back to the generator, ensuring there is no chance of a stray energy burn to the patient. The outer insulation provides an additional layer of insulation for all AEM instruments.

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[1]Pearce, John A. PhD (1986), Electrosurgery, page 217. New York: Wiley Medical.

Power Calculation: $P= (I^2)*(R) = (4000\ \Omega)*(0.0177\ A)^2$ for 5 seconds= 1.25 W for 5 seconds or 3.13 W for 2 seconds

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Appendix A:
Comparative Study Test Method and Equipment

1. **Insulation Failure Study Conditions:**
    a. Non-AEM Test Setup:
        i. ESU Settings:
            1. Covidien ForceTriad™ - Valleylab Mode set to output 21 W from the tip of the instrument (set power of 35W, of which ~60% is output from the active tip).
            2. Covidien Force FX™ - Standard Coag Mode set to output 21 W from the tip of the instrument (set power of 35W, of which ~60% is output from the active tip).
            3. ConMed System5000™ - Lap Mode set to output 21 W from the tip of the instrument (set power of 35W, of which ~60% is output from the active tip).
        ii. Instrument contact; lunchmeat ham kept moist with saline for insulation failure measurements.
        iii. Instrument used for all tests – Covidien Autosuture™ Minishears, 5mm scissors

    b. AEM Instrument Test Setup:
        i. All conditions were identical to the non-AEM test setup, with the exception of the instrument used for the test. An AEM instrument and AEM monitor were used in place of the Covidien Autosuture™ Minishears 5mm scissors. For comparison purposes an Encision AEM 3500 series fixed tip electrode was used with an Encision EM-2+ monitor. However, due to the actively monitored shielding technology included in every AEM instrument, the test results do not vary based upon the instrument style or AEM monitor style used.

    c. Measurement Equipment Used:
        i. Pearson 4100 current transformer.
        ii. Tektronix p6015 voltage probe.
        iii. Tektronix DPO5034 oscilloscope.
        iv. Resistors to simulate a return electrode.
        v. Appropriate cables to connect to the generator monopolar output.

    d. Test Method:
        i. The oscilloscope was set to acquire 10 megapoints of data at 10 megasamples per second with 900 ms of data displayed.
        ii. Voltage and current data were collected after stabilization (typically 0.2 seconds) to the end of the sample.
        iii. The oscilloscope was set to compute the power via real – time v*I and taking the mean over the acquisition period.

Appendix A:
Comparative Study Test Method and Equipment

e. Notes on power output:
   i. During ESU activation there is a spark between the instrument contact and the tissue. This is true for both an electrode tip contact (i.e. intentional contact during MIS between the tip of the instrument and the operative site) and an insulation fault contact (i.e. unintentional contact through the side of the instrument shaft, burning the patient at a non-operative site). There is considerable variation in the measured amount of current and power under sparking conditions due to the inherent variability of the sparking process itself. The largest source of variation is test to test variation, however ESU to ESU variation also affects the outcome. In this testing the actual measured power in 150 mS of spark discharge varied from 12.4 watts (W) to 29.3 W, with the mean being 21.0 W. The 21 W value is used in the reporting for both tip discharge and fault discharge for each generator.

2. Capacitive Coupling Study Conditions:

a. Non-AEM Test Setup:
   i. ESU Settings:
      1. Covidien ForceTriad™ - Valleylab Mode set to output 21 W from the tip of the instrument (set power of 35W, of which ~60% is output from the active tip).
      2. Covidien Force FX™ - Standard Coag Mode set to output 21 W from the tip of the instrument (set power of 35W, of which ~60% is output from the active tip).
      3. ConMed™ System5000™ - Lap Mode set to output 21 W from the tip of the instrument (set power of 35W, of which ~60% is output from the active tip).
   ii. Load; 4000 ohms.
   iii. Instrument contact; 1 inch foil wet with 0.9% saline (to ensure a 1:1 comparison between test setups) for capacitive measurements.
   iv. Instrument used for all tests – Covidien Autosuture™ Minishears, 5mm scissors.

b. AEM Instrument Test Setup:
   i. All conditions were identical to the non-AEM test setup, with the exception of the instrument used for the test. An AEM instrument and AEM monitor were used in place of the Covidien Autosuture™ Minishears 5mm scissors. For comparison purposes an Encision AEM 3500 series fixed tip electrode was used with an Encision EM-2+ monitor. However, due to the actively monitored shielding technology included in every AEM instrument, the test results do not vary based upon the instrument style or AEM monitor style used.

Appendix A:
Comparative Study Test Method and Equipment

c. Measurement Equipment Used:
   i. Pearson 4100 current transformer.
   ii. Tektronix p6015 voltage probe.
   iii. Tektronix DPO5034 oscilloscope.
   iv. Resistors to simulate a return electrode.
   v. Appropriate cables to connect to the generator monopolar output.

d. Test Method:
   i. The oscilloscope was set to acquire 10 megapoints of data at 10 megasamples per second with 900 ms of data displayed.
   ii. 150 mS of current data was sampled after the generator's startup transient (typically 0.2 seconds) had stabilized.
   iii. Root mean squared (RMS) values were computed by the oscilloscope and P = i2R was computed in Excel.
   iv. If there was a significant variation on the 900 mS of data displayed, the variation was noted and the rms value was computed over the full 900 mS displayed.