ENCISION
AEM® LAPAROSCOPIC INSTRUMENTS

White Paper: AEM® Technology Versus Adaptive Technologies to Protect the Laparoscopic Patient

There is considerable confusion pertaining to claims made by electrosurgical generator manufacturers about their adaptive technologies (Instant Response™ Technology by Covidien and Dynamic Response™ technology from ConMed). Their marketing literature is actually accurate in describing these technologies that essentially detect load impedance and adjust their electrosurgical output accordingly to produce a consistent tissue effect.

Another advantage of these technologies is their ability to reduce capacitive coupling, especially in an open circuit condition. However, we have received reports that these claims have been stretched to suggest that AEM technology with its ability to detect and protect against stray monopolar electrosurgical energy in laparoscopic procedures is not required when these adaptive technologies are used.

The following resource from Covidien (Recommendations to Avoid Electrosurgical Patient Complications in MIS)[i] sums it up best, describing various guidelines to avoid potential problems: "Utilize available technology, such as a tissue response generator to reduce capacitive coupling **or an active electrode monitoring system, to <u>eliminate</u> concerns about insulation failure and capacitive coupling"** (emphasis and underlining added).

Adaptive electrosurgical technologies can reduce capacitive coupling in ideal conditions (e.g., open circuit), but their ability to do so is also dependent on variables outside the control of the electrosurgical generator. For example, if the insulation of an active electrode is poor (even if that insulation is intact), the electrosurgical generator may sense a loaded condition and may not compensate. Such a condition will produce higher capacitive current and the resultant danger of stray electrosurgical current via capacitive coupling.

Additionally, and most importantly, these adaptive technologies **will not** detect insulation failures. An insulation failure on the electrode, exposing the bare metal of the electrode, is no different than the active tip of the electrode and can result in unintended burns and complications, especially when located outside the field of view during laparoscopic procedures. Four independent studies confirmed that insulation failure is common, with an average of one in five instruments inspected having such a failure[ii]. One study even confirmed that although an improvement, 3% of single-use electrodes demonstrated such insulation failures[iii].

Simply, adaptive technologies for monopolar electrosurgery offer benefits for the clinician, but do not provide the type of protection that AEM technology does. Encision's patented AEM technology is the *<u>only</u>* available technology that can prevent thermal burn injury from stray energy due to insulation failure and capacitive coupling *<u>during</u>* laparoscopy. Since Encision's mission is to improve surgical technique, improve patient outcomes and enhance patient safety – we want to ensure that you, as a valued customer or as a potential customer, have all the facts and avoid a false sense of security. Laparoscopic complications such as bowel perforations carry serious ramifications. AEM technology provides the highest degree of protection for your patients.

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[i] http://www.valleylab.com/education/poes/poes_29.html (accessed 10/19/11)

[ii] Frei R. Safety study of laparoscopic instruments rings alarm bells. *Gen Surg News.* 32(8)(2005), p. 17; Yazdani A, Krause H. Laparoscopic instrument insulation failure: The hidden hazard. J Minim Inv Gynecol. 2007;14:228-232; Espada M, Munoz R, Nobile B, Kho R, Magtibay P, Castle E, Magrina J. Insulation failure in robotic and laparoscopic instrumentation: A prospective evaluation. J Minim Invasive Gynecol. 2008;15:S66; Montero PN, Robinson TN, Weaver JS, Stiegmann GV. Insulation failure in laparoscopic instruments. Surg Endosc. 2010;24:462-465.

[iii] Montero PN, Robinson TN, Weaver JS, Stiegmann GV. Insulation failure in laparoscopic instruments. Surg Endosc. 2010;24:462-465.

