FMS Shaver Interface Cables – Technical Functionality Report

By I.D. McRury, Ph.D.

Purpose: The purpose of this report is to explain the technical functionality of certain FMS interface cables and confirm they **do not** interfere with the core functionality of shaver systems they interface with.

Introduction: Many surgeons want to use a competitive shaver system with the FMS unit and prefer to use their own shaver co-located push button controls. In order to satisfy these customers, FMS provides interface cables that serve one purpose: to detect when the hand switch on competitive shavers is activated and co-activate the pump.

Abstract: There have been occasional inferences from competitive agencies claiming the use of FMS pumps with interface cables affect negatively competitive shaver consoles. These allegations are unwarranted. This paper gives a description of the interface cable, its safety apparatus and the testing and accreditation justifying its release.

Test Methods: Universal Laboratory Report # E240563-A3-IT-1 (dated March 29, 2006) summarizes the testing. UL testing was done against standards IEC 60601-1:1988 +A1: 1991 +A2: 1995.

Results: FMS interface cables only detect when the hand switch on competitive shavers is activated, and co-activates the pump. Optical couplers are designed for electrical isolation: shaver control boxes do not recognize that there is another device in line. In summary, the interface cables were designed as state-of-the-art signal detectors and **will not alter**, intentionally or unintentionally, the communication between shaver hand piece and shaver console. Interface devices **do not change the class of the hand piece shaver.** If a competitive shaver is rated BF by its manufacturer, it remains a BF-rated device when used with the FMS interface cables.

This information has been tested by Universal Laboratories prior to the release of the device. Subsequent to all tests passing, a UL certificate # 110406-E240563 was issued.

Interface Cables Included in this Report (Hand Control Interfaces Only):

282001 - Stryker TPS and CORE consoles / 12K and Formula Shavers (Product code 4220-01)

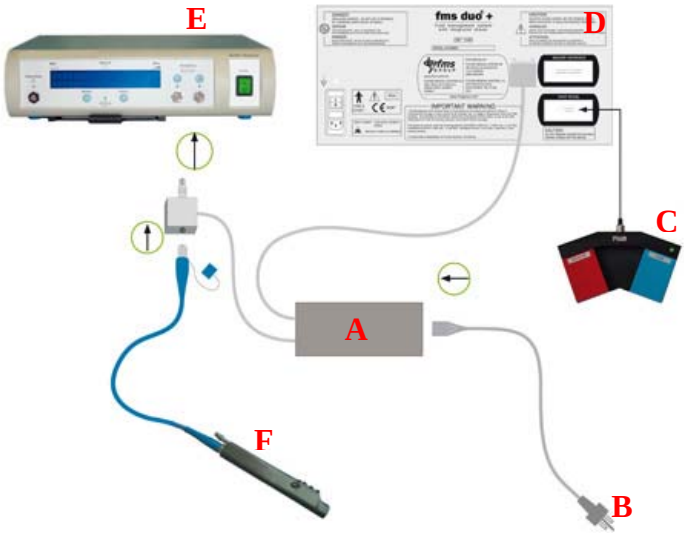
282005 - Linvatec Advantage and Advantage Turbo Shavers (Product code 4220-05)

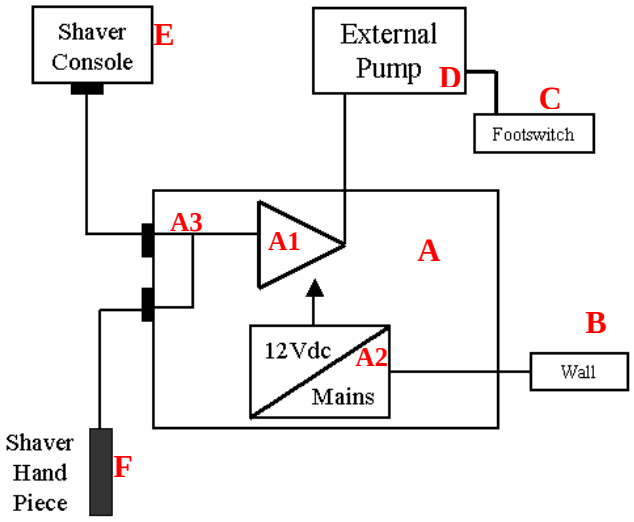
282003 – Smith & Nephew Dyonics EPI, Power, and Powermax Shavers (Product code 4220-03)

References:

- Universal Laboratory Report. Ref # E240563-A3-IT-1. Issue date: 03/29/2006, 46 pages.
- Agilent Technologies product description 5989-2112EN, 16 pages.

System Description: The interface cable set-up is shown in the drawing on the left below, a schematic of the parts is shown on the right below. Each component in the system is labeled with lettering corresponding to the schematic component to be discussed. The schematic is taken from the Universal Lab report (Ref # E240563-A3-IT-1, dated March 29, 2006 - page 6 of 46) and rearranged to mirror the drawing.





Item A is the interface module. The shaver and the shaver console are attached to the interface module at point A3. Point A3 is monitored by A1, an optical coupler. When a switch is pressed at the handpiece F, the activation signal is used to light a LED in the Optical coupler A1, and passes unchanged to the shaver console E, which activates the shaver F.

The coupler light detector passes its own activation signal (supplied by wall source B) on to the FMS External pump D. In this manner, every time the shaver is activated, the pump is activated, and when the shaver is off, the shaver suction is deactivated. It should be stressed here – ***optical couplers EXIST for electrical isolation***. The shaver control box does not recognize there is another device in line. It only sees what is happening in the shaver.

Optical coupler: The Optical coupler A1 used in the FMS interface cable is a very common isolation device. When the LED is lit, the light passes through an optically transparent dielectric barrier to a light detector. A dielectric barrier is insulation that does not allow passage of electricity, but allows the passage of light through a glass or plexi-glass type material.

In report # E240563-A3-IT-1 (Table 20 page 39), dielectric strength was tested per IEC 60601-1 and passed all the requirements.

Per standard UL1577, the dielectric barrier in the FMS Optical coupler is rated to resist 5000V for 1 minute (Agilent product description 5989-2112EN, page 1). This means that it would require maintaining a signal of 5000V for more than 1 minute to break through the dielectric barrier and send a harmful signal back to the isolated equipment (shaver and shaver console). Most switch voltages are 5V so it stands to reason that the optical coupler will perform adequately.