

Date: April 29, 2013

Re: Power-LOAD Cot Fastener Sole Source Information

To Whom It May Concern:

Stryker Medical certifies that we are the sole manufacturer of the Stryker EMS Power-LOAD (Model 6390). This correspondence is to inform you of the unique characteristics of the Power-LOAD Cot Fastener. These characteristics can be broken down into two primary categories: Independent Qualification, and Ease of Use.

The Stryker EMS Power-LOAD (Model 6390) cot fastening system is mounted within the patient compartment and is intended to aid in the loading/unloading of patients. The Stryker Power-LOAD is the only powered cot fastening system that meets the following:

#### Independent Qualification

- IPX6: The system is rated to withstand powerful water jets.
- IEC 60601-1 and IEC 60601-1-2: This certification indicates that Power-LOAD conforms to industry standards for mechanical and electrical safety for medical electrical devices, as well as electromagnetic compatibility and immunity.
- BS EN-1789 clause 4.5.9: This is a European dynamic crash test which subjects a 50<sup>th</sup> percentile dummy to a nominal 10g deceleration for a minimum of 50ms. Following the test there shall be no sharp edges or danger to the safety of persons in the road ambulance.

#### Ease of Use

- Device must provide a linear guide when loading and unloading the cot
- Device must allow for remote actuation from Power-PRO foot end controls
- Device must engage to the cot during loading and unloading, providing a means of lifting and lowering
- Device must allow for manual back-up operation in the event of power failure or system error
- Device must have a safe working load of 870 lbs and be capable of lifting patients weighing up to 700lbs.
- Device must be mounted inside the patient compartment to prevent environmental exposure and corrosion
- Device must be power washable
- Device must be capable of inductively charging the Stryker SMRT cot battery

Please contact your Stryker Sales Representative for further information.