

Product Bulletin

For Distribution To:

- International Distributors
- International Management
- U.S. Field Sales & Clinical Specialists
- U.S. Technical & Field Service

Date: April, 2015

RE: Using MEDIVATORS® ENDOGATOR™ and ENDO STRATUS® Irrigation Pump and CO₂ Insufflators in low-humidity environments

MEDIVATORS manufactures and distributes the ENDOGATOR EGP-100, ENDO STRATUS EGA-500, and ENDO STRATUS EGA-501. These three electromedical devices have been tested according to the appropriate sections of EN 60601-1-2 and related standards for electrical safety and electromagnetic compatibility (EMC). Portions of the testing were conducted under conditions of varying relative humidity and temperature. The tests performed at a relative humidity at or below 35% and the corresponding results were as follows.

Product	Test Standard	Test conditions	Result
EGP-100 family of ENDOGATOR Irrigation Pumps Tested according to: IEC 60601-1-2: 2001, EN 60601-1-2: 2001	EN 61000-3-2 Harmonic Currents	Ambient Temp: 25.9°C RH: 33%	Pass
	EN 61000-3-3 Voltage Fluctuations & Flicker	Ambient Temp: 24.3°C RH: 31%	Pass
	IEC 61000-4-3 Radiated RF Immunity	Ambient Temp: 24.6°C RH: 35%	Pass
	IEC 61000-4-6 Conducted RF Immunity	Ambient Temp: 24.1°C RH: 34%	Pass
	IEC 61000-4-11 Voltage Dips/ Interruptions Immunity	Ambient Temp: 24.4°C & 26.6°C RH: 31% & 29%	Pass
	EN 55011 (CISPR 11) Radiated Emissions	Ambient Temp: 22.5°C RH: 32%	Pass
	EN 55011 (CISPR 11) Conducted Emissions	Ambient Temp: 26.0°C RH: 32%	Pass
EGA-500 family of ENDO STRATUS Irrigation Pumps Tested according to: IEC 60601-1-2, ed3.0 (2007-03)	IEC 61000-4-3 Radiated RF Immunity	Ambient Temp: 21°C RH: 15%	Pass
	IEC 61000-4-4 Fast Transient/ Burst Immunity	Ambient Temp: 21°C RH: 19%	Pass
	IEC 61000-4-5 Immunity to Surge	Ambient Temp: 21°C RH: 31%	Pass
	IEC 61000-4-6 Conducted RF Immunity	Ambient Temp: 21°C RH: 18%	Pass
	IEC 61000-4-8 Power Frequency Magnetic Field Immunity	Ambient Temp: 21°C RH: 23%	Pass
	IEC 61000-4-11 Voltage Dips/ Interruptions Immunity	Ambient Temp: 21°C RH: 19%	Pass
	CISPR 11 Conducted Emissions	Ambient Temp: 27°C RH: 19%	Pass



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Product Bulletin

Product	Test Standard	Test conditions	Result
EGA-501 family of ENDO STRATUS CO ₂ Insufflators. Tested according to: IEC 60601-1-2, ed3.0 (2007-03) and EN 60601-1-2:2007	IEC/EN 61000-4-3 Radiated RF Immunity	Ambient Temp: 23°C RH: 21% & 20%	Pass
	IEC/EN 61000-4-4 Fast Transient/ Burst Immunity	Ambient Temp: 23°C & 22°C RH: 16% & 24%	Pass
	IEC/EN 61000-4-5 Immunity to Surge	Ambient Temp: 23°C RH: 4%	Pass
	IEC/EN 61000-4-6 Conducted RF Immunity	Ambient Temp: 22°C RH: 10%	Pass
	IEC/EN 61000-4-8 Power Frequency Magnetic Field Immunity	Ambient Temp: 22°C RH: 35%	Pass
	IEC/EN 61000-4-11 Voltage Dips/Interruptions Immunity	Ambient Temp: 22°C RH: 21%	Pass
	IEC/EN 61000-3-2 Harmonics	Ambient Temp: 21°C RH: 34%	Pass
	IEC/EN 61000-3-3 Flicker	Ambient Temp: 21°C RH: 34%	Pass

As demonstrated by passing results from the tests above, the devices noted here can be safely used in the above-mentioned atmospheric conditions.

Should you have any further questions, please contact MEDIVATORS Customer Support at 1-800-444-4729.