THE SONICISION™ SYSTEM CLINICAL PERFORMANCE

Performance of the Sonicision™ cordless ultrasonic dissection device compared to the Harmonic ACE™* and Harmonic ACE+™*

COMPARABLE

The Sonicision™ device mean thermal spread, vessel burst pressure, seal time and blade temperature are comparable to the Harmonic ACE™* and Harmonic ACE+™*[1]

CLICK TO THE TABLE >

FASTER

The Sonicision™ device provides faster dissection[1,†] and has a faster active blade cool down time[2] than the Harmonic ACE™*.

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RELIABLE

The Sonicision™ device reliably seals vessels up to 5 mm in diameter[1]

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LESS PLUME

The Sonicision™ device produces up to 5x less plume than Harmonic ACE™*[3]

CLICK TO THE TABLE >

Background

Energy-based hemostatic devices have evolved over the past century to become an essential tool in the surgical field. The latest innovation from Medtronic to enter the arena is the completion of the Sonicision™ cordless ultrasonic portfolio. Now with four available shaft lengths, inclusive of both the longest and the shortest pistol grip ultrasonic device on the market with optimized ergonomic design. In turn this portfolio utilizes advanced ultrasonic technology to provide rapid dissection and hemostasis without the need for a stand-alone generator or cord, therefore increasing ease of operation and freedom of movement. A variety of tests have been performed to date by Medtronic to evaluate the performance of the Sonicision™ device compared to the Harmonic ACE™* and Harmonic ACE+™*.

Summary

The differences between the Sonicision™ cordless ultrasonic dissection device and the Harmonic ACE™* were found to be non-significant in regards to mean vessel burst pressure, mean thermal spread, mean peak active blade temperature and mean seal time.[1] The Sonicision™ device was statistically faster in terms of mean dissection speed[†,1], and mean active blade cool down time to 60 °C[2] in these tests.

Results

The tables on page 2 summarize summarizes the pre-clinical comparative testing between the Sonicision™ device and the Harmonic ACE™* device

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Further, Together

The following table summarizes the pre-clinical comparative testing between the Sonicision™ device and the Harmonic ACE™*:

	RELIABLE	FASTER				
	Mean Vessel Burst Pressure[1] (mmHg ± SD)	Mean Dissection Speed[1] (sec ± SD)	Mean Peak Active Blade[4] Temperature (°C ± SD)	Mean Active Blade Cool Down[2] Time to 60 °C (sec ± SD)	Mean Thermal Spread[1] (mm ± SD)	Mean Seal Time[1] (sec ± SD)
Sonicision™ device	578 ± 284	24.8 ± 4.9	249.7 ± 24.3	41.2 ± 1.3	1.06 ± 0.05	5.2 ± 1.7
ACE™*	605 ± 288	33.8 ± 5.4	239.3 ± 28.4	50.4 ± 7.5	1.08 ± 0.5	4.9 ± 1.5
P-Value	0.48	<0.001	0.173	0.006	0.82	0.20
Statistical Relevance	NS	**Statistically Significant**	NS	**Statistically Significant**	NS	NS

The Sonicision™ provides faster dissection[2] and has a faster active blade cool down time[4] than the Harmonic Ace™*.

	LESS PLUME	
	Average Coagulation Obstruction Maximum Obstruction (%)[3]	Average Cutting Obstruction Maximum Obstruction (%)[3]
Sonicision™ device	4.80 ± 0.86	8.76 ± 1.49
ACE™*	26.63 ± 3.70	12.65 ± 0.97
Statistical Relevance	**Statistically Significant**	**Statistically Significant**

Sonicision™ produces up to 5x less plume than the Harmonic Ace™*[3]

The following table summarizes benchtop testing between the Sonicision™ device and the Harmonic ACE+™*:

	RELIABLE	COMPARABLE				
	Mean Vessel Burst Pressure[5] (mmHg ± SD)	Mean Dissection Speed[6] (sec ± SD)	Mean Peak Active Blade[6] Temperature (°C ± SD)	Mean Active Blade Cool Down[6] Time to 60 °C (sec ± SD)	Mean Thermal Spread[7] (mm ± SD)	Mean Seal Time[8] (sec ± SD)
Sonicision™ device	868.4 ± 419.9	43.4 ± 7.0	263.1 ± 18.8	37.6 ± 4.4	1.44 ± 0.5	8.40 ± 3.60
ACE+™*	1030.1 ± 405.1	44.6 ± 4.3	266.3 ± 20.2	37.4 ± 5.8	1.25 ± 0.2	8.12 ± 3.74
P-Value	P = 0.18	P = 0.777	P = 0.771	P = 0.704	P = 0.100	P = 0.62
Statistical Relevance	NS	NS	NS	NS	NS	NS

The Harmonic Ace+™* showed no statistical improvements compared to the Sonicision™ ultrasonic dissector.

† When compared to the Harmonic ACE™* on maximum power through 10 cm of porcine mesentery. Results show a statistically significant (P < 0.0001) difference in mean dissection speed.

1. Tsirline VB, Lau KN, Swan RZ, Montero PN, Sindram D, Martinie JB, Iannitti DA., Evaluation of an Innovative, Cordless Ultrasonic Dissector. Surg Innov, 2013.
2. Based on internal test report R0022948 Rev A. Comparison of Active Blade Cool Down Time to 60 °C – Milwaukee P4 vs. ACE36B, done on maximum power through 15 cm of porcine mesentery. July 16, 2010.
3. Kim FJ, Sehrt D, Pompeo A, Molina WR., Comparison of surgical plume among laparoscopic ultrasonic dissectors using a realtime digital quantitative technology. Surg Endosc, 2012. Based on a 3-way ANOVA comparison, the Harmonic ACE™* had significantly higher obstruction than the Sonicision™ and Olympus Sonosurg™* devices.'
4. Based on internal testing done on maximum power through 15 cm of porcine mesentery. Covidien report May 17, 2010 R0014725.
5. Based on internal testing using minimum mode on isolated vessels. Covidien report December 12, 2013 R0047124 Rev A.
6. Based on internal test report R0047122 Rev A. Thermal Profile Study of Various Competitor Devices versus Covidien Sonicision™, LigaSure™ LF1637, and LigaSure™ LF1737 Devices
7. Based on internal testing using minimum mode on isolated vessels. Covidien report Nov 18, 2013 R0047634_A.
8. Based on internal testing using minimum mode on various isolated vessels and tissue types. Covidien report Nov 18, 2013. R0047634_A.

IMPORTANT: Please refer to the package insert for complete instructions, contraindications, warnings and precautions.

*This is a global website. It is not specific to Canada.

Claims made throughout this brochure are based on clinical trials.

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