



**PRIMED INSTRUMENTS INC.**  
 1080 Tristar Drive, Unit 14  
 Mississauga, Ontario L5T 1P1 Canada  
 Phone: 905 565 0565  
 Fax: 905 565 0566  
 Email: info@primedendo.com

## SuperDART® Endoscopic Channel Cleaning Brushes Post Processing Residual Analyte Test Results

### Protein Analyte Test Results<sup>2</sup>

Channel <sup>A</sup> Cleaned	SuperDART® Channel Cleaning Device	Residual (µg/cm <sup>2</sup> ) Protein								
		Positive Control	Negative Control	After only ONE (1) PASS through the channel. Acceptance Criteria <sup>1</sup> ≤ 6.4 µg/cm <sup>2</sup>					SD σ	SD + Highest Value
				Efficacy Cycle (N=3)			SD σ	SD + Highest Value		
				1	2	3				
2.0mm Worn Channel	9253 (channel size range 2.0 - 2.8mm)	1909.966	<0.169	<0.169	<0.169	<0.169	0	0.169		
2.8mm Worn Channel	9253 (channel size range 2.0 - 2.8mm)	1903.129	<0.170	<0.170	0.205	<0.170	0.020	0.225		
2.8mm Worn Channel	9292 (channel size range 2.8 - 4.2mm)	2110.123	<0.172	<0.172	<0.172	0.341	0.098	0.439		
4.2 mm Worn Channel	9292 (channel size range 2.8 - 4.2mm)	1016.868	<0.177	<0.177	<0.177	<0.177	0	0.177		

### Hemoglobin Analyte Test Results<sup>3</sup>

Channel <sup>A</sup> Cleaned	SuperDART® Channel Cleaning Device	Residual (µg/cm <sup>2</sup> ) Hemoglobin								
		Positive Control	Negative Control	After only ONE (1) PASS through the channel. Acceptance Criteria <sup>1</sup> ≤ 2.2 µg/cm <sup>2</sup>					SD σ	SD + Highest Value
				Efficacy Cycle (N=3)			SD σ	SD + Highest Value		
				1	2	3				
2.0mm Worn Channel	9253 (channel size range 2.0 - 2.8mm)	5385.009	<0.837	<0.837	<0.837	<0.837	0	0.837		
2.8mm Worn Channel	9253 (channel size range 2.0 - 2.8mm)	5877.698	<0.837	<0.837	<0.837	<0.837	0	0.837		
2.8mm Worn Channel	9292 (channel size range 2.8 - 4.2mm)	5236.651	<0.835	<0.835	<0.835	<0.835	0	0.835		
4.2 mm Worn Channel	9292 (channel size range 2.8 - 4.2mm)	7242.960	<0.836	<0.836	<0.836	<0.836	0	0.836		

## Total Organic Carbon (TOC) Analyte Test Results<sup>4</sup>

Channel <sup>A</sup> Cleaned	SuperDART® Channel Cleaning Device	Residual (µg/cm <sup>2</sup> ) Total Organic Carbon (TOC)						
		Positive Control	Negative Control	After only ONE (1) PASS through the channel. Acceptance Criteria <sup>1</sup> ≤ 12 µg/cm <sup>2</sup>				
				Efficacy Cycle (N=3)			SD σ	SD + Highest Value
1	2	3						
2.0mm Worn Channel	9253 (channel size range 2.0 - 2.8mm)	3060.549	<1.61	<1.610	<1.610	<1.610	0	1.610
2.8mm Worn Channel	9253 (channel size range 2.0 - 2.8mm)	5936.737	<1.605	<1.605	<1.605	<1.605	0	1.605
2.8mm Worn Channel	9292 (channel size range 2.8 - 4.2mm)	1954.209	<1.608	<1.608	<1.608	<1.608	0	1.608
4.2 mm Worn Channel	9292 (channel size range 2.8 - 4.2mm)	3900.920	<1.618	<1.618	<1.618	<1.618	0	1.618

### CONCLUSION:

The residual analytes levels were significantly below the acceptance criteria for endpoints set by ANSI/AAMI ST98:2022 for routine manual cleaning of flexible endoscopes to allow the disinfection/sterilization processes to achieve the proper sterility assurance level. All testing was conducted by Highpower VtIs, which is an ISO 17025 accredited third-party lab.”

The ANSI/AAMI ST98:2022 standard mandates the use of at least two quantitative analytes to evaluate cleaning efficacy. In this study, three (3) analytes were included to meet this requirement.

Three (3) data points were generated for the analytes; Standard deviation added to the highest values do not exceed the acceptance criterion – data generated demonstrated reproducibility and stability of the cleaning process.

### NOTE:

<sup>A</sup> All studies were conducted using worn channels to more accurately simulate real-world conditions. The channels were exposed to one-thousand (1000) biopsy forceps insertions in order to recreate micro scratches that are always present in endoscopes’ channels. A scratched channel will retain more contaminants and presents a more challenging condition for the validation of the brush efficacy when compared to an unused channel.

### References:

<sup>1</sup> Association for the Advancement of Medical Instrumentation (AAMI). “ANSI/AAMI ST98:2022 Cleaning validation of health care products – Requirements for development and validation of cleaning process for medical devices.” Section 8.2.3, Table 1 – Acceptance criteria for endpoints. Jun. 17, 2022.

<sup>2</sup> Highpower Validation Testing & Lab Services Study No. 2206-408 & 2210-652. Study No. 2206-408 Protocol and Final Report titled “Manual Cleaning Validation of Worn GI Endoscope Channels when using the PriMed Instruments 9292 SuperDART® Brush Protein Analysis.” July 2022. Study No. 2210-652 Protocol and Final Report titled “Manual Cleaning Validation of Worn GI Endoscope Channels when using the PriMed Instruments 9291 (aka 9253) SuperDART® Brush Protein Analysis.” November 2022. Test reports on file with PriMed Instruments Inc.

<sup>3</sup> Highpower Validation Testing & Lab Services Study No. 2310-628 Protocol and Final Report titled “Manual Cleaning Validation of Worn GI Endoscope Channels when using the PriMed Instruments 9253 and 9292 SuperDART® Single-Use Channel Cleaning Brushes Hemoglobin Analysis.” November 2023. Test reports on file with PriMed Instruments Inc.

<sup>4</sup> Highpower Validation Testing & Lab Services Study No. 2310-629 Protocol and Final Report titled “Manual Cleaning Validation of Worn GI Endoscope Channels when using the PriMed Instruments 9253 and 9292 SuperDART® Single-Use Channel Cleaning Brushes Total Organic Carbon Analysis.” November 2023. Test reports on file with PriMed Instruments Inc.

SuperDART® is a registered trademark of PriMed Instruments Inc.