

HALYARD ONE-STEP*
STERILIZATION WRAP
PHYSICAL PROPERTIES TESTING



HALYARD ONE-STEP*

Sterilization Wrap

PHYSICAL PROPERTIES TEST METHODOLOGY AND RESULTS FOR HALYARD ONE-STEP* H100 STERILIZATION WRAP

Test	Methodology	Interpretation of Results	HALYARD ONE-STEP* H100 Sterilization Wrap Results ¹
Bacterial Filtration Efficiency	Staphylococcus aureus particles are aerosolized and sprayed onto the fabric. Results are reported as percent efficiency and correlate with the ability of the fabric to resist bacterial penetration. ^{2,3}	Higher numbers in this test indicate better barrier efficiency.	98.9% ⁴
Grab Tensile	Force is applied to the test fabric until the fabric breaks. The force required to break the fabric – grab tensile load – is measured. Results are reported as pounds of force required to break the fabric. The lower result of CD or MD direction is reported. ⁵	Higher numbers indicate a stronger fabric.	25.2 lbs ⁶
Resistance to Linting	In a controlled environment, a 9"X9" sample of fabric is clamped inside a Gelbo Dry Particle Generator. It is then flexed one time every second for a period of five minutes. Particles generated during the test period are counted using a laser particle counter. Results are expressed as the average number of lint particles generated greater than 10 microns in size. ⁷	Lower numbers in this test indicate less lint, which is desirable in the operating room environment.	3 particles ⁶
Hydrostatic Pressure	The fabric sample is clamped onto the bottom of a vertical column, into which water is poured. When leakage is observed on the underside of the fabric, the amount of water in the column is measured. Results are expressed in millibar (mbar) of water pressure a fabric can repel before leaking. ⁸	A higher number indicates greater resistance to water penetration.	59.5 mbar ⁶
Flammability	The fabric sample is held at a 45° angle and a standardized flame is applied to the bottom edge of the specimen for 30 seconds or until sustained ignition occurs, whichever comes sooner. Four classes are recognized by the National Fire Prevention Association (NFPA) for fabrics used for clothing: Class 1: Slow burning fabrics which have a flame spread time of 20 seconds or more. Class 2: Moderately flammable fabrics which have a flame spread time of 8 to 19 seconds inclusive. Class 3: Relatively flammable fabrics which have a flame spread time of 3 to 7 seconds inclusive. Class 4: Dangerously flammable fabrics which have a flame spread time of less than 3 seconds. Results are reported by classification and seconds until sustained ignition. ⁹	A lower class (longer time) indicates a more flame-resistant fabric.	Class 1 (30 sec.) ⁶

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PHYSICAL PROPERTIES TEST METHODOLOGY AND RESULTS FOR HALYARD ONE-STEP* H200 STERILIZATION WRAP

Test	Methodology	Interpretation of Results	HALYARD ONE-STEP* H200 Sterilization Wrap Results ¹
Bacterial Filtration Efficiency	Staphylococcus aureus particles are aerosolized and sprayed onto the fabric. Results are reported as percent efficiency and correlate with the ability of the fabric to resist bacterial penetration. ^{11,12}	Higher numbers in this test indicate better barrier efficiency.	99.7% ¹³
Grab Tensile	Force is applied to the test fabric until the fabric breaks. The force required to break the fabric – grab tensile load – is measured. Results are reported as pounds of force required to break the fabric. The lower result of CD or MD direction is reported. ¹⁴	Higher numbers indicate a stronger fabric.	29.1 lbs ¹⁵
Resistance to Linting	In a controlled environment, a 9"X9" sample of fabric is clamped inside a Gelbo Dry Particle Generator. It is then flexed one time every second for a period of five minutes. Particles generated during the test period are counted using a laser particle counter. Results are expressed as the average number of lint particles generated greater than 10 microns in size. ¹⁶	Lower numbers in this test indicate less lint, which is desirable in the operating room environment.	4 particles ¹⁵
Hydrostatic Pressure	The fabric sample is clamped onto the bottom of a vertical column, into which water is poured. When leakage is observed on the underside of the fabric, the amount of water in the column is measured. Results are expressed in millibar (mbar) of water pressure a fabric can repel before leaking. ¹⁷	A higher number indicates greater resistance to water penetration.	77.4 mbar ¹⁵
Flammability	The fabric sample is held at a 45° angle and a standardized flame is applied to the bottom edge of the specimen for 30 seconds or until sustained ignition occurs, whichever comes sooner. Four classes are recognized by the National Fire Prevention Association (NFPA) for fabrics used for clothing: Class 1: Slow burning fabrics which have a flame spread time of 20 seconds or more. Class 2: Moderately flammable fabrics which have a flame spread time of 8 to 19 seconds inclusive. Class 3: Relatively flammable fabrics which have a flame spread time of 3 to 7 seconds inclusive. Class 4: Dangerously flammable fabrics which have a flame spread time of less than 3 seconds. Results are reported by classification and seconds until sustained ignition. ¹⁸	A lower class (longer time) indicates a more flame-resistant fabric.	Class 1 (30 sec.) ¹⁵

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PHYSICAL PROPERTIES TEST METHODOLOGY AND RESULTS FOR HALYARD ONE-STEP* H300 STERILIZATION WRAP

Test	Methodology	Interpretation of Results	HALYARD ONE-STEP* H300 Sterilization Wrap Results ¹⁹
Bacterial Filtration Efficiency	Staphylococcus aureus particles are aerosolized and sprayed onto the fabric. Results are reported as percent efficiency and correlate with the ability of the fabric to resist bacterial penetration. ^{20,21}	Higher numbers in this test indicate better barrier efficiency.	99.9% ²²
Grab Tensile	Force is applied to the test fabric until the fabric breaks. The force required to break the fabric – grab tensile load – is measured. Results are reported as pounds of force required to break the fabric. The lower result of CD or MD direction is reported. ²³	Higher numbers indicate a stronger fabric.	36.7 lbs ²⁴
Resistance to Linting	In a controlled environment, a 9"X9" sample of fabric is clamped inside a Gelbo Dry Particle Generator. It is then flexed one time every second for a period of five minutes. Particles generated during the test period are counted using a laser particle counter. Results are expressed as the average number of lint particles generated greater than 10 microns in size. ²⁶	Lower numbers in this test indicate less lint, which is desirable in the operating room environment.	1 particles ²⁴
Hydrostatic Pressure	The fabric sample is clamped onto the bottom of a vertical column, into which water is poured. When leakage is observed on the underside of the fabric, the amount of water in the column is measured. Results are expressed in millibar (mbar) of water pressure a fabric can repel before leaking. ²⁶	A higher number indicates greater resistance to water penetration.	85.2 mbar ²⁴
Flammability	The fabric sample is held at a 45° angle and a standardized flame is applied to the bottom edge of the specimen for 30 seconds or until sustained ignition occurs, whichever comes sooner. Four classes are recognized by the National Fire Prevention Association (NFPA) for fabrics used for clothing: Class 1: Slow burning fabrics which have a flame spread time of 20 seconds or more. Class 2: Moderately flammable fabrics which have a flame spread time of 8 to 19 seconds inclusive. Class 3: Relatively flammable fabrics which have a flame spread time of 3 to 7 seconds inclusive. Class 4: Dangerously flammable fabrics which have a flame spread time of less than 3 seconds. Results are reported by classification and seconds until sustained ignition. ²⁷	A lower class (longer time) indicates a more flame-resistant fabric.	Class 1 (30 sec.) ²⁴

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PHYSICAL PROPERTIES TEST METHODOLOGY AND RESULTS FOR HALYARD ONE-STEP* H400 STERILIZATION WRAP

Test	Methodology	Interpretation of Results	HALYARD ONE-STEP* H400 Sterilization Wrap Results ²⁸
Bacterial Filtration Efficiency	Staphylococcus aureus particles are aerosolized and sprayed onto the fabric. Results are reported as percent efficiency and correlate with the ability of the fabric to resist bacterial penetration. ^{29,30}	Higher numbers in this test indicate better barrier efficiency.	99.9% ³¹
Grab Tensile	Force is applied to the test fabric until the fabric breaks. The force required to break the fabric – grab tensile load – is measured. Results are reported as pounds of force required to break the fabric. The lower result of CD or MD direction is reported. ³²	Higher numbers indicate a stronger fabric.	51.8 lbs ³³
Resistance to Linting	In a controlled environment, a 9"X9" sample of fabric is clamped inside a Gelbo Dry Particle Generator. It is then flexed one time every second for a period of five minutes. Particles generated during the test period are counted using a laser particle counter. Results are expressed as the average number of lint particles generated greater than 10 microns in size. ³⁴	Lower numbers in this test indicate less lint, which is desirable in the operating room environment.	1 particles ³³
Hydrostatic Pressure	The fabric sample is clamped onto the bottom of a vertical column, into which water is poured. When leakage is observed on the underside of the fabric, the amount of water in the column is measured. Results are expressed in millibar (mbar) of water pressure a fabric can repel before leaking. ³⁵	A higher number indicates greater resistance to water penetration.	88.6 mbar ³³
Flammability	The fabric sample is held at a 45° angle and a standardized flame is applied to the bottom edge of the specimen for 30 seconds or until sustained ignition occurs, whichever comes sooner. Four classes are recognized by the National Fire Prevention Association (NFPA) for fabrics used for clothing: Class 1: Slow burning fabrics which have a flame spread time of 20 seconds or more. Class 2: Moderately flammable fabrics which have a flame spread time of 8 to 19 seconds inclusive. Class 3: Relatively flammable fabrics which have a flame spread time of 3 to 7 seconds inclusive. Class 4: Dangerously flammable fabrics which have a flame spread time of less than 3 seconds. Results are reported by classification and seconds until sustained ignition. ³⁶	A lower class (longer time) indicates a more flame-resistant fabric.	Class 1 (30 sec.) ³³

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PHYSICAL PROPERTIES TEST METHODOLOGY AND RESULTS FOR HALYARD ONE-STEP* H500 STERILIZATION WRAP

Test	Methodology	Interpretation of Results	HALYARD ONE-STEP* H500 Sterilization Wrap Results ³⁷
Bacterial Filtration Efficiency	Staphylococcus aureus particles are aerosolized and sprayed onto the fabric. Results are reported as percent efficiency and correlate with the ability of the fabric to resist bacterial penetration. ^{38,39}	Higher numbers in this test indicate better barrier efficiency.	99.9% ⁴⁰
Grab Tensile	Force is applied to the test fabric until the fabric breaks. The force required to break the fabric – grab tensile load – is measured. Results are reported as pounds of force required to break the fabric. The lower result of CD or MD direction is reported. ⁴¹	Higher numbers indicate a stronger fabric.	56.9 lbs ⁴²
Resistance to Linting	In a controlled environment, a 9"X9" sample of fabric is clamped inside a Gelbo Dry Particle Generator. It is then flexed one time every second for a period of five minutes. Particles generated during the test period are counted using a laser particle counter. Results are expressed as the average number of lint particles generated greater than 10 microns in size. ⁴³	Lower numbers in this test indicate less lint, which is desirable in the operating room environment.	2 particles ⁴²
Hydrostatic Pressure	The fabric sample is clamped onto the bottom of a vertical column, into which water is poured. When leakage is observed on the underside of the fabric, the amount of water in the column is measured. Results are expressed in millibar (mbar) of water pressure a fabric can repel before leaking. ⁴⁴	A higher number indicates greater resistance to water penetration.	109.4 mbar ⁴²
Flammability	The fabric sample is held at a 45° angle and a standardized flame is applied to the bottom edge of the specimen for 30 seconds or until sustained ignition occurs, whichever comes sooner. Four classes are recognized by the National Fire Prevention Association (NFPA) for fabrics used for clothing: Class 1: Slow burning fabrics which have a flame spread time of 20 seconds or more. Class 2: Moderately flammable fabrics which have a flame spread time of 8 to 19 seconds inclusive. Class 3: Relatively flammable fabrics which have a flame spread time of 3 to 7 seconds inclusive. Class 4: Dangerously flammable fabrics which have a flame spread time of less than 3 seconds. Results are reported by classification and seconds until sustained ignition. ⁴⁵	A lower class (longer time) indicates a more flame-resistant fabric.	Class 1 (30 sec.) ⁴²

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PHYSICAL PROPERTIES TEST METHODOLOGY AND RESULTS FOR HALYARD ONE-STEP* H600 STERILIZATION WRAP

Test	Methodology	Interpretation of Results	HALYARD ONE-STEP* H600 Sterilization Wrap Results ⁴⁶
Bacterial Filtration Efficiency	Staphylococcus aureus particles are aerosolized and sprayed onto the fabric. Results are reported as percent efficiency and correlate with the ability of the fabric to resist bacterial penetration. ^{47,48}	Higher numbers in this test indicate better barrier efficiency.	99.9% ⁴⁹
Grab Tensile	Force is applied to the test fabric until the fabric breaks. The force required to break the fabric – grab tensile load – is measured. Results are reported as pounds of force required to break the fabric. The lower result of CD or MD direction is reported. ⁵⁰	Higher numbers indicate a stronger fabric.	83.0 lbs ⁵¹
Resistance to Linting	In a controlled environment, a 9"X9" sample of fabric is clamped inside a Gelbo Dry Particle Generator. It is then flexed one time every second for a period of five minutes. Particles generated during the test period are counted using a laser particle counter. Results are expressed as the average number of lint particles generated greater than 10 microns in size. ⁵²	Lower numbers in this test indicate less lint, which is desirable in the operating room environment.	3 particles ⁵¹
Hydrostatic Pressure	The fabric sample is clamped onto the bottom of a vertical column, into which water is poured. When leakage is observed on the underside of the fabric, the amount of water in the column is measured. Results are expressed in millibar (mbar) of water pressure a fabric can repel before leaking. ⁵³	A higher number indicates greater resistance to water penetration.	118.3 mbar ⁵¹
Flammability	The fabric sample is held at a 45° angle and a standardized flame is applied to the bottom edge of the specimen for 30 seconds or until sustained ignition occurs, whichever comes sooner. Four classes are recognized by the National Fire Prevention Association (NFPA) for fabrics used for clothing: Class 1: Slow burning fabrics which have a flame spread time of 20 seconds or more. Class 2: Moderately flammable fabrics which have a flame spread time of 8 to 19 seconds inclusive. Class 3: Relatively flammable fabrics which have a flame spread time of 3 to 7 seconds inclusive. Class 4: Dangerously flammable fabrics which have a flame spread time of less than 3 seconds. Results are reported by classification and seconds until sustained ignition. ⁵⁴	A lower class (longer time) indicates a more flame-resistant fabric.	Class 1 (30 sec.) ⁵¹

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REFERENCES

- 1 The above results are averages based upon testing of representative samples selected randomly from distribution. Since HALYARD ONE-STEP* sterilization wrap consists of two layers bonded together, all testing was conducted on two layers.
- 2 Nelson Laboratories, Inc., Salt Lake City, Utah, "Bacterial Filtration Efficiency," Procedure No. SOP/ARO/0071.1.
- 3 ASTM F2101-07. "Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus" 2007.
- 4 Test data generated by Nelson Laboratories, Inc., Salt Lake City, Utah via lab # 421675.
- 5 ASTM D5034-95(2001). "Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)" 2001.
- 6 Test data generated by Integrated Paper Services, Neenah, WI via request # 9051.
- 7 INDA Standard test IST 160.1:1995, "Resistance to Linting of Nonwoven Fabrics," 1995.
- 8 AATCC 127-2003. "Water Resistance: Hydrostatic Pressure Test" 2003. "Standard Test Method for Repellency of Nonwoven Fabrics Using the Hydrostatic Pressure Test", IST 80.4, INDA Standard Tests.
- 9 NFPA 702-1980. "Flammability of wearing apparel".
- 10 The above results are averages based upon testing of representative samples selected randomly from distribution. Since HALYARD ONE-STEP* sterilization wrap consists of two layers bonded together, all testing was conducted on two layers.
- 11 Nelson Laboratories, Inc., Salt Lake City, Utah, "Bacterial Filtration Efficiency," Procedure No. SOP/ARO/0071.1.
- 12 ASTM F2101-07. "Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus" 2007.
- 13 Test data generated by Nelson Laboratories, Inc., Salt Lake City, Utah via lab # 421674.
- 14 ASTM D5034-95(2001). "Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)" 2001.
- 15 Test data generated by Integrated Paper Services, Neenah, WI via request # 9051.
- 16 INDA Standard test IST 160.1:1995, "Resistance to Linting of Nonwoven Fabrics," 1995.
- 17 AATCC 127-2003. "Water Resistance: Hydrostatic Pressure Test" 2003. "Standard Test Method for Repellency of Nonwoven Fabrics Using the Hydrostatic Pressure Test", IST 80.4, INDA Standard Tests.
- 18 NFPA 702-1980. "Flammability of wearing apparel".
- 19 The above results are averages based upon testing of representative samples selected randomly from distribution. Since HALYARD ONE-STEP* sterilization wrap consists of two layers bonded together, all testing was conducted on two layers.
- 20 Nelson Laboratories, Inc., Salt Lake City, Utah, "Bacterial Filtration Efficiency," Procedure No. SOP/ARO/0071.1.
- 21 ASTM F2101-07. "Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus" 2007.
- 22 Test data generated by Nelson Laboratories, Inc., Salt Lake City, Utah via lab # 421673.
- 23 ASTM D5034-95(2001). "Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)" 2001.
- 24 Test data generated by Integrated Paper Services, Neenah, WI via request # 9051.
- 25 INDA Standard test IST 160.1:1995, "Resistance to Linting of Nonwoven Fabrics," 1995.
- 26 AATCC 127-2003. "Water Resistance: Hydrostatic Pressure Test" 2003. "Standard Test Method for Repellency of Nonwoven Fabrics Using the Hydrostatic Pressure Test", IST 80.4, INDA Standard Tests.
- 27 NFPA 702-1980. "Flammability of wearing apparel".
- 28 The above results are averages based upon testing of representative samples selected randomly from distribution. Since HALYARD ONE-STEP* sterilization wrap consists of two layers bonded together, all testing was conducted on two layers.
- 29 Nelson Laboratories, Inc., Salt Lake City, Utah, "Bacterial Filtration Efficiency," Procedure No. SOP/ARO/0071.1.
- 30 ASTM F2101-07. "Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus" 2007.
- 31 Test data generated by Nelson Laboratories, Inc., Salt Lake City, Utah via lab # 421672.
- 32 ASTM D5034-95(2001). "Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)" 2001.
- 33 Test data generated by Integrated Paper Services, Neenah, WI via request # 9051.
- 34 INDA Standard test IST 160.1:1995, "Resistance to Linting of Nonwoven Fabrics," 1995.
- 35 AATCC 127-2003. "Water Resistance: Hydrostatic Pressure Test" 2003. "Standard Test Method for Repellency of Nonwoven Fabrics Using the Hydrostatic Pressure Test", IST 80.4, INDA Standard Tests.
- 36 NFPA 702-1980. "Flammability of wearing apparel".
- 37 The above results are averages based upon testing of representative samples selected randomly from distribution. Since HALYARD ONE-STEP* sterilization wrap consists of two layers bonded together, all testing was conducted on two layers.
- 38 Nelson Laboratories, Inc., Salt Lake City, Utah, "Bacterial Filtration Efficiency," Procedure No. SOP/ARO/0071.1. 39 ASTM F2101-07. "Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus" 2007.
- 40 Test data generated by Nelson Laboratories, Inc., Salt Lake City, Utah via lab # 421671.
- 41 ASTM D5034-95(2001). "Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)" 2001.
- 42 Test data generated by Integrated Paper Services, Neenah, WI via request # 9051.
- 43 INDA Standard test IST 160.1:1995, "Resistance to Linting of Nonwoven Fabrics," 1995.
- 44 AATCC 127-2003. "Water Resistance: Hydrostatic Pressure Test" 2003. "Standard Test Method for Repellency of Nonwoven Fabrics Using the Hydrostatic Pressure Test", IST 80.4, INDA Standard Tests.
- 45 NFPA 702-1980. "Flammability of wearing apparel".
- 46 The above results are averages based upon testing of representative samples selected randomly from distribution. Since HALYARD ONE-STEP* sterilization wrap consists of two layers bonded together, all testing was conducted on two layers.
- 47 Nelson Laboratories, Inc., Salt Lake City, Utah, "Bacterial Filtration Efficiency," Procedure No. SOP/ARO/0071.1.
- 48 ASTM F2101-07. "Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus" 2007.
- 49 Test data generated by Nelson Laboratories, Inc., Salt Lake City, Utah via lab # 421670.
- 50 ASTM D5034-95(2001). "Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)" 2001.
- 51 Test data generated by Integrated Paper Services, Neenah, WI via request # 9051.
- 52 INDA Standard test IST 160.1:1995, "Resistance to Linting of Nonwoven Fabrics," 1995.
- 53 AATCC 127-2003. "Water Resistance: Hydrostatic Pressure Test" 2003. "Standard Test Method for Repellency of Nonwoven Fabrics Using the Hydrostatic Pressure Test", IST 80.4, INDA Standard Tests.
- 54 NFPA 702-1980. "Flammability of wearing apparel".

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