



EN 868-5 and ASTM F88

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Highlights

- Acknowledgments
- Requirements
- Test Methods
- Disconnect
- Initial Comparison Study
 - Study Design
 - Results
 - Analysis
- ASTM Work Item

Acknowledgements

- Sameer Upadhyaya
- Salin Yousefnia
- Mark Ralph
- Jim Domke

Sterile Barrier System Requirements

- ISO 11607-1
 - *Clause 5.1.8 c) Materials shall demonstrate minimum specified seal strength when a seal is formed with another specified material under specified conditions.*
 - *Clause 5.1.9 b) If formed by sealing, the specified requirements for seal width and seal strength (tensile and/or burst) shall be met.*

Seal Strength Test Methods

- ISO 11607-1, Annex B
 - Seal Strength
 - ASTM F88 – Standard test method for seal strength of flexible barrier materials
 - ASTM F1140 – Standard test method for failure resistance of unrestrained and non rigid packages for medical applications
 - ASTM F2054 – Standard test method for burst testing of flexible package seals using internal air pressurization within restraining plates
 - EN 868-5:1999, Annex D – Packaging materials and systems for medical devices which are to be sterilized – Part 5 Heat and self sealable pouches and reels of paper and plastic film construction – Requirements and test methods

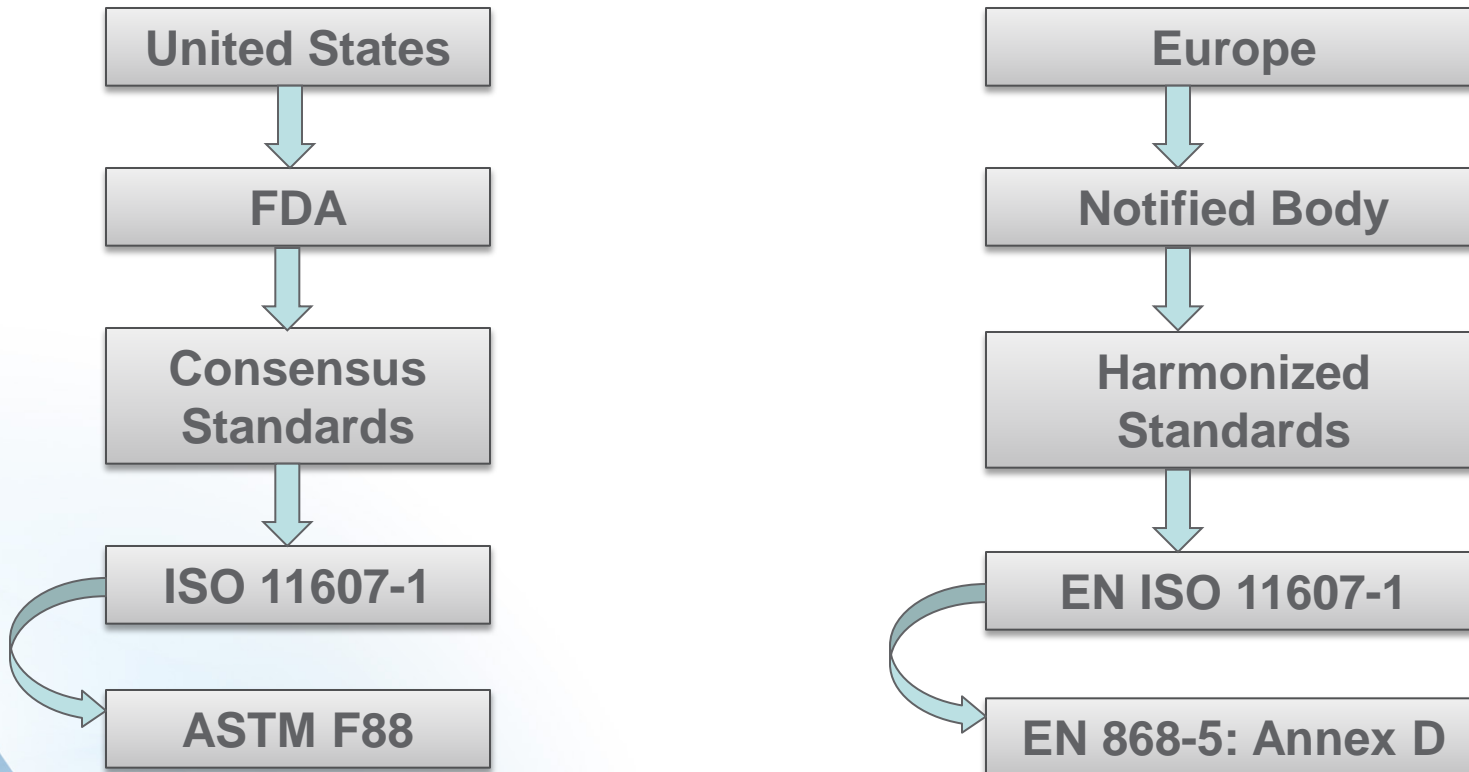
As listed in 11607-1

Seal Strength Test Methods

- ISO 11607-1, Annex B
 - Seal Strength
 - ASTM F88 – Standard test method for seal strength of flexible barrier materials
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 - EN 868-5:1999, Annex D – Packaging materials and systems for medical devices which are to be sterilized – Part 5 Heat and self sealable pouches and reels of paper and plastic film construction – Requirements and test methods

As listed in 11607-1

Disconnect



State of the Art

EN 868-5 A closer look

- Particular requirements of clause 4.2 and 4.5 can be used to demonstrate compliance with one or more but not all requirements of EN ISO 11607-1.
- 4.2 – Materials
 - 4.2.1 Porous material
 - 4.2.2 Plastic film
- 4.5 - Performance requirements and test methods

Scope: limited to pouches and reels.

EN 868-5 A closer look

- 4.5 - Performance requirements and test methods
 - 4.5.1 When tested in accordance with the method described in Annex D the strength of the seal joint shall not be less than required for the intended purpose, both before and after being subjected to the sterilization process.
 - Requirement (Healthcare facility for steam) = 1.5N / 15mm
 - Requirement (all other sterilization) = 1.2N / 15 mm
 - *NOTE 2: For applications outside of healthcare facilities, requirements are given in EN ISO 11607-1.*
 - 4.5.2 The seal shall be continuous and cover the specified width. There shall be no disruption of the surface of the porous material adjacent to the seal lines upon opening. Compliance shall be tested in accordance with Annex E.

EN 868-5 - Annex D (normative)

Method for the determination of the strength of the seal joint for pouches and reel material

- Units: N / 15mm
- Principal: strips cut at 90° through seals (right angles)
- Preparation: 15 ± 0.1 mm
- Procedure: rate of separation 200 ± 10 mm / minute
- Report:
 - Record max strength in N / 15mm width
 - Supported/unsupported, specs, data sheets
 - Electronic device frequency rate
 - Identification of the product under test, test house, date
 - Number of the standard used for the test.

15mm – 8"/minute

ASTM F88 – A closer look

- Current designation: F88/F88M-09
 - Title: Standard Test Method for Seal Strength of Flexible Barrier Materials
- Scope:
 - Measurement of seal strength between flexible materials
 - May be used on seals between a flexible material and a rigid material
 - Measure the force required to separate the test strip of material containing the seal as well as the mode of specimen failure.

ASTM F88 – A closer look

- Significance and Use
 - Discusses minimum and maximum seal strength, but does not have a required value.
 - Discusses maximum force and average force
 - Discusses / provides basic guidance on techniques and consistent use of a technique

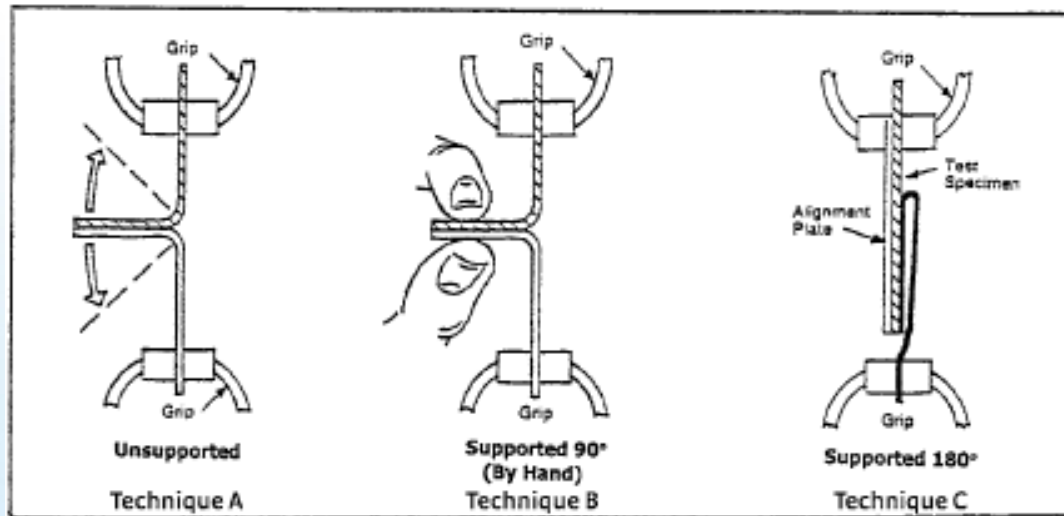


FIG. 1 Tail Holding Methods

ASTM F88 – A closer look

- Procedure:
 - Calibrated tensile tester
 - Sample prep, perpendicular to the seal, **width = 1 inch (also calls out 0.984, and 0.591) (0.591 = 15mm)**
 - Sealed area approximately equidistant between the grips
 - Center the test strip laterally in the grips
 - **Detail any technique used to control tail orientation**
 - **Rate of separation 8 to 12 inches /minute**
 - **Record maximum force and mode of failure**
 - If the strip peels apart in the seal area, average force may be important
 - Plot of force vs. grip travel is useful
 - Caution on the effect of other failure modes (elongation, break, delamination)

Comparison Summary (F88 and EN 868-5)

- Add comparison summary table

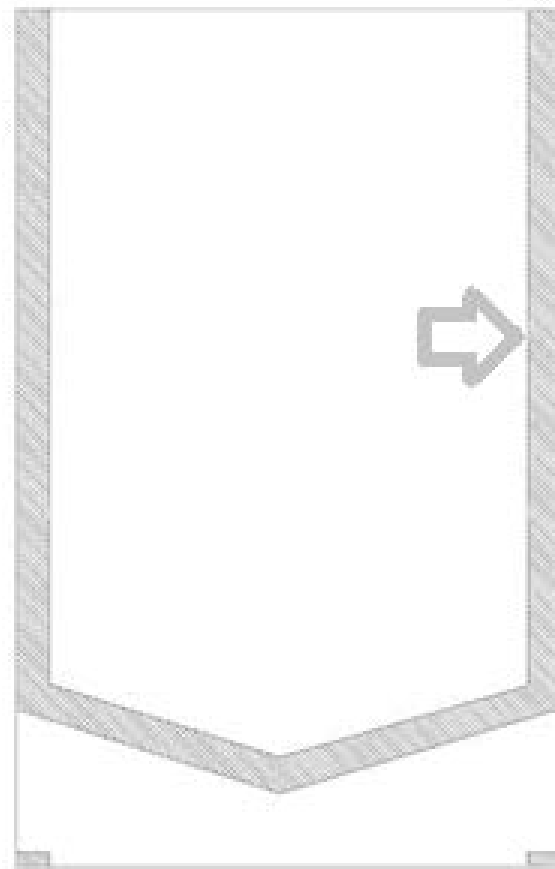
	EN 868-5	ASTM F88
Test Strip Width	15mm (0.591")	1", 0.984", 0.591"
Rate of Separation	200 mm/min (7.9"/min)	8-12"/min (203-305mm/min)
Scope	Flexible	Flexible, flexible/rigid
Technique	Report supported or unsupported	A, B or C

Comparison Study

- A small study was conducted to form a baseline for comparison between the methods.
- Key variables for comparison chosen:
 - Test strip width (1 inch vs. 15mm)
 - Rate of Separation (8 inches / minute versus 12 inches per minute)

Comparison Study Design

- One material used throughout
 - Porous web: Tyvek 1073B coated with CR-27
 - Film: 36603-S, 5 mil nylon laminated
- All test strips came from one lot of pouches
- All test strips cut from approximately the same location.



Comparison Study Design

- All samples prepped in 1 lab, by 1 person
- Samples were not subjected to sterilization
- Sample size of 15 used for each group
- 3 labs
- 4 groups per lab
- Unsupported tail
- Maximum force recorded in lbs / width

Comparison Study Design

Test Group	Lab	Sample Width	Rate of Separation	Sample Size
A	CRDM	1 inch	8 inch / min	15
B	CV	1 inch	8 inch / min	15
C	Neuromodulation	1 inch	8 inch / min	15
D	CRDM	1 inch	12 inch / min	15
E	CV	1 inch	12 inch / min	15
F	Neuromodulation	1 inch	12 inch / min	15
G	CRDM	15mm	8 inch / min	15
H	CV	15mm	8 inch / min	15
I	Neuromodulation	15mm	8 inch / min	15
J	CRDM	15mm	12 inch / min	15
K	CV	15mm	12 inch / min	15
L	Neuromodulation	15mm	12 inch / min	15

Results – Pooled Data (n = 45)

Test (width – speed)	Average* (lbs / width)	Standard Deviation
1" – 8"/minute	1.16	0.13
1" – 12"/minute	1.14	0.10
15mm – 8"/minute	0.69	0.06
15mm – 12"/minute	0.68	0.07

* Average of the peak values

Results – Pooled Data (n = 45)

Test (width – speed)	Average* (N / 15mm)	Standard Deviation
1" – 8"/minute	3.05	0.35
1" – 12"/minute	3.00	0.27
15mm – 8"/minute	3.07	0.28
15mm – 12"/minute	3.03	0.32

* Average of the peak values

Conversion of lbs/inch width to N / 15mm:

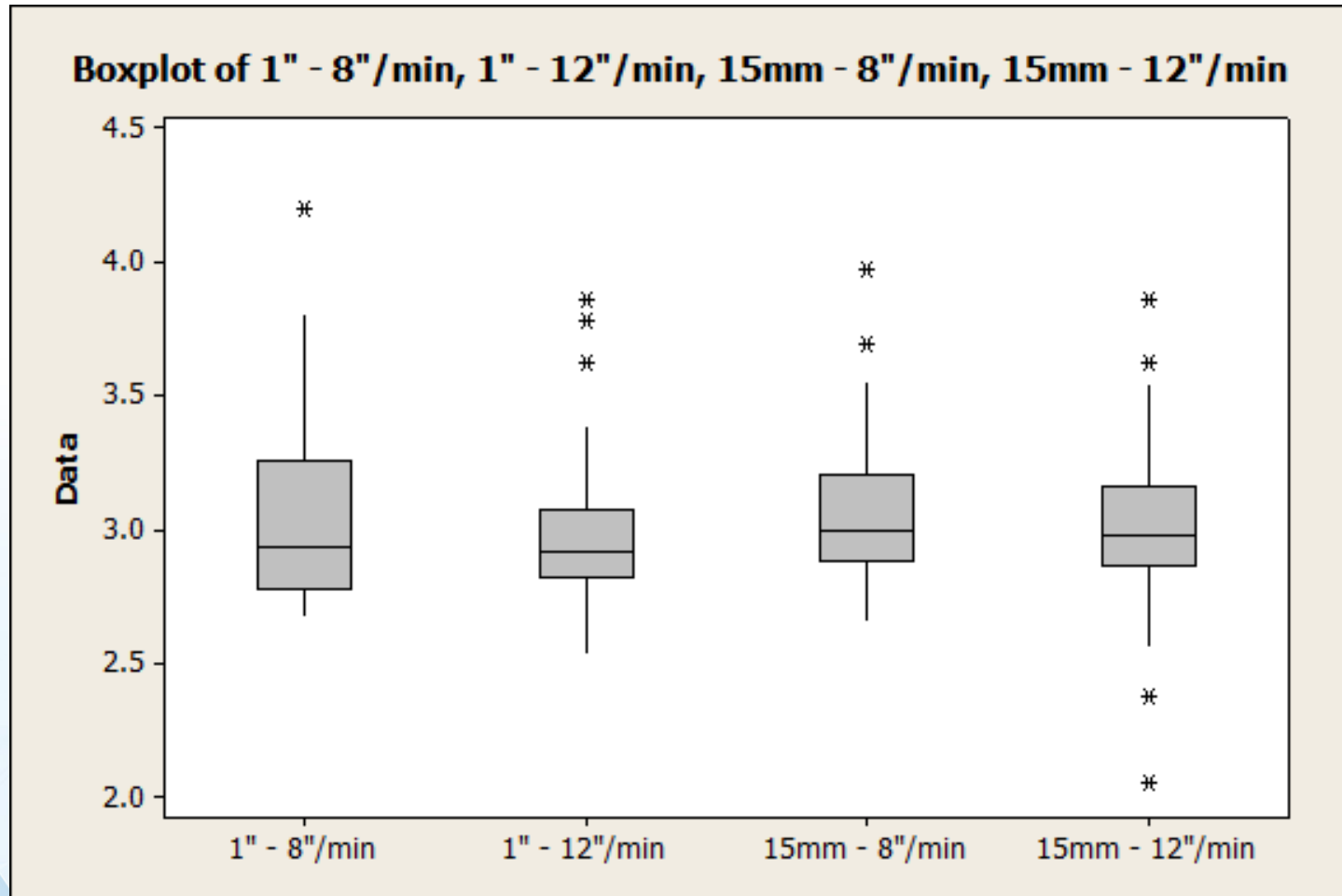
$$\frac{1.16lb}{1\text{ inch}} \times \frac{4.45N}{1\text{ lb}} \times \left(\frac{15}{25.4}\right) = 3.05\text{ N/15mm}$$

Conversion of lbs/15mm width to N / 15mm:

$$\frac{0.69lb}{15mm} \times \frac{4.45N}{1\text{ lb}} = 3.07\text{ N/15mm}$$

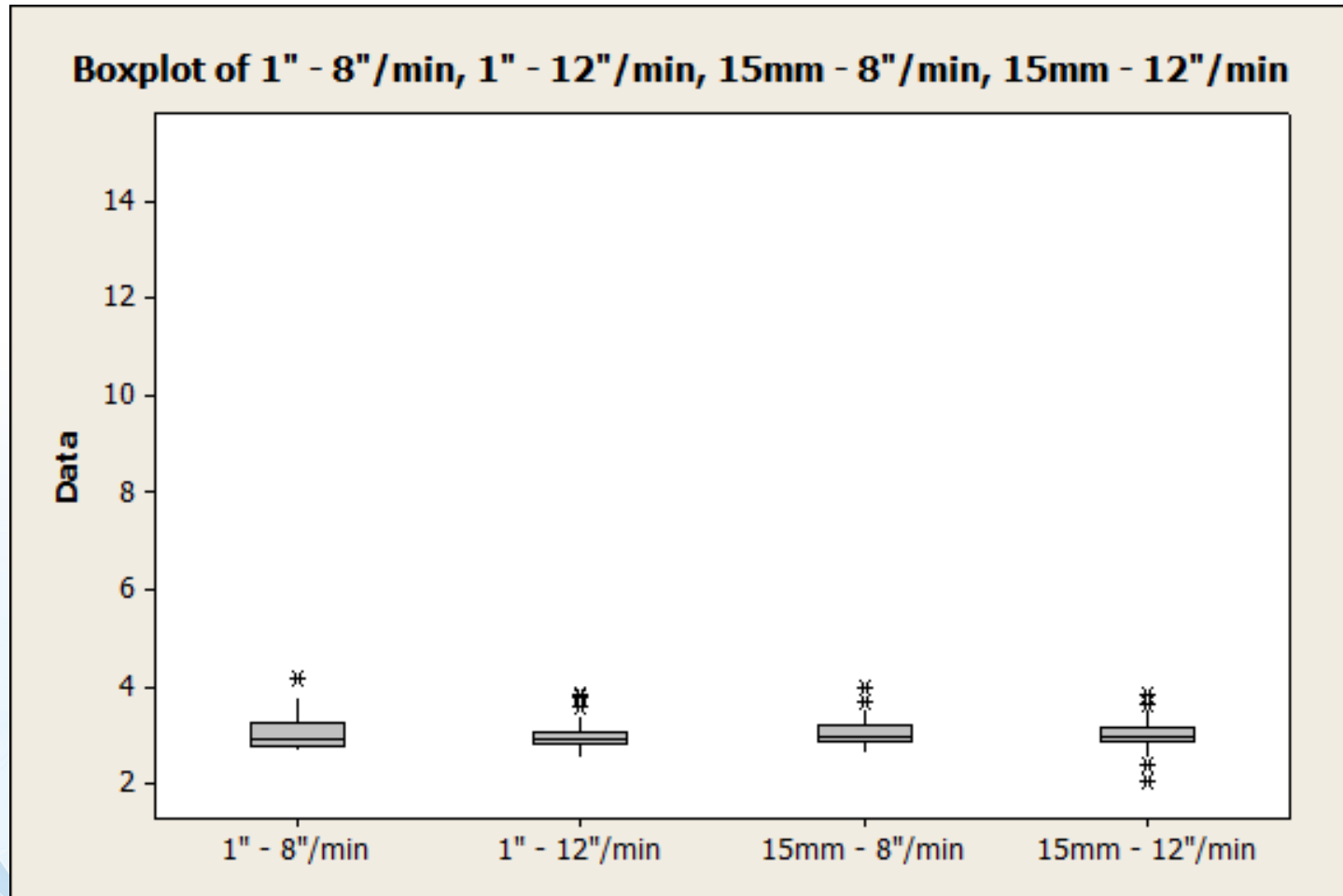
1 inch = 25.4 mm

Boxplot of the results



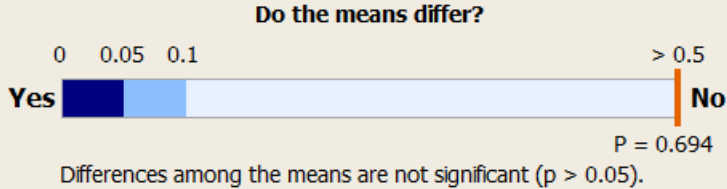
Boxplot of the results – with spec limits used for y-axis

- Spec limits:
 - 0.5 lbs/in – 6.0 lbs/in
 - 1.3 N/15mm – 15.8 N/15mm



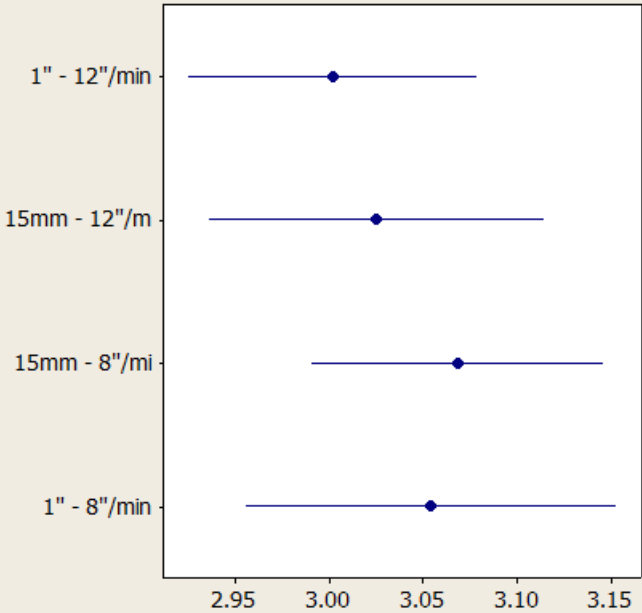
ANOVA – Pooled Data (n = 45)

One-Way ANOVA for 1" - 8"/min, 1" - 12"/min, 15mm - 8"/mi, ... Summary Report



#	Sample	Which means differ? Differs from
1	1" - 12"/min	
2	15mm - 12"/m	
3	15mm - 8"/mi	None Identified
4	1" - 8"/min	

Means Comparison Chart

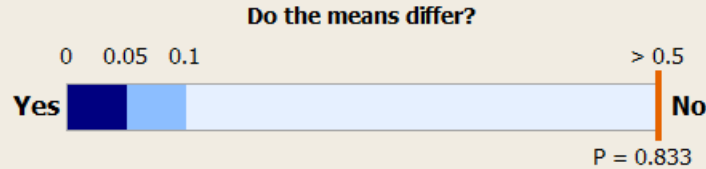


Comments

You cannot conclude that there are differences among the means at the 0.05 level of significance.

Comparison of test strip width 1 inch and 15 mm test strips @ 8" / minute

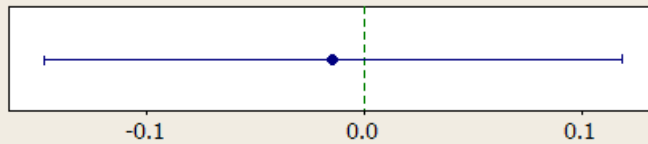
2-Sample t Test for the Mean of 1" - 8"/min and 15mm - 8"/mi Summary Report



The mean of 1" - 8"/min is not significantly different from the mean of 15mm - 8"/mi ($p > 0.05$).

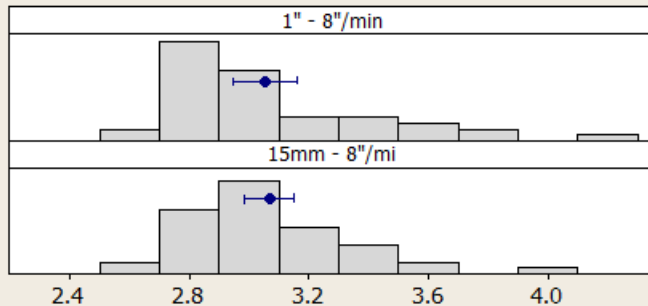
95% CI for the Difference

Does the interval include zero?



Distribution of Data

Compare the data and means of the samples.



Statistics	1" - 8"/min	15mm - 8"/mi
Sample size	45	45
Mean	3.0541	3.0682
95% CI	(2.948, 3.160)	(2.9846, 3.1518)
Standard deviation	0.35234	0.27821
Difference between means*		-0.014136
95% CI		(-0.14724, 0.11897)

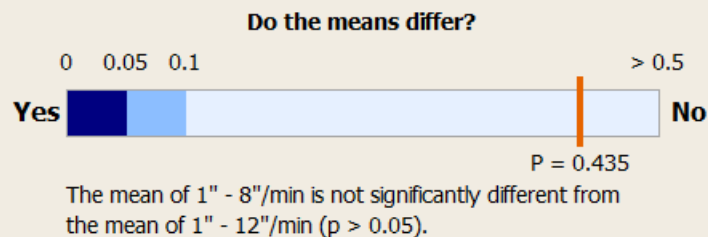
* The difference is defined as 1" - 8"/min - 15mm - 8"/mi.

Comments

- Test: There is not enough evidence to conclude that the means differ at the 0.05 level of significance.
- CI: Quantifies the uncertainty associated with estimating the difference from sample data. You can be 95% confident that the true difference is between -0.14724 and 0.11897.
- Distribution of Data: Compare the location and means of samples. Look for unusual data before interpreting the results of the test.

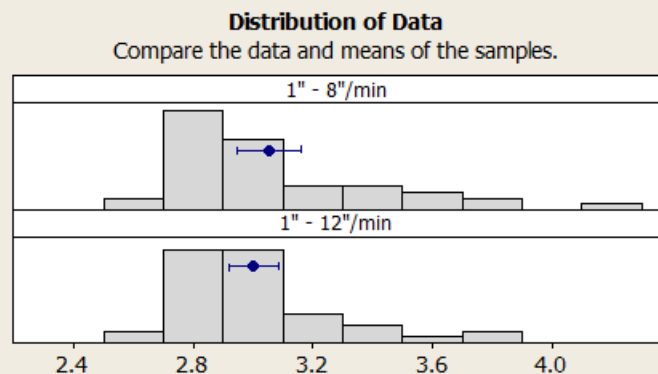
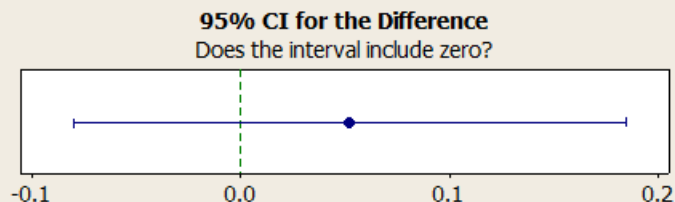
Comparison of test speed, 8"/minute vs. 12"/minute with 1" width test strips

2-Sample t Test for the Mean of 1" - 8"/min and 1" - 12"/min Summary Report



Statistics	1" - 8"/min	1" - 12"/min
Sample size	45	45
Mean	3.0541	3.0018
95% CI	(2.948, 3.160)	(2.9193, 3.0843)
Standard deviation	0.35234	0.27453
Difference between means*		0.052267
95% CI		(-0.080168, 0.18470)

* The difference is defined as 1" - 8"/min - 1" - 12"/min.

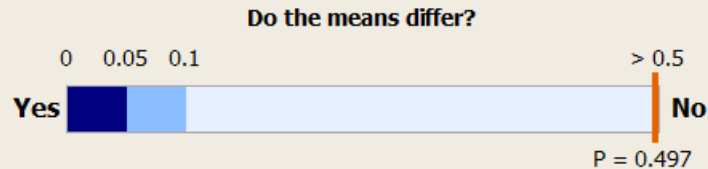


Comments

- Test: There is not enough evidence to conclude that the means differ at the 0.05 level of significance.
- CI: Quantifies the uncertainty associated with estimating the difference from sample data. You can be 95% confident that the true difference is between -0.080168 and 0.18470.
- Distribution of Data: Compare the location and means of samples. Look for unusual data before interpreting the results of the test.

Comparison of test speed, 8"/minute vs. 12"/minute with 15mm width test strips

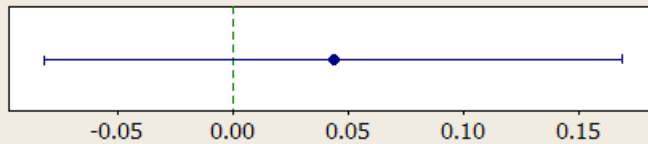
2-Sample t Test for the Mean of 15mm - 8"/mi and 15mm - 12"/m Summary Report



The mean of 15mm - 8"/mi is not significantly different from the mean of 15mm - 12"/m ($p > 0.05$).

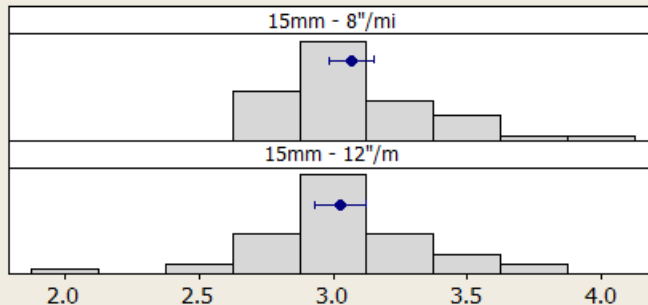
95% CI for the Difference

Does the interval include zero?



Distribution of Data

Compare the data and means of the samples.



Statistics	15mm - 8"/mi	15mm - 12"/m
Sample size	45	45
Mean	3.0682	3.0251
95% CI	(2.985, 3.152)	(2.9288, 3.1214)
Standard deviation	0.27821	0.32041
Difference between means*		0.043116
95% CI		(-0.082634, 0.16886)

* The difference is defined as 15mm - 8"/mi - 15mm - 12"/m.

Comments

- Test: There is not enough evidence to conclude that the means differ at the 0.05 level of significance.
- CI: Quantifies the uncertainty associated with estimating the difference from sample data. You can be 95% confident that the true difference is between -0.082634 and 0.16886.
- Distribution of Data: Compare the location and means of samples. Look for unusual data before interpreting the results of the test.

Preliminary Findings

- No significant difference between test speeds.
- No significant difference between test strip widths when the data is converted to equivalent units.
- No significant difference in results between the labs participating.

Observation: Relationship between test strip width ratio and ratio of the results

$$\text{Test strip width ratio} - \frac{15 \text{ mm}}{25.4 \text{ mm}} = 0.591$$

$$\frac{15\text{mm} - 8"/\text{minute}}{25.4\text{mm} - 8"/\text{minute}} \rightarrow \frac{0.69}{1.16} = 0.595$$

$$\frac{15\text{mm} - 12"/\text{minute}}{25.4\text{mm} - 12"/\text{minute}} \rightarrow \frac{0.68}{1.14} = 0.596$$

ASTM F88: 1 inch = 25.4mm

EN 868-5: 15mm

Preliminary Findings

- No significant difference between test speeds.
- No significant difference between test strip widths when the data is converted to equivalent units.
- No significant difference in results between the labs participating.
- *Ratio of test strip width provides a means of correlating the result to the alternate method.*

ASTM Work Item – WK46566

- The purpose of this work item is to conduct a study that establishes, with empirical data, a correlation between the result of a seal strength test conducted per the process described in ASTM F88 using a test strip width of 1 inch to the result of the same test conducted using a 15 millimeter (mm) test strip width.

Proposed Study Design:

Flexible pouches:

- adhesive coated (Kirkland)
 - uncoated (Signature)
 - 2 techniques (A, C),
 - 9 labs
- Multiple labs to show results are consistent regardless of lab / test equipment / operator.
 - Show the correlation between widths regardless of technique.
 - Uncoated / adhesive coated shows correlation between widths is independent of material.
 - Plan is collect peak seal strength.
 - Could reduce # of samples, I'm open to ideas.

Sample Preparation:

Samples will be prepared with a goal of limiting variability from various sealing parameters, material sources, package designs, etc..

- All uncoated samples will be supplied by X.
 - Samples for each width will be cut from 1 rail seal by X.
- All adhesive coated samples will be supplied by X.

	Kirkland Group							
	Technique A		Technique C		Technique A		Technique C	
	15mm	1 Inch	15mm	1 Inch	15mm	1 Inch	15mm	1 Inch
Lab 1								
Lab 2								
Lab 3								
Lab 4								
Lab 5								
Lab 6								
Lab 7								
Lab 8								
Lab 9								



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Thank You!