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## Name: Pencil Dome Switch - Supplier Change

Windchill Signature History Report			
Signature	Role	Event Date	Vote
Kuykendall, Steve [ETHUS Non-J&J] (SKuykend)	Quality Engineering	26-Feb-2020 10:47:38 EST	Approve
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## 1. REFERENCES

<b>Document Number</b>	<b>Rev.</b>	<b>Document name</b>
IEC 60601-2-2:2009	N/A	Medical Electrical Equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
IEC 60601-1: 2012	N/A	Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance
XENG-IOM-018	A	Telescoping pencils IOM
XENG-PS-013	F	Telescoping Pencils, Product Specification
ENG-WI-001	010	Sterilization Chart
ENG-RMF-043	006	Risk Management Plan - Smoke Evacuation Pencil and Accessories
ENG-RMF-044	002	Hazard Assessment summary - Smoke Evacuation Pencil and Accessories
ENG-RMF-045	009	Risk Analysis - Smoke Evacuation Risk Analysis
ENG-DMR-012	009	Device Master Record - Smoke Evacuation Pencil and Accessories
ENG-IOM-012	005	Input/ Output Conformance Test Matrix – Project Zip
MKT-US-002	002	Usability Requirements Specification – Smoke Evacuation Pencils
ENG-PRT-228	001	Test Protocol – Zip Pencil mechanical protocol
ENG-PRT-230	001	Test Protocol – Zip Pencil fluid ingress protocol
ENG-PRT-302	001	Test Protocol – ISOS2 EO Sterilized Product Design Verification
ENG-PRT-604	001	Pencil Dome Switch - Supplier Change - Shipping Conditioning Test Protocol
ENG-PRT-605	001	EO Sterilization of ZIP Pen ACE700 blade Dome Switch Change
ENG-RPT-776	001	Pencil Dome Switch - Supplier Change - Sterilization Conditioning Test Report
ENG-RPT-777	001	Pencil Dome Switch - Supplier Change – Shipping and Thermocycling Conditioning Test Report
4010343 or X4010343	D	MG existing dome – drawing
4010345 or X4010345	B	MG proposed dome – drawing
6020350	001	ZIP Pencil w/ ND Dome sub-assembly
X6020351	001	ACE Blade 700, w/ ND Dome sub-assembly
6020348	001	Rally Pencil w/ ND Dome sub-assembly
X6020349	001	Rally GEM Modified w ND Dome sub-assembly
X252510N	A	ZIP Pencil w/ ND Dome
XME725M1CN	A	ACE Blade 700, w/ ND Dome
X251010JN	A	Rally Pencil w/ ND Dome
XME725M1STN	A	Rally GEM Modified w ND Dome

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## 2. SCOPE

This protocol report pertains to the electrical and mechanical testing performed on the new dome switch (4010345-01) component to be found in the ZIP, ACE, Rally, Rally GEM and Refine products.

Prior to testing all samples were exposed to their respective sterilization cycle, EO (refer to ENG-PRT-605) for the ACE and Rally GEM products, and Gamma (refer to ENG-RPT-776) sterilization for the ZIP and Rally products. The sterilization applied was designed to be worst case scenario for each of the products and is at a minimum the maximum dosage.

All products were conditioned through thermal cycling and shipping conditions (refer to protocol ENG-RPT-777).

## 3. PURPOSE

The purpose of this test report is to summarize the electrical and mechanical testing of the stainless-steel dome switch which is integral in the function of the above mentioned electrosurgical pencils. The change was prompted because the existing tool for the existing dome switch (4010343-01) reached end of life and can no longer support production needs. This report summarizes the testing performed on the proposed dome switch to verify the standards and input documents, and ensure other requirements are met.

## 4. RESULTS

Note: that the devices were labeled per a labeling scheme listed in Section 10.2 of ENG-PRT-594.

The training record for the testing document in this report can be found under **Appendix VI**.

### 4.1. Handpiece High Frequency Dielectric Withstand Test

A synapsis of the test results can be found in the following tables. Full results for each pencil set can be found the **Appendix I**.

*Table 1: Handpiece High Frequency Dielectric Withstand Test Results*

Set	ZIP Pencil (X252510N)		
Component	COAG	CUT	Device

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Test	Pre-cycle Continuity		Pre-cycle Continuity		Dielectric	High Frequency		Mains
Criteria or Unit	Open> 100kΩ	Closed <50Ω	Open> 100kΩ	Closed <50Ω	Leakage mA	Max V kV	P/V	P/V
Results	Pass	Pass	Pass	Pass	7.18*	7.58*	Pass*	Pass*
Set	ACE Pencil (XME725M1CN)							
Component	COAG		CUT		Device			
Test	Pre-cycle Continuity		Pre-cycle Continuity		Dielectric	High Frequency		Mains
Criteria or Unit	Open> 100kΩ	Closed <50Ω	Open> 100kΩ	Closed <50Ω	Leakage mA	Max V kV	P/V	P/V
Results	Pass	Pass	Pass	Pass	6.81	7.13	Pass	Pass
Set	Rally Pencil (X251010JN)							
Component	COAG		CUT		Device			
Test	Pre-cycle Continuity		Pre-cycle Continuity		Dielectric	High Frequency		Mains
Criteria or Unit	Open> 100kΩ	Closed <50Ω	Open> 100kΩ	Closed <50Ω	Leakage mA	Max V kV	P/V	P/V
Results	Pass	Pass	Pass	Pass	9.35	6.85	Pass	Pass
Set	Rally GEM Pencil (XME725M1STN)							
Component	COAG		CUT		Device			
Test	Pre-cycle Continuity		Pre-cycle Continuity		Dielectric	High Frequency		Mains
Criteria or Unit	Open> 100kΩ	Closed <50Ω	Open> 100kΩ	Closed <50Ω	Leakage mA	Max V kV	P/V	P/V
Results	Pass	Pass	Pass	Pass	11.58	7.01	Pass	Pass

\* See section 4.1.7

#### 4.1.7. Sample failure during dielectric withstands

During the dielectric withstands testing of the ZIP (X252510N) product, a failure was observed in the form of an electrical burn through. Upon examination by the engineer performing the testing, the lab manager and the quality engineer on staff, it was determined that the failure was an artifact of an adulterated sample.

**Figures 1 through 3** show the failure on the device and anomalies which are considered adulterations to the sample.

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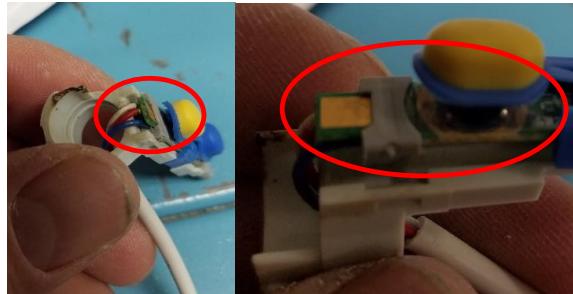


Figure 1: PCB shows no failure



Figure 2: Vacuum Shroud, failures at electrical connection. Circles outline fluid adulteration.



Figure 3: Pencil Body, failure to grounded pencil body.

#### 4.2. Fluid Ingress Test

A synapsis of the test results can be found in the following tables. Full results for each pencil set can be found the **Appendix II**.

Table 2

Set	ZIP Pencil (X252510N)				
Button	COAG		CUT		
Test	Pre-test Continuity		Fluid Ingress	Pre-test Continuity	Post-cycle Continuity
Criteria	Open > 100kΩ	Closed < 50Ω	No Fluid Ingress	Open > 100kΩ	Closed < 50Ω
Results	Pass	Pass	Pass	Pass	Pass

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Set	ACE Pencil (XME725M1CN)				
Button	COAG		CUT		
Test	Pre-test Continuity		Fluid Ingress	Post-cycle Continuity	
Criteria	Open> 100kΩ	Closed <50Ω	No Fluid Ingress	Open> 100kΩ	Closed <50Ω
Results	Pass	Pass	Pass	Pass	Pass
Set	Rally Pencil (X251010JN)				
Button	COAG		CUT		
Test	Pre-test Continuity		Fluid Ingress	Post-cycle Continuity	
Criteria	Open> 100kΩ	Closed <50Ω	No Fluid Ingress	Open> 100kΩ	Closed <50Ω
Results	Pass	Pass	Pass	Pass	Pass
Set	Rally GEM Pencil (XME725M1STN)				
Button	COAG		CUT		
Test	Pre-test Continuity		Fluid Ingress	Post-cycle Continuity	
Criteria	Open> 100kΩ	Closed <50Ω	No Fluid Ingress	Open> 100kΩ	Closed <50Ω
Results	Pass	Pass	Pass	Pass	Pass

#### 4.3. Activation Force Test

A synapsis of the test results can be found in the following tables. Full results for each pencil set can be found the **Appendix III**.

*Table 3*

Set	ZIP Pencil (X252510N)			
Button	COAG		CUT	
Force	Force (pounds)	Force (grams)	Force (pounds)	Force (grams)
Maximu	1.18951	539.55	1.06097	481.25
Minimu	.92427	419.24	0.88082	399.53
Mean	1.065833	483.45	0.96365	437.10
Standard	.05399	24.49	.0424	19.23
Set	ACE Pencil (XME725M1CN)			
Button	COAG		CUT	
Force	Force (pounds)	Force (grams)	Force (pounds)	Force (grams)
Maximu	1.13761	516.01	1.02536	465.10

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Minimu	0.95746	434.30	0.84129	381.60
Mean	1.055856333	478.93	0.951911333	431.78
Standard	0.041557832	18.85	0.040333072	18.29
Set	Rally Pencil (X251010JN)			
Button	COAG		CUT	
Force	Force (pounds)	Force (grams)	Force (pounds)	Force (grams)
Maximu	1.11347	505.06	1.1014	499.59
Minimu	0.82288	373.25	0.76585	347.38
Mean	0.951861333	431.76	0.911375667	413.39
Standard	0.062301666	28.26	0.07873143	35.71
Set	Rally GEM Pencil (XME725M1STN)			
Button	COAG		CUT	
Force	Force (pounds)	Force (grams)	Force (pounds)	Force (grams)
Maximu	1.02868	466.60	1.05342	477.82
Minimu	0.8944	405.69	0.73386	332.87
Mean	0.960784	435.80	0.916003667	415.49
Standard	0.039656376	17.99	0.064052235	29.05

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#### 4.4. Activation Over Time Test

A synapsis of the test results can be found in the following tables. Full results for each pencil set can be found the **Appendix IV**.

*Table 4*

Set	ZIP Pencil (X252510N)							
Button	COAG				CUT			
Test	Pre-cycle Continuity		Post-cycle Continuity		Pre-cycle Continuity		Post-cycle Continuity	
Criteria	Open> 100kΩ	Closed <50Ω	Open> 100kΩ	Closed <50Ω	Open> 100kΩ	Closed <50Ω	Open> 100kΩ	Closed <50Ω
Results	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Set	ACE Pencil (XME725M1CN)							
Button	COAG				CUT			
Test	Pre-cycle Continuity		Post-cycle Continuity		Pre-cycle Continuity		Post-cycle Continuity	
Criteria	Open> 100kΩ	Closed <50Ω	Open> 100kΩ	Closed <50Ω	Open> 100kΩ	Closed <50Ω	Open> 100kΩ	Closed <50Ω
Results	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Set	Rally Pencil (X251010JN)							
Button	COAG				CUT			
Test	Pre-cycle Continuity		Post-cycle Continuity		Pre-cycle Continuity		Post-cycle Continuity	
Criteria	Open> 100kΩ	Closed <50Ω	Open> 100kΩ	Closed <50Ω	Open> 100kΩ	Closed <50Ω	Open> 100kΩ	Closed <50Ω
Results	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Set	Rally GEM Pencil (XME725M1STN)							
Button	COAG				CUT			
Test	Pre-cycle Continuity		Post-cycle Continuity		Pre-cycle Continuity		Post-cycle Continuity	
Criteria	Open> 100kΩ	Closed <50Ω	Open> 100kΩ	Closed <50Ω	Open> 100kΩ	Closed <50Ω	Open> 100kΩ	Closed <50Ω
Results	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

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## 5. ACCEPTANCE CRITERIA

### 5.1. Continuity Measurement Test

- 5.1.1. Acceptance criteria – The device is considered acceptable if the button resistance is less than  $50\ \Omega$  when depressed. The device is considered acceptable if the button resistance is greater than  $100,000\ \Omega$  when the button is not depressed
- 5.1.2. Products – Each of the following products directly or by comparison has met the criteria of the continuity measurement testing.
  - 5.1.2.1.X252510N – This product is representative of the ZIP surgical pencil line of products. 252510, 252510BN, 252510EC, 252510ECBN, 252515, 252515EC.
  - 5.1.2.2.XME725M1CN – This product is representative of the ACE surgical pencil line of products. ME7251C, ME7251E, ME725M1C, ME725M1E.
  - 5.1.2.3.X251010JN – This product is representative of the Rally surgical pencil line of products. 251010J, 251010BN, 251015J, 251015BN.
  - 5.1.2.4.XME725M1STN – This product is representative of the Rally GEM surgical pencil line of products. ME7251ST, ME725M1ST, ME7251T, ME725M1T.

### 5.2. Handpiece High Frequency Dielectric Withstand and Mains Frequency Dielectric Withstand Test

- 5.2.1. Acceptance Criteria – The device is considered acceptable if the test voltage is maintained for 30 seconds, and there were no visible signs of damage such as melted insulation.
- 5.2.2. Products – Each of the following products directly or by comparison has met the criteria of the Handpiece High frequency withstands, Dielectric withstands, and Mains withstands testing
  - 5.2.2.1.X252510N – This product is representative of the ZIP surgical pencil line of products. 252510, 252510BN, 252510EC, 252510ECBN, 252515, 252515EC.
  - 5.2.2.2.XME725M1CN – This product is representative of the ACE surgical pencil line of products. ME7251C, ME7251E, ME725M1C, ME725M1E.
  - 5.2.2.3.X251010JN – This product is representative of the Rally surgical pencil line of products. 251010J, 251010BN, 251015J, 251015BN.

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5.2.2.4.XME725M1STN – This product is representative of the Rally GEM surgical pencil line of products. ME7251ST, ME725M1ST, ME7251T, ME725M1T.

### 5.3. Handpiece Fluid Ingress Test

5.3.1. The device is considered acceptable if, after applying saline in the Standard orientation, the button can be operated 10 times with the current being less than or equal to 2.5 mA (measured as 2.5 mV on the oscilloscope at a time period of 0.5 seconds after the button is released. (The standard requires the AC impedance of the switch to exceed 2.0 kW within 0.5 seconds after release. Using a voltage of 10 V<sub>p-p</sub>, a current of 5.0 mA or less is necessary to meet this requirement). The inverted orientation test of pencil (buttons down) is performed as a worst-case situation and is not a requirement of the standard. With that noted, any inadvertent activation of the pencil due to fluid ingress in this orientation should be noted and engineering notified for further investigation.

5.3.2. Products – Each of the following products directly or by comparison has met the criteria of the Handpiece Fluid Ingress testing

5.3.2.1.X252510N – This product is representative of the ZIP surgical pencil line of products. 252510, 252510BN, 252510EC, 252510ECBN, 252515, 252515EC.

5.3.2.2.XME725M1CN – This product is representative of the ACE surgical pencil line of products. ME7251C, ME7251E, ME725M1C, ME725M1E.

5.3.2.3.X251010JN – This product is representative of the Rally surgical pencil line of products. 251010J, 251010BN, 251015J, 251015BN.

5.3.2.4.XME725M1STN – This product is representative of the Rally GEM surgical pencil line of products. ME7251ST, ME725M1ST, ME7251T, ME725M1T.

### 5.4. Button Activation Force Testing

5.4.1. The pencil button activation force shall be within the range specified by the DMR. This range is 250 to 700 grams.

5.4.2. Products – Each of the following products directly or by comparison has met the criteria of the Button Activation Force testing

5.4.2.1.X252510N – This product is representative of the ZIP surgical pencil line of products. 252510, 252510BN, 252510EC, 252510ECBN, 252515, 252515EC.

5.4.2.2.XME725M1CN – This product is representative of the ACE surgical pencil line of products. ME7251C, ME7251E, ME725M1C, ME725M1E.

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5.4.2.3.X251010JN – This product is representative of the Rally surgical pencil line of products. 251010J, 251010BN, 251015J, 251015BN.

5.4.2.4.XME725M1STN – This product is representative of the Rally GEM surgical pencil line of products. ME7251ST, ME725M1ST, ME7251T, ME725M1T.

#### 5.5. Button Activation Over Time Testing

5.5.1. Button resistance is less than  $50\ \Omega$  after 500 activations. Resistance is greater than  $100,000\ \Omega$  when button is not depressed after 500 activations.

5.5.2. Products – Each of the following products directly or by comparison has met the criteria of the Button Activation Over Time testing

5.5.2.1.X252510N – This product is representative of the ZIP surgical pencil line of products. 252510, 252510BN, 252510EC, 252510ECBN, 252515, 252515EC.

5.5.2.2.XME725M1CN – This product is representative of the ACE surgical pencil line of products. ME7251C, ME7251E, ME725M1C, ME725M1E.

5.5.2.3.X251010JN – This product is representative of the Rally surgical pencil line of products. 251010J, 251010BN, 251015J, 251015BN.

5.5.2.4.XME725M1STN – This product is representative of the Rally GEM surgical pencil line of products. ME7251ST, ME725M1ST, ME7251T, ME725M1T.

## 6. CONCLUSIONS

### 6.1. Handpiece High Frequency Dielectric Withstand Test

6.1.1. The X252510N and XME725M1CN pencils created with the new dome switch X4010345 is representative of the ZIP and ACE surgical pencil line of products: 252510, 252510BN, 252510EC, 252510ECBN, 252515, 252515EC, ME7251C, ME7251E, ME725M1C, ME725M1E. These products meet the product specification requirement from ENG-PS-007 – PRS 1407: The hand held portion of the device meets the requirements for high frequency dielectric withstand per the requirements of IEC 60601-2-2 clause 201.8.8.3.103. The rated voltage of the device is 5.5 kV peak. And ENG-PS-007 – PRS 1408: The hand held portion of the device meets the requirements for mains frequency dielectric withstand per the requirements of IEC 60601-2-2 clause 201.8.8.3.104. The rated voltage of the device is 5.5 kV peak.

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6.1.2. The X251010JN and XME725M1STN pencils created with the new dome switch X4010345 is representative of the Rally, Rally GEM and Reliance surgical pencil line of products: 251010J, 251010BN, 251015J, 251015BN, ME7251ST, ME725M1ST, ME7251T, ME725M1T. These products meet the product specification requirement from XENG-PS-013 – PRS 1408: The hand-held portion and holster of the device meets the requirements for high frequency dielectric withstand per the requirements of IEC 60601-2-2 clause 201.8.8.3.103. The rated voltage of the device is 5.5 kV peak. (6.6 kV peak is the test voltage used for 30 sec. test). And XENG-PS-013 – 1409: The hand-held portion and holster of the device meets the requirements for mains frequency dielectric withstand per the requirements of IEC 60601-2-2 clause 201.8.8.3.104. The rated voltage of the device is 5.5 kV peak. (6.6 kV peak is the test voltage used for 30 sec. test)

#### 6.2. Fluid Ingress Test

6.2.7. The X252510N and XME725M1CN pencils created with the new dome switch X4010345 is representative of the ZIP and ACE surgical pencil line of products: 252510, 252510BN, 252510EC, 252510ECBN, 252515, 252515EC, ME7251C, ME7251E, ME725M1C, ME725M1E. These products meet the product specification requirement from ENG-PS-007 – PRS 1409: The handheld portion of the device meets the requirements for fluid ingress per the requirements of IEC 60601-2-2 clause 201.11.6.5 b).

6.2.8. The X251010JN and XME725M1STN pencils created with the new dome switch X4010345 is representative of the Rally, Rally GEM and Reliance surgical pencil line of products: 251010J, 251010BN, 251015J, 251015BN, ME7251ST, ME725M1ST, ME7251T, ME725M1T. These products meet the product specification requirement from XENG-PS-013 – PRS 1410: The hand-held portion of the device meets the requirements for fluid ingress per the requirements of IEC 60601-2-2 clause 201.11.6.5 b, which is after saline application in the Standard orientation, the button can be operated 10 times with a measured current of  $\leq 2.5$  mA, at 0.5 seconds after release.

#### 6.3. Activation Force Test

6.3.1. The X252510N and XME725M1CN pencils created with the new dome switch X4010345 is representative of the ZIP and ACE surgical pencil line of products: 252510, 252510BN, 252510EC, 252510ECBN, 252515, 252515EC, ME7251C, ME7251E, ME725M1C, ME725M1E. These products meet the product specification requirement from ENG-PS-007 –

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PRS 1301: The Button peak activation force is between 250 grams to 700 grams. This is applicable to both buttons (“CUT” and “COAG”) per device.

- 6.3.2. The X251010JN and XME725M1STN pencils created with the new dome switch X4010345 is representative of the Rally, Rally GEM and Reliance surgical pencil line of products: 251010J, 251010BN, 251015J, 251015BN, ME7251ST, ME725M1ST, ME7251T, ME725M1T. These products meet the product specification requirement from XENG-PS-013 – PRS 1301: Button activation force is between 250 and 700 grams. This is applicable to both buttons (“CUT” and “COAG”) per device.

#### 6.4. Activation Over Time Test

- 6.4.1. The X252510N and XME725M1CN pencils created with the new dome switch X4010345 is representative of the ZIP and ACE surgical pencil line of products: 252510, 252510BN, 252510EC, 252510ECBN, 252515, 252515EC, ME7251C, ME7251E, ME725M1C, ME725M1E. These products do not have a requirement for reliability of the switch component, but this test helps meet ENG-PS-007 – PRS 1402: Device continuity for each circuit, CUT and COAG, shall have resistance no greater than 50 ohms with the button depressed. And ENG-PS-007 1403: Device resistance for each circuit, CUT and COAG, shall have resistance greater than 100,000 ohms without buttons depressed. With the additional assurance that the continue to maintain this specification over 500 cycles.
- 6.4.2. The X251010JN and XME725M1STN pencils created with the new dome switch X4010345 is representative of the Rally, Rally GEM and Reliance surgical pencil line of products: 251010J, 251010BN, 251015J, 251015BN, ME7251ST, ME725M1ST, ME7251T, ME725M1T. These products meet the product specification requirement from XENG-PS-013 – PRS 1402: Device continuity for each circuit, CUT and COAG, shall have resistance no greater than 50 ohms with the button depressed. And XENG-PS-013 – 1403: Device resistance for each circuit, CUT and COAG, shall have resistance greater than 100,000 ohms without buttons depressed. Additionally, XENG-PS-013 – PRS 1106: The product shall demonstrate reliability by meeting specification after a minimum of 500 activation cycles for each button - After cycling, Cut and Coag should each measure less than 50 ohms when depressed and greater than 10,000 ohms when released.

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#### 6.5. Dome Switch Inversion

A total of 960 dome switches were fully depressed and activated over the course of the designated design verification tests. There were zero occurrences of dome switch inversion.

### 7. RECOMMENDATIONS

#### 7.1. Handpiece High Frequency Dielectric Withstand Test

The dome switch assembly's ability to withstand dielectric standoff, high frequency standoff and mains high frequency acceptance criteria of the test protocol and is recommended for production.

#### 7.2. Fluid Ingress Test

The dome switch assembly's ability to withstand fluid ingress has met the acceptance criteria of the test protocol and is recommended for production.

#### 7.3. Activation Force Test

The activation force measurement testing was successful in demonstrating that the single use pencil switches have the required activation forces for good user feedback and is recommended for production.

#### 7.4. Activation Over Time Test

The reliability of the "CUT" and "COAG" switches on all the button pencils continued to maintain the proper continuity (Open>100kΩ and Closed<50Ω) after full activation of 500 cycles and is recommended for production.

#### 7.5. Dome Switch Inversion

The battery of design verification tests fully depressed and activated a total of 960 dome switches without a single incident of a dome switch inverting. It is recommended that the dome switch proceed to use in production of these tested devices and their subsequent family of devices.

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## 8. APPENDICES

- 8.1. [Appendix I – Handpiece High Frequency Dielectric Withstand Test Data](#)
- 8.2. [Appendix II – Fluid Ingress Test Data](#)
- 8.3. [Appendix III – Activation Force Test Data](#)
- 8.4. [Appendix IV – Activation Over Time Test Data](#)
- 8.5. [Appendix V – Equipment Calibration Information](#)
- 8.6. [Appendix VI – Training Record](#)
- 8.7. [Appendix VII – Build Report](#)

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## Appendix I – Handpiece High Frequency Dielectric Withstand Test Data

Megadyne Medical Products, Inc.	<b>TEST PROTOCOL</b>				<b>Document Number</b> <b>ENG-PRT-594</b>	
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### Appendix III: Datasheet for Handpiece High Frequency Dielectric Withstand and Mains Frequency Testing

Samples	Configuration X.Y.ZZ	High Frequency		Mains	Button Activation			
					CUT		COAG	
		Max V <sub>peak</sub> (kV)	P/V		P/V	Open >100kΩ	Closed <50Ω	Open >100kΩ
1	Z.A.29	6.80	Pass	Pass	Pass	Pass	Pass	Pass
2	Z.A.26	6.88	Pass	Pass	Pass	Pass	Pass	Pass
3	Z.A.30	6.80	Pass	Pass	Pass	Pass	Pass	Pass
4	Z.A.25	6.80	Pass	Pass	Pass	Pass	Pass	Pass
5	Z.A.24	6.72	Pass	Pass	Pass	Pass	Pass	Pass
6	Z.A.23	6.88	Pass	Pass	Pass	Pass	Pass	Pass
7	Z.A.28	6.96	Pass	Pass	Pass	Pass	Pass	Pass
8	Z.A.21	7.36	Pass	Pass	Pass	Pass	Pass	Pass
9	Z.A.22	7.36	Pass	Pass	Pass	Pass	Pass	Pass
10	Z.A.19	7.22	Pass	Pass	Pass	Pass	Pass	Pass
11	Z.A.20	7.20	Pass	Pass	Pass	Pass	Pass	Pass
12	Z.A.18	7.36	Pass	Pass	Pass	Pass	Pass	Pass
13	Z.A.16	7.12	Pass	Pass	Pass	Pass	Pass	Pass
14	Z.A.17	7.36	Pass	Pass	Pass	Pass	Pass	Pass
15	Z.A.10	7.36	Pass	Pass	Pass	Pass	Pass	Pass
16	Z.A.27	7.36	Pass	Pass	Pass	Pass	Pass	Pass
17	Z.A.06	7.41	Pass	Pass	Pass	Pass	Pass	Pass
18	Z.A.15	7.28	Fail	N/A	Pass	Pass	Pass	Pass
19	Z.A.19	7.28	Pass	Pass	Pass	Pass	Pass	Pass
20	Z.A.13	7.36	Pass	Pass	Pass	Pass	Pass	Pass
21	Z.A.03	7.44	Pass	Pass	Pass	Pass	Pass	Pass
22	Z.A.11	7.36	Pass	Pass	Pass	Pass	Pass	Pass
23	Z.A.09	7.36	Pass	Pass	Pass	Pass	Pass	Pass
24	Z.A.12	7.20	Pass	Pass	Pass	Pass	Pass	Pass
25	Z.A.04	7.28	Pass	Pass	Pass	Pass	Pass	Pass
26	Z.A.01	7.04	Pass	Pass	Pass	Pass	Pass	Pass
27	Z.A.05	7.04	Pass	Pass	Pass	Pass	Pass	Pass
28	Z.A.02	7.20	Pass	Pass	Pass	Pass	Pass	Pass
29	Z.A.08	7.28	Pass	Pass	Pass	Pass	Pass	Pass
30	Z.A.07	7.20	Pass	Pass	Pass	Pass	Pass	Pass

Operator Name (Print)	Operator Signature	Date
Brian Taylor		10 Feb 2020

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LEAKAGE – ZIP (X252510N)								
	Configuration X.Y.ZZ	D (mm)	L (mm)	f <sub>test</sub> (kHz)	U <sub>peak</sub> (V <sub>p-p</sub> ) / 2	Measured Leakage Current (mA)	Calculated Acceptable	
							Leakage	P/F
1	Z.A.01	9.3	323.85	400	400	1.94	433.70	Pass
2	Z.A.02	9.3	323.85	400	400	1.15	433.70	Pass
3	Z.A.03	9.3	323.85	400	400	0.33	433.70	Pass
4	Z.A.04	9.3	323.85	400	400	1.40	433.70	Pass
5	Z.A.05	9.3	323.85	400	400	1.57	433.70	Pass
6	Z.A.06	9.3	323.85	400	400	1.45	433.70	Pass
7	Z.A.07	9.3	323.85	400	400	1.02	433.70	Pass
8	Z.A.08	9.3	323.85	400	400	1.46	433.70	Pass
9	Z.A.09	9.3	323.85	400	400	1.45	433.70	Pass
10	Z.A.10	9.3	323.85	400	400	1.08	433.70	Pass
11	Z.A.11	9.3	323.85	400	400	1.02	433.70	Pass
12	Z.A.12	9.3	323.85	400	400	1.56	433.70	Pass
13	Z.A.13	9.3	323.85	400	400	1.27	433.70	Pass
14	Z.A.14	9.3	323.85	400	400	1.13	433.70	Pass
15	Z.A.15	9.3	323.85	400	400	1.20	433.70	Pass
16	Z.A.16	9.3	323.85	400	400	1.58	433.70	Pass
17	Z.A.17	9.3	323.85	400	400	1.76	433.70	Pass
18	Z.A.18	9.3	323.85	400	400	1.67	433.70	Pass
19	Z.A.19	9.3	323.85	400	400	1.75	433.70	Pass
20	Z.A.20	9.3	323.85	400	400	1.31	433.70	Pass
21	Z.A.21	9.3	323.85	400	400	1.98	433.70	Pass
22	Z.A.22	9.3	323.85	400	400	1.21	433.70	Pass
23	Z.A.23	9.3	323.85	400	400	1.14	433.70	Pass
24	Z.A.24	9.3	323.85	400	400	1.21	433.70	Pass
25	Z.A.25	9.3	323.85	400	400	1.56	433.70	Pass
26	Z.A.26	9.3	323.85	400	400	1.68	433.70	Pass
27	Z.A.27	9.3	323.85	400	400	1.47	433.70	Pass
28	Z.A.28	9.3	323.85	400	400	1.46	433.70	Pass
29	Z.A.29	9.3	323.85	400	400	1.27	433.70	Pass
30	Z.A.30	9.3	323.85	400	400	1.45	433.70	Pass

Operator Name (Print)

Brian Taylor

Operator Signature

Date

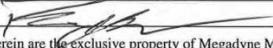
6 Feb 2020

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**Appendix III: Datasheet for Handpiece High Frequency Dielectric Withstand and Mains Frequency Testing**

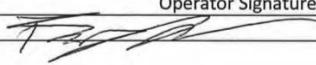
Samples	Configuration X.Y.ZZ	High Frequency		Mains	Button Activation			
					CUT		COAG	
		Max V <sub>peak</sub> (kV)	P/V	P/V	Open >100kΩ	Closed <50Ω	Open >100kΩ	Closed <50Ω
1	A.A.24	6.96	Pass	Pass	Pass	Pass	Pass	Pass
2	A.A.21	7.04	Pass	Pass	Pass	Pass	Pass	Pass
3	A.A.28	6.96	Pass	Pass	Pass	Pass	Pass	Pass
4	A.A.23	6.88	Pass	Pass	Pass	Pass	Pass	Pass
5	A.A.18	6.96	Pass	Pass	Pass	Pass	Pass	Pass
6	A.A.15	6.96	Pass	Pass	Pass	Pass	Pass	Pass
7	A.A.27	7.04	Pass	Pass	Pass	Pass	Pass	Pass
8	A.A.26	6.92	Pass	Pass	Pass	Pass	Pass	Pass
9	A.A.25	6.88	Pass	Pass	Pass	Pass	Pass	Pass
10	A.A.10	7.12	Pass	Pass	Pass	Pass	Pass	Pass
11	A.A.12	6.96	Pass	Pass	Pass	Pass	Pass	Pass
12	A.A.30	7.04	Pass	Pass	Pass	Pass	Pass	Pass
13	A.A.29	7.04	Pass	Pass	Pass	Pass	Pass	Pass
14	A.A.04	7.04	Pass	Pass	Pass	Pass	Pass	Pass
15	A.A.07	7.20	Pass	Pass	Pass	Pass	Pass	Pass
16	A.A.14	7.04	Pass	Pass	Pass	Pass	Pass	Pass
17	A.A.08	7.20	Pass	Pass	Pass	Pass	Pass	Pass
18	A.A.09	7.04	Pass	Pass	Pass	Pass	Pass	Pass
19	A.A.05	7.04	Pass	Pass	Pass	Pass	Pass	Pass
20	A.A.06	7.28	Pass	Pass	Pass	Pass	Pass	Pass
21	A.A.03	7.28	Pass	Pass	Pass	Pass	Pass	Pass
22	A.A.01	7.12	Pass	Pass	Pass	Pass	Pass	Pass
23	A.A.02	7.28	Pass	Pass	Pass	Pass	Pass	Pass
24	A.A.19	7.28	Pass	Pass	Pass	Pass	Pass	Pass
25	A.A.20	7.36	Pass	Pass	Pass	Pass	Pass	Pass
26	A.A.16	7.28	Pass	Pass	Pass	Pass	Pass	Pass
27	A.A.13	7.36	Pass	Pass	Pass	Pass	Pass	Pass
28	A.A.17	7.27	Pass	Pass	Pass	Pass	Pass	Pass
29	A.A.22	7.52	Pass	Pass	Pass	Pass	Pass	Pass
30	A.A.11	7.44	Pass	Pass	Pass	Pass	Pass	Pass

Operator Name (Print)	Operator Signature	Date
Brian Taylor		11 Feb 2020

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	Configuration X.Y.ZZ	D (mm)	L (mm)	f <sub>test</sub> (kHz)	U <sub>peak</sub> (V <sub>p-p</sub> ) / 2	Measured Leakage Current (mA)	Calculated Acceptable		Power (W)
							Leakage	P/F	
1	A.A.01	9.3	323.85	400	400	6.42	433.70	Pass	10
2	A.A.02	9.3	323.85	400	400	9.15	433.70	Pass	10
3	A.A.03	9.3	323.85	400	400	8.03	433.70	Pass	10
4	A.A.04	9.3	323.85	400	400	7.75	433.70	Pass	10
5	A.A.05	9.3	323.85	400	400	7.06	433.70	Pass	10
6	A.A.06	9.3	323.85	400	400	6.84	433.70	Pass	10
7	A.A.07	9.3	323.85	400	400	5.25	433.70	Pass	10
8	A.A.08	9.3	323.85	400	400	6.10	433.70	Pass	10
9	A.A.09	9.3	323.85	400	400	5.69	433.70	Pass	10
10	A.A.10	9.3	323.85	400	400	5.98	433.70	Pass	10
11	A.A.11	9.3	323.85	400	400	5.11	433.70	Pass	10
12	A.A.12	9.3	323.85	400	400	6.04	433.70	Pass	10
13	A.A.13	9.3	323.85	400	400	5.84	433.70	Pass	10
14	A.A.14	9.3	323.85	400	400	5.72	433.70	Pass	10
15	A.A.15	9.3	323.85	400	400	7.63	433.70	Pass	10
16	A.A.16	9.3	323.85	400	400	5.89	433.70	Pass	10
17	A.A.17	9.3	323.85	400	400	5.54	433.70	Pass	10
18	A.A.18	9.3	323.85	400	400	5.95	433.70	Pass	10
19	A.A.19	9.3	323.85	400	400	6.81	433.70	Pass	10
20	A.A.20	9.3	323.85	400	400	5.95	433.70	Pass	10
21	A.A.21	9.3	323.85	400	400	5.27	433.70	Pass	10
22	A.A.22	9.3	323.85	400	400	8.26	433.70	Pass	10
23	A.A.23	9.3	323.85	400	400	6.19	433.70	Pass	10
24	A.A.24	9.3	323.85	400	400	8.98	433.70	Pass	10
25	A.A.25	9.3	323.85	400	400	5.75	433.70	Pass	10
26	A.A.26	9.3	323.85	400	400	8.28	433.70	Pass	10
27	A.A.27	9.3	323.85	400	400	6.24	433.70	Pass	10
28	A.A.28	9.3	323.85	400	400	6.15	433.70	Pass	10
29	A.A.29	9.3	323.85	400	400	9.13	433.70	Pass	10
30	A.A.30	9.3	323.85	400	400	7.55	433.70	Pass	10
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Brian Taylor						5 Feb 2020			

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**Appendix III: Datasheet for Handpiece High Frequency Dielectric Withstand and Mains Frequency Testing**

Samples	Configuration X.Y.ZZ	High Frequency		Mains	Button Activation			
					CUT		COAG	
		Max V <sub>peak</sub> (kV)	P/V	P/V	Open >100kΩ	Closed <50Ω	Open >100kΩ	Closed <50Ω
1	R.A.29	6.80	Pass	Pass	Pass	Pass	Pass	Pass
2	R.A.28	6.80	Pass	Pass	Pass	Pass	Pass	Pass
3	R.A.24	6.80	Pass	Pass	Pass	Pass	Pass	Pass
4	R.A.27	6.80	Pass	Pass	Pass	Pass	Pass	Pass
5	R.A.30	6.72	Pass	Pass	Pass	Pass	Pass	Pass
6	R.A.25	6.72	Pass	Pass	Pass	Pass	Pass	Pass
7	R.A.22	6.72	Pass	Pass	Pass	Pass	Pass	Pass
8	R.A.20	6.80	Pass	Pass	Pass	Pass	Pass	Pass
9	R.A.13	6.72	Pass	Pass	Pass	Pass	Pass	Pass
10	R.A.12	6.80	Pass	Pass	Pass	Pass	Pass	Pass
11	R.A.05	6.64	Pass	Pass	Pass	Pass	Pass	Pass
12	R.A.04	6.80	Pass	Pass	Pass	Pass	Pass	Pass
13	R.A.26	6.96	Pass	Pass	Pass	Pass	Pass	Pass
14	R.A.23	6.88	Pass	Pass	Pass	Pass	Pass	Pass
15	R.A.19	6.80	Pass	Pass	Pass	Pass	Pass	Pass
16	R.A.10	6.88	Pass	Pass	Pass	Pass	Pass	Pass
17	R.A.16	6.88	Pass	Pass	Pass	Pass	Pass	Pass
18	R.A.15	6.96	Pass	Pass	Pass	Pass	Pass	Pass
19	R.A.07	7.04	Pass	Pass	Pass	Pass	Pass	Pass
20	R.A.06	6.88	Pass	Pass	Pass	Pass	Pass	Pass
21	R.A.03	6.88	Pass	Pass	Pass	Pass	Pass	Pass
22	R.A.02	6.96	Pass	Pass	Pass	Pass	Pass	Pass
23	R.A.01	6.88	Pass	Pass	Pass	Pass	Pass	Pass
24	R.A.21	6.96	Pass	Pass	Pass	Pass	Pass	Pass
25	R.A.14	6.96	Pass	Pass	Pass	Pass	Pass	Pass
26	R.A.09	6.88	Pass	Pass	Pass	Pass	Pass	Pass
27	R.A.18	6.80	Pass	Pass	Pass	Pass	Pass	Pass
28	R.A.17	6.96	Pass	Pass	Pass	Pass	Pass	Pass
29	R.A.11	6.88	Pass	Pass	Pass	Pass	Pass	Pass
30	R.A.08	6.88	Pass	Pass	Pass	Pass	Pass	Pass

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Brian Taylor		11 Feb 2020

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	Configuration X.Y.ZZ	D (mm)	L (mm)	f <sub>test</sub> (kHz)	U <sub>peak</sub> (V <sub>p-p</sub> )/2	Measured Leakage Current (mA)	Calculated Acceptable		Power (W)
							Leakage	P/F	
1	R.A.01	9.0	349.25	400	400	8.69	452.63	Pass	10
2	R.A.02	9.0	349.25	400	400	8.88	452.63	Pass	10
3	R.A.03	9.0	349.25	400	400	9.22	452.63	Pass	10
4	R.A.04	9.0	349.25	400	400	9.47	452.63	Pass	10
5	R.A.05	9.0	349.25	400	400	7.31	452.63	Pass	10
6	R.A.06	9.0	349.25	400	400	9.35	452.63	Pass	10
7	R.A.07	9.0	349.25	400	400	10.13	452.63	Pass	10
8	R.A.08	9.0	349.25	400	400	9.72	452.63	Pass	10
9	R.A.09	9.0	349.25	400	400	10.41	452.63	Pass	10
10	R.A.10	9.0	349.25	400	400	9.87	452.63	Pass	10
11	R.A.11	9.0	349.25	400	400	8.04	452.63	Pass	10
12	R.A.12	9.0	349.25	400	400	9.65	452.63	Pass	10
13	R.A.13	9.0	349.25	400	400	9.72	452.63	Pass	10
14	R.A.14	9.0	349.25	400	400	10.28	452.63	Pass	10
15	R.A.15	9.0	349.25	400	400	9.94	452.63	Pass	10
16	R.A.16	9.0	349.25	400	400	8.54	452.63	Pass	10
17	R.A.17	9.0	349.25	400	400	8.99	452.63	Pass	10
18	R.A.18	9.0	349.25	400	400	9.47	452.63	Pass	10
19	R.A.19	9.0	349.25	400	400	8.32	452.63	Pass	10
20	R.A.20	9.0	349.25	400	400	9.27	452.63	Pass	10
21	R.A.21	9.0	349.25	400	400	9.96	452.63	Pass	10
22	R.A.22	9.0	349.25	400	400	8.84	452.63	Pass	10
23	R.A.23	9.0	349.25	400	400	9.23	452.63	Pass	10
24	R.A.24	9.0	349.25	400	400	7.83	452.63	Pass	10
25	R.A.25	9.0	349.25	400	400	9.63	452.63	Pass	10
26	R.A.26	9.0	349.25	400	400	9.83	452.63	Pass	10
27	R.A.27	9.0	349.25	400	400	9.35	452.63	Pass	10
28	R.A.28	9.0	349.25	400	400	9.38	452.63	Pass	10
29	R.A.29	9.0	349.25	400	400	10.16	452.63	Pass	10
30	R.A.30	9.0	349.25	400	400	10.93	452.63	Pass	10

Operator Name (Print)

Brian Taylor

Operator Signature

Date

6 Feb 2020

<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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<b>Megadyne Medical Products, Inc.</b>	<b>TEST PROTOCOL</b>			<b>Document Number</b> <b>ENG-PRT-594</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Mechanical Test Protocol</b>			<b>Revision: 001</b>

**Appendix III: Datasheet for Handpiece High Frequency Dielectric Withstand and Mains Frequency Testing**

Samples	Configuration X.Y.ZZ	High Frequency		Mains	Button Activation			
					CUT		COAG	
		Max V <sub>peak</sub> (kV)	P/V		Open >100kΩ	Closed <50Ω	Open >100kΩ	Closed <50Ω
1	G.A.19	7.12	Pass	Pass	Pass	Pass	Pass	Pass
2	G.A.18	7.12	Pass	Pass	Pass	Pass	Pass	Pass
3	G.A.17	7.04	Pass	Pass	Pass	Pass	Pass	Pass
4	G.A.20	7.04	Pass	Pass	Pass	Pass	Pass	Pass
5	G.A.15	7.04	Pass	Pass	Pass	Pass	Pass	Pass
6	G.A.07	7.04	Pass	Pass	Pass	Pass	Pass	Pass
7	G.A.30	7.04	Pass	Pass	Pass	Pass	Pass	Pass
8	G.A.04	7.04	Pass	Pass	Pass	Pass	Pass	Pass
9	G.A.01	7.04	Pass	Pass	Pass	Pass	Pass	Pass
10	G.A.08	7.04	Pass	Pass	Pass	Pass	Pass	Pass
11	G.A.03	7.04	Pass	Pass	Pass	Pass	Pass	Pass
12	G.A.02	6.96	Pass	Pass	Pass	Pass	Pass	Pass
13	G.A.16	7.04	Pass	Pass	Pass	Pass	Pass	Pass
14	G.A.06	6.96-9.96 <sup>b1/2/20</sup>	Pass	Pass	Pass	Pass	Pass	Pass
15	G.A.28	7.04	Pass	Pass	Pass	Pass	Pass	Pass
16	G.A.29	6.96	Pass	Pass	Pass	Pass	Pass	Pass
17	G.A.14	6.88	Pass	Pass	Pass	Pass	Pass	Pass
18	G.A.05	6.96-9.96 <sup>b1/2/20</sup>	Pass	Pass	Pass	Pass	Pass	Pass
19	G.A.09	6.88	Pass	Pass	Pass	Pass	Pass	Pass
20	G.A.11	7.04	Pass	Pass	Pass	Pass	Pass	Pass
21	G.A.12	6.96	Pass	Pass	Pass	Pass	Pass	Pass
22	G.A.13	6.96	Pass	Pass	Pass	Pass	Pass	Pass
23	G.A.10	7.12	Pass	Pass	Pass	Pass	Pass	Pass
24	G.A.21	7.04	Pass	Pass	Pass	Pass	Pass	Pass
25	G.A.25	7.04	Pass	Pass	Pass	Pass	Pass	Pass
26	G.A.23	7.04	Pass	Pass	Pass	Pass	Pass	Pass
27	G.A.22	6.96	Pass	Pass	Pass	Pass	Pass	Pass
28	G.A.24	6.96	Pass	Pass	Pass	Pass	Pass	Pass
29	G.A.27	7.04	Pass	Pass	Pass	Pass	Pass	Pass
30	G.A.26	6.96	Pass	Pass	Pass	Pass	Pass	Pass

Operator Name (Print)	Operator Signature	Date
Brian Taylor		11 Feb 2020

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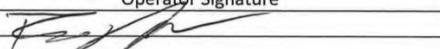
<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
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LEAKAGE – Rally GEM (XME725M1STN)								
	Configuration X.Y.ZZ	D (mm)	L (mm)	ftest (kHz)	Upeak (Vp-p)/2	Measured Leakage Current (mA)	Calculated Acceptable	Power (W)
							Leakage	
1	G.A.01	9.0	349.25	400	400	9.25	PASS	10
2	G.A.02	9.0	349.25	400	400	9.78	PASS	10
3	G.A.03	9.0	349.25	400	400	10.15	PASS	10
4	G.A.04	9.0	349.25	400	400	10.62	PASS	10
5	G.A.05	9.0	349.25	400	400	11.88	PASS	10
6	G.A.06	9.0	349.25	400	400	10.90	PASS	10
7	G.A.07	9.0	349.25	400	400	11.55	PASS	10
8	G.A.08	9.0	349.25	400	400	11.24	PASS	10
9	G.A.09	9.0	349.25	400	400	11.98	PASS	10
10	G.A.10	9.0	349.25	400	400	10.69	PASS	10
11	G.A.11	9.0	349.25	400	400	11.13	PASS	10
12	G.A.12	9.0	349.25	400	400	11.22	PASS	10
13	G.A.13	9.0	349.25	400	400	11.51	PASS	10
14	G.A.14	9.0	349.25	400	400	11.64	PASS	10
15	G.A.15	9.0	349.25	400	400	11.21	PASS	10
16	G.A.16	9.0	349.25	400	400	10.06	PASS	10
17	G.A.17	9.0	349.25	400	400	10.56	PASS	10
18	G.A.18	9.0	349.25	400	400	10.69	PASS	10
19	G.A.19	9.0	349.25	400	400	9.90	PASS	10
20	G.A.20	9.0	349.25	400	400	12.02	PASS	10
21	G.A.21	9.0	349.25	400	400	10.32	PASS	10
22	G.A.22	9.0	349.25	400	400	10.22	PASS	10
23	G.A.23	9.0	349.25	400	400	15.23	PASS	10
24	G.A.24	9.0	349.25	400	400	15.40	PASS	10
25	G.A.25	9.0	349.25	400	400	15.62	PASS	10
26	G.A.26	9.0	349.25	400	400	12.52	PASS	10
27	G.A.27	9.0	349.25	400	400	11.14	PASS	10
28	G.A.28	9.0	349.25	400	400	12.73	PASS	10
29	G.A.29	9.0	349.25	400	400	11.52	PASS	10
30	G.A.30	9.0	349.25	400	400	14.70	PASS	10

Operator Name (Print)

Brian Taylor

Operator Signature



Date

5 Feb 2020

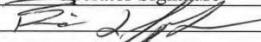
<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
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## Appendix II – Fluid Ingress Test Data

Megadyne Medical Products, Inc.	<b>TEST PROTOCOL</b>		<b>Document Number</b> <b>ENG-PRT-594</b>
	<b>Pencil Dome Switch - Supplier Change - Mechanical Test Protocol</b>		<b>Revision: 001</b>
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### Appendix VI: Datasheet for Handpiece Fluid Ingress Testing

Samples	Configuration X.Y.ZZ	Fluid Ingress		Button Activation			
		Pass	Fail	CUT		COAG	
				Open >100kΩ	Closed <50Ω	Open >100kΩ	Closed <50Ω
1	Z.B.01	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
2	Z.B.02	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
3	Z.B.03	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
4	Z.B.04	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
5	Z.B.05	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
6	Z.B.06	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
7	Z.B.07	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
8	Z.B.08	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
9	Z.B.09	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
10	Z.B.10	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
11	Z.B.11	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
12	Z.B.12	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
13	Z.B.13	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
14	Z.B.14	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
15	Z.B.15	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
16	Z.B.16	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
17	Z.B.17	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
18	Z.B.18	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
19	Z.B.19	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
20	Z.B.20	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
21	Z.B.21	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
22	Z.B.22	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
23	Z.B.23	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
24	Z.B.24	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
25	Z.B.25	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
26	Z.B.26	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
27	Z.B.27	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
28	Z.B.28	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
29	Z.B.29	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
30	Z.B.30						

Operator Name (Print)	Operator Signature	Date
Brian Taylor		31 Jan 2020

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<b>Megadyne Medical Products, Inc.</b>	<b>TEST PROTOCOL</b>	<b>Document Number</b> <b>ENG-PRT-594</b>
	<b>Pencil Dome Switch - Supplier Change - Mechanical Test Protocol</b>	<b>Revision: 001</b> <b>Page 33 of 42</b>

#### Appendix VI: Datasheet for Handpiece Fluid Ingress Testing

Samples	Configuration X.Y.ZZ	Fluid Ingress		Button Activation			
		Pass	Fail	CUT		COAG	
				Open >100kΩ	Closed <50Ω	Open >100kΩ	Closed <50Ω
1	A.B.01	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
2	A.B.02	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
3	A.B.03	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
4	A.B.04	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
5	A.B.05	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
6	A.B.06	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
7	A.B.07	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
8	A.B.08	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
9	A.B.09	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
10	A.B.10	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
11	A.B.11	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
12	A.B.12	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
13	A.B.13	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
14	A.B.14	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
15	A.B.15	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
16	A.B.16	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
17	A.B.17	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
18	A.B.18	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
19	A.B.19	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
20	A.B.20	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
21	A.B.21	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
22	A.B.22	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
23	A.B.23	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
24	A.B.24	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
25	A.B.25	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
26	A.B.26	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
27	A.B.27	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
28	A.B.28	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
29	A.B.29	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass
30	A.B.30	Pass / Pass	N/A / N/A	Pass	Pass	Pass	Pass

Operator Name (Print)	Operator Signature	Date
Brian Taylor		30 Jan 2020

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	<b>Pencil Dome Switch - Supplier Change - Mechanical Test Protocol</b>	<b>Revision: 001</b> <b>Page 33 of 42</b>

#### Appendix VI: Datasheet for Handpiece Fluid Ingress Testing

Samples	Configuration X.Y.ZZ	Fluid Ingress		Button Activation					
		Pass	Fail	CUT	COAG	Open >100kΩ	Closed <50Ω	Open >100kΩ	Closed <50Ω
1	R.B.01	Pass/Pass	N/A / N/A	Pass	Pass	Pass	Pass	Pass	Pass
2	R.B.02	Pass/Pass	N/A / N/A	Pass	Pass	Pass	Pass	Pass	Pass
3	R.B.03	Pass/Pass	N/A / N/A	Pass	Pass	Pass	Pass	Pass	Pass
4	R.B.04	Pass/Pass	N/A / N/A	Pass	Pass	Pass	Pass	Pass	Pass
5	R.B.05	Pass/Pass	N/A / N/A	Pass	Pass	Pass	Pass	Pass	Pass
6	R.B.06	Pass/Pass	N/A / N/A	Pass	Pass	Pass	Pass	Pass	Pass
7	R.B.07	Pass/Pass	N/A / N/A	Pass	Pass	Pass	Pass	Pass	Pass
8	R.B.08	Pass/Pass	N/A / N/A	Pass	Pass	Pass	Pass	Pass	Pass
9	R.B.09	Pass/Pass	N/A / N/A	Pass	Pass	Pass	Pass	Pass	Pass
10	R.B.10	Pass/Pass	N/A / N/A	Pass	Pass	Pass	Pass	Pass	Pass
11	R.B.11	Pass/Pass	N/A / N/A	Pass	Pass	Pass	Pass	Pass	Pass
12	R.B.12	Pass/Pass	N/A / N/A	Pass	Pass	Pass	Pass	Pass	Pass
13	R.B.13	Pass/Pass	N/A / N/A	Pass	Pass	Pass	Pass	Pass	Pass
14	R.B.14	Pass/Pass	N/A / N/A	Pass	Pass	Pass	Pass	Pass	Pass
15	R.B.15	Pass/Pass	N/A / N/A	Pass	Pass	Pass	Pass	Pass	Pass
16	R.B.16	Pass/Pass	N/A / N/A	Pass	Pass	Pass	Pass	Pass	Pass
17	R.B.17	Pass/Pass	N/A / N/A	Pass	Pass	Pass	Pass	Pass	Pass
18	R.B.18	Pass/Pass	N/A / N/A	Pass	Pass	Pass	Pass	Pass	Pass
19	R.B.19	Pass/Pass	N/A / N/A	Pass	Pass	Pass	Pass	Pass	Pass
20	R.B.20	Pass/Pass	N/A / N/A	Pass	Pass	Pass	Pass	Pass	Pass
21	R.B.21	Pass/Pass	N/A / N/A	Pass	Pass	Pass	Pass	Pass	Pass
22	R.B.22	Pass/Pass	N/A / N/A	Pass	Pass	Pass	Pass	Pass	Pass
23	R.B.23	Pass/Pass	N/A / N/A	Pass	Pass	Pass	Pass	Pass	Pass
24	R.B.24	Pass/Pass	N/A / N/A	Pass	Pass	Pass	Pass	Pass	Pass
25	R.B.25	Pass/Pass	N/A / N/A	Pass	Pass	Pass	Pass	Pass	Pass
26	R.B.26	Pass/Pass	N/A / N/A	Pass	Pass	Pass	Pass	Pass	Pass
27	R.B.27	Pass/Pass	N/A / N/A	Pass	Pass	Pass	Pass	Pass	Pass
28	R.B.28	Pass/Pass	N/A / N/A	Pass	Pass	Pass	Pass	Pass	Pass
29	R.B.29	Pass/Pass	N/A / N/A	Pass	Pass	Pass	Pass	Pass	Pass
30	R.B.30	Pass/Pass	N/A / N/A	Pass	Pass	Pass	Pass	Pass	Pass

Operator Name (Print)	Operator Signature	Date
Jillian Taylor		4 Feb 2020

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	<b>Pencil Dome Switch - Supplier Change -</b> <b>Mechanical Test Protocol</b>	<b>Revision: 001</b>

#### Appendix VI: Datasheet for Handpiece Fluid Ingress Testing

Samples	Configuration X.Y.ZZ	Fluid Ingress		Button Activation			
		Pass	Fail	CUT		COAG	
1	G.B.01	Pass/COAG	Cut/COAG	Open >100kΩ	Closed <50Ω	Open >100kΩ	Closed <50Ω
2	G.B.02	Pass/Pass	N/A/N/A	Pass	Pass	Pass	Pass
3	G.B.03	Pass/Pass	N/A/N/A	Pass	Pass	Pass	Pass
4	G.B.04	Pass/Pass	N/A/N/A	Pass	Pass	Pass	Pass
5	G.B.05	Pass/Pass	N/A/N/A	Pass	Pass	Pass	Pass
6	G.B.06	Pass/Pass	N/A/N/A	Pass	Pass	Pass	Pass
7	G.B.07	Pass/Pass	N/A/N/A	Pass	Pass	Pass	Pass
8	G.B.08	Pass/Pass	N/A/N/A	Pass	Pass	Pass	Pass
9	G.B.09	Pass/Pass	N/A/N/A	Pass	Pass	Pass	Pass
10	G.B.10	Pass/Pass	N/A/N/A	Pass	Pass	Pass	Pass
11	G.B.11	Pass/Pass	N/A/N/A	Pass	Pass	Pass	Pass
12	G.B.12	Pass/Pass	N/A/N/A	Pass	Pass	Pass	Pass
13	G.B.13	Pass/Pass	N/A/N/A	Pass	Pass	Pass	Pass
14	G.B.14	Pass/Pass	N/A/N/A	Pass	Pass	Pass	Pass
15	G.B.15	Pass/Pass	N/A/N/A	Pass	Pass	Pass	Pass
16	G.B.16	Pass/Pass	N/A/N/A	Pass	Pass	Pass	Pass
17	G.B.17	Pass/Pass	N/A/N/A	Pass	Pass	Pass	Pass
18	G.B.18	Pass/Pass	N/A/N/A	Pass	Pass	Pass	Pass
19	G.B.19	Pass/Pass	N/A/N/A	Pass	Pass	Pass	Pass
20	G.B.20	Pass/Pass	N/A/N/A	Pass	Pass	Pass	Pass
21	G.B.21	Pass/Pass	N/A/N/A	Pass	Pass	Pass	Pass
22	G.B.22	Pass/Pass	N/A/N/A	Pass	Pass	Pass	Pass
23	G.B.23	Pass/Pass	N/A/N/A	Pass	Pass	Pass	Pass
24	G.B.24	Pass/Pass	N/A/N/A	Pass	Pass	Pass	Pass
25	G.B.25	Pass/Pass	N/A/N/A	Pass	Pass	Pass	Pass
26	G.B.26	Pass/Pass	N/A/N/A	Pass	Pass	Pass	Pass
27	G.B.27	Pass/Pass	N/A/N/A	Pass	Pass	Pass	Pass
28	G.B.28	Pass/Pass	N/A/N/A	Pass	Pass	Pass	Pass
29	G.B.29	Pass/Pass	N/A/N/A	Pass	Pass	Pass	Pass
30	G.B.30	Pass/Pass	N/A/N/A	Pass	Pass	Pass	Pass

Operator Name (Print)	Operator Signature	Date
Brianna Taylor		3 Feb 2020

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<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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### Appendix III - Activation Force Test Data

Wednesday, January 29, 2020

ZC.is\_comp

	Compressive load at Preset Point (Cursor ) (lbf)	Specimen label	Notes
1	1.08450	Z.C.01-COAG	
2	0.97135	Z.C.01-CUT	
3	1.07424	Z.C.02-COAG	
4	0.97165	Z.C.02-CUT	
5	1.09537	Z.C.03-COAG	
6	0.96199	Z.C.03-CUT	
7	1.02324	Z.C.04-COAG	
8	1.01299	Z.C.04-CUT	
9	0.95415	Z.C.05-COAG	
10	1.00303	Z.C.05-CUT	
11	1.13339	Z.C.06-COAG	
12	0.90586	Z.C.06-CUT	
13	1.14485	Z.C.07-COAG	
14	0.99549	Z.C.07-CUT	
15	1.09838	Z.C.08-COAG	
16	0.93966	Z.C.08-CUT	
17	1.11769	Z.C.09-COAG	
18	1.01269	Z.C.09-CUT	
19	1.00212	Z.C.10-COAG	
20	1.06097	Z.C.10-CUT	
21	1.02898	Z.C.11-COAG	
22	0.92819	Z.C.11-CUT	
23	1.10442	Z.C.12-COAG	
24	0.96350	Z.C.12-CUT	
25	1.03532	Z.C.13-COAG	
26	0.98734	Z.C.13-CUT	
27	0.92427	Z.C.14-COAG	
28	0.94419	Z.C.14-CUT	
29	1.04890	Z.C.15-COAG	
30	0.99820	Z.C.15-CUT	
31	1.01178	Z.C.16-COAG	
32	0.91311	Z.C.16-CUT	
33	1.04196	Z.C.17-COAG	
34	0.92065	Z.C.17-CUT	
35	1.09899	Z.C.18-COAG	
36	0.93121	Z.C.18-CUT	
37	1.06458	Z.C.19-COAG	
38	0.88082	Z.C.19-CUT	
39	1.12192	Z.C.20-COAG	
40	0.88534	Z.C.20-CUT	
41	1.06549	Z.C.21-COAG	
42	0.97647	Z.C.21-CUT	
43	1.18951	Z.C.22-COAG	
44	0.95415	Z.C.22-CUT	
45	1.05251	Z.C.23-COAG	
46	0.96772	Z.C.23-CUT	
47	1.08450	Z.C.24-COAG	
48	0.94268	Z.C.24-CUT	
49	1.03683	Z.C.25-COAG	
50	0.89862	Z.C.25-CUT	
51	1.03622	Z.C.26-COAG	
52	1.01902	Z.C.26-CUT	
53	1.06458	Z.C.27-COAG	
54	0.98342	Z.C.27-CUT	
55	1.11951	Z.C.28-COAG	
56	0.99910	Z.C.28-CUT	
57	1.03713	Z.C.29-COAG	
58	0.99156	Z.C.29-CUT	
59	1.07967	Z.C.30-COAG	
60	0.98854	Z.C.30-CUT	
Maximum	1.18951		

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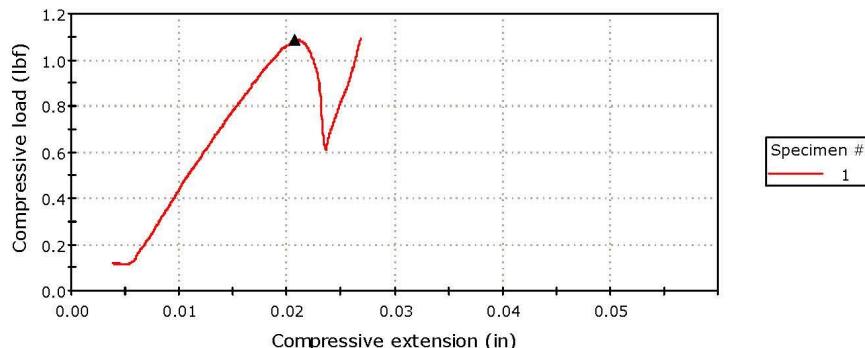
ETHICON a Johnson & Johnson company	TEST REPORT	Document Number <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change - Test Report</b>	<b>Revision: A</b>
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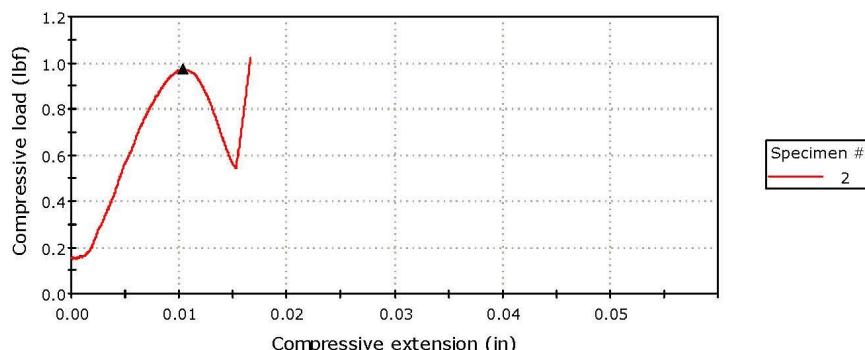
ZC.is\_comp

	Compressive load at Preset Point (Cursor ) (lbf)	Specimen label	Notes
Minimum	0.88082		
Mean	1.01474		
Standard Deviation	0.07		

Specimen 1 to 1



Specimen 2 to 2

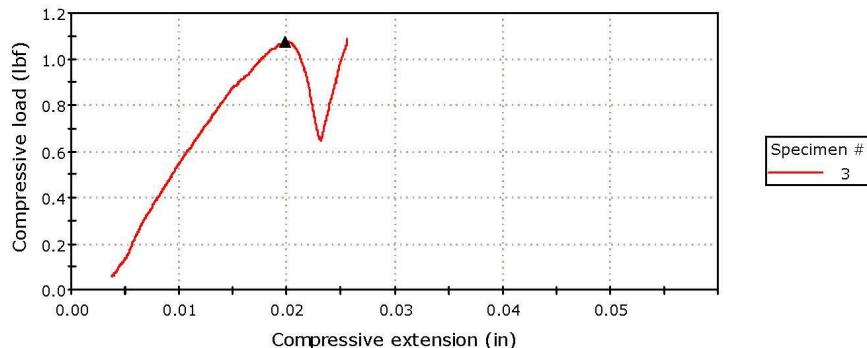


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	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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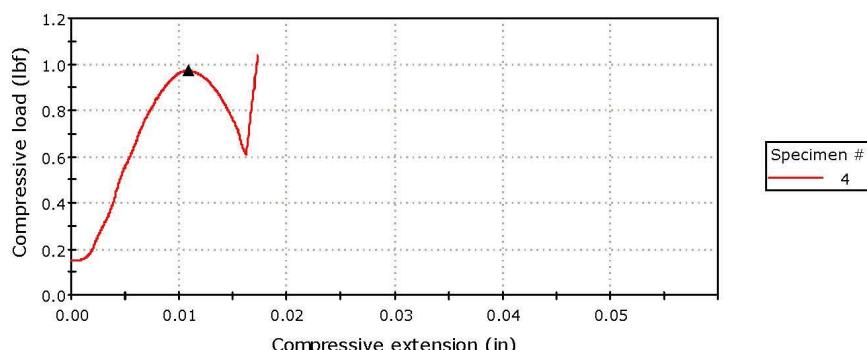
Wednesday, January 29, 2020

ZC.is\_comp

Specimen 3 to 3



Specimen 4 to 4

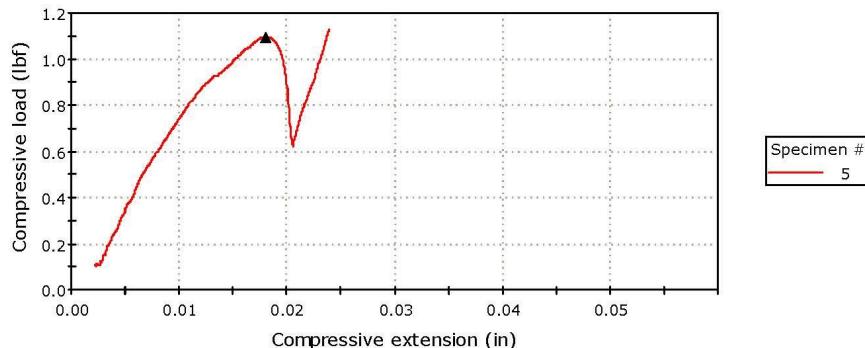


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	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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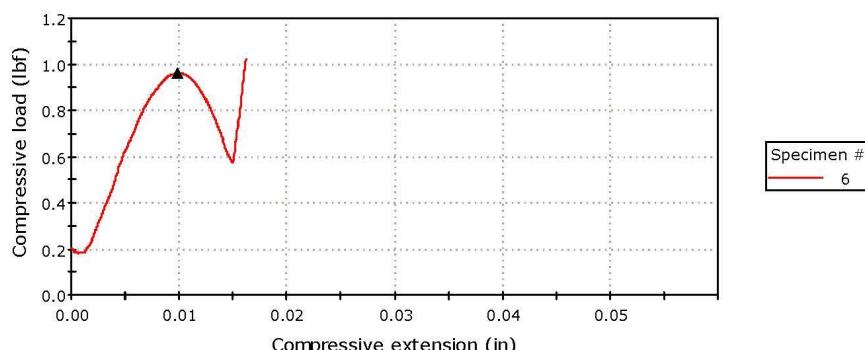
Wednesday, January 29, 2020

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Specimen 5 to 5



Specimen 6 to 6

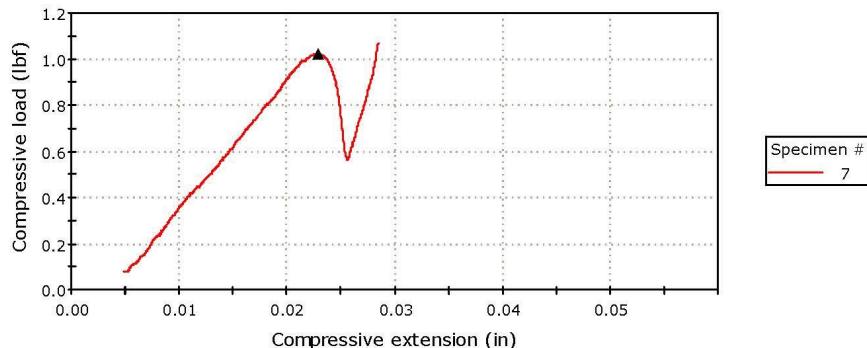


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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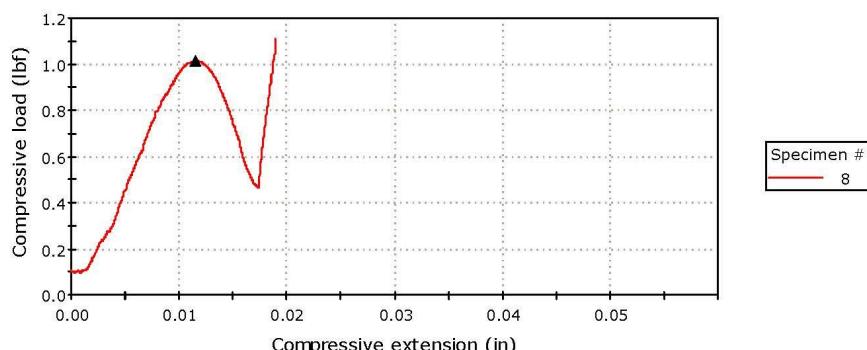
Wednesday, January 29, 2020

ZC.is\_comp

Specimen 7 to 7



Specimen 8 to 8

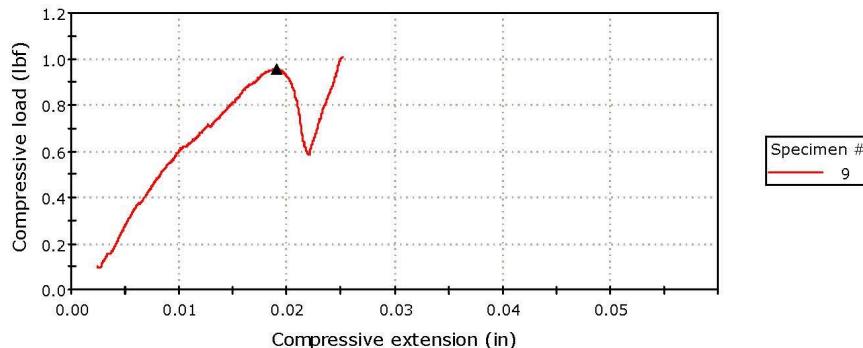


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	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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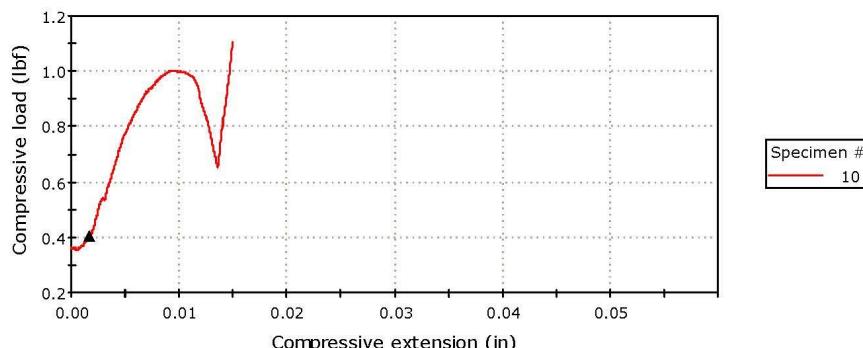
Wednesday, January 29, 2020

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Specimen 9 to 9



Specimen 10 to 10

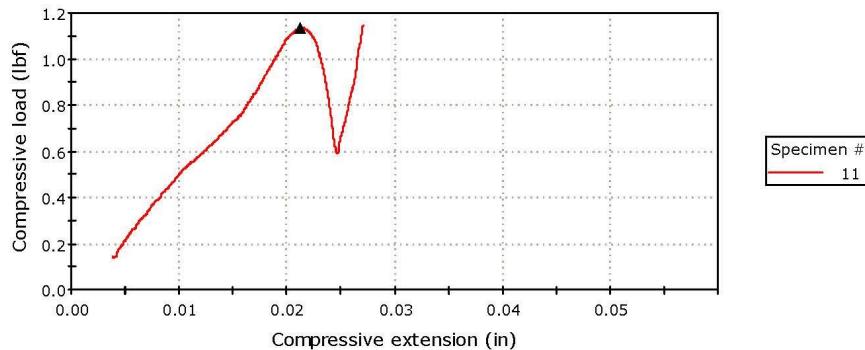


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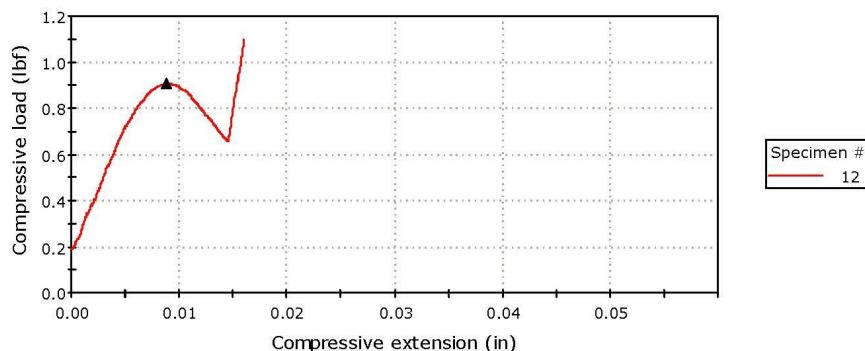
Wednesday, January 29, 2020

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Specimen 11 to 11



Specimen 12 to 12

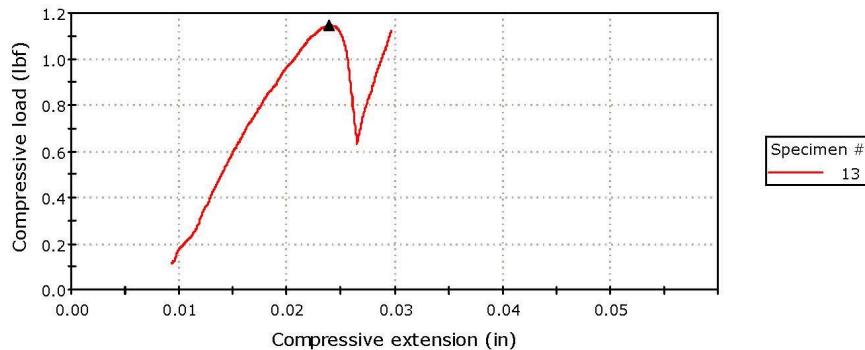


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	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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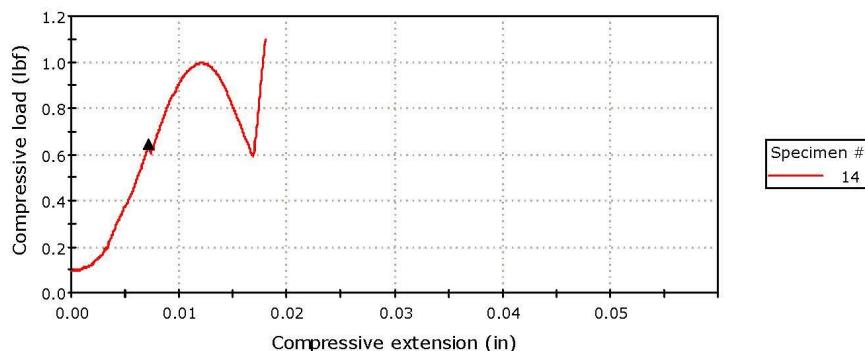
Wednesday, January 29, 2020

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Specimen 13 to 13



Specimen 14 to 14

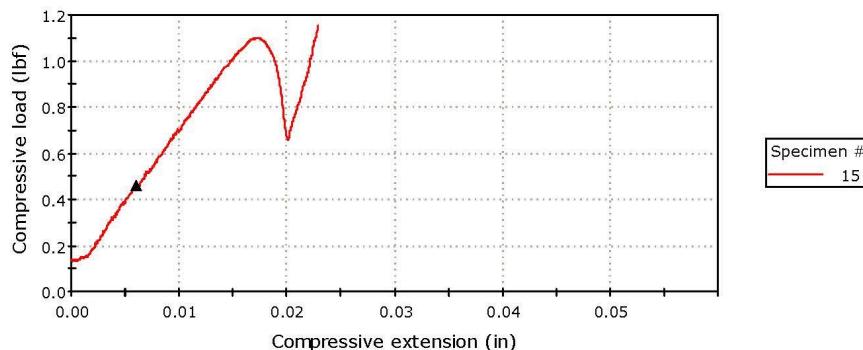


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	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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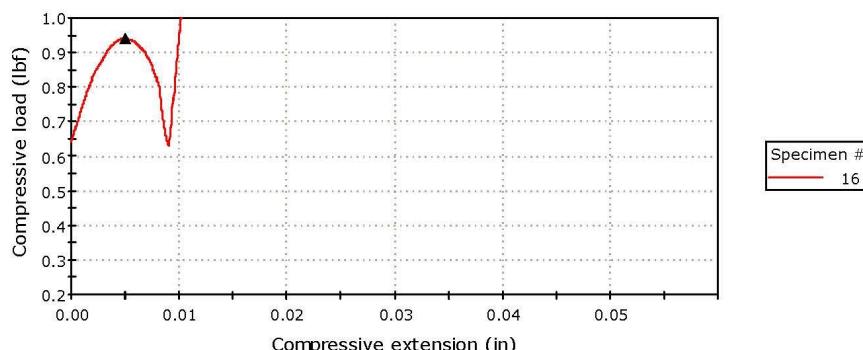
Wednesday, January 29, 2020

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Specimen 15 to 15



Specimen 16 to 16

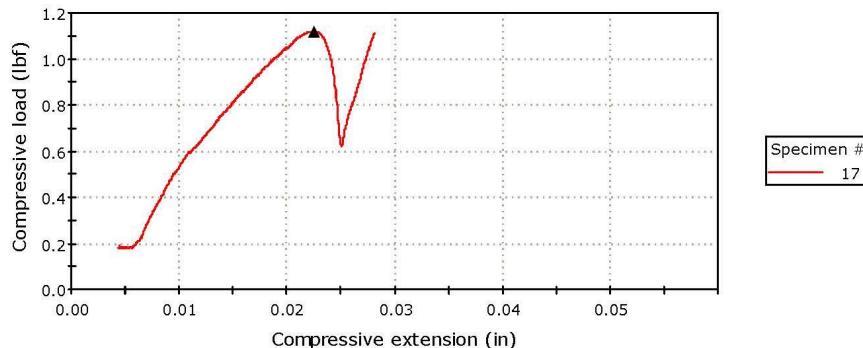


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	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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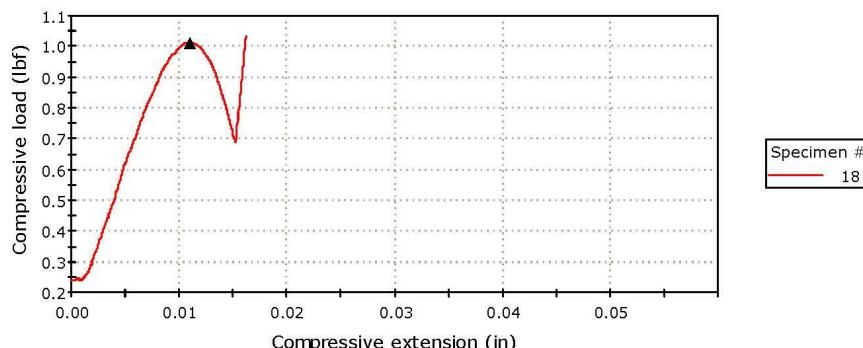
Wednesday, January 29, 2020

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Specimen 17 to 17



Specimen 18 to 18

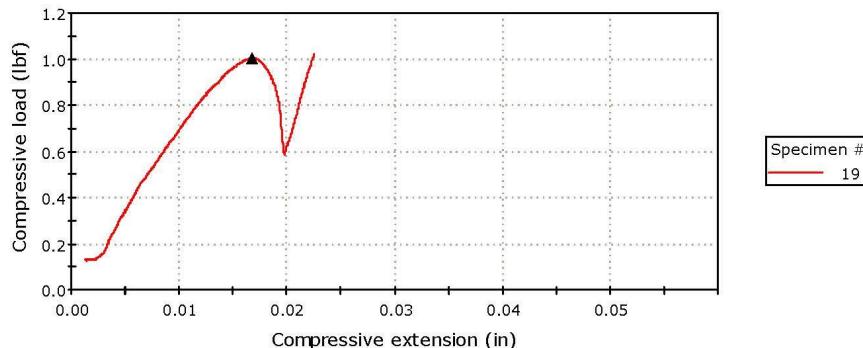


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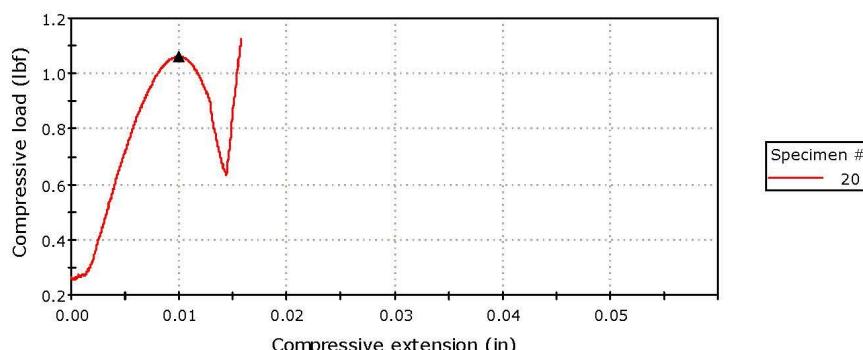
Wednesday, January 29, 2020

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Specimen 19 to 19



Specimen 20 to 20

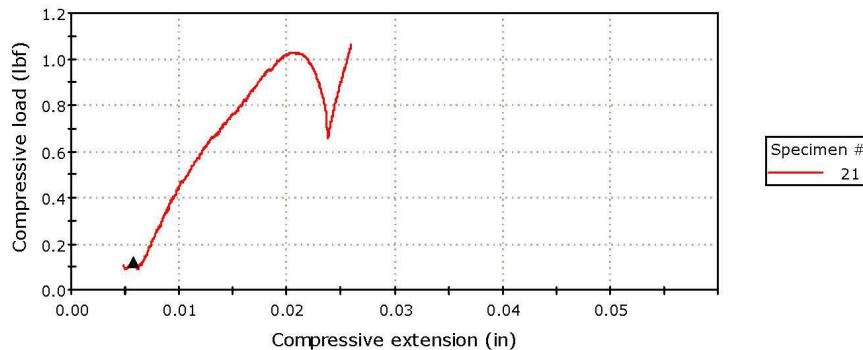


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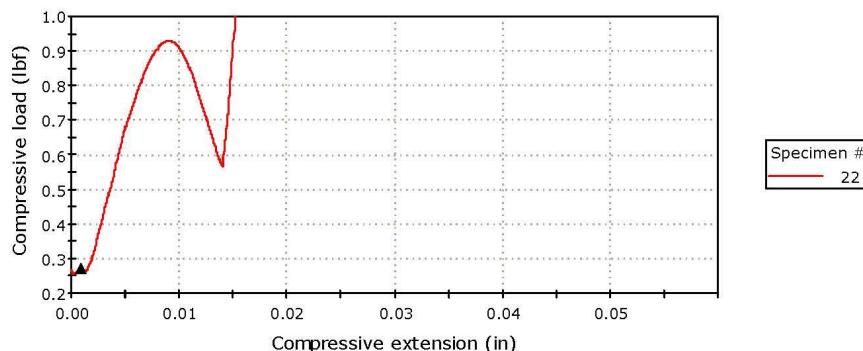
Wednesday, January 29, 2020

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Specimen 21 to 21



Specimen 22 to 22

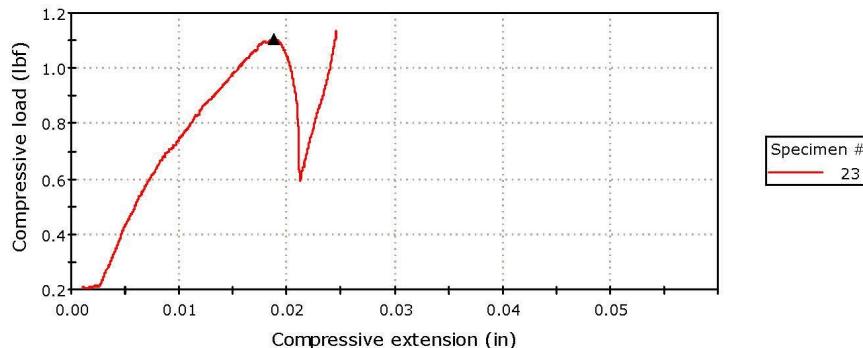


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	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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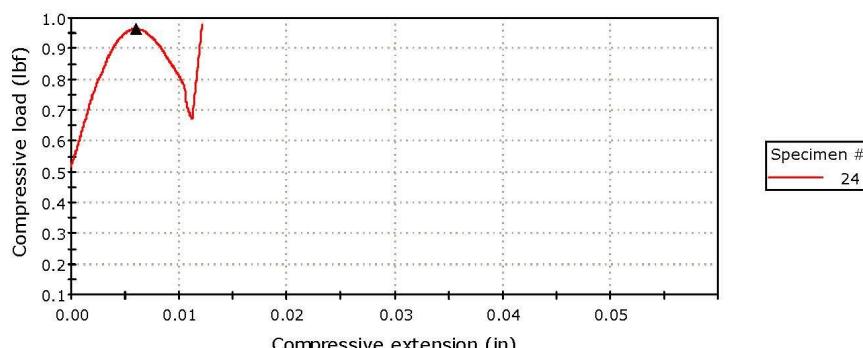
Wednesday, January 29, 2020

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Specimen 23 to 23



Specimen 24 to 24

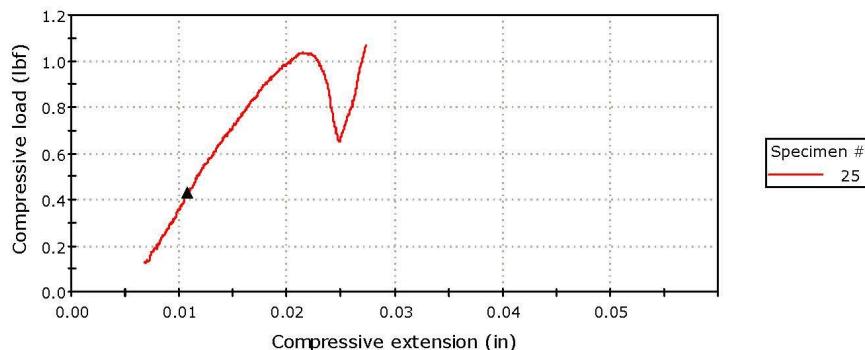


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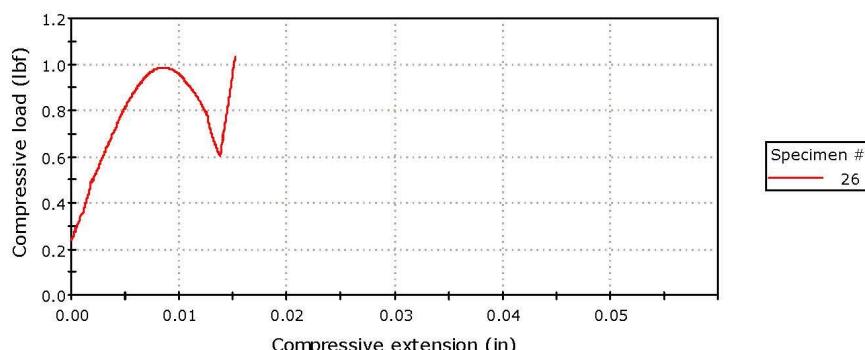
Wednesday, January 29, 2020

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Specimen 25 to 25



Specimen 26 to 26

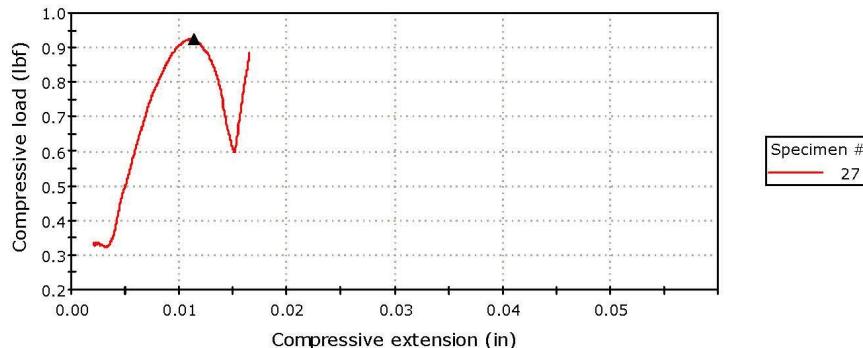


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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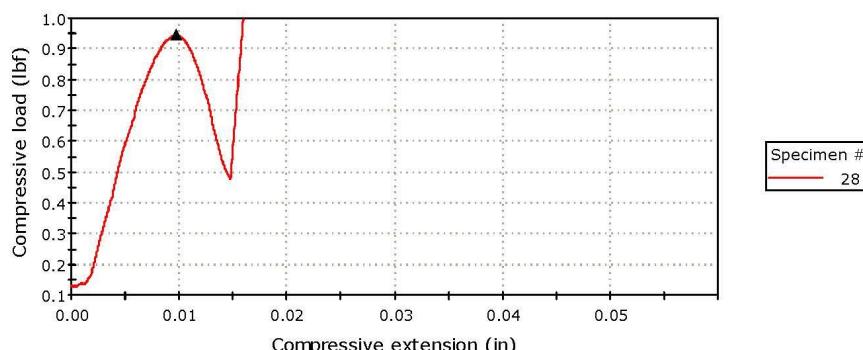
Wednesday, January 29, 2020

ZC.is\_comp

Specimen 27 to 27



Specimen 28 to 28

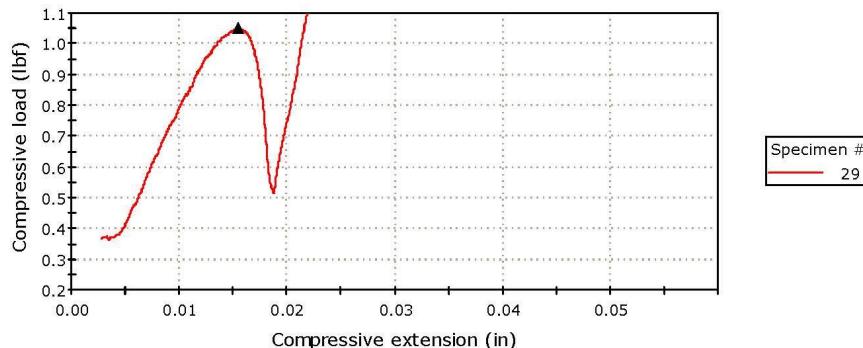


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	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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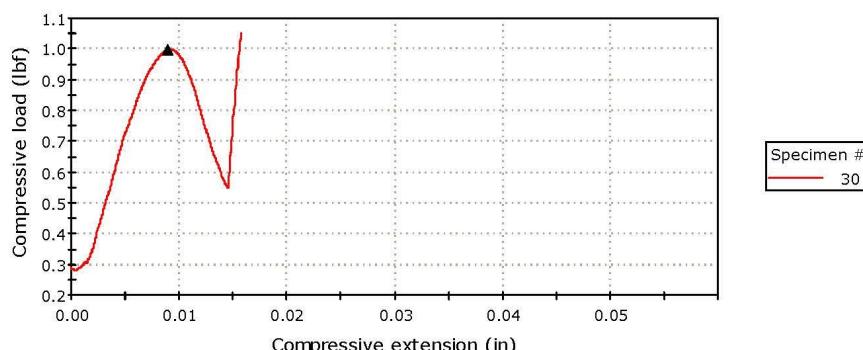
Wednesday, January 29, 2020

ZC.is\_comp

Specimen 29 to 29



Specimen 30 to 30

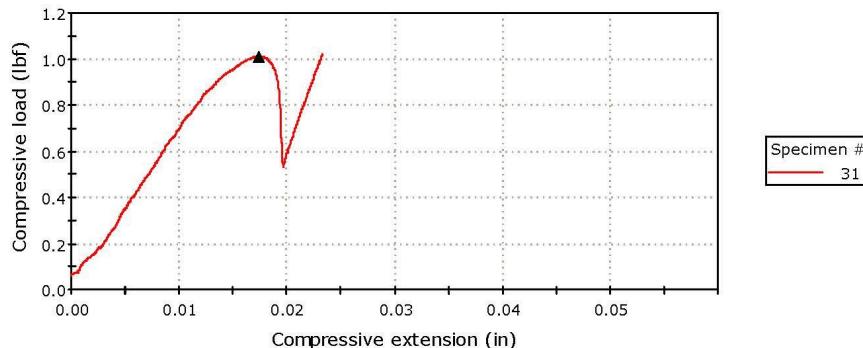


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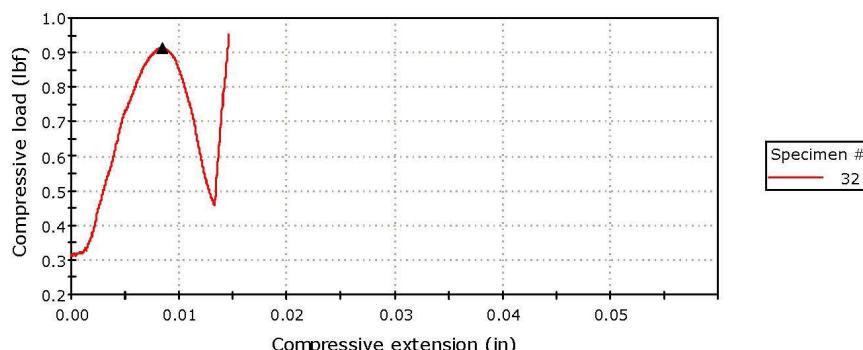
Wednesday, January 29, 2020

ZC.is\_comp

Specimen 31 to 31



Specimen 32 to 32

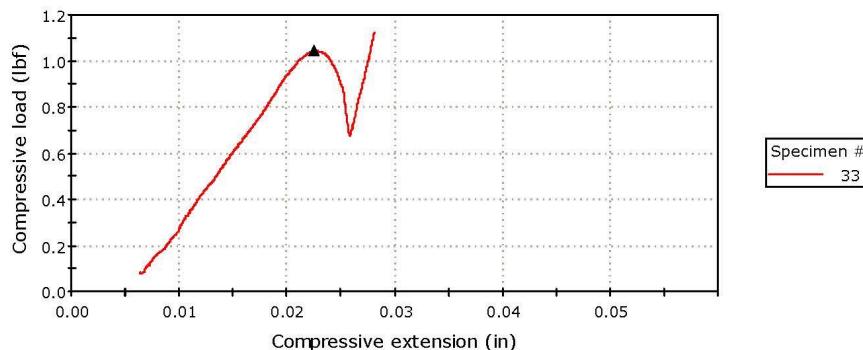


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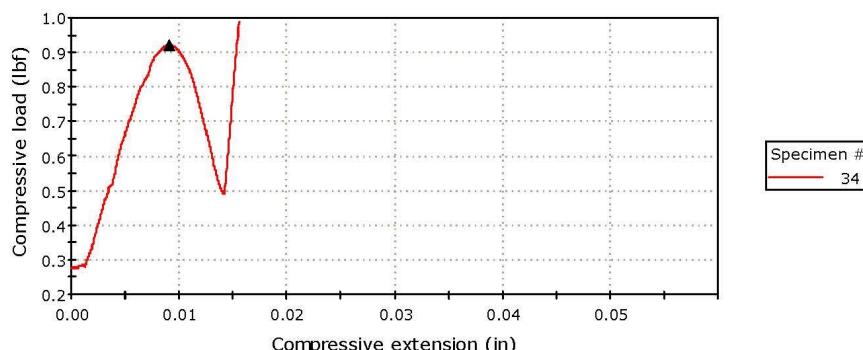
Wednesday, January 29, 2020

ZC.is\_comp

Specimen 33 to 33



Specimen 34 to 34

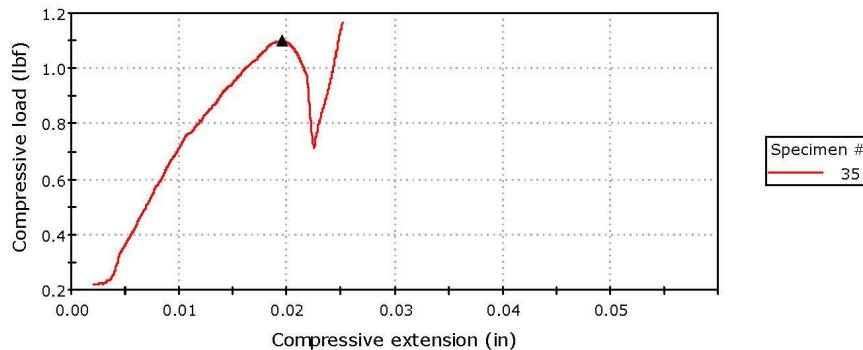


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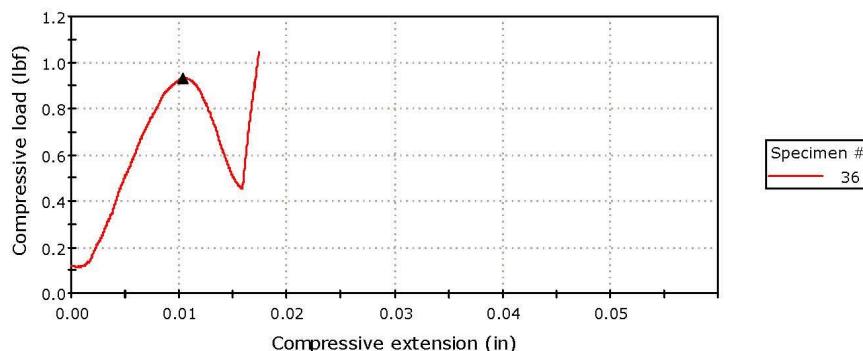
Wednesday, January 29, 2020

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Specimen 35 to 35



Specimen 36 to 36

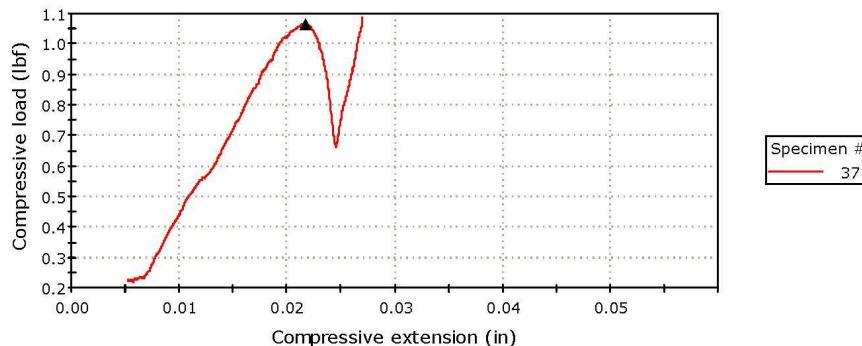


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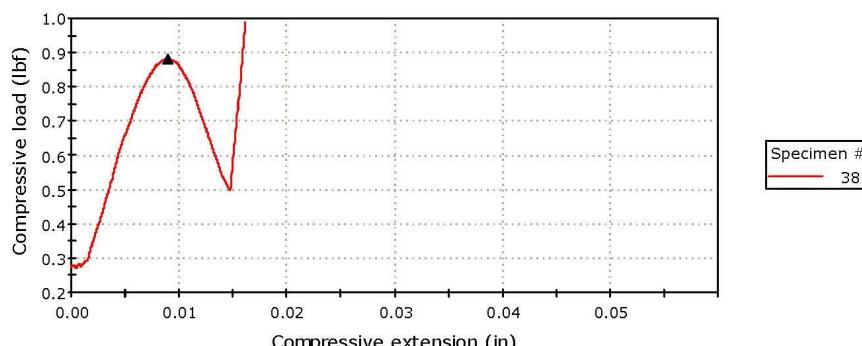
Wednesday, January 29, 2020

ZC.is\_comp

Specimen 37 to 37



Specimen 38 to 38

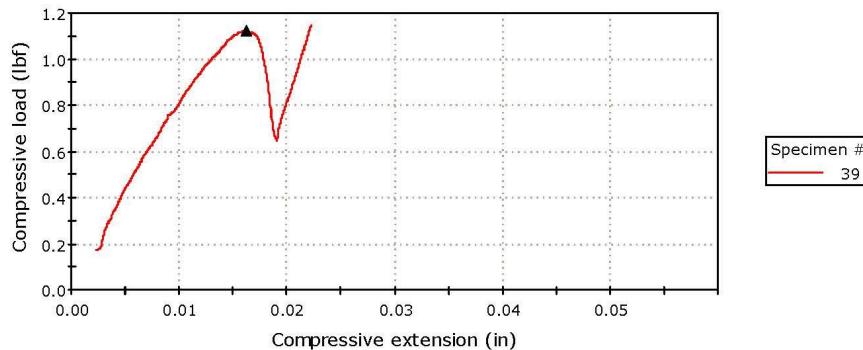


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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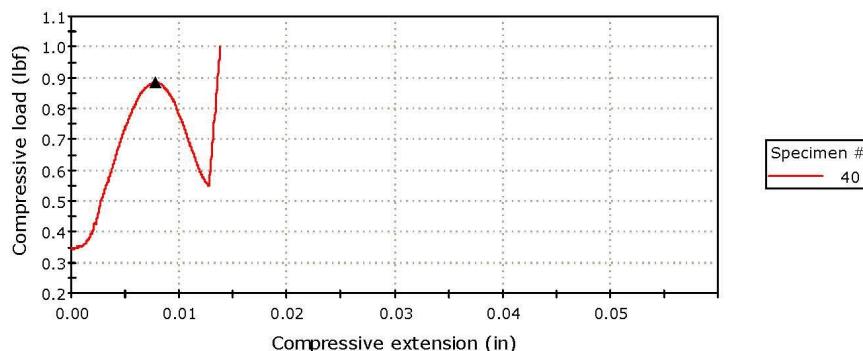
Wednesday, January 29, 2020

ZC.is\_comp

Specimen 39 to 39



Specimen 40 to 40

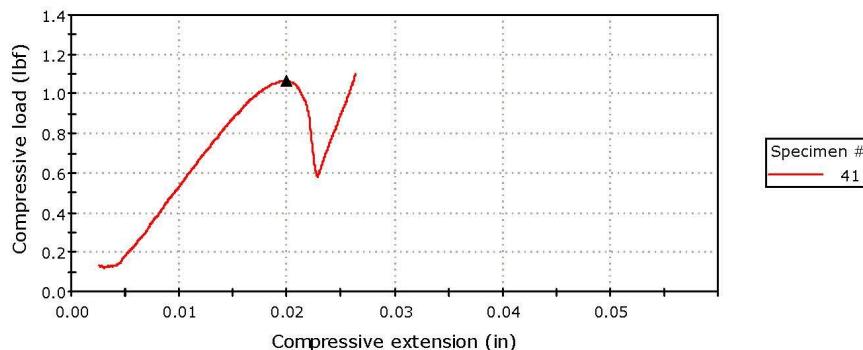


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	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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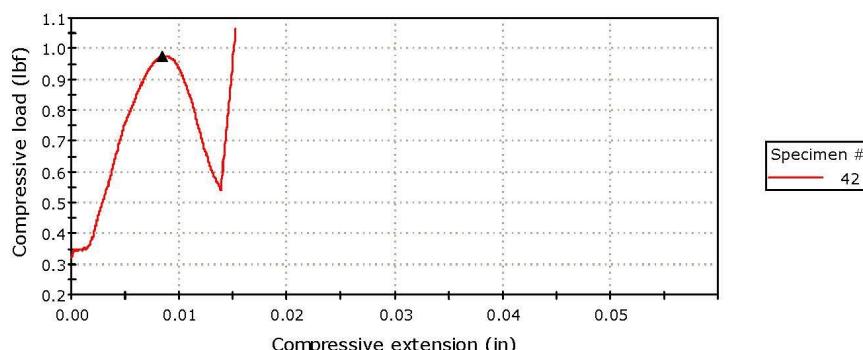
Wednesday, January 29, 2020

ZC.is\_comp

Specimen 41 to 41



Specimen 42 to 42

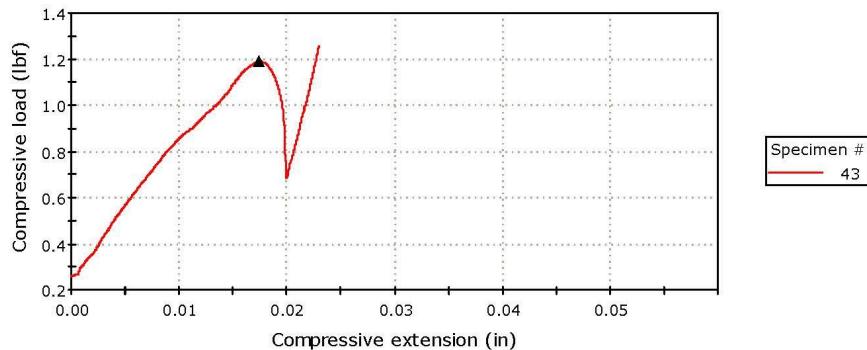


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	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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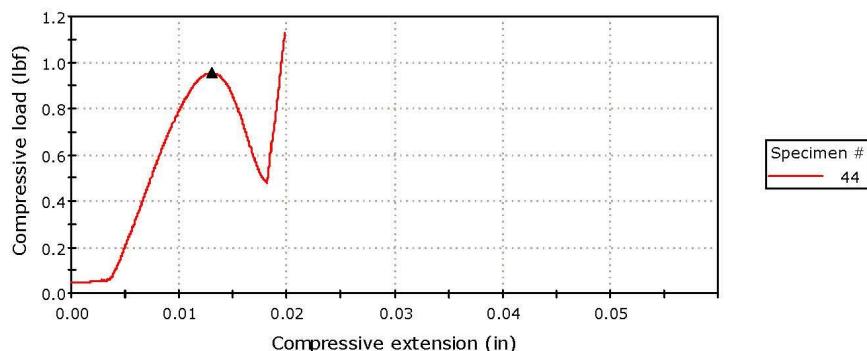
Wednesday, January 29, 2020

ZC.is\_comp

Specimen 43 to 43



Specimen 44 to 44

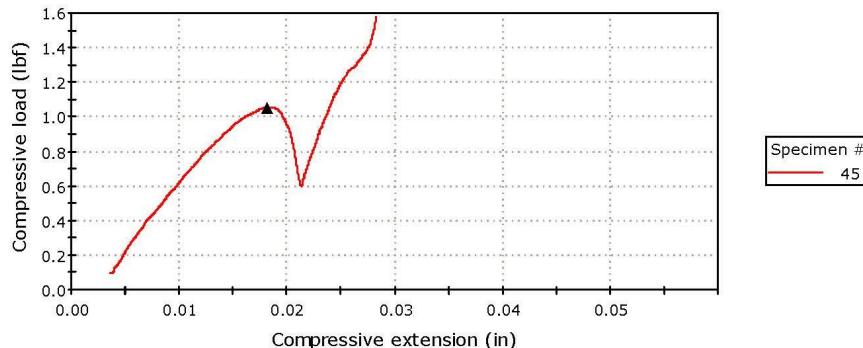


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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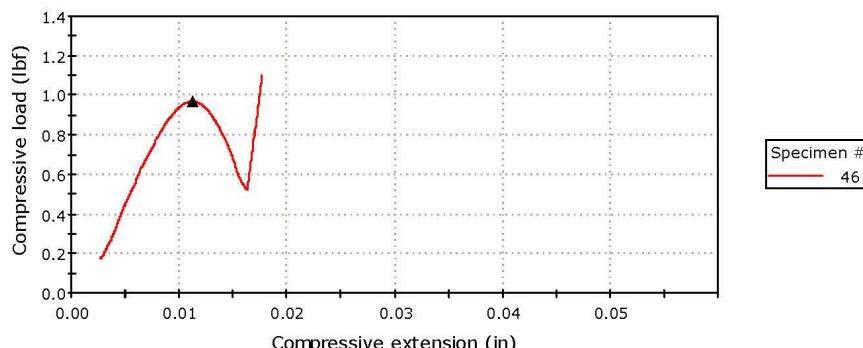
Wednesday, January 29, 2020

ZC.is\_comp

Specimen 45 to 45



Specimen 46 to 46

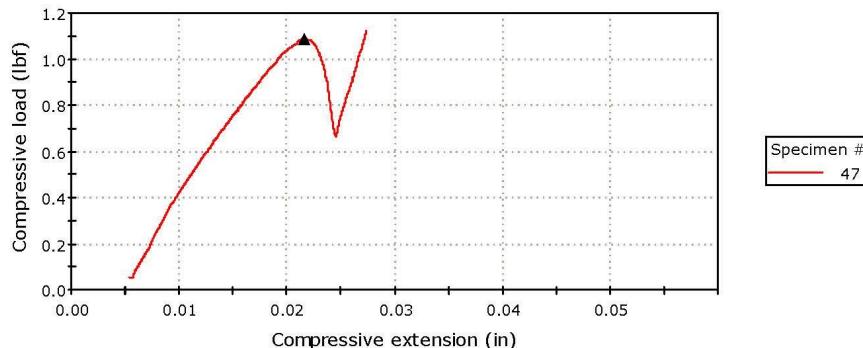


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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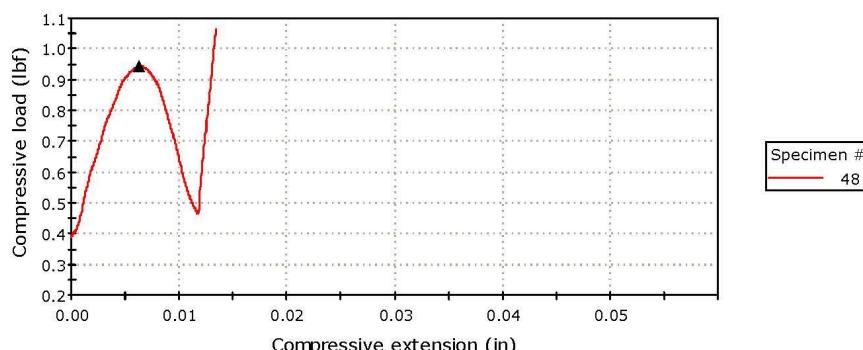
Wednesday, January 29, 2020

ZC.is\_comp

Specimen 47 to 47



Specimen 48 to 48

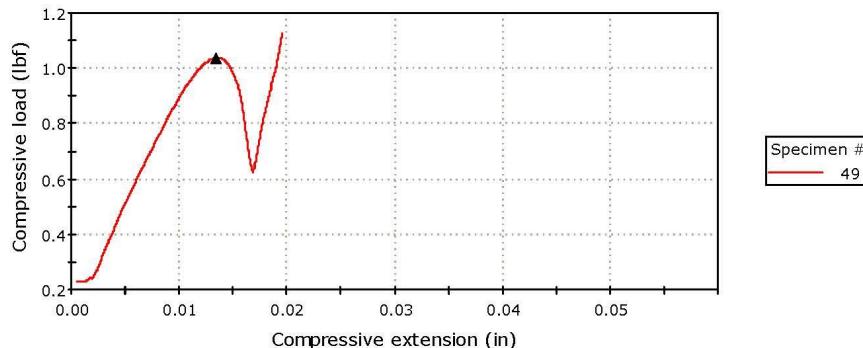


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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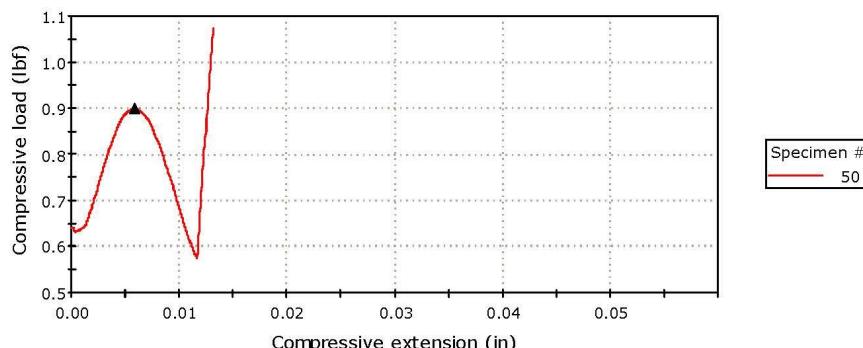
Wednesday, January 29, 2020

ZC.is\_comp

Specimen 49 to 49



Specimen 50 to 50

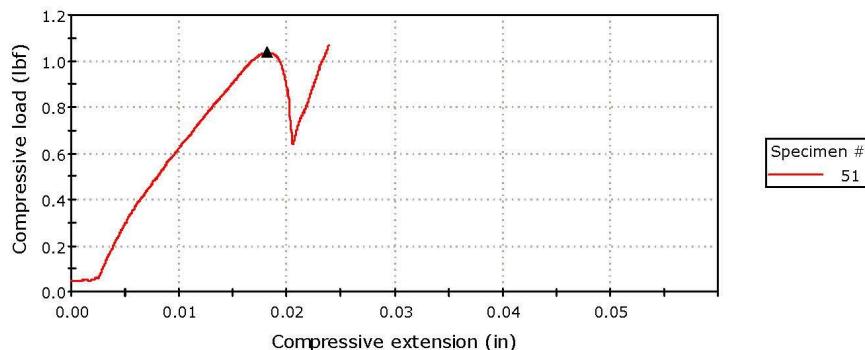


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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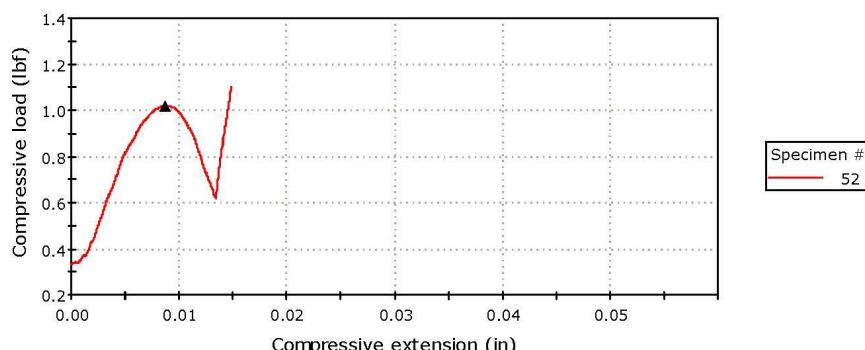
Wednesday, January 29, 2020

ZC.is\_comp

Specimen 51 to 51



Specimen 52 to 52

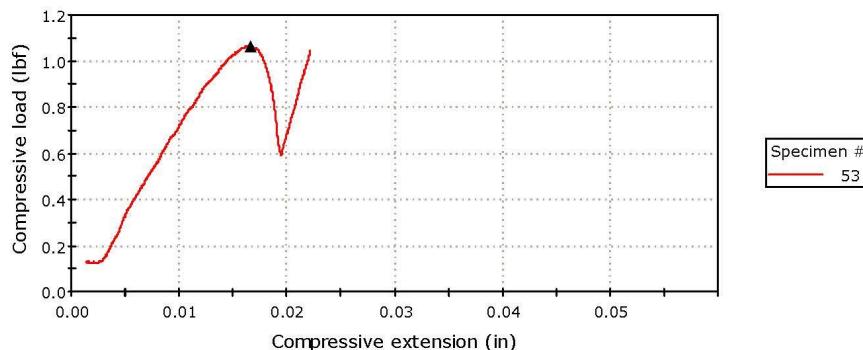


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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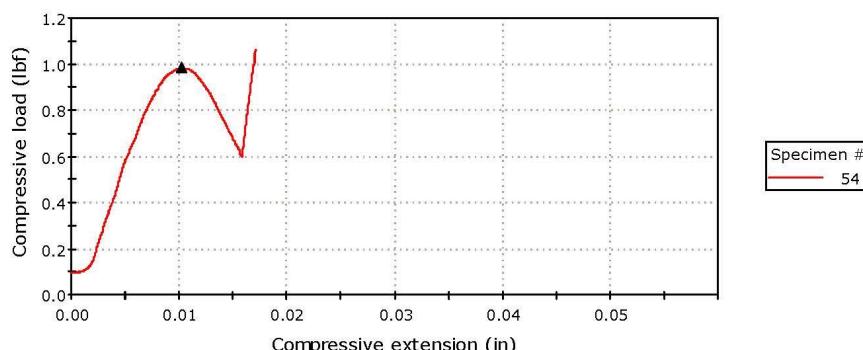
Wednesday, January 29, 2020

ZC.is\_comp

Specimen 53 to 53



Specimen 54 to 54

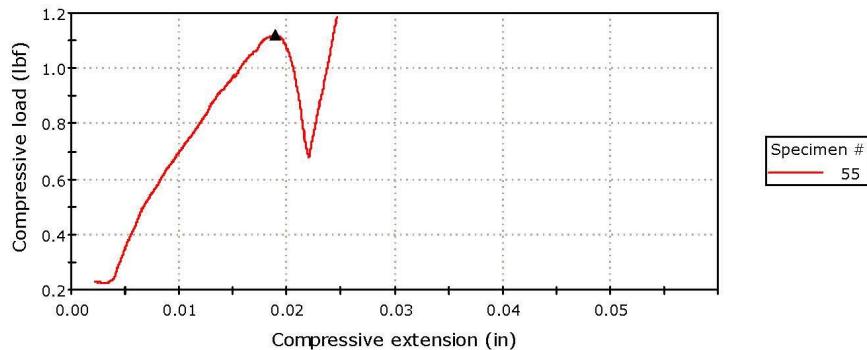


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	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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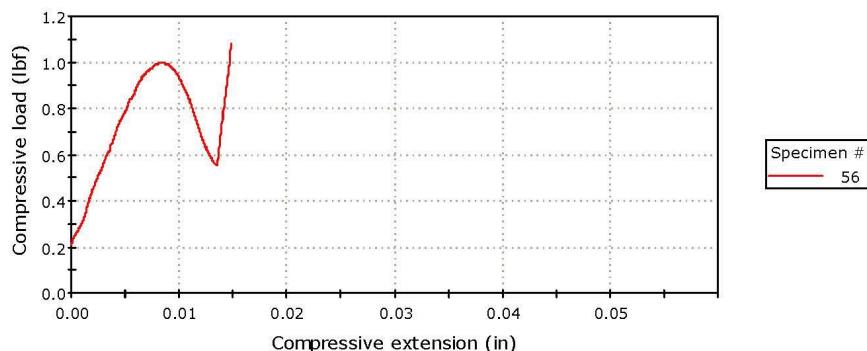
Wednesday, January 29, 2020

ZC.is\_comp

Specimen 55 to 55



Specimen 56 to 56

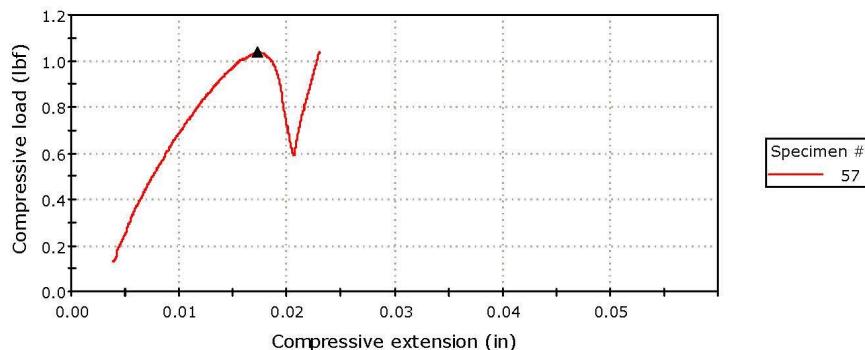


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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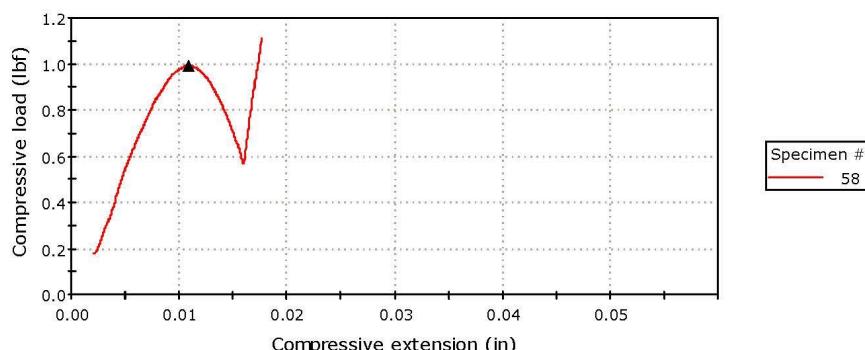
Wednesday, January 29, 2020

ZC.is\_comp

Specimen 57 to 57



Specimen 58 to 58

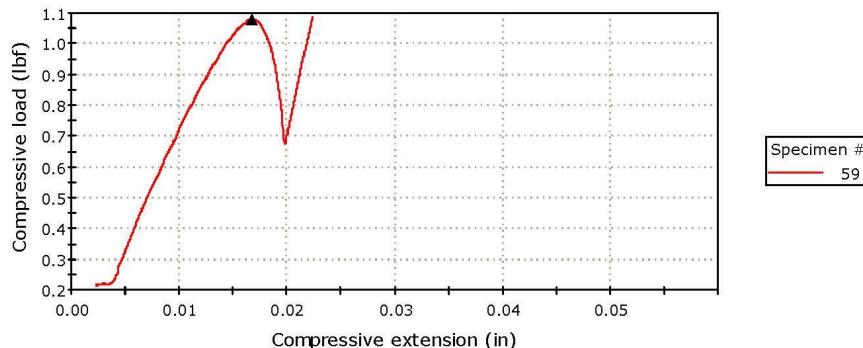


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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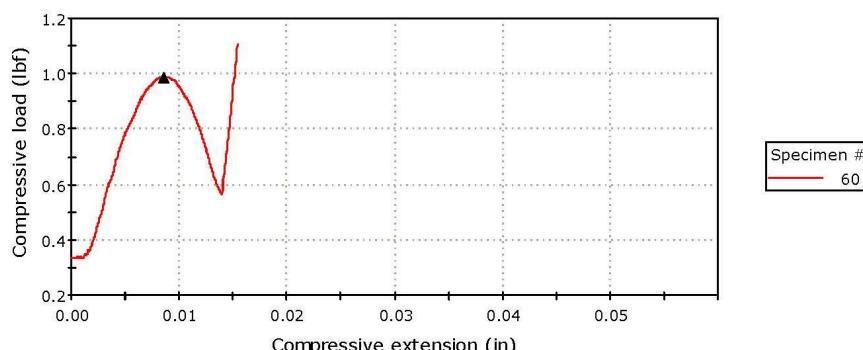
Wednesday, January 29, 2020

ZC.is\_comp

Specimen 59 to 59



Specimen 60 to 60



<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
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AC.is\_comp

	Compressive load at Preset Point (Cursor ) (lbf)	Specimen label	Notes
1	1.03170	A.C.01-COAG	
2	0.98794	A.C.01-CUT	
3	1.13761	A.C.02-COAG	
4	0.94419	A.C.02-CUT	
5	1.06006	A.C.03-COAG	
6	0.91250	A.C.03-CUT	
7	1.05825	A.C.04-COAG	
8	0.96863	A.C.04-CUT	
9	1.00997	A.C.05-COAG	
10	1.00182	A.C.05-CUT	
11	1.05251	A.C.07-COAG	
12	0.91612	A.C.07-CUT	
13	1.11588	A.C.08-COAG	
14	0.98915	A.C.08-CUT	
15	1.00273	A.C.08-COAG	
16	0.99156	A.C.08-CUT	
17	1.08390	A.C.09-COAG	
18	0.99096	A.C.09-CUT	
19	1.09899	A.C.10-COAG	
20	0.99186	A.C.10-CUT	
21	1.04256	A.C.11-COAG	
22	0.95776	A.C.11-CUT	
23	1.10744	A.C.12-COAG	
24	0.97527	A.C.12-CUT	
25	1.09054	A.C.13-COAG	
26	0.95595	A.C.13-CUT	
27	1.05523	A.C.14-COAG	
28	0.91160	A.C.14-CUT	
29	1.03139	A.C.15-COAG	
30	0.94147	A.C.15-CUT	
31	0.95746	A.C.16-COAG	
32	0.84129	A.C.16-CUT	
33	1.09476	A.C.17-COAG	
34	0.93242	A.C.17-CUT	
35	1.00605	A.C.18-COAG	
36	0.92638	A.C.18-CUT	
37	1.04105	A.C.19-COAG	
38	0.99096	A.C.19-CUT	
39	1.02113	A.C.20-COAG	
40	0.93695	A.C.20-CUT	
41	1.01208	A.C.21-COAG	
42	0.96229	A.C.21-CUT	
43	1.03170	A.C.22-COAG	
44	0.96289	A.C.22-CUT	
45	1.05795	A.C.23-COAG	
46	0.97587	A.C.23-CUT	
47	0.99096	A.C.24-COAG	
48	0.95626	A.C.24-CUT	
49	-----	A.C.24-COAG	
50	1.07364	A.C.25-COAG	
51	1.02536	A.C.25-CUT	
52	1.05101	A.C.26-COAG	
53	0.92789	A.C.26-CUT	
54	1.12071	A.C.27-COAG	
55	0.91371	A.C.27-CUT	
56	1.08330	A.C.28-COAG	
57	0.96622	A.C.28-CUT	
58	1.05976	A.C.29-COAG	
59	0.85215	A.C.29-CUT	
60	1.09537	A.C.30-COAG	
61	0.94992	A.C.30-CUT	

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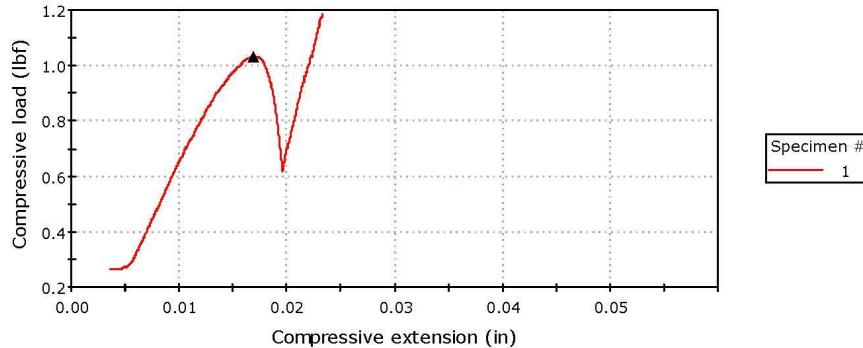
<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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AC.is\_comp

	Compressive load at Preset Point (Cursor ) (lbf)	Specimen label	Notes
Maximum	1.13761		
Minimum	0.84129		
Mean	1.00388		
Standard Deviation	0.07		

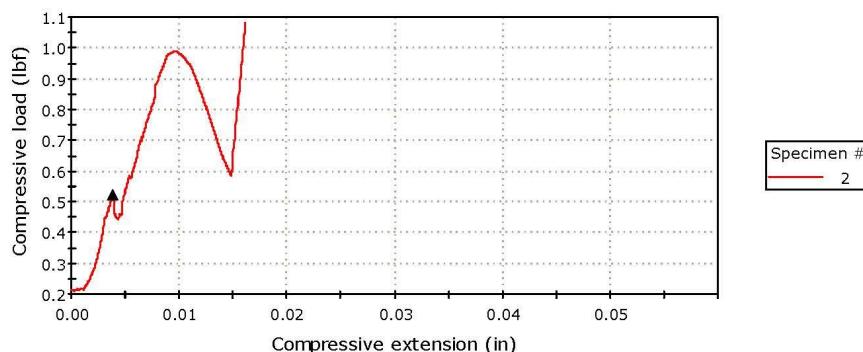
Specimen 1 to 1



Specimen #

1

Specimen 2 to 2



Specimen #

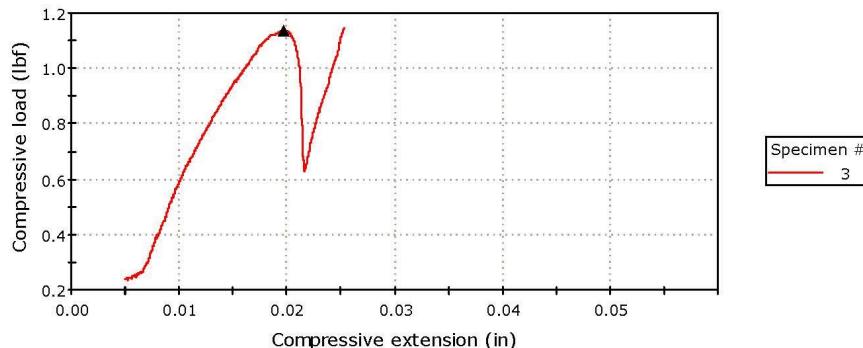
2

<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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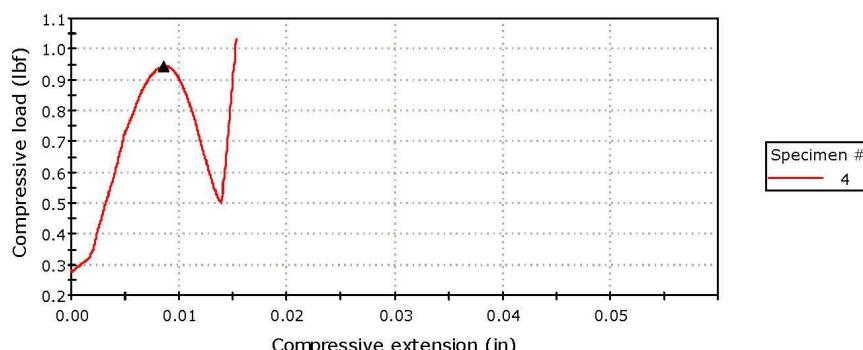
Wednesday, January 29, 2020

AC.is\_comp

Specimen 3 to 3



Specimen 4 to 4

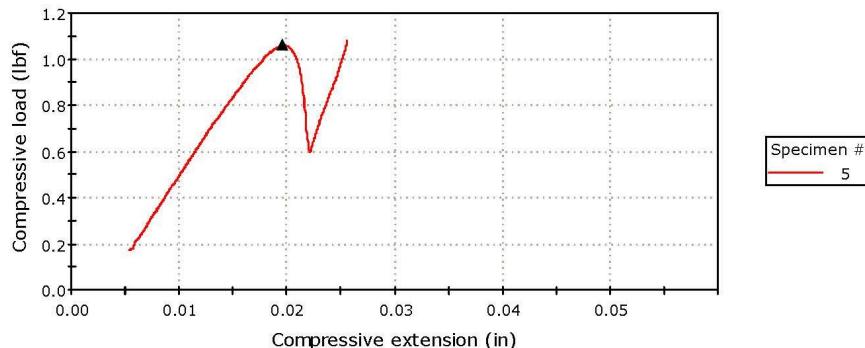


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
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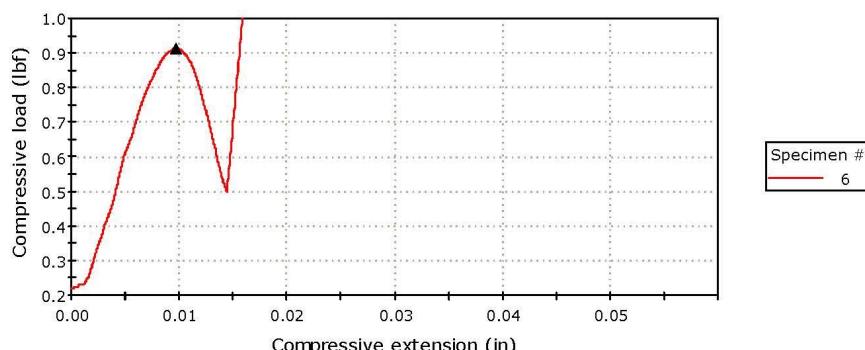
Wednesday, January 29, 2020

AC.is\_comp

Specimen 5 to 5



Specimen 6 to 6

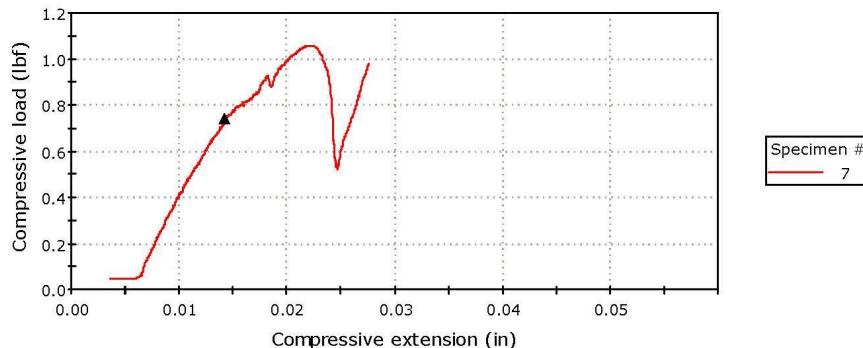


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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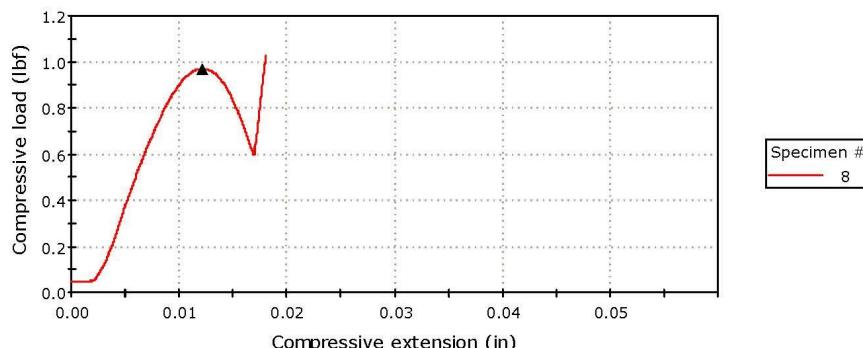
AC.is\_comp

Specimen 7 to 7



Specimen #  
7

Specimen 8 to 8



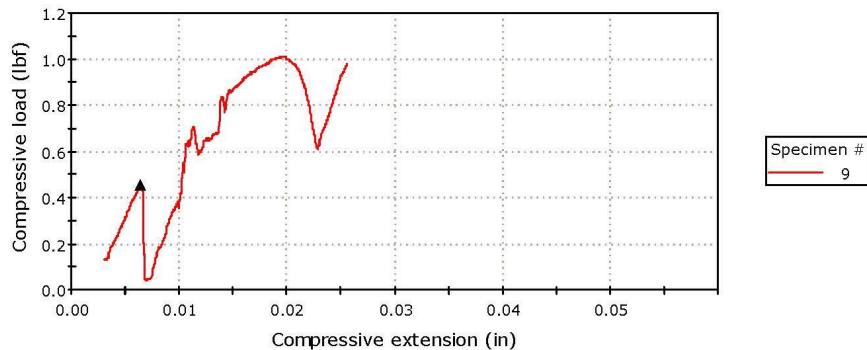
Specimen #  
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<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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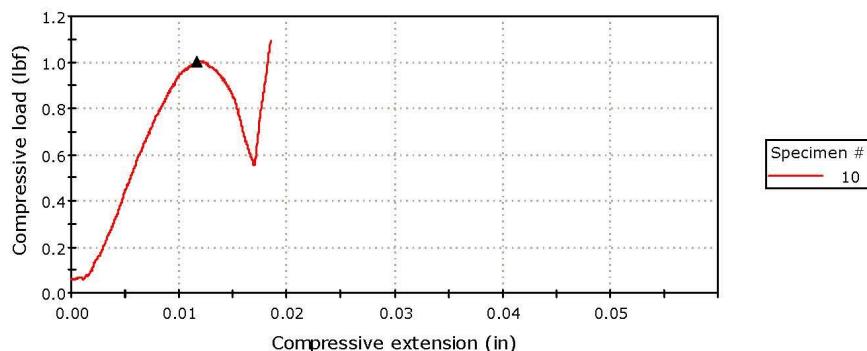
Wednesday, January 29, 2020

AC.is\_comp

Specimen 9 to 9



Specimen 10 to 10

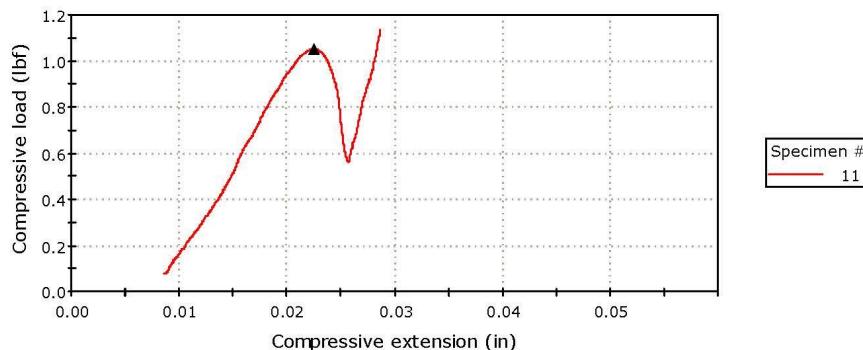


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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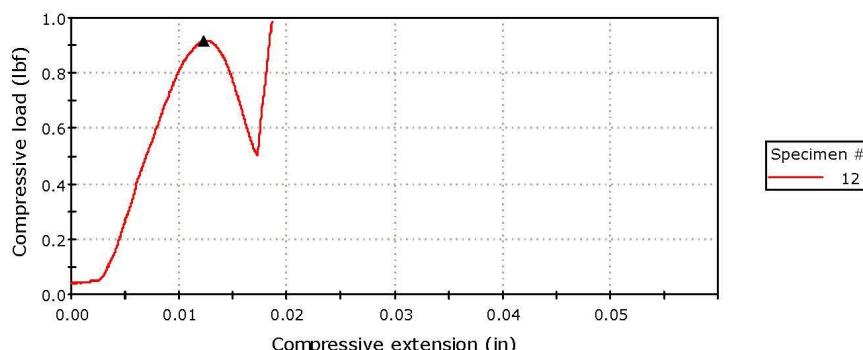
Wednesday, January 29, 2020

AC.is\_comp

Specimen 11 to 11



Specimen 12 to 12

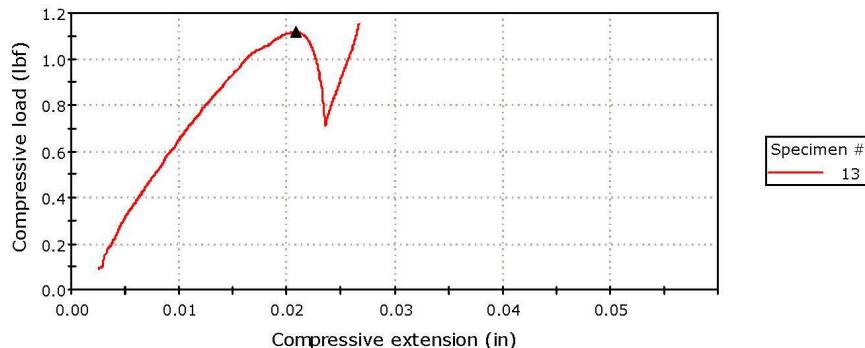


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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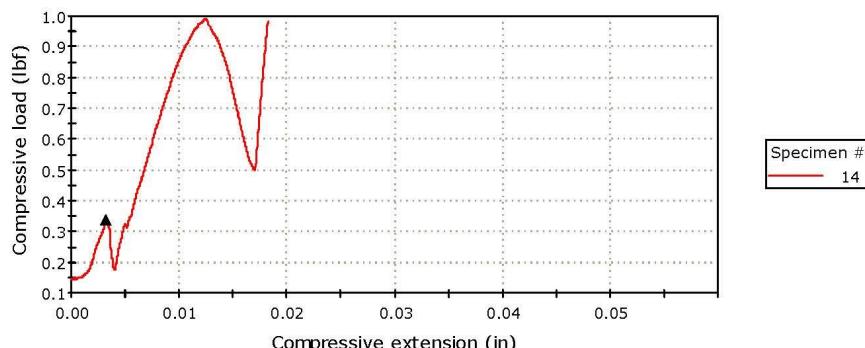
Wednesday, January 29, 2020

AC.is\_comp

Specimen 13 to 13



Specimen 14 to 14

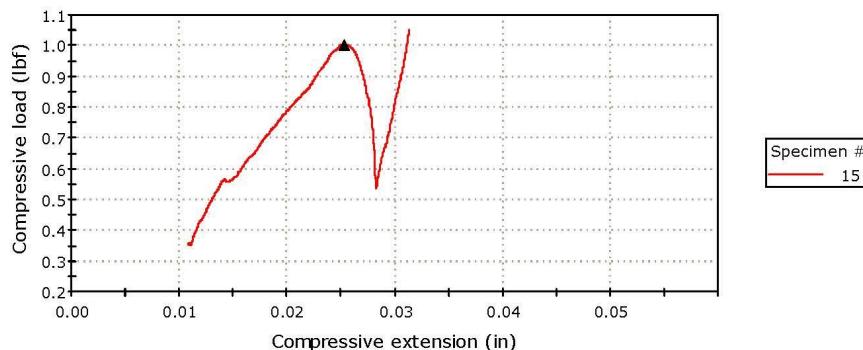


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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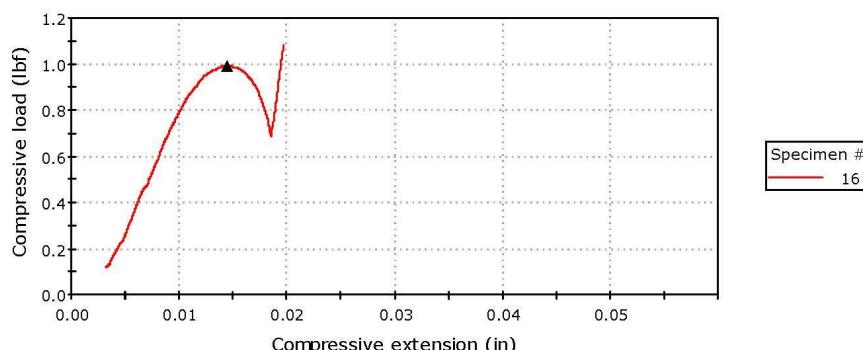
Wednesday, January 29, 2020

AC.is\_comp

Specimen 15 to 15



Specimen 16 to 16

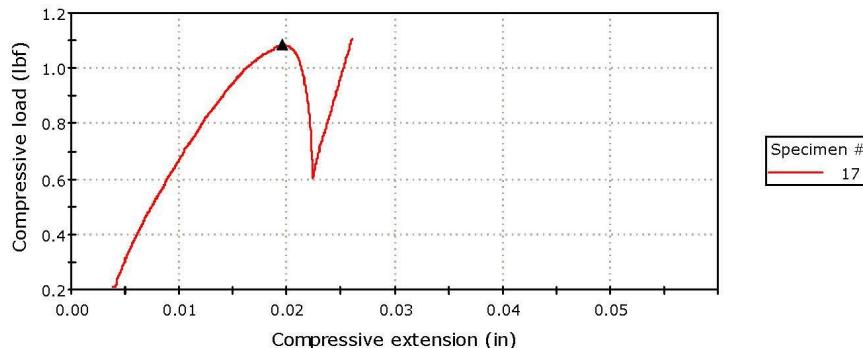


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
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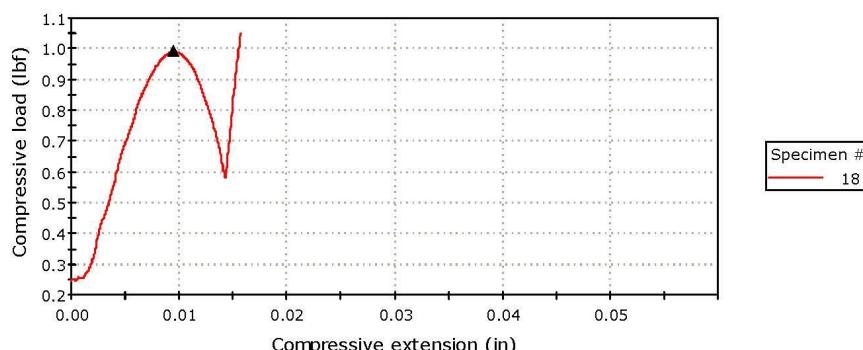
Wednesday, January 29, 2020

AC.is\_comp

Specimen 17 to 17



Specimen 18 to 18

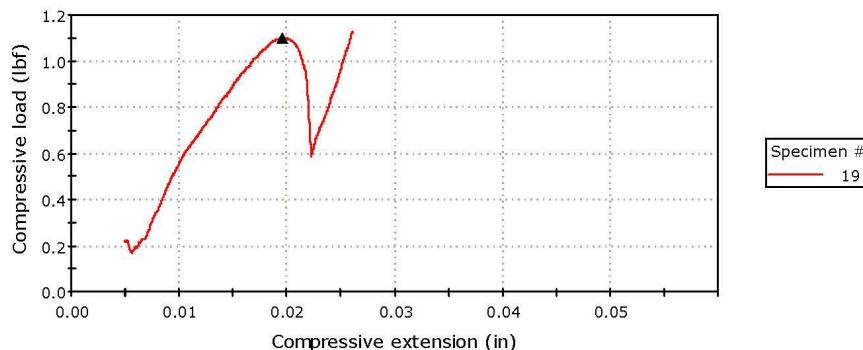


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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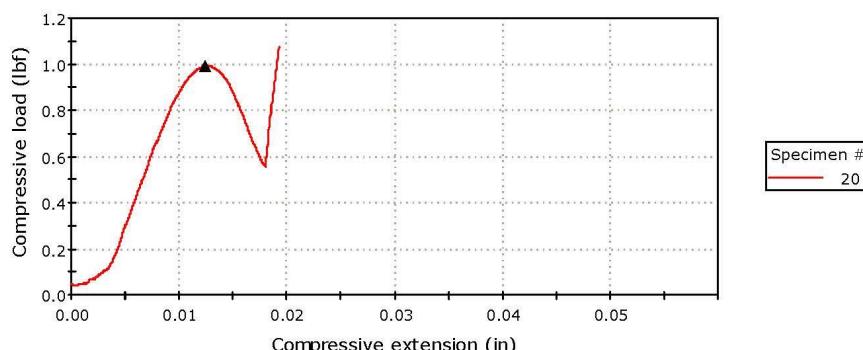
Wednesday, January 29, 2020

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**Specimen 19 to 19**



**Specimen 20 to 20**

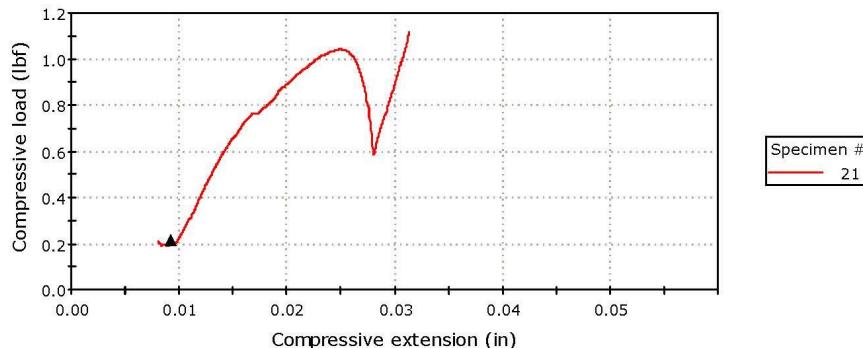


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
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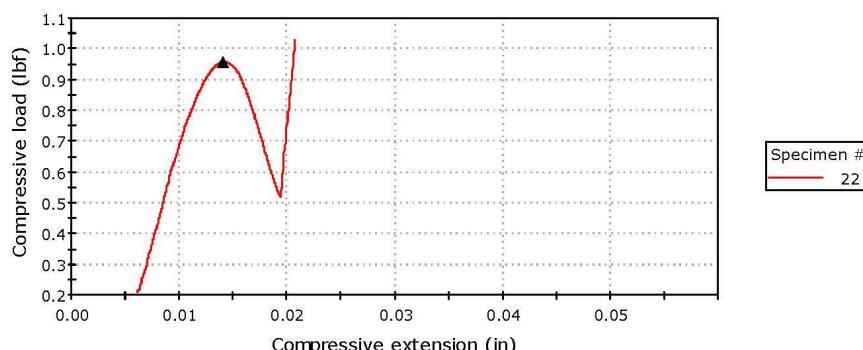
AC.is\_comp

Specimen 21 to 21



Specimen #  
21

Specimen 22 to 22



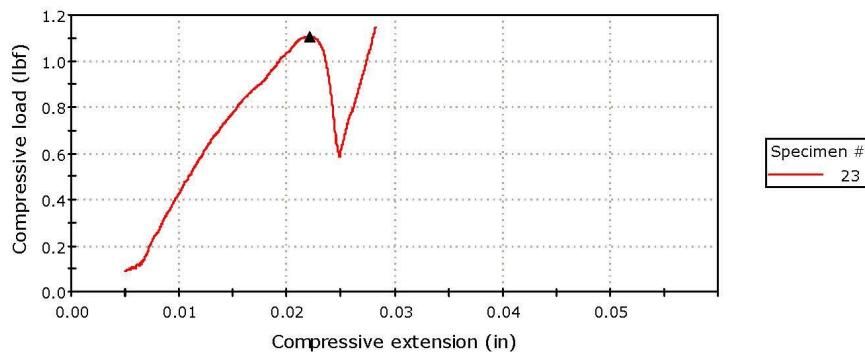
Specimen #  
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<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
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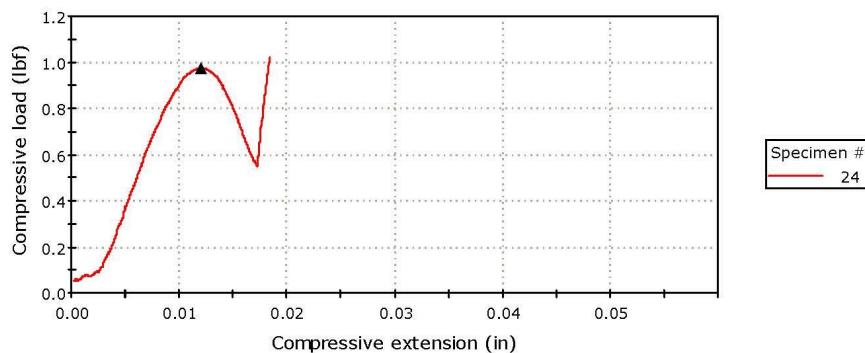
Wednesday, January 29, 2020

AC.is\_comp

Specimen 23 to 23



Specimen 24 to 24

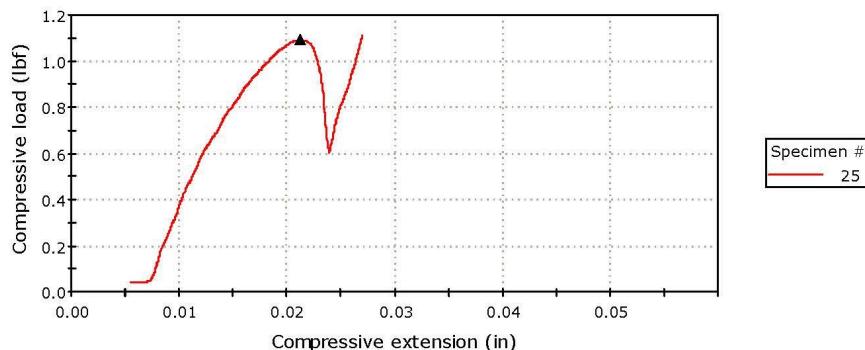


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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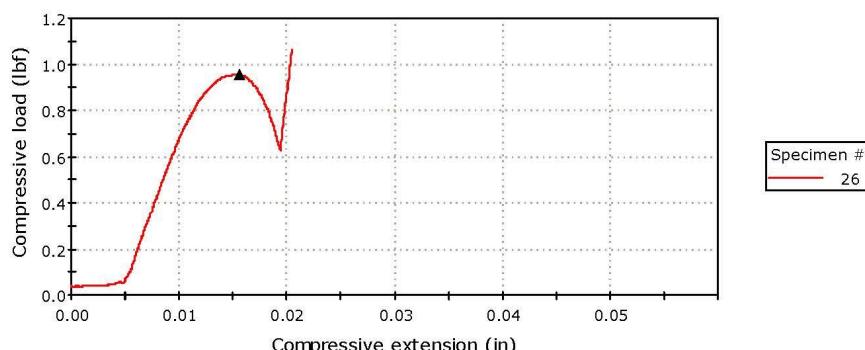
Wednesday, January 29, 2020

AC.is\_comp

Specimen 25 to 25



Specimen 26 to 26

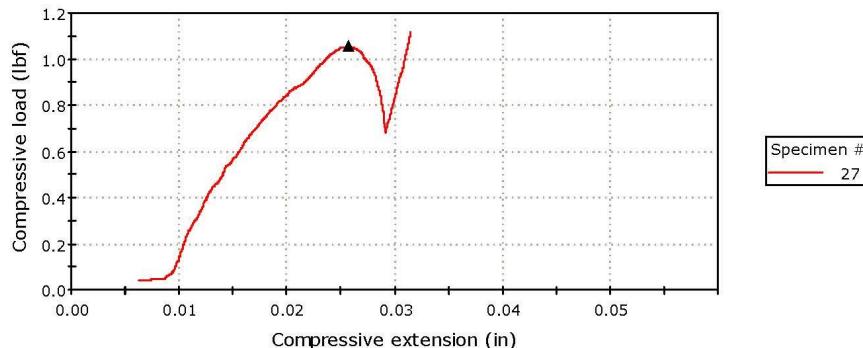


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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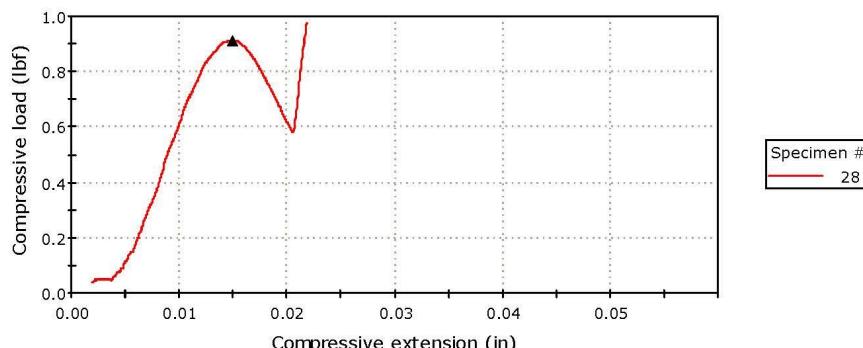
Wednesday, January 29, 2020

AC.is\_comp

Specimen 27 to 27



Specimen 28 to 28

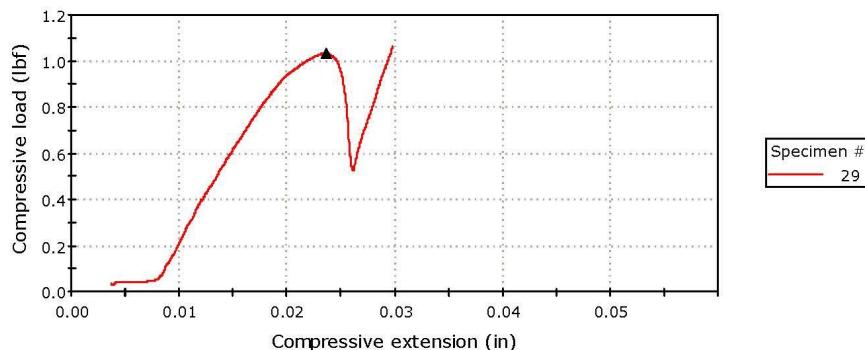


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
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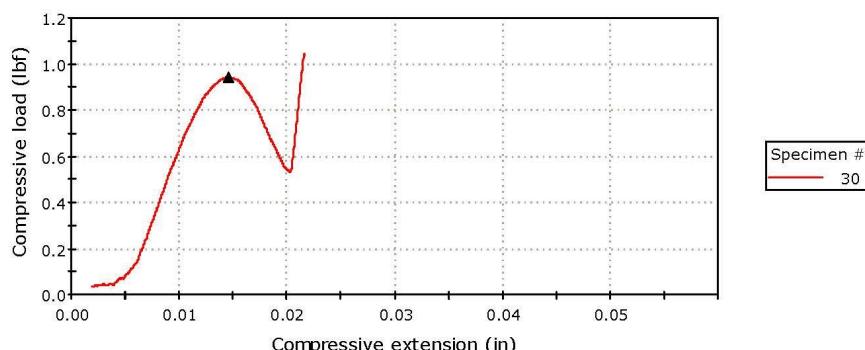
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AC.is\_comp

Specimen 29 to 29



Specimen 30 to 30

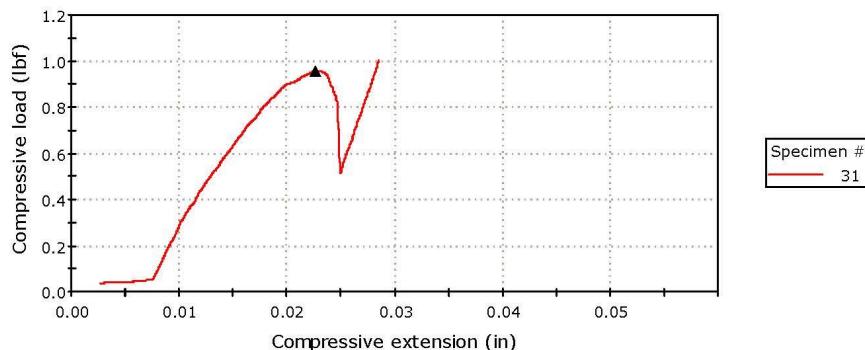


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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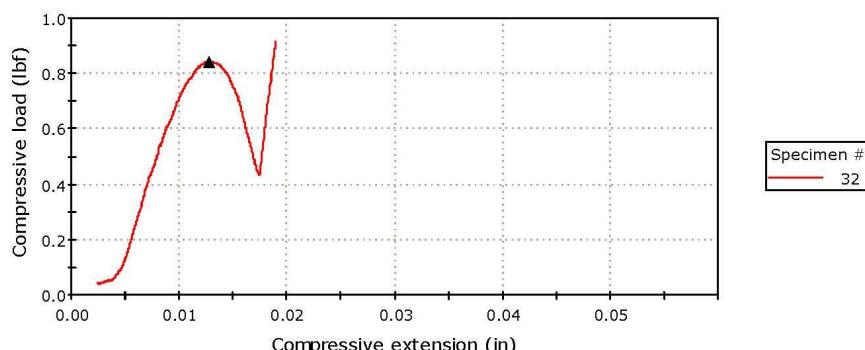
Wednesday, January 29, 2020

AC.is\_comp

Specimen 31 to 31



Specimen 32 to 32

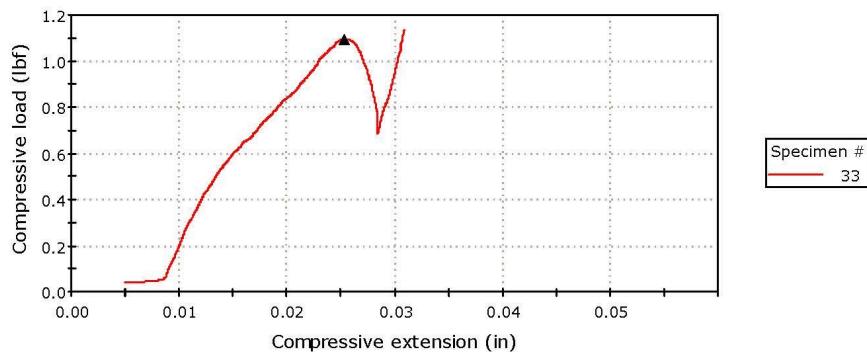


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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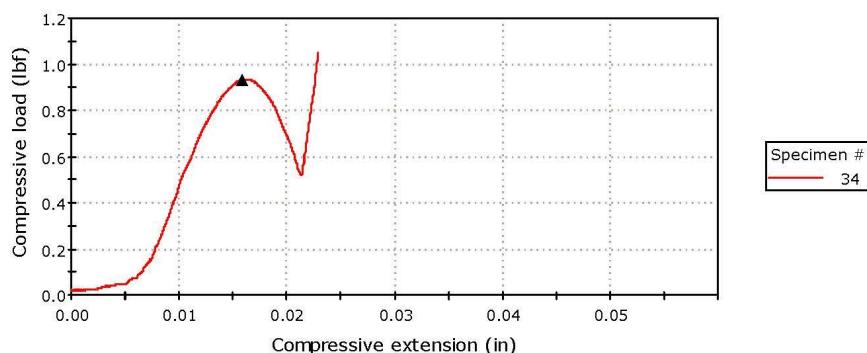
Wednesday, January 29, 2020

AC.is\_comp

Specimen 33 to 33



Specimen 34 to 34

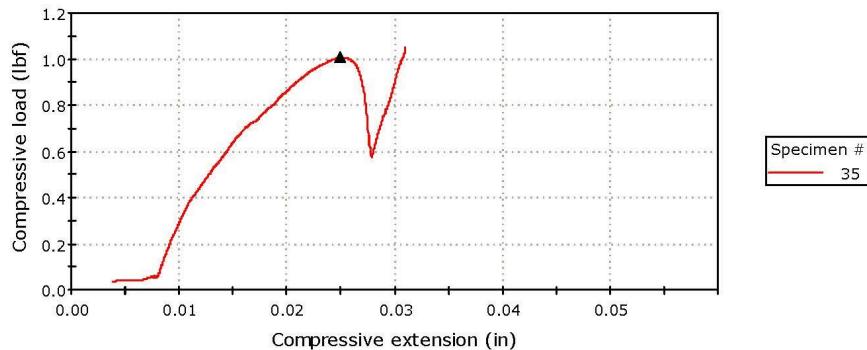


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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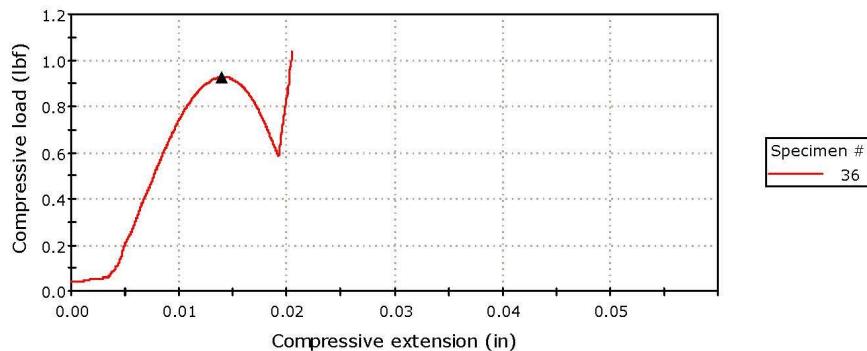
Wednesday, January 29, 2020

AC.is\_comp

Specimen 35 to 35



Specimen 36 to 36

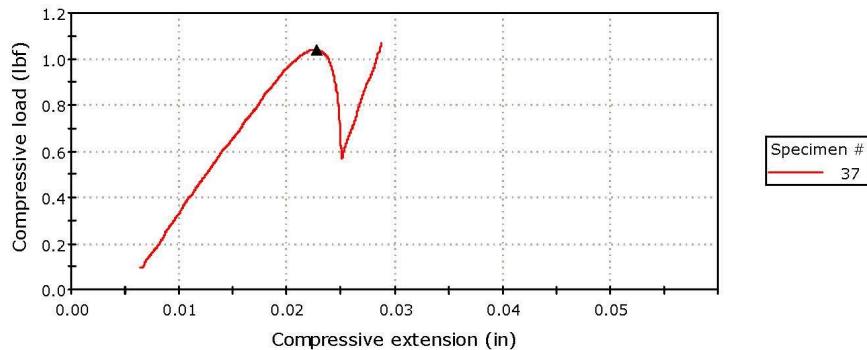


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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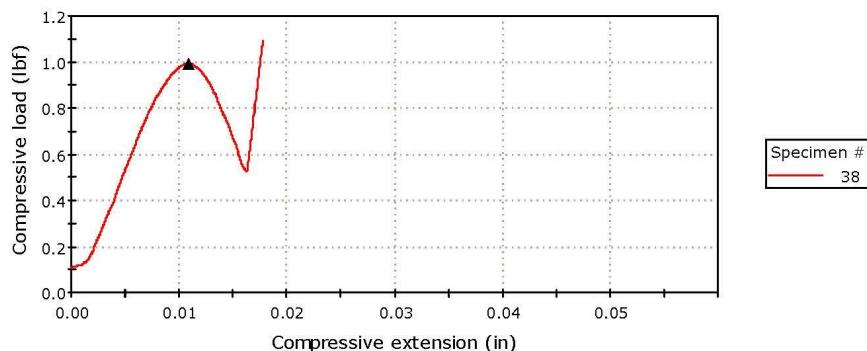
Wednesday, January 29, 2020

AC.is\_comp

Specimen 37 to 37



Specimen 38 to 38

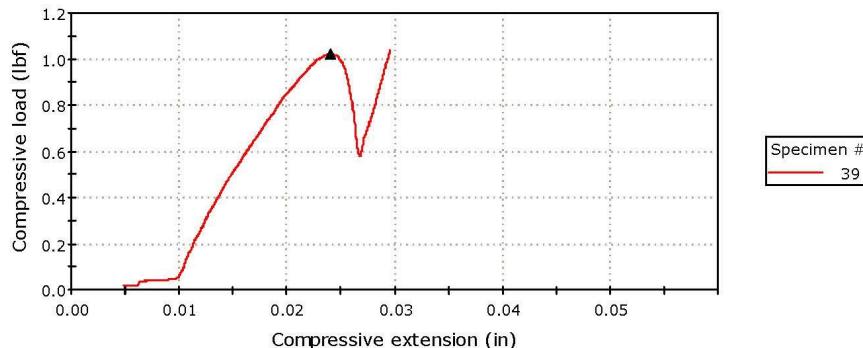


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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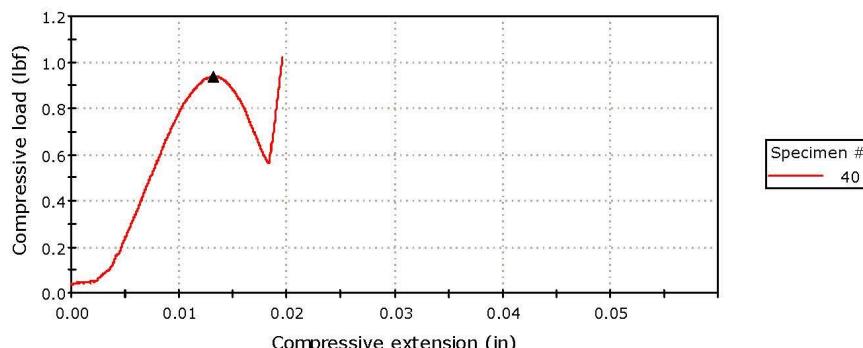
Wednesday, January 29, 2020

AC.is\_comp

Specimen 39 to 39



Specimen 40 to 40

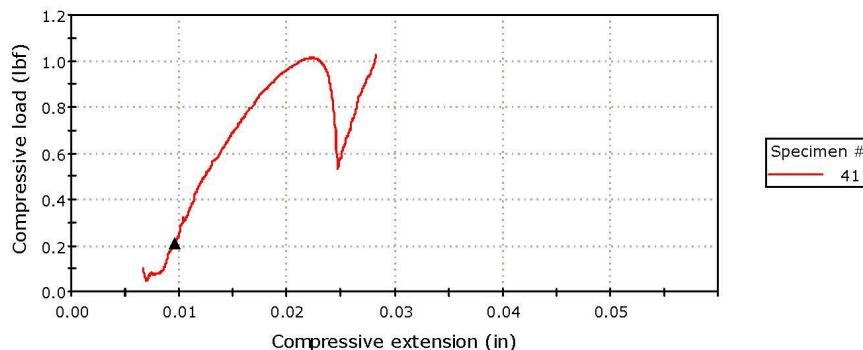


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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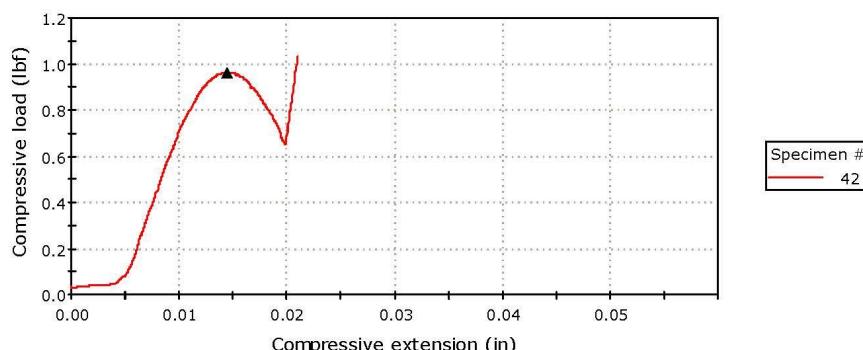
Wednesday, January 29, 2020

AC.is\_comp

Specimen 41 to 41



Specimen 42 to 42

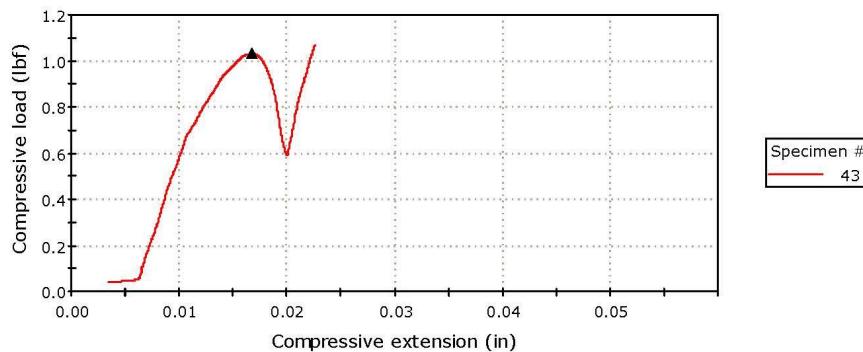


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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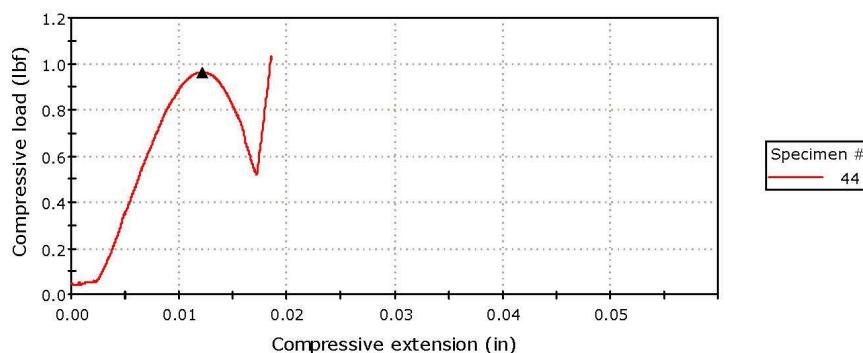
Wednesday, January 29, 2020

AC.is\_comp

Specimen 43 to 43



Specimen 44 to 44

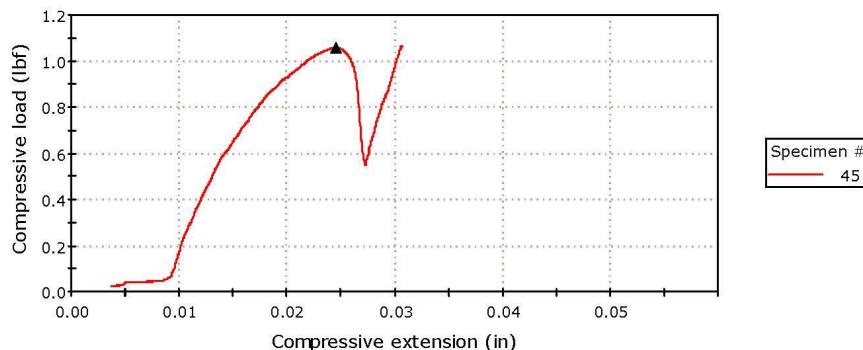


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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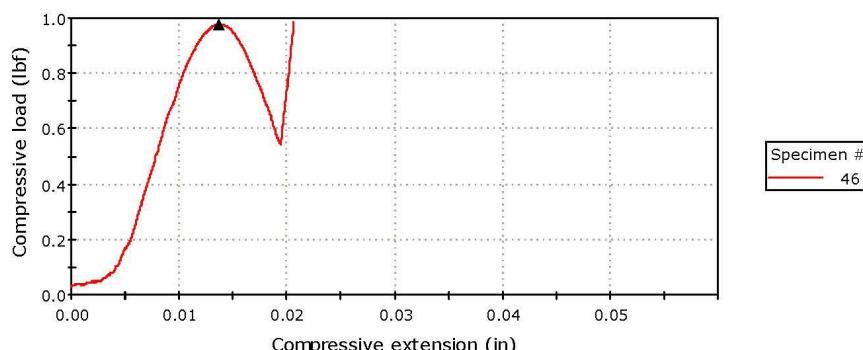
Wednesday, January 29, 2020

AC.is\_comp

Specimen 45 to 45



Specimen 46 to 46

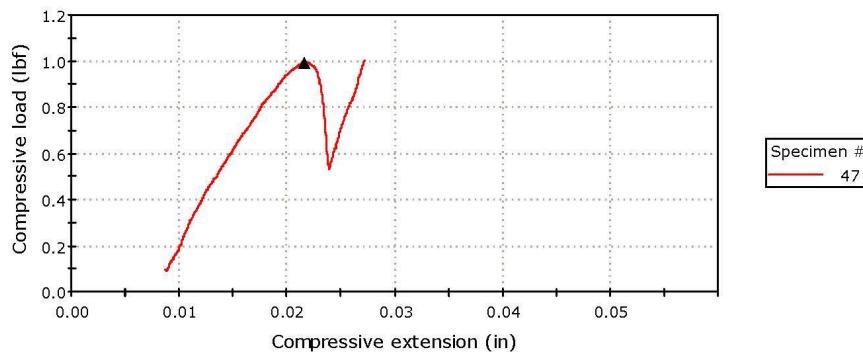


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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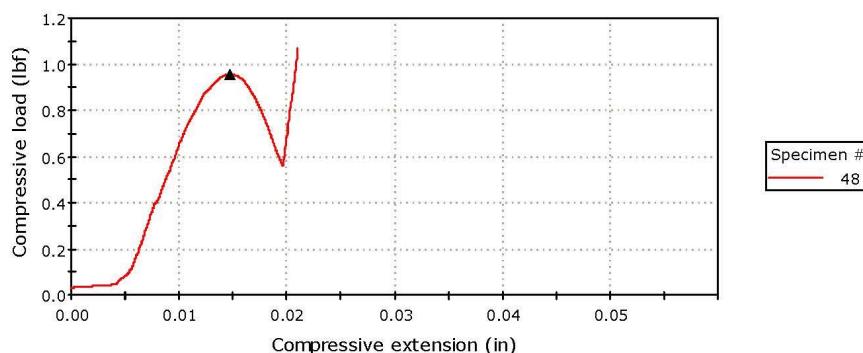
Wednesday, January 29, 2020

AC.is\_comp

Specimen 47 to 47



Specimen 48 to 48

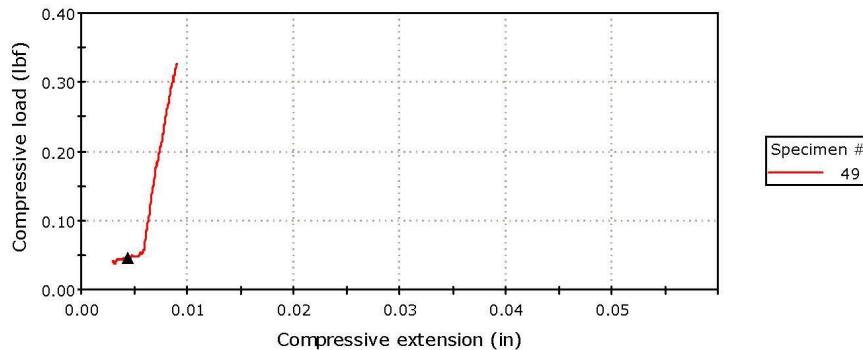


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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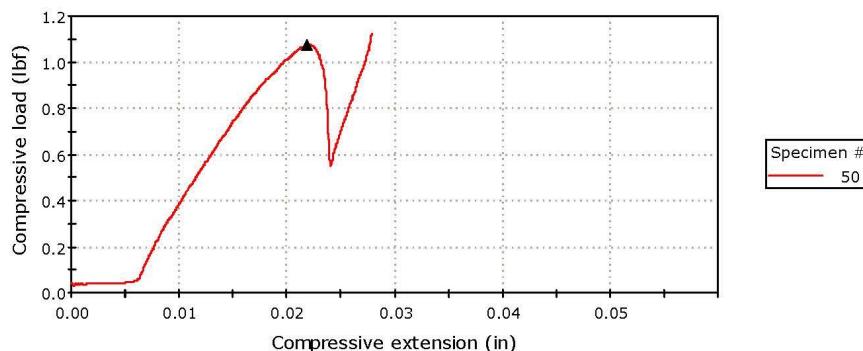
Wednesday, January 29, 2020

AC.is\_comp

Specimen 49 to 49



Specimen 50 to 50

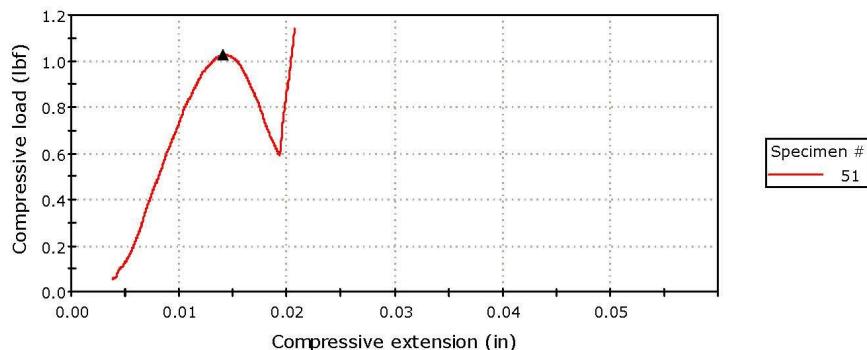


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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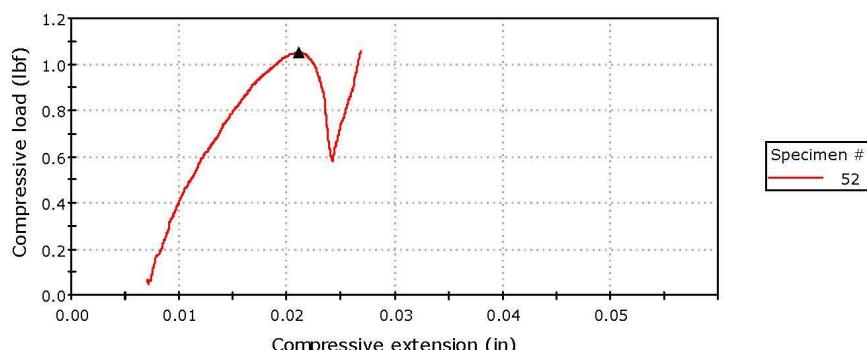
Wednesday, January 29, 2020

AC.is\_comp

Specimen 51 to 51



Specimen 52 to 52

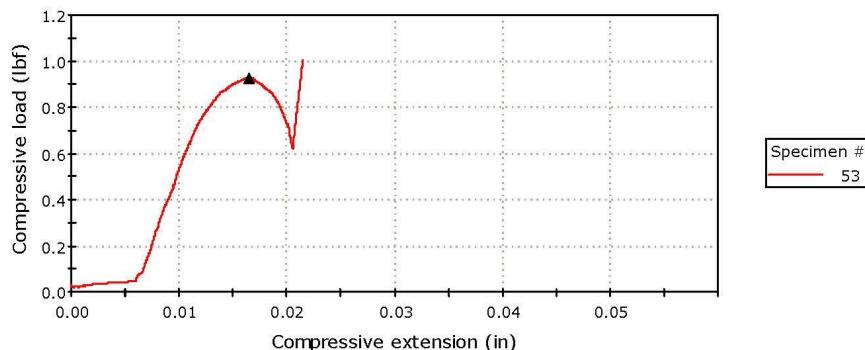


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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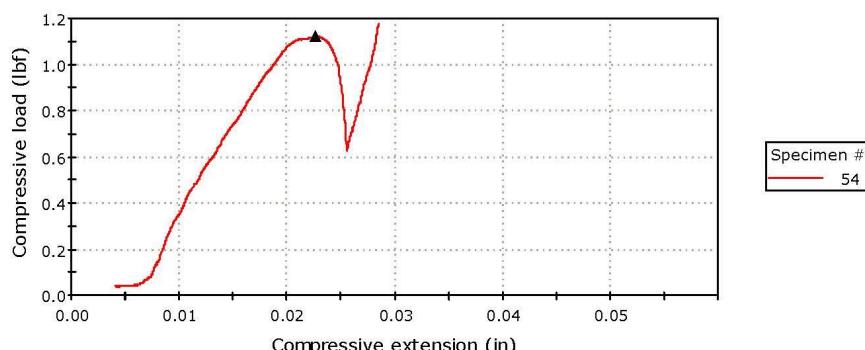
Wednesday, January 29, 2020

AC.is\_comp

Specimen 53 to 53



Specimen 54 to 54

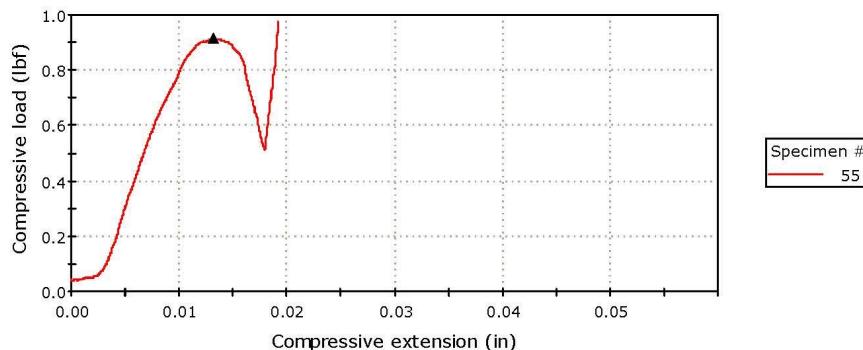


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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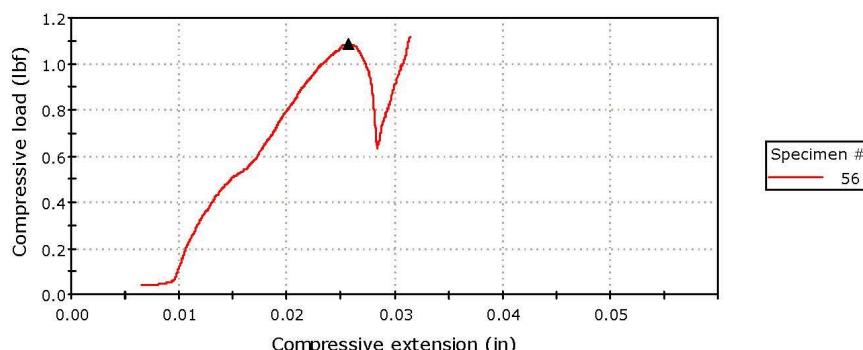
Wednesday, January 29, 2020

AC.is\_comp

Specimen 55 to 55



Specimen 56 to 56

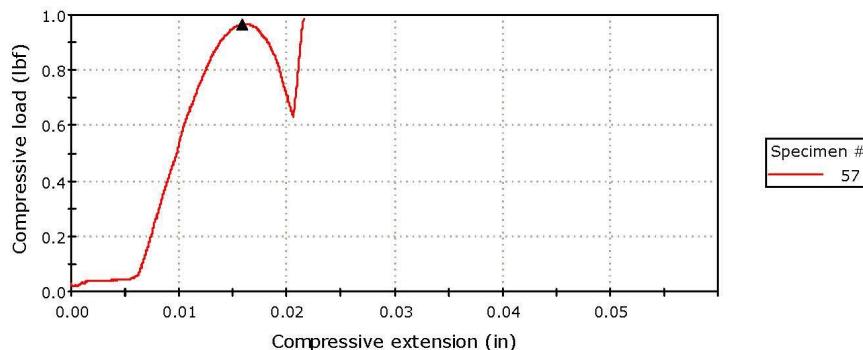


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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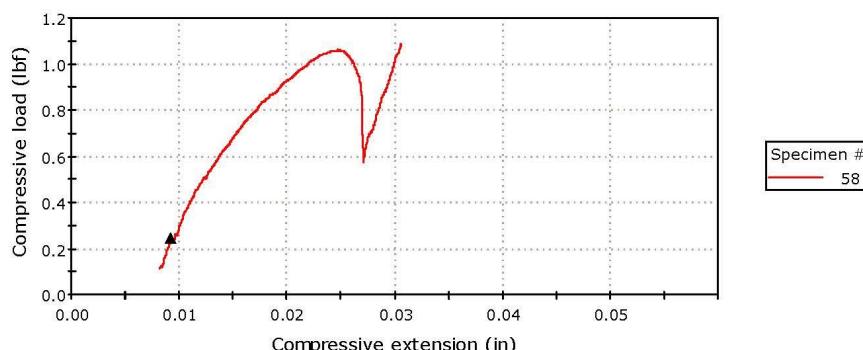
Wednesday, January 29, 2020

AC.is\_comp

Specimen 57 to 57



Specimen 58 to 58

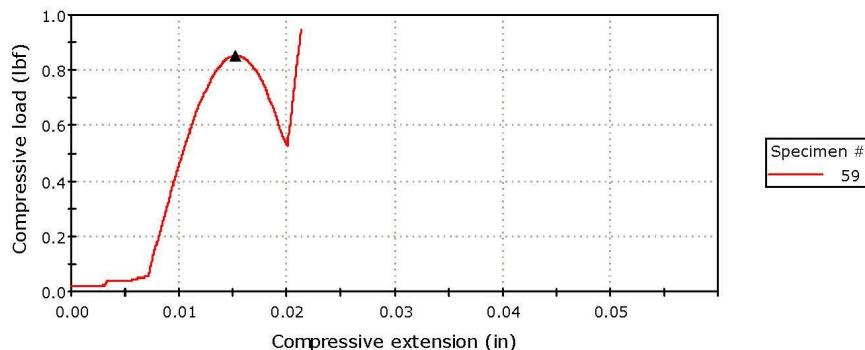


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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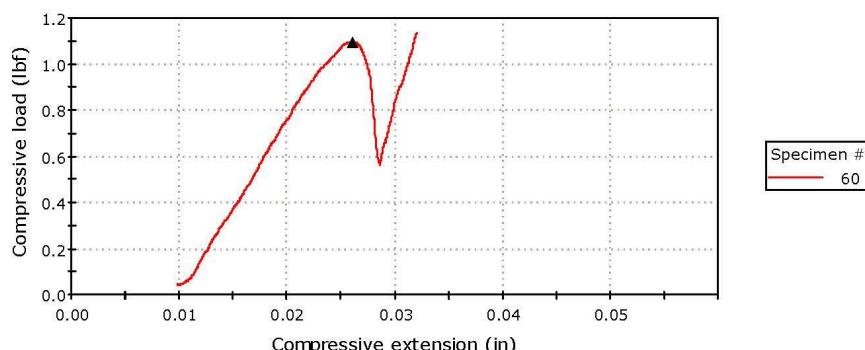
Wednesday, January 29, 2020

AC.is\_comp

Specimen 59 to 59



Specimen 60 to 60

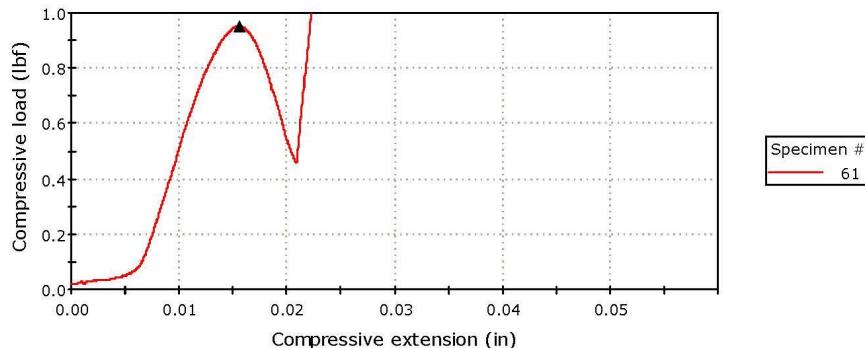


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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Specimen 61 to 61



<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
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RC.is\_comp

	Compressive load at Preset Point (Cursor ) (lbf)	Specimen label	Notes
1	0.93574	R.C.01-COAG	
2	0.76585	R.C.01-CUT	
3	0.95233	R.C.02-COAG	
4	0.91371	R.C.02-CUT	
5	0.86603	R.C.03-COAG	
6	0.83737	R.C.03-CUT	
7	0.99036	R.C.04-COAG	
8	0.88172	R.C.04-CUT	
9	0.87991	R.C.05-COAG	
10	0.96742	R.C.05-CUT	
11	0.95958	R.C.06-COAG	
12	0.93302	R.C.06-CUT	
13	0.91703	R.C.07-COAG	
14	0.91522	R.C.07-CUT	
15	1.09114	R.C.08-COAG	
16	0.95626	R.C.08-CUT	
17	0.93000	R.C.09-COAG	
18	0.86452	R.C.09-CUT	
19	1.00001	R.C.10-COAG	
20	0.85698	R.C.10-CUT	
21	0.94781	R.C.11-COAG	
22	0.78033	R.C.11-CUT	
23	0.90586	R.C.12-COAG	
24	0.86694	R.C.12-CUT	
25	0.89078	R.C.13-COAG	
26	0.76645	R.C.13-CUT	
27	0.99730	R.C.14-COAG	
28	0.85788	R.C.14-CUT	
29	0.82288	R.C.15-COAG	
30	0.91492	R.C.15-CUT	
31	0.93423	R.C.16-COAG	
32	0.92427	R.C.16-CUT	
33	0.93785	R.C.17-COAG	
34	0.91824	R.C.17-CUT	
35	0.91311	R.C.18-COAG	
36	0.81504	R.C.18-CUT	
37	1.02415	R.C.19-COAG	
38	0.96320	R.C.19-CUT	
39	0.93875	R.C.20-COAG	
40	0.92216	R.C.20-CUT	
41	0.95656	R.C.21-COAG	
42	0.97798	R.C.21-CUT	
43	0.86935	R.C.22-COAG	
44	0.92819	R.C.22-CUT	
45	0.94962	R.C.23-COAG	
46	0.96863	R.C.23-CUT	
47	1.00423	R.C.24-COAG	
48	1.01540	R.C.24-CUT	
49	1.04437	R.C.25-COAG	
50	1.07967	R.C.25-CUT	
51	1.11347	R.C.26-COAG	
52	1.10140	R.C.26-CUT	
53	0.93574	R.C.27-COAG	
54	0.83012	R.C.27-CUT	
55	0.95746	R.C.28-COAG	
56	0.93212	R.C.28-CUT	
57	0.91281	R.C.29-COAG	
58	0.94147	R.C.29-CUT	
59	0.97738	R.C.30-COAG	
60	0.94479	R.C.30-CUT	
Maximum	1.11347		

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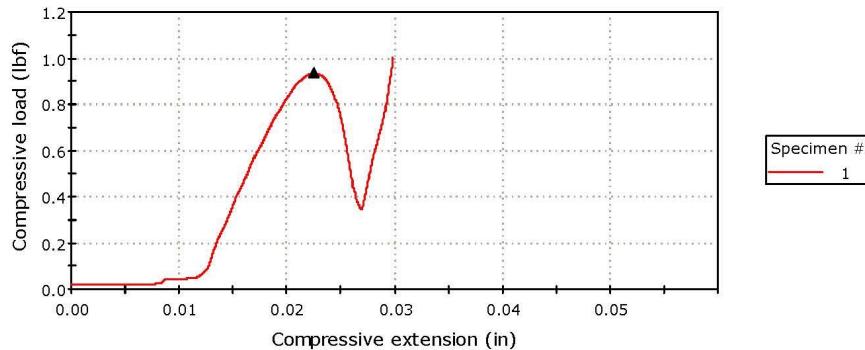
ETHICON a Johnson & Johnson company	TEST REPORT	Document Number <b>500433702</b>
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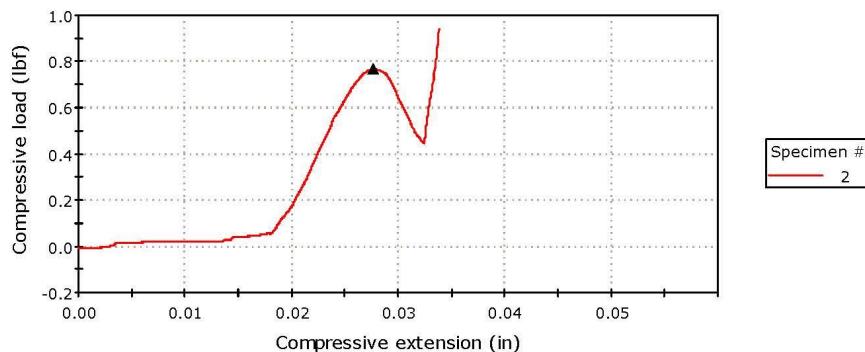
RC.is\_comp

	Compressive load at Preset Point (Cursor ) (lbf)	Specimen label	Notes
Minimum	0.76585		
Mean	0.93162		
Standard Deviation	0.07		

Specimen 1 to 1



Specimen 2 to 2

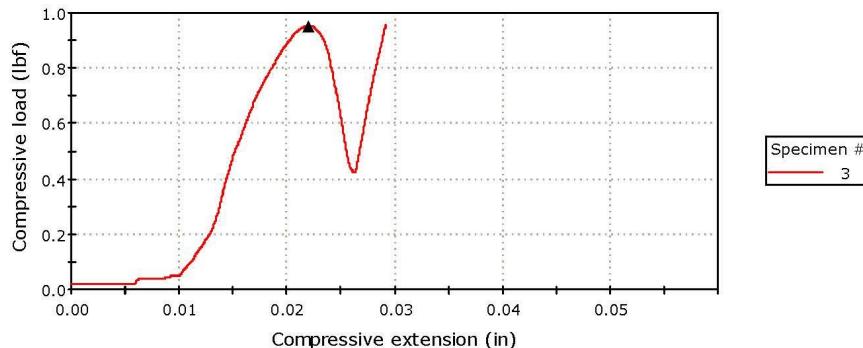


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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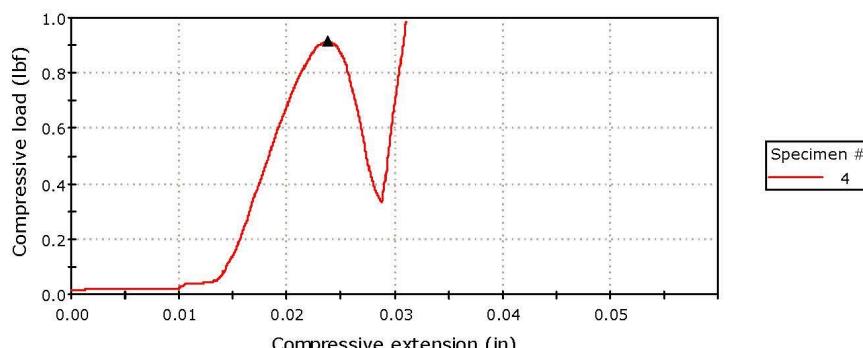
Thursday, January 30, 2020

RC.is\_comp

Specimen 3 to 3



Specimen 4 to 4

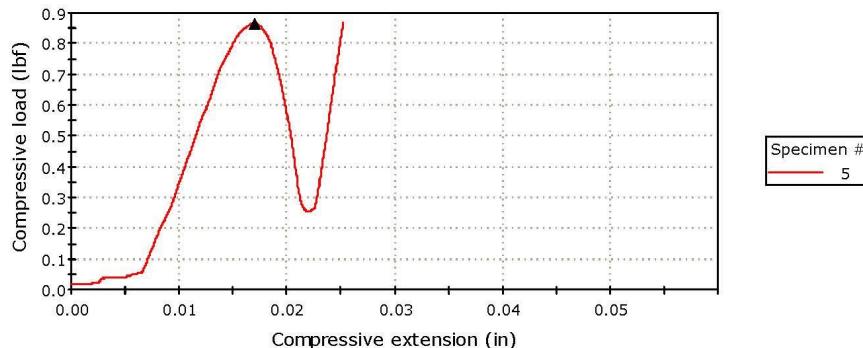


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
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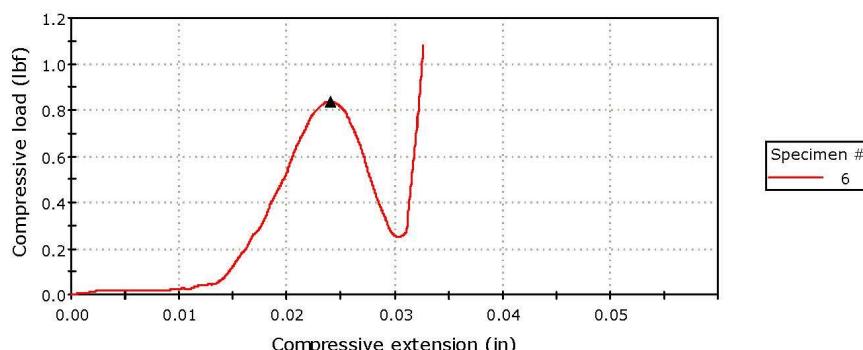
Thursday, January 30, 2020

RC.is\_comp

Specimen 5 to 5



Specimen 6 to 6

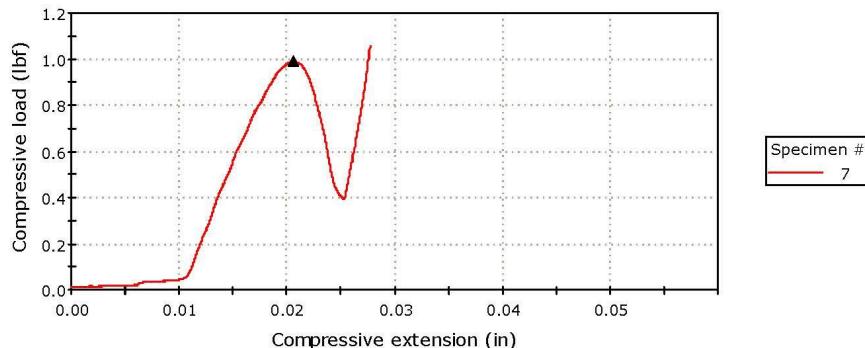


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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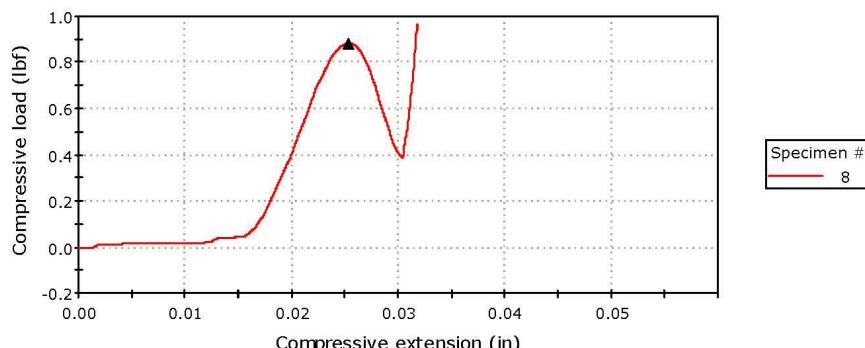
RC.is\_comp

Specimen 7 to 7



Specimen #  
7

Specimen 8 to 8



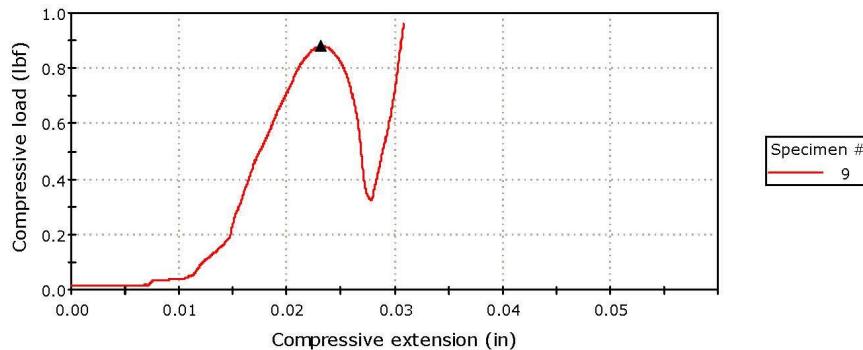
Specimen #  
8

<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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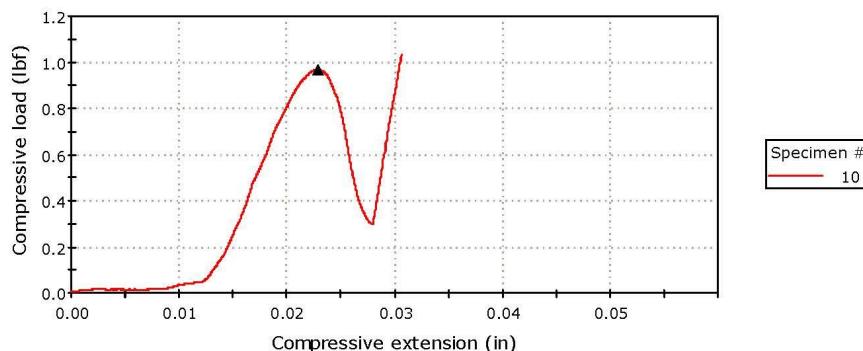
Thursday, January 30, 2020

RC.is\_comp

Specimen 9 to 9



Specimen 10 to 10

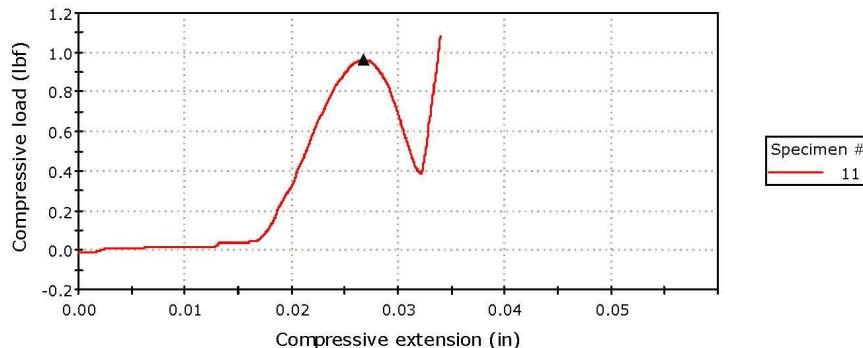


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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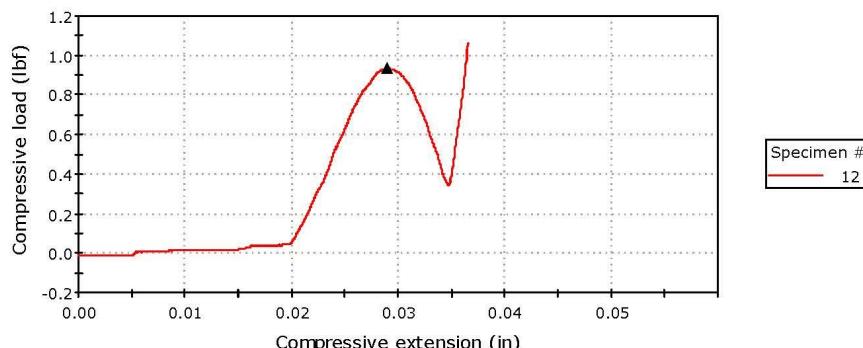
Thursday, January 30, 2020

RC.is\_comp

Specimen 11 to 11



Specimen 12 to 12

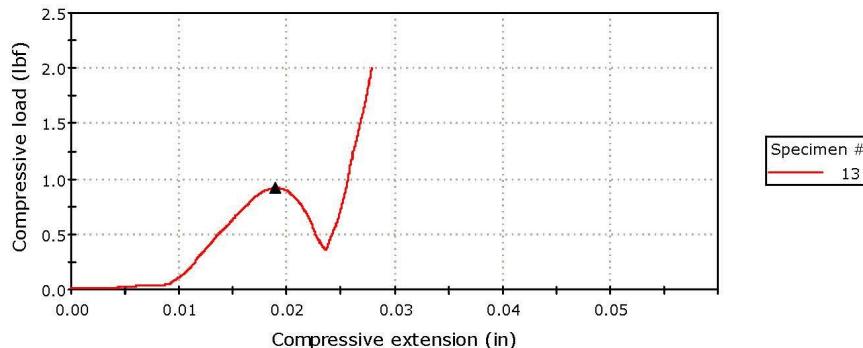


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
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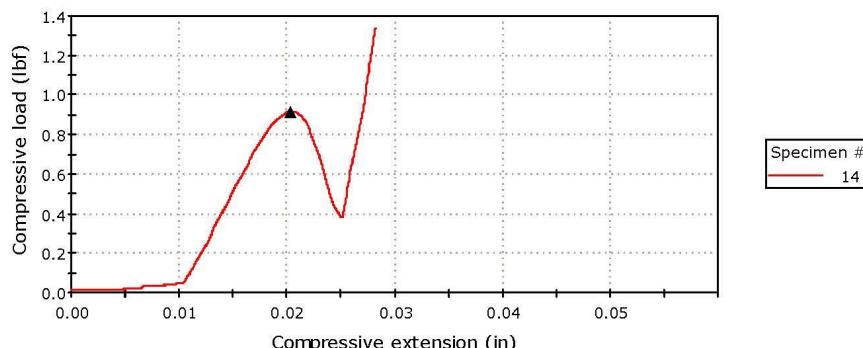
Thursday, January 30, 2020

RC.is\_comp

Specimen 13 to 13



Specimen 14 to 14

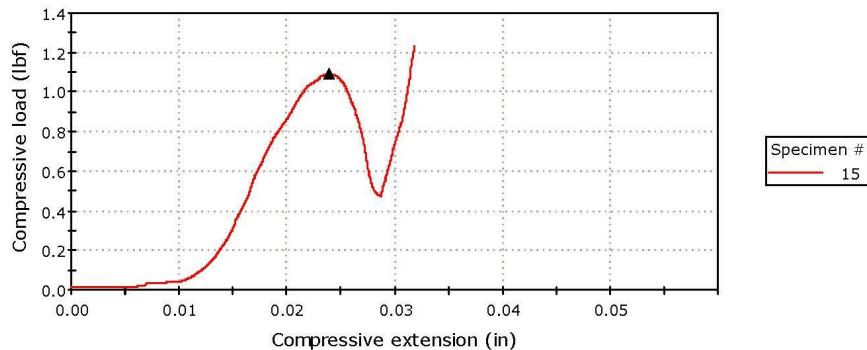


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
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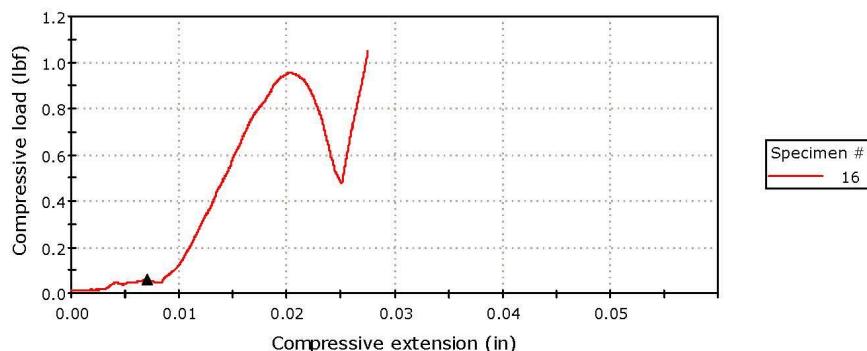
RC.is\_comp

Specimen 15 to 15



Specimen #  
15

Specimen 16 to 16



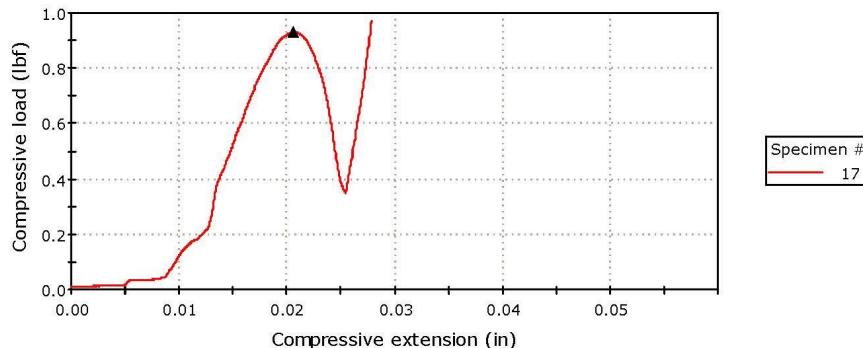
Specimen #  
16

<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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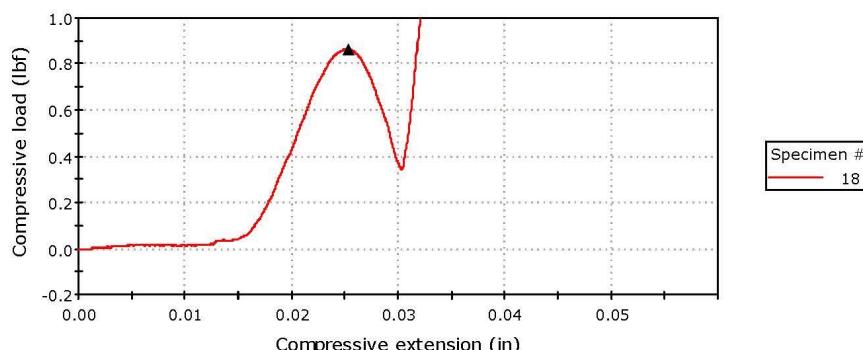
Thursday, January 30, 2020

RC.is\_comp

Specimen 17 to 17



Specimen 18 to 18

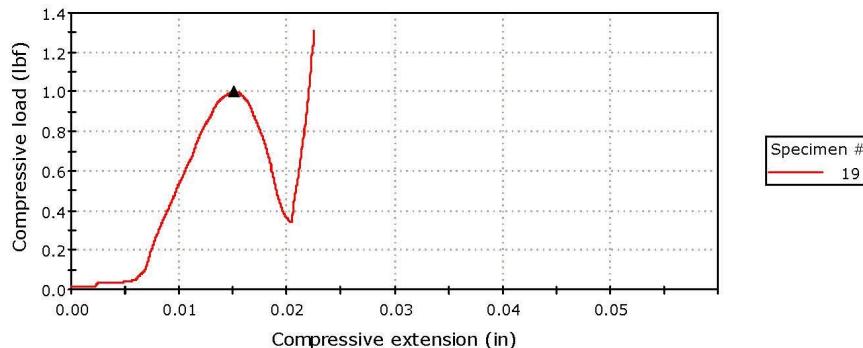


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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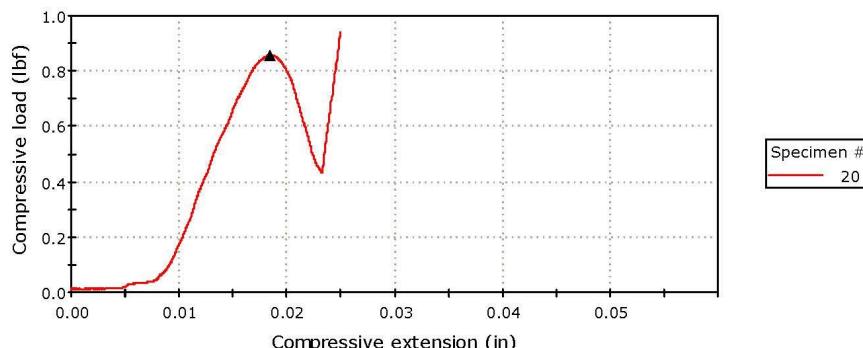
Thursday, January 30, 2020

RC.is\_comp

Specimen 19 to 19



Specimen 20 to 20

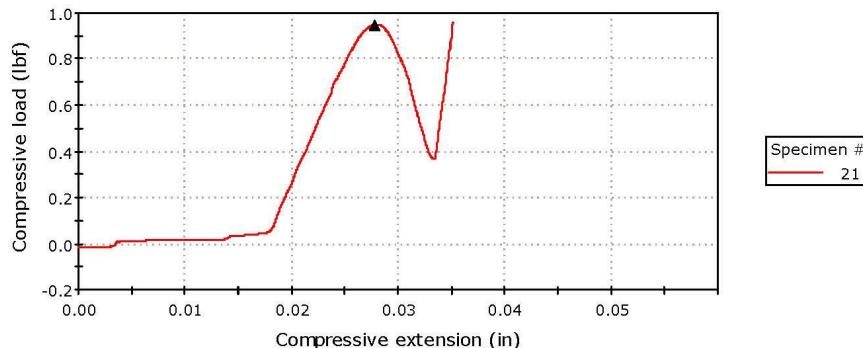


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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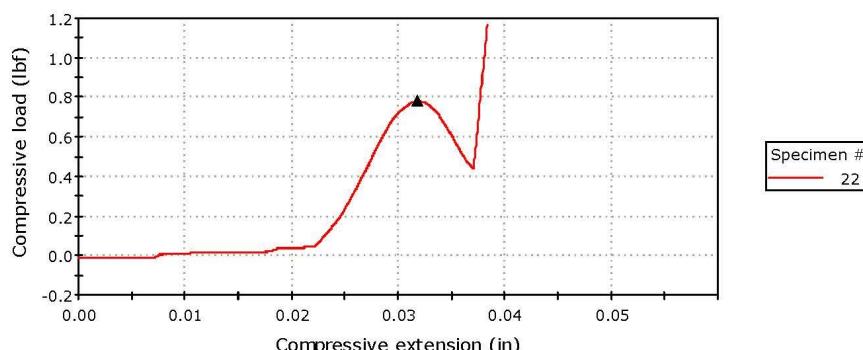
Thursday, January 30, 2020

RC.is\_comp

Specimen 21 to 21



Specimen 22 to 22

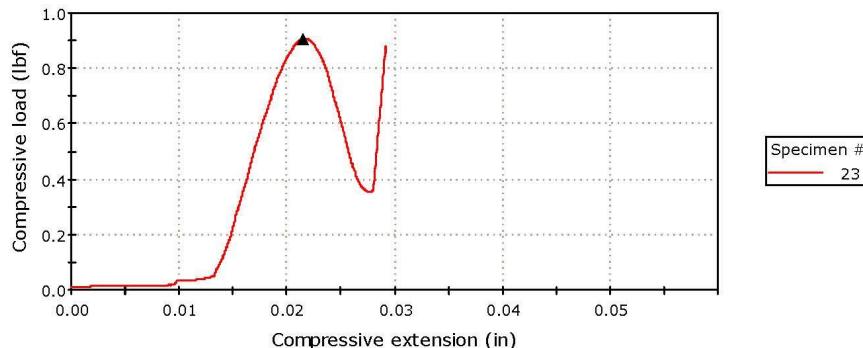


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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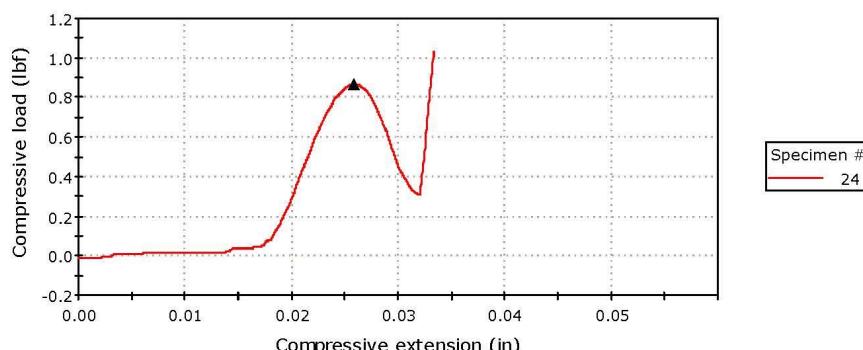
Thursday, January 30, 2020

RC.is\_comp

Specimen 23 to 23



Specimen 24 to 24

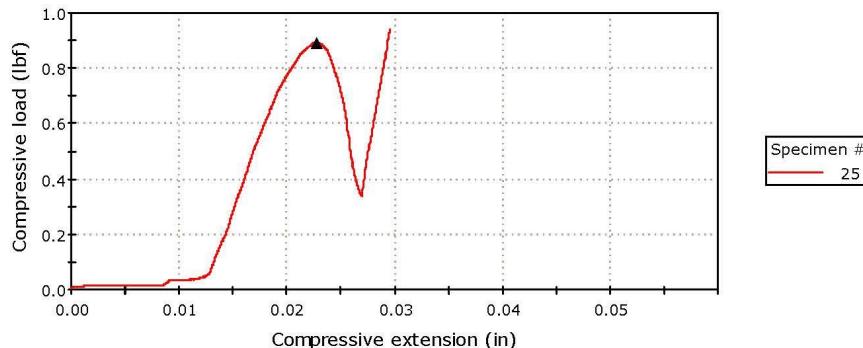


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
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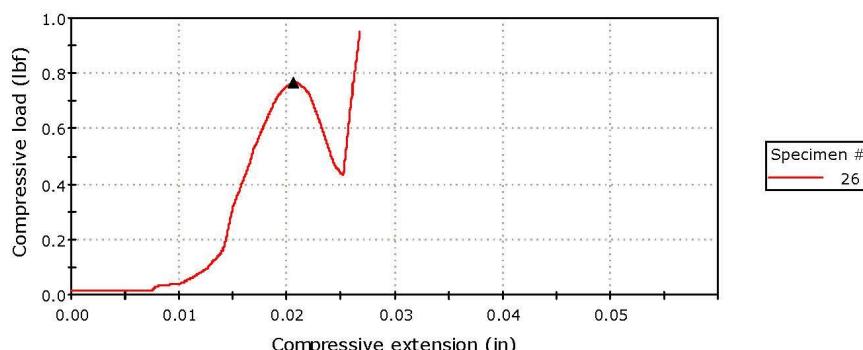
Thursday, January 30, 2020

RC.is\_comp

Specimen 25 to 25



Specimen 26 to 26

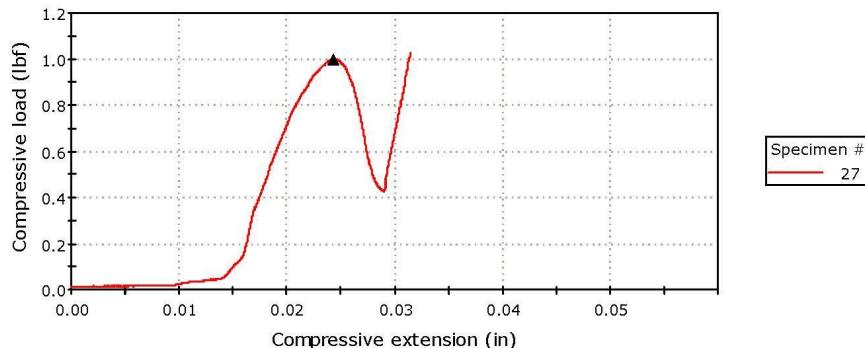


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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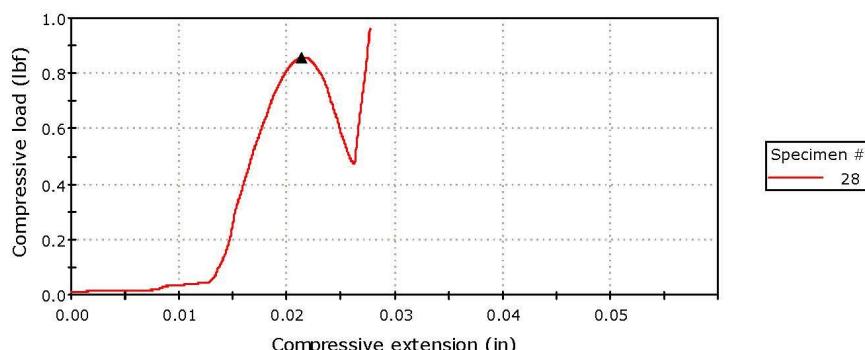
Thursday, January 30, 2020

RC.is\_comp

Specimen 27 to 27



Specimen 28 to 28

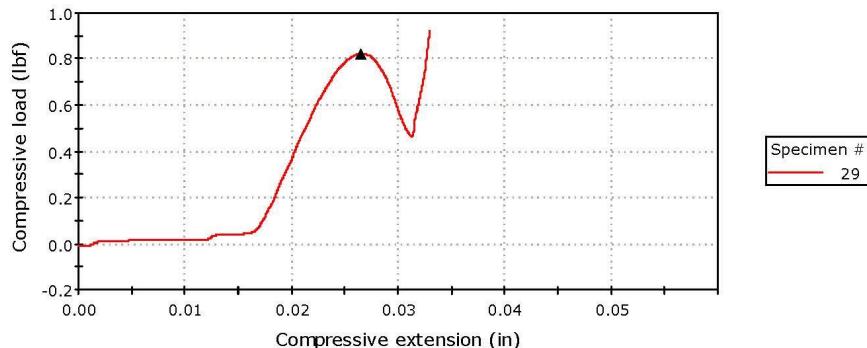


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
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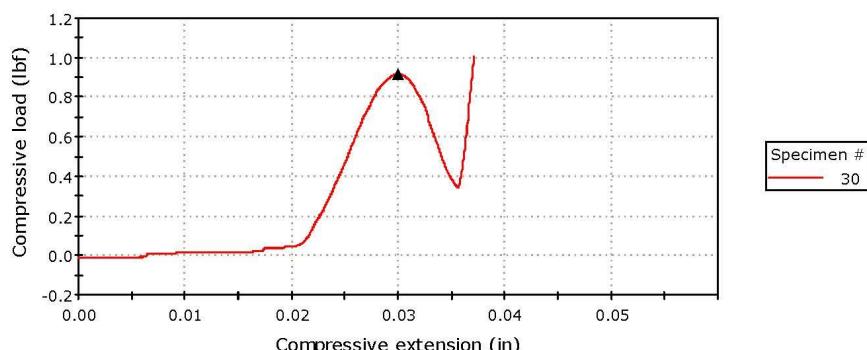
Thursday, January 30, 2020

RC.is\_comp

Specimen 29 to 29



Specimen 30 to 30

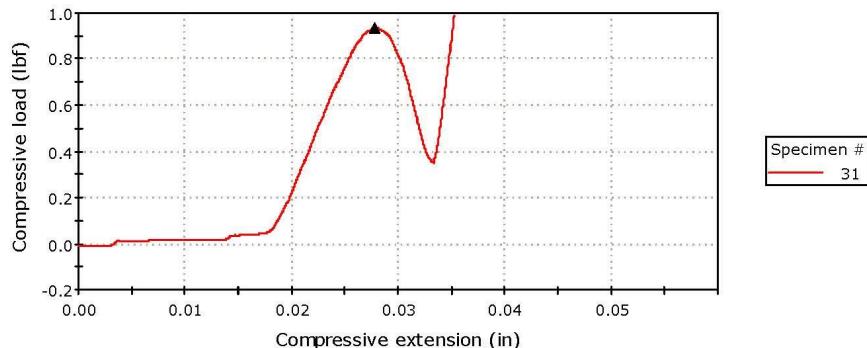


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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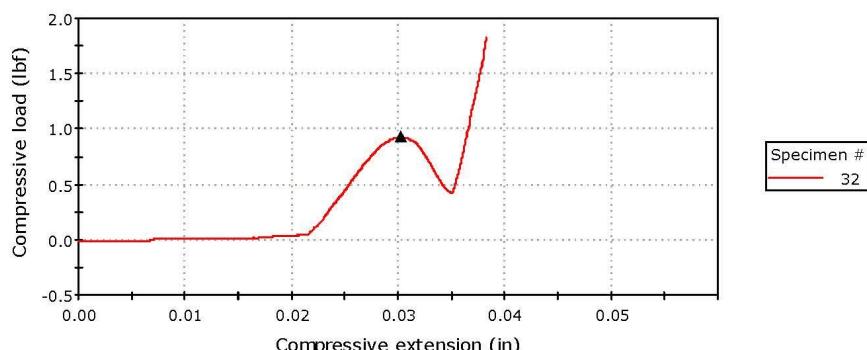
Thursday, January 30, 2020

RC.is\_comp

Specimen 31 to 31



Specimen 32 to 32

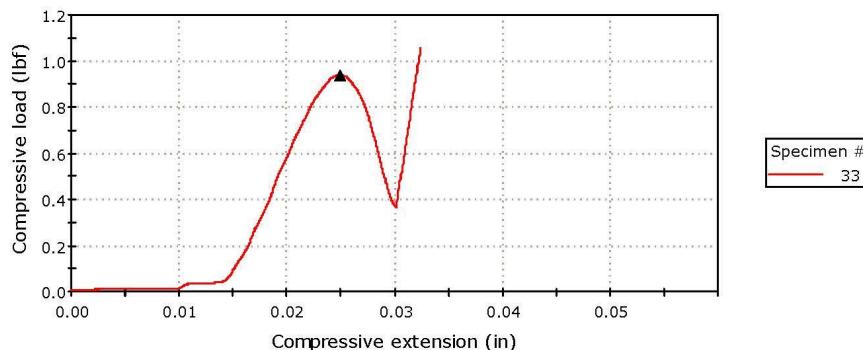


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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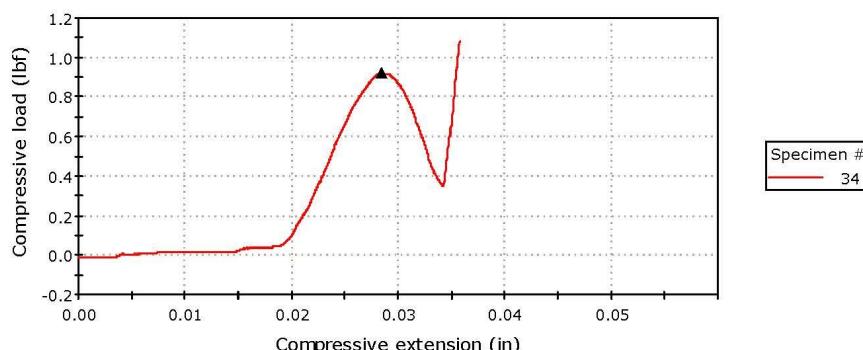
Thursday, January 30, 2020

RC.is\_comp

Specimen 33 to 33



Specimen 34 to 34

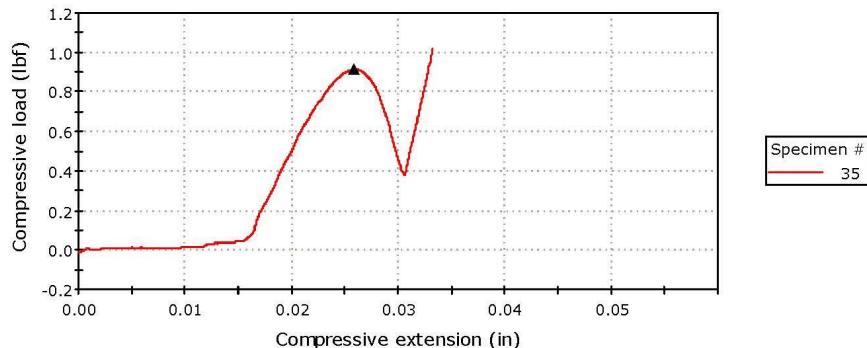


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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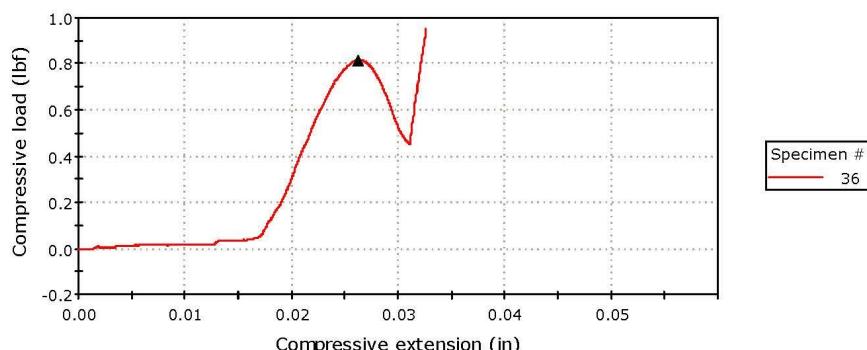
Thursday, January 30, 2020

RC.is\_comp

Specimen 35 to 35



Specimen 36 to 36

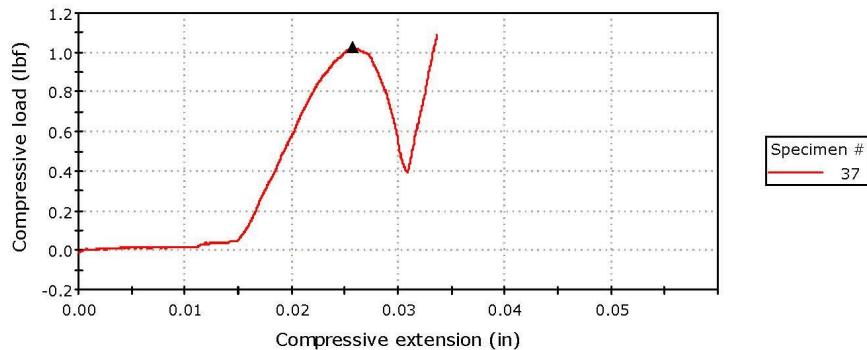


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
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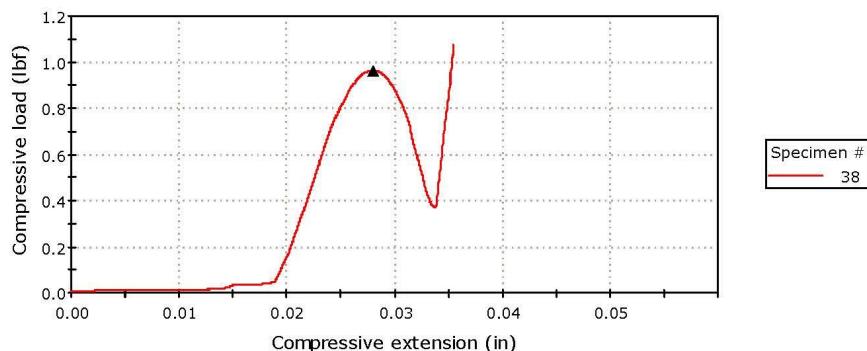
Thursday, January 30, 2020

RC.is\_comp

Specimen 37 to 37



Specimen 38 to 38

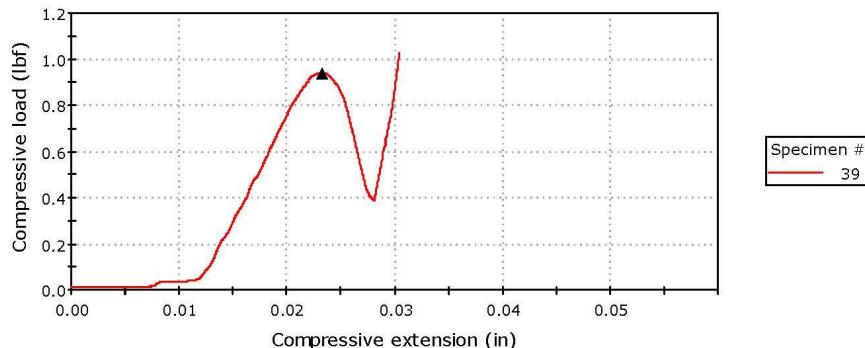


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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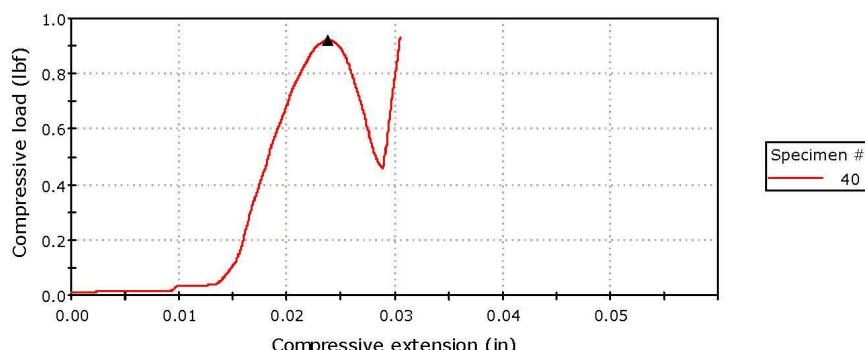
Thursday, January 30, 2020

RC.is\_comp

Specimen 39 to 39



Specimen 40 to 40

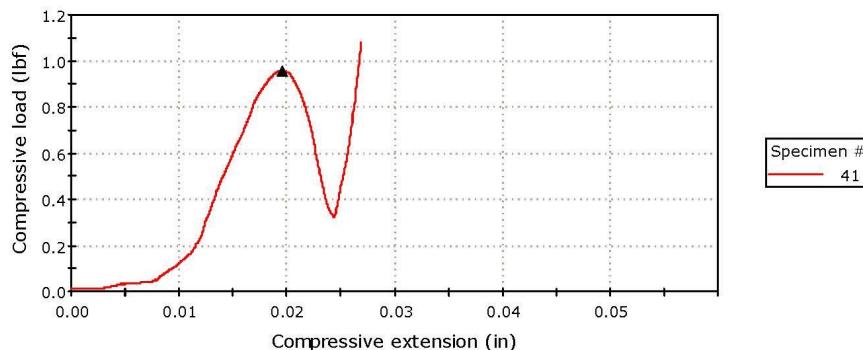


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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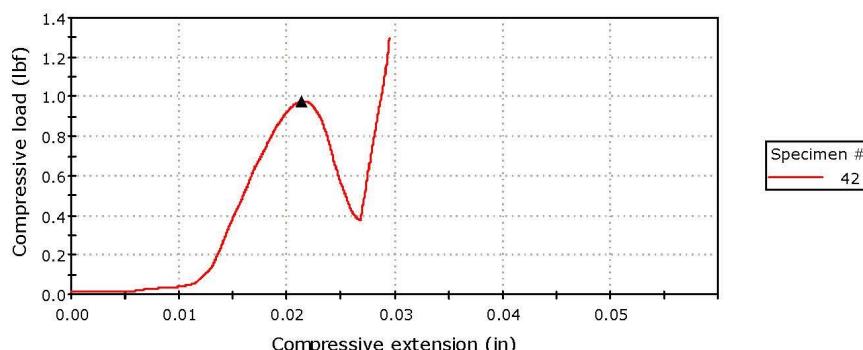
Thursday, January 30, 2020

RC.is\_comp

Specimen 41 to 41



Specimen 42 to 42

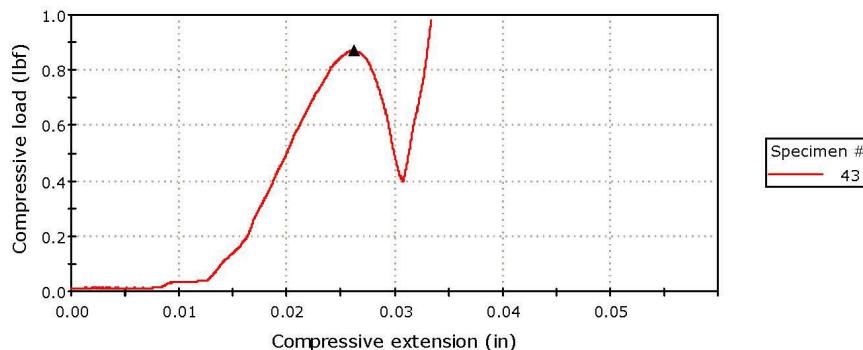


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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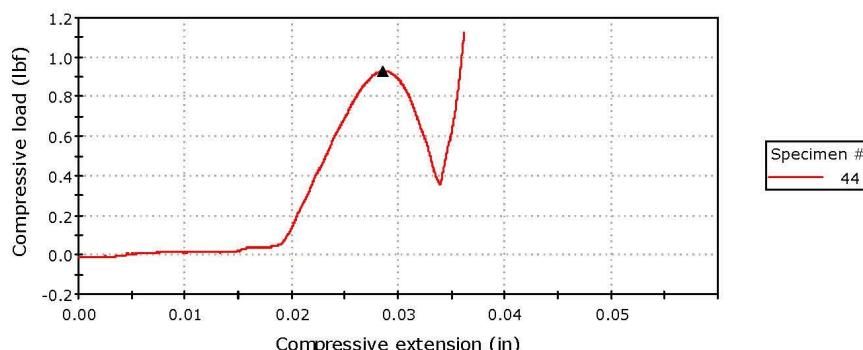
Thursday, January 30, 2020

RC.is\_comp

Specimen 43 to 43



Specimen 44 to 44

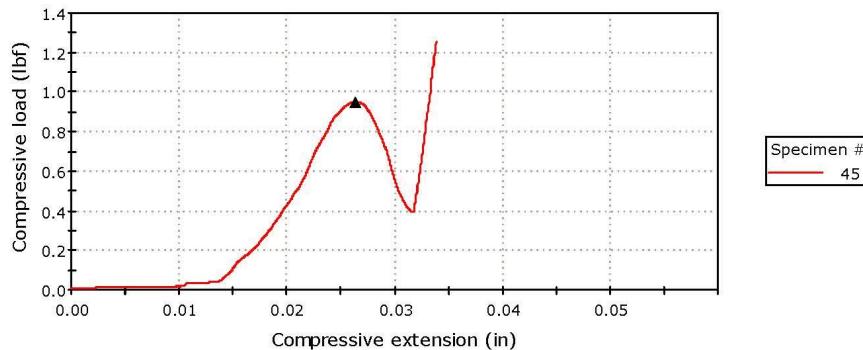


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
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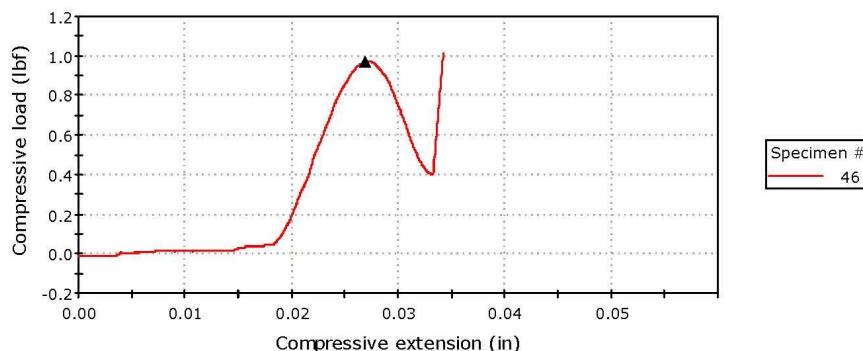
Thursday, January 30, 2020

RC.is\_comp

Specimen 45 to 45



Specimen 46 to 46

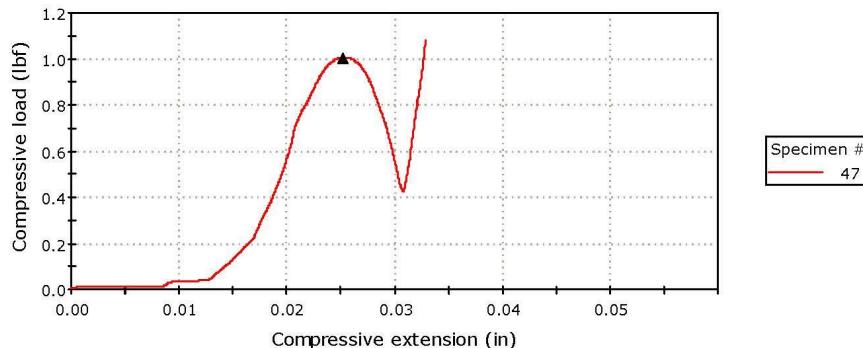


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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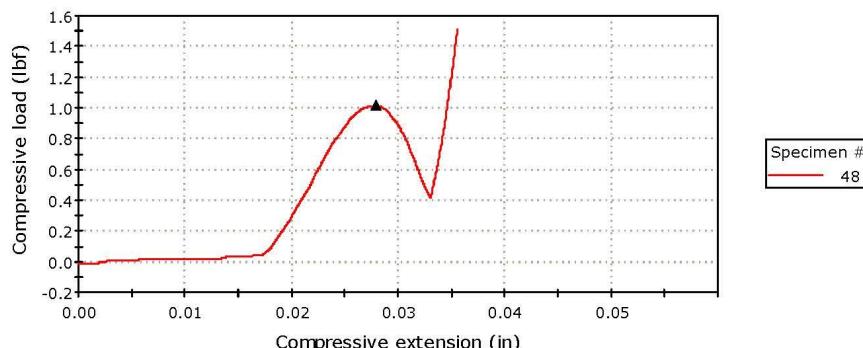
Thursday, January 30, 2020

RC.is\_comp

Specimen 47 to 47



Specimen 48 to 48

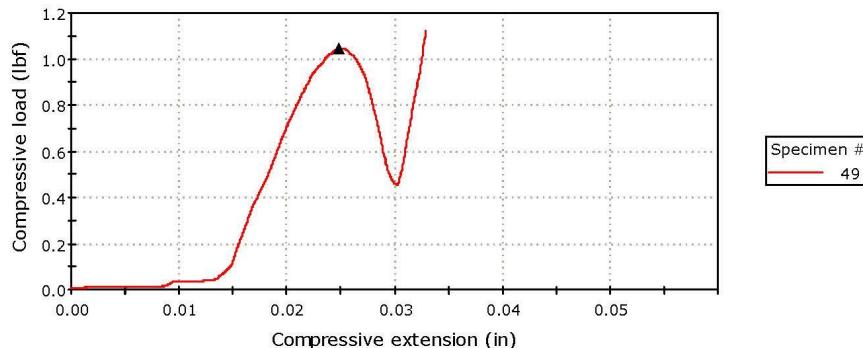


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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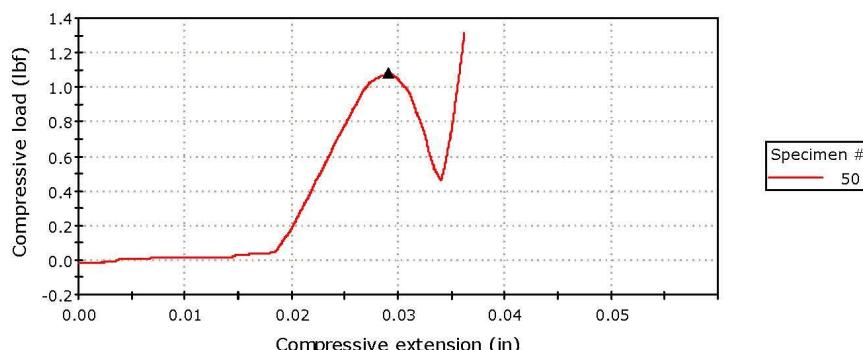
Thursday, January 30, 2020

RC.is\_comp

Specimen 49 to 49



Specimen 50 to 50

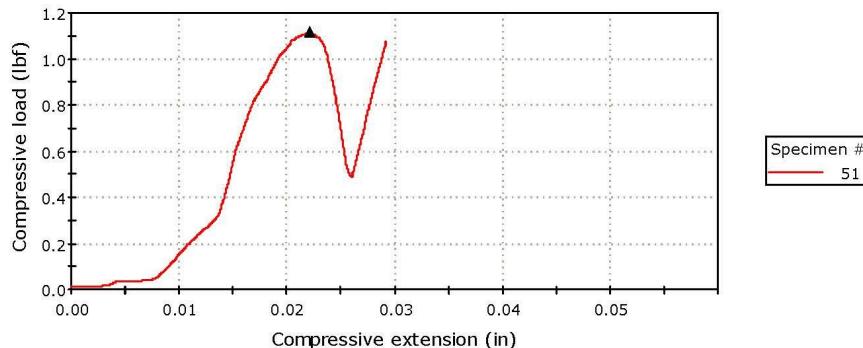


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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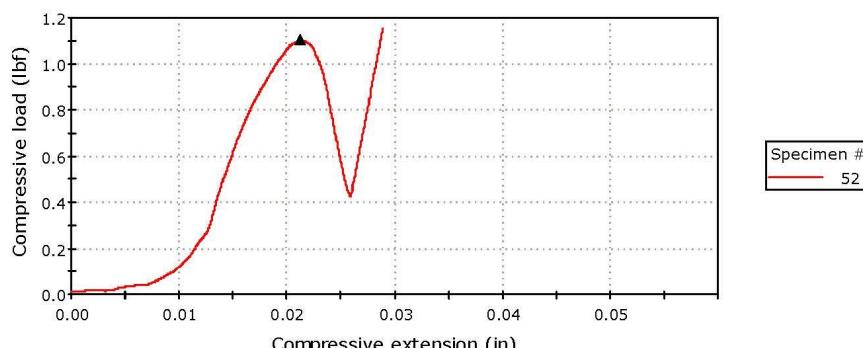
Thursday, January 30, 2020

RC.is\_comp

Specimen 51 to 51



Specimen 52 to 52

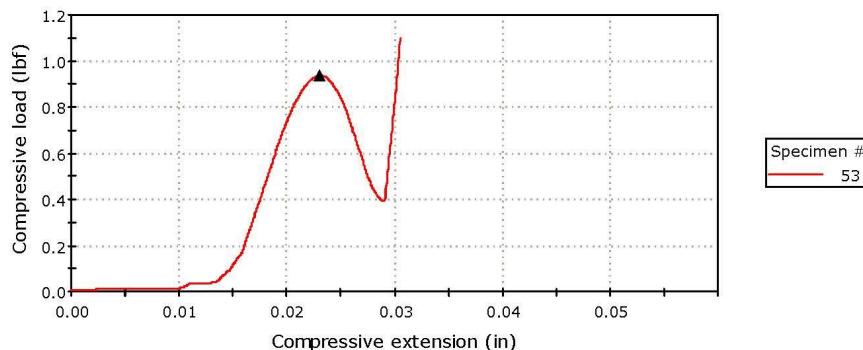


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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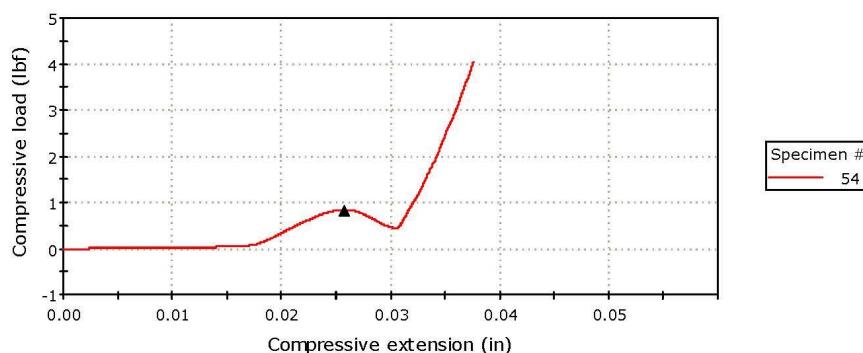
Thursday, January 30, 2020

RC.is\_comp

Specimen 53 to 53



Specimen 54 to 54

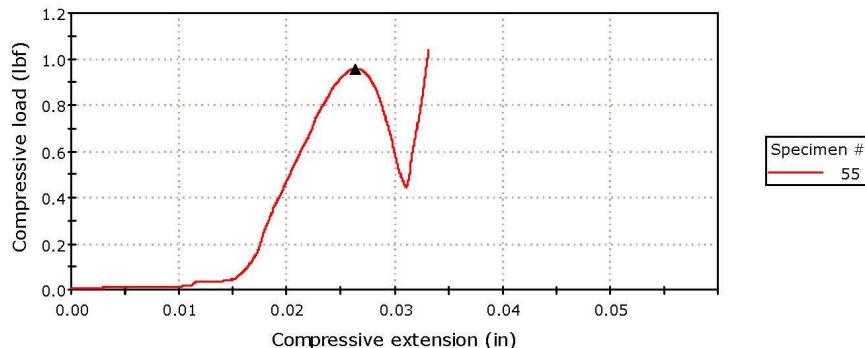


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
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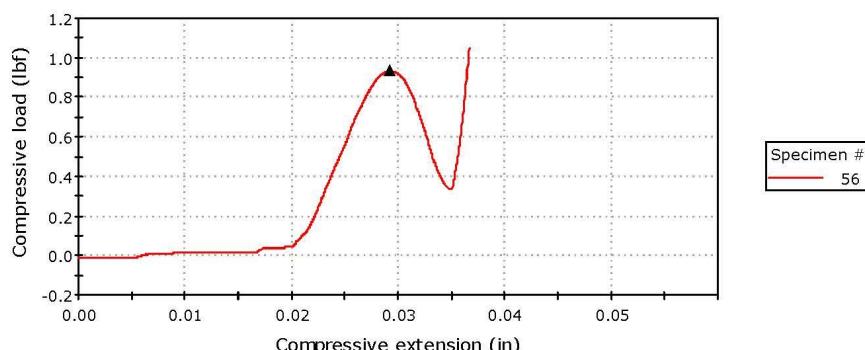
Thursday, January 30, 2020

RC.is\_comp

Specimen 55 to 55



Specimen 56 to 56

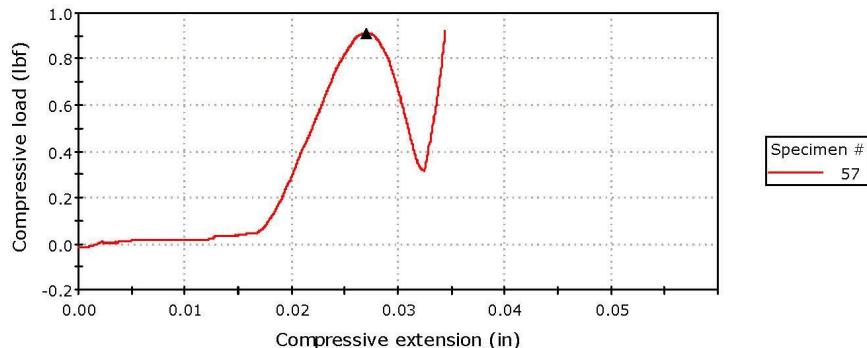


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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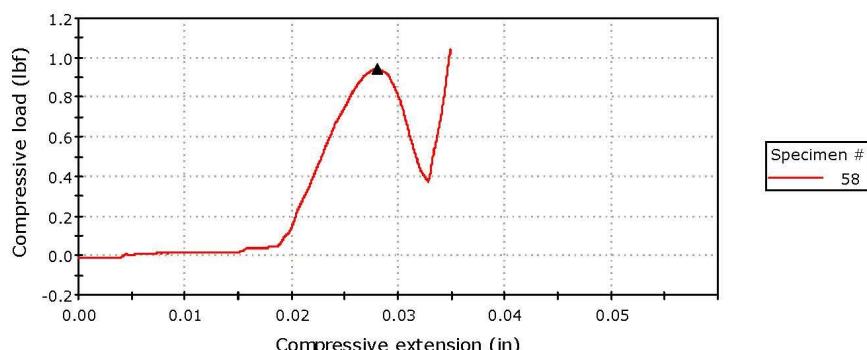
Thursday, January 30, 2020

RC.is\_comp

Specimen 57 to 57



Specimen 58 to 58

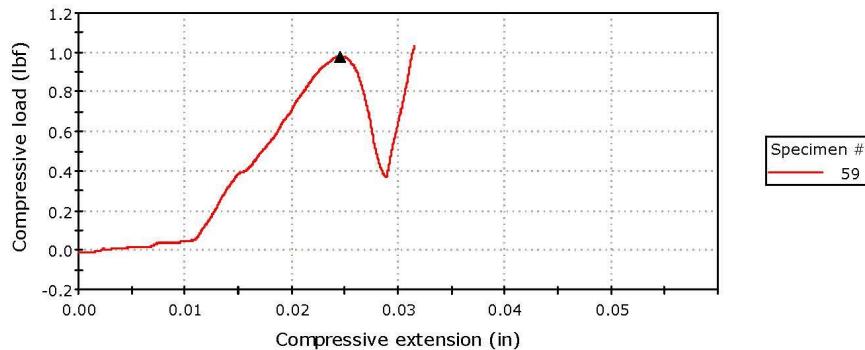


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
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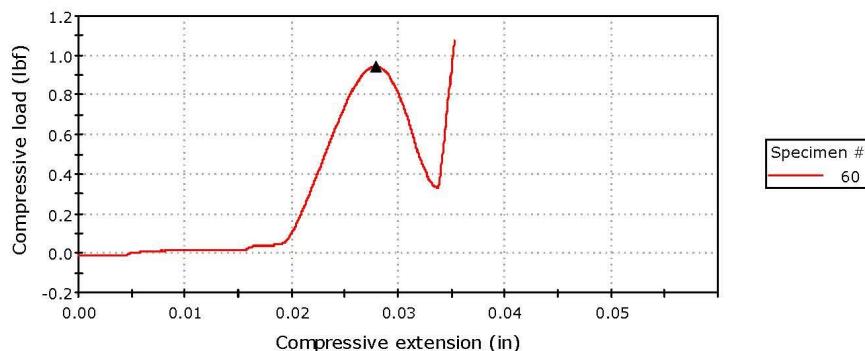
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RC.is\_comp

Specimen 59 to 59



Specimen 60 to 60



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GC.is\_comp

	Compressive load at Preset Point (Cursor ) (lbf)	Specimen label	Notes
1	0.99307	G.C.01-COAG	
2	0.95988	G.C.01-CUT	
3	0.91492	G.C.02-COAG	
4	0.75046	G.C.02-CUT	
5	1.00001	G.C.03-COAG	
6	0.84310	G.C.03-CUT	
7	0.91673	G.C.04-COAG	
8	0.91461	G.C.04-CUT	
9	0.91944	G.C.05-COAG	
10	0.91673	G.C.05-CUT	
11	0.98372	G.C.06-COAG	
12	0.94751	G.C.06-CUT	
13	0.98160	G.C.07-COAG	
14	0.88565	G.C.07-CUT	
15	0.98251	G.C.08-COAG	
16	0.93061	G.C.08-CUT	
17	0.90858	G.C.09-COAG	
18	0.93242	G.C.09-CUT	
19	0.98613	G.C.10-COAG	
20	0.92518	G.C.10-CUT	
21	0.90768	G.C.11-COAG	
22	0.88957	G.C.11-CUT	
23	0.93996	G.C.12-COAG	
24	0.87931	G.C.12-CUT	
25	0.99971	G.C.13-COAG	
26	0.91975	G.C.13-CUT	
27	-----	G.C.14-COAG	
28	0.96622	G.C.14-COAG	
29	1.05342	G.C.14-CUT	
30	0.95415	G.C.15-COAG	
31	0.96682	G.C.15-CUT	
32	0.89440	G.C.16-COAG	
33	0.88414	G.C.16-CUT	
34	0.99850	G.C.17-COAG	
35	0.97979	G.C.17-CUT	
36	-----	G.C.18-COAG	
37	1.02868	G.C.18-COAG	
38	0.87599	G.C.18-CUT	
39	1.01148	G.C.19-COAG	
40	0.94509	G.C.19-CUT	
41	1.01540	G.C.20-COAG	
42	0.98885	G.C.20-CUT	
43	0.99941	G.C.21-COAG	
44	0.97285	G.C.21-CUT	
45	0.90345	G.C.22-COAG	
46	0.93513	G.C.22-CUT	
47	-----	G.C.23-COAG	
48	0.92789	G.C.23-COAG	
49	0.96742	G.C.23-CUT	
50	0.98915	G.C.24-COAG	
51	0.92186	G.C.24-CUT	
52	0.93755	G.C.25-COAG	
53	0.94117	G.C.25-CUT	
54	0.95626	G.C.26-COAG	
55	0.90134	G.C.26-CUT	
56	0.91884	G.C.27-COAG	
57	0.82892	G.C.27-CUT	
58	0.91461	G.C.28-COAG	
59	0.73386	G.C.28-CUT	
60	0.96742	G.C.29-COAG	
61	0.95143	G.C.29-CUT	

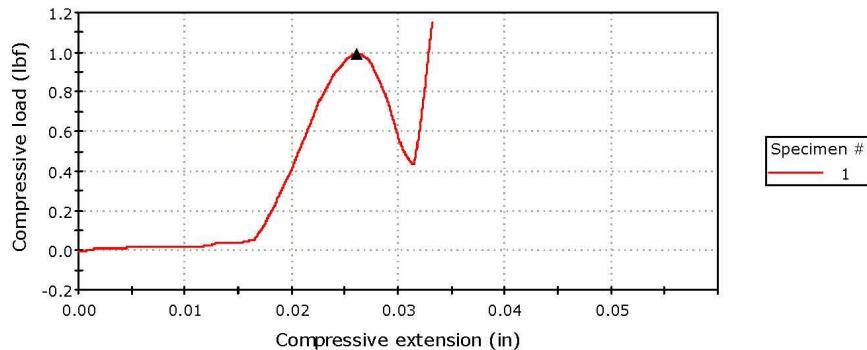
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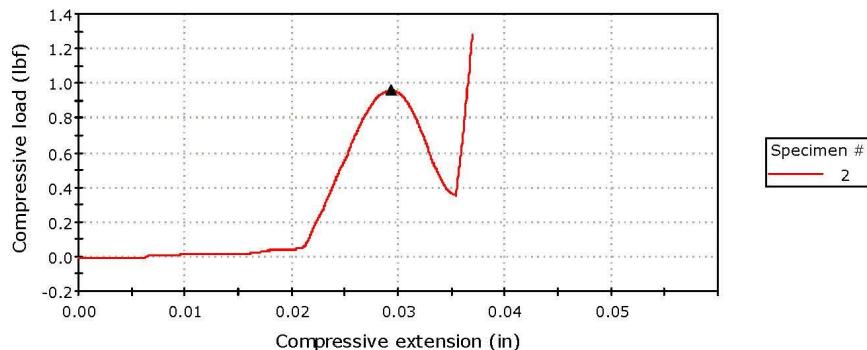
GC.is\_comp

	Compressive load at Preset Point (Cursor ) (lbf)	Specimen label	Notes
62	1.00605	G.C.30-COAG	
63	0.93725	G.C.30-CUT	
Maximum	1.05342		
Minimum	0.73386		
Mean	0.93839		
Standard Deviation	0.06		

#### Specimen 1 to 1



#### Specimen 2 to 2

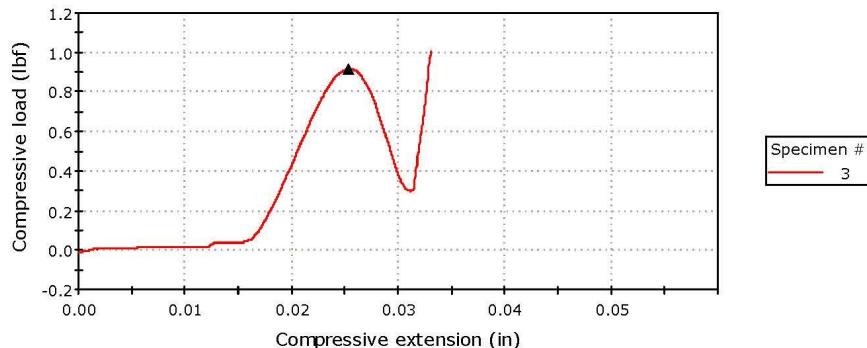


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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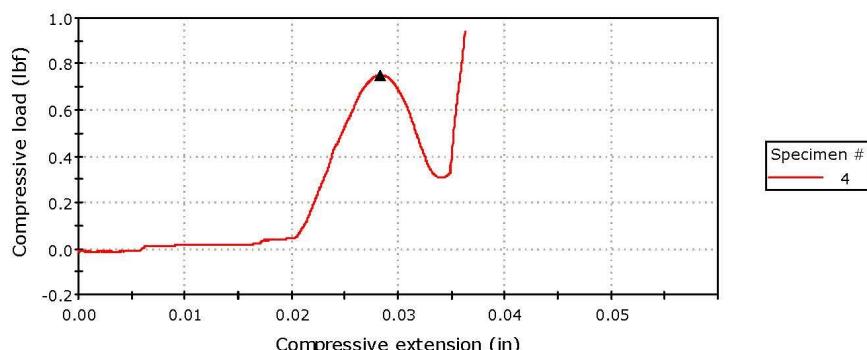
Thursday, January 30, 2020

GC.is\_comp

Specimen 3 to 3



Specimen 4 to 4

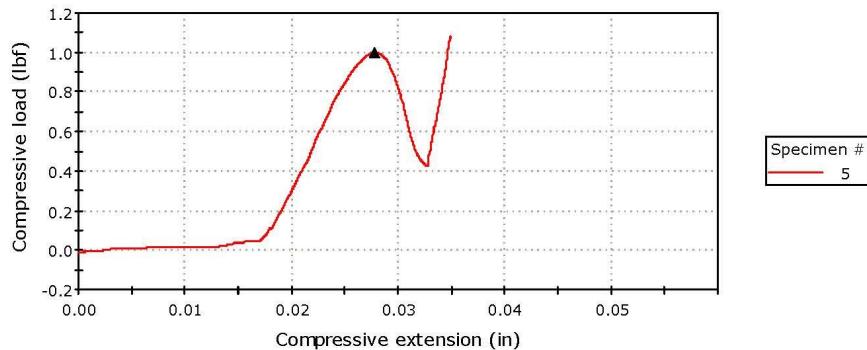


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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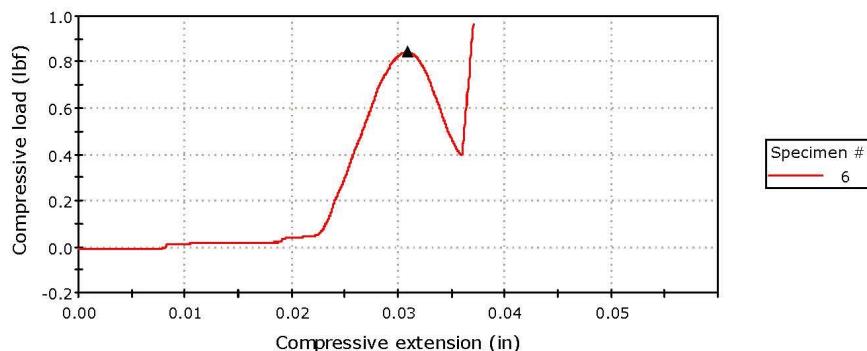
GC.is\_comp

Specimen 5 to 5



Specimen #  
5

Specimen 6 to 6



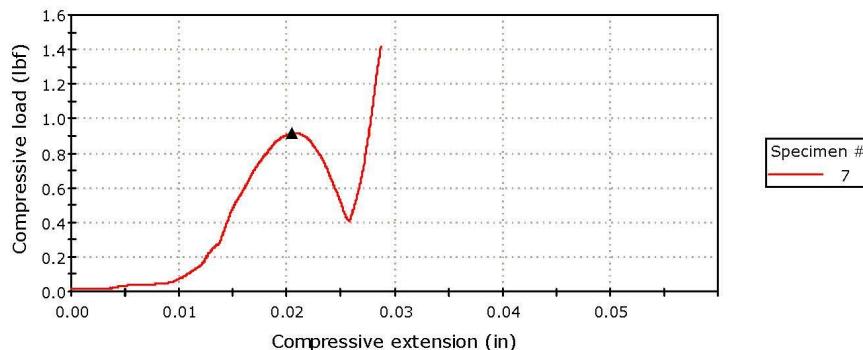
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<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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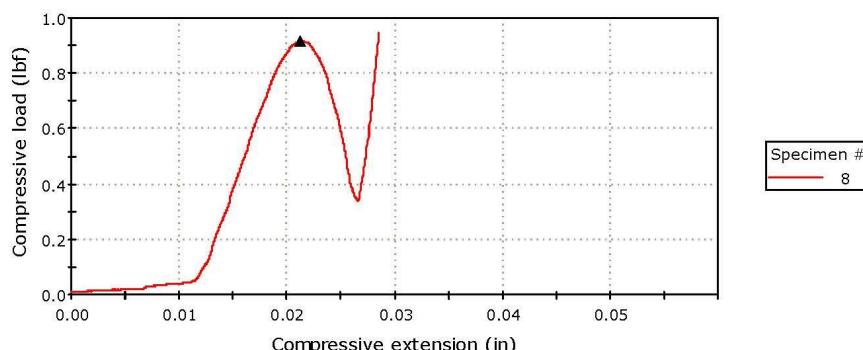
GC.is\_comp

Specimen 7 to 7



Specimen #  
— 7

Specimen 8 to 8



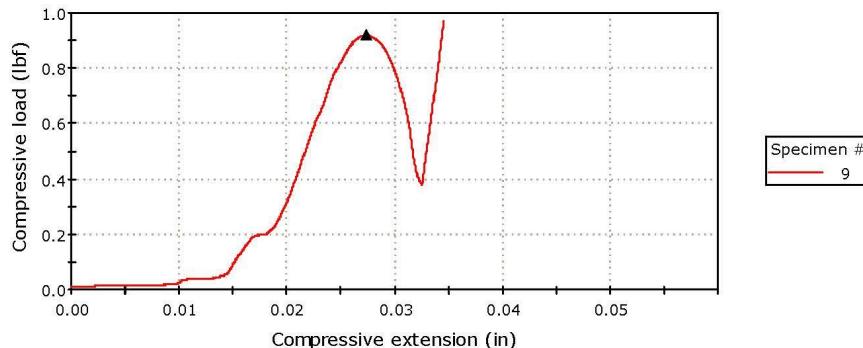
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<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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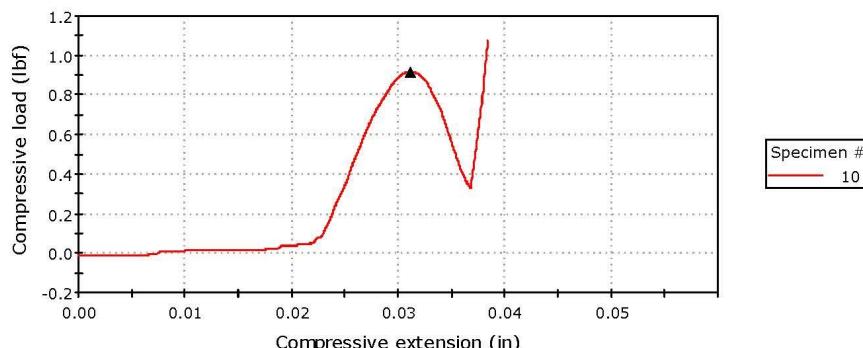
Thursday, January 30, 2020

GC.is\_comp

Specimen 9 to 9



Specimen 10 to 10

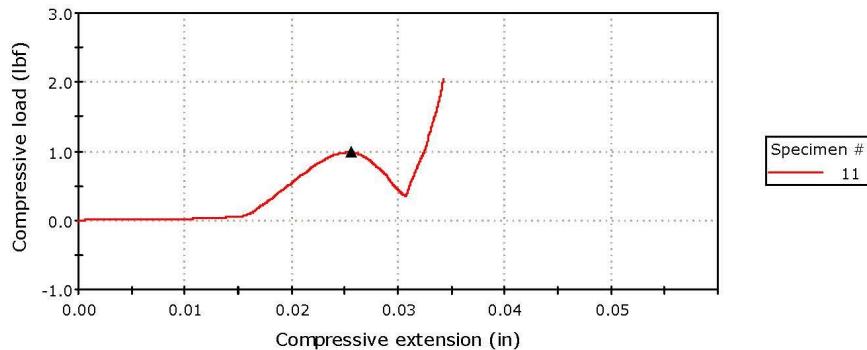


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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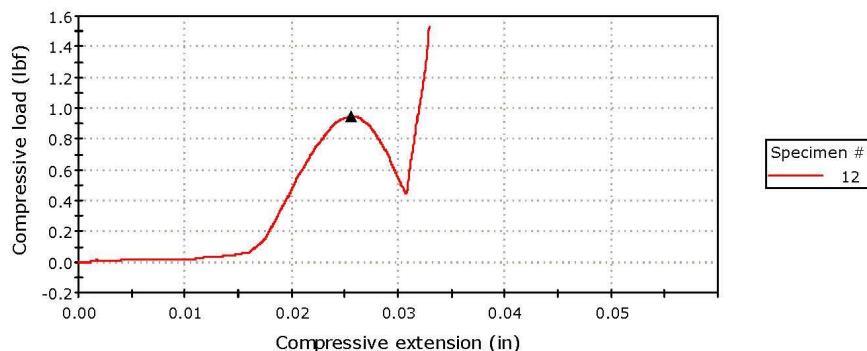
Thursday, January 30, 2020

GC.is\_comp

Specimen 11 to 11



Specimen 12 to 12

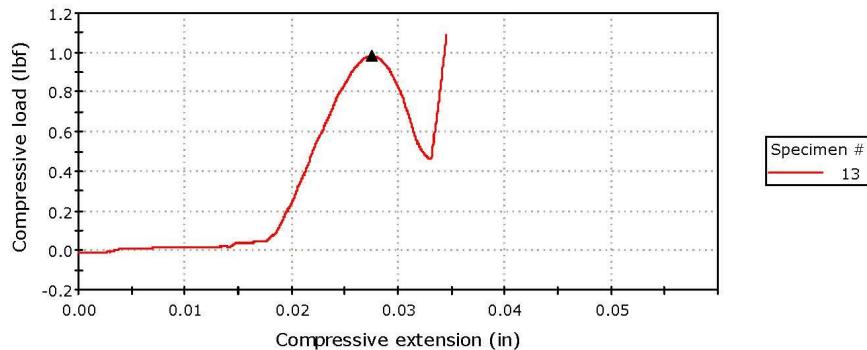


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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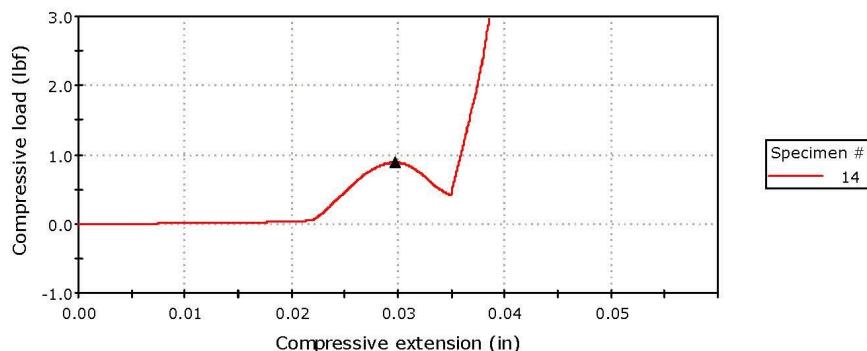
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Specimen 13 to 13



Specimen #  
13

Specimen 14 to 14



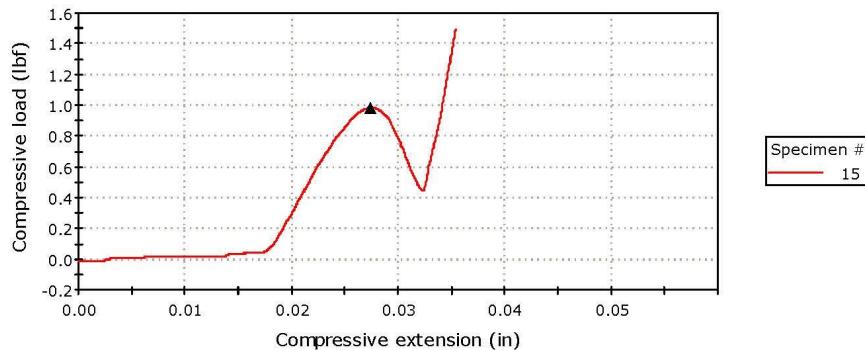
Specimen #  
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<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
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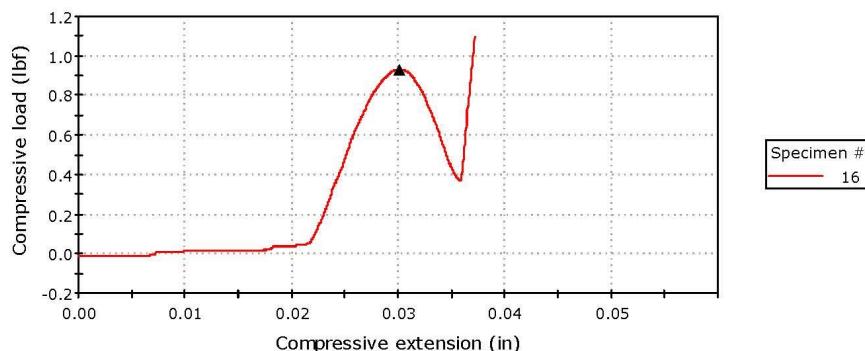
Thursday, January 30, 2020

GC.is\_comp

Specimen 15 to 15



Specimen 16 to 16

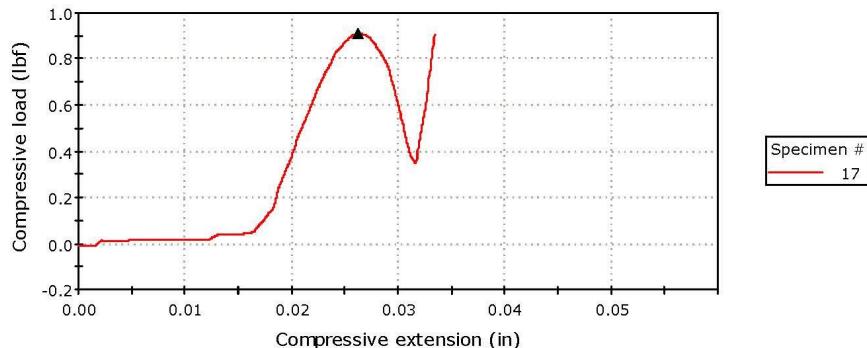


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	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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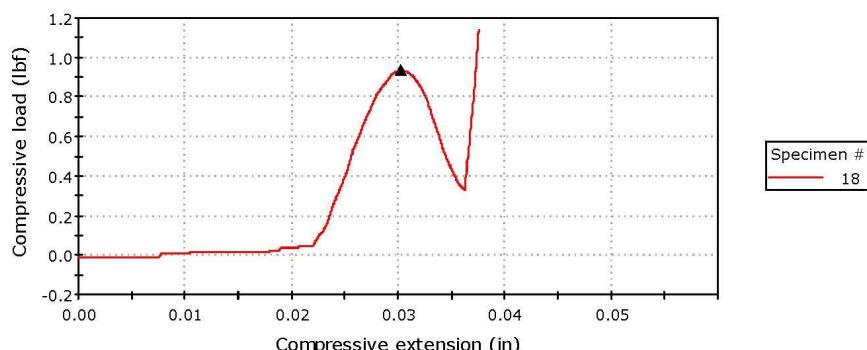
Thursday, January 30, 2020

GC.is\_comp

Specimen 17 to 17



Specimen 18 to 18

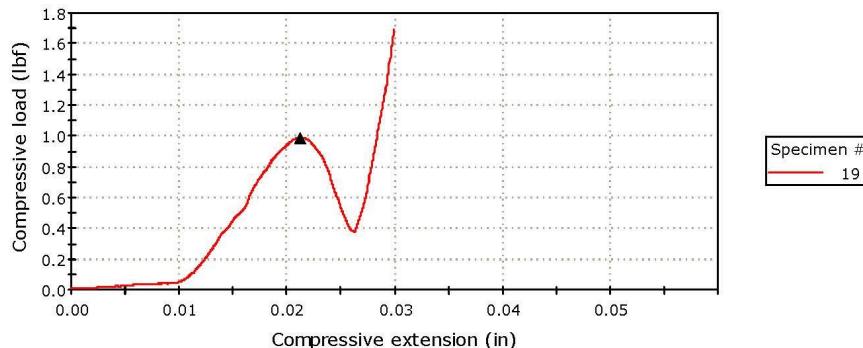


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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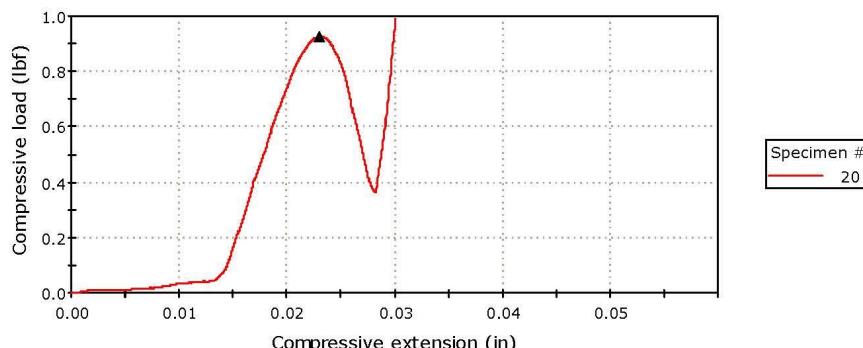
Thursday, January 30, 2020

GC.is\_comp

Specimen 19 to 19



Specimen 20 to 20

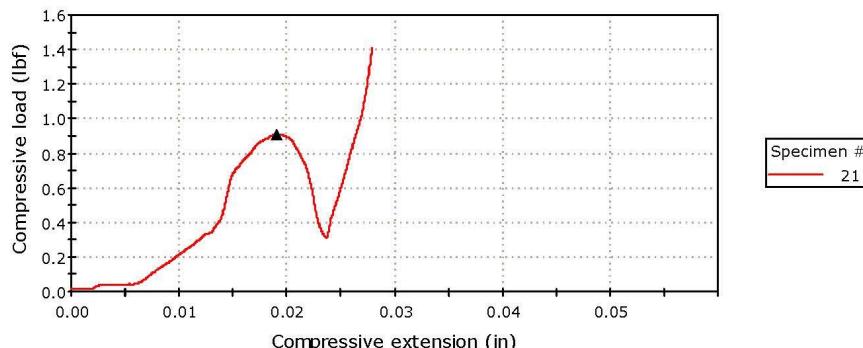


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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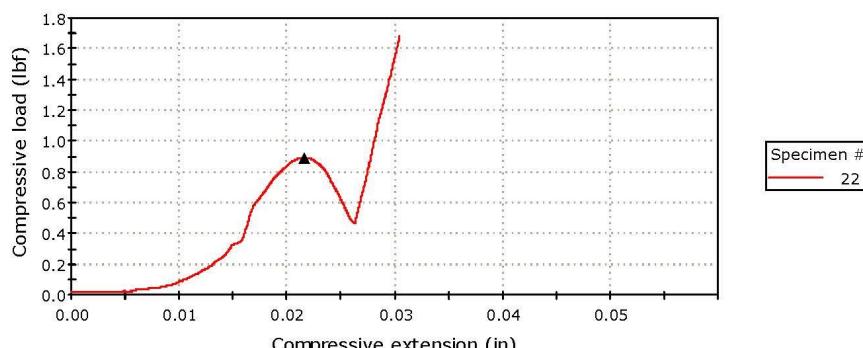
Thursday, January 30, 2020

GC.is\_comp

Specimen 21 to 21



Specimen 22 to 22

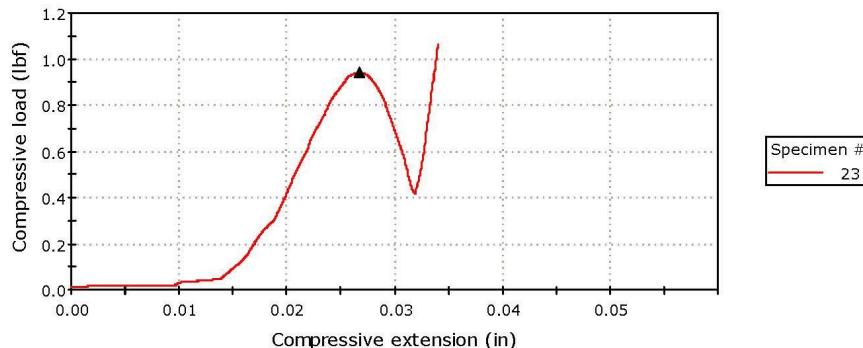


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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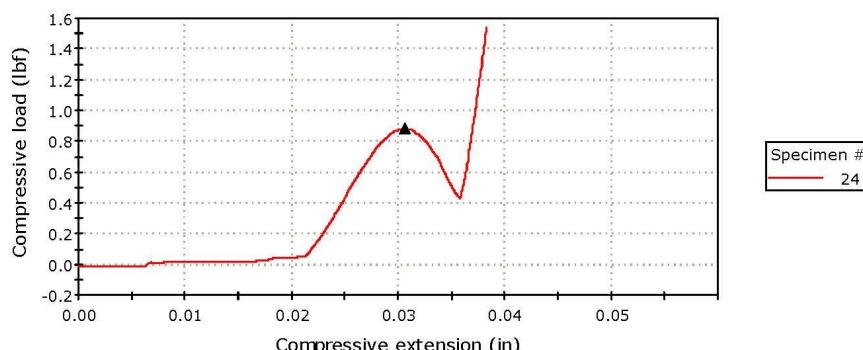
Thursday, January 30, 2020

GC.is\_comp

Specimen 23 to 23



Specimen 24 to 24

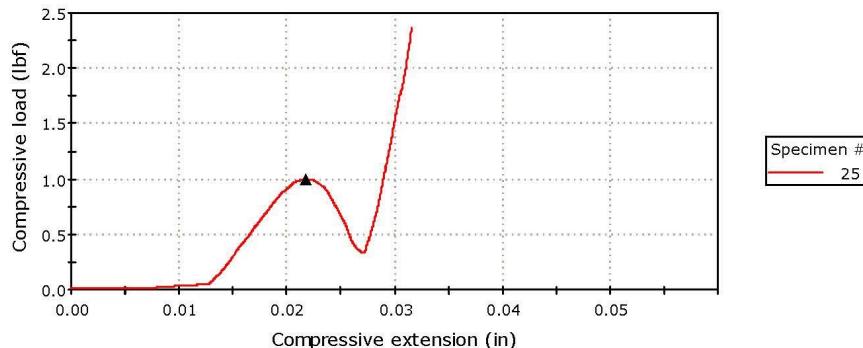


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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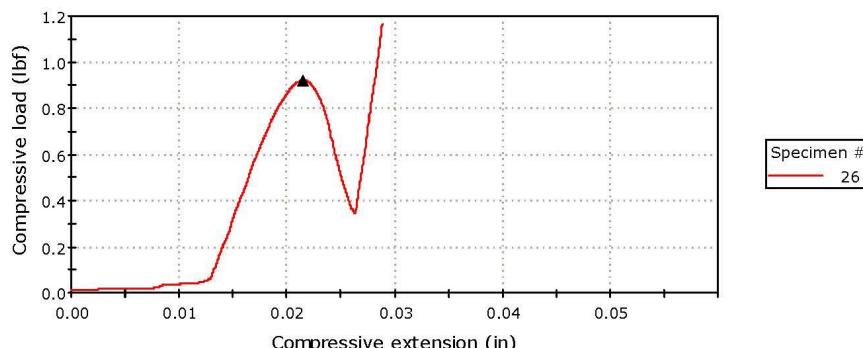
Thursday, January 30, 2020

GC.is\_comp

Specimen 25 to 25



Specimen 26 to 26

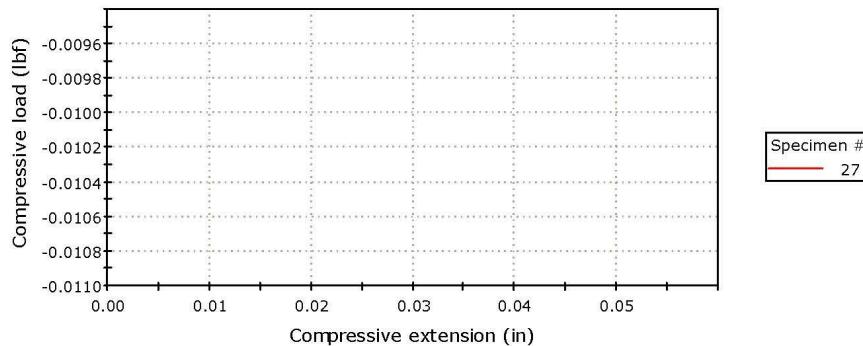


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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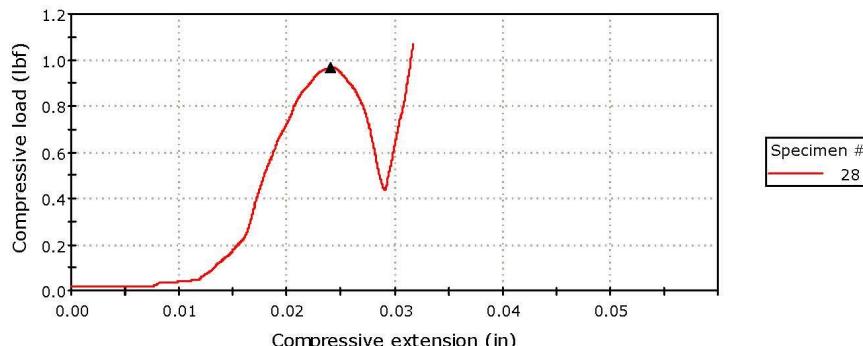
Thursday, January 30, 2020

GC.is\_comp

Specimen 27 to 27



Specimen 28 to 28

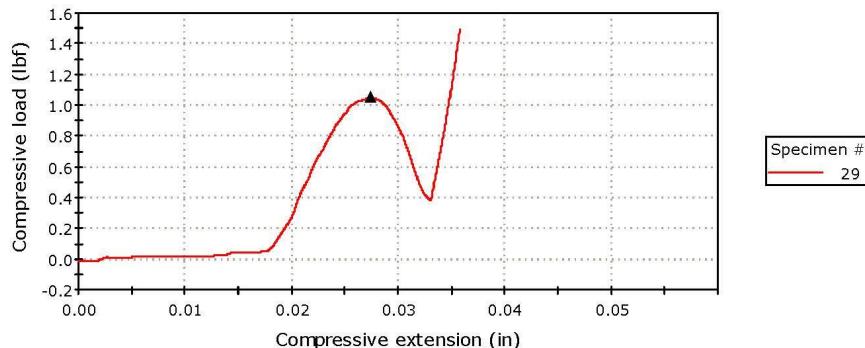


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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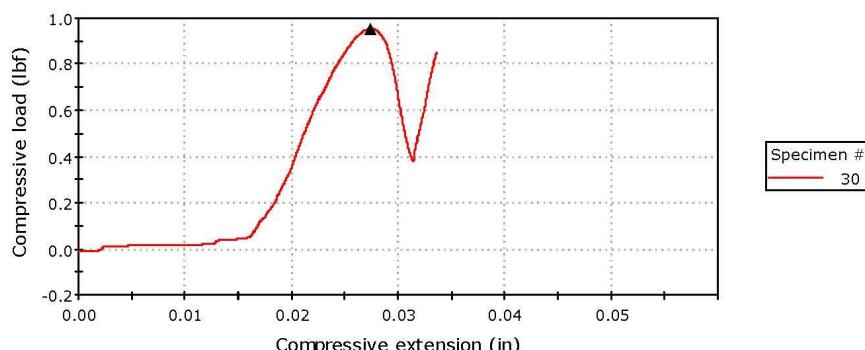
Thursday, January 30, 2020

GC.is\_comp

Specimen 29 to 29



Specimen 30 to 30

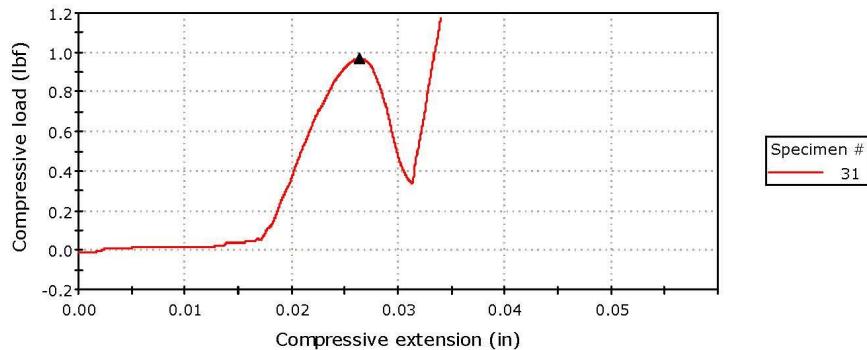


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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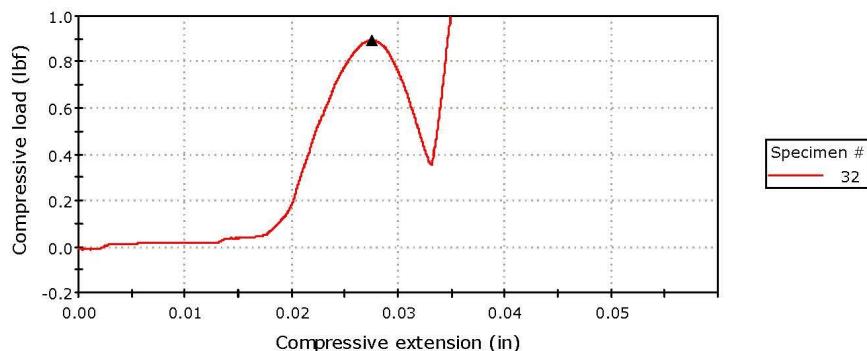
Thursday, January 30, 2020

GC.is\_comp

Specimen 31 to 31



Specimen 32 to 32

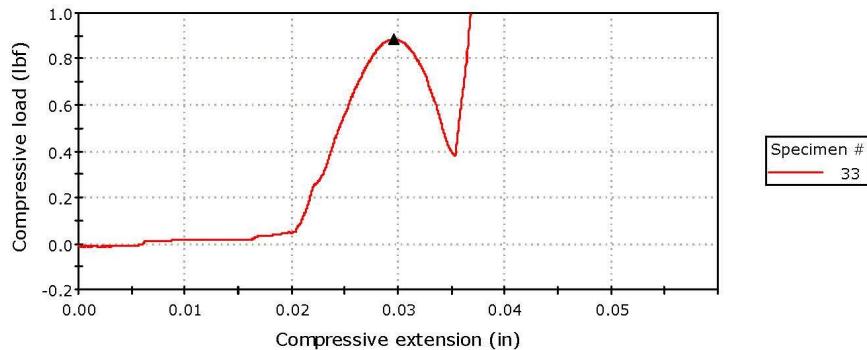


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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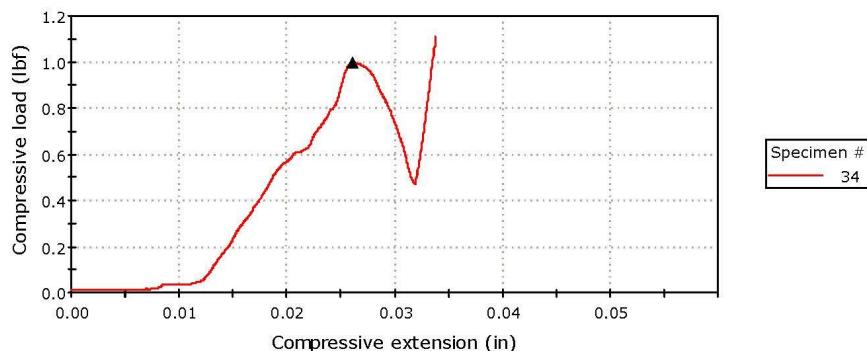
Thursday, January 30, 2020

GC.is\_comp

Specimen 33 to 33



Specimen 34 to 34

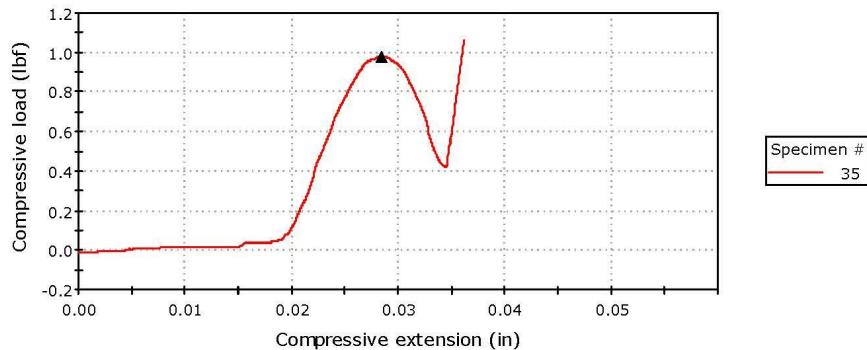


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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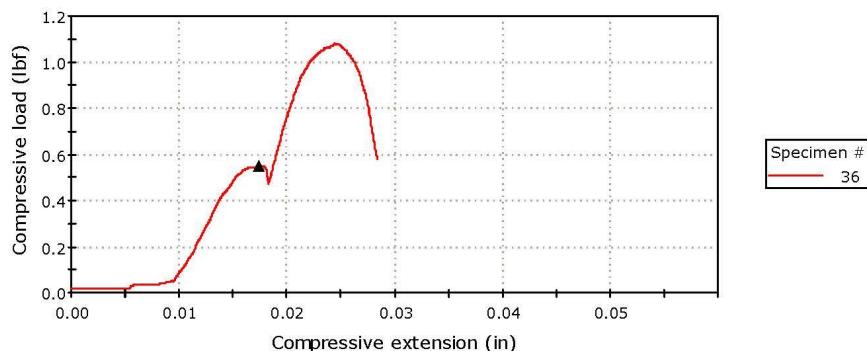
Thursday, January 30, 2020

GC.is\_comp

Specimen 35 to 35



Specimen 36 to 36

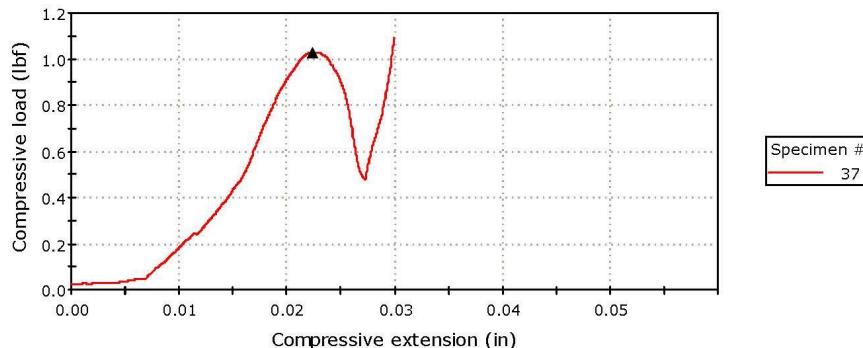


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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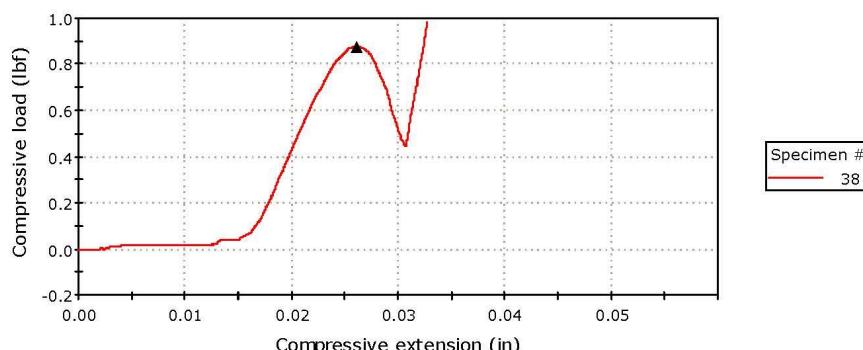
Thursday, January 30, 2020

GC.is\_comp

Specimen 37 to 37



Specimen 38 to 38

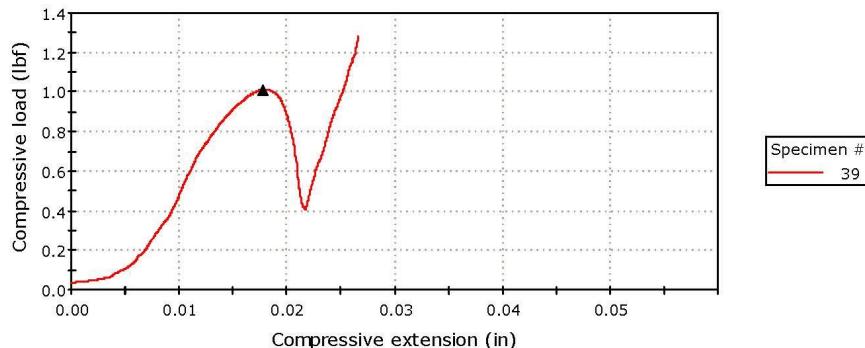


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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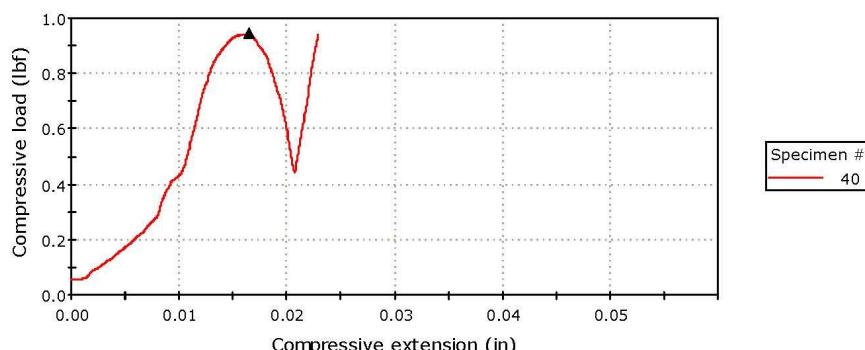
Thursday, January 30, 2020

GC.is\_comp

Specimen 39 to 39



Specimen 40 to 40

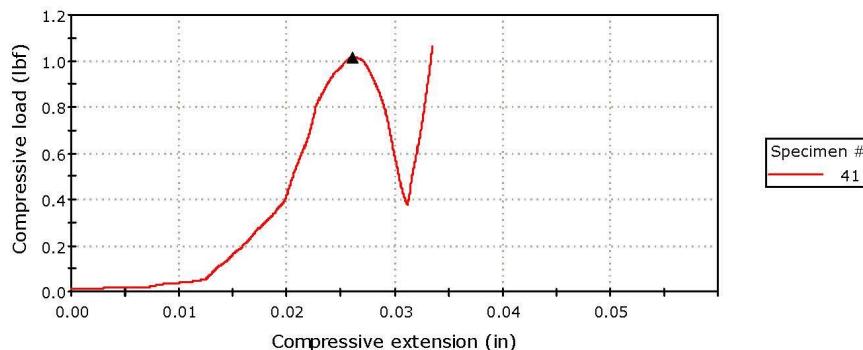


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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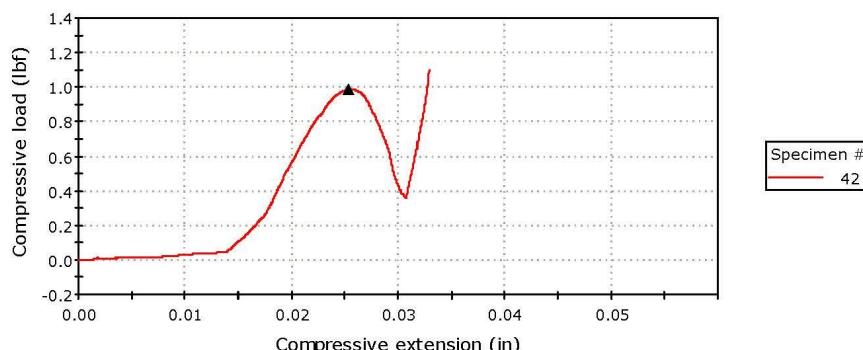
Thursday, January 30, 2020

GC.is\_comp

Specimen 41 to 41



Specimen 42 to 42

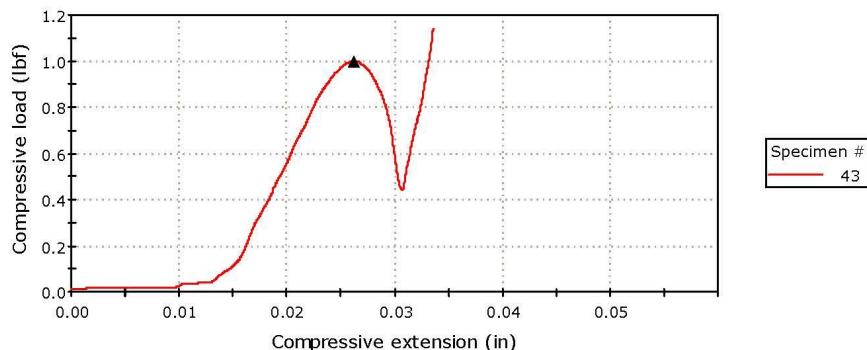


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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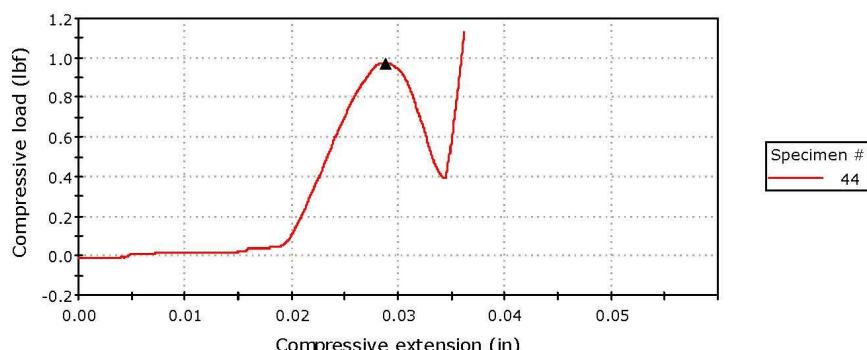
Thursday, January 30, 2020

GC.is\_comp

Specimen 43 to 43



Specimen 44 to 44

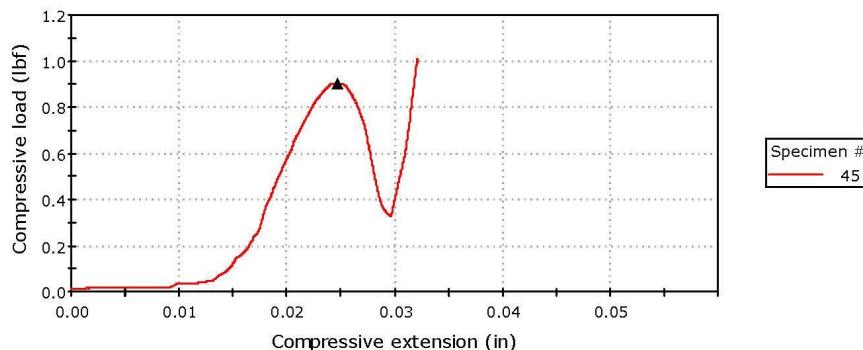


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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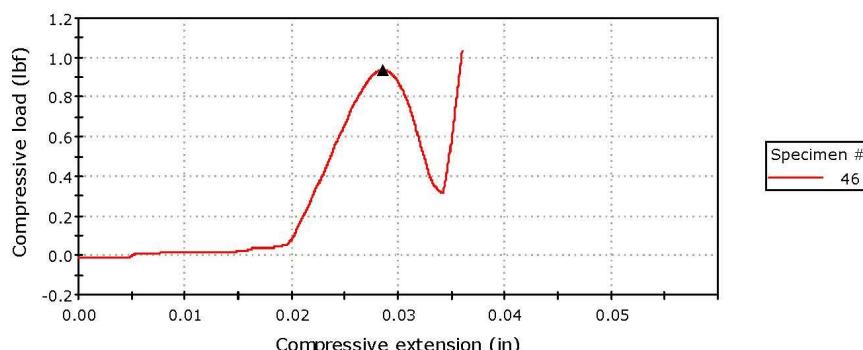
Thursday, January 30, 2020

GC.is\_comp

Specimen 45 to 45



Specimen 46 to 46

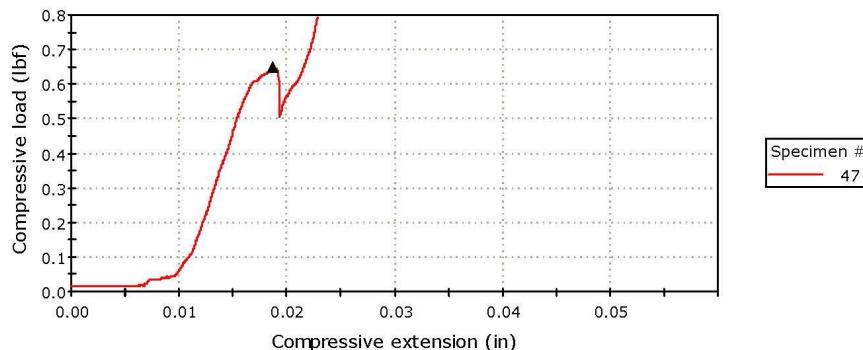


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
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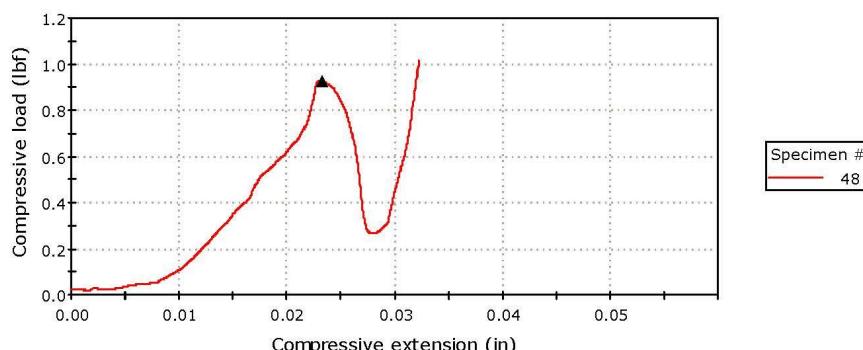
GC.is\_comp

Specimen 47 to 47



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47

Specimen 48 to 48



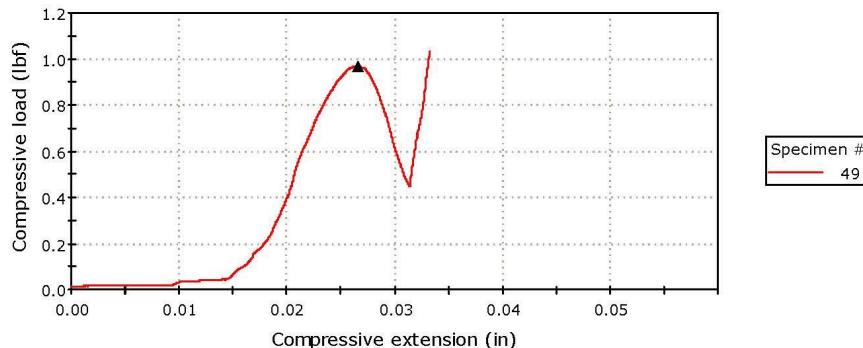
Specimen #  
48

<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
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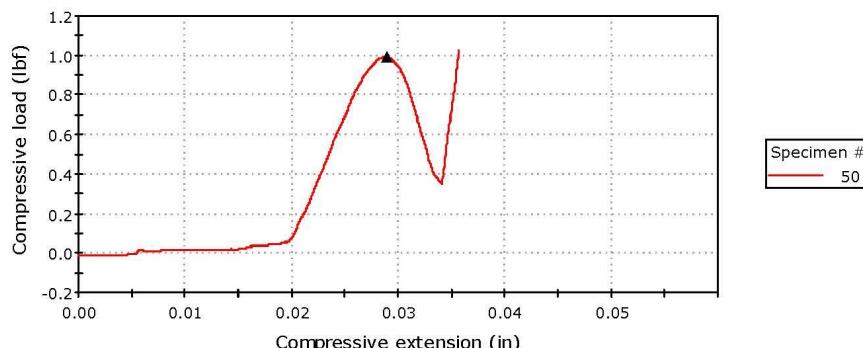
Thursday, January 30, 2020

GC.is\_comp

Specimen 49 to 49



Specimen 50 to 50

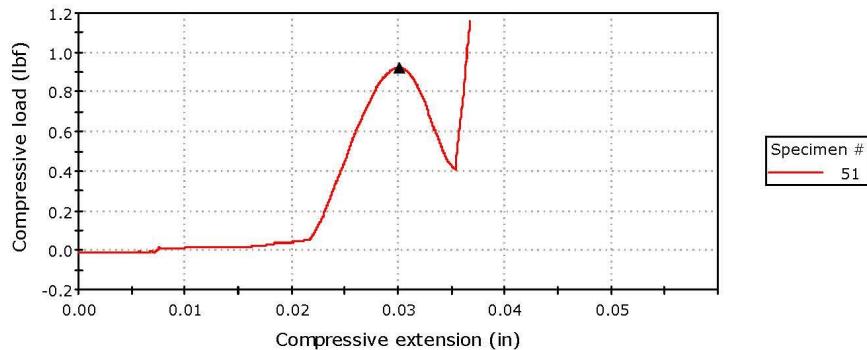


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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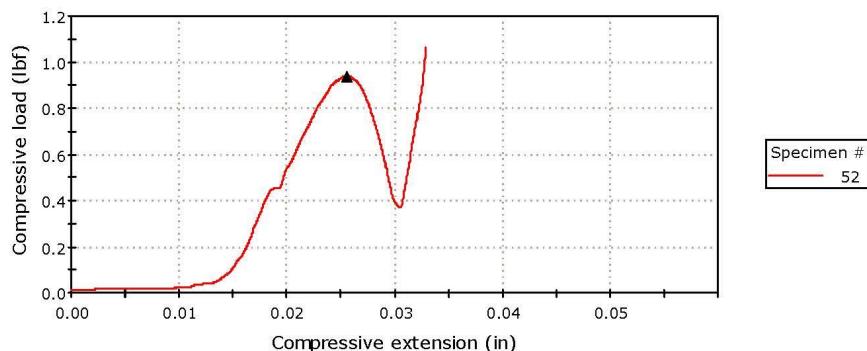
Thursday, January 30, 2020

GC.is\_comp

**Specimen 51 to 51**



**Specimen 52 to 52**

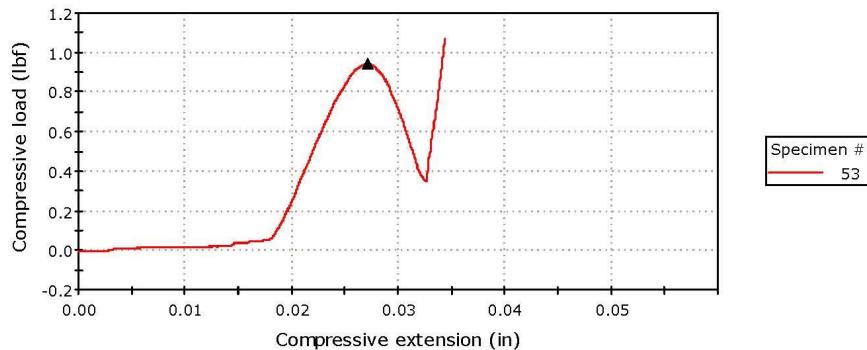


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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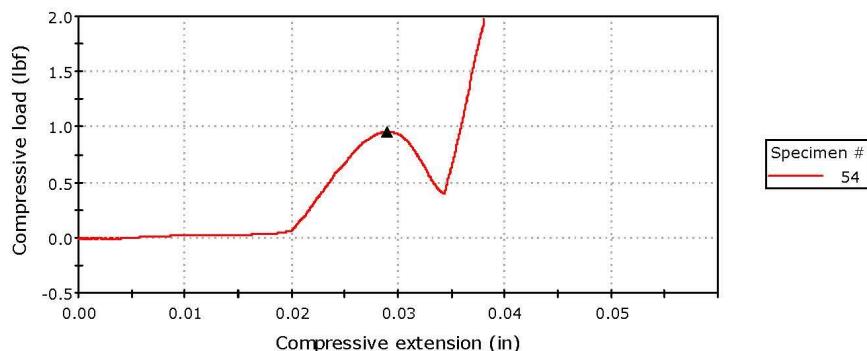
Thursday, January 30, 2020

GC.is\_comp

Specimen 53 to 53



Specimen 54 to 54

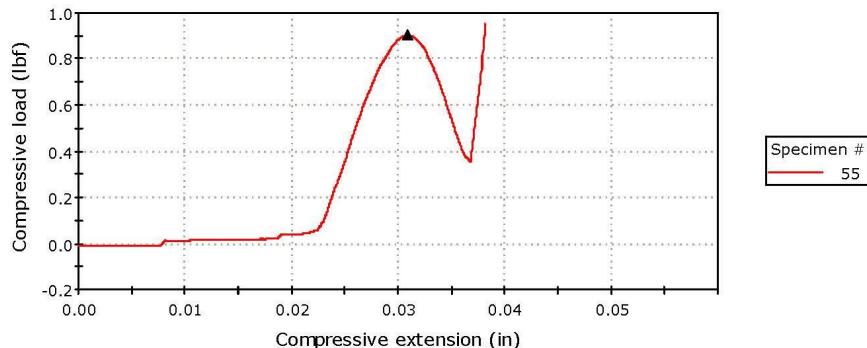


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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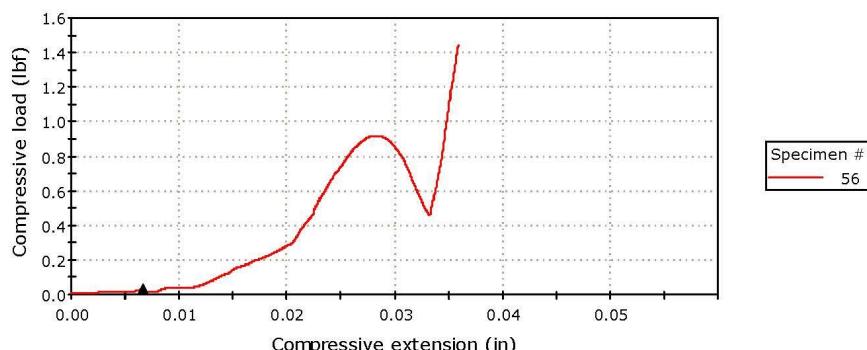
Thursday, January 30, 2020

GC.is\_comp

Specimen 55 to 55



Specimen 56 to 56

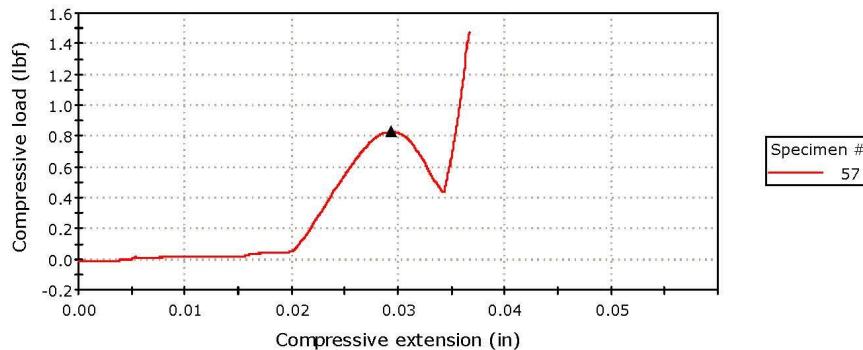


<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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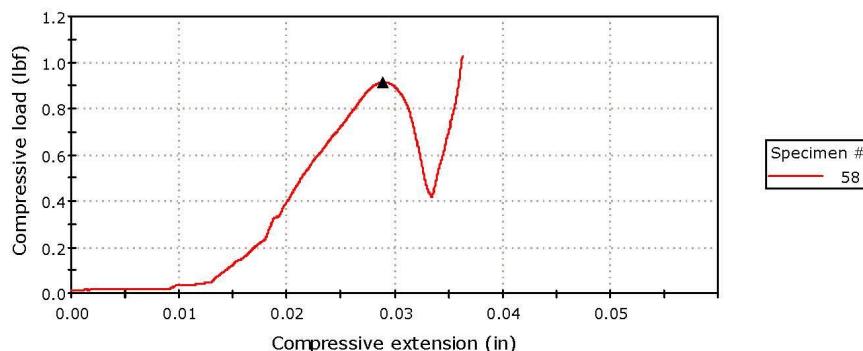
Thursday, January 30, 2020

GC.is\_comp

Specimen 57 to 57



Specimen 58 to 58

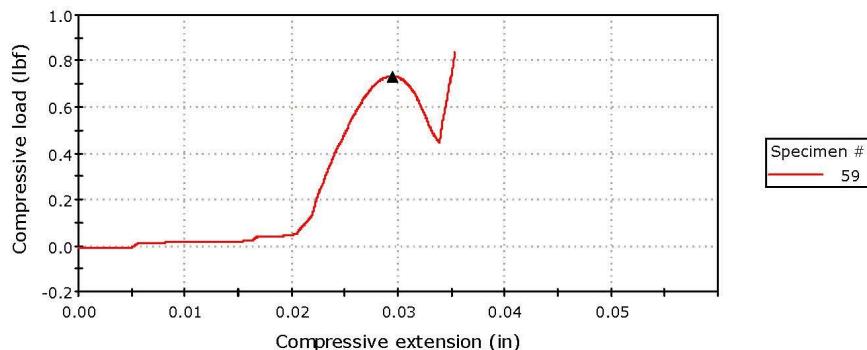


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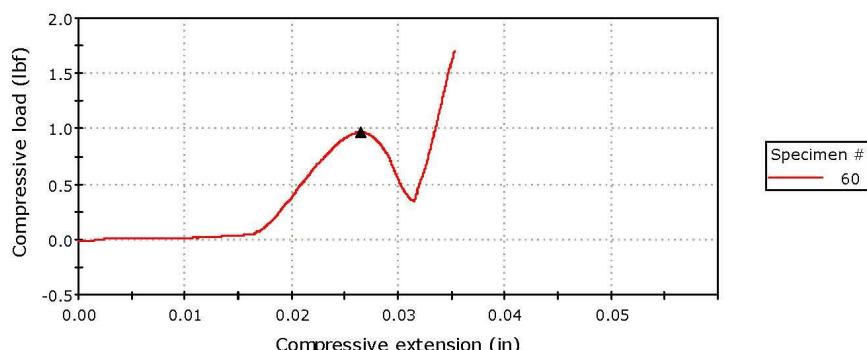
Thursday, January 30, 2020

GC.is\_comp

Specimen 59 to 59



Specimen 60 to 60

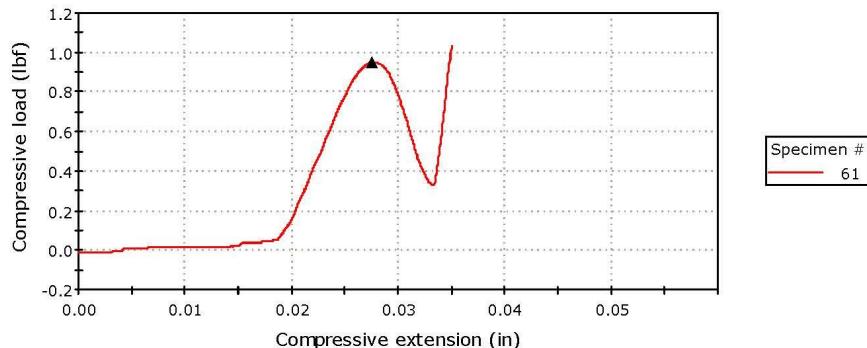


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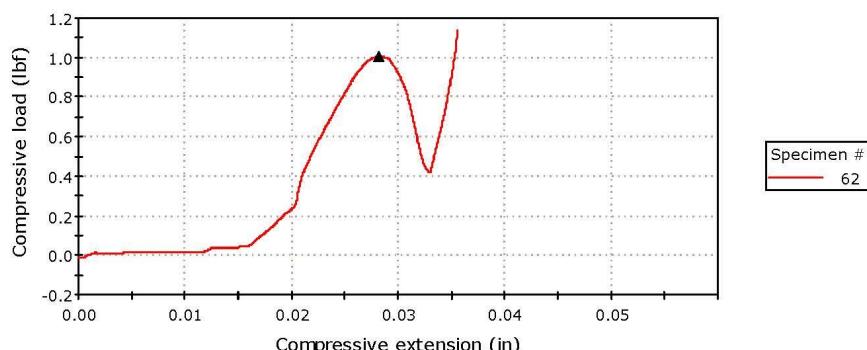
Thursday, January 30, 2020

GC.is\_comp

Specimen 61 to 61



Specimen 62 to 62

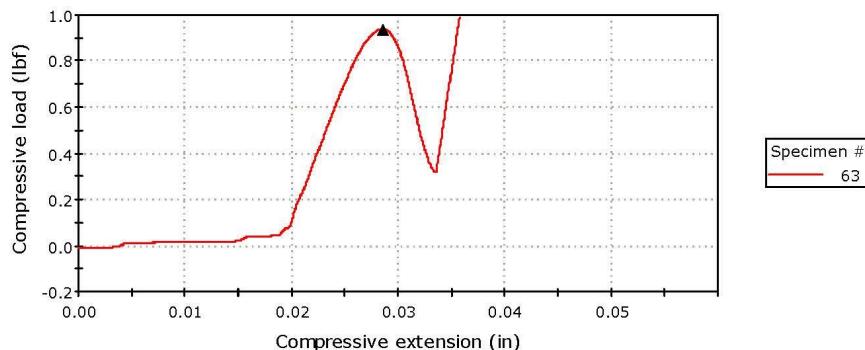


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Specimen 63 to 63



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## Appendix IV – Activation Over Time Test Data

<b>Megadyne Medical Products, Inc.</b>	<b>TEST PROTOCOL</b>	<b>Document Number</b> <b>ENG-PRT-594</b>
	<b>Pencil Dome Switch - Supplier Change - Mechanical Test Protocol</b>	<b>Revision: 001</b>

### Appendix XII: Datasheet for Handpiece Force Over Time Testing

Samples	Configuration X.Y.ZZ	Button Activation Pre Cycle Testing				Button Activation Post Cycle			
		CUT		COAG		CUT		COAG	
		Open >100kΩ	Closed <50Ω	Open >100kΩ	Closed <50Ω	Open >100kΩ	Closed <50Ω	Open >100kΩ	Closed <50Ω
1	Z.P.01	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
2	Z.D.02	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
3	Z.D.03	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
4	Z.D.04	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
5	Z.P.05	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
6	Z.D.06	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
7	Z.D.07	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
8	Z.P.08	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
9	Z.P.09	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
10	Z.D.10	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
11	Z.D.11	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
12	Z.D.12	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
13	Z.D.13	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
14	Z.D.14	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
15	Z.P.15	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
16	Z.P.16	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
17	Z.D.17	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
18	Z.P.18	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
19	Z.D.19	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
20	Z.D.20	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
21	Z.D.21	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
22	Z.P.22	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
23	Z.D.23	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
24	Z.D.24	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
25	Z.D.25	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
26	Z.P.26	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
27	Z.D.27	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
28	Z.D.28	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
29	Z.D.29	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
30	Z.P.30	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

Operator Name (Print)	Operator Signature	Date
Brian Taylor		28 Jan 2020

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Megadyne Medical Products, Inc.	TEST PROTOCOL								Document Number ENG-PRT-594	
	Pencil Dome Switch - Supplier Change -									
	Mechanical Test Protocol									
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#### Appendix XII: Datasheet for Handpiece Force Over Time Testing

Samples	Configuration X.Y.ZZ	Button Activation Pre Cycle Testing				Button Activation Post Cycle			
		CUT		COAG		CUT		COAG	
		Open >100kΩ	Closed <50Ω	Open >100kΩ	Closed <50Ω	Open >100kΩ	Closed <50Ω	Open >100kΩ	Closed <50Ω
1	A.D.01	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
2	A.D.02	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
3	A.D.03	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
4	A.D.04	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
5	A.D.05	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
6	A.D.06	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
7	A.D.07	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
8	A.D.08	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
9	A.D.09	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
10	A.D.10	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
11	A.D.11	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
12	A.D.12	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
13	A.D.13	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
14	A.D.14	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
15	A.D.15	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
16	A.D.16	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
17	A.D.17	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
18	A.D.18	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
19	A.D.19	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
20	A.D.20	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
21	A.D.21	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
22	A.D.22	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
23	A.D.23	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
24	A.D.24	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
25	A.D.25	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
26	A.D.26	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
27	A.D.27	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
28	A.D.28	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
29	A.D.29	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
30	A.D.30	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

Operator Name (Print)	Operator Signature	Date
Brian Taylor		28 Jan 2020

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Megadyne Medical Products, Inc.	<b>TEST PROTOCOL</b>								<b>Document Number</b> <b>ENG-PRT-594</b>
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#### Appendix XII: Datasheet for Handpiece Force Over Time Testing

Samples	Configuration X.Y.ZZ	Button Activation Pre Cycle Testing				Button Activation Post Cycle			
		CUT		COAG		CUT		COAG	
		Open >100kΩ	Closed <50Ω	Open >100kΩ	Closed <50Ω	Open >100kΩ	Closed <50Ω	Open >100kΩ	Closed <50Ω
1	R.D.01	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
2	R.D.02	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
3	R.D.03	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
4	R.D.04	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
5	R.D.05	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
6	R.D.06	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
7	R.D.07	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
8	R.D.08	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
9	R.D.09	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
10	R.D.10	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
11	R.D.11	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
12	R.D.12	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
13	R.D.13	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
14	R.D.14	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
15	R.D.15	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
16	R.D.16	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
17	R.D.17	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
18	R.D.18	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
19	R.D.19	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
20	R.D.20	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
21	R.D.21	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
22	R.D.22	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
23	R.D.23	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
24	R.D.24	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
25	R.D.25	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
26	R.D.26	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
27	R.D.27	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
28	R.D.28	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
29	R.D.29	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
30	R.D.30	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

Operator Name (Print)	Operator Signature	Date
Brian Taylor		20 Jan 2020

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#### Appendix XII: Datasheet for Handpiece Force Over Time Testing

Samples	Configuration X.Y.ZZ	Button Activation Pre Cycle Testing				Button Activation Post Cycle			
		CUT		COAG		CUT		COAG	
		Open >100kΩ	Closed <50Ω	Open >100kΩ	Closed <50Ω	Open >100kΩ	Closed <50Ω	Open >100kΩ	Closed <50Ω
1	G.D.01	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
2	G.D.02	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
3	G.D.03	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
4	G.D.04	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
5	G.D.05	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
6	G.D.06	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
7	G.D.07	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
8	G.D.08	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
9	G.D.09	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
10	G.D.10	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
11	G.D.11	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
12	G.D.12	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
13	G.D.13	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
14	G.D.14	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
15	G.D.15	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
16	G.D.16	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
17	G.D.17	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
18	G.D.18	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
19	G.D.19	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
20	G.D.20	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
21	G.D.21	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
22	G.D.22	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
23	G.D.23	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
24	G.D.24	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
25	G.D.25	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
26	G.D.26	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
27	G.D.27	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
28	G.D.28	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
29	G.D.29	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
30	G.D.30	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

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## Appendix V – Equipment Calibration Information

<b>Megadyne Medical Products, Inc.</b>	<b>TEST PROTOCOL</b>	<b>Document Number</b> <b>ENG-PRT-594</b>
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### Appendix IV: Handpiece High Frequency Dielectric Withstand and Mains Frequency Equipment Calibration Log

Calibration Information			
Multimeter		Generator	
Fluke 179 True RMS Multimeter		Mega Power 1000	
Serial Number	33660160	Serial Number	10353001
Megadyne Number	01508	Megadyne Number	N/A
Calibration Date	01/21/2020	Calibration Date	N/A
Calibration Due	01/31/2021	Calibration Due	N/A
Oscilloscope			
Tektronix TDS 3042B	3042B-7014	HiPot Test Generator	Hipotronics Model HD 100 Series
Serial Number	C038411	Serial Number	N/A
Megadyne Number	01221	Megadyne Number	01037
Calibration Date	09/10/2019	Calibration Date	12/23/2019
Calibration Due	09/30/2020	Calibration Due	12/31/2020
High Voltage Probe			
Tektronix P6015A High Voltage Probe		Inductive Current Coil	Peerson Current Monitor, Model 2100
Serial Number	N/A	Serial Number	82358
Megadyne Number	N/A	Megadyne Number	01025
Calibration Date	N/A	Calibration Date	11/05/2019
Calibration Due	N/A	Calibration Due	11/30/2020
RMS Voltmeter			
Fluke 8920A True RMS Voltmeter			
Serial Number	4540017		
Megadyne Number	01255		
Calibration Date	05/24/2019		
Calibration Due	05/31/2020		

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<b>Megadyne Medical Products, Inc.</b>	<b>TEST PROTOCOL</b>	<b>Document Number</b> <b>ENG-PRT-594</b>
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#### Appendix VII: Fluid Ingress Calibration Information

Calibration Information		
HiPot Test Generator		Multimeter
Hipotronics Model HD 100 Series		Fluke 179 True RMS Multimeter
Serial Number	111A	Serial Number
Megadyne Number	D1037	Megadyne Number
Calibration Date	12/23/2019	Calibration Date
Calibration Due	12/31/2020	Calibration Due
Oscilloscope	BL	Inductive Current Coil
Tektronix TDS 3012B-204Y		Peerson Current Monitor, Model 2100
Serial Number	C038411	Serial Number
Megadyne Number	01221	Megadyne Number
Calibration Date	09/10/2019	Calibration Date
Calibration Due	09/30/2020	Calibration Due

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<b>Megadyne Medical Products, Inc.</b>	<b>TEST PROTOCOL</b>	<b>Document Number</b> <b>ENG-PRT-594</b>
	<b>Pencil Dome Switch - Supplier Change - Mechanical Test Protocol</b>	<b>Revision: 001</b>

#### Appendix X: Button Force Activation Calibration Information

Calibration Information			
Instron		Multimeter	
Instron 4464		Fluke 179 True RMS Multimeter	
Serial Number	4464C2820	Serial Number	33660160
Megadyne Number	01028	Megadyne Number	01508
Calibration Date	01/15/2020	Calibration Date	01/21/2020
Calibration Due	01/15/2021	Calibration Due	01/31/2021

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<b>Megadyne Medical Products, Inc.</b>	<b>TEST PROTOCOL</b>	<b>Document Number</b> <b>ENG-PRT-594</b>
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**Appendix XIII: Button Activation Over Time Calibration Information**

Calibration Information	
Multimeter	
Fluke 179 True RMS Multimeter	
Serial Number	3F60160
Megadyne Number	01508
Calibration Date	01/21/2020
Calibration Due	01/31/2021

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### Appendix VI – Training Record

Megadyne Medical Products, Inc.	<b>Form</b>	<b>Document Number</b> <b>HR-FRM-003</b>
	<b>Training Record Form</b>	<b>Revision: 001</b>
		<b>Page 1 of 2</b>

COMPLETE THIS FORM IN BLUE OR BLACK INK ONLY.					
Method of Training: <input checked="" type="checkbox"/> Instructor Led <input checked="" type="checkbox"/> Self Training <input type="checkbox"/> External Training <input type="checkbox"/> Awareness					
Instructor's Name & Signature (Print "N/A" if Self): Paul Valpreda <i>Paul Valpreda</i> 1-28-2020					
Course, NC/CAPA, or Document Description: (Description of content or course agenda/outline. Course description may include, but not limited to, the complete document title, version and sections/topic covered or brief description of reason for training): ENG-PRT-594 – Test Protocol Sterilized Product Design Verification					
Course Code, Title, NC/CAPA Number, or Document Number	Document Revision Number	Training Start Date	Training End Date	Training Duration	For Training Dept Use Only
					Course Code (Optional)
Handpiece Force Over Time Testing	001	28 Jan 2020	28 Jan 2020	30 min	
Handpiece Button Force Activation Testing	001	29 Jan 2020	29 Jan 2020	30 min	
Handpiece Fluid Ingress Testing	001	30 Jan 2020	30 Jan 2020	30 min	
Handpiece High Frequency Dielectric withstand	001	5 Feb 2020	5 Feb 2020	30 min	
N/A	N/A	N/A	N/A	N/A	

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<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change -</b> <b>Test Report</b>	<b>Revision: A</b>
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Megadyne Medical Products, Inc.	<b>Form</b>	<b>Document Number</b> <b>HR-FRM-003</b>
	<b>Training Record Form</b>	<b>Revision: 001</b>
		<b>Page 2 of 2</b>

*My signature below indicates I have self-trained / reviewed or participated in Instructor Led Training as described on page 1 and I understand the information or concepts covered.*

TYPE / PRINT NAME	SIGNATURE	DATE (MM/DD/YYYY)	WWID #
1. Brian Taylor		01/28/2020	702311424
2. Brian Taylor		01/29/2020	702311424
3. Brian Taylor		01/30/2020	702311424
4. Brian Taylor		02/05/2020	702311424
5.			
6.			
7.			
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18.			

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<b>ETHICON</b> <small>a Johnson &amp; Johnson company</small>	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
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## Appendix VII – Build Report

ZIP – X252510N



### Certificate of Compliance

**Taiwan**  
New Deantronics Taiwan Ltd  
236 新北市土城區中和路 4 段 31 號 12 樓  
12F, No. 51, Sec. 4,  
Zhongxiao Rd., Tucheng Dist.,  
New Taipei City 236  
Taiwan R.O.C.  
Tel: +886 (0) 2268 1726  
Fax: +886 (0) 2268 3600

**Customer Name:** MEGADYNE MEDICAL PRODUCTS, INC.  
**Invoice Number :** MD-1101/19  
**P. O. Number:** 32676  
**Customer P/N:** X252510N  
**Drawing Number:** PB352SM1 Rev.D0 (Redline)  
**New Deantronics P/N:** PB352SM1  
**Lot Number:** SM1910009  
**Manufacture Date:** 2019-10-01  
**Quantity:** 240 Pieces  
**Carton Number:** #001 ~ #012 (12 Cartons)  
**Signed:** *D. Y. Chen*  
**Printed Name:** Da-Yu Chen  
**Title:** Q.A. Director

**Date:** 10-30-2019

**U.S.**  
New Deantronics, Ltd.  
1 New Deantronics Way  
Sparks, NV 89441  
USA  
Tel: +1 (775) 433 1808  
Fax: +1 (775) 433 1806

New Deantronics Ltd. hereby certifies that the product in this shipment meets the requirements in the above referenced document. No material, component, or subassembly changes were made without written approval from Megadyne engineering.

<u>Materials</u>		<u>ND</u> <u>Mat'l Lot#</u>	<u>Megadyne</u> <u>Lot#</u>
Cable	C302600 Conductor : 7/0.16*3BC(26 AWG) Bare copper Insulation: PPE, red/blue/ white Outer jacket: PVC, Gray	19092701	
Plug upper	F507100, ABS PA707	19091604	
Plug lower	F507200, ABS PA707	19091603	
Terminal	T101702 , Nickel plated brass	19091001	
Overmold material	R900801, TPR	19081501	
Swivel, male	F916600, HDPE	A01601510	
Swivel, Female	F917000, HDPE	A01561730	
Connector	F919700, ABS	A02220811	
Collet Terminal	T202502, Phosphor Bronze contact plated nickel	19050701	
Button	F302500, NYLON 66	19080201S	
Tape	A100401, PTFE A100500, SURLYN	19070501 18061101	
PCB	H203102, PCB Isola 370HR	19070101	

QR-002-2

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<b>ETHICON</b> <small>a Johnson &amp; Johnson company</small>	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change - Test Report</b>	<b>Revision: A</b>
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NEW DEANTRONICS TAIWAN LTD.

Taiwan	Solder wire	S200300, SAC305	19060401
	Dome	M101900, Stainless Steel SUS304	19100701
	Pen Body	F105400 ABS+TPR	19062101-19070501
	Ink	S102000, Green, PMS356C	19082001-19083001
	Nozzle	F916300, PC	19070501
	Collet Holder	F918100, PC	19072401
	Glue	S400900, Loctite 4061	19040801
	Carriage	F916500, ABS	19071701
	Snap Swivel, Male	F916400, HDPE	A01238335
	Snap Swivel, Female	F918300, HDPE	A01238435
-----	Tubing, Connector	F916700, HDPE	A02095331-A02095338
U.S.	Tubing, Convoluted	P305600, EVA P305700, EVA	19052101 19051301
New Deantronics, Ltd. 1 New Deantronics Way Sparks, NV 89441	Holster	F916900, HDPE	19071701
USA Tel: +1 (775) 433 1808 Fax: +1 (775) 433 1806	Blade	G102700, Coated Megadyne P/N: 0012BN5 (Provided by Megadyne)	19071504 ( 240 pcs )      193515
	Paper Band	A900300	19050601-19080501
	PE bag	A401600, LDPE	19092401
	Tyvek	A000400, CR-27 1073B	19061401
	Nylon Film	A000500, Nylon	19050602

 <b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
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**中國生化科技股份有限公司**

CHINA BIOTECH CORPORATION

誠信正直 · 顧客感動 · 社會公道

TEL:886-4-23597515 FAX:886-4-23597080

台中市工業區33路10號

10, 33<sup>rd</sup> Road, Taichung Industrial Park,

Taichung,Taiwan R.O.C 407

DATE : 2019/10/28

**照射證明書**  
**CERTIFICATE OF IRRADIATION**

行政院原能會核准設立照射廠執照証號 IRRADIATION PLANT NO : 物字第 1100223 號

客戶名稱 CUSTOMER NAME : 大瓏(股)公司

NEW DEANTRONICS TAIWAN LTD.

照射日期 IRRADIATION RUN DATE : 2019/10/24

照射批號 IRRADIATION RUN NUMBER : NEW19860-N

客戶產品已照射 MATERIALS PROCESSED :

支 數 PCS	內 容 DESCRIPTION	客戶產品批號 LOT NO
243	X252510N(PB352SM1)	SM1910009

總 數 243 支 數  
TOTAL PCS

中國生化科技股份有限公司證明上述產品經本公司劑量偵測系統判讀，吸收劑量如下：

China Biotech Corporation certifies that the material listed above (has described by its manufacturer) received the following doses within the precision limits of the dosimetry system employed

最 低 劑 量 46.7 kGy ; 最 高 劑 量 48.5 kGy  
MINIMUM DOSAGE 46.7 kGy ; MAXIMUM DOSAGE 48.5 kGy

使用放射性同位素 ISOTOPE UTILIZED : 鈷 60 COBALT-60

客戶劑量要求 DOSE REQUIREMENT : 最低劑量MIN 45.0 kGy ; 最高劑量MAX 50.0 kGy

確 認 者: 林志華  
CERTIFIED BY 品保部主管  
QUALITY ASSURANCE

<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change - Test Report</b>	<b>Revision: A</b>
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ACE – XME725M1CN



### Certificate of Compliance

<b>Taiwan</b> 大連金泰股份有限公司 New Deantronics Taiwan Ltd. 236 新北市土城區中正路 4 號 31 樓 12 樓 12F, No. 51, Sec. 4, Zhongxing Rd., Tucheng Dist., New Taipei City 236, Taiwan R.O.C. Tel: +886 (2) 2368 1726 Fax: +886 (2) 2368 3800	<b>Customer Name:</b> MEGADYNE MEDICAL PRODUCTS, INC. <b>Invoice Number :</b> MD-1098/19 <b>P. O. Number:</b> 32676 <b>Customer P/N:</b> XME725M1CN <b>Drawing Number:</b> PB352NM1 Rev.A0 (Redline) <b>New Deantronics P/N:</b> PB352NM1 <b>Lot Number:</b> SM1910010 <b>Manufacture Date:</b> 2019-10-01 <b>Quantity:</b> 240 Pieces <b>Carton Number:</b> #001~# 040 (40 Cartons) <b>Signed:</b> <i>D. Y. Chen</i> <b>Printed Name:</b> Da-Yu Chen <b>Title:</b> Q.A. Director
<b>U.S.</b> New Deantronics, Ltd. 1 New Deantronics Way Sparks, NV 89441 USA Tel: +1 (775) 433 1808 Fax: +1 (775) 433 1806	<b>Date:</b> 10-25-2019 New Deantronics Ltd. hereby certifies that the product in this shipment meets the requirements in the above referenced document. No material, component, or subassembly changes were made without written approval from Megadyne engineering.

<u>Materials</u>		<u>ND</u> <u>Mat'l Lot#</u>	<u>Megadyne</u> <u>Lot#</u>
Cable	C302600 Conductor : 7/0.16*3BC(26 AWG) Bare copper Insulation: PPE, red/blue/ white Outer jacket: PVC, Gray	19092701	
Plug upper	F507100, ABS PA707	19091604	
Plug lower	F507200, ABS PA707	19091603	
Terminal	T101702 , Nickel plated brass	19091001	
Overmold material	R900801, TPR	19081501	
Swivel, male	F916600, HDPE	A01601510	
Swivel, Female	F917000, HDPE	A01561730	
Connector	F919700, ABS	A02220811	
Collet Terminal	T202502, Phosphor Bronze contact plated nickel	19050701	
Button	F302500, NYLON 66	19080201S	
Tape	A100401, PTFE A100500, SURLYN	19070501 18061101	
PCB	H203102, PCB Isola 370HR	19070101	

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<b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
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Solder wire	S200300, SAC305	19060401	
Dome	M101900, Stainless Steel SUS304	19100701	
Pen Body	F105400 ABS+TPR	19062101-19070501	
Taiwan	Ink	S102000, Green, PMS356C	19082001-19083001
大庭企業股份有限公司 New Deantronics Taiwan Ltd. 236 新光市士林區中興路1段51號12樓 12F, No.51, Sec. 4, Zhongyeng Rd., Tucheng Dist., New Taipei City 236, Taiwan R.O.C. Tel +886 (2)2298 1726 Fax +886 (2)2298 3800	Nozzle	F916300, PC	19070501
Collet Holder	F918100, PC	19072401	
Glue	S400900, Loctite 4061	19040801	
Carriage	F916500, ABS	19071701	
Snap Swivel, Male	F916400, HDPE	A01238335	
Snap Swivel, Female	F918300, HDPE	A01238420-A01238440	
Tubing, Connector	F916700, HDPE	A02095338	
U.S.	Tubing, Convoluted	P305600, EVA P305700, EVA	19052101 19051301
New Deantronics, Ltd 1 New Deantronics Way Sparks, NV 89441	Holster	F916900, HDPE	19071701
USA Tel: +1 (775) 433 1608 Fax: +1 (775) 433 1608	Blade	G105100, Coated Megadyne P/N: 6030201-01 rev.002 (Provided by Megadyne)	17082801 ( 240 pcs )      173751
Paper Band	A900300	19050601-19080501	
PE bag	A401600, LDPE	19092401	
Tyvek	A000400, CR-27 1073B	19061401	
Nylon Film	A000500, Nylon	19050602	
Label	L100700	18083101	

QR-002-2

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## Rally – X251010JN



### Certificate of Compliance

**Taiwan**  
大成企業股份有限公司  
New Deantronics Taiwan Ltd.  
236 新北市土城區中興路4段51號12樓  
12F, No. 51, Sec. 4,  
Zhongxing Rd., Tucheng Dist.,  
New Taipei City 236,  
Taiwan R.O.C.  
Tel: +886 (2) 2268 1726  
Fax: +886 (2) 2268 3800

**U.S.**  
New Deantronics, Ltd.  
1 New Deantronics Way  
Sparks, NV 89441  
USA  
Tel: +1 (775) 433 1808  
Fax: +1 (775) 433 1808

**Customer Name:** MEGADYNE MEDICAL PRODUCTS, INC.  
**Invoice Number :** MD-1110 / 19  
**P. O. Number:** 32676  
**Customer P/N:** X251010JN  
**Drawing Number:** X251010JN Rev.A (Redline)  
**New Deantronics P/N:** PB554SM1  
**Lot Number:** SM1910018  
**Quantity:** 240 Pieces  
**Carton Number:** #001 ~#012 ( 12 Cartons)  
**Signed:** *D. Y. Chen* **Date:** 11-14-2019  
**Printed Name:** Da-Yu Chen  
**Title:** Q.A. Director

New Deantronics Ltd. Hereby certifies that the product in this shipment meets the requirements in the above referenced document. No material, component, or subassembly changes were made without written approval from Megadyne engineering.

Materials	Mat'l Lot#	Megadyne Lot#
Cable	C302600 Conductor : 7/0.16*3BC(26 AWG) Bare copper Insulation: PPE, red/blue/ white Outer jacket: PVC, Gray	19101701
Plug upper	F507100, ABS PA707	19100101
Plug lower	F507200, ABS PA707	19100101
Terminal	T101702 , Nickel plated brass	19092405
Overmold material	R905200, TPR	17090601
Swivel insert male	F922100, HDPE	19071601
Straight Swivel. Female	F922600, HDPE	19060301
Swivel Male	F916600, HDPE	A01601501-A01601502
Swivel Female	F917000, HDPE	A01561721
Connector	F935100, HDPE	19032501
Button	F303700, NYLON 66, Yellow F303701, NYLON 66, Blue	19051501 19051501
Tape	A100101, PE	19012201
PCB	H202802, PCB FR-4	19052201-19062401
Dome	M101900, Stainless Steel	19100701

<b>ETHICON</b> <small>a Johnson &amp; Johnson company</small>	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
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Taiwan	Pen Body	F108300, ABS, Gray F108400, ABS, Gray	19071701 19040301-19090401
	Nozzle	F922500	H00189701-H00189705
	Extension Tube	F922000, LCP	19021501
	Glue	S400900, Loctite 4061	19040801
	Lock Nut	F921900, ABS, Gray	19060501
	Snap Lock Ring	F922700, ABS, Gray	19070301
	Tubing, Connector	F916700, HDPE	A01829939-A01830013
	Tubing, Convolute	P308800, EVA 4.5"	18060401
	Tubing, Convolute	P305700, EVA 56"	19051301
	Holster	F906502, HDPE	19100201
U.S.	Blade	G102700, Coated Megadyne P/N: 0012BN5 (Provided by Megadyne)	19071504 (240pcs) 193515
New Deantronics, Ltd. 1 New Deantronics Way Sparks, NV 89441 USA Tel: +1 (775) 433 1808 Fax: +1 (775) 433 1806	Paper Band	A900300	19062601-19080501
	PE bag	A401600	19100801
	Tyvek	A000400	19082001
	Nylon Film	A000500	19061701

 <b>ETHICON</b> a Johnson & Johnson company	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change - Test Report</b>	<b>Revision: A</b>
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中國生化科技股份有限公司

CHINA BIOTECH CORPORATION

誠信正直 · 顧客感動 · 社會公道

TEL: 886-4-23597515 FAX: 886-4-23597080

台中市工業區33路10號  
10, 33<sup>rd</sup> Road, Taichung Industrial Park,  
Taichung, Taiwan R.O.C 407

DATE : 2019/11/8

**照射證明書**  
**CERTIFICATE OF IRRADIATION**

行政院原能會核准設立照射廠執照証號 IRRADIATION PLANT NO : 物字第 1100223 號

客戶名稱 CUSTOMER NAME : 大璣(股)公司  
NEW DEANTRONICS TAIWAN LTD.  
照射日期 IRRADIATION RUN DATE : 2019/11/07

照射批號 IRRADIATION RUN NUMBER : NEW19909-N

客戶產品已照射 MATERIALS PROCESSED :

支 數 PCS	內 容 DESCRIPTION	客戶產品批號 LOT NO
243	X251010JN(PB554SM1)	SM1910018

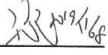
總 數 243 支 數  
TOTAL PCS

中國生化科技股份有限公司證明上述產品經本公司劑量偵測系統判讀，吸收劑量如下：  
China Biotech Corporation certifies that the material listed above (has described by its manufacturer)  
received the following doses within the precision limits of the dosimetry system employed

最 低 劑 量 45.1 kGy ; 最 高 劑 量 47.6 kGy  
MINIMUM DOSAGE 45.1 kGy ; MAXIMUM DOSAGE 47.6 kGy

使用放射性同位素 ISOTOPE UTILIZED : 鈷 60 COBALT-60

客戶劑量要求 DOSE REQUIREMENT : 最低劑量MIN 45.0 kGy ; 最高劑量MAX 50.0 kGy

確 認 者:   
CERTIFIED BY 品保部主管  
QUALITY ASSURANCE

<b>ETHICON</b> <small>a Johnson &amp; Johnson company</small>	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
	<b>Pencil Dome Switch - Supplier Change - Test Report</b>	<b>Revision: A</b>
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### Rally GEM – XME725M1STN



### Certificate of Compliance

**Taiwan**  
大庭企業股份有限公司  
New Deantronics Taiwan Ltd.  
236 新北市土城區中央路4段31號12樓  
12F., No. 51, Sec. 4,  
Zhongyang Rd., Tucheng Dist.,  
New Taipei City 236,  
Taiwan R.O.C.  
Tel: +886 (2) 2268 1736  
Fax: +886 (2) 2268 3800

**U.S.**  
New Deantronics Ltd.  
1 New Deantronics Way  
Sparks, NV 89441  
USA  
Tel: +1 (775) 433 1808  
Fax: +1 (775) 433 1806

**Customer Name:** MEGADYNE MEDICAL PRODUCTS, INC.  
**Invoice Number :** MD-1109 / 19  
**P. O. Number:** 32676  
**Customer P/N:** XME725M1STN  
**Drawing Number:** XME725M1STN Rev.A (Redline)  
**New Deantronics P/N:** PB554NM1  
**Lot Number:** SM1910019  
**Quantity:** 240 Pieces  
**Carton Number:** #001 ~#040 ( 40 Cartons)  
**Signed:** *D. Y. Chen*      **Date:** 11-07-2019  
**Printed Name:** Da-Yu Chen  
**Title:** Q.A. Director

New Deantronics Ltd. Hereby certifies that the product in this shipment meets the requirements in the above referenced document. No material, component, or subassembly changes were made without written approval from Megadyne engineering.

<u>Materials</u>		<u>Mat'l Lot#</u>	<u>Megadyne Lot#</u>
Cable	C302600 Conductor : 7/0.16*3BC(26 AWG) Bare copper Insulation: PPE, red/blue/ white Outer jacket: PVC, Gray	19101701	
Plug upper	F507100, ABS PA707	19100101	
Plug lower	F507200, ABS PA707	19100101	
Terminal	T101702 , Nickel plated brass	T101702	
Overmold material	R905200, TPR	17090601	
Swivel insert male	F922100, HDPE	19071601	
Straight Swivel, Female	F922600, HDPE	19060301	
Swivel Male	F916600, HDPE	A01601501	
Swivel Female	F917000, HDPE	A01561721-A01561726	
Connector	F935100, HDPE	19032501	
Button	F303700, NYLON 66, Yellow F303701, NYLON 66, Blue	19051501 19051501	
Tape	A100101, PE	19012201	
PCB	H202802, PCB FR-4	19062401	
Dome	M101900, Stainless Steel	19100701	

<b>ETHICON</b> <small>a Johnson &amp; Johnson company</small>	<b>TEST REPORT</b>	<b>Document Number</b> <b>500433702</b>
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Taiwan	Pen Body Top	F108300, ABS, Gray F108400, ABS, Gray & Brass	19071701 19090401
	Nozzle	F922500, PC 2081-15 Purple & Brass	H00189701
	Extension Tube	F922000, LCP	19021501
	Glue	S400900, Loctite 4061	19040801
	Lock Nut	F921900, ABS, Gray	19060501
	Snap Lock Ring	F922700, ABS, Gray	19070301
	Tubing, Connector	F916700, HDPE	A01830013
	Tubing, Convoluted	P308800, EVA 4.5"	17052301-18060401
	Tubing, Convoluted	P305700, EVA 56"	19051301
	Holster	F906502, HDPE	19100201
-----	Blade	G105100, Coated Megadyne P/N: 6030201-01 (Provided by Megadyne)	17082801 (240pcs)      173757
U.S.	Paper Band	A900300	19062601-19080501
	PE bag	A401600	19100801
	Tyvek	A000400	19082001
	Nylon Film	A000500	19061701