


	DOC No: AEU00540	TITLE: MEASUREMENT PROCEDURE FOR FLAP RETURN SPRING			<b>Advanex Europe Ltd</b> Head Office: Southwell Site Mill Park Way, Southwell Nottinghamshire, UK, NG25 0ET ☎: 00 44 (0) 1636 815555 ☎: 00 44 (0) 1636 817725 Bilborough Site ☎: 00 44 (0) 115 9293931 ☎: 00 44 (0) 115 9295773 Video Conference IP: 80.176.189.113 www.advanexeurope.co.uk
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#### DOCUMENT APPROVAL


##### Author's Signature:

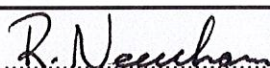
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## 1.0 PURPOSE

- 1.1. The purpose of the document is to define the SOP (Standard Operating Procedures) to be followed by ADVANEX EUROPE Ltd, in order to ensure all Flap Return spring components are measured in a controlled and consistent manner.

## 2.0 SCOPE

- 2.1. The measurement method for the specified characteristics of the Flap Return spring.
- 2.2. All equipment and processes on the Pharmaceutical section have been formally qualified and validated. All personnel working on the Pharmaceutical section are responsible for ensuring that no changes are made to the process without full change control as defined in SOP/PH001 (Document number AEU00226).

## 3.0 TERMS, DEFINITIONS & ABBREVIATIONS

- 3.1. Cpk. - Capability index.

## 4.0 HEALTH, SAFETY & ENVIRONMENTAL

- 4.1. GMP (Good Manufacturing Practice) guidelines apply (Document number AEU00389).
- 4.2. Within the factory area safety footwear is mandatory.
- 4.3. Within the factory area safety glasses must be worn at all times.


## 5.0 ASSOCIATED DOCUMENTS

- 5.1. Degrees to Decimal conversion chart (Document Number AEU00243).
- 5.2. MeasurLink Data Entry (Document number AEU00241).
- 5.3. Works Order Instructions allowing full traceability for the batch.

## 6.0 PROCEDURE

### 6.1. General Instructions.

- 6.1.1. All springs must be fully heat-treated before inspection is performed. The results from these checks will be statistically analysed to establish process capability.
- 6.1.2. **Open up MeasurLink Program.** On the appropriate computer terminal set up the MeasurLink program, as described in document MeasurLink Data Entry (Document number AEU00241). In the 'Run ID' box enter the Works Order number followed by a '-' and the machine number, for the SPC tests ensure that the SPC version of the component type is selected and it is saved in the specific SPC folder.

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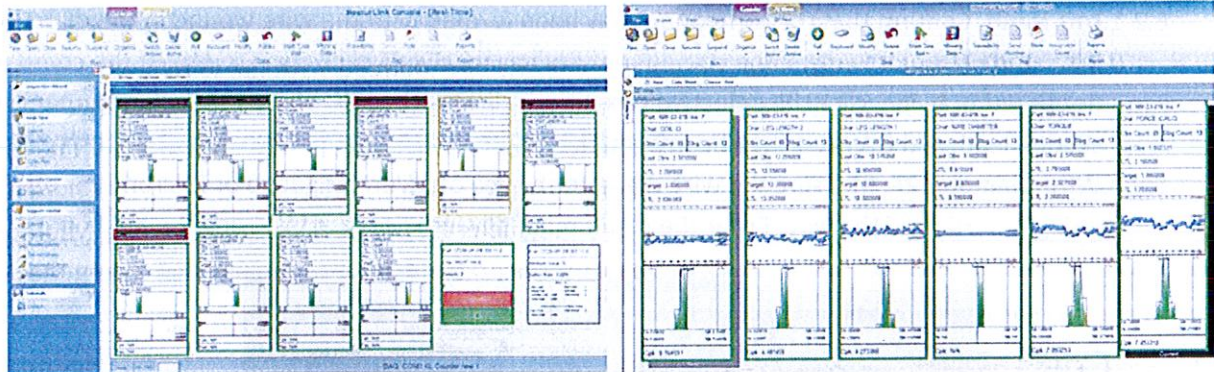


Figure 1: MeasurLink screen showing a results entry page for both a full dimensional and SPC inspection.

6.1.3. Use of MeasurLink. Measure the dimensions in the order they are detailed in on the MeasurLink screen using Figure 1: as an example of both a full dimensional and SPC inspections.

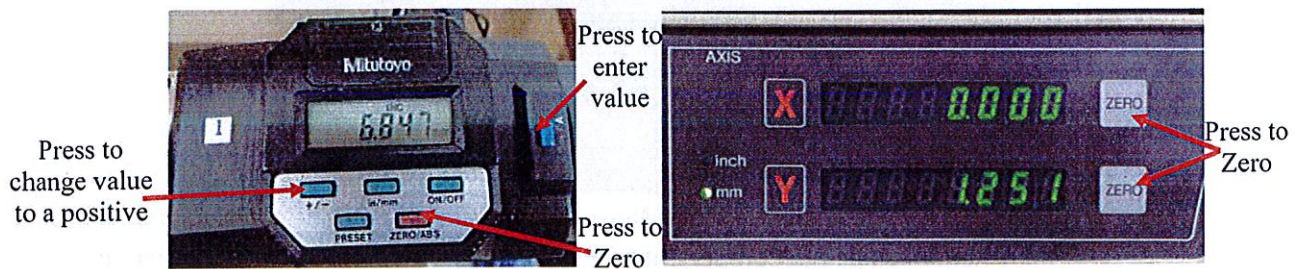


Figure 2: Examples of the different types of data entry used for X and Y axis data entry.

6.1.4. Use of the Projector's Micrometer Heads. These are zeroed by use of the button as shown in Figure 2: ensure that the result is a positive value, if not press the button labelled '+/-' with the measured value is entered by pressing either the foot pedal or the button labelled as 'DATA' shown in Figure 2.

## 6.2. Measurements.

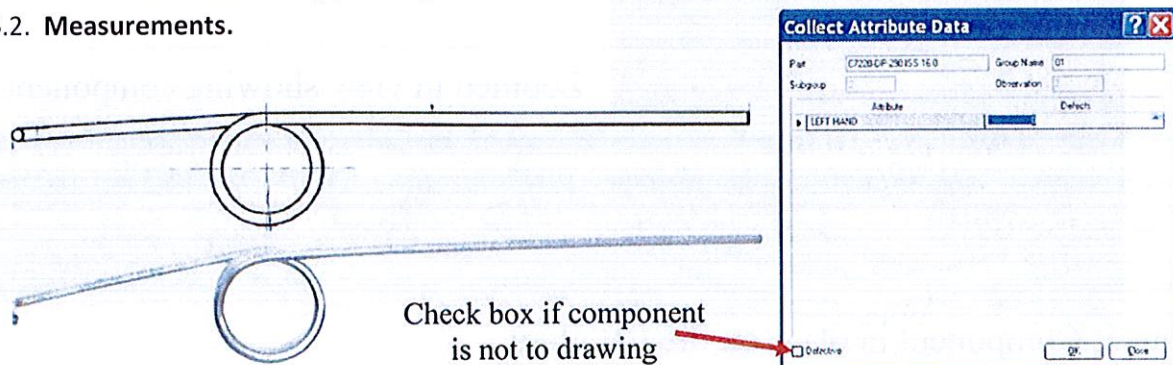



Figure 3: Confirming that the component has been correctly formed.

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**6.2.1.Left Hand.** Confirm that the component has been formed with the wire wound in the direction indicated on the drawing, if the component is as per drawing, click the 'OK' box, if the component is not as per drawing, click the defective box before clicking the 'OK' box, as shown in Figure 3: The section lead, and QA must then be informed.

**6.2.2.Wire Diameter ZF.** Measure the wire diameter by use of a Vernier gauge or Micrometer on a straight portion of the wire. Enter the result manually into MeasurLink using the Keyboard.

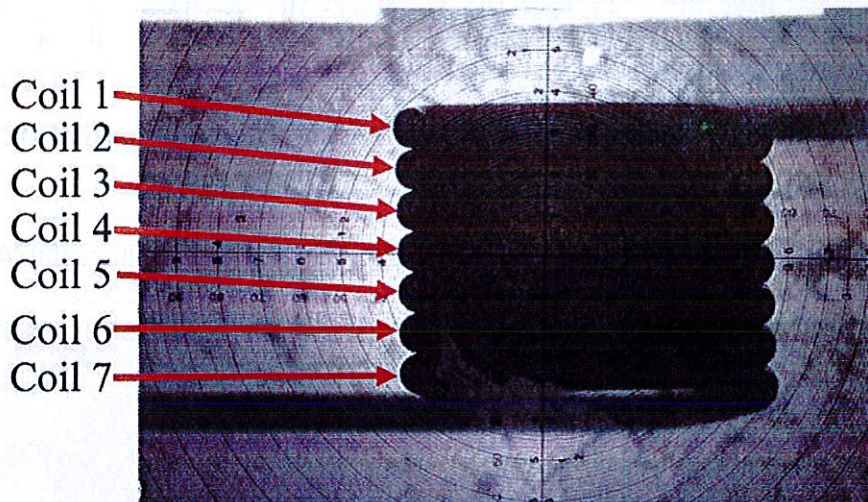


Figure 4: Count the number of coils. Note: Shown Using The Projector For Example, It Is Not Required For The Component To Have Its Coils Counted Using The Projector.

**6.2.3.Number of Coils ZE.** Count the number of coils as shown by the example in Figure 4: and then enter the result manually using the Keyboard.

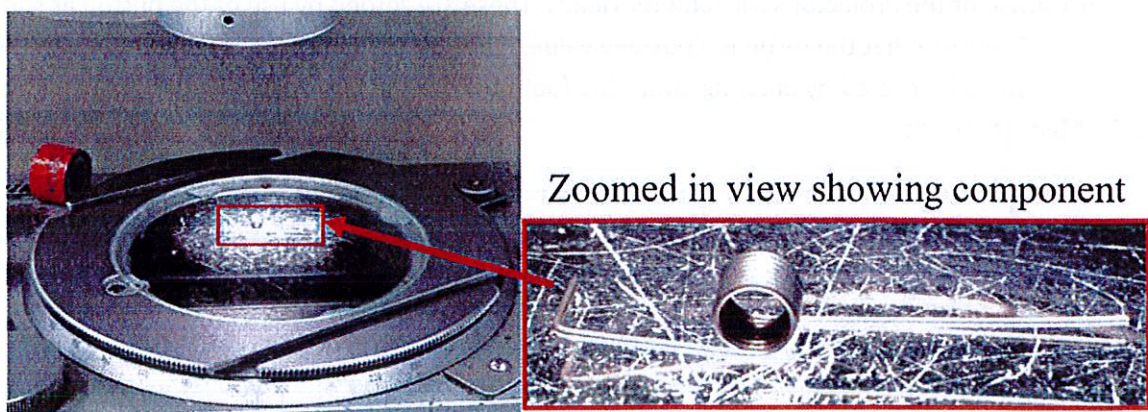



Figure 5: Component in place on the flat glass.

**6.2.4.Set Up for Measurement.** Place the component to be measured flat on the glass stage of the profile projector, as show in Figure 5: ensure the magnification is set to 10x, line the component up as required using rotary stage with the rotating screen set to 90.0°

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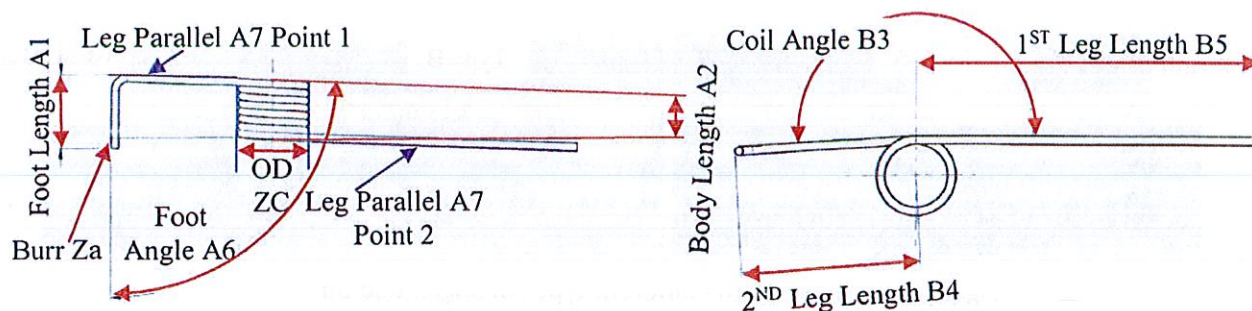


Figure 6: Dimensions to be checked.

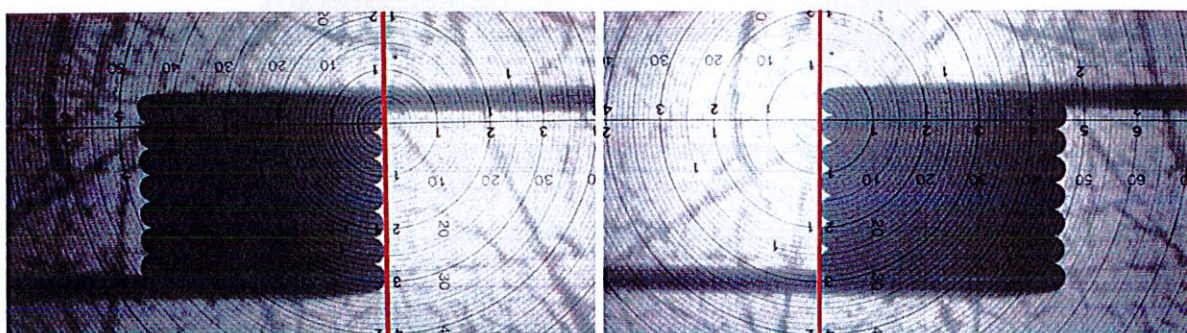


Figure 7: Measuring the Outside Diameter, shown with enhanced axis lines.

6.2.5. **Outside Diameter ZC.** Line the axis to outside edge of coil as shown in Figure 7: zero the X axis by use of the red button as shown in Figure 2: Using the axis readout, measure from the outside edge of coil to the maximum diameter, as shown in Figure 7: To enter the value press the foot pedal or the button as shown in Figure 2:

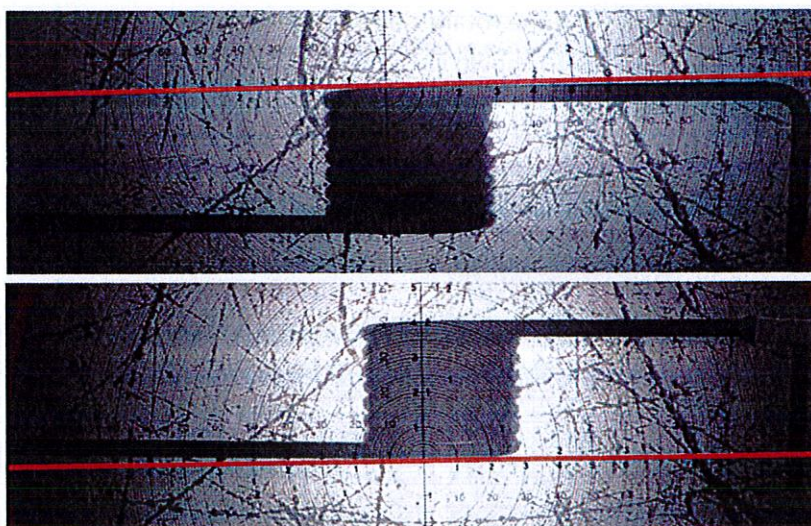



Figure 8: Measure the body length A2, shown with enhanced axis lines.

6.2.6. **Body Length A2.** Confirm the alignment of the axis with the top edge of the coil, zero the Y axis by use of the red button as shown in Figure 2: measure to the lowest point on the bottom of the coil, as shown in Figure 8: To enter the value press the foot pedal or the button as shown in Figure 2:

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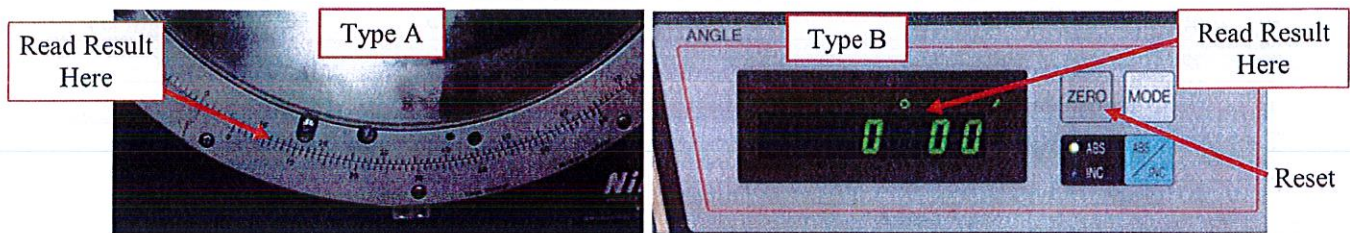


Figure 9: Examples of the different types of angle read out.

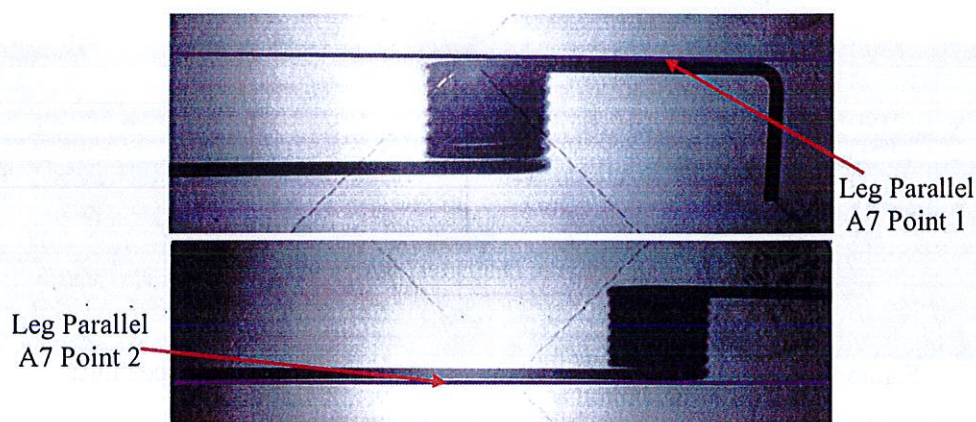


Figure 10: Measure the parallelism of the legs from 2<sup>nd</sup> leg to the 1<sup>st</sup> leg.

6.2.7. **Leg Parallel A7.** Line the Y axis line with the outside edge of the 2nd leg identified as "Leg Parallel A7 Point 1" on Figure 6: zero the rotary stage as shown in Figure 9: move the axis line using a combination of the Y axis and the rotary stage to line up with the 1<sup>st</sup> Leg identified as "Leg Parallel A7 Point 2" on Figure 6: and as shown in Figure 10: To enter the value press the foot pedal or the button as shown in Figure 2:

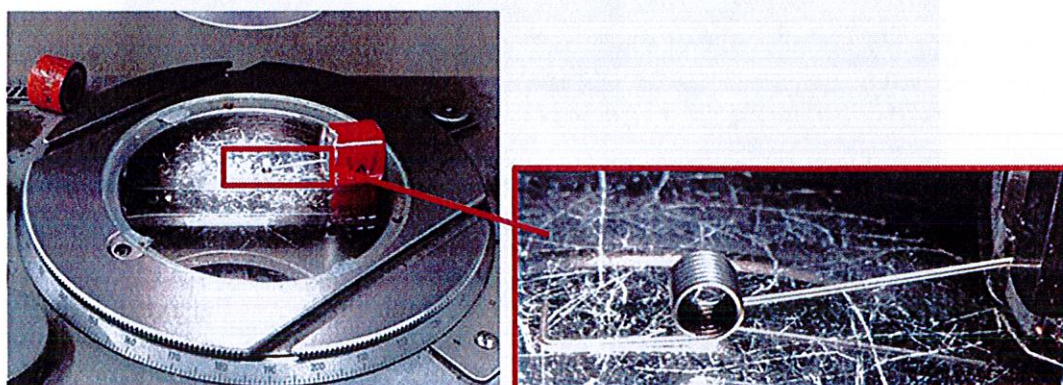



Figure 11: Use the magnet to ensure that the 2nd leg and foot are flat to the glass stage.

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**6.2.8. Adjust Angle of the Component.** With the component still in the same orientation as set up in step 6.2.4, use the magnet to prop up the 1<sup>st</sup> leg to ensure that the 2<sup>nd</sup> leg and foot are flat to the glass stage of the profile projector, as show in Figure 11: with the rotating screen set to 90.0°

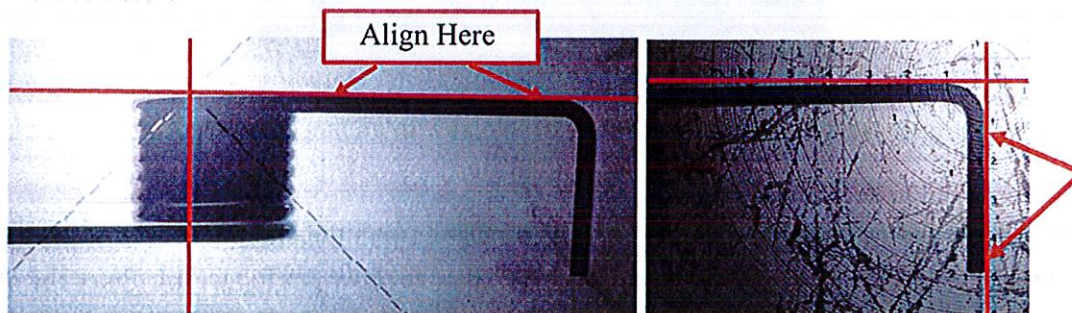


Figure 12: Measuring 2nd Leg Length B4

**6.2.9.2<sup>nd</sup> Leg Length B4.** Use rotary stage to align the component with the axis lines, as shown in Figure 12: Once aligned, using step 6.2.5 and Figure 7: for reference, find the centre of the coil. Measure from the centre of the coil to the end of 2nd Leg Length B4 after aligning the X axis with the outside edge of the foot using the rotating screen, as shown in Figure 12: To enter the value press the foot pedal or the button as shown in Figure 2:

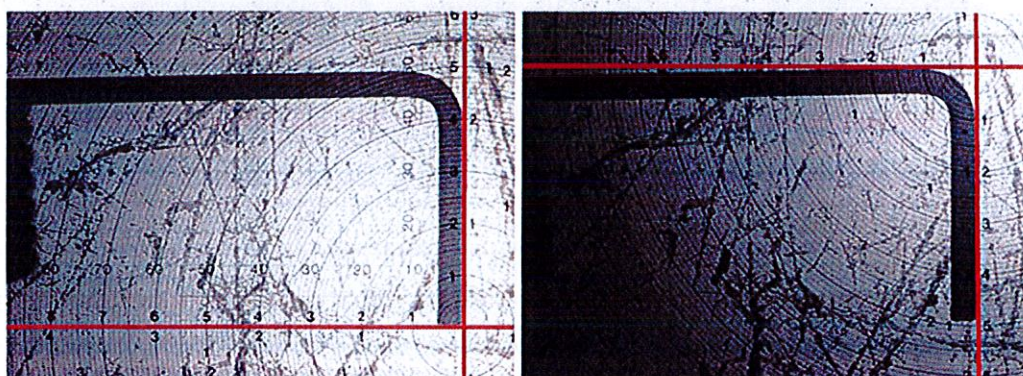


Figure 13: Measure the foot length, shown with enhanced axis lines.

**6.2.10. Foot Length A1.** With the X axis aligned as setup in step 6.2.9, as shown in Figure 13: Move the Y axis to the end of the foot and then zero by use of the red button as shown in Figure 2: measure from the end of the foot to the outside edge of the leg, as shown in Figure 13: To enter the value press the foot pedal or the button as shown in Figure 2:


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Figure 14: Measuring the foot angle, shown with enhanced axis lines.

6.2.11. **Foot Angle A6.** Confirm that the X axis is still aligned with the end of the foot, as set in step 6.2.9, use the rotating screen so it looks as shown in Figure 14: Enter the result read from the angle read out shown Figure 9: manually using the Keyboard. Refer to Degrees — Decimal conversion chart (Document Number AEU00243) to convert the minutes to a decimal. Once measurement is taken, set the rotating screen to 180.0°

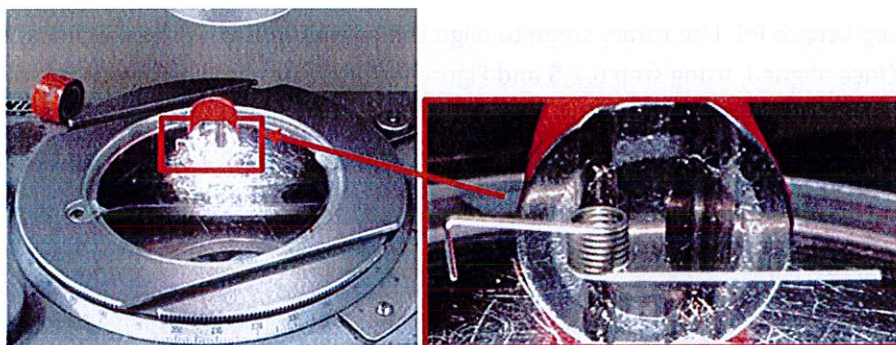



Figure 15: Component orientation change.

6.2.12. Change the Orientation of the Component. Place the component on the magnet and then return them both to the glass stage of the profile projector with the 2nd Leg as identified in Figure 6: at the top, as shown in Figure 15:



Figure 16: Line up both ends of the leg shown with enhanced axis lines.

**Note: It May Not Be Possible to Line Both Ends and The Middle Of The Wire With The Axis Due To The Natural Bow The Wire May Have.**

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6.2.13. Align Component. Align both ends of the 1<sup>st</sup> leg with the Y axis line using rotary stage, ensuring that the rotating screen is still set to 180.0°, as shown in Figure 16:

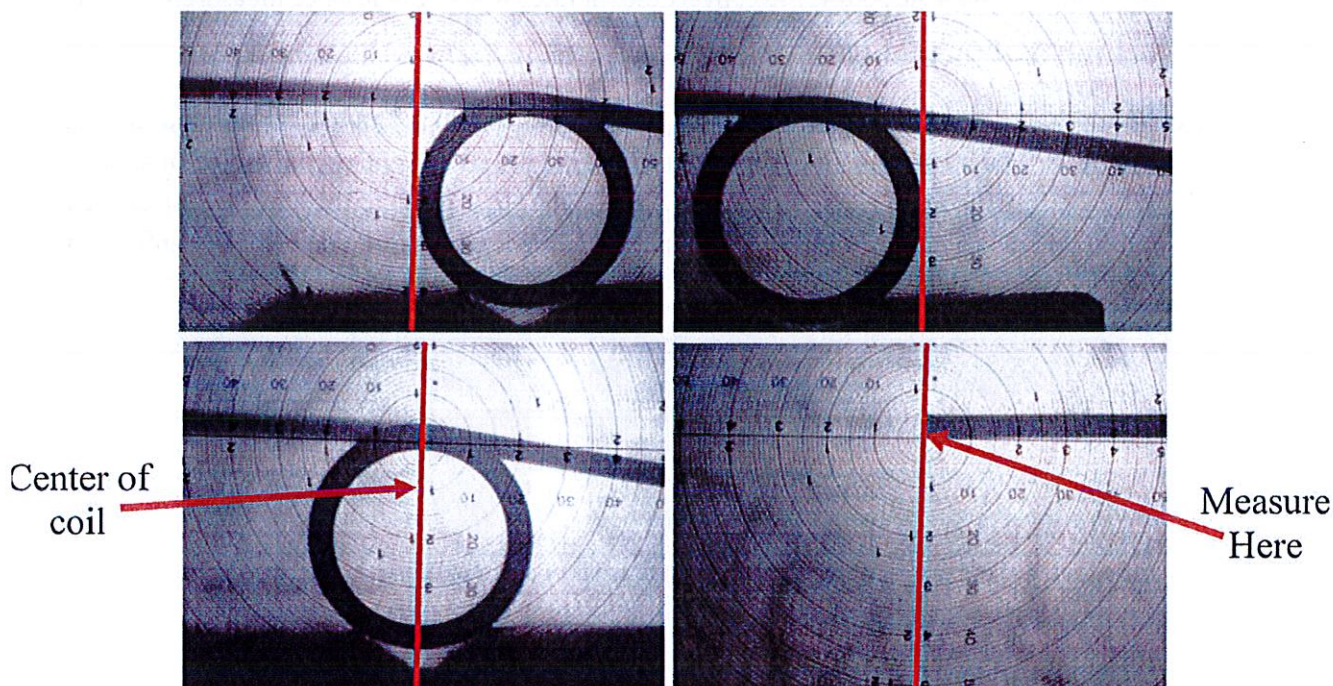


Figure 17: Finding the centre of the coil and then measuring 1<sup>st</sup> Leg Length B2, shown with enhanced axis lines.

6.2.14. **1<sup>st</sup> Leg Length B5.** Using Figure 17: as a guide, line up the X axis line with the outside edge of the coil, zero the X axis by use of the red button as shown in Figure 2: Use the axis readout, measure to the outside edge of the other side of the coil, use half of this measurement to find the centre of the coil, move the axis readout to centre of the coil, zero the X axis by use of the red button as shown in Figure 2: measure from the centre of the coil to the end of 1<sup>st</sup> Leg Length B5, as shown in Figure 6: To enter the value press the foot pedal or the button as shown in Figure 2:

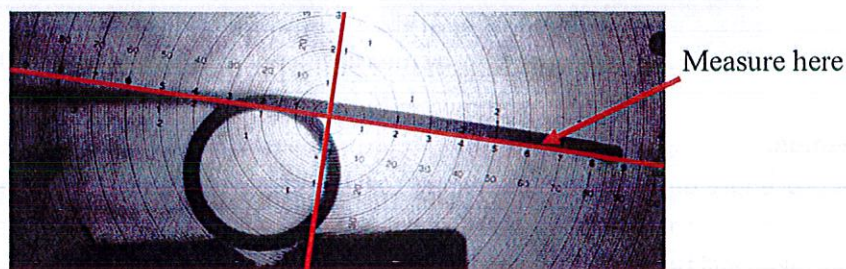



Figure 18: Measuring the coil angle B3, shown with enhanced axis lines.

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6.2.15. **Coil Angle B3.** Confirm that the axis align with the reference as shown in Figure 16: ensuring that the rotating screen is set to 180°. Line up the axis with the 2nd leg using the X, Y axis and the rotating screen so it looks as shown in Figure 18: Enter the result read from the angle read out shown Figure 9: manually using the Keyboard. Refer to Degrees - Decimal conversion chart (Document Number AEU00243) to convert the minutes to a decimal. Once measurement is taken, set the rotating screen to 90.0°.

6.2.16. **Burr ZA.** Position the component on the projector as shown in figure 19 Ensure that the leg circled is angled straight up to ensure a true image of the cut off end on the projector as shown in figure 20. Line the axis up to the side of the foot (Figure 20) and zero the X axis by use of the red button shown in Figure 2. Move the axis to the other side of the foot and press the enter button (Figure 2) to calculate and enter the values to measurLink.

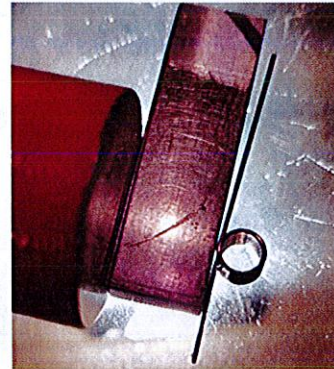
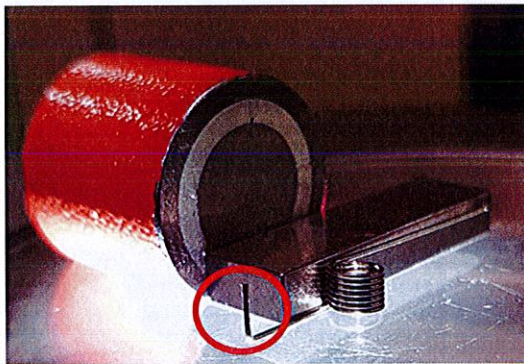


Figure 19: Component position to Check the Burr.

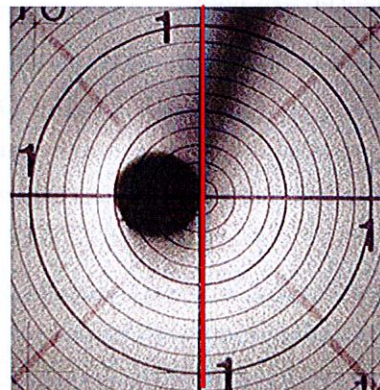
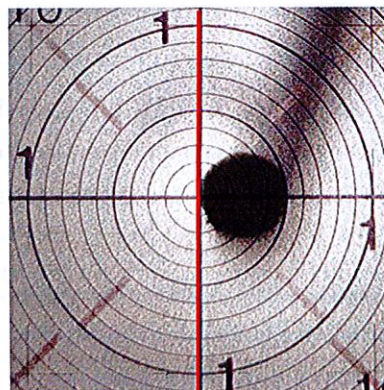



Figure 20: Check the burr by measuring one side of the foot to the other.

### 6.3. Task Completion.

6.3.1. Repeat procedure until required number of test samples results have been entered into MeasurLink and then choose either 'Suspend' if there will be more values to enter at a later stage or 'Close Run' if values taken will be the last for the batch.

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