
	DOC No: AEU00544	TITLE: MEASUREMENT PROCEDURE FOR TRANSFER SPRING			Advanex Europe Ltd 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 general@advanexeurope.co.uk
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DOCUMENT APPROVAL


Author's Signature:

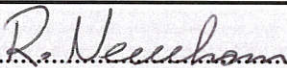
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1.0 PURPOSE

- 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 Transfer spring components are measured in a controlled and consistent manner.

2.0 SCOPE

- 2.1. The measurement method for the specified characteristics of the Transfer 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.


5.0 ASSOCIATED DOCUMENTS

- 5.1. Decimal conversion chart (Document Number AEU00243).
- 5.2. Böhm TG8 and TG9 Torque Tester Setup (Document Number AEU00547).
- 5.3. MeasureLink Data Entry (Document number AEU00241).
- 5.4. 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 in accordance with the Works Order Instructions 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 MeasureLink 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, when entering the traceability data ensure that the number for the box currently being worked on is entered.

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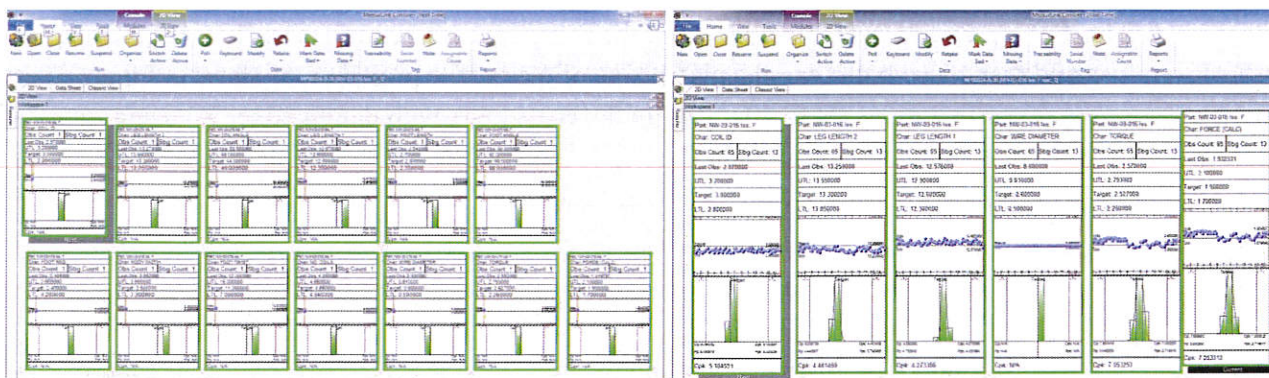


Figure 1: MeasurLink screen showing a results entry page for both a full dimensional and SPC inspection.

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: Use of the projector's Micrometer heads.

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

6.2. Measurements.

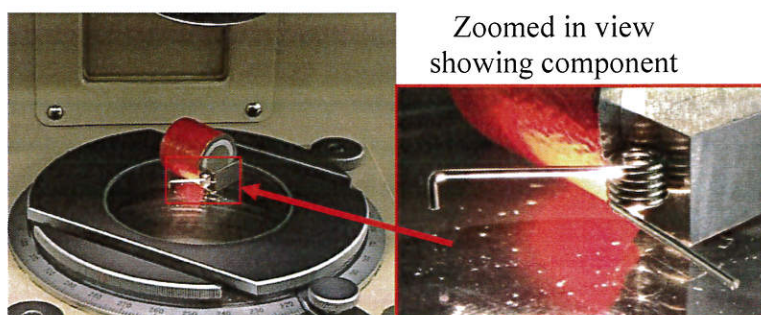



Figure 3: Component in place on the flat glass.

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6.2.1. **Set Up For Measurement.** Attach the component to be measured flat onto the magnetic stand then place both onto the glass stage of the profile projector, as show in Figure 3: ensure the magnification is set to 10x, line up the cross hairs with datum edge 'X' using rotary stage with the rotating screen set to 0.0°.

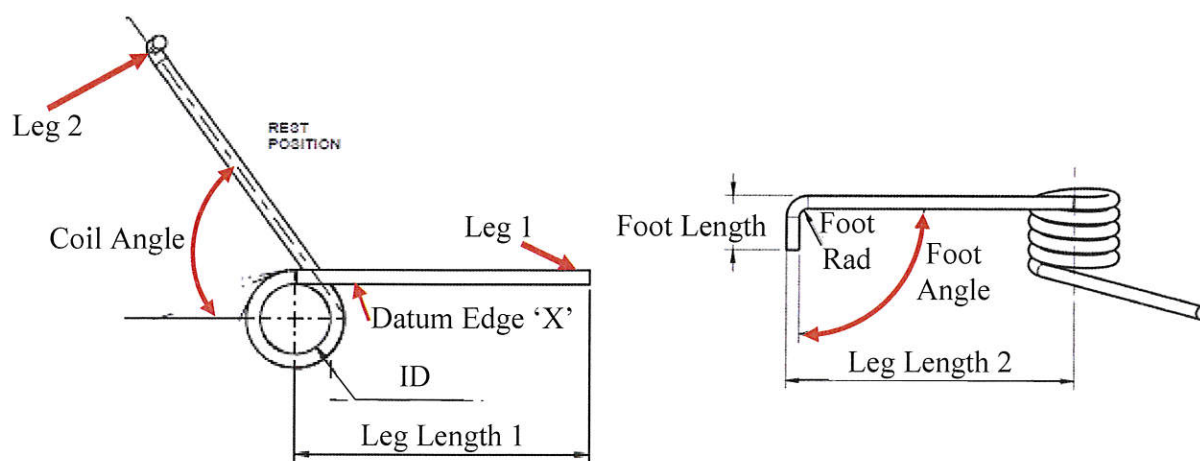


Figure 4: Dimensions to be checked.

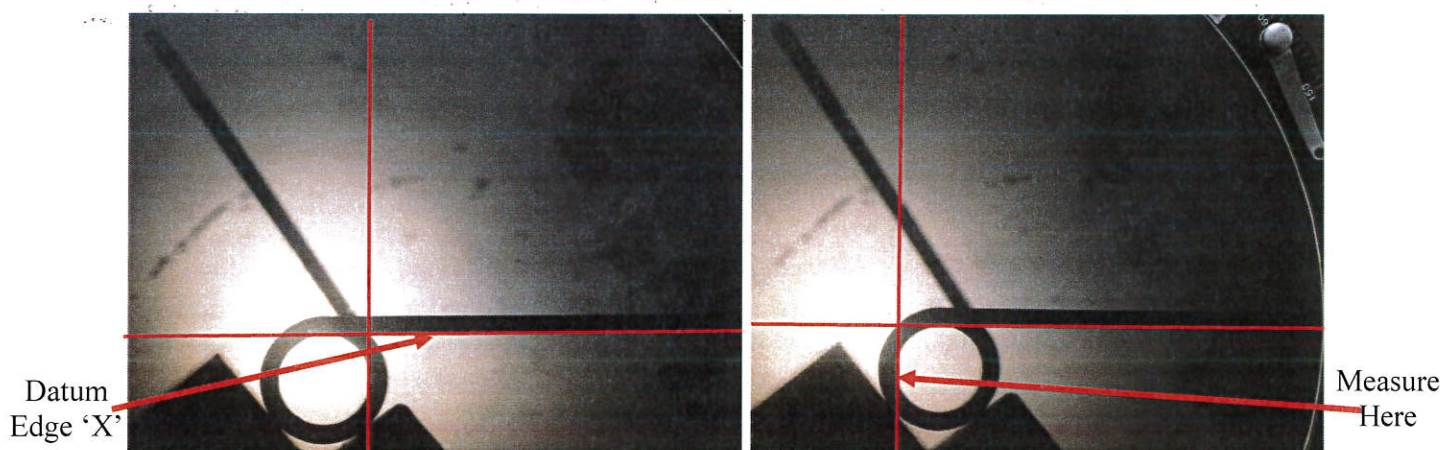



Figure 5: Inside edge of Internal Diameter shown with enhanced axis lines.

6.2.2. **Coil ID.** Zero the X axis by use of the red button as shown in Figure 2: Use the axis readout, measure from the inside edge of the coil to the maximum diameter, as shown in Figure 5: Press the button to enter the value as shown in Figure 2:

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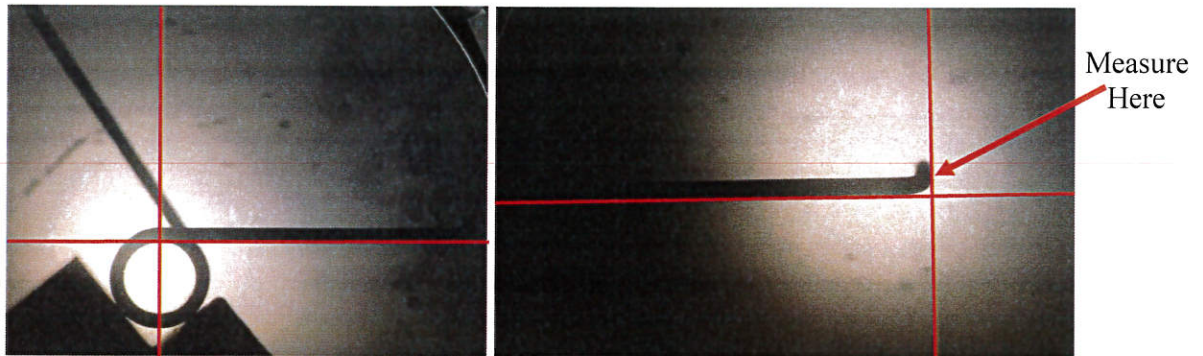


Figure 6: Measuring Leg Length 2, shown with enhanced axis lines.

6.2.3. **Leg Length 2.** Using half of the Coil ID measured in step 6.2.2, 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 leg 2, as shown in Figure 8: Press the button to enter the value as shown in Figure 2:



Figure 7: Angle read out.

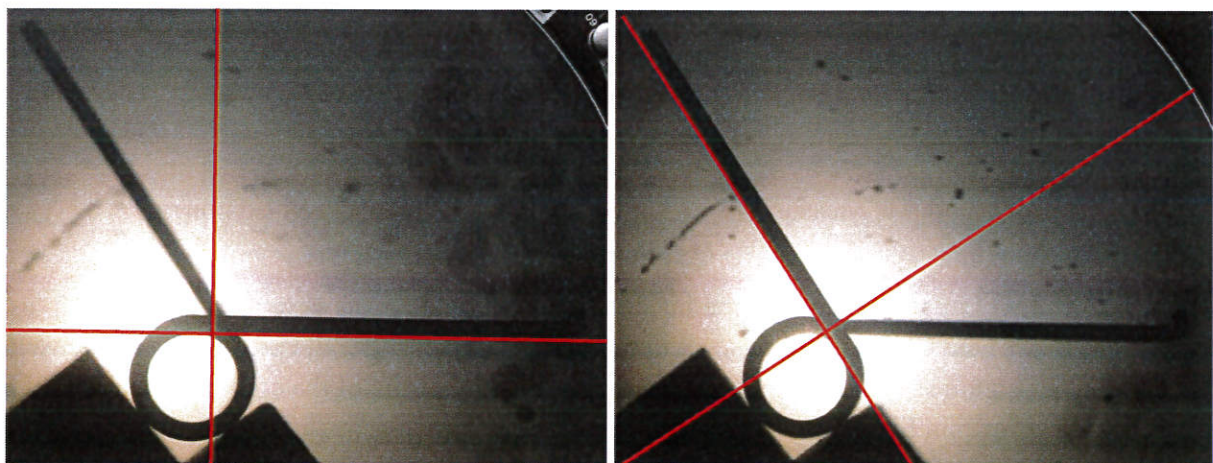



Figure 8: Measuring the angle of the leg 1, shown with enhanced axis lines.

6.2.4. **Coil Angle.** Measure using the rotary screen as shown in Figure 8: Enter the result read from the angle read out shown Figure 7: manually using the Keyboard. Refer to Degrees –

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Decimal conversion chart (Document Number AEU00243) to convert the minutes to a decimal. Once measurement is taken, reset the rotating screen to 0.0°.

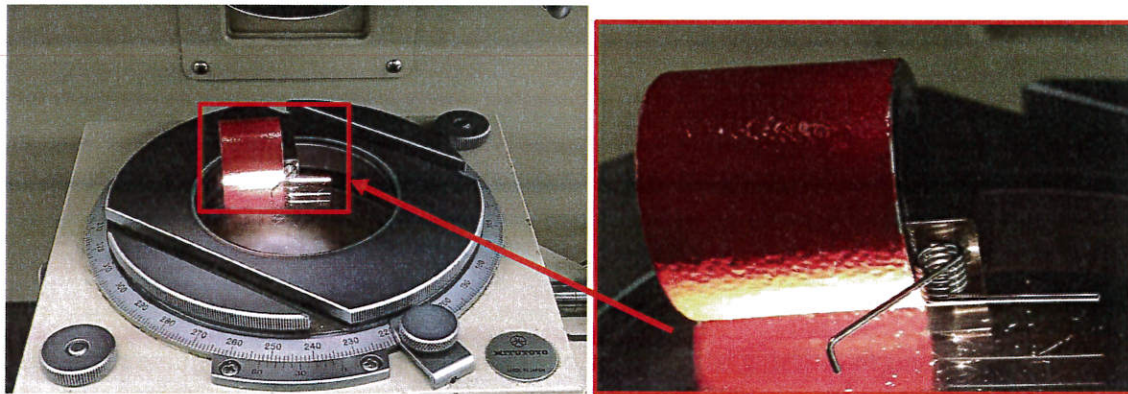


Figure 9: Component orientation change.

6.2.5. Change the Orientation of the Component. Place the component on the magnetic stand with the Leg 2 as identified in Figure 4: at the top, then return it to the flat on the glass stage of the profile projector, as shown in Figure 9:

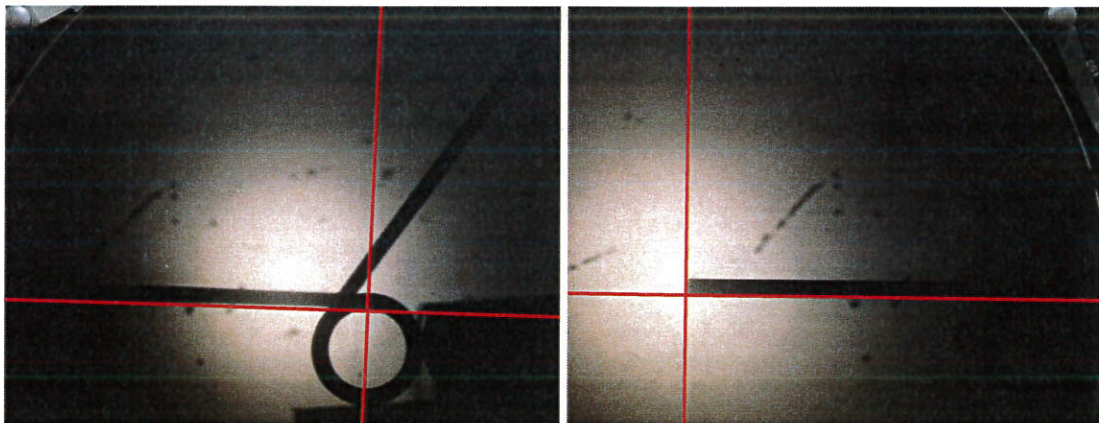



Figure 10: Measuring Leg Length 1, shown with enhanced axis lines.

6.2.6. Leg Length 1. Measure the Inside Diameter of the coil as described in step 6.2.2, using half of the Coil ID, 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 of the end of Leg 1, as shown in Figure 10: Press the button to enter the value as shown in Figure 2:

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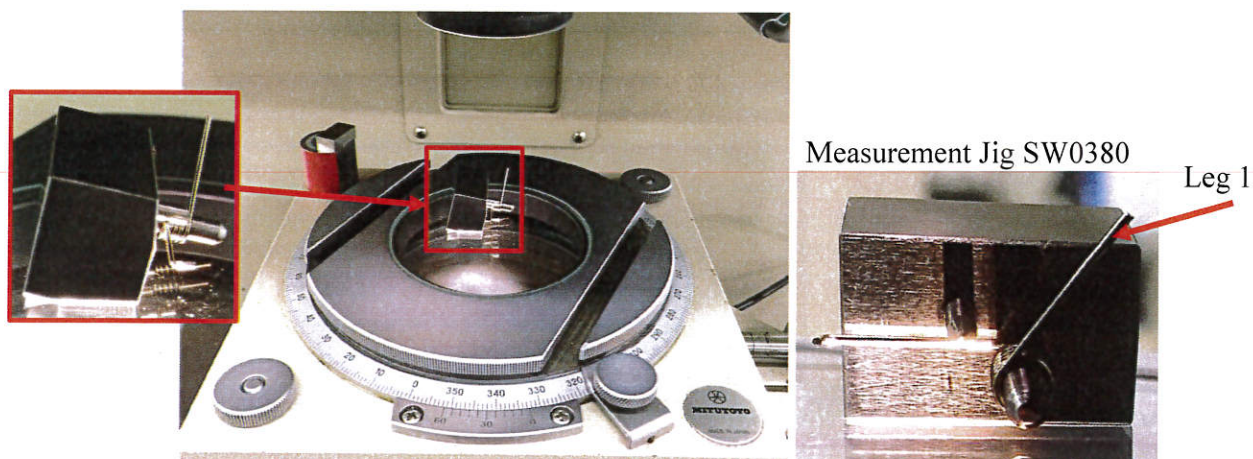


Figure 11: Component in place on the flat glass on the measurement jig SW0380.

6.2.7. **Change the Orientation of the Component.** Place the component on the Measurement jig SW0380 with the Leg 1 as identified in Figure 4: at the top, then return it to the flat on the glass stage of the profile projector, as shown in Figure 11:

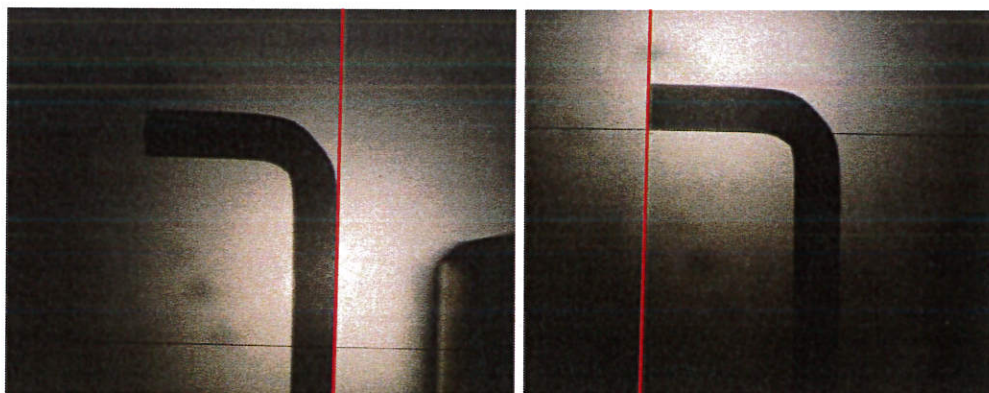



Figure 12: Measure the foot length of the Leg 2, shown with enhanced axis lines.

6.2.8. **Foot Length.** Move the X axis to outside edge of Leg 2, zero the X axis by use of the red button as shown in Figure 2: measure from the centre of the coil to of the end of Leg 2, as shown in Figure 12: Press the button to enter the value as shown in Figure 2:

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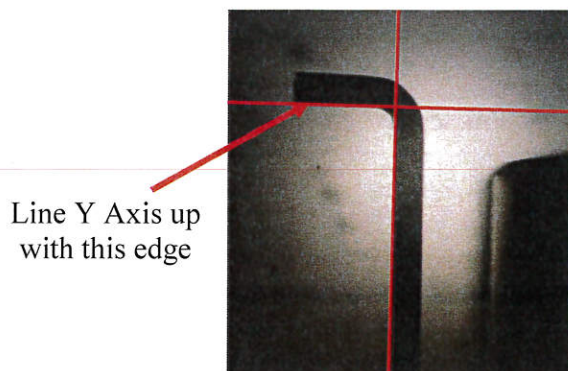


Figure 13: Measuring the foot angle, shown with enhanced axis lines.

6.2.9. **Foot Angle.** Line the X axis with the leg then measure the angle by lining up the Y axis using the rotary screen as shown in Figure 13: to the foot. Enter the result read from the angle read out shown Figure 7: manually using the Keyboard. Refer to Degrees – Decimal conversion chart (Document Number AEU00243) to convert the minutes to a decimal. Once measurement is taken, reset the rotating screen to 0.0°.

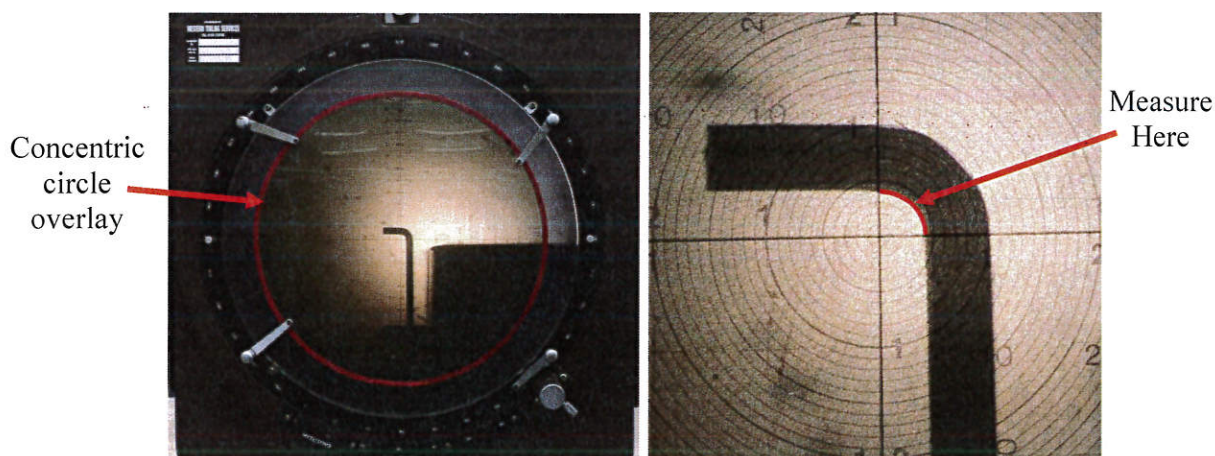



Figure 14: Measure the Foot Radius of Leg 2 by use of the concentric circle overlay.

6.2.10. **Foot Rad.** Use the concentric circle overlay to find the internal radius of the inside angle as shown in Figure 14: Enter the result manually using the Keyboard.

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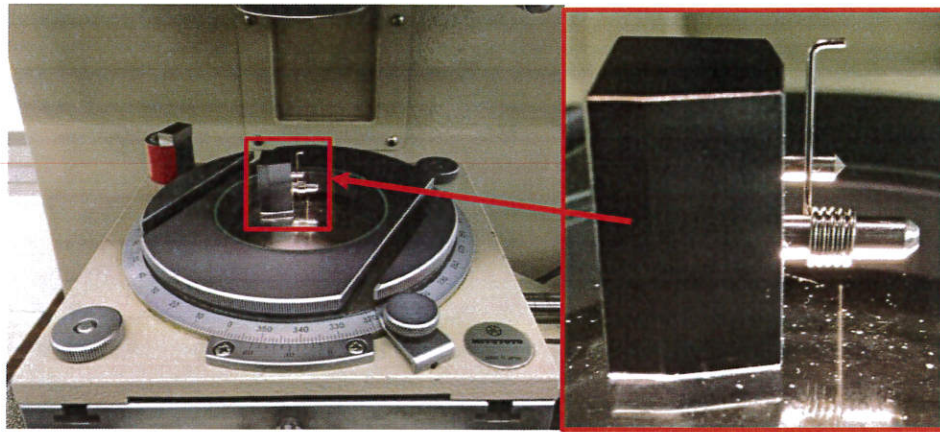


Figure 15: Rotate measurement jig SW0380 onto the smaller end.

6.2.11. Change the Orientation of the Component. Rotate the Measurement jig SW0380 with the component Leg 2 as identified in Figure 4: at the top, then return it to the flat on the glass stage of the profile projector, as shown in Figure 15:

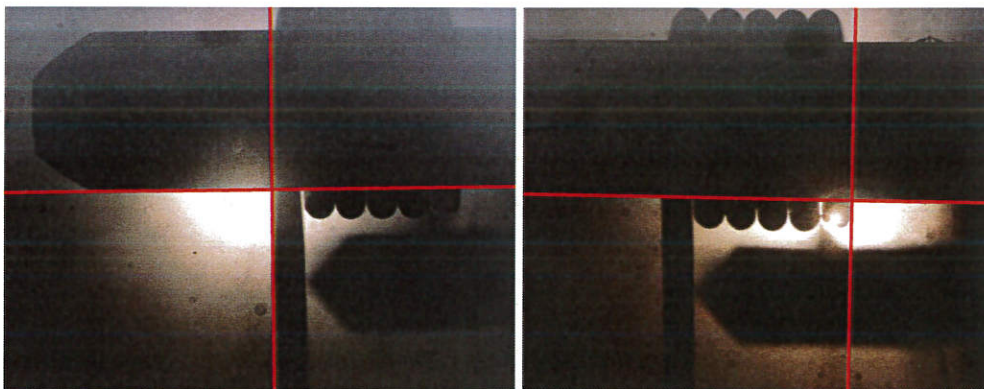



Figure 16: Line the axis with the pin then measure the width of the coil, shown with enhanced axis lines.

6.2.12. Body Width. Aline the axis line with the central shaft of the Measurement jig SW0380, move the X axis to outside edge of Leg 1, zero the X axis by use of the red button as shown in Figure 2: measure from the outside edge of Leg 1 to the outside edge of Leg 2, as shown in Figure 16: Press the button to enter the value as shown in Figure 2:

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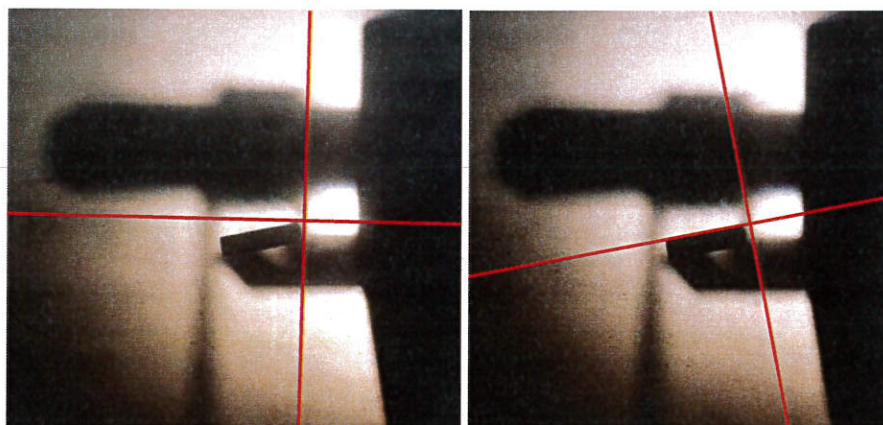


Figure 17: Measure the foot twist off the rotary stage, shown with enhanced axis lines.

- 6.2.13. **Foot Twist.** With the axis still aligned with the central shaft of the Measurement jig SW0380, refocus the shadow graph onto the foot of Leg 2, use the rotary screen to align the X axis to the foot and enter the result read from the angle read out shown Figure 7: manually using the Keyboard. Refer to Degrees – Decimal conversion chart (Document Number AEU00243) to convert the minutes to a decimal. Once the measurement is taken, reset the rotating screen to 0.0°.
- 6.2.14. **Number of Coils.** Count the number of coils and then enter the result read manually using the Keyboard.
- 6.2.15. **Wire Diameter.** Measure the wire diameter by use of vernier gauge or Micrometer on a straight portion of the wire. Enter the result manually into MeasurLink using the Keyboard.

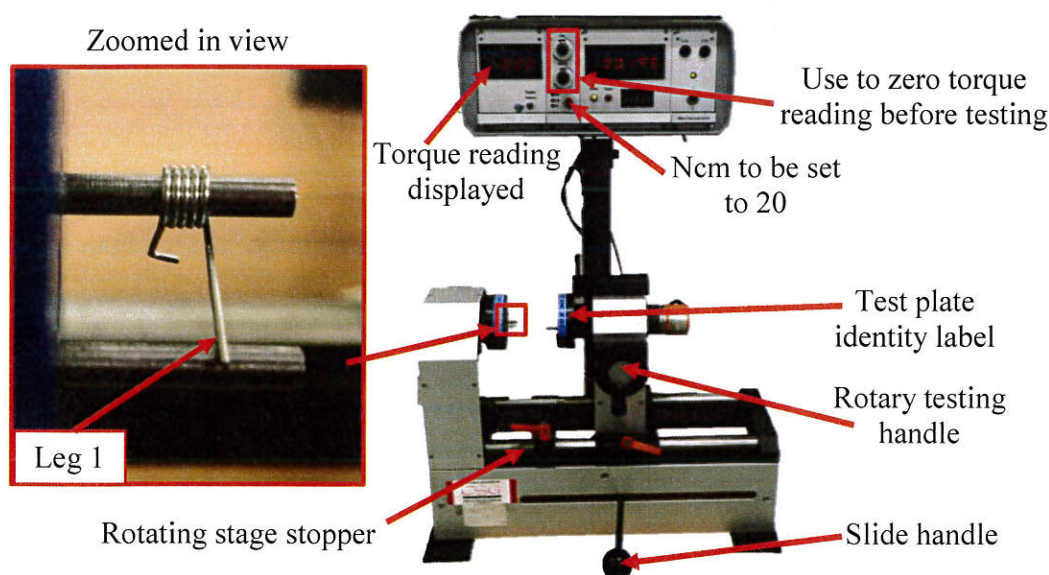



Figure 18: The correct setup and placing of the component on the torque tester.

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- 6.2.16. **Set Up Torque Tester.** Ensure that the required test plates, identified by the blue labels as shown in Figure 18: and as defined on the Works Order Instruction are fitted to the torque tester, if they are not, they are to be installed by use of procedure Böhm TG8 and TG9 Torque Tester Setup (Document Number AEU00547). Using Figure 18: for reference, ensure that the rotating stage correctly engages with the component under test without hitting the fixed stage by use of the stopper, then ensure that the Ncm setting is as shown in Figure 18:
- 6.2.17. **Place Component on Torque Tester.** Place the component on the torque test as shown in Figure 18: Ensuring that Leg 1 is resting on the post, as shown in Figure 18: Then zero the torque reading by use of the adjusters highlighted in Figure 18:

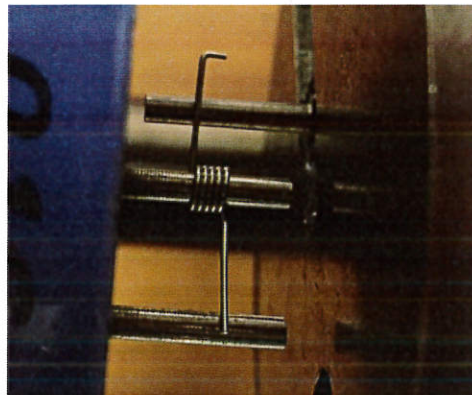


Figure 19: Component under torque testing.

- 6.2.18. **Torque.** Close the rotary side by use of the slide handle, turn the rotary testing handle until it reaches the stops to apply the torque to the component, as shown in Figure 19: once the stops have been reached note the torque displayed, enter the result shown on the display identified in Figure 18: manually using the Keyboard.
- 6.2.19. **Force (Calc).** This result is automatically calculated from the torque reading taken in step 6.2.18. No data entry is required.
- 6.3. **Task Completion.**
- 6.3.1. Repeat procedure until required number of test samples results have been entered into MeasurLink and then chose 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. Note: For SPC do not 'Close Run' until you have printed out the Global Report. As described in document MeasureLink Data Entry (Document number AEU00241).

