

rap.ID Layer Explorer® Application Note Local Silicone Layer Distribution in a Prefilled Syringe



Silicone Layers in Prefilled Syringes

An optimum amount of well distributed silicone oil ensures the smooth operation of a syringe or carpule for the user.

To measure and control the level of silicone oil in a syringe extraction and differential weighing methods are widely used. These methods only give information about the total amount of silicone, and small syringes have to be pooled to give any result. These methods give no information about the local distribution of the silicone oil. The new Layer Explorer technique is able to measure a profile of the silicone oil layer inside the syringe.

Measurement with the Layer Explorer

The Layer Explorer measures automatically the thickness of a silicone layer inside the syringe on an integrated spot with a diameter of 40µm. The syringe was stored flat for more than 48 h.

The length of a line measured on a 1 ml syringe is 40 mm. On this line we measure 40 points at a distance of 1 mm each. To get overview over the radial distribution 12 separate lines at angles of 0°, 60°, 120°, 180°, 240°, 300° were measured. The measurement took 10 minutes, and 40 x12 measurement points were obtained.

Results from the thickness measurement

Figure 1 shows the radial silicone oil distribution on the barrel of the syringe. The syringe was stored flat and the silicone oil is redistributed. On the lower part of the barrel more than 10 times the amount of silicone is visible.

Figure 2 shows the bar plot of the 12 different lines. It is clearly seen that the silicone oil layer shows a maximum in the middle of the syringe, whether at the flange and at the tip a lower amount of silicone is measured.

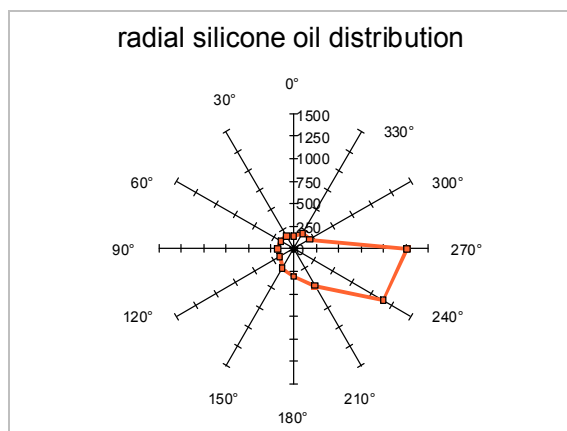


Fig.1: radial scan of the barrel at position 20.

An average over the measurement value is also displayed. Also the total average layer thickness in this syringe was calculated to be 414 nm. From that the total amount of silicone could be calculated to 324 µg. If the syringe is stored flat for more than a day for this estimation the measurement of 12 lines is necessary for a reliable result.

Benefits

The Layer Explorer is able to measure the local distribution of silicone oil in a syringe. With this information it is possible to optimize the local distribution of silicone oil in order to minimize the total amount of silicone and ensure a homogeneous silicone layer in all necessary locations. That information is useful to optimize quickly a silicone spray system and the entire spray profile within a minute.

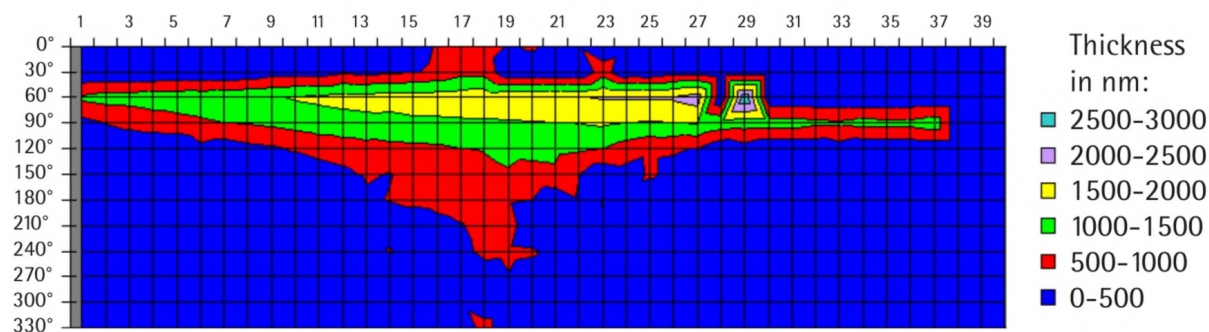


Fig. 2: Silicone layer thickness distribution on the syringe measured on 40 spots on 40 mm on 12 different lines.