

Measuring silicone layer thickness and distribution in cartridges with Bouncer

Introduction

Cartridges are commonly used in pen devices for drug delivery. A commonly used process to ensure optimal cartridge operation is to add lubrication by baking silicone on to the inner surface. When silicone is baked-on the resulting layer can be very thin, in the tens of nanometers. Optimizing the amount and distribution of silicone in the cartridge is critical to proper operation of the device.

Bouncer measures silicone thickness down to 20 nm, which is ideal for the thin silicone layer that results from the baking process (Figure 1). Silicone measurements are made along the length and 360° around the cartridge to provide 2D and 3D representations of silicone thickness and distribution. In this application note, Bouncer is used to measure the thickness, distribution and mass of silicone coating an insulin cartridge.

Methods

A 1 mL insulin cartridge with baked-on silicone (3% PDMS 350 cSt., 25 min @ 280 °C) was analyzed using Bouncer. Bouncer automatically captured 45 data points along the 45 mm length of the cartridge. The cartridge was automatically rotated in 60° increments to capture 6 lines. In total, 270



Figure 1: Bouncer measures silicone thickness, distribution and mass.

measurements were obtained from this cartridge in 25 minutes. Total silicone mass was calculated from the thickness and distribution data.

Results

There is an unusually thick layer of silicone (300–500 nm) for a baked-on cartridge covering approximately the first 13 mm from the flange and from 33 mm to the tip (Figure 2). The silicone layer

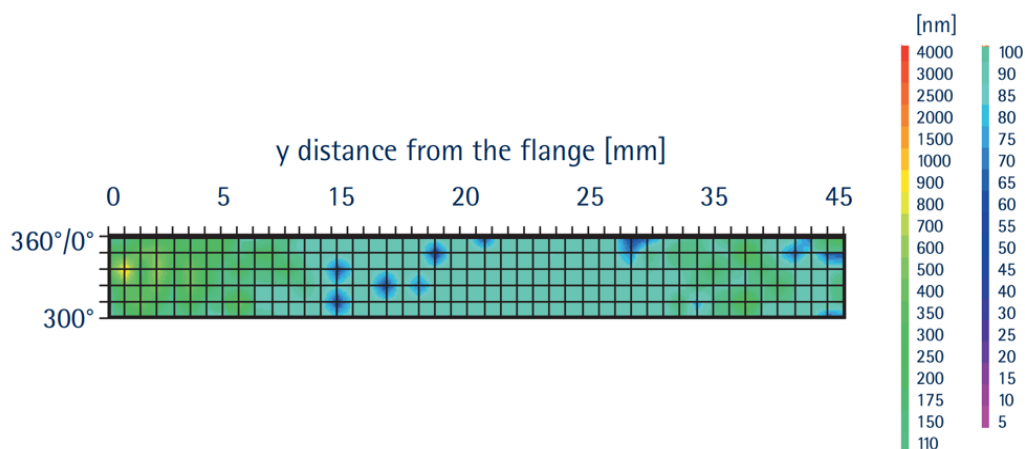


Figure 2: Heat map of silicone oil thickness and distribution in a 1 mL insulin cartridge.

is thinner (60–100 nm) between 13 mm and 33 mm, which is expected for a baked-on silicone layer. On average, the silicone layer is about 114 nm thick and 397 µg of silicone coated this cartridge. The overly thick application of silicone near the flange and tip indicates that the silicone baking process may need to be evaluated and tweaked.

For optimal lubrication and usability, the silicone layer in a cartridge should be thin and homogeneous. Bouncer makes it possible to evaluate silicone coatings, so manufactures can optimize their siliconization, QC incoming lots and ensure drug compatibility.

Summary

Bouncer measured the thickness, distribution, and total weight of the silicone layer for a cartridge with baked-on siliconization.



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