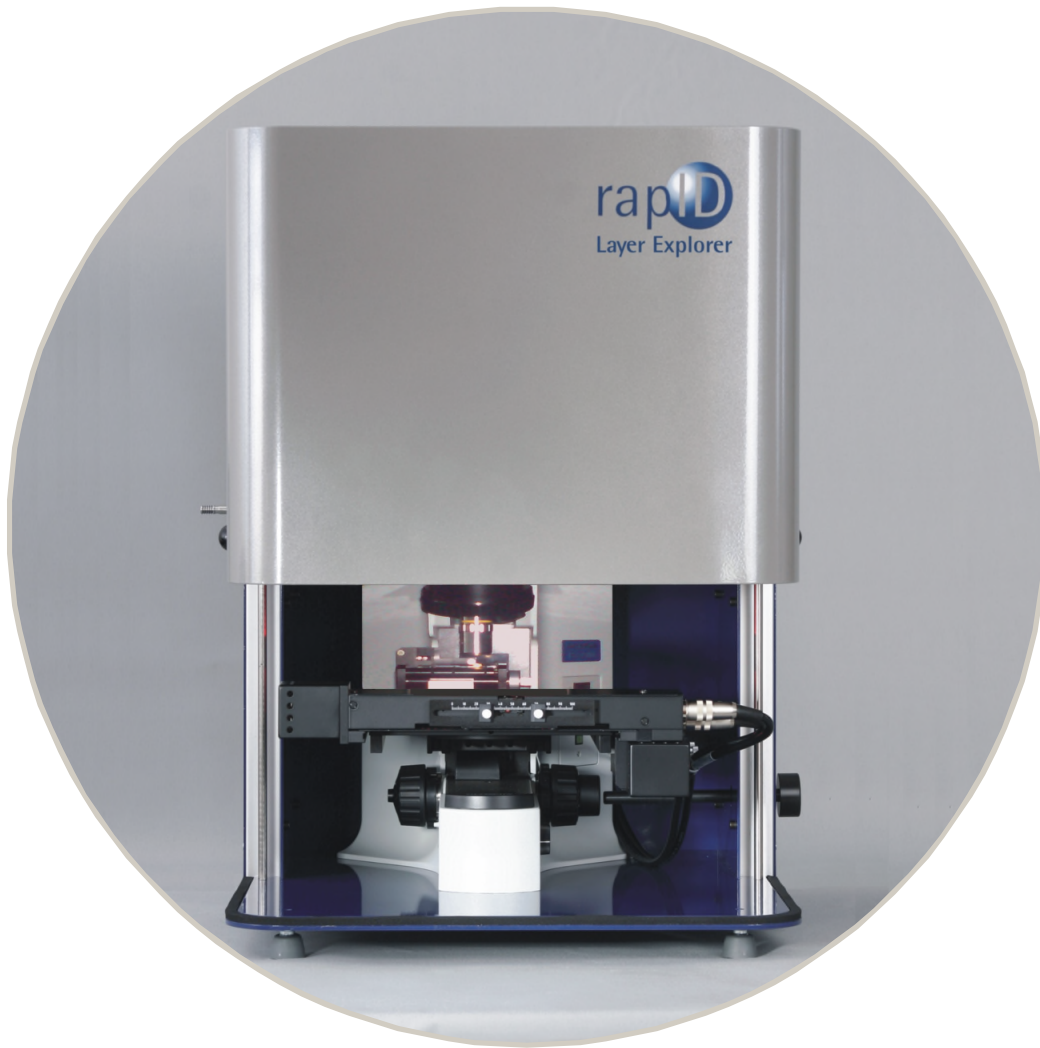


Layer Explorer



Thickness



Homogeneity



Identification



Non-Destructive Test

rapid

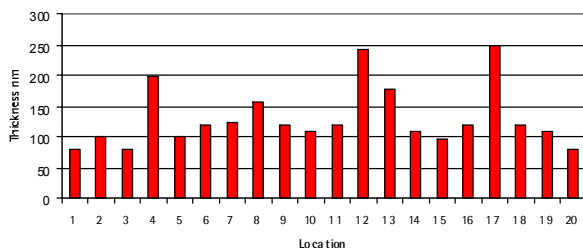
Layer Explorer

Silicone Layer Analysis:

Layer Explorer determines the quality and distribution of silicone layers in your primary packing materials for parenterals, such as syringes, cartridges, carpoules and vials. For the first time ever, you can now analyze and specify the silicone layers essential for proper functioning without destroying them.



Silicone Layer Information:



Thickness



Homogeneity



Identification



Non-Destructive Test

Layer Explorer provides standard-form documentation about the thickness of silicone oil layers on the inside walls of glass and plastic containers. The automated longitudinal and rotational movement of the container then allows for the graphical representation of the overall silicone oil distribution.

Siliconization Control:

- Provides inspection parameters for siliconization as a basis for discussions with suppliers
- Reduces product loss as a result of silicone interaction with biopharmaceuticals
- Minimizes silicone oil quantities while optimizing silicone layer thickness distribution
- Insures optimum homogenous sliding friction forces for sophisticated manufacturing processes, such as the control of auto-injector systems and pre-filled syringes in plastic surgery
- Guarantees non-destructive measurement, preservation of the silicone layer for further analysis of a qualified system
- Allows for worldwide standardized measurement results

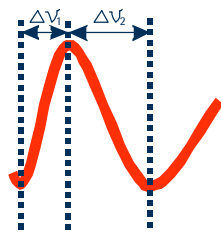
Characteristics and Applications

Interpretation und Documentation:

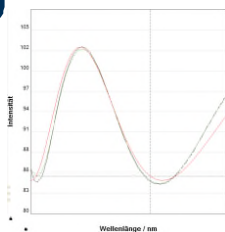
5. Documentation

331 nm

4. Interpretation



3. Spectrum



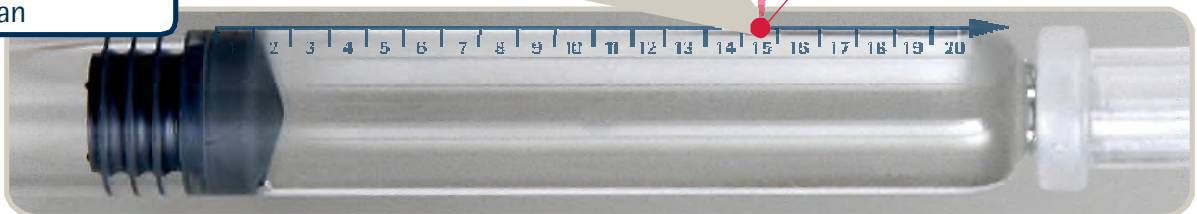
2. Reflectometry

Glass $n=1.46$

Silicone $n=1.40$



1. Scan



Examples:

- Quality control of pre-filled syringes received from vendors
- Siliconization process optimization
- Troubleshooting in case of turbidity and particle formation or reduced activity of biopharmaceuticals

Layer Explorer Features:

- Thickness measurement of layers thicker than 50 nm within 25 ms, on an area of 50 μm in diameter
- Auto-focus controlled positioning in x, y and z directions
- Rotation in steps of up to 10° (36 lines)
- Storage of 810 x 405 μm^2 microscopic silicone layer images
- Thickness measurement calibration and control in compliance with traceable standards
- 21 CFR Part 11-compliant user hierarchy and data storage; programmed according to the GAMP IV IQ, OQ and PQ documentation package
- Worldwide service and distribution
- Reliable and reproducible results

Specifications and Options

Standard Specification:

- Measuring interval for layer thickness measurement 50 - 4,000 nm in glass or COC primary packing materials with an accuracy of within 5%
- Measuring time 1 minute to determine the silicone oil distribution on a 40 mm long syringe body
- Sample holder Manual or automated rotation for 0.5 ml to 20 ml syringes
- X-, Y-, Z- table Motorized X-, Y-, Z- table with auto-positioning and auto-focus
- Camera Integrated digital color camera 1 megapixel
- Documentation Position, reflectometry raw data, interpretation, optionally microscopic image
- Power supply 110 or 220 V
- Operating conditions 18° - 38°C, as well as 20 - 60% humidity, non-condensing, low vibration
- Dimensions and weight Height: 670 mm, Width: 650 mm, Depth: 550 mm; 45 kg
- Software Win XP, 21 CFR PART 11, compliant

Useful Extensions:

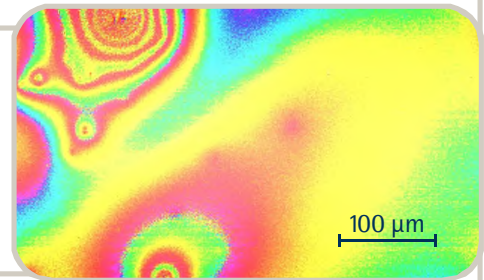


Homogeneity:

The microscopic image provides you with additional information about the local homogeneity of your silicone layer, allowing you to assess your layer visually.

Specification:

810 x 405 μm^2 cutout, Resolution 1280 x 640 pixels, Position $\pm 100 \mu\text{m}$

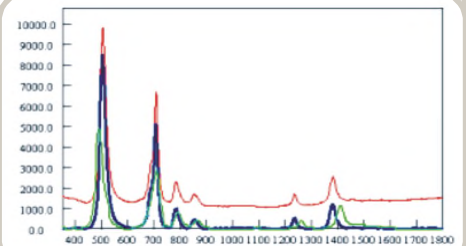


Identification:

Using the integrated Raman spectroscopy confirms that Layer Explorer is measuring the thickness of a silicone layer.

Specification:

Resolution 8 cm^{-1} , area 400 - 2000 cm^{-1} , at 350 nm Silicone



Silicone, Rank: 935



Radial Distribution:

Thanks to the software-controlled syringe rotation and measurement, you are provided with an overview of the silicone oil distribution throughout the entire syringe body.

Specification:

10°-partitioning $\pm 1^\circ$

- more than 250 nm
- 150 - 250 nm
- 100 - 150 nm
- 50 - 100 nm

