



Quality Control of Inhalation Systems

Non-contact In-Line Inspections of Membranes
Application Note



In-line Quality Control with a Laser Vibrometer during Production of Membranes for Inhalation Systems

Inhaling medication plays an important role in treating respiratory illnesses. To be effective, the liquid drugs must be transformed into an aerosol with well-defined drop size distribution. The nebulizer system creates the aerosol to meet the extremely demanding properties.

At Pari GmbH, one of the leading manufacturers of inhalation systems in Germany, the quality of the systems is 100 % tested using a Compact Laser Vibrometer. By measuring the vibration characteristics of the sophisticated membrane, the quality of the aerosol generator – the key element of the nebulizer system – is ensured.

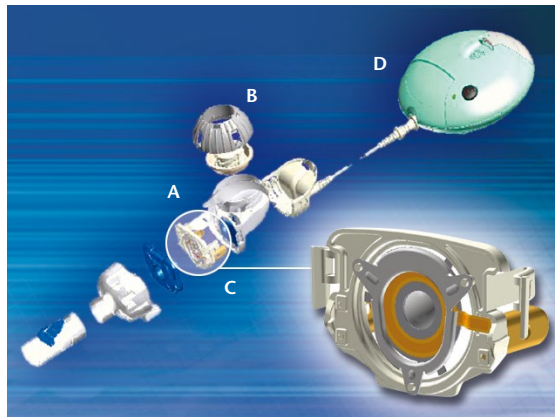
Performance of a Nebulizer System

In figure 1 the components of the aerosol generation system are shown. The dose of the liquid drug intended for inhalation is fed into the reservoir via the medication cap. In the nebulizer, the aerosol is generated from the liquid in the medication reservoir with the aid of a perforated membrane. Piezo elements actuate the membrane at ultrasonic frequencies. The resulting change in pressure behind the membrane forces the fluid through the perforations in the membrane; thus, nebulizing it (figure 2).

Vibration Test on Aerosol Generators

During product development at Pari GmbH, comprehensive tests could characterize the vibrational behaviour of the nebulizer membrane. First, a PSV Scanning Vibrometer was used to precisely analyze the deflection shape of the membrane. On the basis of these results and others, the optimal membrane structure and the most suitable resonant frequencies for optimal inhalation were defined.

A semi-automatic test station was developed and installed in production for quality control (figure 3). This test stand for noise and acoustics comprises the diagnosis software QuickCheck and a compact single-point laser vibrometer. The CLV Compact Laser Vibrometer is made up of a control unit and a compact sensor head connected by a flexible fiber-optic cable. In the production process, the vibration characteristics of each aerosol generator membrane is measured without contact using the CLV with a bandwidth of 350 kHz, and the frequency spectrum is calculated (figure 4).



1
Design of an aerosol generation system. A, Medication reservoir; B, Medication cap; C, Nebulizer; D, Control unit

2 Nebulizer with medication reservoir and medication cap as well as a magnified view of the nebulizer membrane showing micro-machined perforations

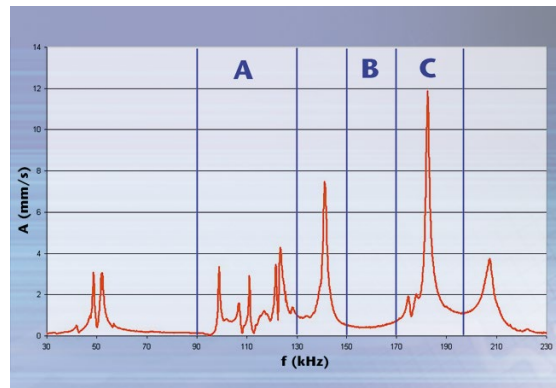


3 Complete test station for 100% quality control of nebulizer membranes

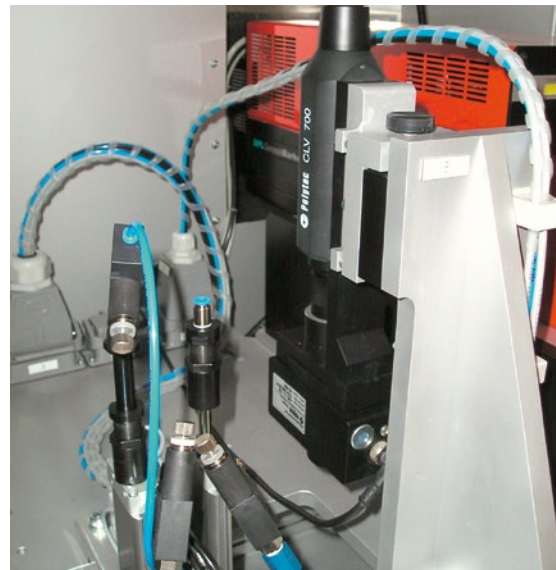
Using Polytec's QuickCheck production testing software, certain frequency ranges are automatically analyzed for critical characteristics in the spectrum (figure 4). Individual areas are thereby examined for the shape of their envelope curve, the presence or absence of peaks as well as the number of peaks (peak-splitting). The signal-to-noise ratio is also calculated as an evaluation criteria for the quality of a measurement. To assure the laser spot is always located on a flat area right between the perforations of the membrane, the laser spot location is evaluated on behalf of the backscattered light for every single sample. If the laser intensity is too low, then the sample point is automatically shifted by a few micrometers using a beam deflector until the full laser intensity is attained (figure 5).

Summary

Non-contact vibration measurements with a compact laser vibrometer and the diagnosis software QuickCheck allow extremely quick quality testing and analysis for aerosol generator membranes. The semi-automatic test station has completed more than 10,000 inspections within the first 6 months of operation. During the course of the measurements, the analysis algorithm has been continuously improved to further minimize the unnecessary false rejects. This non-contact measurement system now guarantees continuous quality of the aerosol generation systems and, most importantly, precise, reproducible delivery of the corresponding medication.



4 Typical spectrum of a membrane:
A Envelope assessment
B Void area (no peak allowed)
C Area in which there may only be one peak



5 The semi-automatic test stand with integrated CLV Compact Laser Vibrometer and beam deflection unit

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