

Application Note VIB-P-02



FIELD OF APPLICATION

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In-line Quality Control with a Laser Vibrometer during Production of Membrane 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 aerosol generation systems in Germany, the quality of the systems is 100 % tested using a Compact Laser Vibrometer. By measuring the vibration characteristics of the aerosol generation 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, extensive tests were carried out on the vibration characteristics of the nebulizer membrane.

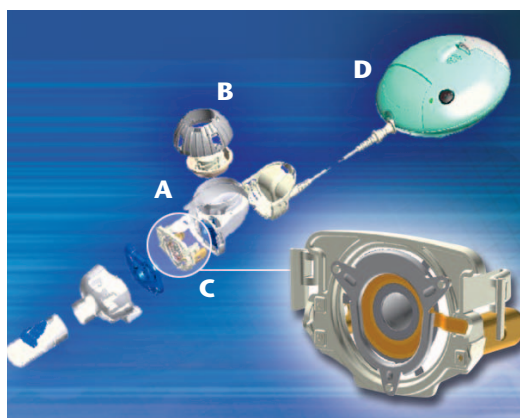


Figure 1:
Design of an aerosol generation system.
A, Medication reservoir; B, Medication cap;
C, Nebulizer; D, Control unit

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Figure 2:
Nebulizer with medication reservoir and medication cap as well as magnified view of the nebulizer membrane showing micromachined perforations.



Figure 3:
Station constructed for 100% quality control of nebulizer membranes.

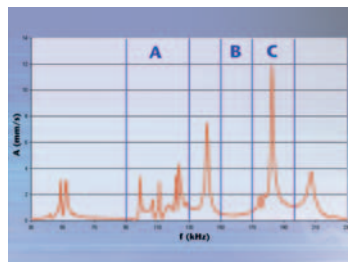


Figure 4:
Typical spectrum of a membrane. a) Envelope assessment b) Void area (no peak allowed) c) Area in which there may only be one peak

The deflection shapes of the nebulizer membrane were precisely analyzed using a Polytec Scanning Vibrometer. On the basis of these results and others, the optimal membrane structure and the most suitable resonant frequencies for optimal inhalation were defined.

A semiautomatic test station was developed and installed in production for quality control (Figure 3). It uses a Polytec Noise Analysis software-driven subsystem based on the CLV Compact Laser Vibrometer. The CLV is made up of a control unit and a compact vibrometer head connected by a flexible fiber-optic cable.

In the production process, the vibration characteristics of each aerosol generating membrane is measured without contact using the CLV with a bandwidth of 350 kHz, and the frequency spectrum is calculated (Figure 4).

Using Polytec's QuickCheck test 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 ensure that during the test, the sample point of the laser vibrometer is always on a flat surface between the perforations in the membrane, an evaluation of the measurement spot is carried out on the basis of the intensity of the laser light reflected back. 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 the CLV Compact Laser Vibrometer and the QuickCheck software allow extremely quick quality testing and analysis for aerosol generating membranes. The semiautomatic 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 rejection of good but wrongly evaluated test items. This measurement system now guarantees continuous quality of the aerosol generation systems and, most importantly, precise, reproducible delivery of the corresponding medication.

Figure 5:
Integration of the Compact Laser Vibrometer equipped with a beam deflector on the test stand



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