

Quality Control of Inhalation Systems



Field of Application

- A Aerospace
- B Audio & Acoustics
- C Automotive
- D Data Storage
- G General Vibrometry
- M MEMS & Microstructures
- P Production Testing
- S Scientific & Medical
- T Structural Testing
- U Ultrasonics

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.

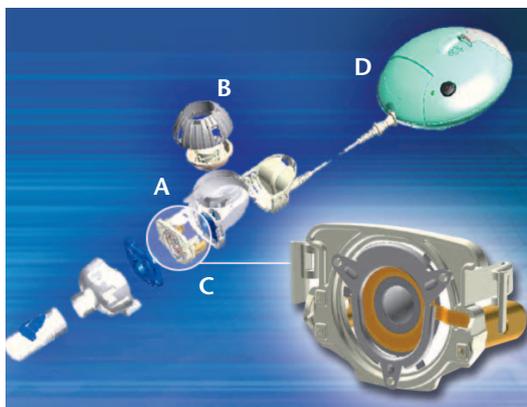


Figure 1: Design of an aerosol generation system.
A, Medication reservoir; B, Medication cap;
C, Nebulizer; D, Control unit

Polytec GmbH
Optical Measurement
Systems
Application Note
VIB-P-02

April 2006



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.

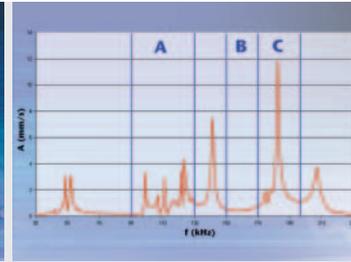


Figure 4: Typical spectrum of a membrane.
a) Envelope assessment
b) Void area (no peak allowed)
c) Area in which there may only be one peak

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.

For more information please contact your local Polytec sales/application engineer or visit our web page www.polytec.com/industrial

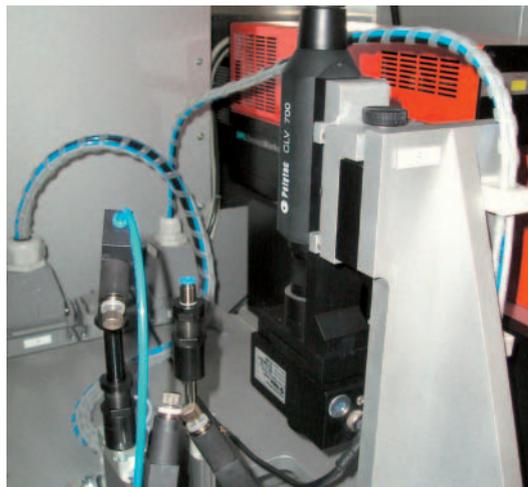


Figure 5: Integration of the Compact Laser Vibrometer equipped with a beam deflector on the test stand

Polytec GmbH (Germany)
Polytec-Platz 1-7
76337 Waldbronn
Tel. +49 7243 604-0
Fax +49 7243 69944
info@polytec.de

Polytec France S.A.S.
Bâtiment Orion – 1^{er} étage
39, rue Louveau
92320 Châtillon
Tel. +33 1 496569-00
Fax +33 1 57214068
info@polytec.fr

Polytec Ltd. (Great Britain)
Lambda House, Batford Mill
Harpenden, Herts AL5 5BZ
Tel. +44 1582 711670
Fax +44 1582 712084
info@polytec-ltd.co.uk

Polytec Japan
Arena Tower, 13th floor
3-1-9, Shinyokohama,
Kohoku-ku, Yokohama-shi,
Kanagawa, 222-0033
Tel. +81 45 478-6980
Fax +81 45 478-6981
info@polytec.co.jp

Polytec, Inc. (USA)
North American Headquarters
16400 Bake Parkway
Suites 150 & 200
Irvine, CA 92618
Tel. +1 949 943-3033
Fax +1 949 679-0463
info@polytec.com

Central Office
1046 Baker Road
Dexter, MI 48130
Tel. +1 734 253-9428
Fax +1 734 424-9304

East Coast Office
25 South Street, Suite A
Hopkinton, MA 01748
Tel. +1 508 417-1040
Fax +1 508 544-1225