

September 27, 2010

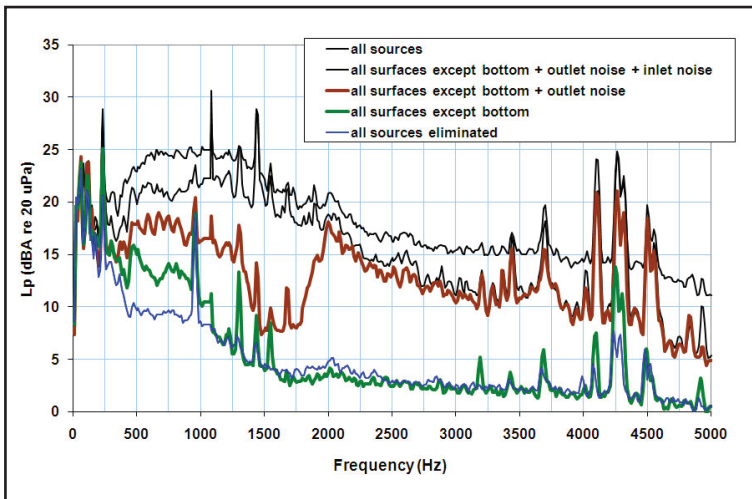
Noise Reduction in Home Health Care Product Design

While not necessarily a barrier to FDA approval, noise created by home health care devices is nonetheless an important design consideration that should not be overlooked in the design and manufacturing process.

Gladys Unger, Ph.D., noise and vibration control specialist, Acentech Inc.

Medical devices are allowing patients to live longer, healthier lives, and remain in their homes when they're ill. But noise from medical devices is one complaint often cited by patients. Noise, then, can be viewed as a product defect, albeit not one that the Food & Drug Administration (FDA) would recognize.

Among the growing list of home health care medical devices increasingly coming to market, CPAP (Continuous Positive Airway Pressure) units - a fairly simple device used to treat sleep apnea - are becoming more and more common. Sleep apnea is a condition in which the individual fails to get enough oxygen while asleep. The CPAP unit is profiled in this article to illustrate how and when medical product designers and manufacturers should consider noise in the design process. Devices to control sleep apnea, such as the CPAP, use a hose and mask to deliver pressure to the respiratory tract, thereby preventing oxygen deprivation.



Contributions of individual sources to the overall sound level produced by a CPAP unit. Source: Acentech Inc.

As much as the snoring associated with sleep apnea might annoy a spouse, CPAP devices are also a source of complaints. The two biggest objections are the discomfort or claustrophobia of wearing a mask to bed and the noise the unit makes. Noise complaints can simply take the form of "too loud," but they can also involve the quality of the sound. When noise is present, hissing, whining, clicking or tonal sounds are readily apparent and disconcerting to the listener, especially since the device is typically placed on a bedside table in an otherwise quiet environment.

CPAP noise is a combination of air flow and motor noise. With another sleep apnea device, known as BiPAP units (Bilevel Positive Airway Pressure), valve clicking can also be audible. These noise

sources can be minimized and the quality of the overall sound enhanced; however, these goals are best accomplished by including noise as a priority during the design process.

Targeting the Source

Good practices exist for designing both quiet products and products with superior sound quality. A simplified approach is to picture noise as a combination of a source mechanism, a transmission path and one or more surfaces radiating sound. A typical CPAP device contains a motor, a fan, a flow path within the unit, a hose and a mask fitted to the patient's face. The sources in this case are the motor and the fan, both of which can create noise and vibration. Two transmission paths exist: an airborne path, in which noise is created by pressure fluctuations in the air itself, and a structure-borne path, whereby vibration forces from the motor and/or fan excite vibration at the mounting location. Vibrating surfaces can then radiate noise like small loudspeakers. Radiating surfaces are most likely the flat outer panels that are good radiators of sound, excited by the vibration traveling from the mounting juncture.

For BiPAP units, impacts from the valves follow a similar vibratory path through the structure. The operation of the valves can also produce airborne noise directly. In both types of devices, exhalation air near the mask can be a source of continuous noise, while an ill-fitting mask can cause short duration noise bursts as the air pressure momentarily lifts the mask from the face, creating a small opening similar to releasing air from the neck of a balloon.

Understanding the Cause

Source noise can have various exciting mechanisms including electrical excitation and mechanical components. DC brushless motors, reputed to be very quiet, can create noise due to poor bearing tolerances and from non-uniformities in their rotation created by the electrical excitation waveform that drives the motor. The fan itself must be selected so it operates near its point of maximum static efficiency. The fan impeller and shroud, unless carefully designed, can cause pulsations at the rotation frequency and especially at the blade passage rate. Blades themselves have structural resonances that can be excited by the interaction of air moving across their surfaces.

The airborne and structure-borne transmission paths must be considered separately. In designing the airflow path, a balance is needed between a circuitous path that hinders sound from leaving the unit, and a path of low resistance that allows the fan to operate at a slow speed. The flow ducts can be lined with FDA-approved sound-absorbing foam, but in order to be effective, the foam will, by necessity, occupy a substantial portion of the interior volume. In some medical devices, designers have set aside a small piece of real estate on the device where an inlet or outlet silencer can be incorporated, should a reduction in noise through the flow path be found to be beneficial once a prototype is built and tested.



This photo shows how a CPAP system fits on the user, as well as the proximity of the base unit to the user, underscoring the need for quiet system operation. Source: American Sleep Apnea Assn.

In comparison with the flow path, the transmission of vibration through the structure can be much more difficult to control, particularly as the market pushes medical devices to be smaller and lighter. In a unit such as a CPAP device, the motor and fan will have little mass, making isolation at lower frequencies (for example 60 Hz) difficult, due to the required softness of the supporting isolators. Lightweight structures often lack stiff attachments points, which are needed to design an effective isolator. Structural ribbing at mounting locations can be used to stiffen attachments points, and new moldable foams can provide a distributed spring which makes local housing stiffness less important.

When noise reduction is examined according to its various elements - noise source, transmission path and radiating surface - it becomes clear that factoring these into the design process in its early stages offers the best opportunity to produce a quiet product. Acoustical noise and vibration consultants can assist designers and manufacturers with noise reduction on a finished product; however, after the design is complete and the unit has gone into production, the noise control options become much more limited.