HYPERSOUND SAFETY INFORMATION

Model HSS-3000 Commercial Product

Abstract

Airborne ultrasound, as employed in the HyperSound® system, shows no measurable effect on the auditory system and shows no adverse effects in safety studies performed by established specialists in acoustical research. The levels and exposure are substantially less than medical applications of ultrasound routinely employed. The ultrasonic sound waves employed in the HyperSound system are below the ultrasonic sound safety limits established by OSHA. A HyperSound medical device using the same technology and output levels received FDA clearance (February 2014) to improve comprehension by those with normal hearing or with hearing loss.

Technology

HyperSound audio creates sound using a modulated carrier frequency with energy between approximately 30kHz to 60kHz. The levels of ultrasound, or sound pressure level (SPL) generally do not exceed 140dB.

Ultrasound in the Air

Individuals are routinely exposed to a wide range of industrial and commercial ultrasonic sound including jet noise, cleaners, drills, welders, emulsifiers, dog repellers, alarms, etc. It is well established that skin is a very poor absorber of airborne ultrasound, typically reflecting 99.90% of the ultrasonic energy.

Occupational/industrial exposure studies have focused on possible auditory effects of occupational ultrasound noise emitted by commercial/industrial devices. Cardiff University (U.K.) (2010/2013) summarized relevant information as follows:

> "The conversion of sound wave energy into audible sound is partly facilitated through the stimulation of fine hair cells in the inner ear. Ultrasound frequencies do not stimulate these hairs and therefore is not converted to audible sound. For this reason ultrasonic frequencies are not believed to contribute to hearing loss or hearing damage. However, in addition to ultrasonic frequencies, it is not uncommon for some ultrasound equipment to produce significant levels of lower frequency sound waves or 'sub-harmonic' noise during their normal operation. It is this audible sub-harmonic noise that is potentially hazardous to our hearing."

HyperSound employs discreet ultrasound frequencies resulting in only desired audible frequencies at normal and safe audible levels without sub-harmonic noise. HyperSound's ultrasonic output is below the 145 dB safety limit established by OSHA and as specified in the OSHA Noise Standard, 29 CFR 1910.95.

Ultrasound Audio for the Hard of Hearing

The technology used in HyperSound's commercial product is the same as the technology used in the HyperSound medical device the FDA cleared for over-the-counter sale to improve comprehension by those with normal hearing or with hearing loss[1] A ten patient clinical study completed in 2013, conducted to support the FDA clearance submission, demonstrated significant gains in speech understanding in those with mild to severe hearing loss versus conventional audio speakers at 70 dB, including in background noise.

Ultrasound in the Body

Exposure guidelines have been established by the international health community for direct contact medical devices to ensure that the imaging and therapeutic uses of ultrasound are harmless. Some devices have such low output levels that their manufacturers are exempt from even declaring them. For example, the following

[1] Compliance with 510k premarket notification and clearance does not denote official approval of the device by the FDA nor evidence safety for any specific use.

statement can be found in *Requirements for the Declaration of the Acoustic Output of Medical Diagnostic Ultrasonic Equipment* world standard document:

> *"This standard includes an exemption clause based on a set of acoustic output levels which is not required of manufacturers to supply technical data. These have been chosen on the basis that the possibility of producing biological damage by a thermal or cavitation mechanism is so low as to be negligible. The output beam intensity level below which equipment is exempt has been set at 20mW/cm². For spatial-peak temporal-average intensity, the exemption level is set at 100mW/cm² and for peak-negative acoustic pressure, it is 1MPa. These values were arrived at by consensus from experts in the field, as not being unrealistically low but still being considered to give a good margin of safety."*

The beam intensity level given above (20mW/ cm²) is twice as high as the highest airborne intensities that are generally associated with HyperSound. Note: 10mW/cm² = 140dB of sound pressure level. The peak level given above (100mW/cm2) is ten times higher than top HyperSound levels in air.

All medical ultrasound devices, such as Sonography and High Intensity Focused Ultrasound (HIFU) devices, couple ultrasound within the body to the hearing mechanism. Because the skin is highly reflective at ultrasonic frequencies, HyperSound delivers at least 12,000 times less acoustic intensity to the interior of the body by comparison. The ultrasonic intensity of HyperSound to the hearing mechanism in the body is therefore well below the limits of safety compared to other medical applications of ultrasound.

Ultrasound as Audio Source

In a study reported in 2002, Martin L. Lenhardt, Ph.D., Au.D., a bioacoustician and specialist in health effects due to airborne ultrasound exposure, examined the risks of exposure to an ultrasound sound beam, and to low frequency (20-100 kHz) airborne ultrasound in general. He concluded from an examination of the published literature that exposure to sound in this range should pose essentially no risk for threshold changes or hearing damage at or below the OSHA limit for exposure to low frequency airborne ultrasound, 145 dB (OSHA occupational ultrasound noise standard). A 20 subject study of hearing thresholds and tympanograms measured before and after exposure concluded no statistically significant auditory effects, either temporary or permanent. The lack of any hearing effects suggests that listening to audio frequencies with this method is comparable to a loudspeaker.

References

1. Cardiff University Occupational Safety, Health and Environment Unit (OSHEU) Guidance Document, *Ultrasonic Radiation*, May 2013.
2. HyperSound Audio System (K133352) cleared by FDA on February 12, 2014.
3. Mehta RP, Mattson SL, and Seitzman RL. Novel Ultrasonic Sound Carrier Significantly Improves Speech Discrimination in Subjects with Hearing Loss. *Manuscript in Preparation*
4. *Occupational Safety and Health Administration Technical Manual*, Section III, Chapter 5, subchapter V: Ultrasonics. Washington, DC: U.S. Department of Labor, 2002.
5. F. J. Pompei, M.L. Lenhardt, D.G. Richards, A.G. Madsen, Ph.D. thesis, Appendix A: *An Assessment of Airborne ultrasound Risk from the Audio Spotlight*, Massachusetts Institute of Technology, 2002.
6. *Requirements for the Declaration of the Acoustic Output of Medical Diagnostic Ultrasonic Equipment*, International Electrotechnical Commission document 1157, p. 53.