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 ultrasonic 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. 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

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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.
References

2. HyperSound Audio System (K133352) cleared by FDA on February 12, 2014.