Do Wireless Hearing Aids Present a Health Risk?

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The facts about electromagnetic radiation and wireless hearing aid technology
By Justin R. Burwinkel, AuD; William J. Mitchell, MSEE; Ezdeen Elghannai, PhD; and Jason A. Galster, PhD

As public awareness of wireless hearing technology grows, hearing healthcare professionals may notice an uptick in long-term safety concerns being expressed. Consumers should be confident knowing that wireless hearing aids are safe and strictly regulated medical devices that meet governmental wireless communication standards in addition to those set forth for medical devices.

The integration of wireless technology and hearing aids has fundamentally reshaped the direction of the hearing industry. Today, wireless hearing aid users benefit from smartphone connectivity, while future changes to the Bluetooth® standard will permit nearly universal hearing aid interconnectivity. These future hearing aids will do more than adapt to the user's environment; rather, they will become part of a mesh of wireless devices that interact with any number of other wireless devices in a given space or across a wireless network.

While many patients and hearing care professionals have welcomed advancing interconnectivity, there may be public concerns as the technology becomes more popular. Health concerns regarding radio frequency (RF) electromagnetic radiation remains a concern among consumers, even in spite of 95% of the US population reporting cell phone ownership.[1,2]

In this article, we will discuss the current state of wireless hearing aid technologies and how wireless hearing aid systems are being designed to be both effective and safe to use.

Health Concerns

While their enabling wireless technologies are not widely understood by the public, RF radiators like cellphones, devices supporting Bluetooth®, and WiFi routers have become ubiquitous. However, the term "radiation" carries a strong negative connotation, a fact recognized by the World Health Organization (WHO) that motivated the creation of material for public education on the topic.[3]

There are various forms of electromagnetic radiation that vary along a frequency spectrum (Figure 1); some types of radiation pose health risks, while others are not believed to result in negative health effects. The most potentially hazardous form of these two types is ionizing radiation, which has ultra-high frequency photons capable of removing electrons from exposed atoms. This disruptive subatomic process can lead to undesirable long-term effects in body tissues, including damage made to genetic material (ie, DNA) and cellular mutations like cancer.[4-6]

The second type is non-ionizing radiation, which is comparatively benign. Non-ionizing electromagnetic energy is emitted by all wireless devices during communication and has a thermal or warming effect rather than an ionizing effect. According to the WHO, RF energy may be converted into heat energy as it is being absorbed by body tissue, but it is safe within certain dosage levels.[3] Some industrial heaters use RF energy for drying; these are the only applications of RF radiation that have been found to raise body temperature by more than 1° C. The thermal effects of low-powered wireless radiators (ie, consumer electronic devices and hearing aids) are almost non-existent.

The possibility of non-thermal health effects due to non-ionizing radiation are an ongoing topic of discussion within the scientific community. Several case-control studies suggested an increased risk for gliomas tumors due to cellphone use.[7-9] However, a large-scale epidemiological study, funded by the National Institutes of Health (NIH) and the National Cancer Institute, countered these results by concluding that the projections were not consistent with documented medical trends. Specifically, if the effects of cellphone use on glioma risk were to have been assumed to be accurate, the incidence rates would be 44% higher than those actually observed within that time frame.[10]

Numerous organizations and government agencies, who each share an interest in promoting public health, occupational safety, and environmental protection, have helped to shape many of the global wireless safety regulations.[11] The WHO and the Federal Communications Commission (FCC) have both stated that, even in the presence of evidence that confirms safety, the organizations will continue to monitor and promote research relating to the possible health impacts

that might result from non-ionizing RF radiation.[3,11] Clinicians should feel comfortable with the recommendations of these governing authorities and remain cognizant of the body of audiological literature that is overwhelmingly in support of wireless hearing aid and cochlear implant system capabilities when formulating evidence-based treatment decisions for patients.[12,13]

Wireless Regulations

Wireless technologies, including those used by the hearing aid industry, are strictly regulated to ensure both public safety and communication reliability are maintained. Even governments in developing countries have adopted regulations consistent with those enforced in the United States or the European Union (EU).

In the United States, wireless hearing aids are classified as Class II medical devices while traditional hearing aids are classified as Class I medical devices. This elevated classification requires that wireless hearing aids conform to the regulations set forth by both the US Food and Drug Administration (FDA) and the FCC. Similarly, wireless hearing aids must conform to both the Medical Device Directive[14] and Radio Equipment Directive[15] in order to become certified for distribution within the EU.

The regulations set forth by the FCC and Radio Equipment Directive each define the appropriate frequency bands and respective broadcast strengths at which wireless devices may communicate. Much like air traffic control, these wireless regulations were established to prevent overcrowding certain frequency bands, which could lead to excessive interferences. Limits on overall power output also serve to protect the population from being exposed to hazardous levels of electromagnetic radiation.

The wireless regulations currently in place were developed with health concerns in the forefront:

"The [FCC] carefully considered the large number of comments submitted in its rule-making proceeding, and particularly those submitted by the U.S. Environmental Protection Agency (EPA), the FDA, and other federal health and safety agencies. The new guidelines…represent a consensus view of the federal agencies responsible for matters relating to public safety and health."[16]

In terms of public safety, Specific Absorption Rates (SAR) are, perhaps, even more informative than output energy levels. In fact, the FCC states that "Guidelines for human exposure to RF fields are based on SAR thresholds where adverse biological effects may occur."[16] Theoretically, RF radiation could become problematic when an excessive amount of energy is absorbed by body tissues. Similar to how excessive exposure to the sun's ultraviolet (UV) radiation causes sunburn and could eventually lead to increased risk of melanoma,[17] high levels of absorbed RF energy could cause body tissue to heat up and potentially cause damage to the living cells within the body.

At extreme levels, non-ionizing electromagnetic radiation would act similarly to how food is heated within a microwave oven. Therefore, the FCC and the Radio Equipment Directive each regulate the maximal SAR levels at which wireless devices may operate. The regulations which regulate wireless hearing aid Output Power and SAR are summarized for the US and EU in Table 1.

Spectrum	Band		Max. Output Power		Max. Absorption Rate (SAR)	
	US	EU	US	EU	US	EU
900 MHz	902-928 MHz	863-865 MHz	0.46 mW	10 mW	1.6 W/kg	2.0 W/kg
2.4 GHz	2.4000-2.4835 GHz		1,000 mW	10 mW		
NFMI	Varies		~30 uV/m at 30 meters	Depends on frequency		

Table 1. Summary of maximum allowable output and Specific Absorption Rate (SAR) limits which govern wireless hearing aids in the United States18,19 and the European Union.20-23 The Output Power data were converted from dBm to mW for comparison.

By design, hearing aids radiate extremely low levels of energy; therefore, the levels of electromagnetic energy that wireless hearing aids radiate are well below the maximum levels permitted by governing regulations. The amount of conducted power output for various 2.4 GHz hearing aids are compared to the conducted power output of a representative smartphone in Figure 2. Based on these measured data, it is reasonable to conclude that the conducted power of 2.4 GHz hearing aids are significantly lower than those of cellular phones.

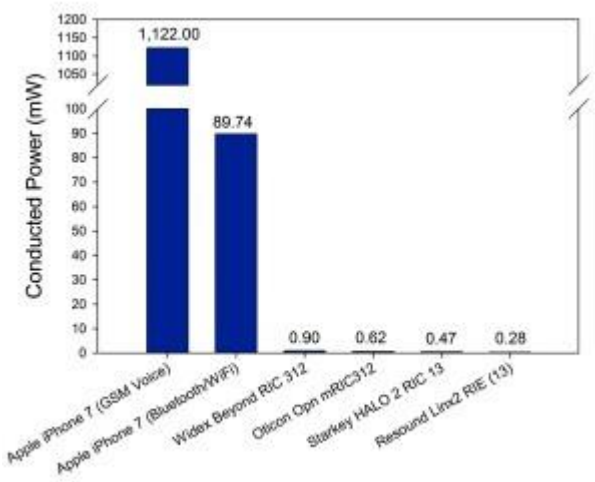

Figure 2. Summary of the conducted RF power output measurement of the Apple® iPhone® 7 (model A1660)24,25 and various 2.4 GHz wireless hearing aids are plotted.26-29 The GSM Voice measurement was made at 1900 MHz.

The typical SAR values for wireless hearing aids range between 0.001-0.02 W/kg. In other words, the amount of electromagnetic radiation absorbed from wireless hearing aids is anywhere between *80 to 2,000 times less* than what regulations would allow (1.6-2.0 W/kg). The variability in this range is directly tied to the wireless technology and radio frequency spectrum used in the device. At these measured levels, a patient would have to wear either *75 individual hearing aids that broadcast at 2.4 GHz or 1,125 individual hearing aids that broadcast at 900 MHz, simultaneously*, in order to absorb the same amount of energy that we experience when holding a mobile phone to our ear.

Prior to being released to the market, a wireless hearing aid's conformity to each country's wireless regulations is certified. In the United States, a third-party Telecommunications Certification Body (TCB) laboratory must measure and certify the device's compliance to FCC standards.[29] A TCB is then also able to audit the manufacturer's devices for ongoing conformance, at any time, following the certification of the device. It should also be noted that each wireless hearing aid must meet the wireless standards of the country in which they are intended to be used, not the regulations of the device's country of origin.

Wireless Hearing Aid Design

Hearing aid manufacturers strive to optimize their wireless hearing aid offerings both in terms of connection reliability as well as power efficiency. Variance across patients and listening conditions can make optimizing wireless hearing aid systems a complex process.

Factors such as connection distance, proximity of reflective surfaces, interference from other wireless devices, and energy loss through body absorption must all be factored into the hearing aid design. For example, indoor wireless performance may be very different from wireless performance experienced outdoors, where the only reflective surface may be the ground on which the hearing aid user is standing. Furthermore, individual differences in body geometry increase the variability that wireless engineers must account for when designing a system that provides each user with a consistent and reliable experience.

The RF radiation of hearing aids is so slight that highly specialized equipment must be used to measure and optimize the performance of hearing aid prototypes. At Starkey Hearing Technologies, wireless engineers leverage a state-of-art, anechoic SATIMO chamber (Figure 3) to measure the propagation of RF radiation from various antennae and hearing aid designs. Simulations and measurements can be performed either in free space, fixed to a mannequin head, or worn by a research participant. The goal of wireless optimization is to provide consistent signal transmission and reception while using the least amount of energy possible. An emphasis on energy efficiency maximizes battery life and allows for more signal processing resources.

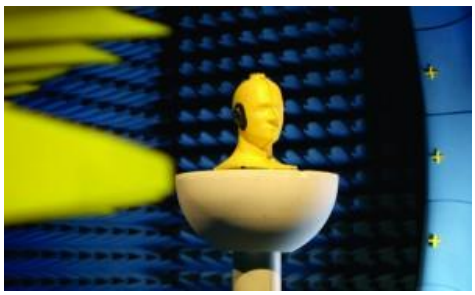

Figure 3. Mannequin head placed within the anechoic SATIMO chamber at Starkey Hearing Technologies' research facility in Eden Prairie, Minn.

Summary

As awareness of wireless hearing technology grows, hearing healthcare professionals may notice an uptick in long-term safety concerns. Consumers should be confident knowing that wireless hearing aids are safe and strictly regulated medical devices that meet governmental wireless communication standards in addition to those set forth for medical devices.

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CORRESPONDENCE can be addressed to *HR* or Dr Burwinkel at: justin_burwinkel@starkey.com