

Over-the-counter (OTC) hearing aid regulatory verification

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In August 2022, the White House announced the OTC Hearing Aids Act in response to the growing number of people with hearing loss and the low penetration rate of hearing aids. This act offers a fresh solution for individuals with mild to moderate hearing loss, enabling easy access to hearing aids at reduced costs and improved availability. However, ensuring the safety and effectiveness of these OTC hearing aids remains the major challenge in the market.

According to the regulations established in the United States for over-the-counter hearing aids, in order to protect users' hearing, the maximum output sound pressure level for linear compensation is limited to 111 dB SPL (Sound Pressure Level in decibels). The part of the hearing aid inserted into the ear canal must be at least 10 millimeters away from the eardrum. Additionally, over-the-counter hearing aids cannot be sold to children under 18 years of age. In terms of acoustic performance, these hearing aids must comply with the ANSI S3.22 standard:

- Total harmonic distortion rate is less than 5%.
- Internal noise is less than 32 dBA.
- Signal processing delay should be less than 15 ms.
- Frequency range should extend to 250 Hz or lower and 5000 Hz or higher.
- Frequency response curve should not exceed an average of 12 dB.

The Rehear research and development team places a strong emphasis on product safety. Throughout the product development and adjustment process, we utilize the Frye FONIX 7000 and Audioscan

verifit2 for sound-electric measurements to ensure compliance with the ANSI S3.22 standards.

The measurement results of the Rehear chip are as follows:

| Rehear Solution Testing Items: | Pass / Fail |
|---------------------------------------|-------------|
| Total Harmonic Distortion (THD) ratio | Pass |
| Equivalent Input Noise (EIN) | Pass |
| Signal processing delay | Pass |
| Frequency range | Pass |

Rehear's research and development team can adjust chip parameters according to specific product requirements, enabling us to customize the chips based on particular demands. This ensures adherence to criteria such as HFA Max OSPL90, HFA full-on gain, and reference testing gains. Choosing Rehear's hearing solution grants clients access to our team's vast expertise in acoustic-electric adjustments, greatly improving the likelihood of their products meeting OTC hearing aid regulations. We are dedicated to providing personalized solutions to meet the unique needs of each client.