OVER-THE-COUNTER HEARING AIDS

APPLICATION NOTE 7/2020-OTC_HEARING_AIDS

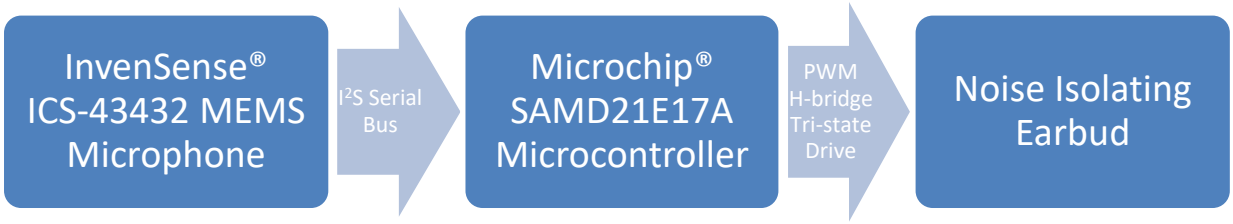
MARKET:

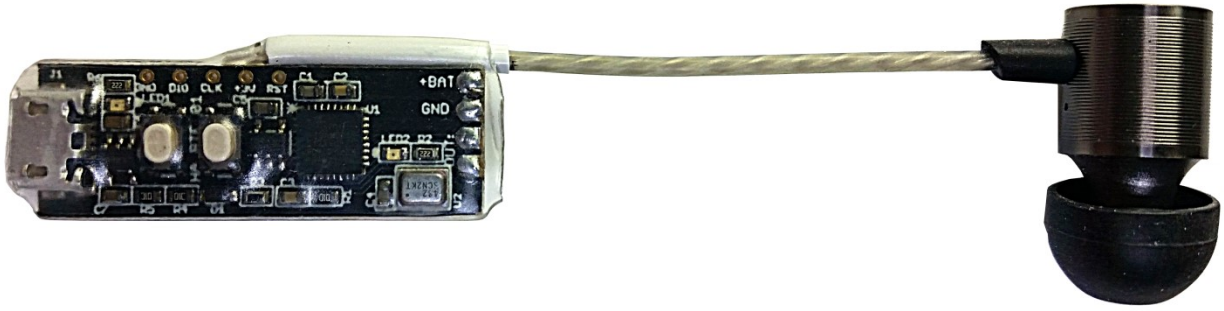
"Over 5% of the world's population – or 466 million people – has disabling hearing loss (432 million adults and 34 million children). It is estimated that by 2050 over 900 million people – or one in every ten people – will have disabling hearing loss.

Disabling hearing loss refers to hearing loss greater than 40 decibels (dB) in the better hearing ear in adults and a hearing loss greater than 30 dB in the better hearing ear in children. The majority of people with disabling hearing loss live in low- and middle-income countries.

Approximately one third of people over 65 years of age are affected by disabling hearing loss."[1]

OTC HEARING AID FOR MAXIMUM EFFICACY, SAFETY, AND MINIMUM COST:



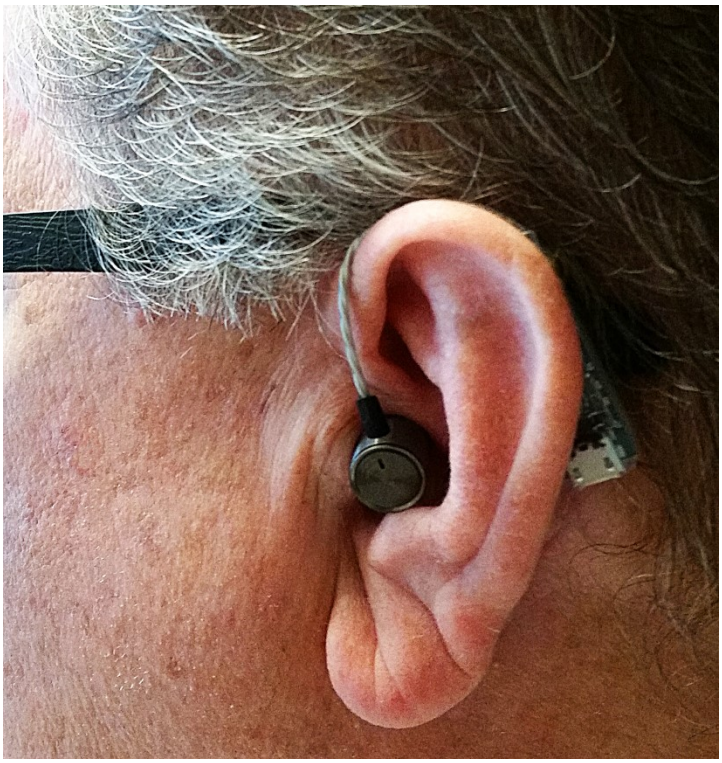


THEORY OF OPERATION:

Hearing aid efficacy (benefit) is measured by random word recognition scoring at different presentation levels (volumes) and in different competing sound environments (such as multi-talker babble from a noisy restaurant). Sound exposure safety is determined by hearing aid output levels in various sound environments. For prescriptive hearing aids, hearing healthcare professionals are responsible for safety. Such professionals are not available in many countries. Over-the-counter hearing aids will be purchased without hearing healthcare professional services. Sound exposure safety must therefore be inherent in hearing aid design.

[1] https://www.who.int/news-room/fact-sheets/detail/deafness-and-hearing-loss -20 March 2019

The Microchip® based hearing aid design relies upon a minimalist hardware approach to achieve affordability in even low-income level markets. The firmware implementation determines performance and safety.



The National Institute for Occupational Safety and Health (NIOSH) has published[2] a Recommended Exposure Limit (REL) for occupational noise exposure of 85 decibels, A-weighted, as an 8-hour time-weighted average (85 dBA as an 8-hr TWA) using a 3-dB exchange rate.

A reference example is given as follows: A sound level meter will measure approximately 85 dBA TWA when placed 10 centimeters (cm) or 4 inches away from the mouth of an adult male speaking continuously at a raised voice level. For an individual not wearing hearing aids and having moderately severe hearing loss (70 dBHL[3]), you must speak at a raised voice level with your mouth a mere 10 centimeters distant from the hearing impaired individual's ear for intelligibility (comprehendible speech).

The Inverse Square Law teaches that for every doubling of the distance from a sound source in a free field situation, sound intensity will diminish by 6 decibels (dB). The individual having moderately severe hearing loss (70 dBHL) will need 6 dB of amplification to hear the same speaker at 20 cm; 12 dB of amplification to hear the same speaker at 40 cm (standing immediately in front); 18 dB of amplification to hear the same speaker at 80 cm (sitting next to each other); or, 24 dB of amplification to hear the same speaker at 160 cm (sitting across from each other at a quiet dinner table). Binaural fusion (hearing in both ears) yields an equivalent 3 to 6 dB of gain. If the individual having moderately severe hearing loss in both ears has 24 dB of binaural amplification, this individual will need to sit in the front row of a classroom to understand the teacher.

Some hearing impaired individuals have profound hearing loss or a total lack of hearing at some frequencies important for intelligibility. For these individuals, hearing aids employ frequency shifting to audible bands or alternative strategies to improve efficacy.

The Microchip® based hearing aid uses a completely digital approach for sound processing and amplification. The MEMS microphone produces a serial digital data output. The receiver (speaker) is a

[2] https://www.cdc.gov/niosh/topics/noise/default.html
[3] dBHL = dB Hearing Level

noise isolating earbud driven directly by 2 digital output pins from the Microchip® microcontroller using Pulse Width Modulation (PWM). The receiver is connected directly to the microcontroller in an H-bridge, tri-state configuration.

FIRMWARE REQUIREMENTS:

Firmware should maximize intelligibility especially for hearing-in-noise.

Firmware should allow the user to set their most comfortable listening level with a simple up/down control.

Firmware should improve the signal-to-noise ratio (SNR) with low level expansion at the environmental noise floor.

For noisy environments, amplification should be based on an extended determination of the environmental noise floor to facilitate dip listening (catching brief "acoustic glimpses" of speech when fluctuating background noise levels momentarily decrease).

Firmware should impose NIOSH safety criterion.

Firmware should advance beyond current WDRC[4] strategies.

Firmware implementation suggestions include:

1. Using a high fidelity audio approach with:
    a. 31.25 kHz microphone sampling.
    b. PWM output at 10.4 nanosecond pulse width resolution; error diffused and updated at 62.5 kHz.
    c. Seven octave bandwidth (3dB: 50 Hz to 9 kHz) for speaker discrimination in multi-talker environments and speech reproduction quality assessment.
2. Placing digital noise sources beyond the audible range:
    a. Input sampling @ 31.25 kHz.
    b. Output PWM @ 62.5 kHz.
    c. Microcontroller throttling @ 62.5 kHz.
3. Suppressing feedback so that:
    a. General purpose silicone ear tips may be used.
    b. Custom ear molds are not required.
4. Means to calibrate receiver sensitivity via in-situ algorithms.

Pixation Corp. has firmware available for the Microchip® based hearing aid.

[4] Wide Dynamic Range Compression (WDRC) is a compression strategy that gives more gain to soft sounds and less gain to loud sounds. WDRC degrades intelligibility with reduced temporal and spectral contrast in the resulting acoustic signal. WDRC makes hearing-in-noise difficult with the degraded signal-to-noise ratio (SNR). WDRC is subject to attack and release time constants which users find fatiguing for relearning speech in changing soundscapes. A high compression ratio is required for significant hearing loss if NIOSH safety criterion is imposed.

WARNINGS, RESTRICTIONS, AND DISCLAIMER

Pixation Corp. application notes, brochures, reference designs, and demo boards have not been evaluated by any regulatory agency (such as the FDA or FCC in the U.S., EU or CE in Europe, etc.). Pixation Corp. application notes, brochures, reference designs, and demos are intended only for evaluation and development purposes. They are not intended for medical diagnostic or treatment use. Therefore, any Pixation Corp. reference design should never go directly to production. For any reference design that Pixation Corp. shares with a customer, the customer is responsible to do the required development, testing, calibrations and labeling for safety, medical, environmental, and regulatory purposes before taking a design to production. Use of Pixation Corp. firmware, reference designs, demos, etc. in medical, life support and/or safety applications is entirely at the customers' risk, and the customer agrees to defend, indemnify and hold harmless Pixation Corp. from any and all damages, claims, suits, or expenses resulting from such use. Pixation Corp. reserves the right to make changes to their products or to discontinue any product or service without notice, and advises customers to obtain the latest version of relevant information to verify, before placing orders, that information being relied on is current and complete.

Photos and illustrations are provided for illustrative purposes only. Photos, illustrations, and specification of component manufacturers do not constitute recommendations or endorsements.

HARDWARE WARNING: Small parts choking hazard.

Safety guidance provided for the use of Pixation Corp. firmware follows:

1. Instructions to the end user shall include recommendations to avoid sound environments where sound levels exceed 85 decibels, A-weighted, as an 8-hour time-weighted average (85 dBA as an 8-hr TWA) using a 3-dB exchange rate (see: https://www.cdc.gov/niosh/topics/noise/default.html).

2. Instructions to the end user shall include recommendations to limit device usage to 8 hours/day.

3. Instructions to the end user shall include recommendations to limit device usage to no more than 40 hours/week.

Contact: Pixation@Pixation.com for firmware or printed circuit board (PCB) files.

See additional Application Notes at www.Pixation.com