HEARING AID DEMO HARDWARE DESIGN

APPLICATION NOTE

3/2020-HA-V/X

INTRODUCTION:

Hearing loss can have a negative effect on communication, relationships, school/work performance, and emotional well-being. Recent research from Johns Hopkins¹ also reveals that hearing loss is linked with walking problems, falls and even dementia.

From the World Health Organization² (20 March 2019):

"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."

OVERVIEW:

A hearing aid is a device used to improve hearing by making sound audible to a person with hearing loss. Hearing aids are classified as regulated medical devices in most countries.

This application note demonstrates an implementation of a hearing aid demo hardware design. The implementation is cost-effective for even low-income level countries and stresses efficacy and safety. FIGURE 1 shows a simplified block diagram of a hearing aid demo hardware design. The basic design consists of just 3 components: a digital microphone, a digital microcontroller, and an earbud connected directly to 2 digital output pins of the microcontroller.

FIGURE 1: SIMPLIFIED HEARING AID DEMO HARDWARE DESIGN BLOCK DIAGRAM



¹ https://www.hopkinsmedicine.org/health/wellness-and-prevention/the-hidden-risks-of-hearing-loss

² https://www.who.int/news-room/fact-sheets/detail/deafness-and-hearing-loss

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 device design.

The hearing aid demo hardware design of FIGURE 1 relies upon a minimalist hardware approach to achieve affordability in even low-income level markets. Without the use of a more expensive application specific microcontroller, performance and safety become the burden of the minimalist design and/or the microcontroller's firmware implementation.

The National Institute for Occupational Safety and Health (NIOSH) has published 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 (see: https://www.cdc.gov/niosh/topics/noise/default.html).

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 dBHL³), 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.

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³ dBHL = dB Hearing Level

The hearing aid demo hardware design of FIGURE 1 uses a completely digital approach for sound processing and amplification. The MEMS microphone produces a serial digital data output. The receiver (speaker) is a noise isolating earbud driven directly by 2 digital output pins from the microcontroller using Pulse Width Modulation (PWM). The receiver is connected to the microcontroller in an H-bridge, tri-state configuration. This hardware implementation becomes a means to insulate sound exposure levels produced by Digital Signal Processing (DSP) firmware with hardware specifications for: receiver sensitivity, power supply voltage output, and microcontroller digital output capabilities.

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 WDRC⁴ 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 multitalker 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.

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.

- b. Custom ear molds are not required.
- 4. Means to calibrate receiver sensitivity via in-situ algorithms.

Pixation Corp. (see: www.pixation.com) has firmware available for the hearing aid demo hardware design shown in FIGURE 1.

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.

APPENDICES:

Refer to APPENDIX A for a Behind-The-Ear (BTE) hearing aid demo hardware design prototype.

Refer to APPENDIX B for a Body Worn Hear Aid (BWHA) demo hardware design prototype.

Refer to APPENDIX C for Pixation Personalized Audio (Example Usage Instructions).

Refer to APPENDIX D for warnings, restrictions and disclaimers.

Refer to APPENDIX E for a schematic of the Behind-The-Ear (BTE) hearing aid demo hardware design.

Refer to APPENDIX F for a schematic of the Body Worn Hear Aid (BWHA) demo hardware design.

APPENDIX A: BEHIND-THE-EAR (BTE) HEARING AID DEMO DESIGN PROTOTYPE

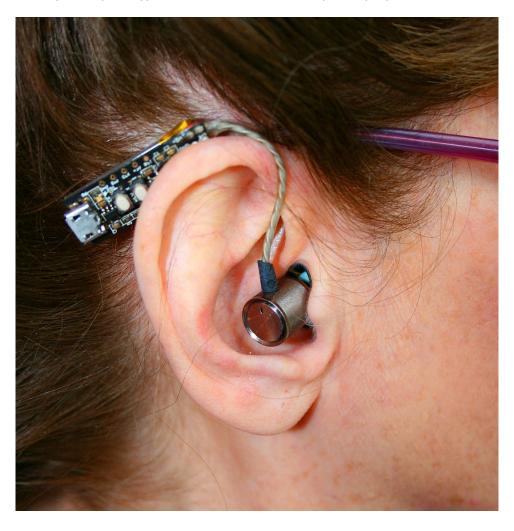
A Behind-The-Ear (BTE) hearing aid is distinguished by battery and electronics which hangs behind the pinna; and, in this case, an air-conduction dynamic receiver positioned at the entrance of the external auditory canal.

For this demo hardware design, the BTE hearing aid is powered by a lithium-polymer (LiPo) battery.

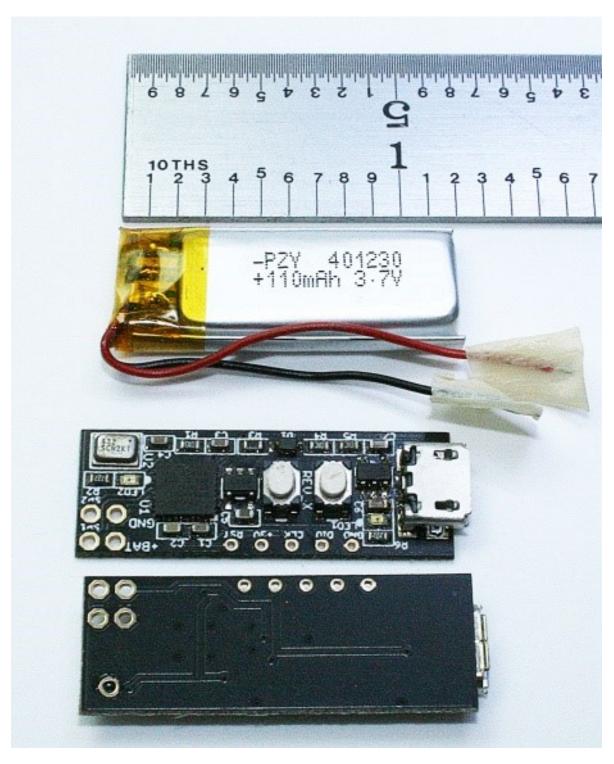
This BTE hearing aid demo hardware design includes provisions for firmware development through a serial wire debug interface (RESET, SWCLK, SWDIO, POWER, and GROUND). The demo hardware design includes 5 pogo pin receptors spaced on 1/10 inch centers for interface to a programmer/debugger such as the Microchip ATATMEL-ICE.

The BTE hearing aid demo hardware design schematic includes 2 buttons for volume up/down control, a green LED light for visual indications, and a voltage regulator. The BTE hearing aid demo hardware design includes a USB Micro-B Receptacle and charging circuit with a red charging LED indicator light.

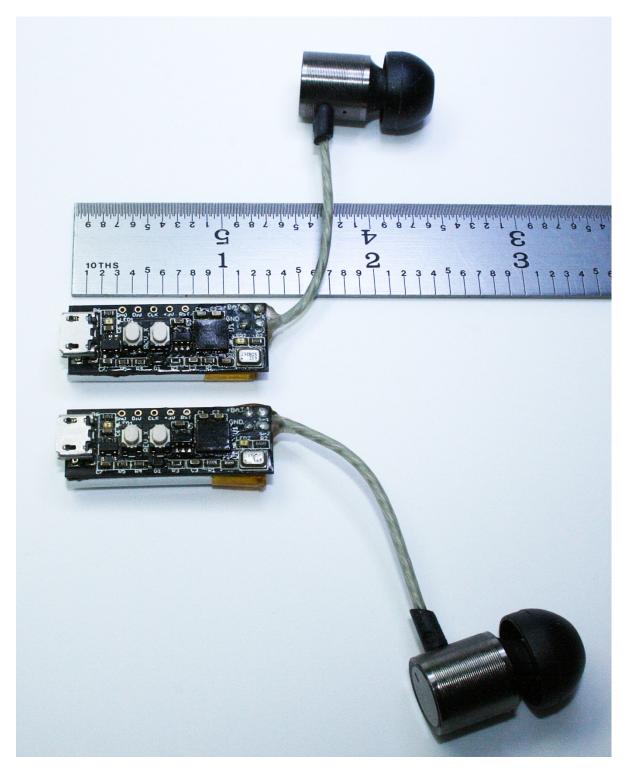
The photos below picture prototypes for evaluation and development purposes:



The 2-layer printed circuit board (PCB) measures: 32 millimeters (mm) by 12 mm. The LiPo battery measures: 30 mm by 12 mm by 4 mm. The battery is attached to the back side of the PCB with two part adhesive steel bond epoxy. A small air gap is formed between the bottom port MEMS microphone and the yellow Kapton tape to allow sound passage.



Liquid monomer and acrylic powder were used to provide strain relief to the earbud cables. The individual earbuds were harvested from consumer earbuds. Clear acrylic conformal coating was used to protect circuit board components. Programming receptors for firmware development (RESET, SWCLK, SWDIO, POWER, and GROUND) are pictured on the top edge of the PCBs.



APPENDIX B: BODY WORN HEARING AID (BWHA) DEMO DESIGN PROTOTYPE

A Body Worn Hearing Aid (BWHA) is distinguished by air-conduction earbuds connected to a separate battery and electronics unit which is carried in the pocket, clipped to the shirt, carried in the hand, or placed on a table. A BWHA is designed for emerging markets or for individuals with mobility problems.

In this demo hardware design, the BWHA is powered by an Alkaline or rechargeable NiMH "AAA" battery.

This BWHA demo hardware design includes provisions for firmware development through a serial wire debug interface (RESET, SWCLK, SWDIO, POWER, and GROUND). The demo hardware design includes 5 pogo pin receptors spaced on 1/10 inch centers for interface to a programmer/debugger such as the Microchip ATATMEL-ICE. Receptors are picture on the top edge of the PCB.

The BWHA demo hardware design schematic includes 2 buttons for volume up/down control, a green LED light for visual indications, and a voltage regulator.

The BWHA demo hardware design also includes a 3.5mm headphone jack.

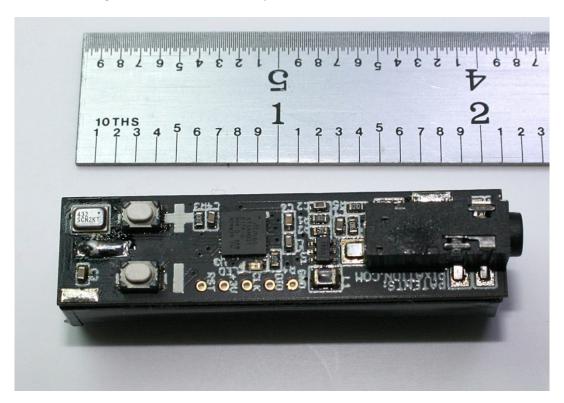
The photos below picture prototypes for evaluation and development purposes:



Mounting tape is used to create a 0.6 mm gap between the PCB and the AAA battery holder. This gap allows sound to enter the bottom port MEMS microphone. The positive lead from the battery holder is bent as shown to allow it to be soldered to the bottom of the PCB (otherwise it would interfere with the 3.5mm headphone jack mounting).



The 2-layer printed circuit board measures: 50 mm by 13 mm. The assembly measures: 19.3 mm tall with alkaline or rechargeable NiMH "AAA" battery installed.



APPENDIX C: PIXATION PERSONALIZE AUDIO (EXAMPLE USAGE INSTRUCTIONS)

Your device has 2 buttons. These buttons are referred to as the "UP" button and the "DOWN" button.

Your device also has a green indicator LED light. Whenever the device is powered ON, pressing either button will cause the green LED to light. The light will also flash after releasing the button to indicate changes to a setting. The number of light flashes corresponds to the setting selected.

POWER ON/OFF:

For the AAA battery powered device:

- 1. Insert the earbuds into the headphone jack to turn the device ON. You will hear "welcome" tones when you turn the device ON. The green LED will also light for a short time when the device is turned ON.
- 2. Remove the earbuds from the headphone jack to turn the device OFF.

For the LiPo powered device:

- 1. When OFF to turn ON: Momentarily press the "UP" button to turn ON. You will hear "welcome" tones when you turn the device ON. The green LED will also light for a short time when the device is turned ON.
- 2. When ON to turn OFF: Press and hold down either the "UP" button or the "DOWN" button for 2 seconds or longer to turn the device OFF. As soon as you have held the button down for 2 seconds you will hear a rapidly alternating series of tones to alert you that you have held the button down sufficiently long. When you release the button, you will hear "goodbye" tones. The green LED will also rapidly flash for 5 seconds to indicate that the device is turning OFF.

All device settings are stored when the device is turned OFF and will be restored when the device is turned ON. Holding down a button for more than 2 seconds will cause the device to sound a rapidly alternating series of tones. Holding down a button for more than 10 seconds will cause the device to sound and light an international Morse coded message: "COPYRIGHT 2020 DEAN R. G. ANDERSON - ALL RIGHTS RESERVED - PATENTS PIXATION.COM".

You will hear a "low battery" tone warning when battery power is nearly depleted. A LiPo powered device will automatically turn off when the battery voltage reaches a minimum level.

SETTING YOUR COMFORTABLE LISTENING LEVEL (VOLUME):

Use the "UP" or "DOWN" buttons to set your Comfortable Listening Level. Momentarily press the "UP" button to make the volume louder. Momentarily press the "DOWN" button to make the volume softer or quieter. With each momentary button press, the volume level is changed. After releasing the button, you will hear a number of beeps to indicate your comfortable listening level. The number of beeps

heard will range from 1 beep to 13 beeps. The number of beeps will be grouped in 3's meaning that there will be a brief pause after each 3 beeps to make it easier to count.

A comfortable level indicated by 13 beeps is the loudest listening level you can set. A comfortable level indicated by 1 beep is the softest listening level you can set. Set the comfortable listening level to the volume level you prefer.

CUSTOMIZE YOUR LISTENING EXPERIENCE:

There are more ways you can personalize your listening experience.

By pressing both the "UP" and "DOWN" buttons at the same time, you change what the buttons do:

- 1. Set your Comfortable Listening Level.
- 2. Set Tonal Emphasis.
- 3. Add Synthetic Articulation.
- 4. Start Preference Programming.

Press both buttons a first time to set your Comfortable Listening Level. You will hear 1 set of 10 ascending tones.

Press both buttons a second time to set Tonal Emphasis. You will hear 2 sets of 10 ascending tones.

Press both buttons a third time to Add Synthetic Articulation. You will hear 3 sets of 10 ascending tones.

Press both buttons a fourth time to start Preference Programming. You will hear 4 sets of 10 ascending tones. Preference Programming will immediately begin after pressing both buttons a fourth time.

Perhaps you did something by mistake. You can always restart the device (i.e. turn the device OFF and then back ON) at any time and your previous settings will remain unchanged. Preference Programming changes will not be made until you complete the protocol.

SET TONAL EMPHASIS:

Select Tonal Emphasis button functions as described above.

If speech, music, or natural sounds are dull, momentarily press the "UP" button to sharpen sounds.

If speech, music, or natural sounds are too sharp, momentarily press the "DOWN" button to smooth out sounds.

After releasing the button you will hear up to 13 beeps. With 1 beep, you make your sound environment smooth and deep. With 13 beeps, your sound world will become crisp and punchy.

Press both the "UP" and "DOWN" buttons at the same time to change back to selecting Comfortable Listening Level when you are finished. Alternatively, without pressing any buttons for a period of 1 minute, the device will go back to selecting Comfortable Listening Level.

ADD SYNTHETIC ARTICULATION:

Some people do not articulate or enunciate when they speak. It is hard to change the way another person speaks. Your device however can change your listening experience.

Select Add Synthetic Articulation button functions as described above.

Synthetic Articulation is created for soft sounds made by consonant letters such as: "H", "TH", "S", "F", "T", "K", and "SH". Synthetic Articulation is added to a frequency band of your choice:

- a) Not used.
- b) 391 Hz to 590 Hz.
- c) 488 Hz to 744 Hz.
- d) 613 Hz to 919 Hz.

Momentarily press the "UP" button to cycle to the next frequency band on the list. Momentarily press the "DOWN" button to cycle to the previous frequency band on the list. After pressing the "UP" or "DOWN" buttons, you will hear a 2 second sample of the frequency band selected unless you selected the option for "Not used".

Adding Synthetic Articulation is optional and subjective. It is your prerogative.

Press both the "UP" and "DOWN" buttons at the same time to go back to selecting Comfortable Listening Level when you are finished. Alternatively, without pressing any buttons for a period of 1 minute, the device will go back to selecting Comfortable Listening Level.

PREFERENCE PROGRAMMING:

Start Preference Programming as described above. Make sure the earbud is securely pressed into your ear. You may find it more comfortable to hold the electronics a little below you ear and pinch it to press a button. The electronics does not have to be behind your ear to do Preference Programming but the earbud needs to be firmly in place.

After the fourth set of 10 ascending tones are heard, a pulsing sound will begin to play. At first the pulsing sound may be too faint to even hear!

Press either button as soon as you hear the pulsing sound. After releasing the button, the same process will be repeated.

The sound may sound like pulsing "shushing", "hissing", or "swishing".

There may be long periods where you don't hear anything. Be patient. Please continue to listen and press the button as soon as you can hear a pulsing sound.

Don't worry if you make a mistake! The process is will repeat until your responses are consistent.

This process will take from 1 to 4 minutes depending on your responses.

After completing the process you will hear the normal "welcome" tones. Your preferences for Preference Programming will be set. The device will return to selecting Comfortable Listening Level. Turn up the volume to your comfortable listening level.

You can cancel Preference Programming at any time during the process and return to your previous settings by pressing and holding down either button for more than 2 seconds.

Preference Programming performs these 3 tasks:

- 1. Sets your Comfortable Listening Level.
- 2. Sets Tonal Emphasis.
- 3. Adds Synthetic Articulation.

You are still able change each of these features individually after you perform Preference Programming.

APPENDIX D: WARNINGS, RESTRICTIONS, AND DISCLAIMER

Pixation Corp. 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. 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 and calibrations 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.

