

Zen Programming Guide & Considerations

Description of Device

The Zen program is an optional hearing program within the mind 440 hearing aid series (available from CIC to power BTE) that generates a noise and melodic tones using fractal mathematics. It provides a relaxing sound background for wearers of the mind 440 hearing aid who desire such a sound background in quiet. The Zen sounds are treated by the hearing aid as external sounds and amplified according to the hearing loss of the wearer. Thus, the Zen sounds are adjusted spectrally to the hearing loss for consistent audibility. For hearing-impaired adults who suffer from tinnitus, this special program may provide a distraction from, and/or fully or partly mask their tinnitus to provide relief. The Zen program may be used alone (without amplification) in quiet when the wearer is not required to hear surrounding sounds. Or, it may be used with amplification so both the surrounding sounds and the generated sounds (fractal tones and noise) are heard together. Its level may be adjusted by the professional during programming and by the wearer in daily use.

Indications for Use

The Zen program is intended to provide a relaxing sound background for adults (21 years and older) who desire to listen to such a background in quiet. It may be used as a sound therapy tool in a tinnitus treatment program that is prescribed by a licensed hearing healthcare professional (audiologists, hearing aid specialists, otolaryngologists) who is trained in tinnitus management.

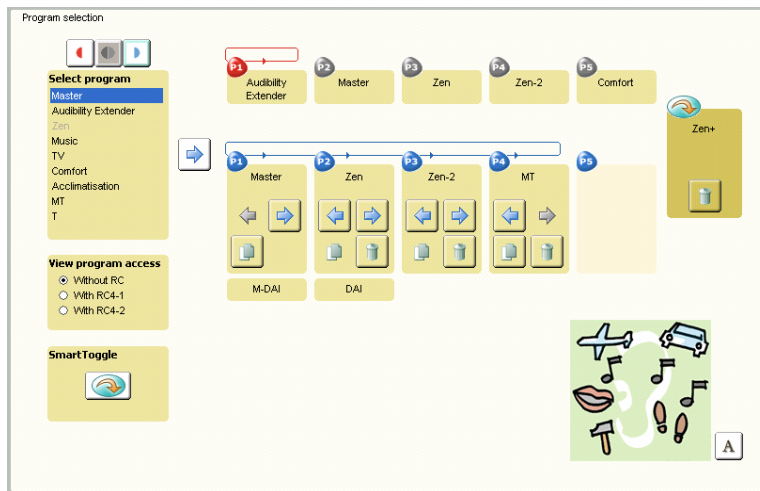
Directions for Use

Precaution: *The Zen program should be used along with proper counseling conducted by hearing healthcare professionals who are trained in tinnitus management. Do not prescribe this program to your patients for tinnitus reduction unless you are trained in tinnitus treatment. Training in the selection and fitting of the mind 440 hearing aid does not qualify the hearing healthcare professional to be proficient in tinnitus management. Referral to another hearing healthcare professional who is trained in tinnitus treatment and on the Zen program adjustment is recommended.*

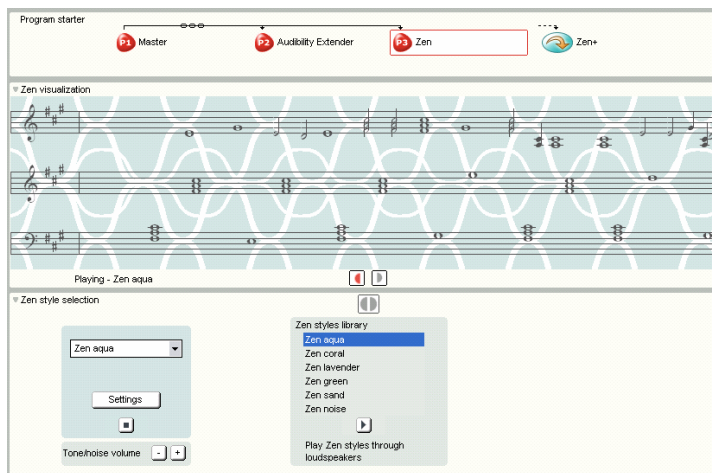
Familiarity with using Compass (the programming software) is assumed in the fitting and programming of the Zen.

Steps in programming the Zen:

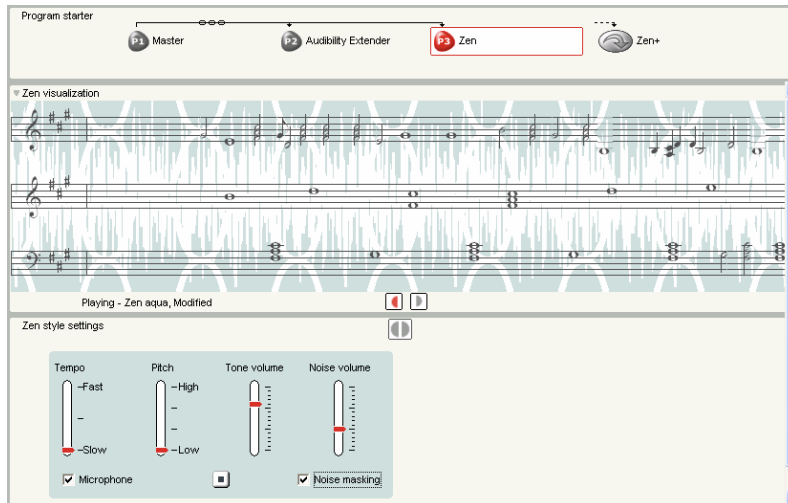
- After completion of the basic fitting (sensogram and feedback test), proceed to the “program selection” screen.
- Select the appropriate listening programs (such as T-coil, TV etc, in addition to the Master default program) for the patients based on their expressed needs. Include “Zen” as one of the listening programs (recommended option).



- Alternatively, you can activate “Smart Toggle” button to allow the patient access to the Zen program in any listening programs with a “long press” of the program button (either on the hearing aid or via the RC4 remote control).
 - There can be up to three Zen programs that the patient may access via the Smart Toggle mode. To change Zen program, the patient simply presses the program button for less than one second (short press).
- There are a total of 5 different Zen styles that can be selected by the clinician. Each Zen program has its own default but allows adjustment of the intensity, the tempo, the pitch, and the level of a broadband noise. In addition, there is also a separate Zen noise program.



- In addition, each Zen style allows the clinician to specify the sound source within that program. The available sources are: tones alone, tones + noise, tones + master, and tones + noise + master.



- To make sure that the Zen program is acceptable to the patient, go to the selected Zen program and activate the Zen program so the patient may hear the stimuli. Adjust the intensity (of tone and noise, if appropriate), tempo, and pitch level of the Zen stimulus to make sure that the Zen stimuli are acceptable (audible but not too loud as to interfere with communications) for its intended use.
- Repeat the adjustment for other selected Zen styles. Choose only the number of Zen styles that are necessary. Leave the Sound Diary to “On” in order to log the frequency of use of the Zen programs.
- Instruct the patients on how to activate the Zen program. Make sure that the patient is able to activate and deactivate the program as desired.
- Instruct the patient on the use of the Zen program (when to use the program, how long to use etc).
- Make sure that you alert the patient to the warnings (on interfering with hearing everyday sounds). Also schedule the patient for a follow-up to make sure that the patient benefits from the mind 440 hearing aid and the Zen program.

Contraindications

The following symptoms are contraindications for hearing aid use.

- Congenital or traumatic deformity of the ear
- Active drainage from the ear within 90 days
- History of rapid progressive hearing loss within previous 90 days
- Acute or chronic dizziness
- Sudden unilateral hearing loss in previous 90 days

Warnings

There are no known adverse reactions from the use of the Zen program. However, because the use of the Zen program may interfere with hearing everyday sounds including speech, it should not be used when hearing such sounds are important. Switch the hearing aid to a non-Zen program in those situations.

Precautions

Because the Zen program simply provides a sound background, its safety and effectiveness is contingent on its proper application. To ensure its safety and effectiveness when used as a sound therapy tool for tinnitus, it must be part of a tinnitus management program (e.g. Tinnitus Retraining Therapy, Behavioral Cognitive Therapy) designed and conducted by Hearing Healthcare Professionals who are trained in tinnitus management. A tinnitus management program should include a complete audiological evaluation, tinnitus diagnosis, counseling, use of proper amplification and/or sound therapy tools. Prior to any tinnitus management program, it is advisable that the wearer seek medical attention to exhaust any medical or surgical treatment options.