

HyperFit™ Desktop Fitting Guide

Supplemental Instructions for the HyperSound® Tinnitus Module

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FOR HEARING PROFESSIONALS ONLY

Introduction to this Supplement

This supplement to the HyperFit™ Desktop Fitting Guide for the HyperSound Clear™ 500P provides guidance on how to use HyperFit to activate and program the HyperSound Tinnitus Module. Please be sure to read the full Fitting Guide as it contains important prerequisite information pertinent to this Supplement. This Supplement also references the 500P User Guide that accompanies each 500P system.

Hearing Care Professionals

Activation of the HyperSound Tinnitus Support option for the HyperSound Clear 500P (“500P”) group hearing device is targeted for licensed Hearing Care Professionals (audiologists, hearing aid specialists, or otolaryngologists) who are familiar with the evaluation and treatment of tinnitus and hearing losses. The activation and fitting of the optional HyperSound Tinnitus Support Module must be done under the guidance of a Hearing Care Professional and is recommended to be a part of a tinnitus management program.

Intended Use of the HyperSound Tinnitus Module

The HyperSound Tinnitus Module is indicated for patient home use in the temporary relief of tinnitus symptoms. The device is available in HyperSound Clear 500P audio systems to generate and deliver personalized sound output to tinnitus patients with or without hearing loss and with or without hearing aids. Any fitting of the device must be done by a hearing care professional.

The target population is primarily adults (18 years or older).

Prescription Use Only

CAUTION:

Good health practice requires that a person reporting tinnitus have a medical evaluation by a licensed ear physician before using a sound generator. The purpose of such an evaluation is to ensure that any medically treatable condition that may cause tinnitus is identified and treated prior to using a sound generator.

Federal law restricts this device to sale by or on the order of a doctor, audiologist or other hearing care practitioner licensed to dispense hearing instruments in your state-in accordance with all applicable rules and regulations. Federal law permits a fully informed adult to sign a waiver statement declining the medical evaluation for religious or personal beliefs that preclude consultation with a physician – in accordance with all applicable state rules and regulations.

The process of activating the HyperSound Tinnitus Module requires that you, the Hearing Care Professional, affirmatively acknowledge that you are authorized to prescribe the 500P device for tinnitus therapy and that the Patient has been provided a HyperSound Tinnitus Module User Guide describing the use of the tinnitus module. A link to download the guide is provided during the tinnitus activation process to assure the Patient has the latest version of the tinnitus user guide. Make sure your Patient is advised as to the important Patient information and Warnings in the HyperSound Tinnitus Module User Guide.

Caution Regarding Volume Level

The maximum output level of tuned tinnitus programming settings that may be employed by a Hearing Care Professional can reach up to 115 dB SPL, which may cause short-term noise exposure at a level beyond OSHA guidance for normal hearing listeners.

Listening to HyperSound Clear audio at excessive volume (e.g., volume programmed or optimized for a person with hearing loss or tinnitus) can cause permanent hearing damage. As described above prescription tinnitus mode may also result in excessive volume output and should not be used at volumes not prescribed by a Hearing Care Professional or used by persons with normal hearing.

Advising Patients on HyperSound Settings and Speaker Placement

You may wish to advise your Tinnitus Patient on how the general Volume and Balance settings in HyperSound affect the delivery of Tinnitus therapy. When using the Tinnitus Module, your Patient will also have the ability to fine-tune the masking sounds by using the 9-band graphic equalizer. When the tinnitus module is activated, users can access the “TINNITUS EQ” option from the main menu. The user is able to adjust the gain (volume) in range of frequency bands from 1kHz to 16kHz by plus or minus 10 dB. You may wish to advise how these adjustments may affect any specific Tinnitus hearing loss and shaping programmed for the Patient.

The volume levels of masking therapy may change as the user changes his or her distance from the speakers. While the recommended listening distance is 3 to 10 feet from the speakers, a change in positioning from 3 to 10 feet will generally require a 2 or 3 step volume increase to achieve the same intensity. Likewise, a move from 10 to 3 feet will generally require a 2 or 3 step volume decrease. This volume/distance relationship should be considered when advising your Patient on a recommended volume level for masking.

The HyperSound speakers are correctly positioned when the Patient can see his or her reflection centered in each speaker. However, for Patients with asymmetric hearing loss or situations in which you have customized a right and left hearing or tinnitus profile, you may wish to suggest a speaker positioning that provides for a better separation of the left and right beams by positioning the Patient so that only the ears are visible in the speaker reflection, as indicated below.



Centered reflection for typical operation



Off-centered reflection for asymmetrical hearing loss

Enabling the HyperSound Tinnitus Module

The HyperSound Tinnitus Module is activated in the HyperSound Clear 500P through the HyperFit software. Activation requires that you have (1) the latest HyperFit software and (2) the 500P intended to be activated has the latest firmware update. You will automatically be prompted to update the HyperFit software when you launch the HyperFit program and are connected to the internet (refer to Section 5 of the HyperFit™ Desktop Fitting Guide for HyperSound Clear™ 500P). You will also be instructed to download and install the latest 500P firmware to the device prior to activating the Tinnitus Module.

Note that you must be connected to the Internet to download the latest HyperFit software and 500P firmware and to activate the Tinnitus Module in a 500P device.

Programming the HyperSound Tinnitus Module

The degree of hearing loss and the Patient’s intended use of the device (with or without hearing aids) are important factors to consider prior to programming the Tinnitus EQ setting in the HyperSound Tinnitus Module of the 500P device. See also the information on volume levels and speaker placement above.

After the latest version of HyperFit is installed on your PC, you will be able to activate the Tinnitus module as a Quick Fit, which programs a standard, flat response or you may customize the programming to your Patient’s hearing loss or further shape the response for particular therapy or preferences.

If you choose a customized program, HyperFit will use the Patient’s audiogram as captured from NOAH as the base for programming. If NOAH is not being used, you may input the audiogram values directly into HyperFit. You may further shape or adjust the Tinnitus EQ output for your Patient’s hearing loss and tinnitus therapy preferences using the Fitting screen. Since audio is delivered to each ear by a directed beam, the beam width may affect programmed output that is also influenced by distance, speaker positioning, SPL and relief content frequency. The following table illustrates the isolation at various frequencies and distances and should serve as a guide for programming where disparate gain is considered.

Frequency (kHz)	Isolation (dB)			
	0.5 m	1m	2m	3m
1	-7	-3.5	-1	-0.5
2	-10	-4	-2	-1
4	-16	-7	-4	-2
6	-19	-11	-7	-3
8	-21	-14	-10	-5
10	-25	-17	-13	-7
12	-20	-21	-17	-8

Individual ear isolation versus frequency at selected distances.

Depending on the required gain the effective distance range may be limited. If dramatically disparate gain is prescribed for each ear, the isolation and effect may be limited depending on frequency and distance. Patients with severe hearing loss, including asymmetrical hearing loss, may perceive improved masking if the 500P is programmed for use with their hearing aid(s).

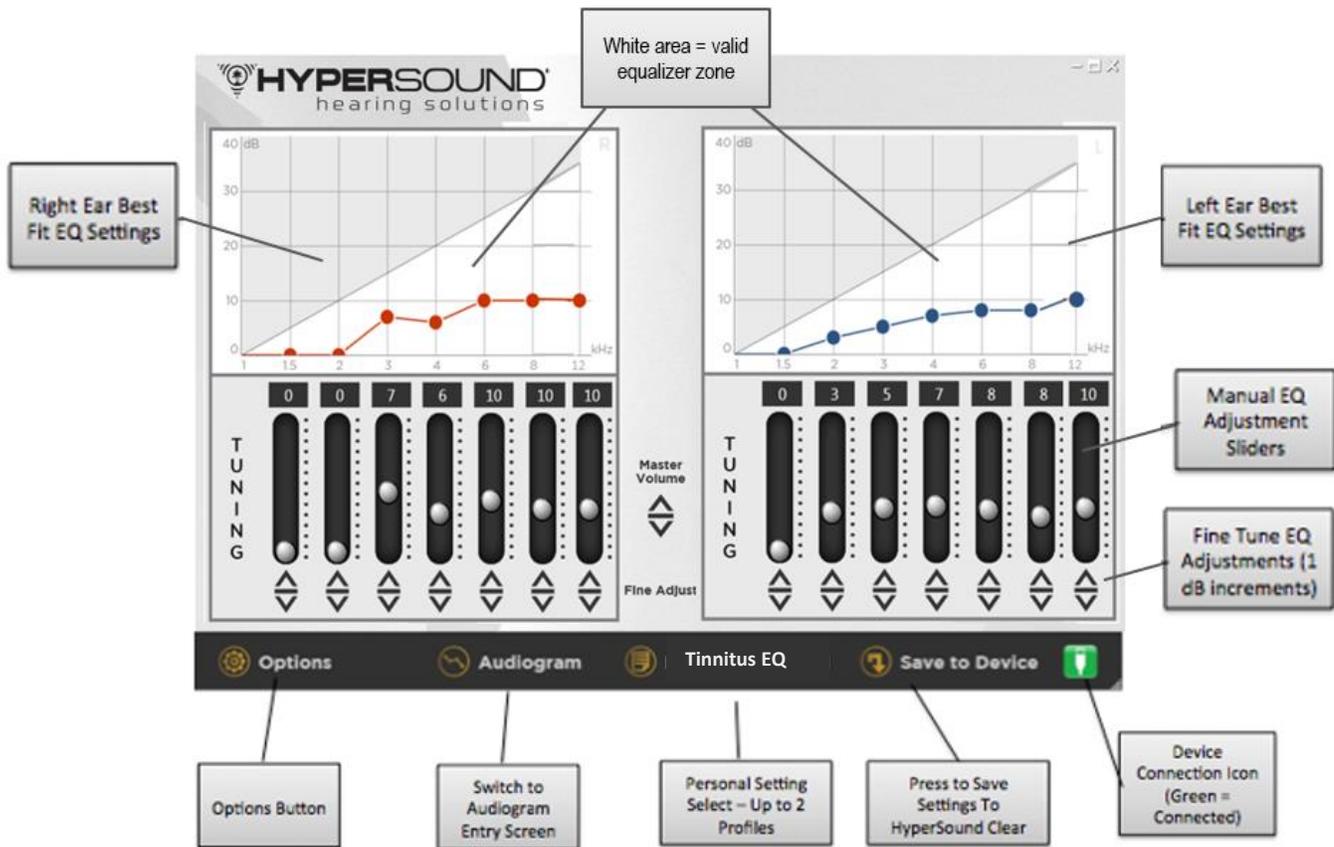


Figure 11 - Fitting Window Displays and Controls

The fitting screen offers a variety of methods to adjust the fitting parameters to adjust and optimize the system to the Patient’s hearing loss, tinnitus profile and preferences:

- The individual equalizer settings can be changed by moving the sliders up and down to add or reduce the amount of amplification in each frequency band.
- The individual equalizer settings can also be adjusted in 1 dB increments by pressing the Fine Adjustment arrows.
- The overall volume of all the equalizers can be adjusted by pressing the Master Volume up and down buttons.

Proceed to Section 5.6 of the HyperFit User Guide to store the profile and program the HyperSound Clear 500P.

Assisting Patients on Relief Sounds and Use

The HyperSound Tinnitus Module offers nine relief sounds named as: Stream, Rain, Wind, Fan, Shower, Forest, Waves, White Noise and Brown Noise. It is recommended that the selection of the relief sound and the frequency and duration of use be communicated with your Patient as part of a tinnitus management program.

Because HyperSound audio is focused, a Patient may need to decrease the volume or sensitivity of their hearing aid when used with the 500P. It is recommended that you test the 500P with the Patient's hearing aids to ensure that there is no audible interference, acoustic feedback (squeal or whistle sound) or any other sound artifacts.

For more information:

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