

HyperSound[®] Tinnitus Module USER GUIDE

(an optional feature of the HyperSound Clear™ 500P Directed Audio Solution)

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HyperSound Tinnitus Module USER GUIDE

(an optional feature of the HyperSound Clear 500P Directed Audio Solution)

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).

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 by a Hearing Care Professional and is recommended to be a part of a tinnitus management program.

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.

Guidelines for tinnitus sound generator users

These instructions contain information about the HyperSound Tinnitus Module, which may have been enabled in your 500P by your Hearing Care Professional. The HyperSound Tinnitus Module is a tinnitus management device intended to generate sounds of sufficient intensity and bandwidth to help manage ringing in the ears or internal head noises. Your Hearing Care Professional will also be able to offer the appropriate follow-up care. It is important to follow the advice and directions regarding such care including the frequency and duration of use and recommendations as to intensity or loudness.

You can use the HyperSound Tinnitus Module with your 500P at any time—day or night. You may want to use your device when you are relaxing, contemplating or performing quiet tasks. The relief sound tracks have been selected to maximize your relaxation response, but not to be too distracting. The device can also aid the onset of sleep and help you get a good night's rest.

OPERATING THE HYPER SOUND TINNITUS MODULE

It is important that you become familiar with the operation of the HyperSound Clear 500P system prior to using the HyperSound Tinnitus Module. **Please read all instructions, cautions and warnings in the 500P User Guide. See additional cautions and warnings starting on page 9 of this guide.**

Just as HyperSound Clear can be fit to your hearing profile by a hearing care professional, the Tinnitus Module can be customized to your particular hearing and tinnitus situation by your Hearing Care Professional. If you have any questions about the customization of your Tinnitus Module to your hearing or tinnitus profile please consult your Hearing Care Professional.

Setup and Positioning of the Speakers

It is important that you first setup your 500P properly for best results. This includes positioning of the speakers to target each ear (see the "Set-up and Alignment" section of the 500P User Guide). Since many patients prefer modest volume for relief sounds and the audio from the 500P speakers is directional, it is important to properly position the speakers to target each ear as described in the 500P User Guide. We recommend listening to relief sounds at a distance of 3 to 10 feet for ease of speaker setup and positioning.

As described in the SET UP AND ALIGNMENT section of the 500P User Guide, your HyperSound speakers are correctly positioned when you can see your reflection centered in each speaker. However, for users with asymmetric hearing loss or situations where your Hearing Care Professional has customized a right and left hearing or tinnitus profile, you may wish a setup positioning that provides for a better separation of the left and right beams by positioning yourself so that only your ears are visible in the speaker reflection, as indicated below.



Centered reflection for typical operation Off-centered reflection for asymmetrical hearing loss

If you have any questions about the proper setup of your 500P device for Tinnitus use, please consult your Hearing Care Professional.

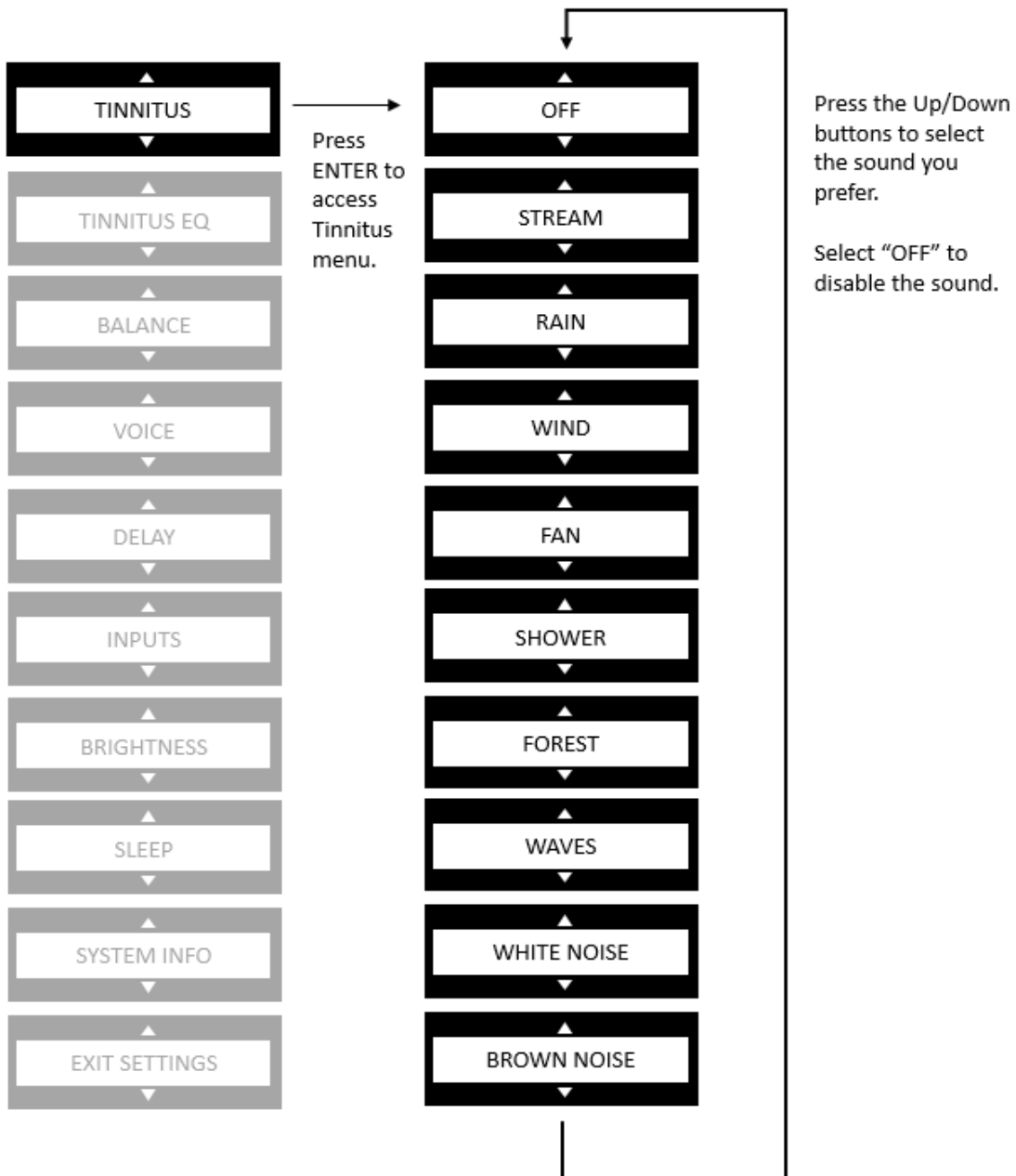
Selecting the Tinnitus Module Mode

All functions of the HyperSound Tinnitus Module can be selected through the amplifier front panel keys or the Remote Control (see the 500P User Guide for information on these controls). Your selection results will be displayed on the device's display. To operate the Tinnitus module, select "Tinnitus" from the main menu by pressing the ENTER button (see page 7 below for an illustration of the main menu).

Selecting Relief Sound Options (Selecting a Track)

Your 500P system may have been fitted to your hearing loss and preferences for tinnitus relief by your Hearing Care Professional. Your Hearing Care Professional may also have helped you identify the relief sounds and audio settings preferred by you.

The HyperSound Tinnitus Module offers nine relief sounds, including *Stream, Rain, Wind, Fan, Shower, Forest, Waves, White Noise* and *Brown Noise*. Selection of the relief sounds can be made with the remote control or through the front panel of the system as follows.

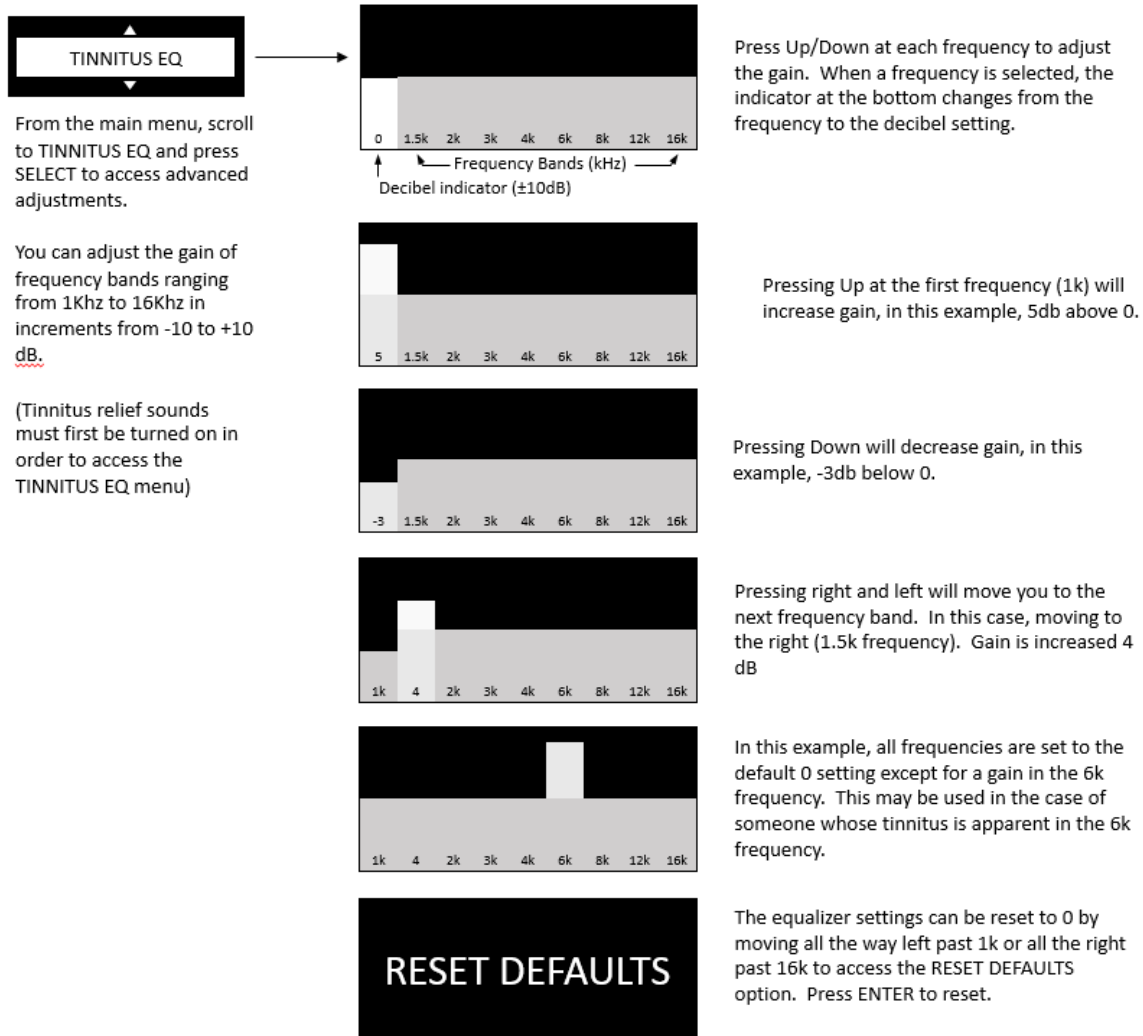


User Adjustments in Tinnitus Mode (Volume, Balance, Mute and Tinnitus EQ Preferences)

In addition to selecting your preferred relief sound, you may adjust the volume of the device and balance – left or right to further adjust the volume of relief sound targeting each ear. Use the volume controls on the display or the remote control to make adjustments (see the “Operation” section of the 500P User Guide for more information on volume control). You can also use the Mute button on the remote control to mute relief sounds at any time.

Please note that the volume of your relief therapy may change if you change your positioning distance from the speakers. While we recommend a listening distance of 3 to 10 feet, 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. If you are sensitive to the volume of relief therapy or your Hearing Care Professional has recommended a volume setting at a certain listening distance, consider this information as you modify your listening distance.

For each relief sound you can further tune the frequency or Tinnitus equalization (EQ) output for a particular relief sound to your preference or that suggested by your Hearing Care Professional by adjusting the Tinnitus EQ settings. After the Tinnitus feature has been activated and with relief sounds playing as described above, you can adjust these settings in the TINNITUS EQ setting in the menu with the remote or front panel controls as indicated below:



TINNITUS EQ

From the main menu, scroll to TINNITUS EQ and press SELECT to access advanced adjustments.

You can adjust the gain of frequency bands ranging from 1Khz to 16Khz in increments from -10 to +10 dB.

(Tinnitus relief sounds must first be turned on in order to access the TINNITUS EQ menu)

Press Up/Down at each frequency to adjust the gain. When a frequency is selected, the indicator at the bottom changes from the frequency to the decibel setting.

Pressing Up at the first frequency (1k) will increase gain, in this example, 5db above 0.

Pressing Down will decrease gain, in this example, -3db below 0.

Pressing right and left will move you to the next frequency band. In this case, moving to the right (1.5k frequency). Gain is increased 4 dB

In this example, all frequencies are set to the default 0 setting except for a gain in the 6k frequency. This may be used in the case of someone whose tinnitus is apparent in the 6k frequency.

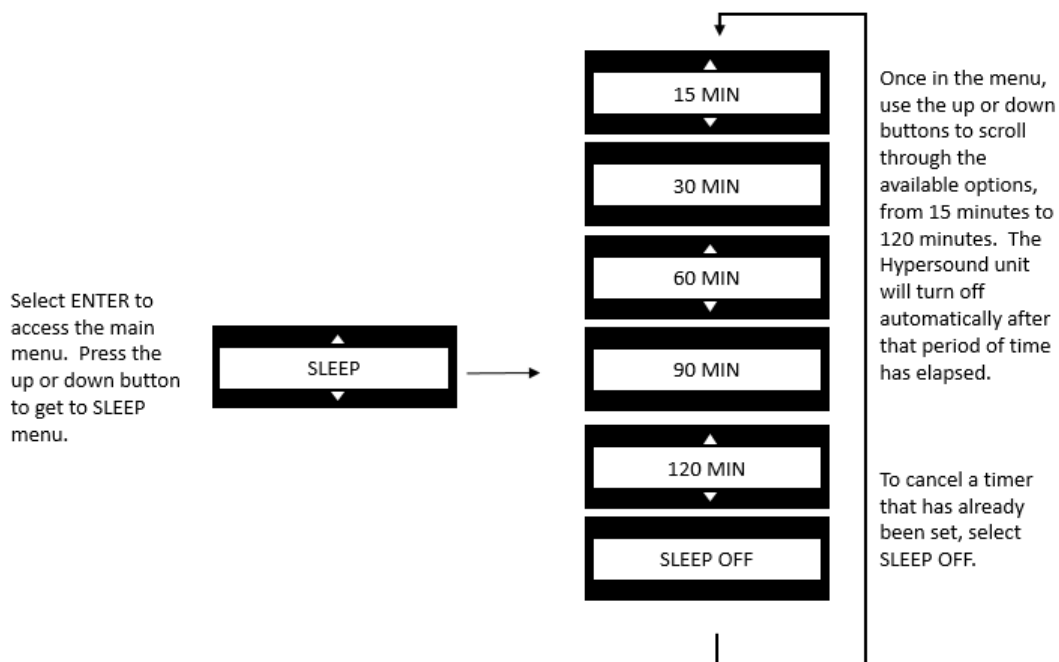
The equalizer settings can be reset to 0 by moving all the way left past 1k or all the right past 16k to access the RESET DEFAULTS option. Press ENTER to reset.

RESET DEFAULTS

You can further adjust the volume and balance until you have your preferred settings or those recommended by your Hearing Care Professional.

Operating the Sleep Timer

A sleep timer is available in the main menu, allowing you to program the device to turn off after a set period of time. This timer is accessed through the SLEEP function in the main menu and is set as illustrated below. The timer function is available in both the tinnitus module and during normal TV listening operation. Once the sleep timer has been set you can return to normal operation and the timer indication will be included in the main display. The unit will display a message one minute prior to powering off.



Exiting the HyperSound Tinnitus Module

While you are in the HyperSound Tinnitus Module you can only play/listen to relief sounds. Other audio inputs for the 500P are deactivated. In order to use your 500P with your TV or other audio device you first must exit the HyperSound Tinnitus Module.

To exit the Tinnitus module, you can select “off” in the Tinnitus menu as described above in the “Selecting Relief Sound Options (Selecting a Track)” section. Alternatively, you can hit the Input button on the remote, followed by the Enter button, to return to the last TV input setting. Turning the power off and then on again will also disable the Tinnitus module and return the unit to the last TV Input setting.

To re-enter the tinnitus module, refer to the instructions above for “Selecting Relief Sound Options

(Selecting a Track).”

CAUTION - daily use

Your Hearing Care Professional should advise you of the maximum amount of time per day you should use HyperSound Tinnitus Module. It should never be used at uncomfortable levels.

Troubleshooting

If the relief sounds do not play:

- Make sure that the speakers are connected and producing sound. The speakers may take up to a minute after initially being turned on to reach their operating voltage and begin to make sound.
- Make sure that the speakers are aimed at the target listening area.
- Make sure that the volume is turned up, using either the remote control or knob on front panel.
- Make sure that the power is on and the display is illuminated.

If the sounds you hear seem unbalanced, then:

- Check the positioning of the speakers (See page 3 of this guide and refer to the “Set up and Alignment” of the 500P User Guide).
- Check the left / right balance control (See the “Operation” section of the 500P User Guide).

If you cannot play your TV audio:

- Make sure that the Input selection is set to the input that corresponds with your TV or other source. Use the Input button on the remote or the input menu through the front panel to toggle through the input options until you hear your TV signal.
- Refer to the “Troubleshooting” section of the 500P User Guide).

If you cannot locate the Tinnitus screen in the main menu, make sure that the HyperSound Tinnitus Module has been activated by your Hearing Care Professional.



- Please observe all Warnings in the 500P User Guide when operating your 500P system for tinnitus therapy.
- 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. The 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.

Warnings Related to Tinnitus

If your Hearing Care Professional has activated the sound generator HyperSound Tinnitus Module, please pay attention to the below warnings.

- **IMPORTANT WARNING FOR TINNITUS USERS WEARING HEARING AIDS** - Because HyperSound audio is focused, you may need to decrease the volume or sensitivity of your hearing aid if you feel that the sound is too loud or you experience any acoustic feedback (squeal or whistle sound) or any other sound artifacts in the ears. If you are unable to adjust your hearing aid and you are experiencing any discomfort to your ears while listening to relief sounds, please remove your hearing aids, step outside of the HyperSound sound zone, and discontinue use of the HyperSound Clear with your hearing aid. Consult with your Hearing Care Professional before again using the HyperSound Tinnitus Module with your hearing aids.
- Exposure to sound beyond the maximum allowable dosage of noise exposure according to Occupational Safety Health Administration (OSHA) regulations (e.g., 90 dB for 8 hours) may cause noise-induced hearing loss.
- There are some potential concerns associated with the use of any sound generated by a tinnitus management device. Among them are the potential for worsening of tinnitus and or a possible change in hearing thresholds.
- Should you experience or notice a change in hearing or tinnitus, or any dizziness, nausea, headaches, or heart palpitations, you should immediately discontinue use of the device and seek a consultation with a medical, audiology or other Hearing Care Professional.
- Do not adjust the volume during your sessions so that the relief sound is uncomfortably loud. It is important to listen at a comfortable level, even if you are still able to hear your tinnitus. Contact your Hearing Care Professional if you are unable to set your device to a comfortable listening volume.
- As with any device, misuse of the sound generator feature could present some potentially harmful effects. Care should be taken to prevent the unauthorized use and to keep the device out of the reach of children and pets.
- A Hearing Care Professional should advise a prospective sound generator user to consult promptly with a licensed physician (preferably an ear specialist) before using a sound generator if the Hearing Care Professional determines through inquiry, actual observation, or review or any other available information concerning the prospective user that the prospective user has any of the following conditions:
 - i. Visible congenital or traumatic deformity of the ear.

- ii. History of active drainage from the ear within the previous 90 days.
- iii. History of sudden or rapidly progressive hearing loss within the previous 90 days.
- iv. Acute or chronic dizziness.
- v. Unilateral hearing loss of sudden or recent onset within the previous 90 days.
- vi. Audiometric air-bone gap equal to or greater than 15 decibels at 500 hertz (Hz), 1,000 Hz, and 2,000 Hz.
- vii. Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.
- viii. Pain or discomfort in the ear.

For More Information

For questions or inquiries regarding your tinnitus therapy please contact your Hearing Care Professional. For information on your HyperSound Clear 500P please consult your 500P User Guide or visit: <http://hypersoundhearing.com/support> or contact as at the telephone numbers below.

US & Canada:	1-888-496-8001
UK & other EU:	+44 (0) 20 7 0987948
Germany:	+49 (0) 69 13372826
France:	+33 (0) 17 6700030

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