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(54) **APPARATUS FOR TREATMENT OF MONO-FREQUENCY TINNITUS**

GERÄT ZUR BEHANDLUNG VON MONOFREQUENZ-TINNITUS

DISPOSITIF SERVANT AU TRAITEMENT D'UN ACOUPHENE MONOFREQUENCE

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GB-A- 2 134 689
US-A- 5 325 872
US-A- 5 788 656
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Description

TECHNICAL FIELD

[0001] The present inventions relate to the treatment of tinnitus patients and more particularly to apparatus for treatment of mono-frequency tinnitus patients utilizing phase shift cancellation principles.

BACKGROUND

[0002] Tinnitus is defined as the perception of sound by an individual when no external sound is present, and often takes the form of a hissing, ringing, roaring, chirping or clicking sound which may be intermittent or constant. According to the American Tinnitus Association, tinnitus afflicts more than 50 million Americans, and more than 12 million of those suffer so severely from tinnitus that they seek medical attention and many cannot function normally on a day-to-day basis.

[0003] Tinnitus, often referred to as ringing in the ears, is estimated to be present in approximately 50% of the US population over 65 years of age. In general, tinnitus takes many and varied forms, which may be related to its underlying cause. Tinnitus may be caused by, or related to, such diverse factors as trauma, drugs, hearing loss, the normal aging process or other unknown causes.

[0004] Previous approaches to treating tinnitus have focused on masking the tinnitus noise experienced by patients. While previous masking techniques have been unable to alleviate the problems of tinnitus patients, significant research has been done. In reporting on studies at the Oregon Tinnitus Clinic, Jack Vernon, director of the Oregon Hearing Research Center, stated that, in patient tinnitus studies, phase and tone relationships are of obvious and critical importance in tone masking of tinnitus. Vernon goes on to observe that one cannot repress the idea of canceling tinnitus by a proper phase adjustment of the external tone used in masking.

[0005] In commenting on Wegel's earlier tinnitus treatment findings that a slight mistuning of a masking external tone produced a beat-like sensation with the tinnitus sound, Vernon reported that, in a 100 patient study, he was able to detect a slight beat-like sensation in only four instances. Vernon therefore concluded that the beat-like sensation found by Wegel was most probably due to octave confusion resulting from Wegel not using a single pure tone, but rather a narrow band of noise. In conclusion, Vernon observed that phase manipulation justifies further patient studies as a masking parameter for tonal tinnitus treatments. Vernon's report on possible phase manipulation for treating tinnitus patients remained unchanged from its original publication in 1991 and as included in the 1997 edition of Shulman's treatise entitled "Tinnitus Diagnosis and Treatment."

[0006] In his above-referenced U.S. Application, Dr. Choy reports on favorable patient data from blind clinical studies utilizing a 180-degree phase shift of an externally generated tinnitus tone. More than 79% of patients studied reported either elimination of, or substantial reduction in the level of, tinnitus noise.

[0007] Neither current medical procedures nor electronic or sonic instrumentation permit or facilitate an objective determination of either the frequency or amplitude of the tinnitus noise a patient experiences. It is also not possible to subjectively determine an instantaneous phase of a point on a patient's virtual mono-frequency tinnitus tone.

[0008] This current state of tinnitus treatment has been bothersome for the tinnitus patient because the current state of medical knowledge and acoustic/electronics instrumentation does not yet permit one to objectively determine at what point on a patient's virtual endogenous tinnitus sound wave tinnitus tone (sine wave) an exogenous phase-shifted sine wave would be inserted in an attempt to cancel the patient's virtual tinnitus noise.

[0009] US-A-5 795 287 discloses tinnitus maskers for direct drive hearing devices. A circuit generates signals corresponding to sounds to mask tinnitus a user perceives. A direct drive hearing device which is coupled to a structure in the user vibrates in response to the signals. The vibrating direct drive hearing device stimulates hearing by vibrating the structure to which it is coupled. A user may select the frequency, intensity and phase of a tone generated. Additionally, a second tone or a background sound may be selected.

[0010] GB-A-2 134 689 discloses an arrangement for helping to overcome the problem of characterising sounds which are of use in generating sounds in a hering aid, including a sound generator containing tone and noise generators controlled by a microprocessor system and a terminal to generate a variety of types and intensities of sounds in earphones. The arrangement is used to characterise sounds which help a sufferer and data used to generate these sounds are recorded at. A similar sound generator may then form part of a personal masker controlled by a microprocessor using the data characterising the sufferer's tinnitus which is held in a read-only memory. Other forms of masker are also described. The sound generator may be synchronised with the heartbeat, using a pulse rate monitor.

[0011] US-A-5 325 872 relates to a tinnitus masker with one or more signal generators, a controllable amplifier, one or two electroacoustic transducers for conversion of electrical signals into acoustic signals and a voltage source, whereby at least one of the signal generators generates a continuously repeated, sinusoidal pure tone signal which slowly moves through the audio frequency range and whose cycle duration can be adjusted between 0.1 and 1000 seconds.

[0012] US-A-5 788 656 discloses an electronic stimulation system for treating a patient suffering from a tinnitus disorder

in which the patient hears ringing or other sounds originating in the ear. The system includes an electronically actuated probe to which is applied a complex signal in the auditory range to cause the probe to vibrate in accordance with the signal. The probe is placed at a site on the patient in proximity to the cochlea of the inner ear whereby the probe vibrations are transmitted to the cochlea to stimulate this organ and thereby alleviate the tinnitus disorder. In this system, use is made of two adjustable audio-frequency oscillators, one operating in a low frequency range whose upper limit is about 400 Hz, the other operating in a high-frequency whose upper limit is about 1000 Hz. The outputs of these oscillators are combined and amplified to produce the complex signal applied to the probe. The mechanical vibrations transmitted by the probe in accordance with the complex signal must be properly related to the sonic frequencies of the tinnitus sounds being heard by the patient.

SUMMARY

[0013] According to the present invention there is provided an apparatus for treating mono-frequency tinnitus patients comprising: a sound generator having selectable frequency and amplitude output wave controls, an amplifier for audibly applying the output of said sound generator to a tinnitus patient whereby the patient subjectively defines his/her tinnitus tone in terms of frequency and amplitude; and a phase shift network for incrementally shifting the generated output wave subjectively selected by a patient to match said patient's tinnitus tone and amplitude to thereby achieve sound cancellation of said patient's tinnitus tone, by selectively shifting said generated output wave form through a plurality of incremental segments totalling a 180 phase shift relative to a predetermined starting point of said generated wave, wherein said phase shift network for generating a plurality of successive angular increments comprises an automatic sequencing switch.

[0014] The present invention also preferably provides a portable electronic audio storage member programmed to facilitate self treatment by a tinnitus patient, and means for generating a specific audio signal corresponding to a tinnitus tone perceived by said tinnitus patient including a speaker or headset for audibly outputting said audio signal to be heard by said tinnitus patient.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] The accompanying drawings illustrate various embodiments of the present invention and are a part of the specification. The illustrated embodiments are merely examples of the present invention and do not limit the scope of the invention. The method described herein is not part of the claimed invention.

[0016] Fig. 1 is a block diagram of mono-frequency tinnitus treatment apparatus in accordance with an embodiment of the present invention.

[0017] Figs. 2A, 2B, 2C, 2D and 2E are a series of sine waves that graphically illustrate phase shift cancellation principles in accordance with embodiments of the present invention.

[0018] Figs. 3A, 3B and 3C graphically illustrate the summation and cancellation for an assumed patient tinnitus wave form and an externally generated wave form having an arbitrary assumed offset of θ degrees in accordance with embodiments of the present invention.

[0019] Fig. 4 is a logic block diagram illustrating another embodiment of the present invention suitable for generating a self-treatment tinnitus recording.

[0020] Fig. 5 illustrates another embodiment of the self-treatment tinnitus process.

[0021] Fig. 6 illustrates an embodiment of the self-treatment recorded disk protocol of the present invention.

[0022] Fig. 7 illustrates a logic flow diagram for assessment of applicant's phase shift treatment protocol in accordance with embodiments of the present invention.

[0023] Figs. 8A, 8B and 8C illustrate various time lines for embodiments and layouts of the sequential self-treatment protocol in accordance with embodiments of the present invention.

[0024] Fig. 9 is a logic block diagram illustrating various features and steps for an objective testing of applicant's phase shift tinnitus treatment protocols in accordance with embodiments of the present invention.

[0025] Throughout the drawings, identical reference numbers designate similar, but not necessarily identical, elements.

DETAILED DESCRIPTION

[0026] To remedy the current deficiencies in diagnosing and treating tinnitus patients, and more particularly mono-frequency (single tone) tinnitus, applicant has developed a new, more efficient phase cancellation treatment apparatus that overcomes many of the shortcomings in the prior art. There is a long-felt need for an effective treatment for mono-frequency tinnitus patients to substantially reduce, relieve or eliminate the often substantially debilitating condition of tonal tinnitus.

[0027] Referring now to Fig. 1, a preferred embodiment of a phase shift treatment system for mono-frequency tinnitus

patients is illustrated in block diagram form. A sound generator 10, for example, an Agilent model 33120A function generator or any equivalent commercially available wave form generator, is coupled to a patient's headset 12 and to an input of an oscilloscope 14 which may, for example, be of the type commercially available in the U.S. from Tektronics, Inc. A second sound generator 16 is also coupled to another input of oscilloscope 14.

[0028] Sound generator 10 has a plurality of adjustable knobs, 18 and 20, and an output terminal 24. As will be hereinafter explained in further detail particularly with respect to Fig. 3, a mono-frequency tinnitus patient 11 is asked to adjust the frequency and amplitude of an audio signal generated by the sound generator 10 using, respectively, knobs 18 and 20, until the output of the sound generator applied to headphones 12 matches the tinnitus mono-frequency tone heard by the patient.

[0029] This subjective "sound-typing" is preferably repeated a plurality of times on a blind basis, i.e. the patient cannot see the oscilloscope 14. A barrier 36 maybe placed between the patient 11 and the oscilloscope 14 and the sound generator 10. Additionally, either this is no display on the sound generator 10 that a patient 11 can observe, or any such display is masked and concealed from the patient 11. In this manner, if the patient is able to subjectively select roughly the same parameters a number of times to match his or her perceived tinnitus noise with the sound generator 10, there can be confidence that the output of the sound generator 10 accurately approximates the tinnitus noise experienced by the patient 11.

[0030] The subjective sound typing data for each of the self-typing steps is preferably recorded by an attending audiologist or physician. Additionally, the output of the first sound generator 10 can be matched by adjusting a second sound generator 16 to produce the same output. The outputs of the first sound generator 10 and the second sound generator 16 can be compared on the oscilloscope 14 to ensure they are the same. The output of the second sound generator 16 can be used, as will be described below, to prepare a treatment recording for the patient 11.

[0031] The principles of sound wave cancellation operate by superimposing, e.g. summing, a second sine wave having the same frequency and amplitude, as the first sine wave with a phase shift of 180 degrees. Sound wave cancellation is well understood in the electrical and measurement arts and is utilized in many technical fields including audiology, mechanics and electronics generally. With mono-frequency tinnitus, the patient should be able to adjust the output of the first sound generator 10 to approximate the tinnitus noise that he or she hears.

[0032] The method of accomplishing the phase shift cancellation effect of summing two waves of the same frequency and amplitude, but without any knowledge of the phase relationship of the first wave to the second wave relative to a common point, can be illustrated as follows. Sound generator 10 is set to a first tone having a frequency of f_1 and an amplitude of A (for example in milli-volts as displayed on sound generator 10) and connected to the first input of multi-beam oscilloscope 14. A second generator 16 is also set to the same tone with a like amplitude and the output is connected as a second input to oscilloscope 14.

[0033] With reference to Figs. 2A-2E, it may be seen that by adjusting the phase of sine wave f through a series of steps, illustrated as f_1 ... f_m, the sum of f_1 plus f_m (Fig. 2E) neutralizes or cancels the original signal f_1. As illustrated, f_1 plus f_m cancel when f_m is 180 degrees out of phase with f_1. Unfortunately for tinnitus patients, the structure and operation of the human auditory system is much more complex than the simple addition of two tonal sound waves as illustrated above on a multi-trace oscilloscope 14.

[0034] It is well understood in the field of audiology that humans and animals can determine, to a considerable degree of precision, the direction of a sound wave remote from them and to some extent can also estimate the distance of a sound source. Numerous experiments in the field of audiology have attempted to analyze the mechanics by which so-called binaural localization is accomplished in humans and animals. There are two primary factors which assist one in determining the direction of an arriving sound: (1) relative intensity in the hearer's two ears and (2) the difference in phase between the ears or, for a sinusoidal tone, the difference in phase between the sound waves arriving at the right and left ear of the hearer respectively. Thus, it is clear that a human or animal auditory system can distinguish phase shifts of complex sound generally and for pure or mono-frequency tones specifically. This type of auditory analysis is frequency dependent and, for frequencies above 1 Khz, most observers tend to determine the direction of a sound source from the side of the ear receiving the louder sound. Thus in general, it appears that auditory localization by phase difference is most definite for a band of frequencies in the order of a few kilohertz. As discussed hereinafter, with reference to Fig. 3, in implementing tinnitus treatments, it is important to determine not only the tonal quality of the tinnitus signal but whether the tinnitus patient hears his/her tinnitus in both ears, in only one ear or, as many indicate when asked where they hear the tinnitus, in their head without reference to either ear.

[0035] Referring again to Fig. 1, the structure and operation of applicant's preferred embodiment of apparatus for treating mono-frequency tinnitus patients will be further described. A phase shift network 30 may be of any type known to those skilled in the auditory and electrical arts for applying a desired phase shift to the output of the first sound generator 10. Alternatively, the sound generator 10 may incorporate an output wave form phase shift feature. To select the wave form phase shift feature, an appropriate automatic switching arrangement is used to obtain the desired shifts, e.g. of Δ_1, Δ_2, etc. as shown in Fig. 2, according to the invention.

[0036] As shown in Fig. 1, a switch 32 can selectively send the output of the first sound generator 10 to the patient's

headphones 12. In an alternate position, the switch 32 sends the output of the phase shift network, i.e., the signal from the first sound generator 10 plus a phase shift, to the patient's headphones 12. If the sound generator 10 does not have a phase shift feature, the separate phase shift network 30 is utilized. The headphones 12 are preferably a high quality headset commercially available from, for example, Bose, Inc. of Massachusetts, U.S.A., under the trademark Quiet-Comfort.

[0037] Switch 32, as illustrated, applies the shifted output of the sound generator 10 to the headphones 12. The successively phase-shifted increments of sine wave tone from generator 10, as explained above, are successively generated relative to f_1, as illustrated in Fig. 2, to accomplish the reciprocal 180 degree phase canceling relationship through the steps illustrated as f_2, f_3, ... f_m.

[0038] Referring now to Fig. 3A, there is shown a theoretical graphical representation of the summing of a patient's tinnitus tone P(t) and an externally generated tone I(t) along with their respective mathematical equation representations. As stated above, the patient's tinnitus tone P(t) cannot be measured with existing electronic or sonic instrumentation, but, for convenience of discussion and analysis, it is illustrated as a sine wave of a particular frequency f(t). The respective wave forms for a patient's tinnitus tone P(t) and the generated wave form I(t) are based, as explained above, on the patient self-typing of his/her tinnitus tone as compared to the output of a sound generator 10, as explained in connection with Fig. 1.

[0039] Fig. 3B illustrates a single sine wave representing the sum S(t) of P(t) and I(t) with the initial offset or separation angle θ as shown in Fig. 3A. The sum is expressed by its mathematical equivalent S(t). Fig. 3C illustrates the amplitude of a sine wave representing the arithmetic sum of the patient tinnitus wave P(t) and the input generated wave I(t). As illustrated in Fig. 3C the arithmetic sum S(t) of the two offset wave forms P(t) and I(t) having the aforementioned angular offset θ has an instantaneous amplitude less than the patient's tinnitus tone sound wave due to the cancellation effected by the offset phase shift angle θ which results in a diminution or cancellation of the patient's tinnitus tone as illustrated between the $2\pi/3$ to the $4\pi/3$ degree points on the sum S(t) wave form. Thus for approximately one-third of the 360 degree scale illustrated, partial cancellation occurs. By incrementally shifting the external tinnitus treatment tone I(t), we can theoretically nullify or completely cancel the patient's tinnitus tone P(t) when the input treatment tone I(t) reaches the 180 degree out-of-phase position, as shown in Fig. 2, as it slides across the patient tinnitus tone P(t) as described above. For a more complete understanding of the diminution and cancellation of a theoretical patient's tinnitus tone, reference may be had to Figs. 3A, 3B and 3C and the following mathematical definitions and equations relating thereto:

Patient Sine Wave:

$$P(t) = P_0 \sin 2\pi ft$$

Where P_0 is amplitude, f is frequency and t is time.
Input Sine Wave from Generator:

$$I(t) = I_0 \sin(2\pi ft - \theta)$$

Where θ is the phase shift between P(t) and I(t) in radians. π radians =180°,

$$2\pi = 360°.$$

Sum of P(t) and I(t):

$$S(t) = P(t) + I(t) = (P_0 \sin 2\pi ft) + I_0 \sin(2\pi ft - \theta)$$

Assume that $P_0 = I_0$, then

$$S(t) = P_0 [\sin 2\pi t + \sin (2\pi ft - \theta)]$$
$$= [2P_0 \cos (\tfrac{1}{2}\theta)] \cdot [\sin (2\pi ft - \tfrac{1}{2}\theta)]$$
$$= A \sin (2\pi ft - \tfrac{1}{2}\theta)$$

where A is the amplitude of the sum wave.
Thus,

$$A = 2P_0 \cos (\tfrac{1}{2}\theta);$$

$\sin (2\pi ft - \tfrac{1}{2}\theta)$ is the sinusoidal variation of the sum wave; and $\tfrac{1}{2}\theta$ is the phase shift of the sum wave.

[0040] Referring now to Fig. 4, there is shown a logical block diagram illustrating an embodiment for preparation of a self-treatment disk 40 during a clinical treatment visit by the tinnitus patient. Sound generator 10 preferably is similar in structure and function to that described above in connection with Fig. 1. After the tinnitus patient self-typing, as described above, the appropriate phase shift of the signal from the sound generator 10 is adjusted in a series of incremental time sequenced steps to apply the incrementally phase shift treatment tone segments to the tinnitus patient via earphones 12, with the incremental phase shifts summing to at least 180 degrees or more during one treatment cycle. In the preferred embodiments, the incremental phase shifts relative to a predetermined reference may be either in six degree, 20-degree, or other increments as will be described in more detail in connection with Fig. 8.

[0041] The tinnitus treatment tone may be displayed on a monitor or oscilloscope 14-4 to enable the clinician to monitor the shift from the initial tinnitus tone f to the shifted increments of the tinnitus treatment tone f_m as shown in Fig. 2. During the patient treatment protocol, audio or digital memory 42 records the audio signals of the initial tinnitus treatment tone and each of the phase-shifted increments of the tinnitus treatment tone as it is applied to the patient via headphones 12. Connected to the memory unit 42 is a CD burner or other similar audio recording device 44, which, in response to the output of the memory device 42, creates a self-treatment recording or disk 40. Alternatively, memory unit 42 is coupled to an online transmitter/receiver 46 which may comprise a web-enabled computer or server that is connected to the Internet or World Wide Web. A communication link 48 can then be established with the transmitter/receiver unit 46 via the Internet or World Wide Web. This link 48 can selectively deliver the tinnitus treatment data for a particular patient to the patient's home computer or a remote clinic 49.

[0042] Referring now to Fig. 5, an embodiment of apparatus suitable for home self-treatment system utilizable in accordance with yet another embodiment of the present invention. A tinnitus self-treatment disk 40, designed uniquely for one specific patient, is either delivered to the patient following his or her tinnitus treatment at a clinic as described above in connection with Fig. 4. Alternatively, the audio treatment data may be transmitted to the patient's home PC 49 over a connection 48 to the Internet or World Wide Web. As shown in Fig. 5, a switch 52 selectively couples the output of the PC 49 or a CD player 54 to the patient's headphones 12. Thus the patient 11 is able to utilize a self-treatment disk 40 to obtain relief from tinnitus conveniently in his or her home.

[0043] Referring now to Fig. 6, there is schematically shown a CD disk layout in accordance with yet another embodiment of the present invention. CD disk 40 may comprise a flat, round body 60 having a plurality of audio tracks (e.g., 62 and 64) arrayed in a generally circular pattern on at least one surface thereof. The CD disk 60 may be of any well-known type commercially available. The disk 60 will preferably have a fixed reset or start position 66. The tinnitus treatment data may be recorded on the disk 40 by any well-known audio or digital process. Similarly, the tinnitus treatment data may be stored on any other device capable of recording audio data including, but not limited to, magnetic tape, floppy or optical disk, semiconductor memory, etc. Additionally, the tinnitus treatment data may be recorded in any audio format, including, but not limited to, compact disc, MP3, wave (.wav), etc,

[0044] Referring now to Fig. 7, there is shown a logical flow diagram of an illustrative embodiment of applicant's novel process for generating objective assessment data of applicant's phase shift tinnitus treatment protocol. As hereinabove stated, applicant's treatment protocol begins with a screening of potential tinnitus patients to determine eligibility for the mono-frequency tinnitus phase-shift treatment and the initial screening may be done in accordance with MATTP or an equivalent medical protocol. In addition audiometry hearing tests maybe conducted as part of, or before or after the treatment. In step 1, selected mono-frequency patients are asked to subjectively "sound-type" his/her tinnitus sound frequency utilizing, for example, an adjustable sound wave generator 10, as described above, on a blind basis to quantify his/her tinnitus tone as to frequency and amplitude. Preferably patients are asked to repeat the patient's subjective "sound typing" several times to ensure the accuracy of the patient's subjective matching of his/her tinnitus tone with the

output of the frequency generator as to tone and amplitude.

[0045] Data from step 1 is utilized in step 2 by the attending clinician or physician to generate an appropriate external sine wave treatment tone substantially equal to the patient's tinnitus tone. Then, the generated treatment tone is time-shifted through a plurality of successive substantially equal predetermined step increments totaling 180 degrees whereby the generated wave form is brought through such sequential phase shifting into a series of canceling and eventually into a reciprocal canceling relationship with the patient's tinnitus tone during a treatment period or zone, as will be further described in connection with Figs. 8 and 9 hereinafter.

[0046] In step 3, the tinnitus patient, after completing step 2, maybe subjected to a PET or Functional MRI Brain Scan to objectively assess the patient's current tinnitus activity in order to objectively quantify the elimination or degree of substantial reduction in the amplitude of the patient's tinnitus tone after receiving applicant's phase shift cancellation treatments. These procedures are routinely conducted as part of many on going clinical studies. Recently Danish, Swedish and French investigators have confirmed positive PET Brain Scans in the auditory cortex of tinnitus patients. It should be noted that the Brain Scans of tinnitus patients may be conducted before, during or some time after the phase shift tinnitus treatment has been administered to gain additional objective patient treatment data for tinnitus patients.

[0047] Referring now to Figs. 8A, 8B and 8C, there is illustrated a series of time-sequence line graphs of alternate embodiments for applicant's self-treatment disk 40 layouts. Referring to Fig. 8A, a first section or zone #1 of the tinnitus treatment recording begins at point A, which preferably is the start or reset position of a designated recording track as hereinabove explained with reference to Fig. 6. The reset or start position is shown as to on the time scale which, as shown, increases from left to right on the line graphs. Beginning at point B, there is shown a series of subdivisions of zone #2, namely 2-1,2-2...2-n. The time duration of the subdivisions of zone #2 corresponds to the time duration of each incremental phase shift of a particular patient's protocol. As described above in connection with Figs. 1 and 2, the number of incremental steps is selected by the attending clinician or physician for a particular patient in an appropriate manner whereby the total of the incremental steps sum to at least a 180 degrees during one treatment segment or zone. In a preferred embodiment, applicant has successfully utilized incremental phase shift steps of six degrees with each incremental step lasting a predetermined time, for example one minute. Applicant has likewise achieved favorable patient responses utilizing a series of 20-degree incremental steps with each incremental step lasting ten minutes. As shown in fig. 8A, the first patient treatment recorded in zone #2 of the self-treatment disk 40 ends at t_2 and a subsequent or repeated zone #1 treatment may extend from time t_2 to t_3, etc.

[0048] Referring now to Fig. 8B, zone #1 may comprise the external tinnitus treatment tone f_1 as determined in the patient self-testing procedure as described above. In this embodiment, the phase shift treatment begins in zone #3 with a series of incremental phase shifts of the patient treatment tone, with the incremental shifts graphically illustrated as segments 3-1, 3-2...3-n. Another embodiment of applicant's phase shift tinnitus treatment may involve, for example, a series of nine incremental steps of 20-degree increments, with each increment lasting ten minutes for a total treatment time of 90 minutes. As shown in Fig. 8B, the initial zone #3 treatment time may be followed by a second zone #3 treatment phase identical to that immediately described above.

[0049] As shown in Fig. 8C, a patient self-treatment disk may comprise any number of treatment zones illustrated as treatment zone #4, zone #5 and zone #6. As described above, in connection with Figs. 3A, 3B and 3C, since the instantaneous phase of a patient's internal tinnitus tone cannot be measured or determined using currently available electronic or acoustic instrumentation, there will be, in most instances, a phase offset between the patient's tinnitus tone and the externally generated patient treatment tinnitus tone. Thus in accordance with applicant's phase shift tinnitus treatment protocol a patient's treatment may be tailored in several ways by the clinician to obtain desired patient treatment responses. This may involve adjusting the number of incremental phase shift steps, e.g. 2-2...or 3-2..., to achieve diminution and ultimately a phase shift sequence resulting in a reciprocal canceling relationship between the externally generated tinnitus treatment tone I(t) and the patient tinnitus tone P(t) as shown in Figs. 3A, 3B and 3C.

[0050] As is well known in the medical arts, a tinnitus condition in humans may have many different forms and many, very different causes. For a brief survey of medical tinnitus treatment literature, reference may be had to the above cross-referenced US Application No. 10/083,088. While there is no known "cure" for tinnitus, for those individuals who suffer substantial medical disability from tinnitus any, even temporary, relief can be very significant.

[0051] In the above cross-referenced application, Application No. 10/083,088, patient clinical results from a 28 patient blind tinnitus single step 180-degree phase shift treatment protocol study are reported. In that study, seven patients (25%) experienced excellent results achieving more than 90% reduction in tinnitus loudness. 15 patients (more than 54%) experienced either "Very Good" or "Good" results having achieved temporary relief of at least a 50% reduction in tinnitus loudness. It is believed that utilizing the above-described six-degree phase shift segments protocol, for example, with each segment having a duration of at least one minute will achieve substantially improved results over the techniques described in Application No. 10/083,088.

[0052] Referring now to Fig. 9, there is illustrated a logic block diagram for generating and utilizing objective patient data regarding the efficacy of a particular patient's phase shift tinnitus treatment protocol in accordance with other aspects of applicant's novel treatment protocol.

[0053] Block 70 illustrates the screening process for determining whether a tinnitus patient is a good candidate for the mono-frequency phase shift treatment. As stated above, medical science cannot in most instances identify the exact or likely cause of a patient's tinnitus condition nor describe the precise mechanism or mechanisms causing a particular patient's tinnitus condition.

[0054] As illustrated in block 72, if a patient exhibits mono-frequency tinnitus which, for example is not related to drug use, then the patient is asked to self type his/her tinnitus tone utilizing an externally generated tone from a sound generator wherein the externally generated tone is manipulated to match the subjectively determined patient's tinnitus tone. As stated above, the patient's self-typing process is preferably repeated several times, on a blind basis, to ensure accuracy. Thereafter, as illustrated in block 74, the patient's subjectively determined treatment tone is incrementally phase shifted through at least a full 180 degree shift in a single treatment session to thereby bring the externally generated tone into a reciprocal, wave-canceling relationship with the patient's tinnitus tone.

[0055] Following the phase shift tinnitus treatment protocol as illustrated in block 76, the patient maybe subjected to a PET or MRI Brain Scan procedure to objectively determine the effect of the phase shift treatment to reduce, minimize or eliminate the brain activity in the auditory cortex normally associated with a patient's tinnitus condition. It should be noted that, as shown in Fig. 9 by the dotted lines from block 70 and block 72 to block 76, it may be desirable in some instances to perform a Brain Scan both before and after a patient has received a phase shift treatment. As shown in block 78, a medical review of the Brain Scan data obtained either before and sometime after a patient receives a phase shift tinnitus treatment may assist a clinician in altering or revising, at block 79, a phase shift treatment protocol for individual patients. Whether any such adjustment is needed is determined at block 77.

[0056] As discussed above, there is currently no medical treatment for tinnitus which "cures" a patient's tinnitus condition permanently. Thus, while a particular mono-frequency tinnitus patient experiences substantial reduction or temporary elimination of his/her tinnitus condition following an application of applicant's improved phase shift tinnitus treatment, the residual effect generally lasts only for a limited time, on the order of hours or days, or as long as ten days in a few instances. Thus, the use of the objective brain scan data may assist the clinician as shown in block 80, to classify a patient self-treatment status. As described above in connection with Figs. 4 and 5, in accordance with another aspect of the present invention, a self-treatment disk 40 may be prepared during a clinical tinnitus treatment for certain qualifying patients thus enabling them to utilize a self-treatment disk in the convenience of their home as often as their condition necessitates such follow-up treatments.

[0057] While a number of alternative embodiments of applicant's novel apparatus and process for the treatment of tinnitus have been described, those skilled in the medical and auditory arts will recognize that the described embodiments are illustrative and additional changes or modifications of the described preferred embodiments may be made without departing from the scope of the present inventions embodied in the following claims.

[0058] The preceding description has been presented only to illustrate and describe embodiments of invention. It is not intended to be exhaustive or to limit the invention to any precise form disclosed. Many modifications and variations are possible in light of the above teaching. It is intended that the scope of the invention be defined by the following claims.

Claims

1. Apparatus for treating mono-frequency tinnitus patients comprising:

a sound generator (10) having selectable frequency and amplitude output wave controls, an amplifier for audibly applying the output of said sound generator to a tinnitus patient (11) whereby the patient subjectively defines his/her tinnitus tone in terms of frequency and amplitude; and

a phase shift network (30) for incrementally shifting the generated output wave subjectively selected by a patient to match said patient's tinnitus tone and amplitude to thereby achieve sound cancellation of said patient's tinnitus tone, by selectively shifting said generated output wave form through a plurality of incremental segments totalling a 180 phase shift relative to a predetermined starting point of said generated wave, **characterised in that** said phase shift network (30) for generating a plurality of successive angular increments comprises an automatic sequencing switch.

2. The apparatus of claim 1, additionally comprising an electronic recorder (44) for generating a record of said tinnitus treatment wave as said output of said sound generator is sequentially shifted through said plurality of predetermined angular phase shifts to achieve said reduction in cancellation effects upon said patient's tinnitus tone.

3. The apparatus of claim 2, wherein said generated treatment sound waves are recorded concurrent with a patient's clinical phase shift treatment whereby said recorded treatment sound sequences are available for subsequent self-treatment use by said patient.

4. The apparatus of claim 2 or 3 wherein said record of a patient's tinnitus treatment sound sequence comprises an electronic memory record (42) and additionally comprises memory access means for selectively transferring said patient's tinnitus treatment sound sequence data to a removable memory.

5. The apparatus of claim 2, 3, or 4 additionally comprising an online communication transmitter (46) for selectively transferring said patient's tinnitus treatment sound sequence record to a remote location (49) via an addressable communication link.

6. The apparatus of any one of the preceding claims wherein said phase shift network (30) additionally comprises a calibration control to define each angular phase shift sequence to substantially equal 6 degrees of angular shift relative to a predetermined point of said generated wave form and to define the duration of each segment to substantially equal at least on one minute in duration.

7. Apparatus according to any one of claims 1 to 6 further comprising a portable electronic audio storage member (40) programmed to facilitate self treatment by a tinnitus patient, said programmed portable electronic audio member comprising means for generating a specific audio signal corresponding to a tinnitus tone perceived by said tinnitus patient including a speaker or headset (12) for audibly outputting said audio signal to be heard by said tinnitus patient (11).

8. The apparatus of claim 7 additionally comprising a plurality of audio track sound zones (62; 64) wherein each track zone has a defined selectable patient treatment sequence.

9. The apparatus of claim 8 additionally comprising a synchronized timing control to ensure each track sequence is substantially equal in angular phase shift and in time duration.

Patentansprüche

1. Vorrichtung zum Behandeln von Monofrequenz-Tinnituspatienten, die Folgendes umfasst:

   einen Tongenerator (10) mit Ausgangswellenregelungen mit wählbarer Frequenz und Amplitude, einen Verstärker zum akustischen Anwenden des Ausgangs des genannten Tongenerators auf einen Tinnituspatienten (11), so dass der Patient seinen Tinnituston subjektiv im Sinne von Frequenz und Amplitude definiert; und ein Phasenschiebernetzwerk (30) zum inkrementalen Verschieben der von einem Patienten subjektiv gewählten erzeugten Ausgangswelle passend zu Tinnituston und -amplitude des genannten Patienten, um **dadurch** eine Tonauslöschung des Tinnitustons des genannten Patienten zu erzielen, indem die genannte erzeugte Ausgangswellenform durch mehrere Inkrementalsegmente selektiv verschoben wird, die insgesamt eine 180-Grad-Phasenverschiebung relativ zu einem vorbestimmten Startpunkt der genannten erzeugten Welle ausmachen, **dadurch gekennzeichnet, dass** das genannte Phasenschiebernetzwerk (30) zum Erzeugen mehrerer aufeinander folgender Winkelinkremente einen automatischen Sequenzierschalter umfasst.

2. Vorrichtung nach Anspruch 1, die zusätzlich einen elektronischen Recorder (44) zum Erzeugen einer Aufzeichnung der genannten Tinnitusbehandlungswelle umfasst, wenn der genannte Ausgang des genannten Tongenerators sequentiell über die genannte Mehrzahl von vorbestimmten Winkelphasenverschiebungen verschoben wird, um die genannten Auslöschreduziereffekte auf den Tinnituston des genannten Patienten zu erzielen.

3. Vorrichtung nach Anspruch wobei die genannten erzeugten Behandlungstonwellen gleichzeitig mit einer klinischen Phasenverschiebungsbehandlung des Patienten aufgezeichnet werden, so dass die genannten aufgezeichneten Behandlungstonsequenzen für eine nachfolgende Selbstbehandlungsverwendung durch den genannten Patienten zur Verfügung stehen.

4. Vorrichtung nach Anspruch 2 oder 3, wobei die genannte Aufzeichnung einer Tinnitusbehandlungstonsequenz eines Patienten einen elektronischen Speicherdatensatz (42) und zusätzlich ein Speicherzugriffsmittel zum selektiven Übertragen der Tinnitusbehandlungstonsequenz-Daten des genannten Patienten auf einen entfernbaren Speicher umfasst.

5. Vorrichtung nach Anspruch 2, 3 oder 4, die zusätzlich einen Online-Kommunikationssender (46) zum selektiven Übertragen der Tinnitusbehandlungstonsequenzaufzeichnung des genannten Patienten zu einem fernen Ort (49)

über eine adressierbare Kommunikationsverbindung umfasst.

6. Vorrichtung nach einem der vorherigen Ansprüche, wobei das genannte Phasenschiebernetzwerk (30) zusätzlich eine Kalibrierungsregelung umfasst, um jede Winkelphasenschiebersequenz auf im Wesentlichen gleich 6 Grad Winkelverschiebung in Bezug auf einen vorbestimmten Punkt der genannten erzeugten Wellenform zu definieren und um die Dauer jedes Segments auf im Wesentlichen wenigstens gleich eine Minute Dauer zu definieren.

7. Vorrichtung nach einem der Ansprüche 1 bis 6, die ein tragbares elektronisches Tonspeicherelement (40) umfasst, das so programmiert ist, dass es eine Selbstbehandlung durch einen Tinnituspatienten erleichtert, wobei das genannte programmierte tragbare elektronische Tonelement Mittel zum Erzeugen eines speziellen Tonsignals umfasst, das einem von dem genannten Tinnituspatienten wahrgenommenen Tinnituston entspricht, einschließlich eines Lautsprechers oder Kopfhörers (12) zum akustischen Ausgeben des genannten Tonsignals, so dass es von dem genannten Tinnituspatienten (11) gehört wird.

8. Vorrichtung nach Anspruch 7, die zusätzlich mehrere Audio-Track-Tonzonen (62; 64) umfasst, wobei jede Track-Zone eine definierte wählbare Patientenbehandlungssequenz hat.

9. Vorrichtung nach Anspruch 8, die zusätzlich eine synchronisierte Zeitsteuerung umfasst, um sicherzustellen, dass jede Track-Sequenz im Hinblick auf Winkelphasenverschiebung und Zeitdauer im Wesentlichen gleich ist.

Revendications

1. Appareil pour traiter les patients souffrant d'un acouphène monofréquence comprenant :

   un générateur de son (10) ayant des commandes d'ondes de sortie de fréquence et d'amplitude sélectionnables, un amplificateur pour appliquer de façon audible la sortie dudit générateur de son à un patient souffrant d'un acouphène (11) par lequel le patient définit subjectivement sa tonalité d'acouphène en termes de fréquence et d'amplitude ; et
   un réseau de déphasage (30) pour déplacer de façon incrémentielle l'onde de sortie générée sélectivement sélectionnée par un patient pour la faire correspondre à la tonalité et à l'amplitude de l'acouphène dudit patient et ainsi parvenir à une suppression du son de ladite tonalité d'acouphène du patient, en décalant sélectivement ladite forme d'onde de sortie générée sur une pluralité de segments incrémentiels totalisant un déphasage de 180 degrés par rapport à un point de départ prédéterminé de ladite onde générée, **caractérisé en ce que** ledit réseau de déphasage (30) pour générer une pluralité d'incréments angulaires successifs comprend un commutateur de séquencement automatique.

2. Appareil selon la revendication 1, comprenant de plus un enregistreur électronique (44) pour générer un enregistrement de ladite onde de traitement de l'acouphène au fur et à mesure que ladite sortie dudit générateur de son est décalée séquentiellement sur ladite pluralité de déphasages angulaires prédéterminés de façon à parvenir à ladite réduction des effets de suppression sur ladite tonalité d'acouphène du patient.

3. Appareil selon la revendication 2, dans lequel lesdites ondes sonores de traitement générées sont enregistrées simultanément au traitement clinique par déphasage d'un patient par lequel lesdites séquences sonores de traitement enregistrées sont mises à la disposition dudit patient pour son auto-traitement ultérieur.

4. Appareil selon la revendication 2 ou 3, dans lequel ledit enregistrement d'une séquence sonore de traitement d'acouphène d'un patient comprend un enregistrement en mémoire électronique (42) et comprend de plus un moyen d'accès mémoire pour transférer sélectivement les données de ladite séquence sonore de traitement de l'acouphène du patient dans une mémoire amovible.

5. Appareil selon la revendication 2, 3 ou 4, comprenant de plus un émetteur de communication en ligne (46) pour transférer sélectivement l'enregistrement de séquence sonore de traitement de l'acouphène dudit patient à un endroit distant (49) par l'intermédiaire d'une liaison de communication adressable.

6. Appareil selon l'une quelconque des revendications précédentes, dans lequel ledit réseau de déphasage (30) comprend de plus une commande d'étalonnage afin de définir chaque séquence de déphasage angulaire à une valeur sensiblement égale à 6 degrés de déphasage angulaire par rapport à un point prédéterminé de ladite forme

d'onde générée et définir la durée de chaque segment à une valeur de durée sensiblement égale à au moins une minute.

7. Appareil selon l'une quelconque des revendications 1 à 6, comprenant en outre un élément de mémorisation audio électronique portable (40) programmé pour faciliter l'auto-traitement par un patient souffrant d'un acouphène, ledit élément audio électronique portable programmé comprenant un moyen pour générer un signal audio spécifique correspondant à une tonalité d'acouphène perçue par ledit patient souffrant d'un acouphène comportant un haut-parleur ou casque (12) pour produire en sortie de façon audible ledit signal audio que doit entendre ledit patient souffrant d'un acouphène (11).

8. Appareil selon la revendication 7, comprenant de plus une pluralité de zones sonores sur pistes audio (62, 64) où chaque zone de piste a une séquence de traitement de patient sélectionnable définie.

9. Appareil selon la revendication 8, comprenant de plus une commande de cadencement synchronisé pour garantir que chaque séquence sur piste est sensiblement égale en déphasage angulaire et en durée.

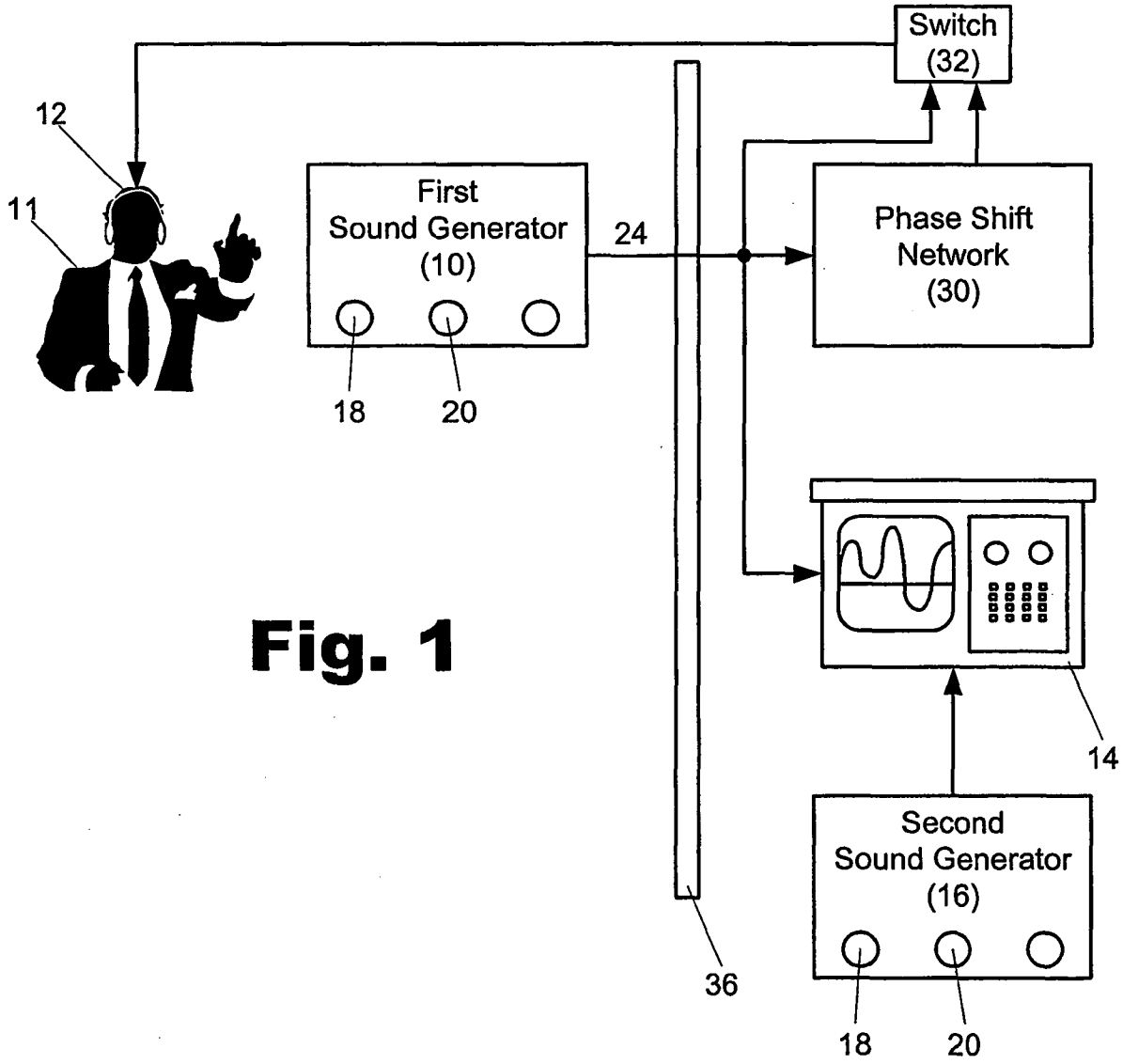

Switch
(32)
12
11
First
Sound Generator
(10)
24
Phase Shift
Network
(30)
18
20
14
Second
Sound Generator
(16)
36
18
20

Fig. 1

Fig. 2A

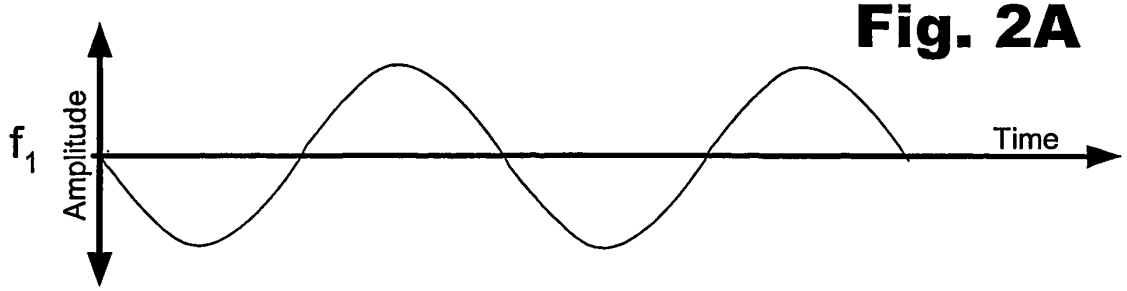


Fig. 2B

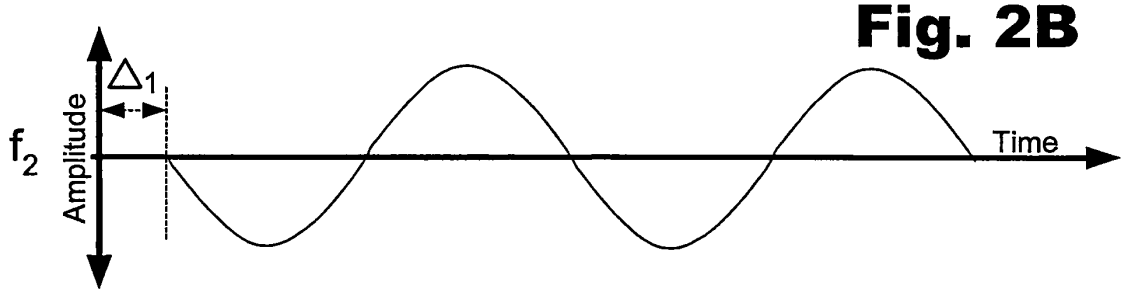


Fig. 2C

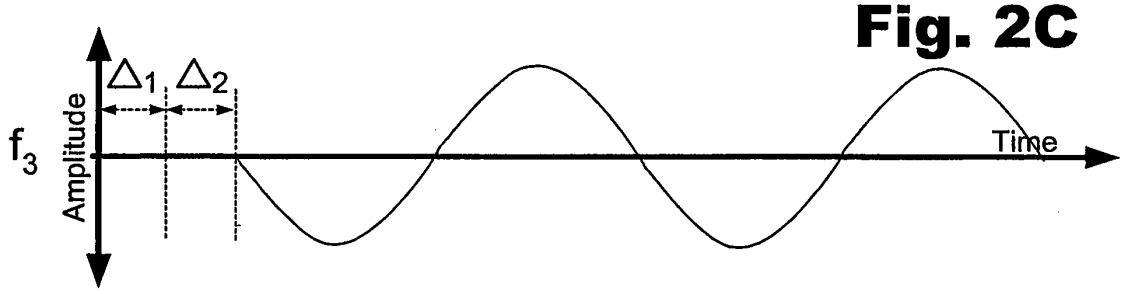


Fig. 2D

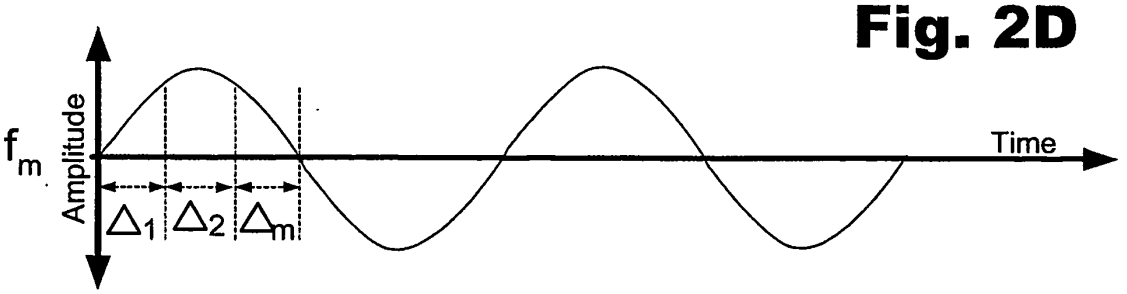
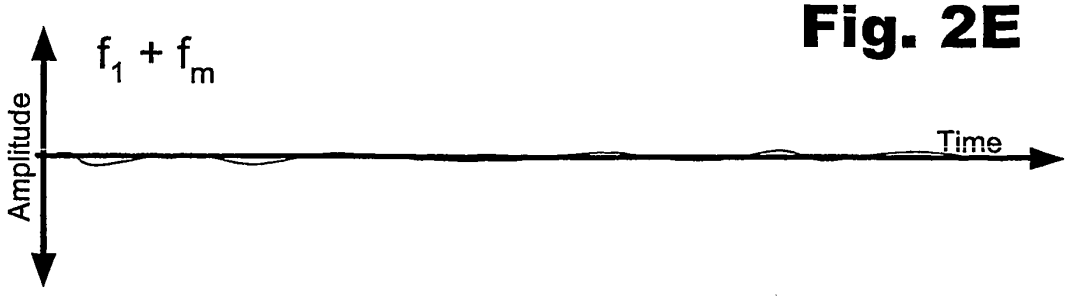


Fig. 2E



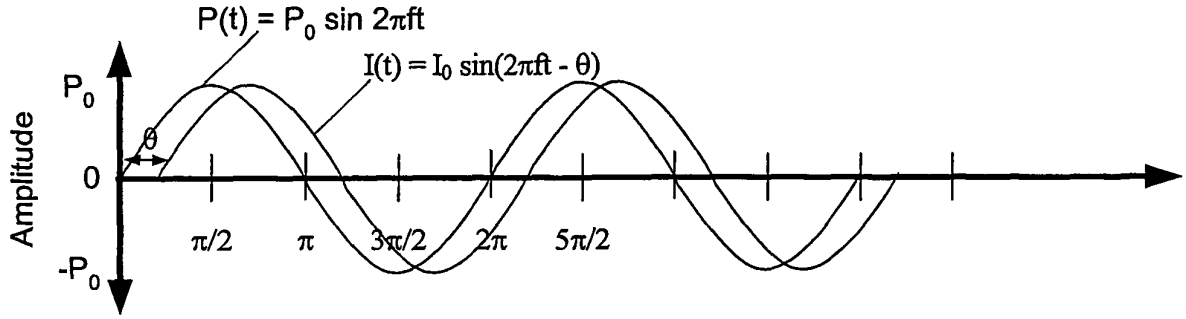


Fig. 3A

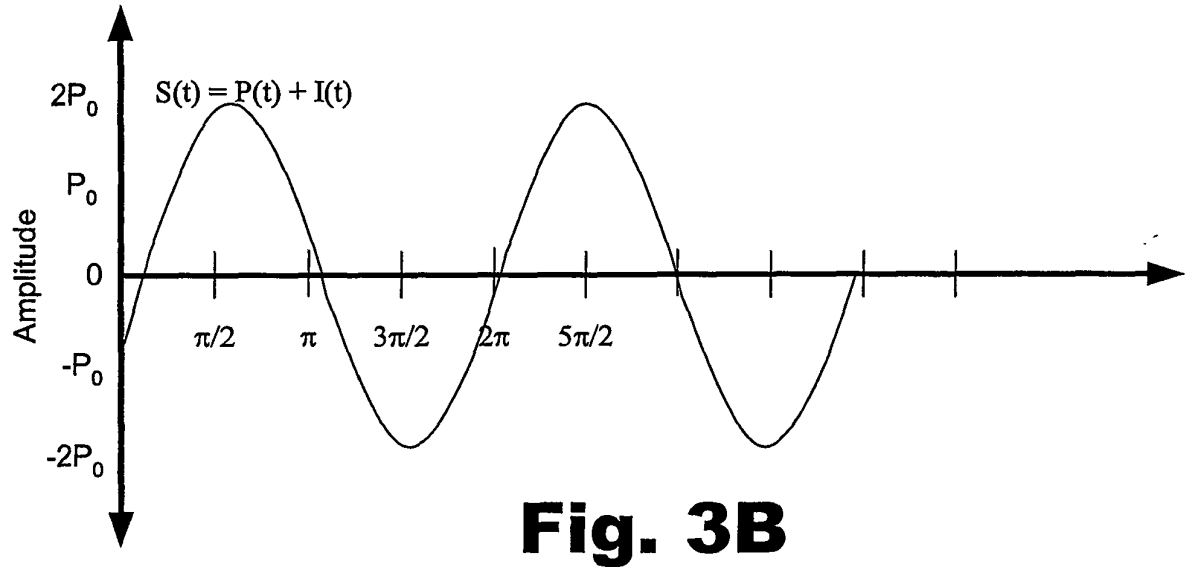


Fig. 3B

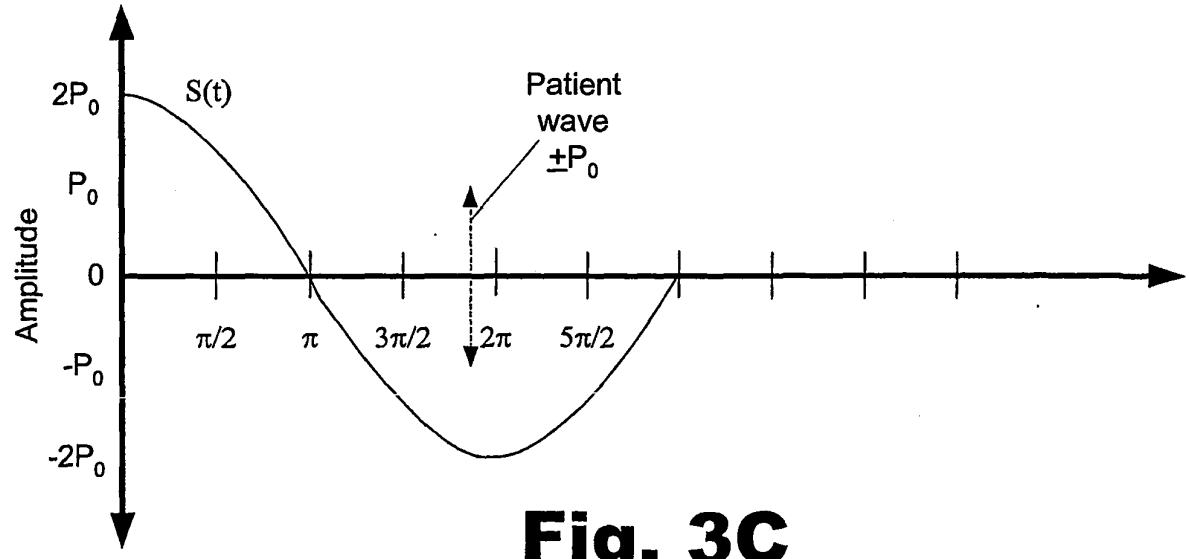


Fig. 3C

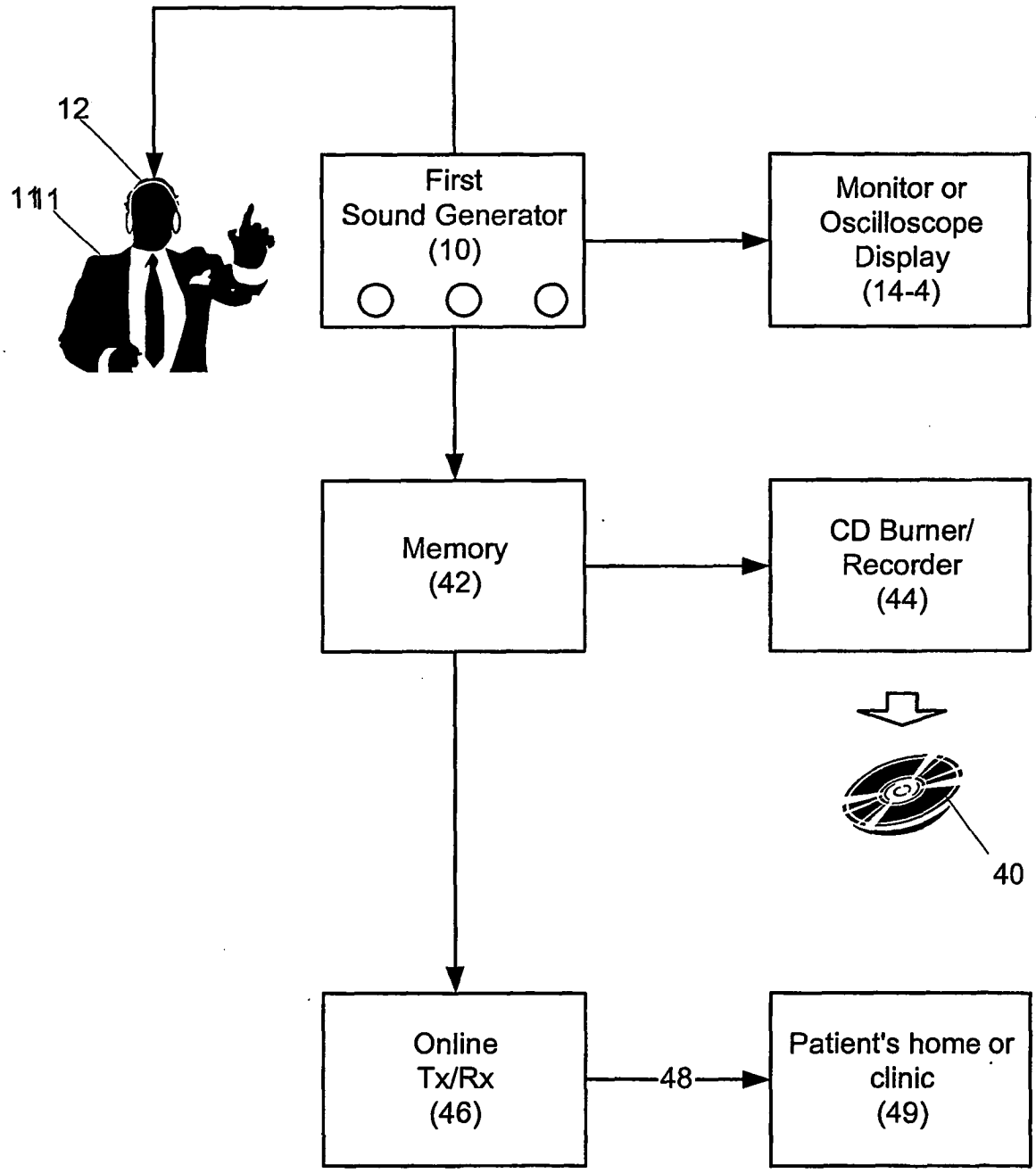

12
111
First
Sound Generator
(10)
Monitor or
Oscilloscope
Display
(14-4)
Memory
(42)
CD Burner/
Recorder
(44)
40
Online
Tx/Rx
(46)
48
Patient's home or
clinic
(49)

Fig. 4

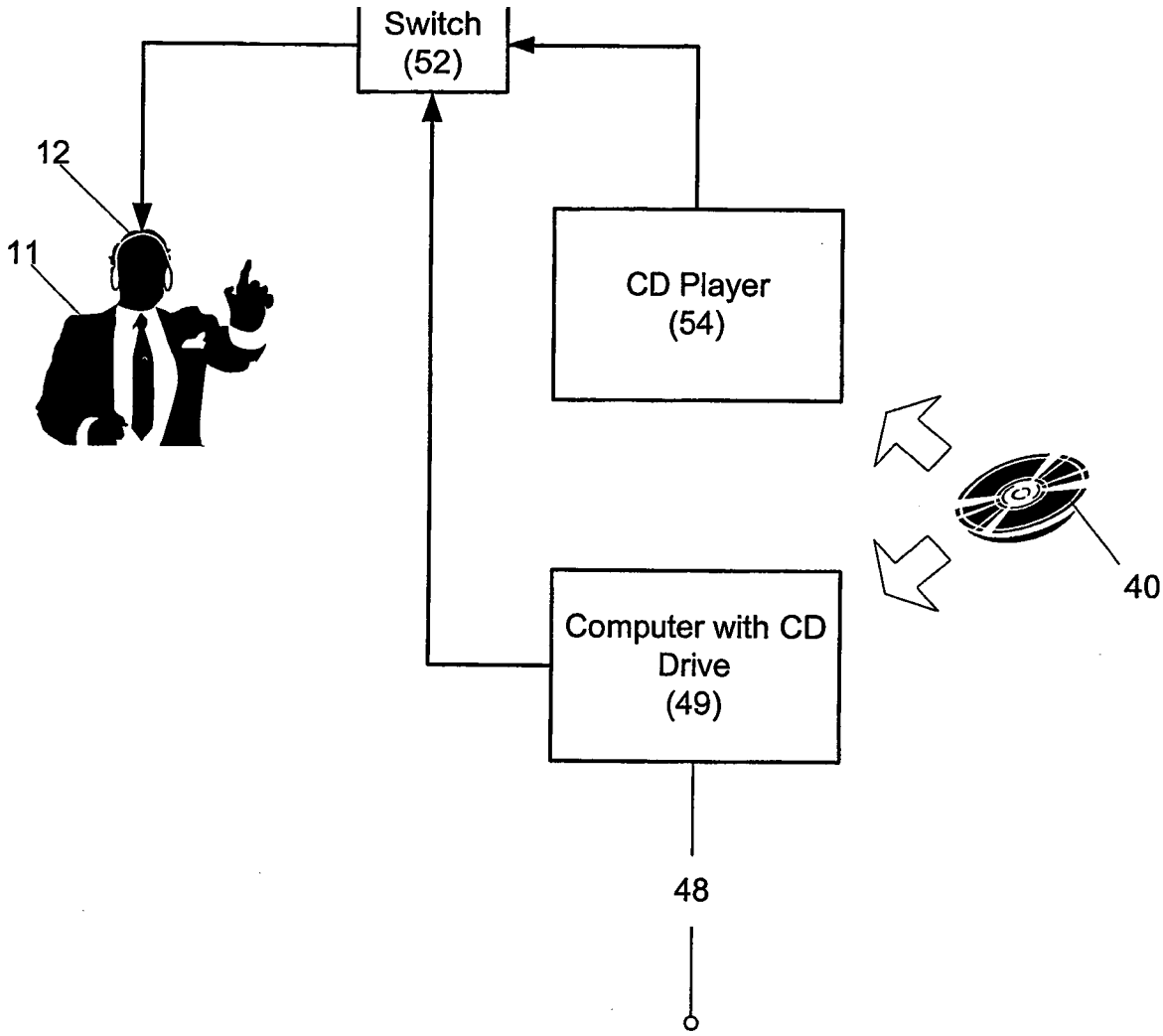


Fig. 5

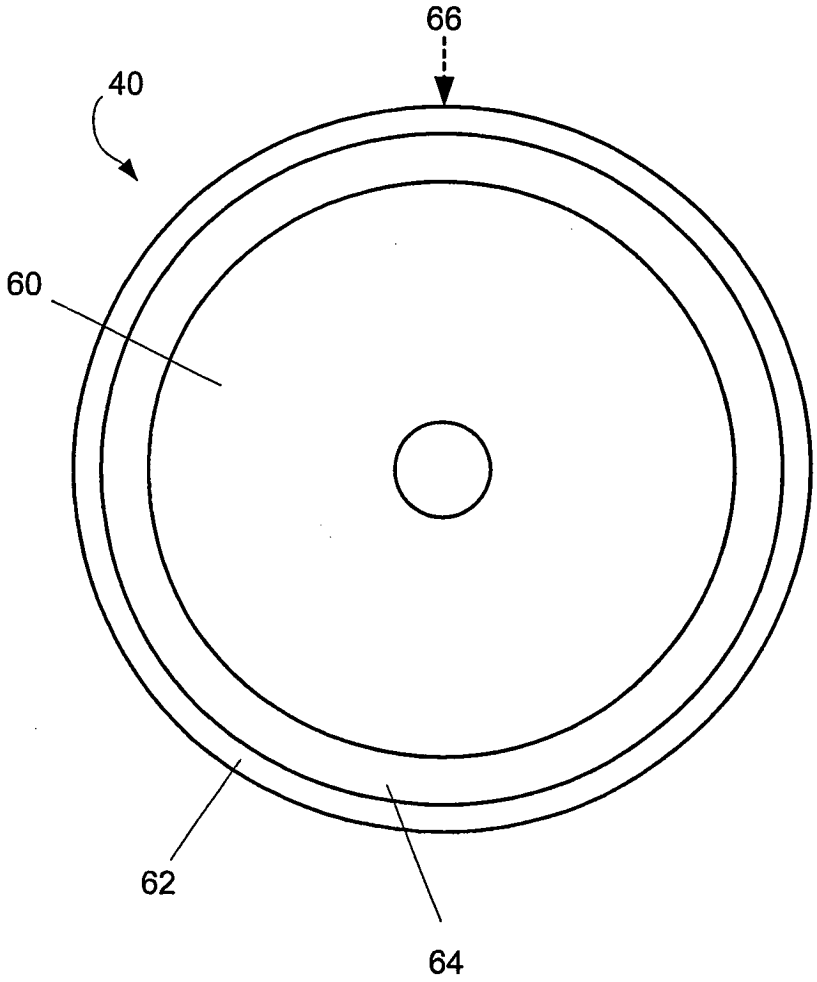


Fig. 6

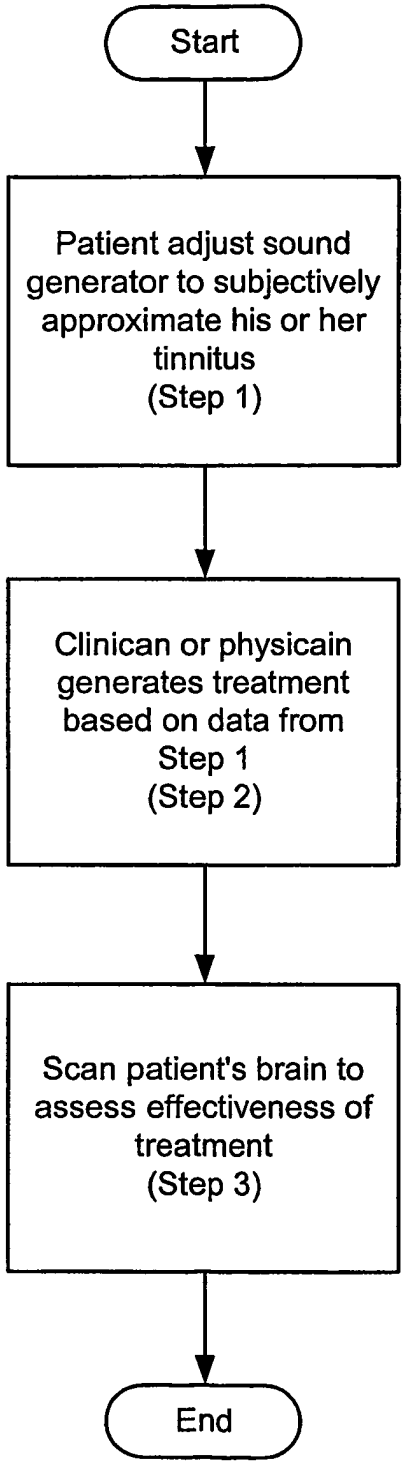

Start
Patient adjust sound generator to subjectively approximate his or her tinnitus (Step 1)
Clinican or physicain generates treatment based on data from Step 1 (Step 2)
Scan patient's brain to assess effectiveness of treatment (Step 3)
End

Fig. 7

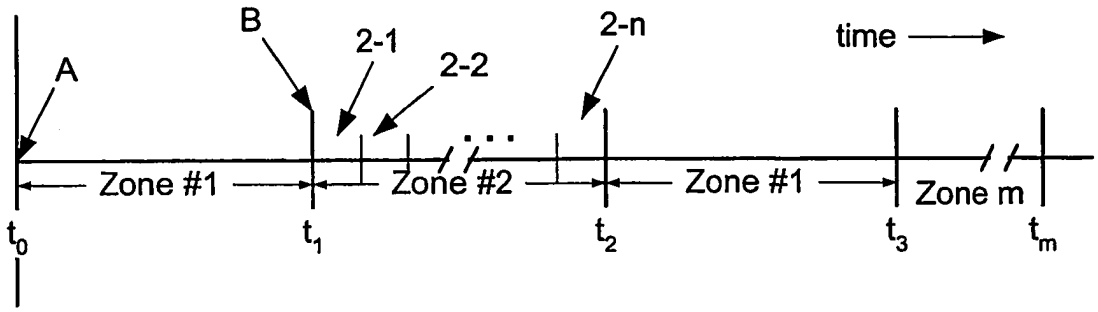


Fig. 8A

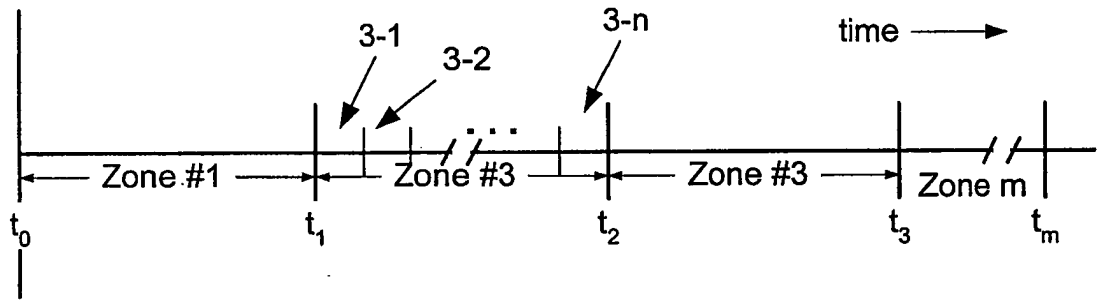


Fig. 8B

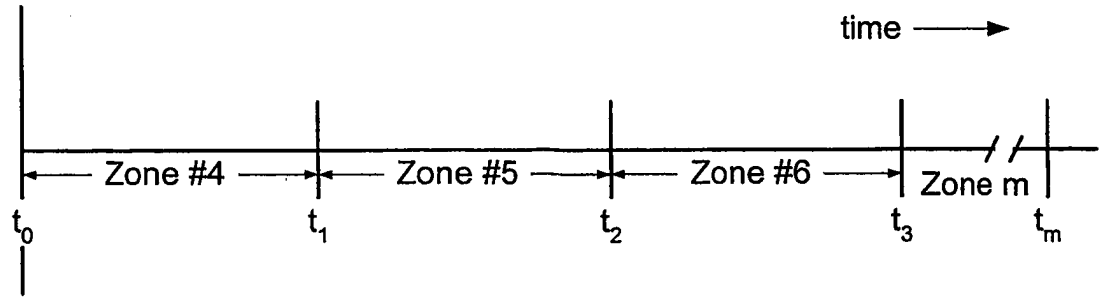


Fig. 8C

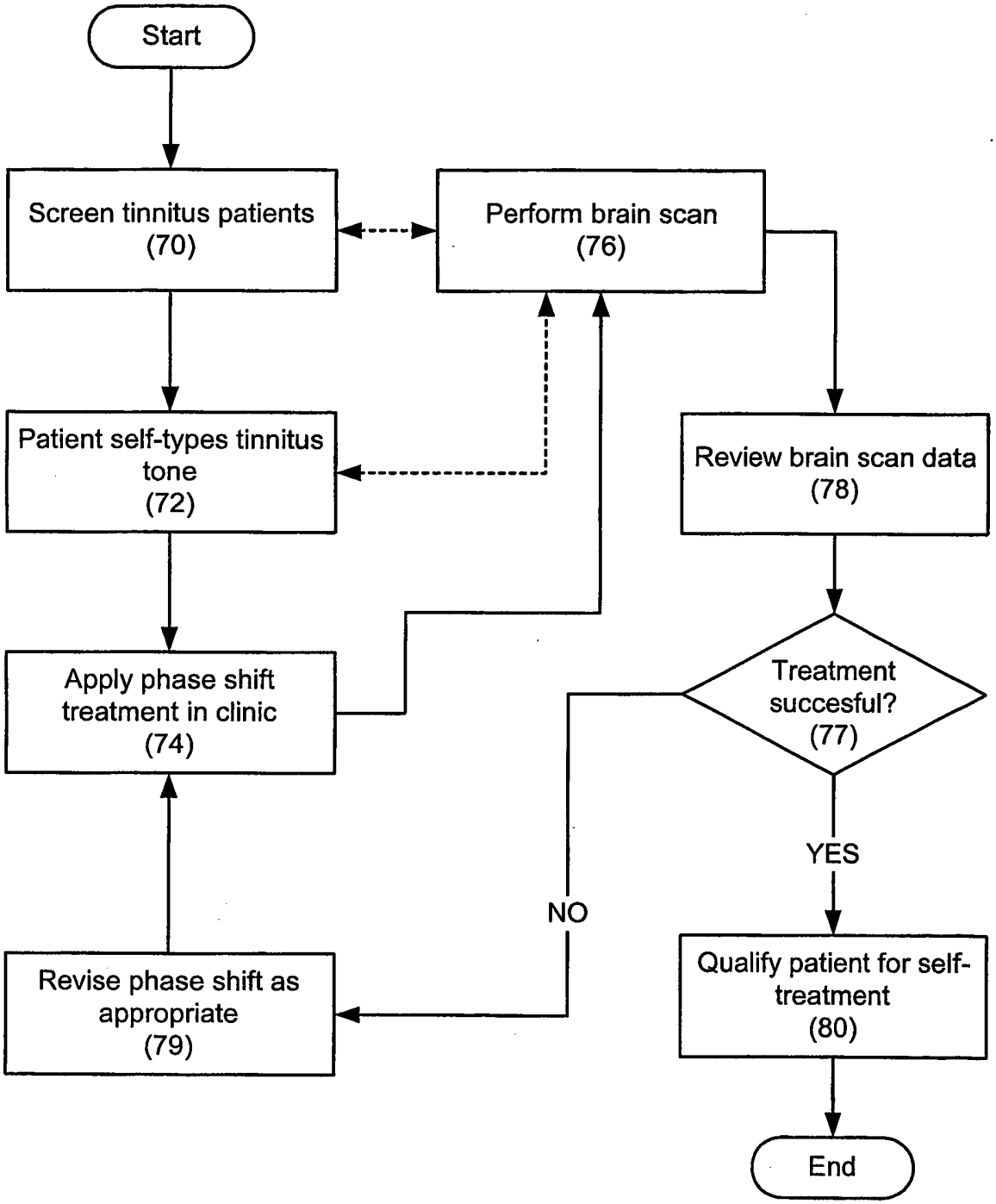

Start
Screen tinnitus patients (70)
Perform brain scan (76)
Patient self-types tinnitus tone (72)
Review brain scan data (78)
Apply phase shift treatment in clinic (74)
Treatment succesful? (77)
YES
NO
Revise phase shift as appropriate (79)
Qualify patient for self-treatment (80)
End

Fig. 9

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

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- GB 2134689 A **[0010]**
- US 5325872 A **[0011]**
- US 5788656 A **[0012]**
- US 10083088 B **[0050] [0051] [0051]**

Non-patent literature cited in the description

- **SHULMAN'S.** Tinnitus Diagnosis and Treatment. 1997 **[0005]**

专利名称(译)	用于治疗单频耳鸣的装置		
公开(公告)号	EP1463444B1	公开(公告)日	2009-02-18
申请号	EP2002799247	申请日	2002-12-13
申请(专利权)人(译)	TINNITUS控制公司		
当前申请(专利权)人(译)	TINNITUS控制公司		
[标]发明人	CHOY DR DANIEL S J		
发明人	CHOY, DR. DANIEL S. J.		
IPC分类号	A61B5/00 A61F11/00 A61M21/00 G10K11/178 H04R25/00		
CPC分类号	G10K11/178 A61B5/128 A61F11/00 A61M21/00 A61M2021/0027 H04R25/00 H04R25/75		
代理机构(译)	FREEMAN，杰奎琳CAROL		
优先权	10/319281 2002-12-12 US 60/340271 2001-12-18 US 10/085088 2002-03-01 US		
其他公开文献	EP1463444A2 EP1463444A4		
外部链接	Espacenet		

摘要(译)

利用外部产生的音调实现患者的单频耳鸣音调的相互噪声消除，该音调由单频耳鸣患者主观地定义，以匹配他/她的频率和幅度的耳鸣音调。通过耳机或扬声器系统首先向耳鸣患者施加外部产生的声波，通过患者的主观观察选择性地指定以匹配患者的耳鸣音，然后相同的外部产生的声波通过多个角度顺序地相移。移动序列步骤以使外部声波移动或滑动通过所产生的信号的至少180度相移，因为它被施加到患者以实现患者耳鸣音调的一系列减少并且在这些移位步骤之一中是互逆的，取消与患者耳鸣音的关系。外部产生的声波的耳鸣处理序列然后相移外部产生的音调实现了患者的耳鸣音调的消除，因为所产生的音调的连续步骤实际上滑过耳鸣声波，导致耳鸣音调的消除。通过重放患者治疗过程的顺序相移片段，患者可以在患者自我治疗过程中利用先前记录的序列。