

## Original Articles

### DESIGN AND STRUCTURE OF A NEW DEVICE FOR AUDITORY ELECTRICAL STIMULATION FOR SUPPRESSION OF TINNITUS

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#### ABSTRACT

Tinnitus is the conscious experience of sound which arises in the head of its owner, but without a voluntary origin obvious to that person. About 10-15% of all adults report prolonged spontaneous tinnitus (PST).

There are a lot of methods for suppressing this complaint. One of these methods is electrical stimulation. Electrical stimulation for tinnitus suppression was investigated by many authors that reported its effectiveness from 22% by Grahams and Hazell (1989) to 87% by Portman (1979).

The purpose of the present project was to design and structure a new Auditory Electrical Stimulation device for tinnitus relief in patients who suffer from tinnitus. Our other goal was to execute a pilot project by modelling of our new device on animals.

In this project an instrument for applying Auditory Electrical Stimulation (AES) is designed. This device consists of two generators: one is a carrier square wave generator (30 KHz to 100 KHz), the second is another low frequency square signal (1 Hz through 20 KHz) that has an adjustable duty cycle. The entire user interface is on PC, and there are a lot of options that the user can adjust.

The PC is connected to a circuit by a serial port and the serial port is isolated from the other parts of the circuit. Modulation can optionally be enabled or disabled. The amplitude of current flow can vary from 1 microamp to 1000 microamp (1milli-

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Amp) with 1 microamp resolution. The impulse duration can be adjusted (this is a third pulse generator) by the user from 500 microsec delivered at 1/sec to 2000/sec. The combined electrical signal has the maximum peak to peak amplitude of 10 V, which varies to make a constant current through electrodes. A warning device indicates insufficient skin electrode contact. In addition the impedance between electrodes can be monitored on PC. There are several parts that increase the safety of this system. The dimension of the PC board is 11cm ×14cm. By now the first version which could be used in hospital and/or clinics is made and could be used by patients who suffer from tinnitus.

We believe that tinnitus reduction occurred or even disappeared during and after the treatment period by AES. Our results applying Auditory Electrical Stimulation (AES) were effective in our many patients who had clinically been identified as having peripheral or central lesion tinnitus sites. We made a new auditory electrical stimulation device for tinnitus relief in patients suffering from tinnitus that can do electrical stimulations. Also, in an experimental study design on rabbits, we had tested this new device, and evaluated the efficiency to deliver electrical currents and other capabilities in tinnitus suppression.

Although study comparisons are confounded by differences in success criteria, subject sampling, methodology and acute tinnitus suppression have been reported in up to 62.5% of subjects (Mahmoudian et al., 2001), AES reduces the effects of tinnitus; several factors could be involved in this reduction, i.e. synchronizing discharge of auditory nerve fibers, inhibition of the abnormal activity of the cochlear nerve, the revival neural coding and positive neural plasticity.

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### INTRODUCTION

Tinnitus is the conscious experience of sound which arises in the head of its owner, but without a voluntary origin obvious to that person.<sup>1</sup>

This symptom is a widespread problem that can cause considerable disability or handicap in tinnitus patients. Davis (1996) reported that tinnitus is a major factor that is associated with hearing impairment.<sup>2</sup> He found that about 10% of all adults report prolonged spontaneous tinnitus (PST) and about 5% of them have moderate or severe tinnitus annoyance. Also he reported that 2-4% of tinnitus patients have been referred to a hospital concerning tinnitus. Sullivan et al., (1988) found that 1-2 percent of adults report tinnitus that has had a severe effect on their quality of life.<sup>3</sup>

A large number of patients with incapacitating tinnitus visit the otolaryngology and audiology outpatient clinic;

however, an effective method of treatment is as yet unknown. Various methods of management to suppress tinnitus have been attempted in different hospitals and clinics.

Therapeutically a dilemma, many hypotheses about tinnitus and places of their emission implicated various methods of treatment. The most popular and frequent therapeutic methods are; pharmacotherapy, tinnitus noise generator therapy, hearing aids, biofeedback, cochlear implantation, acupuncture, tinnitus retraining therapy (TRT), habituation (using Jastreboff's theory that tinnitus is often independent of peripheral disease and the limbic response to tinnitus), cognitive therapy, and electrical stimulation.<sup>4,5,6,7</sup>

For the first time, historically, Feldman reported that Grapergiesser first suppressed tinnitus by transcutaneous stimulation with Volta's platinum-zinc cell.<sup>8</sup> In the 1960s the experimental studies on the cochlear implant were performed and in the next decade cochlear implantation

was widely applied to patients with sensory neural hearing loss. House reported that patients with cochlear implant achieved a reduction in tinnitus during electrical stimulation.<sup>9</sup>

Numerous investigators have described attempts to suppress or mask severe tinnitus through the application of electrical stimulation in the vicinity of the ear. The effectiveness of electrical tinnitus suppression is varied significantly across studies. Kitahara et al. and Ogusa et al. reported the effectiveness of tinnitus suppression by electrical promontory stimulation.<sup>8</sup> Also tinnitus suppression by electrostimulation was reported in 22% by Graham and Hazell, in 57.4% by Matsushima, in 67.6% by Okosa, and up to 87% by Portman.<sup>7,10,11</sup>

Mahmoudian et al. (2002) reported the effectiveness of suppressing tinnitus and showed its changes on auditory electrophysiological tests by using auditory electrical stimulation (AES), also the same author reported auditory electrical tinnitus suppression in implanted and non-implanted patients (2003).<sup>12</sup>

According to the literature review about this field, electrical stimulation is one of the treatments that has been explored for tinnitus suppression and shows benefit.<sup>13,14,15</sup>

The purpose of this project was to design and make a new device for auditory electrical stimulation for tinnitus relief in patients who suffer from tinnitus. Our other goal was to execute a pilot project by modeling our new device on animals.

## MATERIAL AND METHODS

The project of making an Electrical Stimulation System for tinnitus suppression and tinnitus control was based on basic study and positive results in patients who suffered from tinnitus and was documented and approved by the Department and Research Center of Otolaryngology, Head & Neck Surgery in Iran University of Medical Sciences.<sup>12</sup>

This project was constructed by four different phases of research including: studies to design the device, making hardware and software, executing a pilot project by modeling our new device on animals, and finally the study phases of minimizing instrument size making the instrument portable. In this version, our device will be within the dimensions of a hearing aid with special electrode design. The auditory electrical stimulation is carried out without anesthesia as an outpatient procedure.

Tinnitus control systems using AES to suppress

tinnitus can be classified in to two groups with respect to the cochlea, based on the site of electrode placement for electrical stimulation: (a) External systems in which the site of electrode placement is on the skull, external or middle ear, and (b) Internal systems, in which the site of electrode placement for electrical stimulation is in the inner ear or brain (i.e., central auditory system).

In our project one instrument is designed for applying combined external auditory electrical stimulation and acoustical stimulation. AES devices by definition are those that provide electrical stimulation at an electrode skin or mucosal interface. Such a system was studied by numerous investigators followed by applying both AC and DC stimulation with varying reported degrees of success.

### Device components

This device basically consists of two components: hardware and software.

The structure of this device is designed both with client and server divisions. All procedures that should be done are divided between client and server and each one works separately and parallel with the other. Whenever it is needed to make connection between these two components, this connection is done by connective protocol of RS 232.

The data is received from the client by the PC server and the new data is send to the client.

The hardware consists of two generators: one is a carrier square wave's generator (30 KHz to 100 KHz); the second is another square low frequency signal (1 KHz through 20 KHz) that has adjustable cycle.

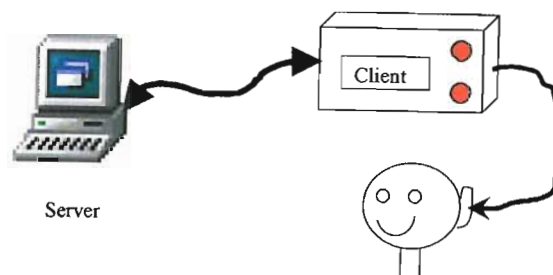


Fig. 1. The block diagram of the client-server system

The entire user interface is on PC, and there are a lot of options that the user can adjust. The PC is connected to this circuit by serial port and the serial port is isolated form the other parts of the circuit. Modulation can optionally be enabled or disabled. The amplitude of current flow can vary from 1 microamp to 1 mA with 1

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microamp resolution.

The impulse duration can be adjusted (this is a third pulse generator) by the clinician from 500 microsec. to 1 second delivered at 1/sec to 2000/sec. The combined electrical signal has the maximum peak to peak amplitude of 10 V, which varies to make a constant current through electrodes. A combined electrical signal is delivered to a pair of electrodes. One of them is gold Mylar-coated and the other one is surface tympanic membrane electrode. The first electrode is applied with electropaste to the skin overlying the forehead and the second electrode is inserted carefully in the external auditory canal to the nearest place to the tympanic membrane (inferior-posterior part).

A warning indicator shows insufficient skin electrode contact. The impedance between the electrodes can be monitored on PC.

There are several parts that increase the safety of this system. The dimension of the PC board is 11 cm × 14 cm. By now the first version which can be used in hospitals and/or in clinics is made and can be provided to patients with tinnitus.

### Software system

An instrument has been made in this project that provides all the needs such as voltage amplitude, maximum current level, frequency and also modulation that are needed for tinnitus suppression. This AES software is run by windows XP.

In designing and making the client part, two stages

have been considered, the first stage was designing and making the hardware, and the second stage was writing the program of low level.

The next process was writing the program of high level for the server part; this software was written with VC language.

In this part all of the software's adjustments and protections and the limitations that are needed for making the waveforms had been taken into consideration. In addition, the protections that should be done while connecting between the server and the client were considered.

Comprehensive software has been designed for recording and filing of the results of auditory electrical stimulation for tinnitus suppression.

Subjective response to AES can be established on the software. Patients essentially have six subjective responses to AES that include: (1) vibration at low current intensities (threshold level: THL) followed by (2) auditory sensation level (ASL), (3) tinnitus suppression level (TSL), (4) electrical most comfortable level (EMCL), (5) electrical uncomfortable level (EUCL), and (6) pain level with increasing current intensities.

Also, the reduction in tinnitus intensity during AES and the continued absence of the tinnitus after the cessation of AES that is named from electrical residual inhibition (ERI) is established as well. The parameters of the AES such as voltage amplitude (intensity), pulse rate (frequency), and duration, can be recorded and stored on the AES software.

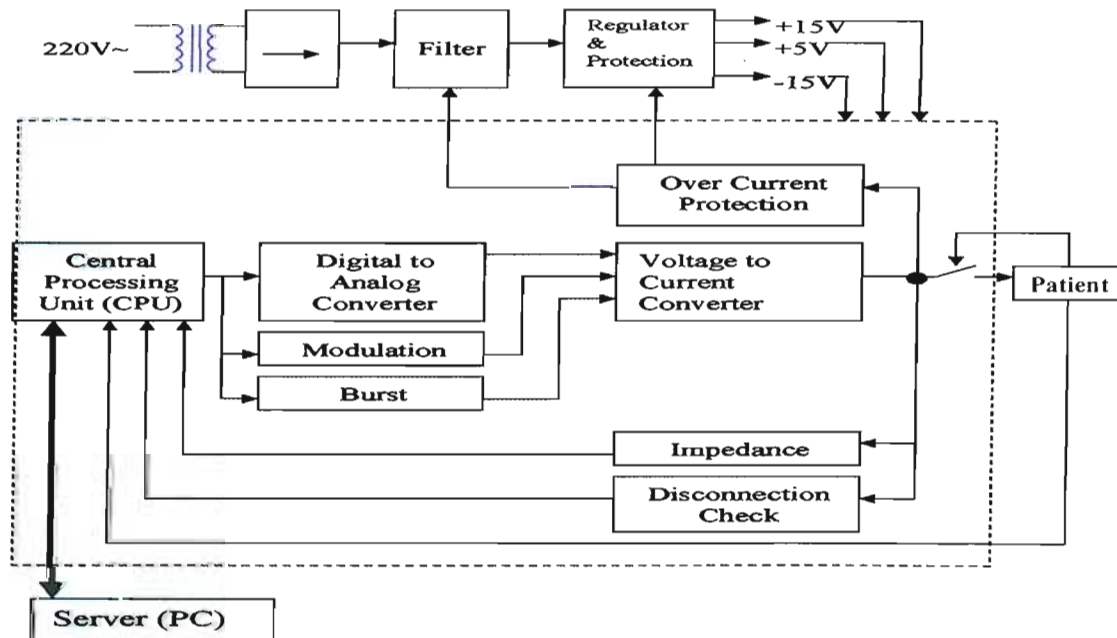


Fig. 2. The block diagram of our device.

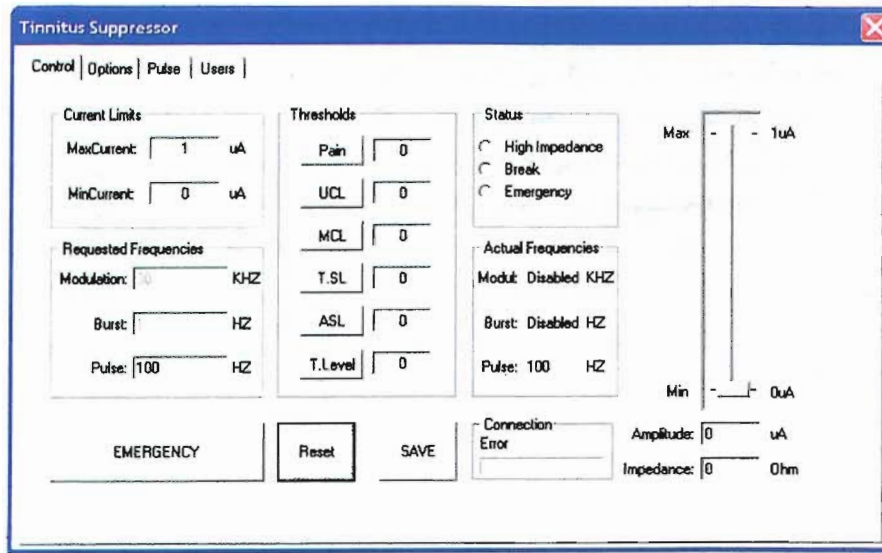


Fig. 3. The software design of the auditory electrical stimulation of the tinnitus suppressor.

### Animal study

In this project, Dutch, male, mature (3 months, 1800 gr.) rabbits were selected. During ABR test, animal cases were anesthetized by ketamine 10% and Rampone 2% (4/3 unit) intra-muscular injection in 1.2cc per 2 Kg. Also, the body temperature of rabbits was constant and controlled.

At the first step, all animals were evaluated to confirm the health of the middle and inner ear prior to AES exposure with immittance audiometry (tympanometry and acoustic reflex threshold). Then ABR testing in different intensity levels was obtained. We used click stimulus (1000-4000 Hz) and tone burst stimuli (250, 500, 1000, 2000, 4000, 8000 Hz) at three intensity levels (50 dB, 70 dB, 110 dB) with an ERA-2250 Madsen ERA instrument.

Early studies determined hearing frequency range of rabbits at 300-42000 Hz. The hearing sensitivity of the rabbit is about 250 Hz and above that, as shown in our results.<sup>16</sup>

The waveforms of ABR were recorded prior to and following exposure to AES. The absolute latency of the V wave was measured in both sides.

AES was performed with the same electrode and position, delivered by our new stimulation system.

Needle type electrodes were used in this study and electrode montage included a non-inverting electrode (positive) in the test ear, an inverting electrode (negative) in the non-test ear and finally the common electrode placed on the forehead. Bipolar 50 Hz burst pulses (square waves) were presented with duration of 0.5 sec. We then stimulated both ears at current levels which were at the

high level. The duration of stimulus of AES was 30 minutes.

It is generally agreed that ABR is generated by the auditory nerve brain stem pathways. The primary generator sites for the ABR were as follows; both waves I and II arised from the auditory nerve, wave I from the distal portion of the nerve in the cochlea and wave II from the proximal portion of the auditory nerve as it enters the brain stem, also wave III-cochlear nucleus, wave IV-superior olivary complex, wave V- lateral lemniscus as it terminates in the inferior colliculus.

In order to assess hearing sensitivity, wave V of the ABR was used because it is the most robust of the waves and also the best correlated with behavioral audiometric threshold.

## RESULTS

Our results with this instrument are considered in two stages. In the first stage, we have executed the pilot study by modeling our device in a limited number of animals (rabbits) and evaluated the efficacy of delivering electrical currents and possible problems in this manner. Overall, the results of the efficacy of our AES instrument continue to confirm our original reports and that of other authors.

We intend to perform electrical stimulation with our new device on rabbits which are having tinnitus due to overdose of ototoxic drugs and acute acoustic trauma and then we will study the efficacy of delivering AES on tinnitus suppression by electrophysiological findings. The

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**Table I.** The mean and standard deviation of V wave in auditory brain stem response audiometry (ABR), pre and post AES exposure with click and tone burst stimuli in three intensity levels.

Intensity (dB)	Stimulus Mode	Latency (ms) (Pre-AES exposure)		Latency (ms) (Post-AES exposure)	
		Mean / Standard Deviation	Mean / Standard Deviation		
110	Tone Burst	250 Hz	5.20 0.24	5.10 0.18	
		500 Hz	5.49 0.23	5.50 0.18	
		1000 Hz	4.81 0.14	4.74 0.18	
		2000 Hz	4.73 0.10	4.14 0.11	
		4000 Hz	4.90 0.14	4.86 0.18	
		8000 Hz	4.80 0.18	4.78 0.18	
	Click	4.64 0.10	4.60 0.18		
70	Tone Burst	250 Hz	6.08 0.38	5.63 0.17	
		500 Hz	5.54 0.17	5.60 0.11	
		1000 Hz	5.64 0.43	5.75 0.27	
		2000 Hz	5.33 0.29	5.39 0.24	
		4000 Hz	5.45 0.39	5.48 0.38	
		8000 Hz	5.28 0.34	5.37 0.30	
	Click	4.96 0.16	5.04 0.11		
50	Tone Burst	250 Hz	7.32 0.37	7.29 0.37	
		500 Hz	6.98 0.77	6.96 0.73	
		1000 Hz	7.01 0.48	7.02 0.48	
		2000 Hz	6.81 0.76	6.89 0.64	
		4000 Hz	7.17 0.81	7.13 0.80	
		8000 Hz	6.14 0.49	6.23 0.52	
	Click	6.10 0.32	6.17 0.31		

(Mean / SD). Statistical comparisons by paired *t* tests =  $p < 0.05$

latency of V wave in normal rabbits is shown at 3 intensities (110, 70, 50 dB) with click and tone burst stimuli in Figure 4.

The results showed that the waveforms were not altered by AES exposure. The mean size of the latency and amplitude ratios in post-exposed animals were not significantly changed compared to that of pre-exposed ones (Paired *t*-test,  $p < 0.05$ ). It may be concluded that the auditory electrical currents of our instrument have no damage on the auditory system. AES was performed with the same electrode and position by our new device as follows:

(a) Bipolar 50-Hz burst current stimuli (square waves) presented with a duration of 0.5 sec. and 1 Hz frequency and without modulation, (b) 1 mA current amplitude, and (c) the duration of stimulus of AES was above 30 minutes in all of the rabbits.

In general, the preliminary observations in humans by the stimulation system (nucleus promontory stimulator) which was used for the evaluation of cochlear implant candidates is as follows:

1) Significant tinnitus suppression and/or electrical residual inhibition were achieved on a test-retest basis.

2) No significant complications were noted.

3) Occasionally, patients reported "hearing improvement".

4) The duration of tinnitus control was individual and varied from hours to months.

(a) For our tinnitus sufferers, we established the definite latency, adaptation, duration of electrical residual inhibition, or duration of tinnitus suppression during and after AES, and recurrence of tinnitus sensation. The latency of electrical residual inhibition for tinnitus suppression varied from minutes to weeks. The duration of post-stimulus electrical suppression was significantly longer than the acoustical suppression.

(b) The tinnitus lesion site may be not only in the auditory but also non-auditory systems peripheral and/or central in location.

### DISCUSSION

At present, three commercial devices are designed and made for tinnitus suppression in America, France and Japan. One of them is named Tinitop, made by Audiologie Recherché-Applications, France. This device delivers acoustic and electrical stimulation simultaneously.



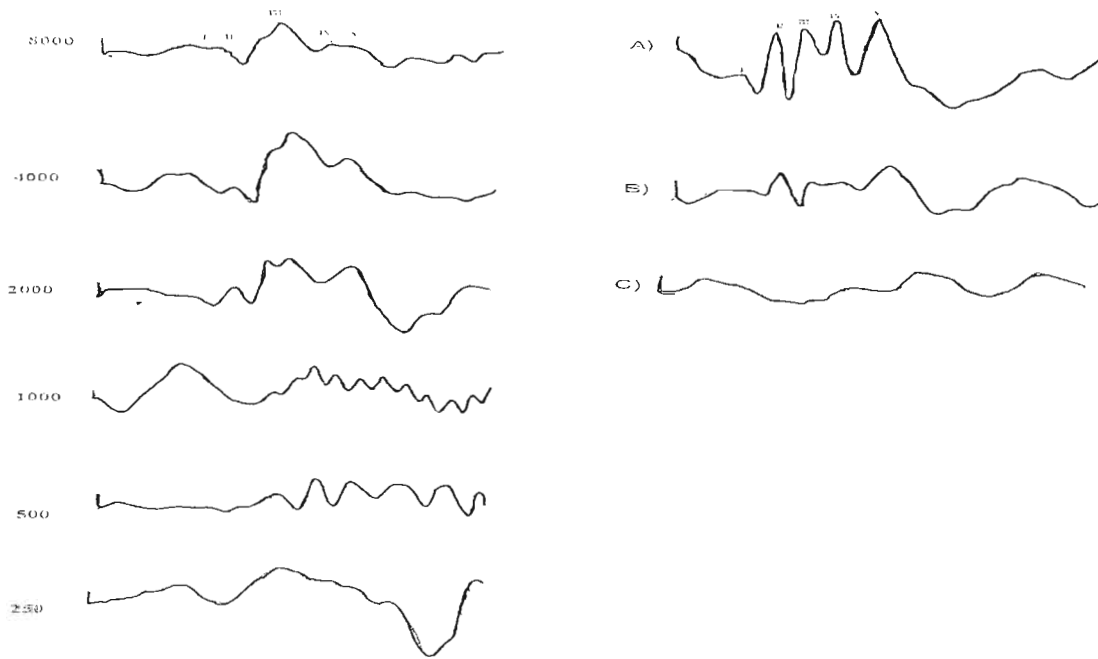


Fig. 4. ABR waveform in normal rabbits at 3 intensities, 110 dB (A), 70 dB (B), 50 dB (C) with click and tone burst stimuli.

Morgan et al. reported on the use of the Tinitop in 50 tinnitus patients. The tinnitus control results were reported positive in 27 out of 50 patients (54%).<sup>17</sup>

The stimulus is a synchronous sound and electrical signal at 144 Hz with impulse duration of 9900 ms delivered at 5/min with a 2-s interval between pulses. The intensity is controlled by an adjustable voltage ranging from 0 to 70 V peak to peak. The electrodes are similar to those used with ABR testing.

The other device is named Theraband. The Theraband/Audimax tinnitus suppressor is made in Audimax Corporation (South Hackensack, NJ, USA). Basically, the device consists of two generators: one is a low radio frequency generator (60 KHz) producing a carrier signal that penetrates the skin; the second is a sweep frequency sine wave generator (200 to 20,000 Hz). Its output is used to modulate the carrier signal by a maximum of 90%. A combined electrical signal (5 V peak to peak) is delivered to a pair of electrodes. The sweep time is approximately 2 to 2.5 /min. The power delivered to the head is below 20 mW. The instrument is completely enclosed.

The on-off switch is the only external control. Lyttkens et al. evaluated the Theraband unit for tinnitus suppression in a double-blind cross-over trial with a placebo unit.<sup>18</sup> The authors reported positive results from electrical stimulation using the device in one out of five

patients and no effect from the placebo. Also, the other authors have investigated the effects of this device and reported some positive results of ES using the theraband device.

Kitajima et al.<sup>19</sup> and Kitahara<sup>20</sup> from Shiga University of Medical Sciences have reported on a device for external electrical stimulation providing transcutaneous suppression of tinnitus with high frequency carrier waves. This device apparently is a modification of the Theraband/ Audimax device, which has included some of the modifications that were suggested by HSCB-SUNY.

The reports of improved results are encouraging and supporting the efficacy of ES to suppress or control tinnitus in selected patients.

As various studies show, the procedure and the electrical signal applied to patients can be completely different with each other. So, our system has a wide range of variability and can be used for different patients. This variability consists of:

1. The current amplitude can be changed between zero to 1 mA (the variability is limited to safety range). The accuracy of current amplitude can be applied to 1 micro A.
2. The applying signals are square waves, burst and amplitude, frequency, pulse interval, and pulse duration between 2 sec through to default setup.

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3. Maximum frequency presentation is limited to 20 KHz like the human audibility.
4. This system is able to present frequency modulation that varies between 30 KHz up to 100 KHz. The modulation can be nonactive and output signal can be without modulation and also independent to burst.
5. This system is able to perform impedance checks between electrodes, and we can monitor it on computer display and pass or fail of electrode attachment can be seen with on or off.
6. This unit works automatically with high safety factors.
7. To lessen the risk of too much electrical stimulation in the patients and also make them sure that there is nothing to be worried about, we give a manual switch to the patients so they can interrupt the output current anytime they want. This circuit can be activated again through the software by the specialist.
8. To apply different adjustments on the electrical stimulation parameters, a software has been designed that can be used by specialists and the main function of the instrument can be controlled by that software. This software is run under windows XP.
9. To connect the main instrument and computer we use a serial port safe (because of the present high amplitude voltage in the serial port; 12V). Also the serial port is isolated by opt coupler from the main instrument for more safety. Therefore if there is a problem in the power supply of the computer it doesn't threaten the patient's life.
10. In order to make sure of transferring correct data from the computer to the main instrument, we have used CRC checking to demonstrate the errors. If there is an error in the received data, the electrical signals will be interrupted.
11. Several safety conditions have been considered in the hardware; one of them is designing and making two separate windings in the power supply transformer; 220V, (primary and secondary windings). Therefore, if there is a problem in the primary winding, it doesn't transfer the extra voltage to the secondary winding.

The currents of AES are conducted from an electrode, via the mucosa of the middle ear, the round window or the oval window, hair cells and the satellite ganglion, to the auditory nerve.<sup>22</sup> The auditory electrical stimulation has an influence both on the hair cells and the cochlear nerve.

Watanabe et al. reported that AES didn't have a significant effect on the auditory thresholds before and after AES.<sup>8</sup> In our study, there was no significant

difference in the ABR latencies before and after AES that confirm a healthy hearing system in rabbits.

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