



Zentralinstitut für Elektronik

***Galvanic Vestibular Stimulation Unit Design
for the Therapeutic Treatment of Neglect
Syndrome Patients***

Goutham C. Yapamanu

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GALVANIC VESTIBULAR STIMULATION UNIT DESIGN FOR THE THERAPEUTIC TREATMENT OF THE NEGLECT SYNDROME

Abstract

Galvanic vestibular stimulation (GVS) is a technique that has been used for a clinical measure. GVS is performed by passing small currents through the vestibular labyrinth, using surface electrodes. To measure the effect on the vestibular system, one may record either eye movements or postural movements (which can be controlled with the help of a computer based Matlab simulink program). Typical stimulus configurations include placing an electrode on each mastoid, one positive and one negative, to produce medial / lateral sway or horizontal / vertical eye movements. The ability of this technique in reducing the neglected region of the patient suffering from the 'Neglect syndrome' is an important issue in therapeutic neurological research.

In the Institute of Medicine (Research Centre Juelich), novel GVS-based stimulation techniques for the therapeutic treatment of the so called 'Neglect syndrome' are under development. There are however only a few systems for Vestibular Galvanic Stimulation available in the market. These systems for GVS are much restricted with their stimulation parameters such as the frequency ranges and stimulation patterns. So we at Central Institute for Electronic, Research Centre Juelich, developed a dual channel GVS unit both in positive and negative directions independently, therefore enabling independent current stimuli in the frequency range from 0 to 10 KHz, voltage range from 0v to ± 35 V, current range from 0 to ± 7.5 mA timer up to 2 hours for the safety of the patient. The purpose of this designed GVS device is to optimize GVS stimulation pattern for reducing the neglected region in Neglect Syndrome patients and can be aimed to be used for research purposes.

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Summary

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In the Institute of Medicine (Research Centre Juelich), novel GVS-based stimulation techniques for the therapeutic treatment of the so called 'Neglect syndrome' are under development. There are however only a few systems for Vestibular Galvanic Stimulation available in the market. These systems for GVS are much restricted with their stimulation parameters such as the frequency ranges and stimulation patterns. So we at Central Institute for Electronic, Research Centre Juelich, developed a dual channel GVS unit both in positive and negative directions independently, therefore enabling independent current stimuli in the frequency range from 0 to 10 KHz, voltage range from 0v to ± 35 V, current ranges from 0 to ± 7.5 mA timer up to 2 hours for the safety of the patient. The purpose of this designed GVS device is to optimize GVS stimulation pattern for reducing the neglected region in Neglect Syndrome patients and is aimed to be used for research purposes.

1. Introduction

1.1 Neglect syndrome

Neglect syndrome is a deficit in attention to the left side of space seen most often after right hemisphere brain injury. Damage associated with the brain areas in temporal, parietal and frontal lobes is associated with the deployment of attention (through eye movements, head turns or limb reaches) into left or right space. More specifically, the disorder is most closely related to damage to the temporal / parietal junction and posterior parietal cortex. The lack of attention to the left side of space can manifest in the visual, auditory, proprioceptive, and olfactory domains. [10]

Hemi spatial neglect, also called unilateral neglect, spatial neglect or neglect syndrome is a deficit in attention of the brain. Although hemi spatial neglect often manifests as a sensory deficit (and is frequently co-morbid with sensory deficit), it is essentially a failure to pay sufficient attention to sensory input. This is particularly evident in a related phenomenon known as extinction. Extinction is evident where a patient will report the presence of an object in left space when it is the only object present. If the same object is presented simultaneously with an object in right space, the patient will only report the object on the right. Hemi spatial neglect is most common after right-hemisphere stroke, but has been identified following left-hemisphere stroke as well (left-hemisphere stroke, results in the neglect of the right side of space). Behaviour associated with neglect include failure to find objects on the left side of a table or in a room, sometimes meaning patients with stroke will only eat food from the right side of a plate, wash or shave only the right half of their face or bump into things on the left side when walking or moving in a wheelchair. The patients with right-hemisphere injury do the vice versa, they neglect the things on the left space. Rehabilitation of neglect is often carried out by Neuro-psychologist occupational therapists. [14]

Contralateral Hemi spatial neglect is a fairly common disorder, usually associated with a stroke or lesion on the right parietal lobe, which results in a neglect or lack of attention to usually the left side of space and vice versa in case of left parietal lobe they neglect the space on right side. Patients with neglect seem to live in a subjective

world that is skewed away from the left side. "In daily life, such patients may eat food from only the right side of their plate, ignore people who approach from their left, miss words on the left of the page when reading, and omit details on the left when copying pictures, and so on". They practically ignore all sounds and sites coming from their left side. In case of left parietal lobe injury the Hemi spatial neglect syndrome patients ignore the things on there right, addition to vision and sound, Hemi spatial neglect can also affect motor function of the patient. Patients with Hemi spatial neglect, tend to behave as if nothing of importance is expected to be happening in the left hemi space or right hemi space and refrain from moving their left side or right side respectively. There is also an emotional factor to this disorder. Patients with Hemi spatial neglect sometimes have a profound hatred towards the left side and may even physically abuse the left side. [9]

1.2 Neglect syndrome symptoms

- Failure to shave, groom or dress the left side of the body
- Failure to orient to events in the left hemi space.
- When copying drawings they omit detail on left side.
- When reading they fail to read the left half of each sentence.
- Hemiplegia due to failure to move the left limbs.
- Unable to recognize and accept the left side as being a part of their body.
- Delusional views concerning left side of body.

Hemi spatial neglect syndrome has at least three behavioural components. The ***perceptual component*** involves patients paying attention only to the right side of space. These patients can also give attention to the left side only if there is no stimulus on the right side. In reality, a person will always be exposed to stimuli from both the right and left side of space (light, sound, objects, etc.). Neglect behaviour also has a ***motor component***. Patients are disinclined to direct scanning, orienting and exploring movements towards the neglected left hemi space. When blindfolded patients are asked to manually retrieve small objects from a table, they show good movement with either hand in the right hemi space but poor movement (even with the right hand) into

the left hemi space of the table. The third component of neglect is *motivational*. Patients with neglect tend to act as if there is nothing happening on the left side of space that is of any importance. [9]

1.3 Directed attention and the Brain

Hemi spatial neglect reflects a disturbance in the spatial distribution of directed attention

(a) Objects on the patient's right-hand side easily capture their attention. They are unable to withdraw their attention from objects on the right in order to attend to the left hemisphere.

(b) Studies regarding Hemi spatial neglect syndrome in humans and monkeys suggest that four cerebral regions provide an integrated network for directed attention. Each component region has a unique functional role and gives rise to a different clinical type of neglect when damaged.

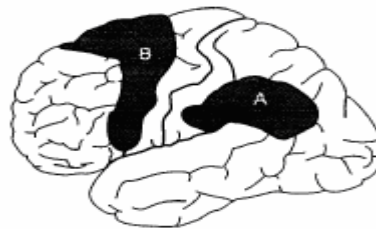


Figure 1.3 showing the regions of the brain the majority of patients the lesion involves the supramarginal gyrus in the inferior parietal lobule (A), at the temporal-parietal junction (black area). Although less frequently, damage to the dorsolateral prefrontal and medial frontal regions (B) can also bring about Hemi spatial neglect syndrome. Lesions confined to the primary motor, somatosensory and visual cortices are not associated with hemi neglect". [9]

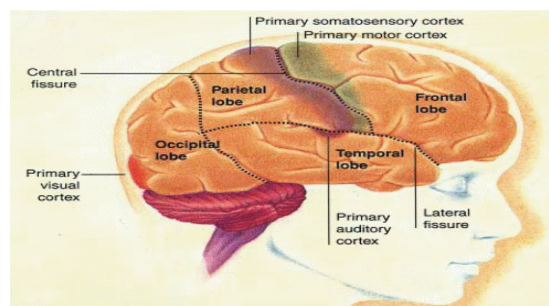


Figure 1.3 (a) Posterior parietal lobe - provides internal sensory mechanism, Limbic component - regulates the spatial distribution, Frontal lobe - coordinates the motor

programs for scanning, reaching and exploring, Reticular component - provides levels of arousal. Lesions in one of the components of this network cause only partial Hemi spatial neglect, while lesions that encompass all the components result in huge deficits and a more severe case of Hemi spatial neglect. [16]

1.4 Hemi spatial neglect and visual awareness

Patients with Hemi spatial neglect syndrome show a loss of visual awareness of the left hemi space even though their primary visual cortex is intact and functional. The most puzzling aspect of Hemi spatial neglect syndrome is why patients are unaware of visual information on the left, even though nothing is wrong with their vision. Studies have shown that when visual stimuli on both the left and right side is present, the patient's attention is fully captured by the visual stimuli on the right. The patient is lacking the ability to give attention to the visual stimuli on the left, even though his primary visual cortex is fully intact. Patients with hemianopia fail to see the left side of space because of damage to their primary visual cortex. [9]

These patients cannot see the left side but they are aware that the left side exists and do not have neglect. In order to see the other half of space, these patients will turn towards their left side so that they can see from their good visual field. Patients who have Hemi spatial neglect syndrome can see both sides of space but their mind convinces them that only the right side is of importance.

Visual Awareness is the key to understanding Hemi spatial neglect syndrome patients. Patients with Hemi spatial neglect don't have the visual awareness that is necessary to process visual signals from the left side. The parietal lobe is known to be responsible for visual awareness because it integrates extra-retinal and retinal information together. Now it makes sense why damage to the right parietal lobe can lead to neglect.

The Hemi spatial neglect deficit differs greatly from the retinotopic scotoma patients caused by damage the primary visual cortex of cerebral hemispheres in the brain. In one study, a female patient with Hemi spatial neglect syndrome appeared to be blind

in the left visual field when she was looking straight ahead or to her left. However, when she looked slightly to her right, she could then see objects in her left visual field. This indicates that the visual information relative to her body and head was critical (extra-retinal information), not the retinal position.

Hemi spatial neglect patients have trouble seeing objects in the left visual field, they can turn their trunk slightly towards those objects and then they can see them (even though the location where visual information hits their retina did not change). These results show that the spatial visual signals which indicate the position of an object relative to the head, body, or the hand, “can contribute to the spatial coordinates in which Hemi spatial neglect arises”. This evidence from Hemi spatial neglect patients suggests that the integration of retinal and extra-retinal information could play a role in visual awareness. [11]

2. Basics

2. 1 Galvanic vestibular stimulation (GVS)

Galvanic vestibular stimulation is performed by passing small DC currents through the vestibular labyrinth using surface electrodes. Typical stimulus configurations include placing an electrode on each mastoid, one positive and one negative, to produce medial – lateral sway or horizontal / torsional eye movements. Previous research and clinical application have been limited by the requirement for relatively high sometimes painful, electric currents to produce recordable horizontal eye movements. A significant advantage of galvanic stimulation is that each labyrinth can be tested separately. However, it is not yet certain which vestibular end organs are responsible for either the eye movements or postural movements induced by such a stimulus. Offsetting this limitation, however, is the fact that galvanic stimulation is believed to excite the synapse between the hairy cell and the eighth cranial afferent nerve. As a result, galvanic stimulation can provide information regarding ‘neural’ versus sensory function. That is individuals with hairy cell damage with preserved eighth nerve function may have normal or increased responses to galvanic stimulation. However it is technically challenging to deliver a well controlled galvanic stimulus while recording eye movements or postural sway determine the stimulation effects. [8]

The technique provides a derived measure of vestibular function that relies upon the ocular motor system. When recording postural responses during galvanic stimulation there is an additional difficulty based on the complexity of the postural control system, which is neither linear nor time invariant. As for Vestibulo-ocular reflex (VOR) tests, recording postural sway during galvanic stimulation provides only a derived measure of peripheral vestibular function. Further, the stimulus may produce a skin sensation that cues the patient. Additional unresolved issues concerning the effect of galvanic stimulation on postural sway include the influence of head- on- torso position the waveform of the electrical stimulus, i.e. constant versus sinusoidal and the timing of the galvanic stimulus with respect to the patient’s own sway. Despite these limitations and unresolved issues, however, with the advent of three dimensional video-oculography and lower cost motion analysis systems galvanic stimulation may emerge as a clinically useful tool. That is, low intensity galvanic currents may produce small but

recordable non-horizontal eye movements and / or small but recordable postural movements that can be measured reliably using sensitive recording instruments. [8]

2.1.1 Vestibular system

The vestibular system, or balance system, is the sensory system that provides the dominant input about our movement and orientation in space. Together with the cochlea, the auditory organ, it is situated in the vestibulum in the inner ear (Figure 2.1.1). As our movements consist of rotations and translations, the vestibular system comprises two components: the semicircular canals, which indicate rotational movements and the otoliths, which indicate linear translations. The vestibular system sends signals primarily to the neural structures that control our eye movements, and to the muscles that keep us upright. The projections to the former provide the anatomical basis of the vestibulo-ocular reflex, which is required for clear vision and the projections to the muscles that control our posture are necessary to keep us upright.

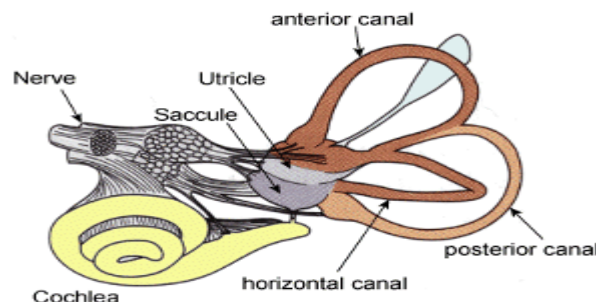


Figure 2.1.1 Human labyrinth, from the left ear. It contains i) the cochlea (yellow), which is the peripheral organ of our auditory system; ii) the semicircular canals (brown), which transduce rotational acceleration and iii) the otoliths in sacculus and utriculus (in the blue/purple pouches), which transduces linear accelerations. The light blue pouch is the endolymphatic sac, and contains only fluid. [14]

2.1.2 Semicircular canals

Our world has three spatial dimensions. Accordingly, our vestibular system contains three semicircular canals in each labyrinth. They are approximately orthogonal to each

other, and are called horizontal, anterior, and posterior canal. (Alternatively, they may be referred to as lateral, superior, and inferior, respectively)

2.1.3 Push-pull systems

The canals are cleverly arranged in such a way that each canal on the left side has an almost parallel counterpart on the right side. Each of these three pair's works in a push-pull fashion: when one canal is stimulated, its corresponding partner on the other side is inhibited, and vice versa.

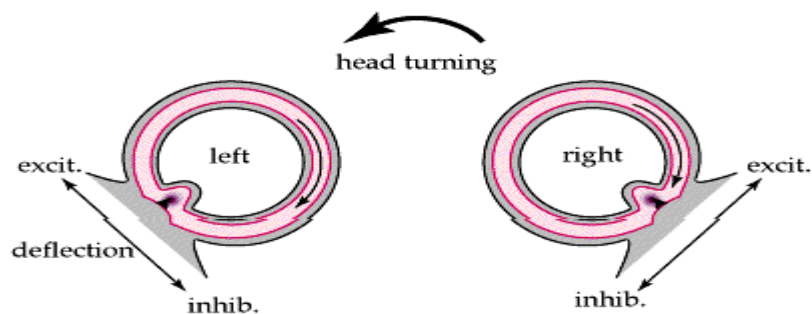


Figure 2.1.3: Push-pull system of the semicircular canals, for head movement. This push-pull system allows us to sense all directions of rotation: while the right horizontal canal gets stimulated during head rotations to the right, the left horizontal canal gets stimulated (and thus predominantly signals) by head rotations to the left. [16]

2.1.4 Vestibulo-ocular reflex (VOR)

The vestibular system needs to be fast: if we want clear vision, head movements need to be compensated almost immediately. Otherwise our vision corresponds to a photograph taken with a shaky hand. To achieve clear vision, signals from the semicircular canals are sent as directly as possible to the eye muscles. This direct connection involves only three neurons, and is correspondingly called Three-neuron-arc (Figure 2.1.4). Using these direct connections, eye movements lag the head movements by less than 10 ms, one of the fastest reflexes in the human body. The automatic generation of eye movements from movements of the head is called vestibulo-ocular reflex, or short VOR.

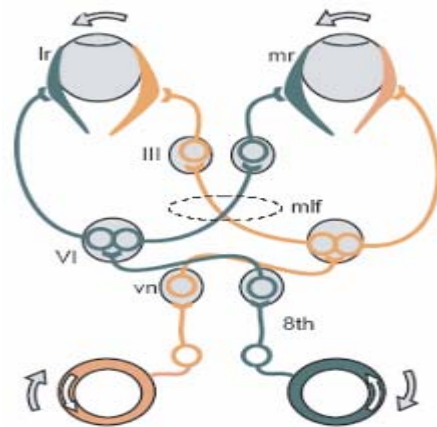


Figure 2.1.4: Three-neuron arc, during a head movement to the right. 8th cranial nerve, from the peripheral vestibular sensors to vn, the vestibular nuclei in the brainstem. VI abducens nucleus. The medial longitudinal fascicle (mlf) projects from the abducens nucleus to III, the oculomotor nucleus. The left lateral rectus muscle lr and the right medial rectus muscle mr get contracted, turning the eyes to the left. The green objects are excited, the orange ones inhibited. [10]

This reflex, combined with the push-pull principle described above, forms the physiological basis of the Rapid head impulse test or Halmagyi-Curthoys-test, when the function of the right balance system is reduced by a disease or by an accident, quick head movements to the right cannot be sensed properly any more. As a consequence, no compensatory eye movements are generated, and the patient cannot fixate a point in space during this rapid head movement.

2.1.5 Mechanics

The mechanics of the semicircular canals can be described by a damped oscillator. If we designate the deflection of the cupula with θ , and the head velocity \dot{q} with, the cupula deflection is approximately

$$\theta(s) = \frac{\alpha s}{(T_1 s + 1)(T_2 s + 1)} \dot{q}(s)$$

α is a proportionality factor, and s corresponds to the frequency. For humans, the time constants T_1 and T_2 are approximately 3 ms and 5s, respectively. As a result, for typical head movements, which cover the frequency range of 0.1 Hz and 10 Hz, the deflection of the cupula is approximately proportional to the head acceleration velocity. This is very useful, since the velocity of the eyes must be opposite to the velocity of the head in order to have clear vision. [10]

2.1.6 Central processing

Signals from the vestibular system also project to the cerebellum (where they are used to keep the VOR working, a task usually referred to as learning or adaptation) and to different areas in the cortex. The projections to the cortex are spread out over different areas, and their implications are currently not clearly understood.

2.1.7 Otoliths

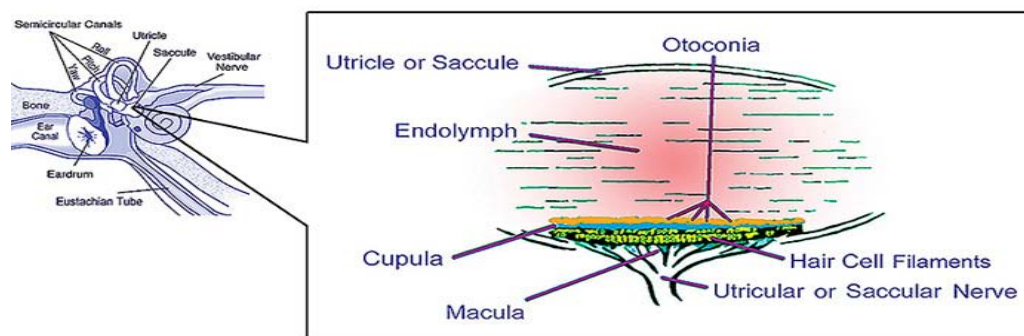


Figure 2.1.7: Otolith or otoconia is a structure in the saccule or utricle of the inner ear. It is comprised of a combination of a gelatinous matrix and calcium carbonate crystals. Otolith crystals are relatively dense and heavy - they are connected to the rest of the body by the sensory processes of the macular cells. [15]

The **otolith organs** (the **utricle** and the **sacculle**) are structures in the inner ear, specifically in the semicircular canals, that are sensitive to gravity and linear acceleration. Because of their orientation in the head, the utricle is sensitive to a change in horizontal movement, and the sacculle gives information about vertical acceleration (such as when in an elevator). Otoliths are small particles of calcium

carbonate in the viscous fluid of the saccule and utricle. The inertia of these small particles causes them to stimulate hair cells when the head moves. The hair cells send signals down sensory nerve fibres, which are interpreted by the brain as motion. The interpretation of the rotation signals from the semicircular canals is straightforward, the interpretation of otoliths signals is more difficult, since gravity is equivalent to a constant linear acceleration we somehow have to distinguish otoliths signals that are caused by linear acceleration such as those caused by gravity. We can do that quite well, but the neural mechanisms underlying this separation are not yet fully understood.

2.1.8 Pathologies

Diseases of the vestibular system can take different forms, and usually induce vertigo and instability, often accompanied by nausea. The most common ones are vestibular neuritis, also called Labyrinthitis, and BPPV (Benign Paroxysmal Positional Vertigo). In addition, the function of the vestibular system can be affected by tumours on the cochleovestibular nerve, an infarct in the brain stem or in cortical regions related to the processing of vestibular signals, and cerebellar atrophy. Less severe, but often also with large consequences, is vertigo caused by the intake of large amounts of alcohol.

2.1.9 Benign paroxysmal positional vertigo (BPPV)

Benign paroxysmal positional vertigo (BPPV) is probably caused by pieces that have broken off from the otoliths, and have slipped into one of the semicircular canals. In most cases it is the posterior canal that is affected. In certain head positions, these particles push on the cupula of the canal affected, which leads to dizziness and vertigo. This problem occurs rather frequently, often after hits to the head or after long bed rest. The tell-tale sign of BPPV are vertigo attacks which repeatedly appear when the head is brought into a specific orientation. In most cases BPPV can be eliminated (for the patient in an almost miraculous way) by lying down, bringing the head in the right orientation and sitting up quickly. [14]

3. Material and methods

3.1 Methods of Stimulation

The objective of the electrical stimulation system is excitation of the desired physiological effect. The desired physiological effect may be considerably different in therapeutic as opposed to functional applications. The electrode type used to elicit the physiological response may thus be quite different. The considerations for selection of electrode type that must be included are the selectivity and gradation of excitation required, the repeatability from one application to the next and the allowable level of invasiveness. Two types of electrodes are used surface (or cutaneous) and subcutaneous, all of which are applied externally.

Surface electrodes include a wide variety of specific types, each of which is placed on the skin surface over the area where the stimulus is to be delivered. Placement is on the individual muscle or muscle group, the peripheral nerve, or over cutaneous skin afferents for the case in which sensory activation is the objective.

Surface electrodes have low impedance, and even distribution of current, flexibility to maintain good skin contact ease of application and removal suitable mounting for days without irritation to the skin. Each of the surface electrode configurations has three elements the conductor, the interfacial layer and the adhesive.

Surface electrodes generally have a geometric surface area of 5cm² or larger. They may be applied in either a monopolar configuration or a bipolar configuration. In the monopolar configuration, the working electrode is placed over the nerve to be excited and the counter (or indifferent) electrode, which is larger in surface area, is placed remotely. In the bipolar configuration, the most common for surface stimulation, both electrodes typically are the same size and are placed over the site to be excited.

The stimulus parameters required for activation over surface electrodes are dependent on the stimulus waveform, the surface area, electrode materials, placement, skin impedance, current density and other factors. Typically, for the rectangular pulsatile waveform frequently used, threshold values are 10 mA. [6]

3.1.1 Caloric vestibular stimulation

One technique to influence the vestibular system is the caloric vestibular stimulation which is not in use today anymore. When around 20 cc of ice water is squirted into the left ear of the Hemi spatial neglect syndrome patient for approximately 1min, dramatic improvements in visual and personal Hemi spatial neglect syndrome are observable in many, but not all, cases a similar result is obtained when a similar amount of warm water is inserted into patients right ears, also found temporary remission of hemianaesthesia following vestibular stimulation. The precise mechanisms for this effect are at present unknown. This method is very unpleasant and therefore not feasible for therapeutic application. [10]

3.1.3 Constant current vs constant voltage

A constant-current stimulator attempts to maintain a specified current between its output terminals, regardless of the load that is connected between the terminals. A constant-voltage stimulator attempts to maintain a specified voltage.

Although both kinds of stimulator can work satisfactorily for nerve stimulation, the constant current type has the advantage of greater consistency in threshold stimulus strength, because the effectiveness of a stimulus is related directly to the current density. Variations in the load do not affect the current from a constant current stimulator, provided only that they are not as extreme as to cause the stimulator to exceed its compliance voltage.

3.1.4 Stimulus generation

The stimulus that is delivered to the nerve should achieve the desired result (e.g. evoke the action potential) without deleterious effects to the tissue or to the electrode. Output impedance to the stimulus circuit determines the degree to which changes in load (i.e. impedance due to leads, electrodes, skin interfaces, and tissue) alter the actual stimulus delivered to the tissue. High-output impedance devices will deliver the set current to the tissue, regardless of the changes in load (e.g. tissue drying) up to

the voltage capacity available. These constant current stimulators are more properly called current-regulated stimulators. Devices having low-output impedance, constant-voltage stimulators, will change the delivered stimulus with change in load. Because the user is generally unaware of the precise load at any point in time, most stimulator devices are current regulated so that the consequences of modest impedance changes can be ignored.

The stimulus waveform selected for the excitation process must take into consideration the desired physiological effect (action potential generation), potential damage to the tissue and the potential degradation of the electrode. The waveform selected generally is rectangular. A non rectangular pulse could be utilized, but the rise time must be sufficiently fast that the nerve membrane does not accommodate and fail to fire if an action potential is wanted. The stimulus waveform may be unidirectional (monophasic) or bidirectional (biphasic).

Biphasic stimulus is recommended for several reasons. Surface stimulation is more safe with biphasic than monophasic stimulation. Tissue damage is believed to be significantly related to the pH change at the electrode tissue interface. At the cathode, the pH may increase due to the production of OH^- , while at the anode the environment will become more acidic. While there exists some buffering capacity of pH changes in the tissue, the changes with monophasic stimulation are greater than those with biphasic. Although reactions at the electrodes are not completely reversed with the biphasic stimulation, this stimulus allows significantly greater charge injection before tissue damage is encountered. [7]

3.2.1 Concept of Galvanic vestibular stimulation unit (GVS)

For designing any medical equipment several safety regulations have to be followed. According to the IEC 60601-1 Medical safety regulations the GVS unit that is to be designed should obey certain rules. In designing we had to follow the requirements given by the researchers. They want to use the equipment to develop new, mild, and effective GVS stimulation for the therapeutic treatment of neglect patients and therefore this new device will be applied to patients. Unfortunately the flexibility needed by the researchers is somehow in contradiction to the safety regulations. To overcome this problem we decided to develop a current controlled GVS device whose stimulation current follows linearly an externally applied voltage over a broad frequency range. A galvanic decoupling within the GVS device is amended and also a micro controller based control unit to double check the control voltage, the applied stimulation voltage and current. With a direct access that can be controlled by a switch to disconnect the patient from the GVS device so as to protect the patient from any electricity based harm.

3.2.2 Specifications of the Galvanic vestibular stimulation unit (GVS)

For designing the equipment according to the flexibility and way of testing of clinicians and researchers, we were provided with certain specifications to fulfil there needs of testing the GVS unit on the Hemi spatial neglect syndrome patient. The following are the specifications given to us.

Table 3.2.2: Specifications of GVS unit

S.no	Description	Range
1	Voltage range	0 to \pm 35V
2	Current range	0 to \pm 7.5mA
3	Bandwidth	0 to 10 kHz
4	Security shutdown	after 2 hours
5	Two channels	\pm polarity
6	Isolation Voltage	1 KV

These specifications as shown in 'table 4.1' were to be achieved while obeying the safety regulations of medical equipment.

3.2.3 General safety regulations IEC 60601-1

The International technical committee (IEC) came up with certain general safety regulations. These safety regulations have to be kept in mind before designing any medical equipment. EQUIPMENT shall, when transported, stored, installed, operated in NORMAL USE, and maintained according to the instructions of the manufacturer, cause no SAFTEY HAZARD which could reasonably be foreseen and which is not connected with its intended application, in NORMAL CONDITION and in SINGLE FAULT CONDITION. EQUIPMENT or parts thereof, using materials or having forms of construction different from those detailed in this Standard, shall be accepted if it can be demonstrated that an equivalent degree of safety is obtained.

The following SINGLE FAULT CONDITIONS are the subject of specific requirements and tests in this Standard:

- a) interruption of a PROTECTIVE EARTH CONDUCTOR
- b) interruption of one supply conductor
- c) appearance of an external voltage on an F-TYPE APPLIED PART
- d) appearance of an external voltage on SIGNAL INPUT or on a SIGNAL OUTPUT PART
- e) leakage of the ENCLOSURE of a FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OT NITROUS OXIDE
- f) failure of an electrical component which might cause SAFTEY HAZARD
- g) failure of mechanical parts which might cause SAFTEY HAZARD
- h) failure of temperature limiting devices

Where a SINGLE FAULT CONDITION results unavoidably in another SINGLE FAULT CONDITION, the two failures are considered as one SINGLE FAULT CONDITION.

The following phenomena are considered by this Standard as unlikely to occur:

- a) Total electrical breakdown of DOUBLE INSULATION
- b) Electrical breakdown of a REINFORCED INSULATION

c) Interruption of a fixed and permanently installed PROTECTIVE EARTH CONDUCTOR.

Earthing of a PATIENT is considered as a NORMAL CONDITION.

Unless otherwise specified in the instructions for use, EQUIPMENT shall not be required to withstand the effects of operation under separate dust covers or sterile covers. Compliance with the requirements of this clause is considered to exist when the criteria of the relevant inspections and tests in this standard are achieved (IEC60601). [7]

To design any medical equipment these general safety considerations are to be considered. So we had to think of a design which would follow these regulations and our purpose of the equipment is therefore fulfilled. The GVS unit was designed and implemented considering the safety hazards to avoid any kind of electrical shock hazards to the patient. Several optocouplers have been used to provide total isolation and insulation. The device will be shutting down itself if it exceeds the desired output voltages, with the help of a fuse. Proper earthing is given to the entire device if in case of a short circuit will ensure no harm is caused to the patient by any of the components on the board.

3.2.4 Galvanic vestibular stimulation unit system design

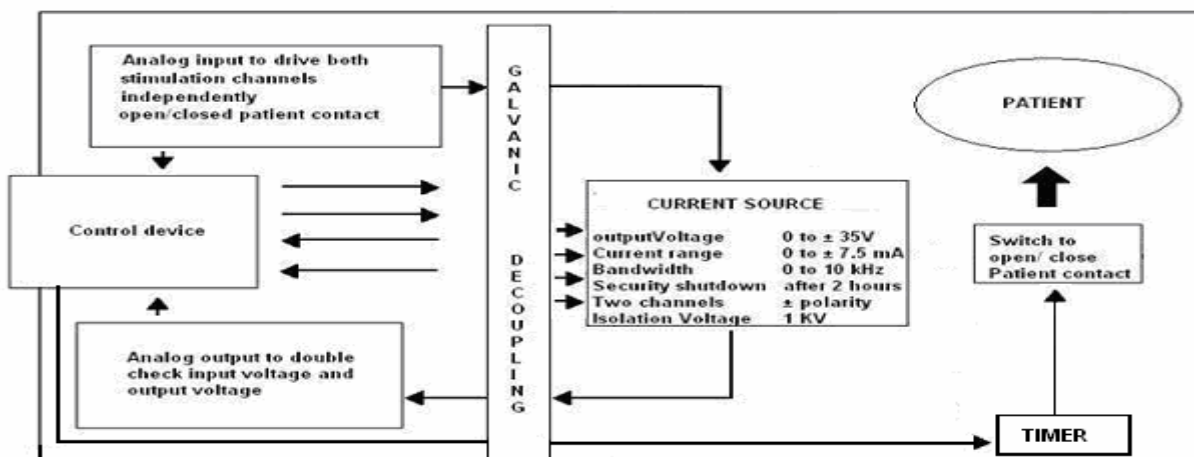


Figure 3.2.4 Block diagram showing the various components in the system design

The basic idea was to design a galvanic vestibular stimulation device with a current source following the researcher's needs for flexibility for any experimental setup and additionally considering very strictly the safety regulations for medical devices. There are several aspects which we have considered in our design such as the isolation voltage, which is limited with the help of optocouplers which carry out galvanic decoupling. The analog inputs from the two channels are being passed through the optocoupler to protect the patient with any kind of electric shock. The voltage should be regulated, so we have used voltage regulators which can shutdown if they are exceeding the voltage limits. To protect the overload in case of a short circuit, a fuse is also being implemented to shut down the entire supply given from the battery. A switch is implemented in the power supply to turn of the device and the supply given to the patient at the two channels. We made use of relays to avoid any kind of inconsistency in the supply. All the operational amplifiers are being provided with capacitors to prevent any kind of overload or noise at the outputs.

The switch is capable of enabling or disabling the patient contact. To ensure constant supply, we have special operational amplifiers have been used only for measurement purposes such as the voltage and current outputs. To make a proper analysis of the analog input/output supply a continuous monitoring of the output voltages is also a priority to double check what the patient is provided with. An micro controller based control unit to double check the control voltage and the applied stimulation voltage and current with direct access to the switch to disconnect the patient from the GVS device should protect the patient from any electricity based harm. However the design of this control unit was not part of this project. This device is also being provided with programmable timer which shall stop the supply to the patient after e.g. 2 hours to ensure patients security. The device after being designed has to undergo various tests before being implemented on a neglect patient. Various safety regulations have been followed as per the International Electro technical Committee (IEC) published IEC 61010-1.

4. Results

4.1.1 Design of current source "TEST CASE"

The task was to design a circuit for a constant current controlled stimulator, adapting change in loads and which can work both long lasting constant current stimulation and short high frequency pulsed current stimuli. With a proceeded 'miniproject' a current source with different specifications had been developed. The required parameters were:

1. Current amplitude 0 - 7.5 mA
2. Voltage range 0 – 35 V
3. Max load up to - 1.5 k Ω
4. Response time to changes in load ~100 μ s
5. Frequency changes of stimulation 0 – 5 KHz

The necessary changes were due to different specifications. It can act equally well in any application where a low power external stimulator with adjustable current and pulse width is required and is also suitable for use with surface electrodes. It is an analog circuit which is using a power source of 5V DC supply. The circuit is designed using 5spice software for simulation.

4.1.2 Task of operational amplifiers (opamps)

The concept is based on operational amplifiers (opamp), with feed back voltage measured on the output. Operational amplifier in general has five pins, two of those are inputs, two of the pins are supply pins and finally there's an output pin. Some opamps may have more pins for external compensation. Some opamps have shutdown pins and some may have a differential output stage. Opamps must have very high input impedance, very high open loop gain and very low output impedance. It is not possible to achieve all these in one single stage. Opamps generally have three different stages.

Stage1: The first stage is a differential amplifier. Stage2: The second stage is the gain stage and finally the third stage is the output stage of the operational amplifier.

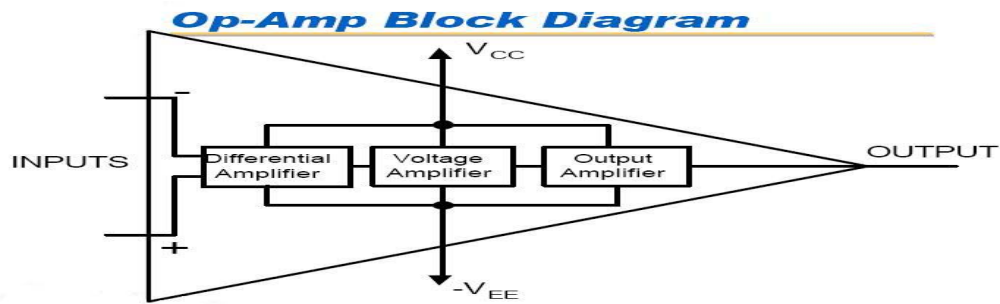


Figure 4.1.2: Operational amplifier (opamp) block diagram, showing various stages

Stage1 (Differential Amplifier Stage):

- Provides differential input for the opamp
- Provides dc gain
- Has very high input impedance which draws negligible input current and enables user to utilize ideal opamp equations for circuit analysis.

The next stage of the opamp is the voltage gain stage. This gain stage is mainly responsible for gaining up the input signal and sending it to the output stage.

Stage2 (HIGH gain voltage amplifier):

- Provides the “gain” of the amplifier
- Gains up the differential signal from input and conveys it to the output stage.

Stage3 (Low Impedance output stage):

- Delivers current to the load
- Very low impedance output stage - To minimize loading the output of the op-amp may have short circuit protection.

The opamp must have very low output impedance. This minimizes the loading of the output of the opamp by stage of the opamp. The output stage delivers current to the opamp’s load and it may or may not have short circuit protection.

Inputs of operational amplifier

Two input terminals

- Positive Input (Non-Inverting)
- Negative Input (Inverting)

Can be used in three different “input” modes

- Different input mode
- Inverting Mode
- Non-Inverting mode

Differential input mode

- Both input terminals are used
- Input signals are 180° out of phase
- Output is in phase with non-inverting input

In general, operational amplifier (opamp) can be setup in three different input modes. These three are differential input mode, inverting input mode and non-inverting input mode. In the differential input mode, the signal is applied to both of the input terminals. These signals have to be out of phase and the output is going to be completely in phase with the non-inverting signal. In case the signals that are applied to both the inputs are in phase, there should be no output and that input signal is referred to as the common mode signal. The output is grounded or output is sitting at mid-supply or output is zero. So basically we have a negative voltage and a positive voltage on the supply ends of the opamp.

Inverting mode

- Non-Inverting input is grounded (connected to mid-supply)
- Signal is applied to the inverting input
- Output is 180° out of phase with input

In the inverting mode the non-inverting input of the amplifier is grounded or it's connected to mid-supply. Input signal is applied to the negative input and the output signal is completely out of phase with the input signal.

Inverting Closed Loop

- R_f is used to feedback "part" of the output to the inverting input

Negative input is at virtual ground characteristics of this circuit almost entirely determined by values of the R_f and R_G fig2.3 (below)

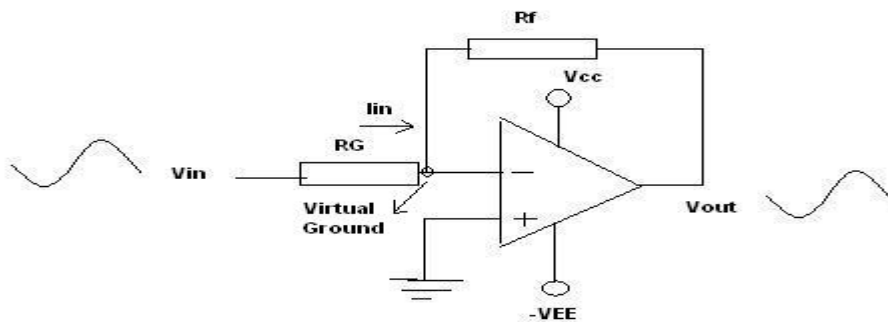


Figure 4.1.2: $i_{in} = V_{in}/R_G$, $I_{feedback} = -V_{out}/R_f$, $I_{feedback} = i_{in}$

The two currents must be equal since input bias current is zero. In this configuration the positive input is grounded. The circuit characteristics are determined by values of feedback resistors and gain resistor. Since no current is flowing into the input pin of the amplifier, all the current that is coming back from the feedback path is going to go through the gain resistor. So basically the input current and the feedback current are going to be equal. Since the non-inverting pin is grounded, the inverting pin is going to be sitting at the virtual ground. Feedback current is equal to $-V_{out}/R_f$. The negative sign indicates that the output signal is completely out of phase with the input signal. The input current is V_{in}/R_G . Now if we set these two currents equal, we find the gain relationship of the operational amplifier is $V_{out}/V_{in} = -R_f/R_G$. This is referred to as the operational amplifier's closed loop gain. As mentioned before the negative sign indicates that the input and output signal are completely out of phase with each other. The op27c is more appropriate for this circuit design.

4.1.3 Operational amplifier (op27c)

The op27c is a precision operational amplifier combines the low offset and drift of the op07 with both high speed and low noise. Offsets down to 25 μ V and maximum drift of 0.6 μ V/ $^{\circ}$ C, makes the 'op27' ideal for the precision instrumentation applications. Exceptionally low noise, $e_n = 3.5\text{nV}/\sqrt{\text{Hz}}$, at 10Hz, a low 1/f noise corner frequency of 2.7Hz and high gain, allow accurate high gain amplification of low-level signals. A gain-bandwidth product of 8MHz and a 2.8V/ μ sec slew rate provides excellent dynamic accuracy in high-speed, data acquisition systems. A low input bias current of $\pm 10\text{nA}$ is achieved by use of a bias-current cancellation circuit. Over the military temperature range, this component typically holds input bias current (I_B) and input offset current (I_{OS}) to $\pm 20\text{nA}$ and 15nA, respectively. The output stage has good load driving capability. A guaranteed swing of $\pm 10\text{V}$ into 600 Ω and low output distortion make the op27c an excellent choice. [4]

4.1.4 Test circuit components:

Table 4.1.4: Test circuit components

S.no	Description	quantity
1	Opamp OP27	2
2	Resistors R6,R5 (1k Ω)	2
3	Resistor R (1.51k Ω)	1
4	Ammeter, Tpi	1
5	Resistor R8, R3 100 Ω	2
6	Resistor R7 -50 Ω	1
7	Voltage source 5V	1
8	Tpv1 , test point	1
9	Ui , test point	1
10	Ua , test point	1
11	Tpi , test point	1

4.1.5 Simulation with 5Spice

5Spice is a general-purpose electronic circuit simulation program with a full graphical user interface. It wraps around a traditional Spice simulation engine, presenting a single application to the user. 5Spice provides specific schematic entry, the ability to define and save an unlimited number of analyses and graph setups, and integrated graphing of simulation results. Spice concepts like sub circuits, coupled inductors, nonlinear functions, initial conditions and node voltages are represented visually in the schematic. The simulation engine is based on Spice version 3.4/3.5 with syntax extensions for improved compatibility with PSpice® sub circuits.

The program is intended to provide the analysis and documentation capabilities needed by experienced circuit designers while remaining easy to use - a step up from student oriented Spice programs. The focus is on analog circuit analysis and circuit design at the component level. 5Spice provides 'DC Bias', 'non-linear analyses': DC, Transient, Harmonic Distortion and DC Sensitivity and 'linearized analyses': AC and 'Noise analysis'. 'AC Sensitivity' analysis is expected soon. Results of Distortion, Noise and Sensitivity analyses are displayed only after the program has been registered. Circuits may contain resistors, capacitors, inductors, transformers (coupled inductors), transmission lines, independent voltage and current sources, four types of linear dependent sources, non-linear (arbitrary formula) dependent sources, linear opamps, switches, and semiconductor devices: diodes, Bipolar Junction Transistor (BJT's), junction field effect transistor (JFET) and Metal-Oxide Semiconductor Field-Effect Transistor (MOSFET). Specific device Models as well as sub circuits built from parts listed above may be stored in the program's library and represented by symbols in the schematic. Almost all manufacturer supplied sub-circuits will work.

4.1.6 Analysis in 5Spice

Analysis consists of a 5Spice simulation such as:

DC bias, DC, AC, Transient, Noise, Distortion and

- Parameters defining the simulation,
- An associated graph (DC bias has no graph)

-
- A selection list of the voltage and current Signal Sources that will be active during the analysis.
 - At least one Test Point that defines the circuit point for graphing or table of results.

Selecting, creating and editing of analyses and associated graphs are performed using the Analysis dialog. Open the Analysis dialog through Main Menu Analyze. There is an Analysis RUN button at the top of the vertical toolbar. [12]

4.1.7 Circuit Analysis

To perform an analysis, each circuit node must have a DC path to ground unless it is terminated with a 'No Connect symbol'. (Circuitry with no AC or DC connection to ground whatsoever is ignored during analysis). There must be at least one ground symbol in the schematic. The circuit was initially simulated using 5Spice software, where we have assembled all the above said components. The simulation was carried out by putting up test points such as the ammeter (Tpi) and voltage test point (Tpv1). The current (Ui) was measured using this test point. The 5Spice software was enabled to make a simulation and learn the circuit outputs at various test points. Voltage and current outputs were studied to make a proper circuit design. The circuit stimulation using the software is represented in below in fig 4.7.

4.1.7 Test Circuit diagram

The below circuit below was modified by placing in a relay/switch in between the two loads as shown below in figure 4.1.7. The opamp enables the circuit to switch between the two loads. From the figure 4.1.7, we can see that we have made use of two OP445A opamps which are additionally supplied with several resistors, battery supply and a voltage source. A relay is implemented across the load resistor, which gives us the flexibility to switch between the loads. Before implementing the above circuit we had to simulate the circuit using 5spice simulation software. After achieving the required results we had to proceed with the assembling of the components on a PCB (printed circuit board) board.

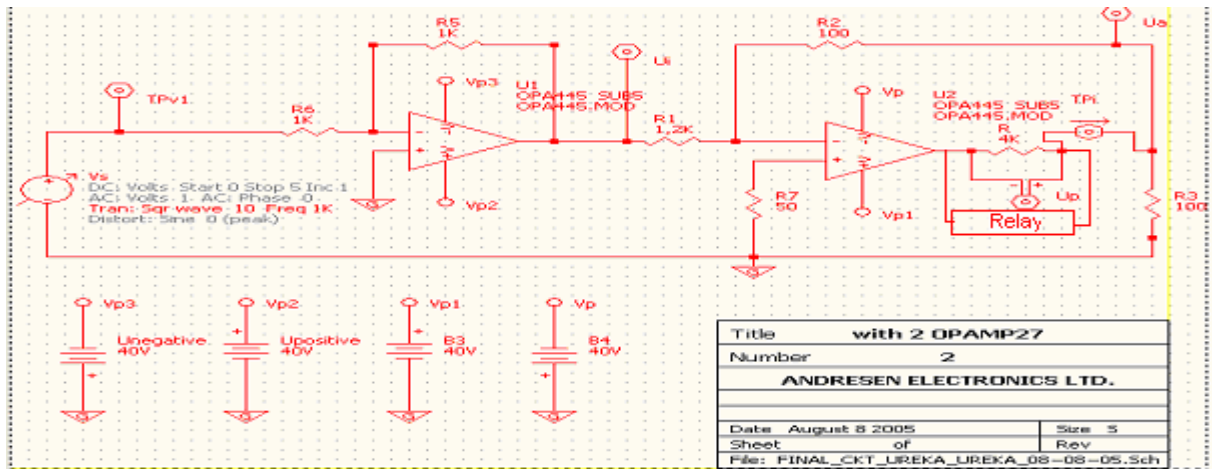


Figure 4.1.7 showing the circuit simulation using 5spice, the two operational amplifiers OP445A along with the relay and the resistors and the DC source along the test points.

4.1.9 Working circuit diagram of an operational amplifier

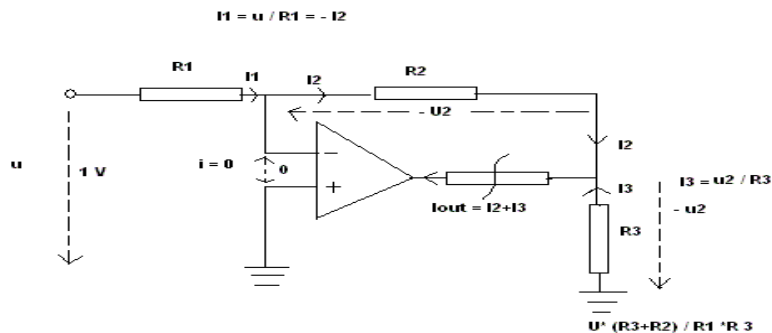


Figure 4.1.9: Working of an operational amplifier (opamp)

$$I_{Out} = (u \cdot (R_2 / R_1) / R_2) + (u \cdot (R_2 / R_1) / R_3)$$

$$I_{OUT} = u \cdot (R_2 / R_1) \cdot R_3 + u \cdot (R_2 / R_1) \cdot R_2$$

$$I_{Out} = (U \cdot (R_2 / R_1) \cdot (R_3 + R_2)) / (R_2 \cdot R_3)$$

From the equations above we have calculated the required resistor values for the simulation of the opamp for the desired current and voltage outputs.

4.1.10 Circuit simulation for DC & Transient bias

The DC-Bias simulation of the circuit gave these values below considering the various test points. Ua, Ui and TPv1 as shown in figure below.

Node	Bias
1 Ua	-1,3262E-6
2	-1,4271E-6
3 Ui	-2,3083E-6
4	-1,2915E-6
5 TPv1	-1,2915E-12
6	-1,3739E-8
7	-1,3262E-6
8	-40
9	40
10	-40
11	40
12	-5,0339E-5
13 Up	4,9012E-5
I@ B3	-0,004003 A
I@ B4	-0,0040029 A
I@ TPi	-1,2253E-8 A
I@ UNEGATI...	-0,0040029 A
I@ UPOSITIVE	-0,004003 A

Figure 4.1.10: The DC simulation values of the circuit that were achieved after the simulation of the circuit.

The values in figure 5.9 are as follows:

The test points Ua = $-1.326 \cdot 10^{-6}$ A

The test point Ui = $-1.4271 \cdot 10^{-6}$ A

The test point TPv1 = $-1.2915 \cdot 10^{-12}$ V

The test point Up = $4.9012 \cdot 10^{-5}$ A

The test point TPi = $-1,225 \cdot 10^{-8}$ A

The test point 'Ua' near the load resistor, gave us a current of $1.326 \cdot 10^{-6}$ A. The test point 'Ui' after the first opamp 'op445' gave us the current value of $-1.4271 \cdot 10^{-6}$ A. The test point 'Tpv1' which is taken after the voltage source was $-1.2915 \cdot 10^{-12}$ V. The test point of 'Up' across the load resistor was $4.9012 \cdot 10^{-5}$ A. The test point 'Tpi' after the load resistor gave us the current value of $-1,225 \cdot 10^{-8}$ A. These values ensured us of a proper output from the simulated circuit.

4.1.11 The transient analysis

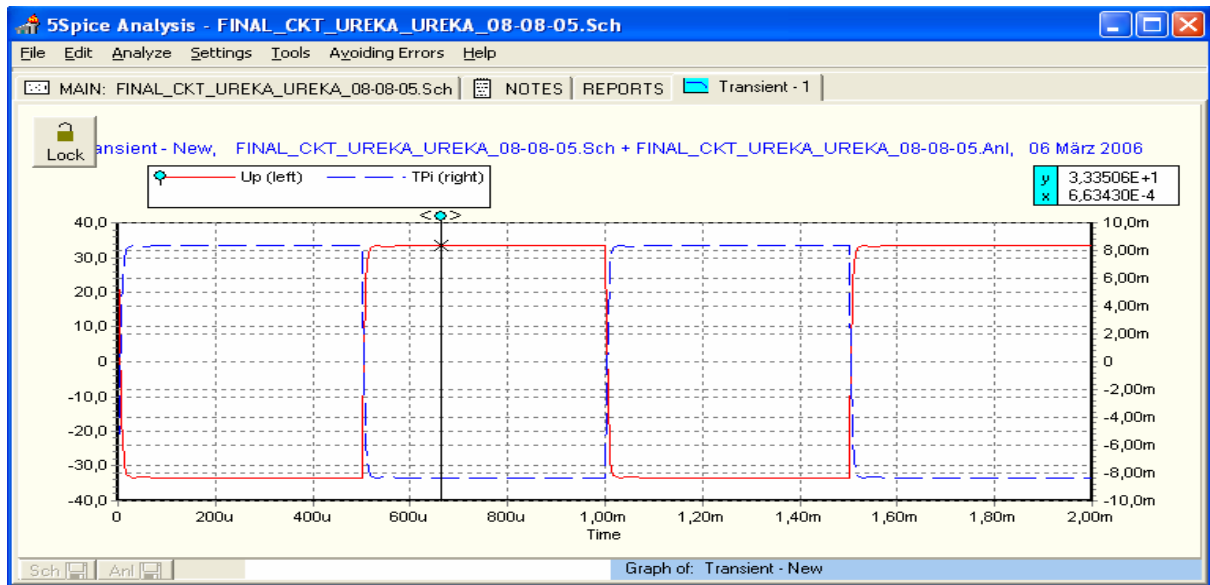


Figure 4.1.11: The transient simulation analysis graph of the circuit

From figure 4.1.11, we can see that, the transient analysis achieved the desired voltage and current ranges. On the right y-axis we have the current ranging from ± 10 mA. The voltage ranges between ± 40 V on the left y-axis. The time range on the x-axis is starting from 0 to 2 ms. The voltage 'Up' starts from zero and ranges up to ± 35 V approximately. The current ranges from ± 8.5 mA. Seeing this result we have proceeded with the circuit assembly.

4.2.1 Testing of the current source circuit

After the circuit designing was complete we built up a test setup for testing the circuit. This included various test equipments such as the DC power supply, DC voltage regulator and an oscilloscope.

4.2.2 Circuit assembled on board

The circuit assembly was done on a single layer printed circuit board (PCB) of 10×6.8 cm, the circuit design was made with the proper assembly and there by soldering was done according to the circuit design as shown below in figure 6.5. This is the final built in Test circuit on the PCB board.

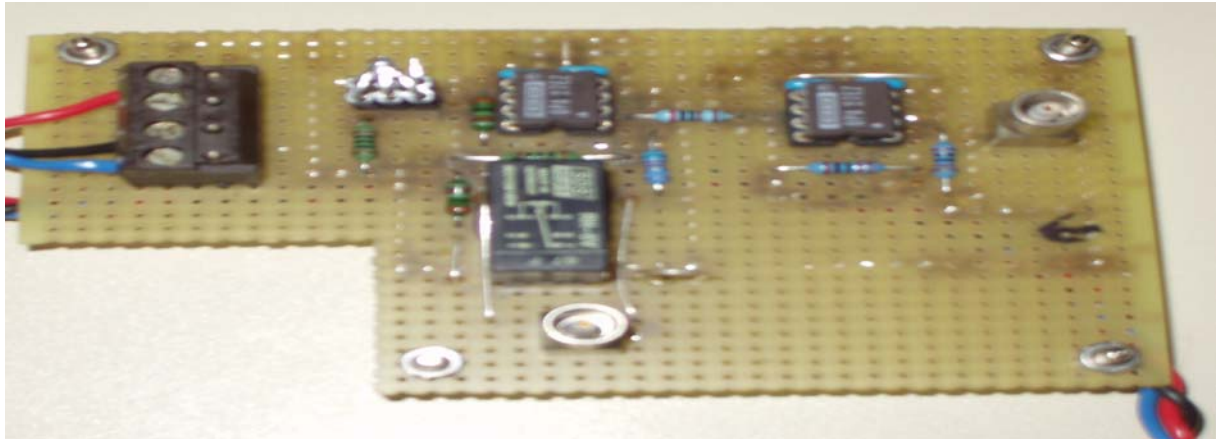


Figure 4.2.2: The designed test circuit

4.2.3 Principal test setup of the circuit

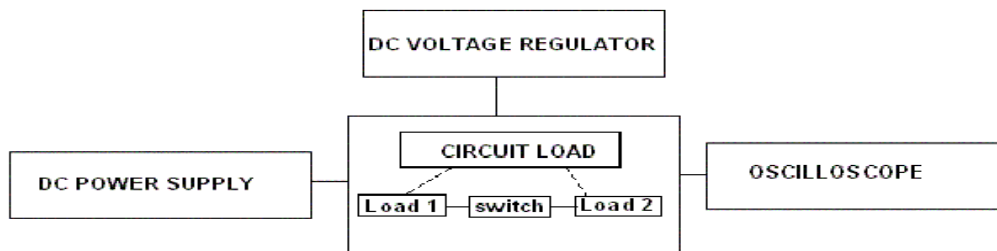


Figure 4.2.3: The principal test setup of the circuit showing, DC power supply, oscilloscope, DC voltage regulator.

DC power supply: - The DC power supply is a constant voltage generator gives a voltage of 5 V to the circuit input.

DC Voltage regulator: - The voltage is regulated by the DC voltage regulator; it maintains adequate power supply as per our settings.

Circuit load: - The circuit loads, load1 and load2 where the opamps switch between with the help of the relay/switch.

Oscilloscope: - The outputs in the form of graphs were collected at the load and can be viewed in the form of graphs by using the oscilloscope.

The circuit after designing was made to test by the above said setup. The DC power supply provides a voltage of 5 V to the circuit the voltage was regulated by the voltage regulator. The DC power supply and the DC voltage regulator provided adequate power supply to the circuit. The opamps after receiving this power supply react to the input voltage supply and thereby enable the circuit loads to switch between loads (load1 & load2). The oscilloscope was connected at the output loads which enabled us to take the graphs for the time delay and the response time. The graph values were there by stored in a floppy with the oscilloscope and then reopened with Microsoft XL. The time delay and the response of the loads were studied by this setup. The values that were collected on testing the circuit were reused to plot the graphs of Time delay and the response of the load.

4.2.3 Current vs Voltage

From figure 6.2.1: The circuit was tested by applying voltages, and the changes in current were measured using an oscilloscope. The graph below shows the current and voltage characteristics. For a given input voltage of ± 5 V the load current varied from ± 12 mA approximately, the time period between the loads is 120 μ s.

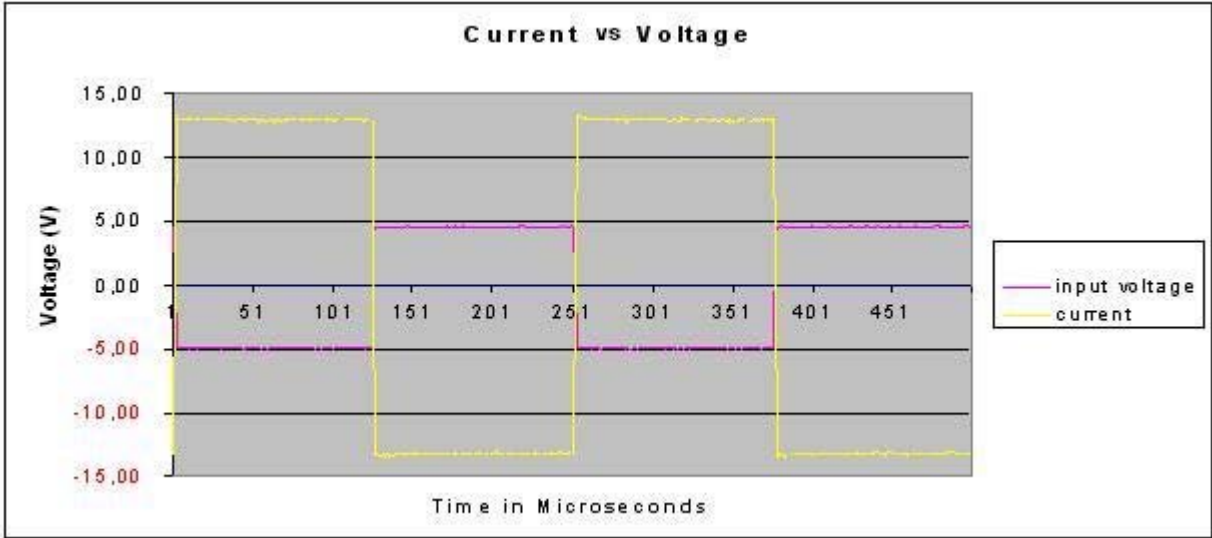


Figure 4.2.3: showing the adaption time to load changes

The figure 4.2.3.1 below shows us the adaptation (reaction) time on the loads changes of 1.5 k Ω . The time needed by the opamp to bring the constant current as the load switches between the two load resistors. The response starts from 61 μ s up to 300 μ s. The duration of this response of the load is 239 μ s.

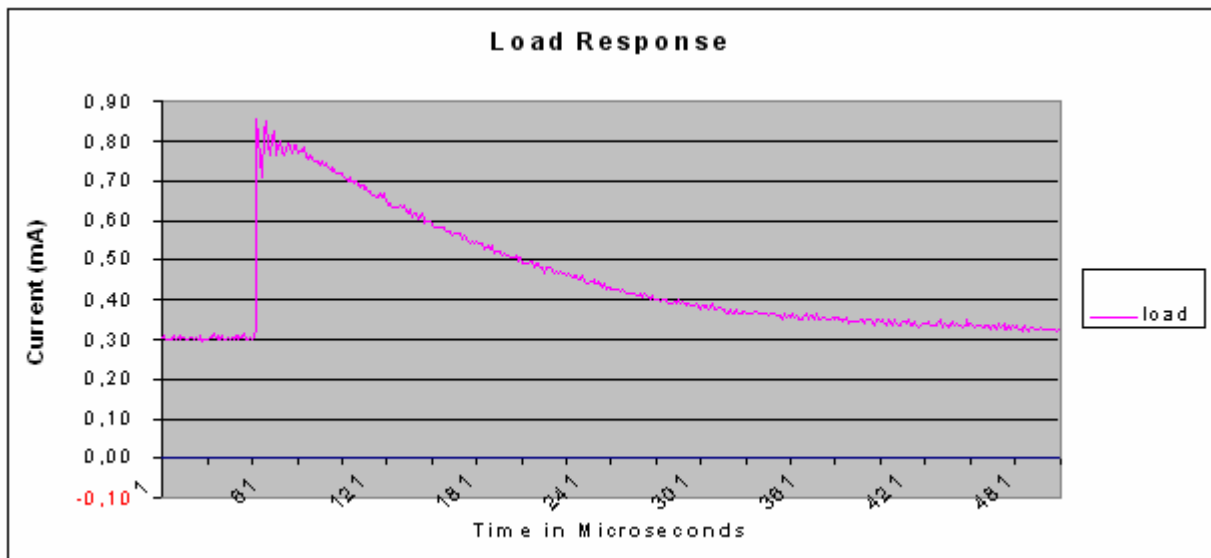


Figure 4.2.3.1: showing the load response value

4.2.4 Adaptation (response time) of the operational amplifier

The figure 4.2.4 shows the response time of the operational amplifier. The measurement was taken such that the response time of the operational amplifier was measured the input voltage is ± 5 V and response current of the opamp starts from -1 mA and crosses over the time period at 125 μ s and then remains constant till it reaches approximately 8 mA.

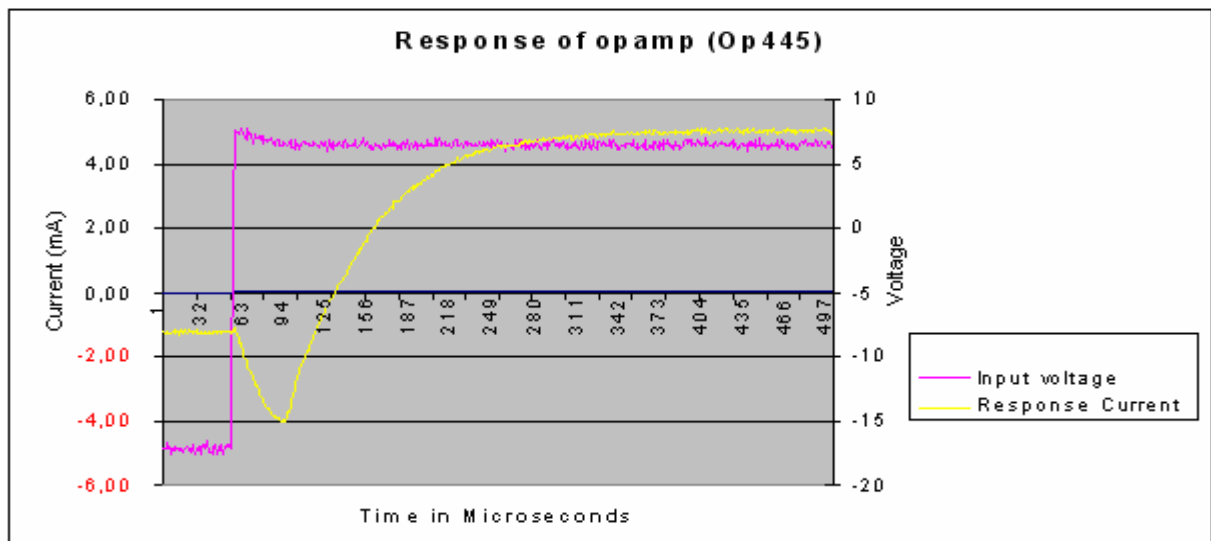


Figure 4.2.4: showing the response time of operational amplifier A445

4.2.4 Voltage vs Load

From the graph 4.2.4 below the load measurement shows the changes in voltage over the load at a frequency of 1 kHz. As seen above from the values of the graph, the load current remains constant. Starting from zero reaching approximately ± 14 mV and the time period between them is measured to be 0.5 ms.

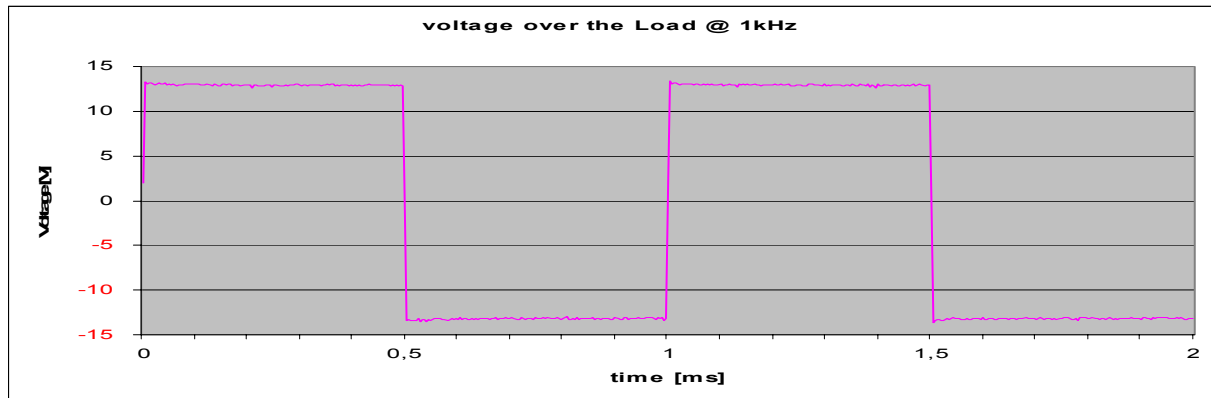


Figure 4.2.4: showing the Voltage over the load graph

After successfully testing with the test circuit for the current source, the complete GVS device was planned to be made using Protel which is more sophisticated software, used in ZEL (Central Institute for Electronics, Research Centre Juelich) for various circuit designs. The difference between the earlier mini project (CONSTANT CURRENT STIMULATION CIRCUIT DESIGN FOR THE BRAIN) is that it had different requirements compared to the Main project test circuit. To achieve the requirements of the Main project test circuit we had to use different operational amplifier op445A where as previously we used operational amplifier op27.

Table 4.2.4: showing the specifications of Mini and Main project

S.no	Description	Miniproject (test circuit)	Main project (test circuit)
1	Current range	0 to ± 10 mA	0 to ± 7.5 mA
2	Voltage range	0 to ± 15 V	0 to ± 35 V
3	Max loads	1.5 k Ω	6.5 k Ω
4	Response time	5 μ s	μ seconds

5. Results II

5.1 Galvanic vestibular stimulation unit design

After the test circuit being successfully tested and implemented we have proceeded with Protel for a final circuit assembly following the safety regulations. Perhaps the greatest challenge when working on a complex electronics design is managing the large number of design objects. From the components, net labels and text strings on the schematic sheets, through to the hundreds of components and the tens of thousands of track objects that make up the routing on the PCB, as the designer we need to be able to access, review and edit these objects. Altium Designer Protel has it all.

The Altium Design Explorer is an integrated environment for electronics design. It provides tools for all tasks from schematic and VHDL design capture, circuit simulation, signal integrity analysis through to PCB design. In addition, the environment can be customized to meet a wide variety of user requirements.

Design explorer allows you to access all documents related to a design via its user Interface. The basis of any design is the project. The project links the elements of your design together, including the source schematics, the netlist, any libraries or models you want to keep in the project and the PCB. The project also stores the project-level options, such as the error checking settings, the multi-sheet connectivity mode, and the multi-channel annotation scheme.

There are three project types – Printed circuit board (PCB) projects, FPGA projects, core projects, Embedded Projects, Script Projects and Library Packages (the source for an integrated library). Related projects can also be linked under a common Workspace, giving easy access to all files related to a particular design. When you add documents to a project, such as a schematic sheet, a link to each document is entered into the project file. The documents can be stored anywhere on your network; they do not need to be in the same folder as the project file. [13]

5.1.1 'Channel1' of the Galvanic vestibular stimulation unit

The following are the given circuit names of 'channel 1' while designing with Protel.

1. 'CURRENT SOURCE-Ch1_100': This is the name given to the 'Current source' of the circuit; it is mainly responsible for the current supply to the patient with the help of timer and a relay. The outputs from this circuit are given to the patient with the help of electrodes. The voltage and current delivered to the patient are being measured by the measuring opamps.
2. 'ISO_lmeas_ch1_400': This is the name given for the 'Current measurement' the purpose of this circuit is the current measurement after galvanic decoupling.
3. 'MEASURE-CH1_900': This is the circuit for the '*enable signal*' the purpose of this circuit is to make the enable signal pass through the galvanic decoupling, so that enable signal does not carry any high currents. The optocoupler provides with the isolation of the enable signal.
4. 'MEASUREMENT-CH1A_800': The purpose of this circuit is to measure the current signal that shall be provided to the current source.
5. 'ISO_Umeas_ch1_200': The purpose of this circuit is the 'voltage measurement'

5.1.2 Working of the Channels (channel 1)

The each block in the above block diagram represent sub circuit diagrams of an entire channel (channel1), the connection between them is being shown by arrows. 'Iso_Umeas-ch1_200' circuit has the connector, which allows several connections such as the *Iprimary*, *Enable primary*, *I measure primary* (Current measurement), Umeas secondary (voltage measurement). To start with the *Iprimary* signal is given to the 'MEASUREMENT_CH1A_800', a current signal, from here in the form of *Isecondary* is given to the 'Current Source-CH2_100'. The *Imeas Secondary* (Current measurement) signal is given to the 'Iso_lmeas-ch1_400' there by enabling the isolation. The *Imeasure primary* from the 'ISO_lmeas-ch1_400' is then passed on to the connector at 'Iso_Umeas-ch1_200'. The *Enable primary* from the 'Iso_Umeas-ch1_200' is given to the 'MEASURE-CH2_900', in the form of *enable secondary* this signal is then passed to the 'CURRENT SOURCE-CH1_100' which has the 'enable signal as an output. The *Imeas Secondary* from the 'CURRENT SOURCE-CH1_100'

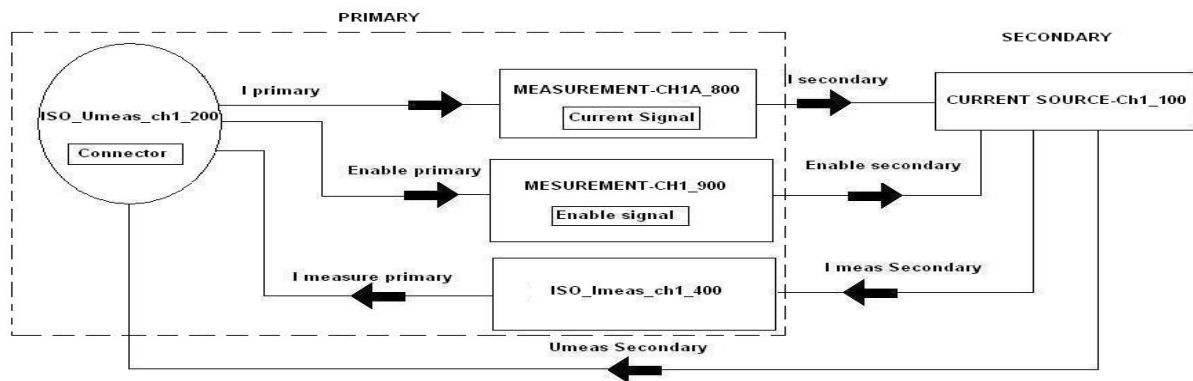


Figure 5.1.2: Block diagram showing various circuits of the channel one

is given to the 'ISO_Imeas-ch1_400'; the Imeasure primary from the 'ISO_Imeas-ch1_400' is then given back to the connector. The Umeas Secondary from the 'CURRENT SOURCE-CH1_100' is also given back to the connector in the 'ISO_Umeas_ch1_200'.

5.1.3 CURRENT SOURCE- Ch1_100 Circuit diagram

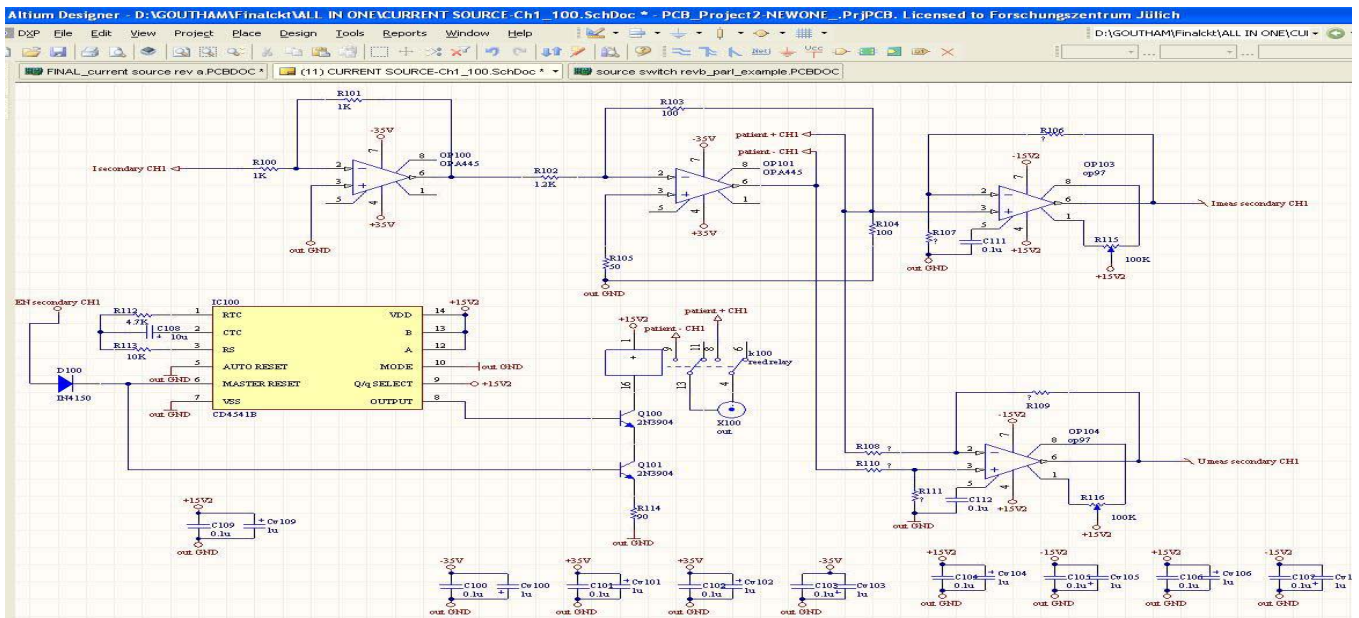


Figure 5.1.3: Circuit 'CURRENT SOURCE- Ch1_100'

For the channel 1 current source we use two OP445A opamps (op100, op101) in series, the output from these two opamps will be given to the patient while passing

through the reed relay (k100). The two other opamps op97 (op103 (+ve), op104 (-ve)) are connected to the outputs from the series connection of the op445A. One of them is used for the measurements of voltages and currents in the positive direction and the other is used for the the negative measurements. CD4541B is a timer which is connected to the reed relay. The outputs from the reed relay are given to the patient. The timer is capable of shutting down the supply entirely after 2 hours. The purpose of the timer is to make the circuit function for example till 2 hours and the patient shall be given no supply voltage or current after this period of time until and unless switched manually. This is to prevent any harm caused to the patient. The 'CURRENT SOURCE-Ch1_100' circuit is provided with I secondary and Enable secondary from 'MEASUREMENT-CH1A_800' and 'MEASUREMENT-CH1A_900' respectively. The I meas secondary from this circuit is given to the 'ISO_I meas_ch1_400'. I meas primary is sent back to the connector in the 'ISO_U meas_ch1_200' circuit.

Table 5.1.3: Component list 'CURRENT SOURCE- Ch1_100'

S.NO	Component	Description	Quantity
1	Opamp	OP445A	2
2	Opamp	OP97	2
3	Diode	IN4150	1
4	Timer	CD4541B	1
5	Resistors	100k	2
6	Resistors	100 Ω	2
7	Resistors	90 Ω	1
8	Resistors	50 Ω	1
9	Resistor	10k Ω	1
10	Resistor	4.7k Ω	1
11	Resistor	1.2k Ω	1
12	Resistor	1k Ω	2
13	Capacitor	10u	1
14	Transistor	2N3904	2
15	Capacitor	1u	9
16	Capacitor	0.1 u	11
17	Reed relay	Relay	1
18	Measuring resistors	-	1

5.1.4 Operational amplifier 'op97'

The op97 is a low power alternative to the industry standard op07 precision amplifier. The op97 maintains the standards of performance set by the op07 while utilizing only 600 μA supply current, less than 1/6 that of an op07. Offset voltage is an ultra low 25 μV , and drift over temperature is below 0.6 $\mu\text{V}/^\circ\text{C}$. External offset trimming is not required in the majority of circuits.

Improvements have been made over op07 specifications in several areas. Notable is bias current, which remains below 250 pA over the full military temperature range. The op97 is ideal for use in precision long-term integrators or sample-and-hold circuits that must operate at elevated temperatures.

Common-mode rejection and power supply rejection are also improved with the op97, at 114 dB minimum over wider ranges of common-mode or supply voltage. Outstanding power supply rejection (PSR) a supply range specified from $\pm 2.25\text{ V}$ to $\pm 20\text{ V}$ and minimal power requirements of op97's combine to make the op97 a preferred device for portable and battery-powered instruments.

The op97 conforms to the op07 pin out, with the null potentiometer connected between pins 1 and 8 with the wiper to $V+$. The op97 will upgrade circuit designs using 725, op05, op07, op12, and 1012 type amplifiers. It may replace 741-type amplifiers in circuits without nulling or where the nulling circuitry has been removed.

Absolute maximum ratings:

Supply voltage.....	$\pm 20\text{V}$
Input Voltage.....	$\pm 20\text{V}$
Differential Input voltage.....	$\pm 1\text{V}$
Differential Input Current.....	$\pm 10\text{mA}$
Output Short-Circuit Duration.....	Indefinite. [5]

5.1.5 Timer 'CD4541B'

CD4541B is a programmable timer, it consists of a 16-stage binary counter, an oscillator that is controlled by external R-C components (2 resistors and a capacitor), an automatic power-on reset circuit, and output control logic. The counter increments on positive-edge clock transitions and can also be reset via the MASTER RESET input. The output from this timer is the Q or \bar{Q} output from the 8th, 10th, 13th, or 16th counter stage. The desired stage is chosen using time-select inputs A and B (see Frequency Select Table). The output is available in either of two modes selectable via the MODE input, pin 10. When this MODE input is a logic "1", the output will be a continuous square wave having a frequency equal to the oscillator frequency divided by 2N. With the MODE input set to logic "0" and after a MASTER RESET is initiated, the output (assuming Q output has been selected) changes from a low to a high state after 2N-1 counts and remains in that state until another MASTER RESET pulse is applied or the MODE input is set to logic "1".

Timing is initialized by setting the AUTO RESET input (pin 5) to logic "0" and turning power on. If pin 5 is set to logic "1", the AUTO RESET circuit is disabled and counting will not start until after a positive MASTER RESET pulse is applied and returns to a low level. The AUTO RESET consumes an appreciable amount of power and should not be used if low-power operation is desired. For reliable automatic power-on reset, VDD should be greater than 5V.

The RC oscillator, shown in Figure 2, oscillates with a frequency determined by the RC network and is calculated using:

$$f = 1 / 2.3 R_{TC} C_{TC}$$

Where f is frequency between 1 kHz and 100 kHz and $R_s \geq 10k\Omega$ and $\approx 2 R_{TC}$

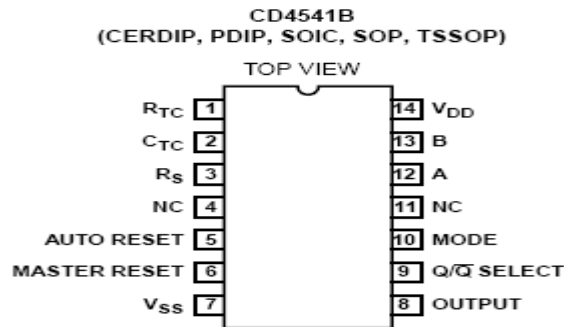


Figure 5.1.5: Block diagram of the timer 'CD4541B'

Absolute Maximum Ratings

DC Supply – voltage Range, V_{DD}

Voltage Referenced Range, V_{DD} Terminal0.5 V to +20 V

Input Voltage Range, All inputs.....-0.5 to V_{DD} +0.5 V

DC input Current, Any one inputs.....± 10 mA

Device Dissipation per Output Transistor for T_A = Full package Temperature Range
(All Package Types)..... 100 mw

Operating Conditions Temperature Range T_A-55 °C to 125 °C

Supply Voltage Range for T_A = Full Package Temperature Range.3V (Min), 18 V (Typ).

[1]

5.1.6 Operational amplifier 'OP445A'

The op445A is a monolithic operational amplifier capable of operation from power supplies up to ±45 V and output currents of 15 mA. It is useful in a wide variety of applications requiring high output voltage or large common-mode voltage swings.

The op445A's high slew rate provides wide power bandwidth response, which is often required for high voltage applications. Field effect transistor (FET) input circuitry allows the use of high-impedance feedback networks, thus minimizing their output loading effects. Laser trimming of the input circuitry yields low input offset voltage and drift.

The op445A is available in standard pin-out TO-99, DIP-8, and SO-8 surface-mount packages. It is fully specified from -25 °C to +125 °C.

Absolute maximum ratings (op445A)

Power supply.....	±50 V
Differential Input voltage.....	±80 V
Input Voltage range.....	±Vs -3V
Operating Temperature range.....	-55 °C to +125 °C. [3]

5.1.7 High-linearity Analog optocouplers

The HCNR200/201 high-linearity analog optocoupler consists of a high-performance AlGaAs LED that illuminates two closely matched photodiodes. The input photodiode can be used to monitor, and therefore stabilize, the light output of the LED. As a result, the nonlinearity and drift characteristics of the LED can be virtually eliminated. The output photodiode produces a photocurrent that is linearly related to the light output of the LED. The close matching of the photodiodes and advanced design of the package ensure the high linearity and stable gain characteristics of the optocoupler.

The HCNR200/201 can be used to isolate analog signals in a wide variety of applications that require good stability, linearity, bandwidth and low cost. The HCNR200/201 is very flexible and, by appropriate design of the application circuit, is capable of operating in many different modes, including unipolar / bipolar, AC / DC and inverting / non-inverting. The HCNR200/201 is an excellent solution for many analog isolation problems. [2]

5.1.8 Simulation of HCNR201 (Optocoupler)

To proceed further with the final circuit design, we had to simulate the optocoupler with 5spice, the circuit to check the optocoupler is shown below:

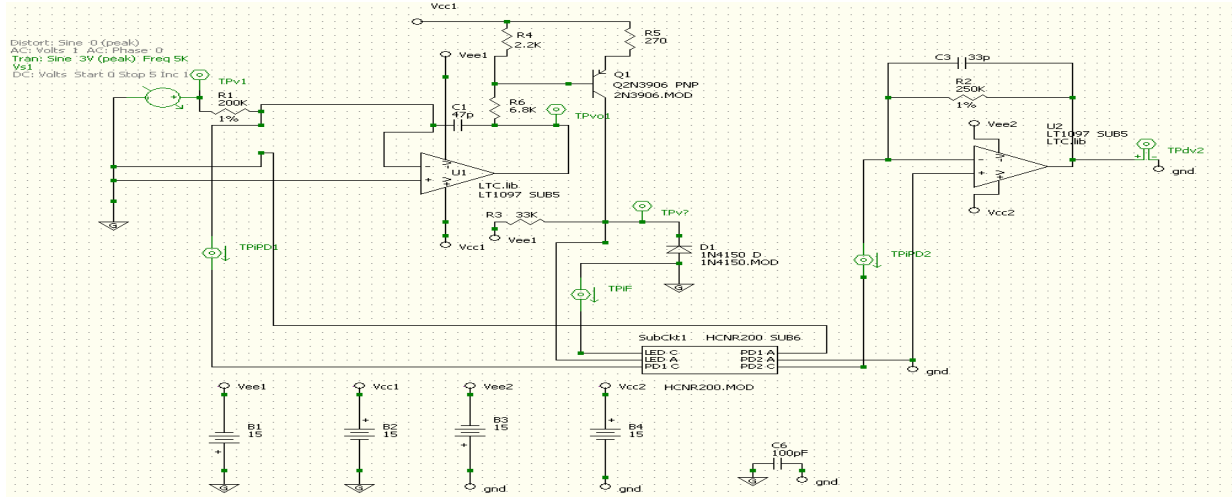


Figure 5.1.8: Simulation circuit of HCNR201

Checking of the optocouplers was carried out according to the datasheet schematic. The transient analysis simulation of the optocoupler gave the waveforms shown in figure 5.1.8.1

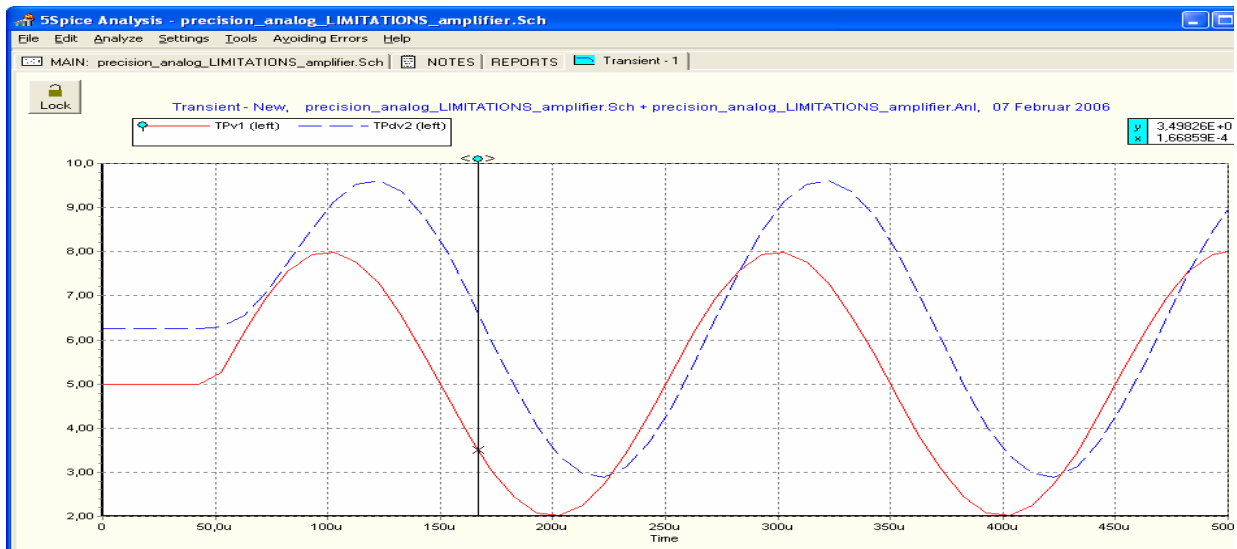


Figure 5.1.8.1: Transient analysis simulation graph of HCNR201

The simulation of the optocoupler gave the above waveforms, the TPv1 and TPdv2 are the test points 'TPv1' is the given input from the voltage source and 'TPdv2' is the

output voltage as show above the blue sine waveform. For a given input voltage of 3 V peak to peak at a frequency of 5 kHz the output voltage was constant and gave a voltage of approximately 9.5 V, thereby making this optocoupler ready to use in our final circuit design for the GVS unit.

5.1.9 The voltage measurement circuit ‘ISO_Umeas_ch1_200’

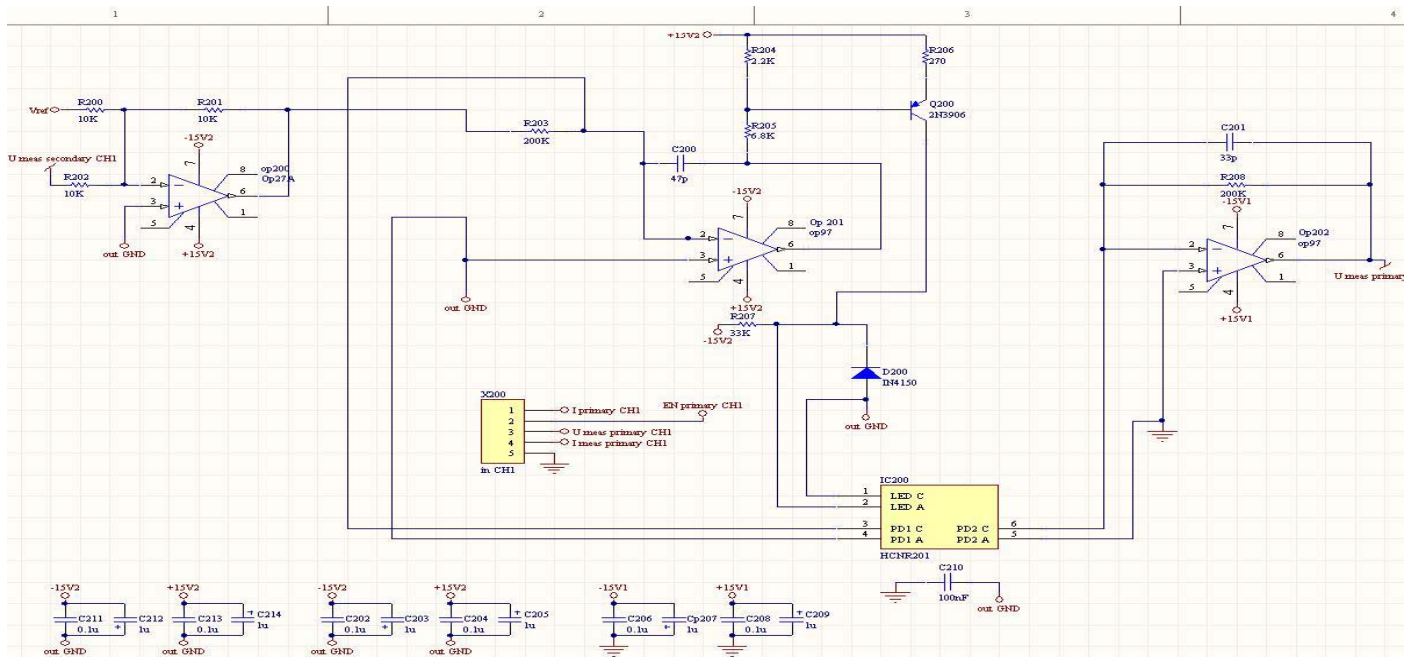


Figure 5.1.9: The circuit diagram of ISO_Umeas_ch1_200

The main function of this circuit is the isolation using the optocoupler (HCNR201). The op27A Operational amplifiers combine outstanding noise performance with excellent precision and high-speed specifications. The wideband noise is only $3 \text{ nV}/\sqrt{\text{Hz}}$ and with the $1/f$ noise corner at 2.7 Hz, low noise is maintained for all low-frequency applications, the feed back from this op27A is passed on to the op97 (Op201) with a resistor of 200 k in between. The output from the *Umeas secondary CH1* is given as the input to the negative pin of the opamp (op27A (op200)). The output from the op97 (Op201) is then given to the HCNR201 (IC200). The output from the HCNR201 is given to the second opamp op97 (op202); the output is given to the *Umeas primary*

CH1. The circuit also has a connector which has the following pins, such as

1. *I*_{primary} CH1,
2. *EN* primary CH1
3. *U*_{meas} primary CH1
4. *I*_{meas} primary CH1,
5. Ground.

The *I*_{primary} current from this circuit is passed on to the 'MEASUREMENT-CH1A_800' circuit. The 'Iso_Umeas_ch1_200' provides the enable signal to the 'MEASUREMENT-CH1_900' circuit.

Table 5.1.9: List of components 'Iso_Umeas_ch1_200'

S.no	Component	Description	Quantity
1	Opamp	op97	2
2	Opamp	op27A	1
3	Diode	IN4150	1
4	Optocoupler	HCNR201	1
5	Resistor	270Ω	1
6	Resistor	200 kΩ	1
7	Resistor	33 kΩ	1
8	Resistor	10 kΩ	1
9	Resistor	2.2 kΩ	1
10	Resistor	6.8 kΩ	1
11	Capacitor	47 p	1
12	Capacitor	33 p	1
13	Capacitor	1 u	6
14	Capacitor	0.1 u	6
15	Connector	-	1
16	Tansistor	2N3906	1

5.1.10 Operational amplifier ‘OP27’ ratings

Absolute maximum ratings over operating free-air temperature range

Supply voltage, V_{CC+}	22 V
Supply voltage, V_{CC-}	-22 V
Input Voltage, V_I	$V_{CC\pm}$
Duration of output short circuit.....	unlimited
Differential input current.....	± 25 mA. [4]

5.1.11 The current measurement circuit ‘ISO_I meas_ch1_400’

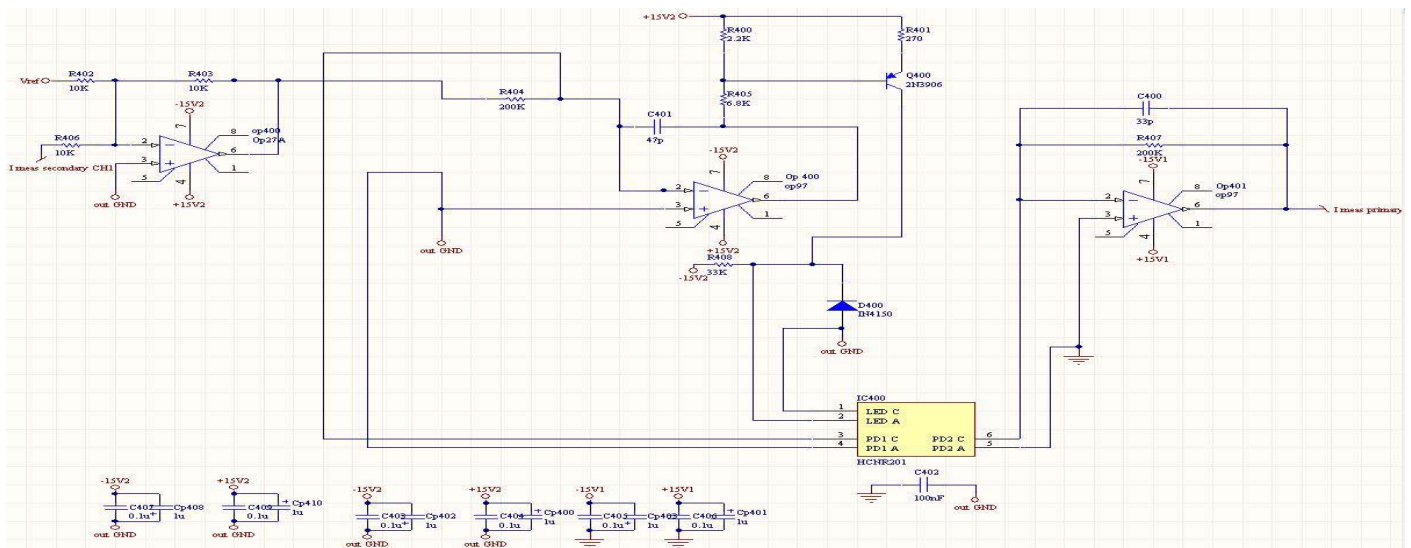


Figure 5.1.11: The circuit diagram of ‘ISO_I meas_ch1_400’

The current output, *I meas secondary CH1* from the ‘Current source-ch1-100’ circuit, is given as an input to the Operational amplifier OP27A (OP400). The output from the OP400 is given to the operational amplifier OP97 (OP400). The isolation is provided by the optocoupler HCNR201 (IC400) the outputs from the opamp OP97 (OP400) are then passed on to the opamp OP97 (OP401) while passing through the optocoupler. Through pin 6 of the opamp (op97 (op401)), the *I meas primary CH1* is given out to the ‘ISO_U meas_CH1_200’. The *I meas secondary* from the ‘Current source-ch1-100’ is given to the ‘Iso_U meas-CH1_400’. The *I meas primary* from the ‘ISO_I meas_ch1_400’ is given to ‘Iso_U meas_CH1_200’.

Table 5.1.11: List of components, 'ISO_Imeas_ch1_400'

S.no	Component	Description	Quantity
1	Opamp	op97	2
2	Opamp	op27A	1
3	Diode	IN4150	1
4	Optocoupler	HCNR201	1
5	Resistor	270Ω	1
6	Resistor	200 kΩ	2
7	Resistor	33 kΩ	1
8	Resistor	10 kΩ	3
9	Resistor	6.8 kΩ	1
10	Capacitor	47 p	1
11	Capacitor	33 p	1
12	Capacitor	1 u	6
13	Capacitor	0.1 u	6
14	Tansistor	2N3906	1

5.1.12 The measuring circuit 'MEASURE-CH1_900'

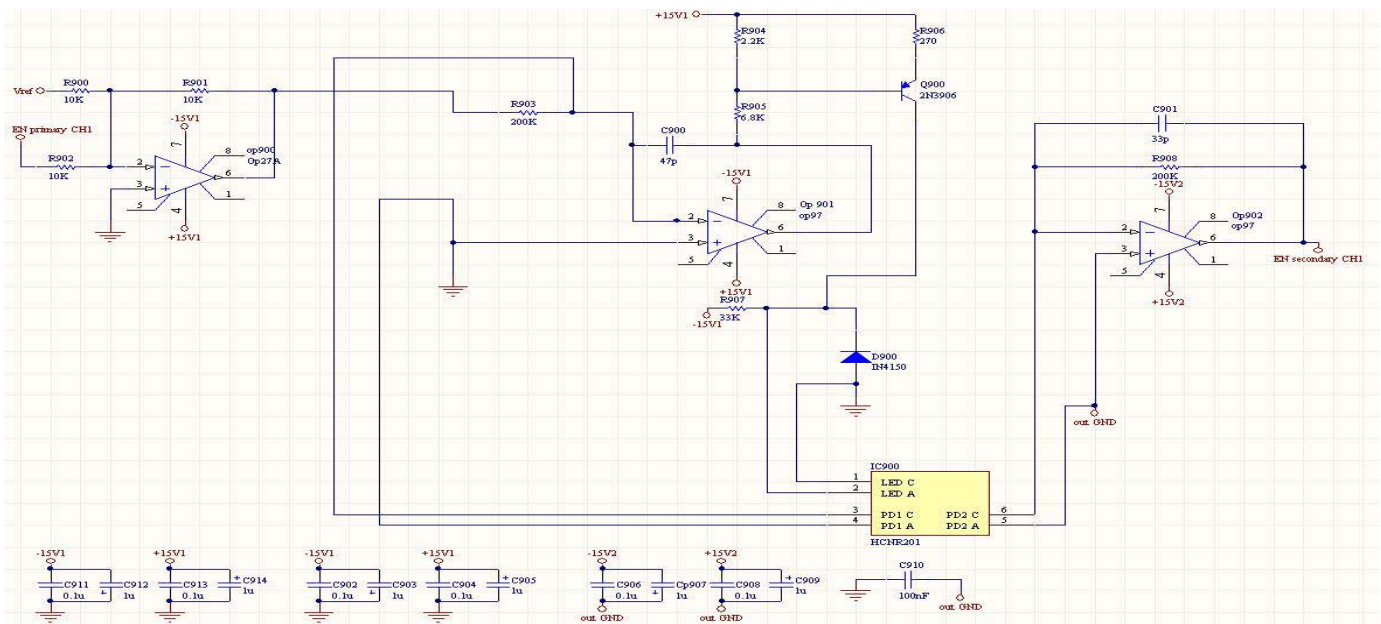


Figure 5.1.12: Circuit diagram, 'MEASURE-CH1_900'

The *EN primary CH1* is the input at the negative (pin2) of the op27A (op900), the feedback is given to the opamp op97 (op901). The output from the op97 (op901) is passed on to the optocouplers HCNR201, the current is then isolated and sent to the other op97 (op902). The *EN secondary CH1* is sent back to the 'Current source-CH1_100'. The *Enable primary* from the 'ISO_Umeas_CH1_100' is given to the 'MEASUREMENT-CH1_900', this is the enable signal. The *enable secondary* is sent onto the 'Current source -CH1_100'.

Table 5.1.12: List of components 'Iso_Umeas_ch1_200'

S.no	Component	Description	Quantity
1	Opamp	Op97	2
2	Opamp	Op27a	1
3	Diode	IN4150	1
4	Optocoupler	HCNR201	1
5	Resistor	270 Ω	1
6	Resistor	200k Ω	2
7	Resistor	33k Ω	1
8	Resistor	10k Ω	3
9	Resistor	6.8k Ω	1
10	Capacitor	47p	1
11	Capacitor	33p	1
12	Capacitor	1u	6
13	Capacitor	0.1u	6
14	Tansistor	2N3906	1
15	Resistor	2.2 k Ω	1

5.1.13 Circuit design for measurement 'MEASUREMENT-CH1A_800'

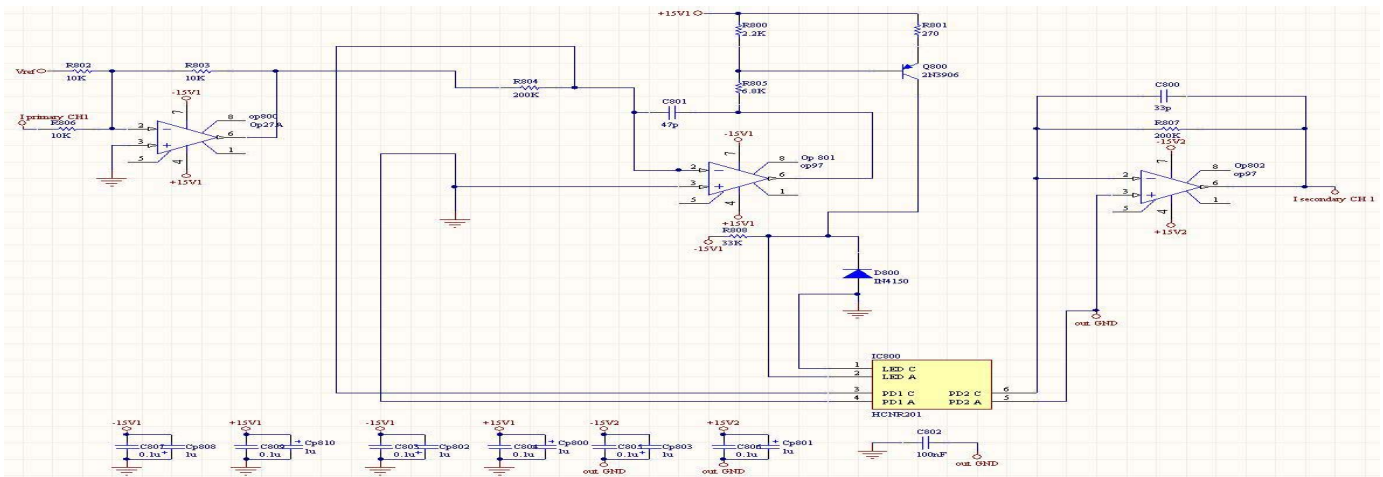


Figure 5.1.13: Circuit diagram 'MEASUREMENT-CH1A_800'

The *Iprimary CH1* from the 'ISO_Umeas_ch1_200' is given to the negative (pin2) of the OP27A (800) of the 'MEASUREMENT-CH1A_800', the feed back is sent to the OP97 (op801). The output from this opamp is sent to the optocoupler HCNR201 (IC800). The output from the optocoupler is given onto the OP97 (op802), the *Isecondary CH1* is given to the 'CURRENT SOURCE-Ch1_100' circuit input.

Table 5.1.13: List of components 'MEASUREMENT-CH1A_800'

S.no	Component	Description	Description
1	Opamp	op97	op97
2	Opamp	op27a	op27a
3	Diode	IN4150	IN4150
4	Optocoupler	HCNR201	HCNR201
5	Resistor	270Ω	270Ω
6	Resistor	200kΩ	200kΩ
7	Resistor	33kΩ	33kΩ
8	Resistor	10kΩ	10kΩ
9	Resistor	6.8kΩ	6.8kΩ
10	Capacitor	47p	47p
11	Capacitor	33p	33p
12	Capacitor	1u	1u

5.1.14 Galvanic vestibular stimulation unit 'CHANNEL 2'

The following are the given names of the circuits under Protel

1. ISO_Umeas_ch2_600 (Voltage measurement)
2. ISO_IMEAS-ch2_1100 (Current measurement)
3. MEASURE-CH2_700 (Enable signal)
4. MEASURE-CH1A_1200 (Current signal)
5. CURRENT SOURCE-CH2_500.

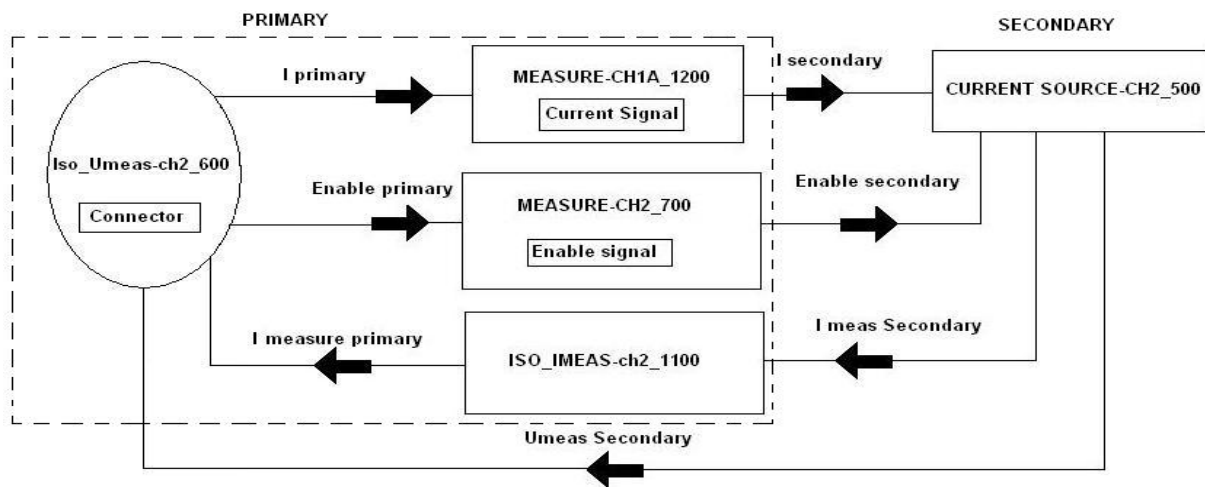


Figure 5.1.14: Block diagram of Galvanic vestibular stimulation unit ' channel 2'

The each block in the above diagram (figure 5.1.14) represent a circuit diagram of an entire channel (channel 2); 'Iso_Umeas-ch2_600' is the connector, which allows several connections such as the *Iprimary*, *Enable primary*, *Imeasure primary*, *Umeas secondary*. To start with the *Iprimary* signal is given to the 'MEASURE_CH1A_1200' which is a current signal from here the *Isecondary* is given to the 'CURRENT SOURCE-CH2_500'. The *I meas Secondary* signal is given to the 'ISO_IMEAS-ch2_1100' there by enabling the isolation. The *Imeasure primary* from the 'ISO_IMEAS-ch2_1100' is then passed on to the connector.

The *Enable primary* from the 'Iso_Umeas-ch2_600' is given to the 'MEASURE-CH2_700', this is where the enable signal is there by in the form of Enable secondary is then passed on to the 'CURRENT SOURCE-CH2_500'. The *I meas Secondary* from

the 'CURRENT SOURCE-CH2_500' is given to the 'ISO_IMEAS-ch2_1100'; the *Imeasure primary* from the 'ISO_IMEAS-ch2_1100' is then given back to the connector. The *Umeas Secondary* from the 'CURRENT SOURCE-CH2_500' is also given back to the connector.

5.1.13 Circuit design 'DC_DC_Converter_300' (power supply)

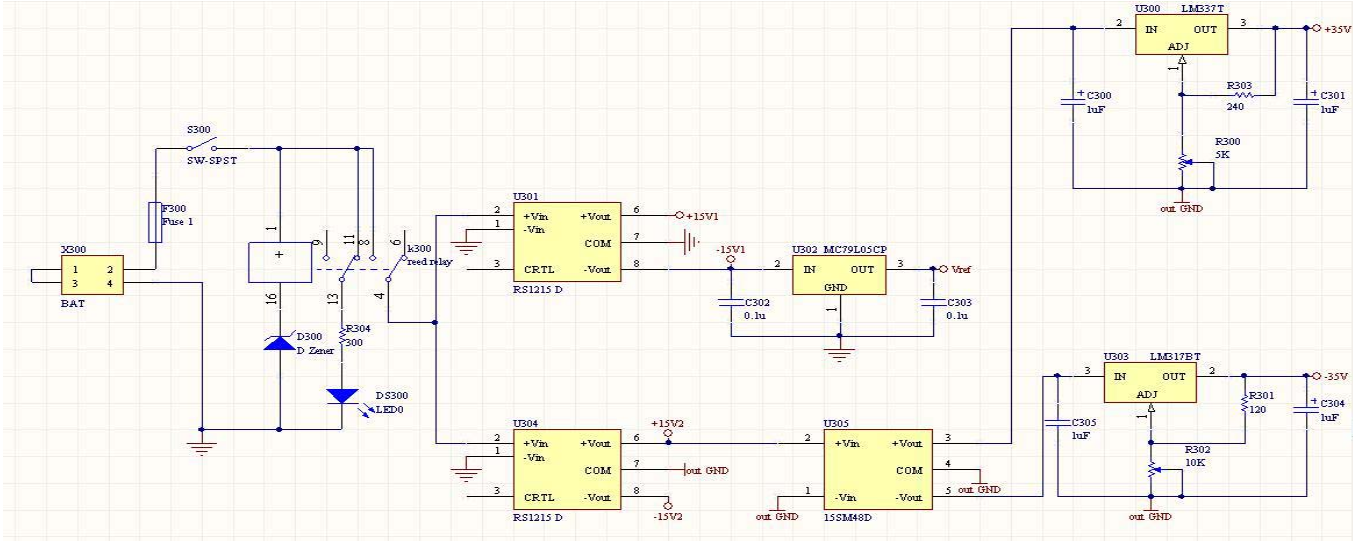


Figure 5.1.13: Circuit diagram 'DC_DC_Converter_300'

The Battery is connected along with a fuse and then a switch in series, which will disconnect if there is a low supply voltage i.e. if the battery is low. A reed relay is connected in between which will allow, voltage to pass through two RS1215D, which is a wide range voltage inputs with an isolation voltage up to 1kV DC isolation. The voltage from the first RS1215D (U301) is made to pass through MC79L05CP which is a three terminal negative voltage regulator. The voltage from the second RS1215D (U304) is sent to the 15SM48D, which is a DC-DC converter. The positive voltage output (+Vout) from the DC-DC converter is passed onto the LM337T (U300), which is a three terminal negative adjustable regulator. LM337 supplies in excess of 1.5 A over an output voltage range of -1.2 V to -37 V. This regulator requires only two external resistors to set the output voltage. The negative voltage (-Vout) is given to the LM317BT, which is a three terminal adjustable output positive voltage regulator capable of supplying in excess of 1.5 A over an output voltage range of 1.2 V to 37 V.

This voltage regulator is exceptionally easy to use and requires only two external resistors to set the output voltage. Further, it employs internal current limiting; thermal shutdown and safe area compensation, making it essentially blow-out proof.

Table 5.1.13 List of components 'DC_DC_Converter_300 '

S.no	COMPONENT	Description	quantity
1	Capacitor	0.1u	2
2	Capacitor	1uf	4
3	Resistor	5k	1
4	Resistor	10k	1
5	DC-DC	15SM48D	1
6	Resistor	120Ω	1
7	Resistor	240Ω	1
8	Resistor	300Ω	1
9	Battery	-	1
10	Diode	zener	1
11	Fuse	-	1
12	LED	-	1
13	+V regulator	LM317BT	1
14	-V regulator	LM337T	1
15	Regulator	MC79L05	1
16	Reed relay	-	1
17	Connector	RS1215D	2
18	Switch	SW-SPST	1

6 Discussion & conclusion

6.1 The Designed Galvanic vestibular stimulation unit Board

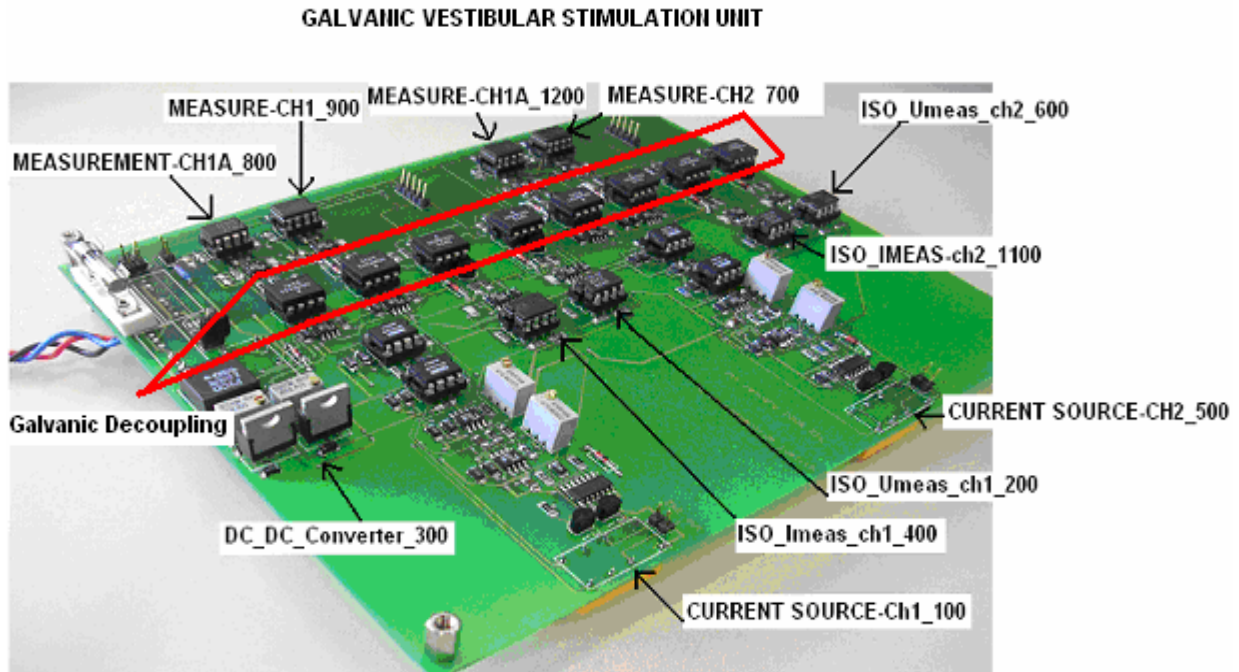


Figure 6.1: The Galvanic vestibular stimulation unit board

The various circuits as planned were being assembled together using the surface mount machine. All the SMD (Surface mount device) components were assembled on the multilayer printed circuit board (PCB) as shown above in figure 8(A).

The process involved using a chemically inert liquid for thermal transfer. A non-corrosive and extremely stable liquid which can be combined with other materials. And which has a boiling point typically at 200 °C or 215 °C. This liquid is pasted on all the contact points of the components on the board. As the liquid boils, a layer of saturated vapour containing no oxygen or other gasses forms above it. The vapour's weight is high therefore it displaces other gasses. Consequently, a pure protective gas atmosphere (0 ppm oxygen) forms without any additional gasses such as e.g. nitrogen having to be used. If the solder material is immersed into the vapour zone, the vapour condenses on the solder material and transfers its heat. Irrespective of the time the solder material remains in the vapour its temperature can never exceed the vapour's temperature.

So the components are put upon the paste and put into the oven. The steps involved in the machine were as follows: - 1. The assembly is moved to the vapour phase after it was preheated by IR radiators from the top side. It is also possible to do preheating on the top boundary of the vapour phase. Then the heat is predominantly transferred from below. Vapour with a boiling point of 200°C. Boiling fluid used to build up the vapour phase.

2. The assembly dives into the vapour phase. There it is heated up. It is possible to control the heat transfer to the assembly to perform smooth temperature gradients.

3. The vapour condenses on the assembly and transfers its heat. Since the vapour is chemically inert it performs an inert gas atmosphere with 0 ppm oxygen. This is done automatically without the use of nitrogen.

4. The assembly can be heated up to a maximum temperature that is limited by the vapours temperature. This temperature cannot be exceeded even if the assembly stays for long time inside the vapour. Therefore it is impossible to overheat.

5. After leaving the vapour phase there is still condensed fluid left on the board. Due to the inner heat of the assembly the liquid evaporates without residues. A completely dry board leaves the machine.

The laws of physics determine the framework conditions. The key factor: The temperature of the vapour can never exceed the temperature of the boiling liquid, and it is fixed. The consequence: The solder process can be reliably reproduced and offers ideal conditions for controlling the process. This enables soldering to be carried out on a wide range of assemblies, from flex print to multi-layer, reliably and without overheating.

6.1.1 Principal test setup for the Galvanic vestibular stimulation unit

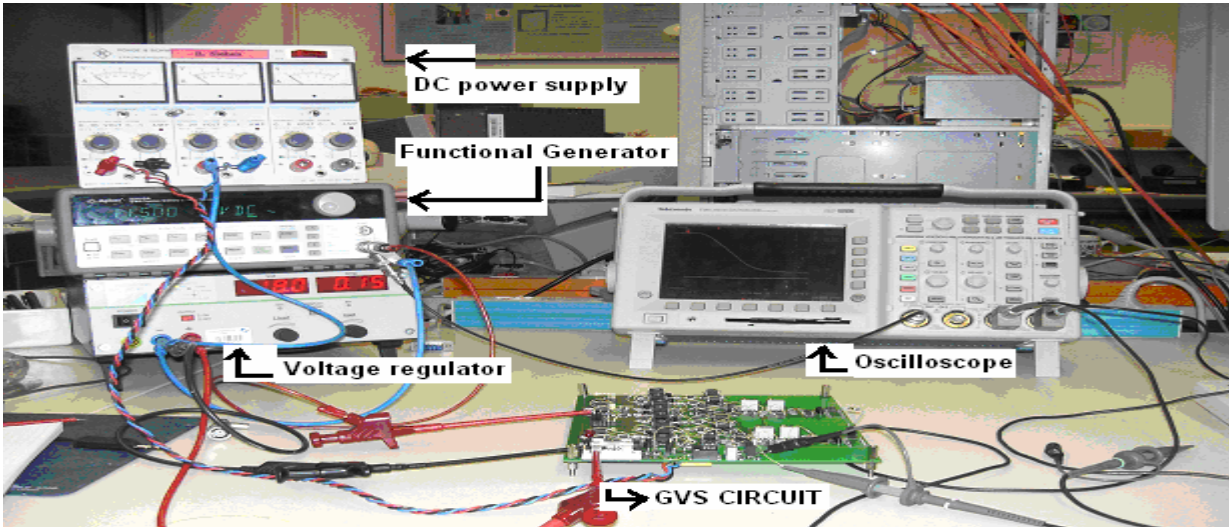
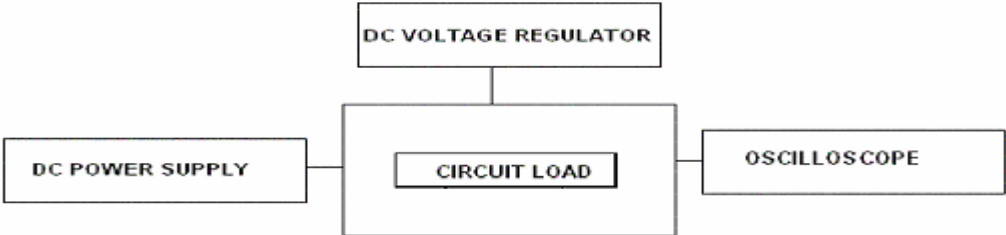


Figure 8.1: The test setup of the Galvanic vestibular stimulation unit board



Figure, showing the test setup for testing the Galvanic stimulation unit board.

The circuit after designing was made to test by the above said setup. The DC power supply provides a voltage of $\pm 35\text{ V}$ to the circuit, the voltage was regulated by the voltage regulator. The DC power supply and the DC voltage regulator provided adequate power supply to the circuit. The opamps after receiving this power supply react to the input voltage supply and thereby enable the circuit. The oscilloscope was connected at the output loads which enabled us to take the graphs for Voltage Vs Current, Voltage over the load and Response time. The graph values were thereby saved in a floppy disk and then we had to put the values that we got from the oscilloscope. The time delay and the response of the loads were studied by this setup. The values that were collected on testing the circuit were reused to plot the graphs. The graphs are shown in the coming section.

6.2.1 Test results of the Galvanic stimulation unit

To test the equipment we had to make use of a DC power supply, functional generator, voltage regulator and an oscilloscope as shown in the figure 8.1(A). Various measurements were to be done such as:

- 1. Voltage vs current measurement
- 2. Voltage over the load resistor (patient)
- 3. Response time

6.2.2 Input voltage vs current: 'Test condition 1': we had to measure the change in current with respect to the change in voltage, for this reason we took the measurement of the input voltage at the enable signal, and the input voltage was measured from the function generator which was given to the oscilloscope at channel 1 and the current outputs were collected at the measuring opamps with a probe and the readings were given to the oscilloscope at channel 3. To measure the voltage and current signal, we have proceed by giving input voltage as an input signal, i.e. 2 V peak to peak voltage, the value on the x-axis is the time scale in microseconds. A frequency of 1 KHz was provided with a function generator, the scale of the voltage was 1 V per division. This gave us an output signal which is the output current. The enable signal at the 'ISO_Umeas_ch1_200' is enabled with the input voltage. The current was measured at the output Umeas primary ch1 of 'ISO_Umeas_ch1_200'. The graph below shows us the voltage vs current output.

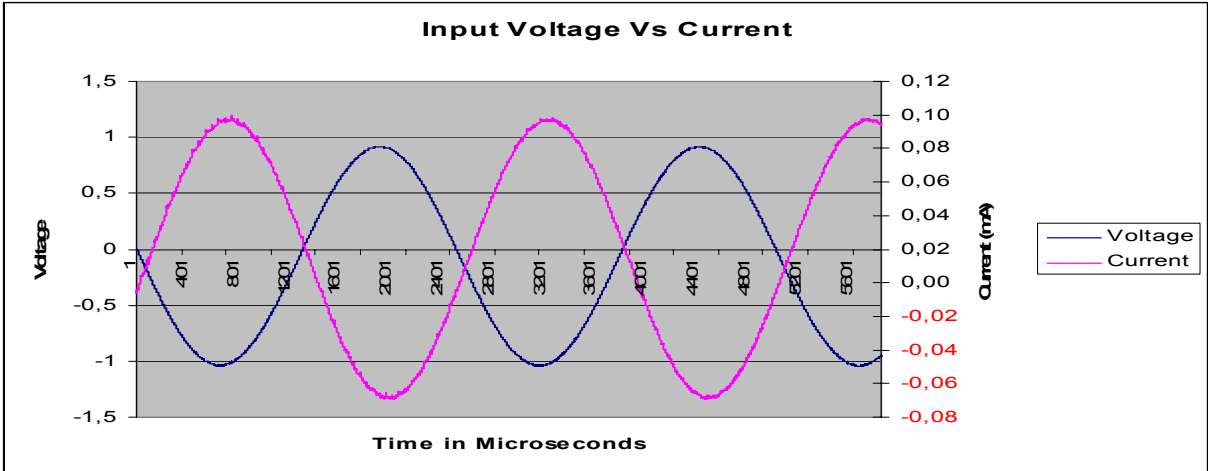


Figure 6.2.2, showing the Input voltage vs current

From figure 6.2.2: For a given voltage of $\pm 1V$, the current varied from $+8.5\text{ mA}$ to -7.5 mA approximately. The current output is constant in the graph the input voltage is driven asymmetrically so as to check the current is constant. The input voltage is more than the positive voltage, where as the output current is constant. The output current remains constant from -6 mA to 9 mA .

6.2.3 Voltage over the load: 'Test condition 2': We had to measure the voltage at the load, for this reason, the probe had to be connected at the load resistor, the input voltage from the function generator was given to the oscilloscope at channel 1 and the outputs from the load resistors were given to the oscilloscope at channel 3 . We wanted to measure the voltage over the load. So we supplied with an input voltage of 4 V peak to peak at a frequency of 1 KHz , the output from the load resistor is the voltage over the load. We have implemented the voltage resistor to be $6.12\text{ K}\Omega$ as we cannot directly test it on patient without testing; we assume the load resistor to be the patient. The output leads from the load resistor are to be given to the patient's mastoid muscles through electrodes.

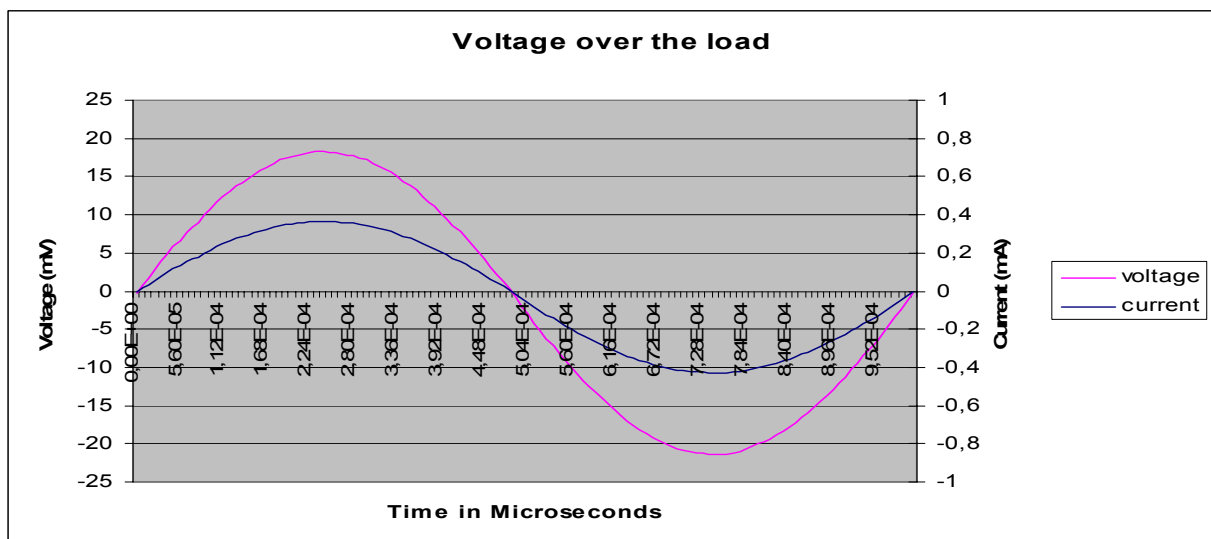


Figure 6.2.3: The voltage over the load

The voltage varied from $+18\text{ mV}$ to -21 mV and the current 'voltage over the load' were given at output as $\pm 4\text{ mA}$.

6.2.3 Adaptation (response) time: 'Test condition 3': We had to measure the response time of the opamps. The output voltage from the function generator was given to the oscilloscope at channel 1 and the outputs from the opamp were given to the scope at channel 3., to measure the response time we had to supply an Input signal of 0 V to 3 V, then we had an output of change in current at, time scale is $10\mu\text{S}$. The time interval between the starting & ending point was $80\mu\text{S}$ (response time) as seen in the oscilloscope.

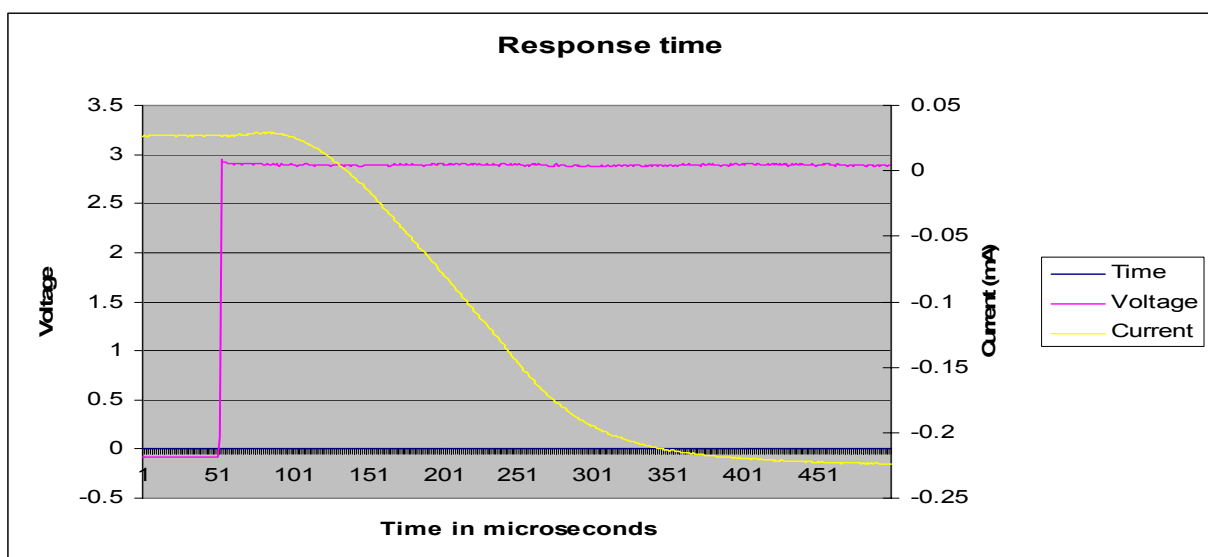


Figure 6.2.3, showing the response time

For a given voltage of 3V, the response time was measured to be $80\mu\text{s}$, on the oscilloscope

The aim of our thesis was to design a galvanic vestibular stimulation unit which provides a complete test environment to the scientists with a flexibility to monitor the effects of stimulation. We came up with an idea to build a GVS unit, which can fulfil the task. During the process, we had to make sure that there should be a galvanic decoupling of the currents/voltages delivered to the patient. There should be also a facility not to burden the patient with continuous stimulus delivery therefore we have built in a security shutdown of the device to the patient after the device has been stimulation for a specified time (e.g. 2 hours). To ensure that there is a correct current

supply, we made use of relays, which only give galvanic contact to the patient, if the current provided is accurate. We also had to consider if in any case due to some failure or the other the patient is not to be given more stimulation the device is capable of shutting down so that no harm is caused to the patient knowing or unknowingly with the help of a fuse.

Various voltage and current regulators have also been installed so that the device delivers precisely the expected stimulation. All of this can be controlled to by a switch which can disconnect the patient contact. We had to go through the Medical equipment norms, to fulfil that this equipment can be used once it attains its patents after implementing the said suggestions. To attain the patents, we have come in contact with a company that is engaged in developing medical devices, bytech (<http://www.bytec-gmbh.de/>) to proceed with the medical testing according to the IEC 60601-1 norms. We showed our designed device to a company, they made some suggestions in improving the GVS unit by changing the battery or power line to the isolation side and also to have more space between the pins. And finally, the equipment is ready for medical safety testing as described in the attachment. Overall the aim of this thesis is being concluded with the desired requirements. However further safety tests have to be carried out to finally use it on a Hemi spatial Neglect syndrome patient and a microcontroller based control unit has to be implemented for research purposes.

The necessary safety tests:

1. Protective Earth Continuity

2. Insulation Tests.

3. Earth Leakage Current

4. Enclosure leakage current

5. Patient leakage current

6. Patient auxiliary current

These safety tests shall be carried out according to the IEC 60601 norms, which shall be carried out with the cooperation of a biomedical company.

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