

Software Safety Analysis for Clinical Programming Software of Cochlear Implant System

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Abstract

Computer based bio-electronic systems are used for replacement of damaged human parts such as Bionic-ear for deafness, Bionic-eye for blindness, Deep Brain Stimulator for diseases of the brain, and Bionic-arm for arm prostheses. Algorithms for controlling bionic system are based on the specific bionic devices like bionic ear with sound processing software and bionic eye with image processing software. A lot of research is going on to improve the performance of bionic systems in respect of achieving near 100% functionality, low cost and smaller sizes with higher reliability and safety. As the use of software in medical devices has improved, the need for specific regulations for healthcare system software has improved. Software for medical systems has to deal with the Health software lifecycle identified by safety analysis in order to make the system safe. The focus of this paper is defining two approaches such as Failure Modes and Effects Analysis (FMEA) and Fault Tree Analysis (FTA) techniques to identify potentially hazardous software faults and development of software safety for clinical programming software (CPS) as medical device software. CPS software to operate on Digital Speech Processor System (DSPS), Impedance Telemetry Monitoring System (ITMS), Implantable Receiver Stimulator (IRS) that is Connections are made from PC to ITMS Unit and ITMS Unit to Receiver Stimulator. A custom built Database Application (DA) for medical development of Bionic Ear is developed under Visual Studio software environment using MS-Access database.

Keywords: Software; Medical device; Cochlear implant; Clinical programming software; Safety critical systems

Introduction

Safety critical software performs functions which could directly cause serious injury to people or/and the environment and cause deaths if they failed to execute properly. Some fields of safety critical software systems are Medicine, Nuclear engineering, Transport, Aviation, Aerospace, and Civil engineering, military. There is a huge demand for low cost and high performance of Cochlear implants in developing countries. Several researchers proposed and attempt to develop a low-cost cochlear implant system but none of these products are available in the market. The development of Cochlear Implant system involves the potpourri of mechanical engineering, physiology, electronics engineering and computer science and engineering. The cochlear implant device has four hardware modules such as are Speech Digital Speech Processor System, Impedance Telemetry Monitoring System, Headset Cable SC), and Implantable Receiver Stimulator (IRS). ITMS are used for finding the active electrodes of electrode array of 12 Electrodes and their respective Threshold Comfort Level (TCL) and Most Comfortable Level (MCL).The valid Electrode numbers with their TCL/MCL are downloaded from PC and upload into speech processor (DSPS) using CPS) in PC. DSPS is connected to patient with implant using headset cable and set comfortable volume levels in DSPS. The main functions of speech processor are speech signal processing, speech data encoding and transmission of encoded speech data to Implanted Receiver Stimulator (IRS) via transcutaneous RF inductive link. Implementation of clinical programming software

without error plays an important role in the development of different modules such as maintaining patient information, impedance measurement, and determination of stimulation parameters (fitting) and mapping THL/MCL of active electrodes into Speech Processor. A failure is caused in CPS software because of a bug and may alter the external behavior of the program.

A software bug can be defined as that part of the code which would result in an error; fault or malfunctioning of the program [1]. Some bugs can be detected easily during development. But some bugs will be found late in the development process. These are low probability errors which are hard to detect and occur on very sparse set of inputs [1]. According to IEEE standards, a 'bug' is an incorrect instruction in a program. A failing is triggered because of a bug and may alter the exterior actions of the system. The major categories are requirement and functionality bugs, structural bugs, data bugs, coding bugs, interface, integration and system bugs, test and test design bugs. These bugs increase the cost and development of CPS of cochlear implant system. The primary task of programmer is minimizing these defects, identify and eliminate existing bugs early in the development process. The defects detected beginning will cause much smaller harm than those which are recognized later in the utilization. A common category of bugs can be done in accordance with the regularity of the incident of that bug and severity of that bug. The effect of bug is depending on the software and the system. However we can generally have following sessions for severity:

Catastrophic: Potential of multiple deaths or serious injuries;

Critical: Defects that could cause serious consequences for the system like losing some important data or potential of death.

Marginal: Potential of injury.

Negligible: These may not necessarily hamper the system performance, but they may give slightly different interpretation and generally avoidable.

Developing safety critical software is a complex process. Due to the fact that medical device software failure can lead to moderate consequences, numerous standards have been developed which govern software development in the medical device domain. Risk management has an important role in medical device software development as it is important to ensure that safe software is developed. Software-based medical devices are playing an increasingly important part in healthcare [2]. Many medical devices must interface with other equipment, connect to medical center and computer lab, and work in high-stress situations. The increased demands on such devices have resulted in increased software complexity and have created powerful growth development challenges for their manufacturers [3]. This improved complexity has led to the need for improved traceability and risk management measures. Programs are vital in guaranteeing traceability from specifications via requirements to execution [4]. In order to market their devices within a nation, a medical device development company must adhere to the regulating specifications of that nation [5]. Although assistance prevails from regulating bodies on what application actions must be performed, no specific method for performing these actions is defined or required [6]. Organizations must demonstrate clear linkages through the software development and maintenance lifecycles. Numerous standards and guidance documents exist which interpret requirements for compliance to regulations. However, deciphering these requirements can be a difficult and onerous task as the requirements for traceability vary between the documents. The variation between the documents extends to other areas such that "In already developed guidance documents different software quality issues, software lifecycle phases and consequences of risk evaluation for software malfunction or fraud are addressed to different extents"[7]. In the listening to system of humans, the function of the ear is to convert audio surf into written sensory styles of activity in the hearing sensors, which are prepared by the brain to produce the understanding of audio. A cochlear enhancement (CI) is a real-time included processing system that can provide a sense of audio to people who are hard of hearing or significantly hearing-impaired [8-10]. The analysis revealed that 242 (or 7.7%) of the recalls could be attributed to software failures. Out of those recalls, 192 (or 79%) were caused by software defects which had been introduced when changes were made to the software after its initial production and distribution [11]. If application used to plan cancer therapy amounts and to management the setting of oncology therapy gadgets, Software used to measure and determine the physiological sites of the body to accomplish the irradiation of surgical involvement, Software included in an inserted beat generator system then the application consider to be healthcare system. The rest of this paper is organized as follows: section 2 describes related work to

medical device software. Section 3 addresses the safety analysis of clinical programming software. Section 4 applies the design of CPS. Section 5 focuses on development and results evaluation and section 6 concludes the discussion.

Related Work to Medical Device Software

Software that is incorporated into a medical device, or which is a standalone medical device in its own right, is of a safety critical nature and subject to regulation from various jurisdictions. In order to satisfy jurisdictional regulations, developers of medical device software often implement standards and guidance provided by international standards bodies and national administrative departments [12]. Cedar Sinai Medical Centre in Los Angeles, California happened between the years February 2008-August 2009 because of Software miss-configuration in CT scanner used for brain perfusion scanning and get Very high level of damage (wrong dosage to 206). A Medtronic heart device was found vulnerable to remote attacks in March 2008. The Therac-25 is a medical linear accelerator manufactured by AECL. A linear accelerator is a particle accelerator, a device that increases the energy of electrically charged atomic particles. The charged particle is accelerated by the introduction of an electric field, producing beams of particles which are then focused by magnets. Linacs are used to treat cancer patients. A patient is exposed to beams of particles, or radiation, in doses designed to kill a malignancy. Since malignant tissues are more sensitive than normal tissues to radiation exposure, a treatment plan can be developed that permits the absorption of an amount of radiation that is fatal to tumor cells but causes relatively minor damage to normal tissue. Shallow tissue is treated with electrons, but to reach deeper tissue, X-ray photons are needed (Grolier, 1985). Accidents occurred because of Therac-25.

Radiation therapy software by Multi data Systems International miscalculated the proper dosage, exposing patients to harmful and in some cases fatal levels of radiation. The physicians, who were legally required to double-check the software's calculations, were indicted for murder. The software calculated radiation dosage based on the order in which data was entered, sometimes delivering a double dose of radiation. Software is found in medical care in a variety of safety-critical programs, from patient records to radiology devices. Over 56000 medical device reports, 1% were reported as deaths, 34% as serious injuries, and 62% as malfunctions. Many of the issues of infusion pumps that have been revealed are relevant to software malfunctions. For example, some pumps do not to activate pre-programmed alarms when problems happen, while others activate an alarm in the absence of a problem. Other software errors can lead to over- or under-infusion. In one case, a program issue known as a 'key bounce' triggered an infusion push to sometimes sign-up one key stroke as several key strokes. Some of incidents involved the Therac-25 radiotherapy device in the mid 1980's, when a software design error several patients to be killed from radiation dosages purchases of scale greater than what had been designed. The immediate cause was a so-called "race condition" where rapidly-entered individual feedback took the device into an unexpected state (Table 1).

DATE	COUNTRY	CAUSE
June 3, 1985	Marietta, GA	Breast removal, loss of use of arm
July 26, 1985	Ontario, Canada	Total hip replacement needed

January 6, 1986	Yakima, WA	Minor disability and scarring
March 21, 1986	Tyler, TX	Death
April 11, 1986	Tyler, TX	Death
January 17,1987	Yakima, WA	Death

Table 1: Causes of hazards.

Safety related incidents in medical devices

Safety related incidents in health devices are systems unable to produce appropriate signals for sufferers or not being managed and modified to indicate new treatment methods, medication name or other language applying mistakes, especially where information is incorporated from different care configurations, computer, or companies, incorrectly calculated ages, Radiotherapy or drug amount rates being measured, presented or conveyed wrongly due to computation or unit transformation mistakes, physicians wrongly decoding medical information coming through an interface from another program when the full perspective for the information was not provided, data losing from individual information without the physician being aware of it, due to resource systems or connections not being available or managed correctly, pictures could not be recovered in regular basis by doctors from Picture Preserving and Interaction Techniques, data migration mistakes when new systems are applied or major program improvements occur, software maintenance mistakes that affect individual recognition and cause lab or analytic results to go to the wrong doctors, clinical decision support rules not being activated continually because some of the resource information was documented in a different perspective or planned wrongly, Privacy or security breaches that bargain program reliability, lack of program functional accessibility for extended time.

The main functionality of CPS

CPI software is responsible for providing functionality in the following main areas such as Manage all required information for each patient, CP software that runs on the personal computer is interfaced with DSPS, ITMS and IR, control the overall safe operation of the patient with DSPS, ITMS and IR, measure the impedances of patient active electrodes, finding THL/MCL for each Active Electrode and adjust sound processing and stimulation parameters in a speech processor, loading/Mapping THL/MCL of Active Electrodes into Speech Processor.

CPS software safety properties

- For the new patient, follow the all steps to identify the implant and electrode type. But not make any assumption. Violation of this requirement will cause misidentification problem.
- Do not edit or alter files generated or used by the Fitting Software. Because it loaded into database when edit that change is not loaded into database. That means backup of patient data in the database is not automatically provided. It is the responsibility of the user/audiologist to backup patient data files.
- Only CPS software should run in our PC no other programs. Violation of this requirement will cause software conflict. Solution is shut down all programs except CPI and sees if the situation improves.

- CPS can be effective tool, but they must be maintained and used correctly otherwise it gives security problems.
- The CPS software does not require calibration, service or maintenance. But periodic updates will be provided by the developer for compatibility to the latest technology updates.
- The display of Hardware not found message appears after patient selection if the user tries to open a task (Fitting, Telemetry or DSPS) and no appropriate hardware is found by CPI because of following reasons those are speech processor switched off or ITMS unit switched off or all cables are not connected properly or the correct COM port is not selected or The batteries of the speech processor and/or the ITMS unit are low or The selected patient does not match with the connected speech processor or A cable is defective or The PC's hardware is defective.
- The display of Connection to hardware failed message appears after patient selection if the user tries to open a task (Fitting, Telemetry or DSPS) and no appropriate hardware is found by CPI because of following reasons those are speech processor switched off or ITMS unit switched off or all cables are not connected properly or The batteries of the speech processor and/or the ITMS unit are low or A cable is defective or The PC's hardware is defective.
- Data Mismatch message appears if the selected patient does not correspond with the patient data stored in the speech processor.
- Upload failed or was incomplete message appears if The serial connection was interrupted or The Log file shows further details about the failed upload or Repeating the upload is possible by closing the Fitting windows and opening again.
- Download failed or was incomplete message appears if the serial connection was interrupted or The Log file shows further details about the failed download or Download can be repeated by pressing the relevant download button again.
- Telemetry measurement not possible message is displayed during a Telemetry measurement if the calibration measurement cannot be performed successfully. To remedy, perform the following steps:
 - Check the distance between the implant and the Headset Coil.
 - Check the cable connection between the ITMS and the Headset Coil.
 - Check if the Headset Coil is positioned correctly on the patient's head over the implant.
 - Be careful not to move the coil during testing.
 - If the cable connection between the ITMS and the Headset Coil is functional and if the Headset Coil is connected and positioned correctly and the problem persists, contact your nearest company representative.
- The display of an error message indicates a severe problem with the software and/or the operating system. In the case of an error message, it will probably be necessary to quit the CPI software and

resolve the problem. It is recommended to remove the coil from the implant site if this occurs.

Software Safety Analysis of Cps

The safety analysis of CPS software functions takes place in two sequential steps.

Software failure mode and effects analysis (SFMEA)

This analysis is performed in order to determine the top events for lower level analysis. SFMEA analysis will be performed following the

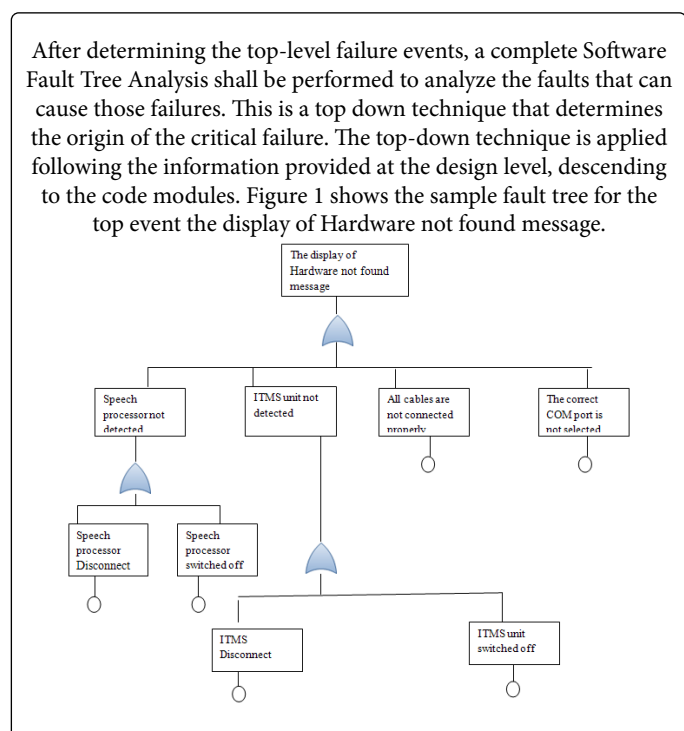
list of failure types. SFMEA will be used to identify critical functions based on the applicable software specification. The severity consequences of a failure, as well as the observability requirements and the effects of the failure will be used to define the criticality level of the function and thus whether this function will be considered in further deeper criticality analysis. The formulation of recommendations of fault related techniques that may help reduce failure criticality is included as part of this analysis step (Table 2).

Failure Mode	Possible Causes	Possible hazards	Effect	Severity	Prevention
Erroneous release of volume	Wrong identification of electrode type	High volume	Serious injury	critical	Software first checks the working status of DSPS and the CPS
Wrong delivery location of volume	Operator error, Data error, Mechanical error, Location calculation error	Incorrect calculation, volume delivered to wrong location	Serious injury to healthy ear	critical	Improve the DSPS and check the status of CPS every time
Wrong patient's treatment	Wrong documentation type	Incorrect history retrieved	Current treatment profile calculated incorrectly which could leads to hazards	critical	First check the CPS software, Software first checks the working status of ITMS,DSPS and all cable connections
communication failure in ITMS	Data error, operator error	Incorrect identification	Bad communication between CPS and ITMS leads to hazards	Marginal	First check the CPS software and ITMS
New CPS system is implemented and upgrades are not done properly	a)If we want to change from one version software to another version software	damage to other system components	Data migration errors or Loss of system operation	Marginal	Software first checks the working status of old system and do all steps for upgrades
Wrong maintenance of CPS software	a)system is maintained by new user b) Occurrence of virus in the CPS	Shock to Patient or patient go to the wrong Physicians	Misidentification of patients	Marginal	Plan for improved maintenance technology
For the new patient, do not follow the all steps to identify the implant and electrode type	a)No. of patients are more b)Take assumptions for implant and electrode type	a) s/w gives wrong command	misidentification problem	Marginal	Follow the each and every step
Alter files used by the Fitting Software	a)Occurrence of virus in the CPS	Wrong Identification of files	backup of patient data will change	Marginal	Software first checks the working status of Anti Virus and Fitting
The display of Hardware not found message	a) logic fault b) interface fault c) data fault d) calculation fault e) memory fault	a)speech processor switched off b)ITMS unit switched off c)all cables are not connected properly d) the correct COM port is not selected	a)User can not open Fitting, Telemetry or DSPS b) s/w gives wrong command	Marginal	Software first checks the working status of ITMS,DSPS,IR
The display of Connection to hardware failed message	a) logic fault b) interface fault c) data fault d) calculation fault e) memory fault	a)speech processor switched off b)ITMS unit switched off c)all cables are not connected properly	User can not open Fitting, Telemetry or DSPS	Marginal	Software first checks the working status of ITMS,DSPS and all cable connections

Running of other programs in PC	a) Occurrence of virus in the CPS software b) Some unknown programs running in background	cause software conflict	damage the CPS software	Marginal	shut down all programs except CPI software
Telemetry measurement not possible message	a) logic fault b) interface fault c) data fault d) calculation fault e) memory fault	Telemetry measurement if the calibration measurement cannot be performed successfully	Other failures in power supply, loss of system operation	Marginal	a) S/w Check the distance between the implant and the Headset Coil. b) Check the cable connection between the ITMS and the Headset Coil. c) Check if the Headset Coil is positioned correctly on the patient's head over the implant. d) Be careful not to move the coil during testing.
Control program software is corrupted	a) logic fault b) interface fault c) data fault d) calculation fault e) memory fault	a) Occurrence of virus in the CPS software b) Some unknown programs running in background	Unpredictable sequence of operations	minor or Marginal	Algorithm logic is verified for accuracy. Data Structures and Memory overflow is checked.

Table 2: SFMEA Analysis of CPS Software.

Software fault tree analysis (sfta) of cps



Design of Cps

Design should include architecture, algorithms, components, initial documentation and validation. Phase of software development following analysis, and concerned with how the problem is to be resolved. The CPS software is designed for our DSPS and ITMS used

by an audiologist for performing post-operative fitting procedure for better recognition of speech/sound. The program contains multiple functional modules such as patient information management, impedance measurement, fitting, and mapping. The software is designed under VB.net2008, with a database MSACCESS. The designed database tables are responsible to record patient basic information, medical record, evaluation of hearing abilities, evaluation of speech and language status, rehabilitation status, evaluation of psychological status, medical and audiological evaluation, processor programming, specific training with processor accessories and so on [13]. The functions of CPS are designed to serve the following functions are maintaining patient information, impedance measurement, determination of stimulation parameters (fitting) and Processor programming.

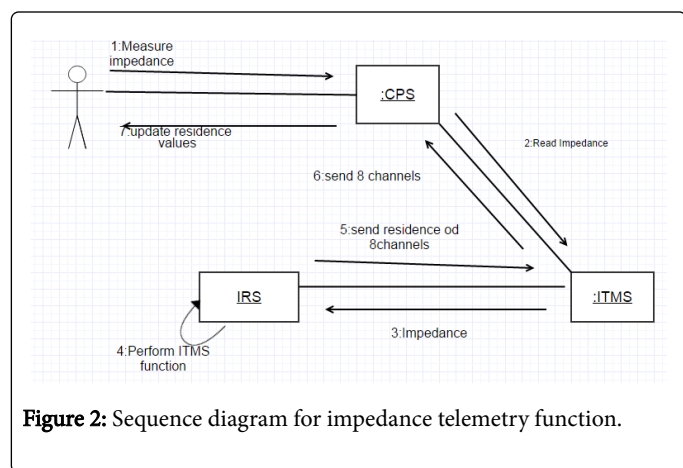
Patient info management

The patient information module maintains the basic requirement of patient information such as patient identification, name and address. CPS provides the facility to search the patient information either by name or patient id. After selecting the patient, the audiologist can perform the following functions (i) Impedance measurement, (ii) Fitting and (iii) Programming the speech processor.

Impedance measurement

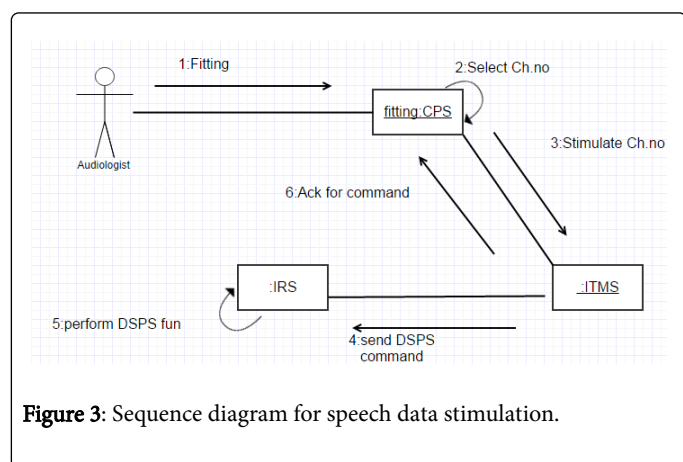
Every implant has to be configured individually for each patient's specific and unique firing properties of the surviving nerves. The identification of surviving nerves is done by means of measuring impedances of electrode contacts. The impedance values give an estimation of how many active electrodes are for stimulation. After active electrode contacts are identified, the estimation of electrical dynamic range of each active electrode is done by identifying the minimum amplitude (or Threshold Level-THL) of the electrical

stimuli needed to obtain a soft hearing percept and the maximum amplitude (or Most Comfort Level-MCL) of the current pulse stimulation needed to cause a comfortably loud sensation. The stimulus amplitude of any acoustic input will then be transformed by the speech processor into an appropriate stimulus current level, falling within the recipient electrical dynamic range (i.e., within the THL-and MCL-levels). For the purpose of measuring electrode interfaces and identifying the threshold and comfort levels, an external interface called Impedance Telemetry unit is developed as interface module to the PC based Clinical Programming Software (CPS). PC based Impedance Telemetry Monitoring System (ITMS) operating procedure is used to finding the number of active electrodes are present in the array, what are Impedance values are present at the each active electrode, to find the minimum threshold level (THL) and maximum comfort level (MCL) and storing these values into the Body Worn speech Processor. The sequence of operations for impedance telemetry function is illustrated by using sequence diagram as shown in Figure 2.



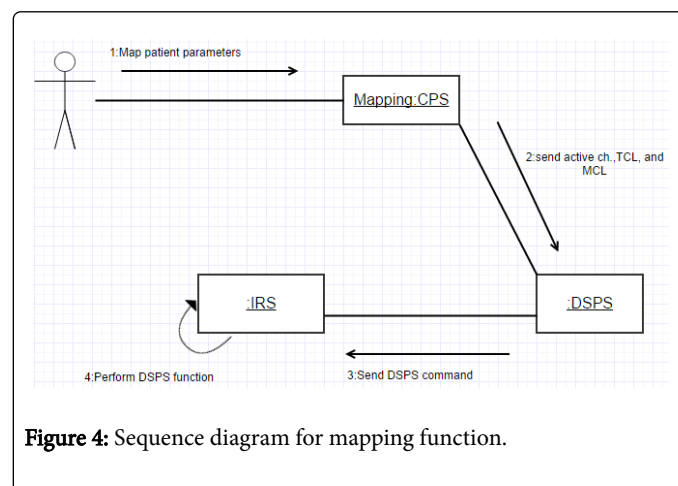
Fitting

The fitting module is used to measure optimized values of the TCL and MCL for each active electrode/channel. Prerequisite for this module is to measure the impedance value of each channel. The sequence of operations for fitting function is illustrated by using sequence diagram as shown in Figure3.



Reprogramming the speech processor

The DSPS must be programmed in order to adapt the cochlear system to patient requirements. It is programmed taking into account the functionality of each electrode and the stimulation levels required for each channel. The stimulation levels are either THL which is the minimum electrical level that the patient can perceive and the MCL is the maximum stimulation level that the patient can accept without experiencing uncomfortable sensations. The acoustical dynamic range in each audio band is mapped into the electrical dynamic range defined by the THL and MCL levels as estimated for each channel by the audiologist. This estimation is very important and varies from patient to patient. To maintain and manage this information a PC based application software is needed, we developed a Clinical Programming Software for configuring each patient and manage all the information required. The sequence of operations for mapping function is illustrated by using sequence diagram as shown in Figure 4.



Development and Results of Cps

Clinical Programming Software is developed and implemented for DSPS and ITMS with Receiver-Stimulator as used by an audiologist for performing post-operative fitting procedure for better recognition of speech/sound. The software is developed in Visual Studio 2008 with VB.NET 2008 with Microsoft Access 2007 database. CPS hardware and software development is described in this section.

Hardware components of cochlear implant system

The cochlear implant device (CID) has four hardware modules:

Digital Speech Processor System (DSPS), Impedance Telemetry Monitoring System (ITMS), Headset Cable(HSC), Implantable Receiver Stimulator(IRS).

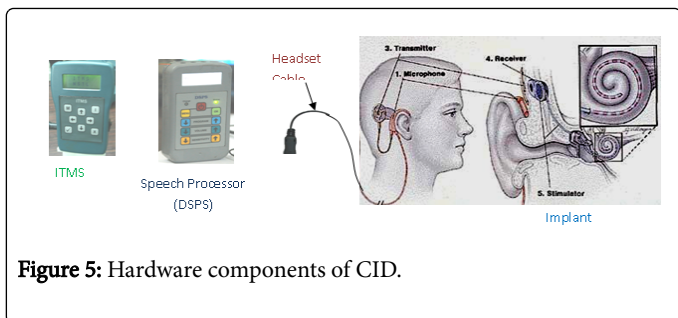


Figure 5: Hardware components of CID.

Impedance telemetry monitoring system

ITMS is used finding the active electrodes of electrode array of 12 Electrodes and their respective TCL (Threshold Comfort Level) and MCL (Most Comfortable Level).

Digital speech processor system

DSPS receives an external sound or speech and generates encoded speech data bits for transmission to IRS via radio frequency transcutaneous link for exciting the electrode array by continuously executing speech/sound processing program embedded in DSPS.

Implantable receiver stimulator

IRS is to stimulate auditory nerve system with the help of electrode array placed inside the cochlea of deafened person. IRS receives directions from the speech processor by way of magnetic induction sent from the transmitter and also IRS receives its power through the transmission.

CPS software developments

Check all connections before running the clinical programming software. The step by step process as follows.

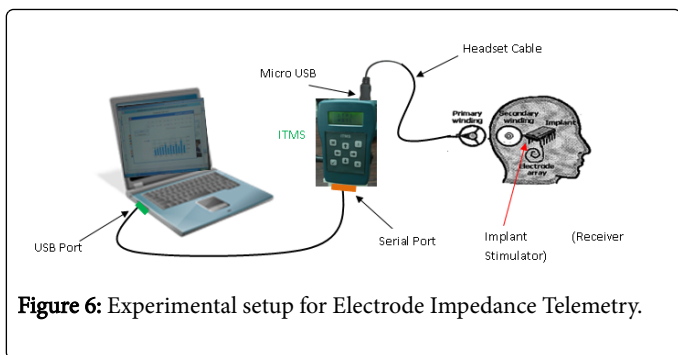


Figure 6: Experimental setup for Electrode Impedance Telemetry.

Audiologist registration

Step 1. Power on PC and install Clinical Programming Software (CPS) and run CPS.

2. CPS opens a Registration window for first time use. See Figure 7 below.

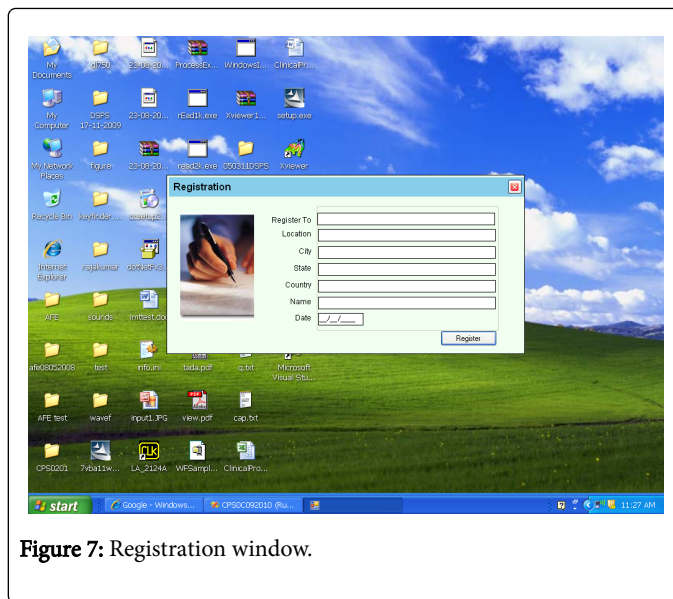


Figure 7: Registration window.

3. In Registration Window all the fields are to be filled by the Audiologist and then click Register button at bottom right corner of the screen. See Figure 8 below.

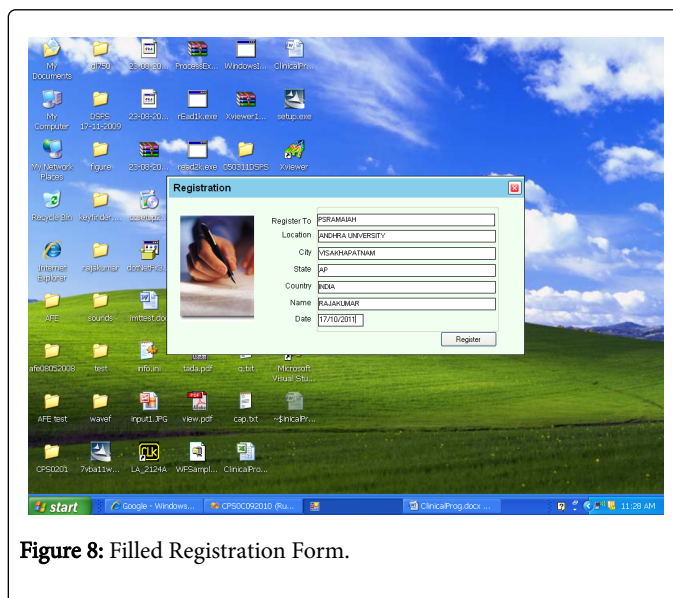


Figure 8: Filled Registration Form.

4. It shows one message window for Registration confirmation. See Figure 9 below.

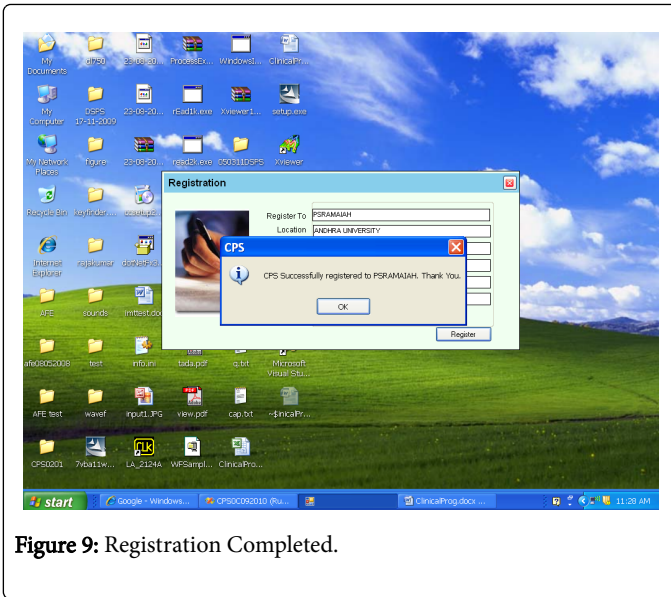


Figure 9: Registration Completed.

5. Click on OK button, It closes the Registration form and opens the Clinical Programming System home page of the Clinical Programming System. See Figure 10 below.

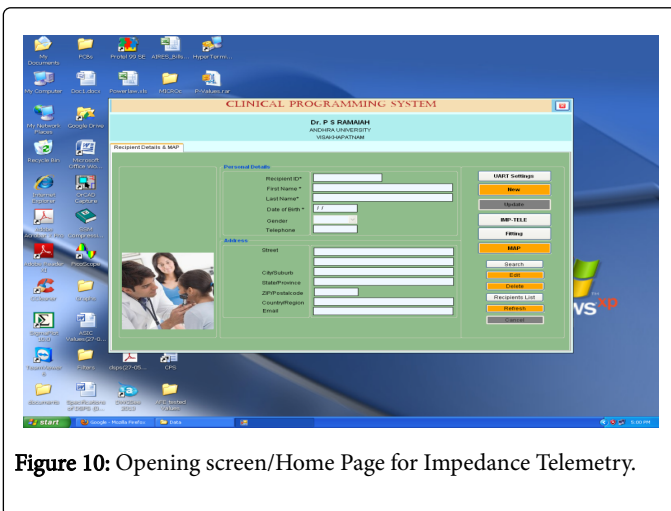


Figure 10: Opening screen/Home Page for Impedance Telemetry.

6. In home page window it shows some optional buttons at right side in single Column. see Figure 6 below.

7. Optional buttons are explained one by one in later sections as per the requirements.

Patient registration

8. To enter new patient details, click on NEW button in Opening/ Home Page, and observe the response. See Figure 11 below.

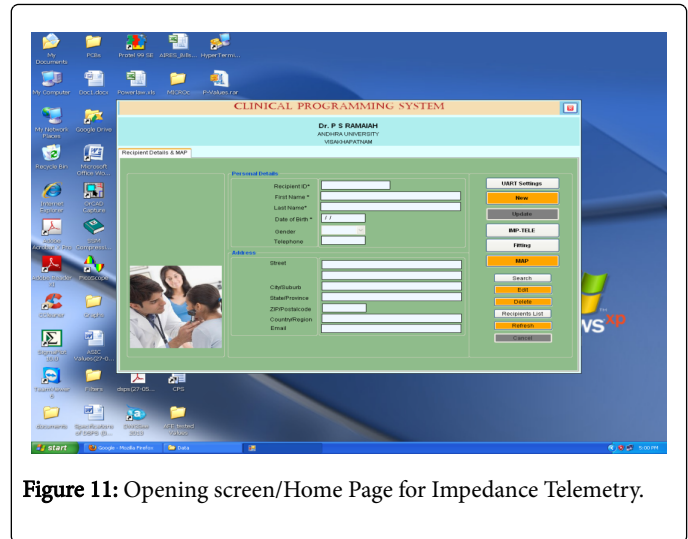


Figure 11: Opening screen/Home Page for Impedance Telemetry.

9. This window generates a Unique ID number automatically for new Recipient, and it requires details from the Patient as Personal details and address details for correspondence. See Figure 12 below.

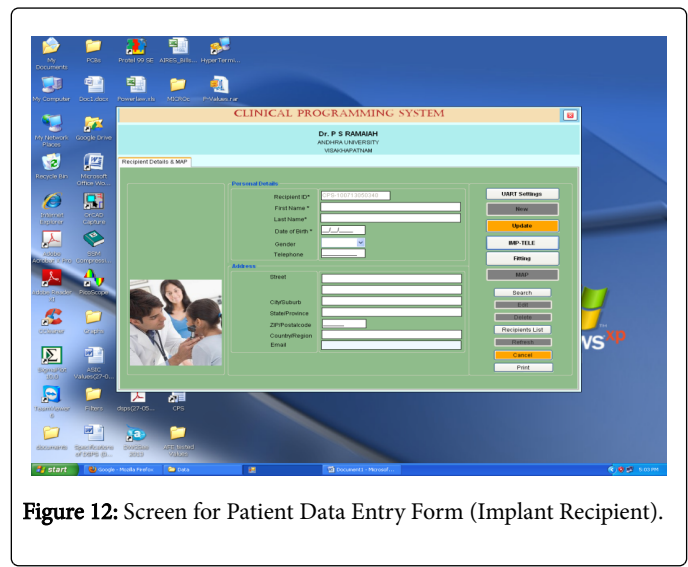


Figure 12: Screen for Patient Data Entry Form (Implant Recipient).

10. After entering the Patient details, press UPDATE button in the same window, it displays message box for confirmation of storing the Patient/Recipient information in the data base. See Figure 13 below.

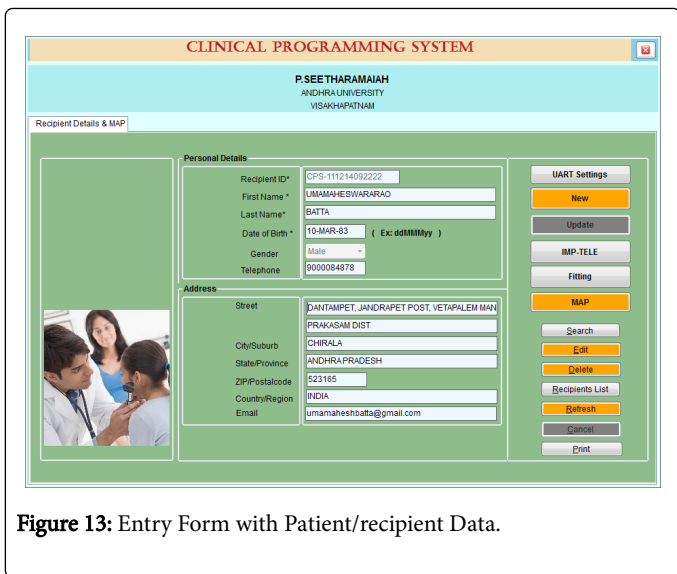


Figure 13: Entry Form with Patient/recipient Data.

11. Click on OK button in the “Recipient Data Stored Successfully” window and shows the Home Page. See Fig. 14 below.

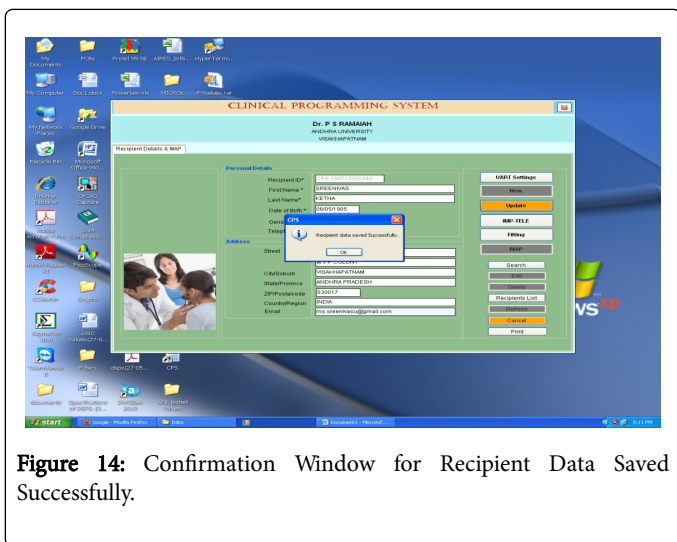


Figure 14: Confirmation Window for Recipient Data Saved Successfully.

12. After entering the patient data in the CPS, it stores Patient data in the CPS data base. But we have to remember the Recipient ID/ Full Name of the Patient. Because, these are keywords for searching the Patient/Recipient data for future use in CPS.

Measuring impedances

13. Power on the ITMS Unit and Press M Key on ITMS key board for Entering into GUI Mode. See Figure 15.

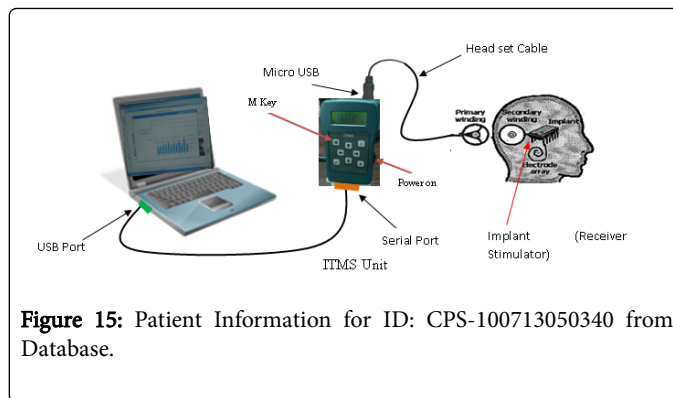


Figure 15: Patient Information for ID: CPS-100713050340 from Database.

14. Receiver stimulator (IMPLANT) unit is powered by ITMS via headset cable.

15. Click on IMP-TELE button in Figure 16. It opens Impedance data/Graph window. See Figure 17.

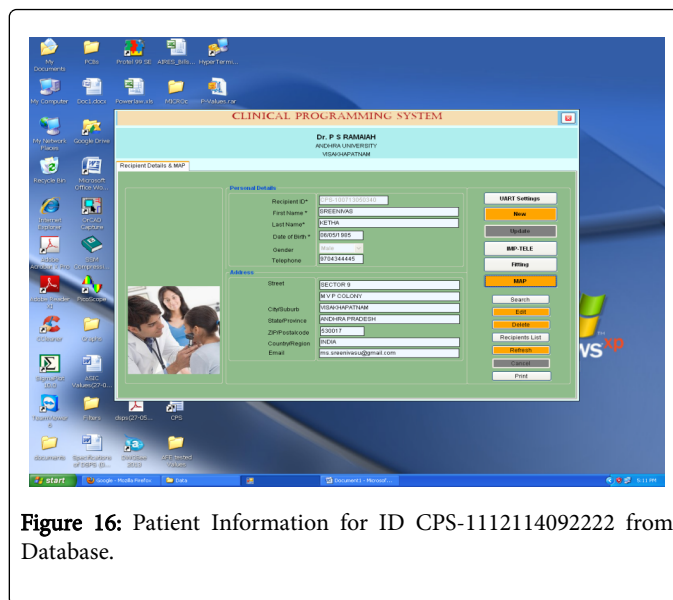


Figure 16: Patient Information for ID CPS-1112114092222 from Database.

16. IMP-TELE button is used to measure the impedances of patient active electrodes contacts with respect to reference electrode.

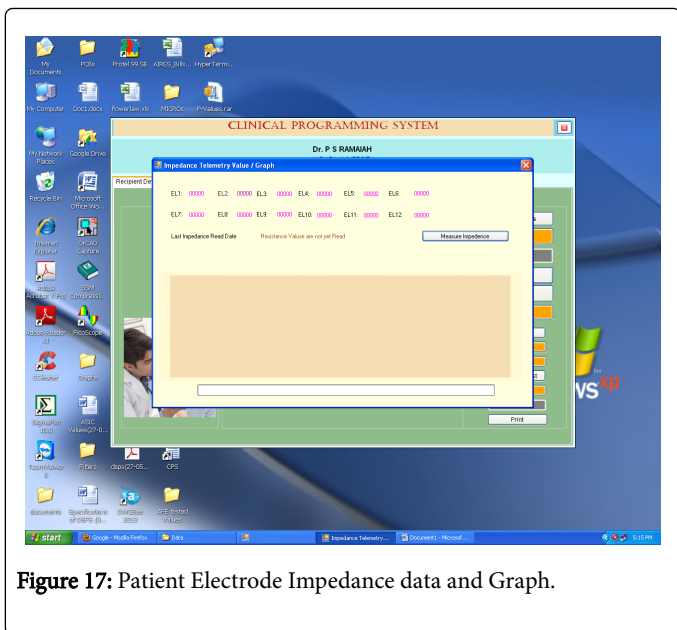


Figure 17: Patient Electrode Impedance data and Graph.

17. In the Impedance Telemetry Values/Graph window (Fig.17), click “Measure Impedance” button and wait for the Successfully Updated Impedance Values message window. See Figure 18.

18. Click OK button on Impedances Updated window in Figure 18.

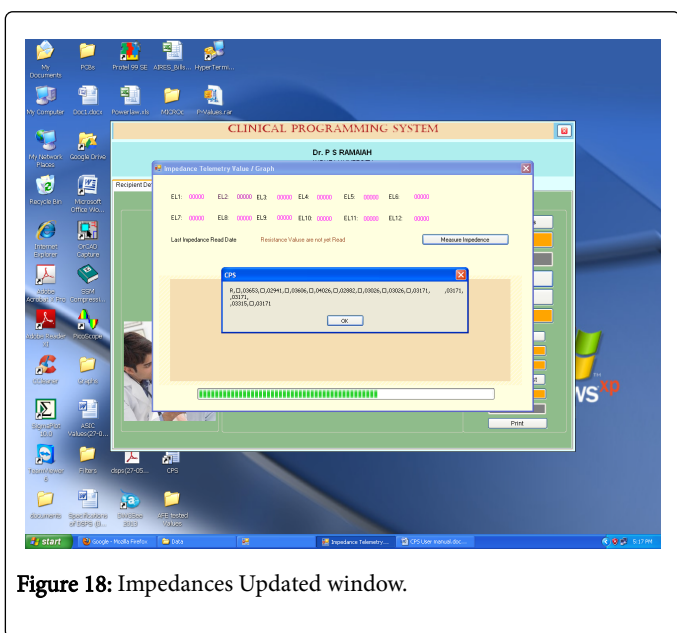


Figure 18: Impedances Updated window.

19. Updated Electrode Impedance values in ohms are shown as Bar graph in Figure 19.

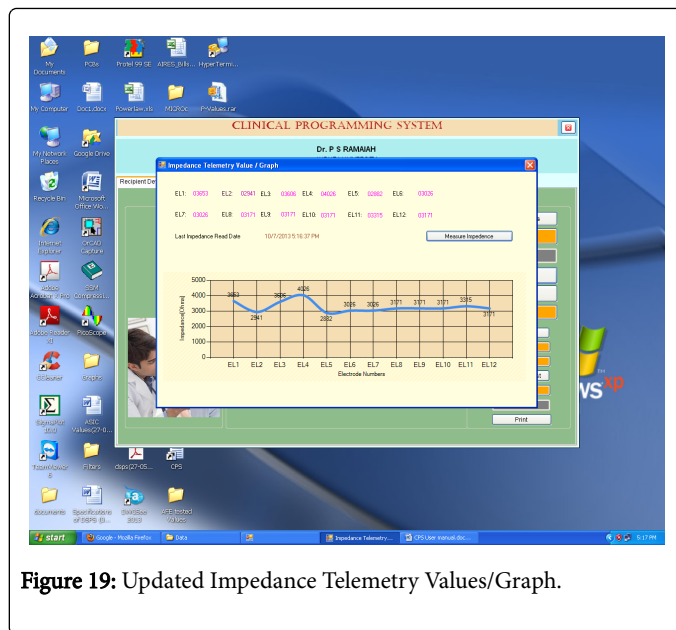


Figure 19: Updated Impedance Telemetry Values/Graph.

20. Click X on Figure 19 to close the Impedance Telemetry Values/Graph window to open the Home page Window as shown in Figure 20.

Finding THL/MCL for each active electrode

21. Click on FITTING button in. See Figure 20 below. It opens the Fitting THL/MCL values window.

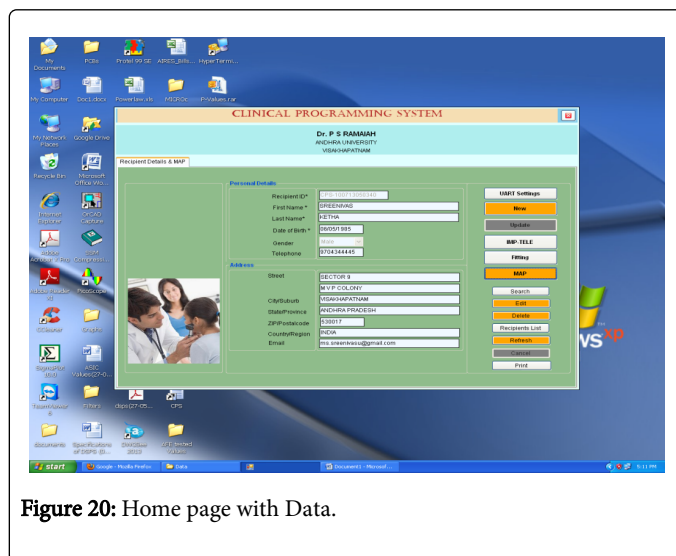


Figure 20: Home page with Data.

22. The Fitting THL/MCL values window for adjusting TCL and MCL Values. See Figure 21 below.

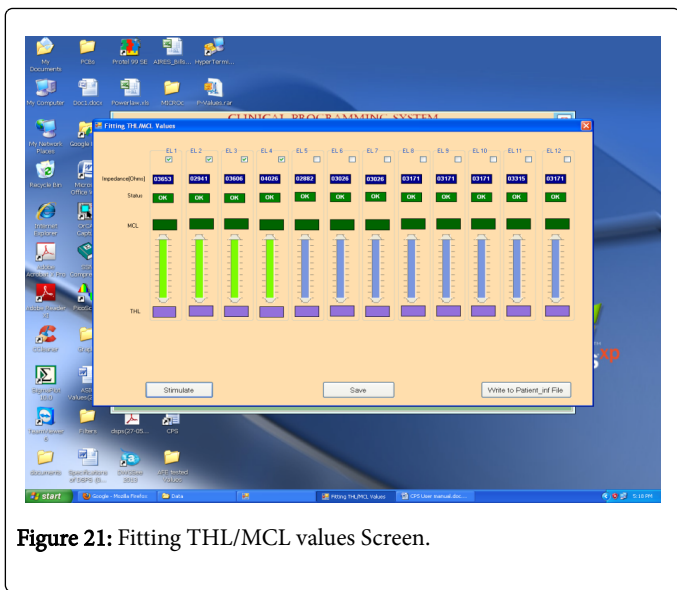


Figure 21: Fitting THL/MCL values Screen.

23. Fitting is used to adjust sound processing and stimulation parameters in a speech processor.

24. Fitting THL/MCL values window shows 12 graphical bars with impedance values. Each bar has two adjustable points TCL & MCL for setting the minimum and maximum comfortable levels of the Electrodes.

25. Select OK Electrodes by clicking selection box above the graphical bar. Adjust THL or MCL movable point for selected Electrode. See Figure 22 below.

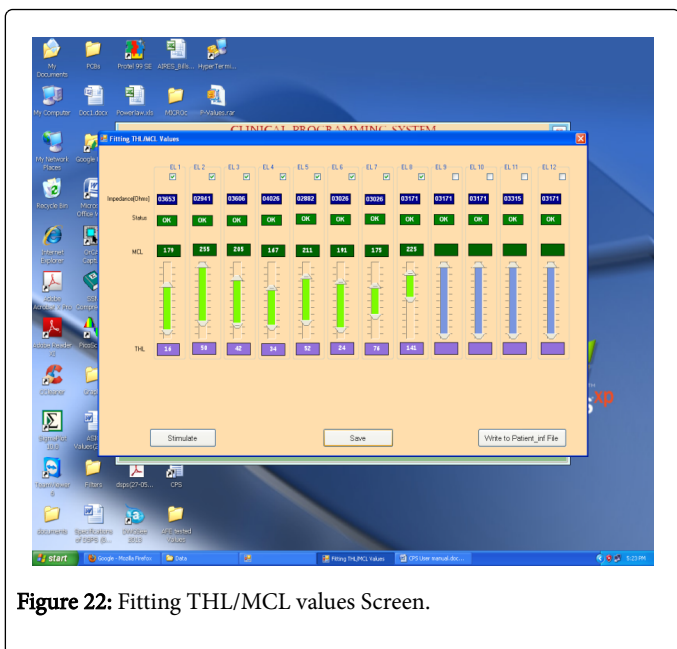


Figure 22: Fitting THL/MCL values Screen.

26. Press STIMULATE button in Fitting THL/MCL Values window. See Figure 23 below.

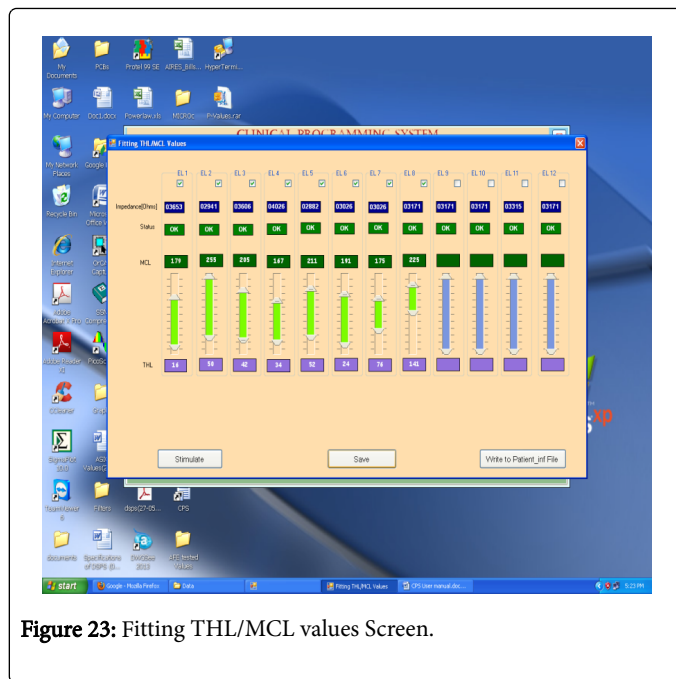


Figure 23: Fitting THL/MCL values Screen.

27. Wait for Electrode Stimulation window and click on OK button. Take feedback from Patient for every THL/MCL Stimulation whether it is comfortable or not. See Figure 24 below.

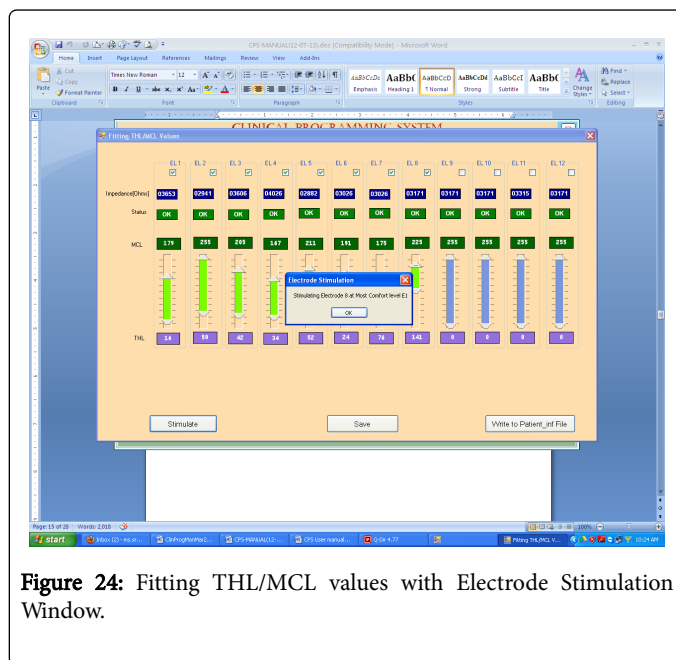


Figure 24: Fitting THL/MCL values with Electrode Stimulation Window.

28. Click on SAVE button and wait for Map Saved window. Click on OK button for storing the patient Electrodes data. See Figure 25 below.

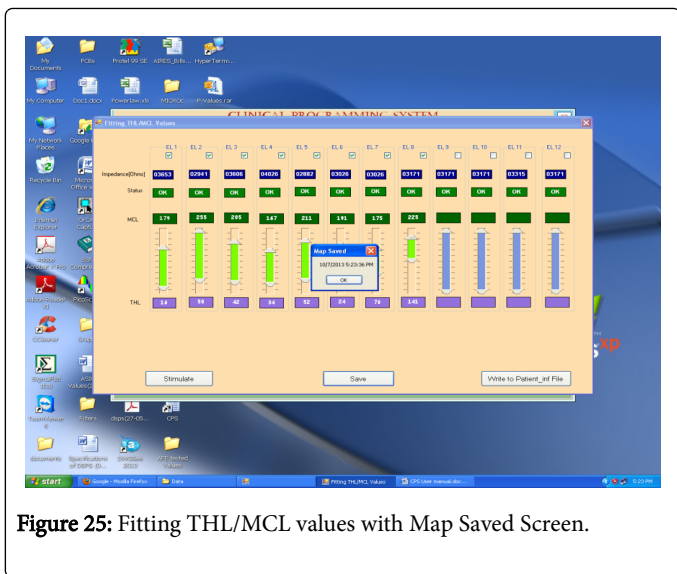


Figure 25: Fitting THL/MCL values with Map Saved Screen.

29. Click on WRITE TO PATIENT_INF File Button. Wait for Patient Info File window. See Figure 26 below.

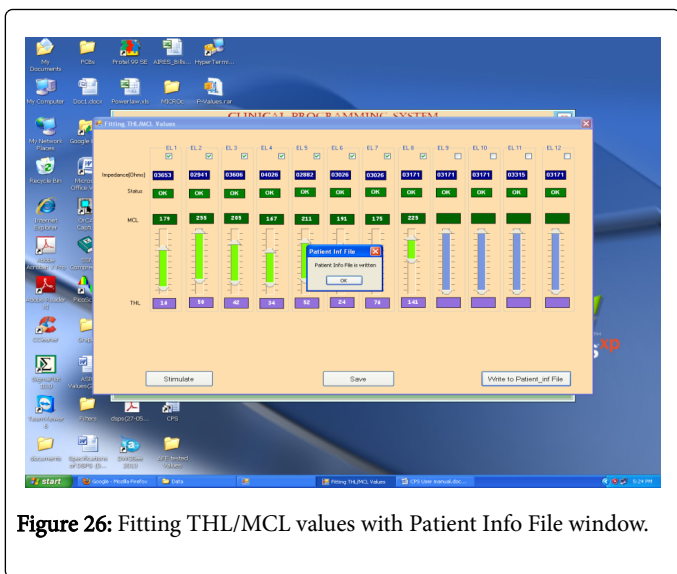


Figure 26: Fitting THL/MCL values with Patient Info File window.

Mapping THL/MCL of active electrodes into DSPS

30. After completion of setting TCL/MCL levels of all active electrodes and getting feedback from Patient, click on X symbol of the Fitting THL/MCL values window for opening the Home Page window again. See Figure 27 below.

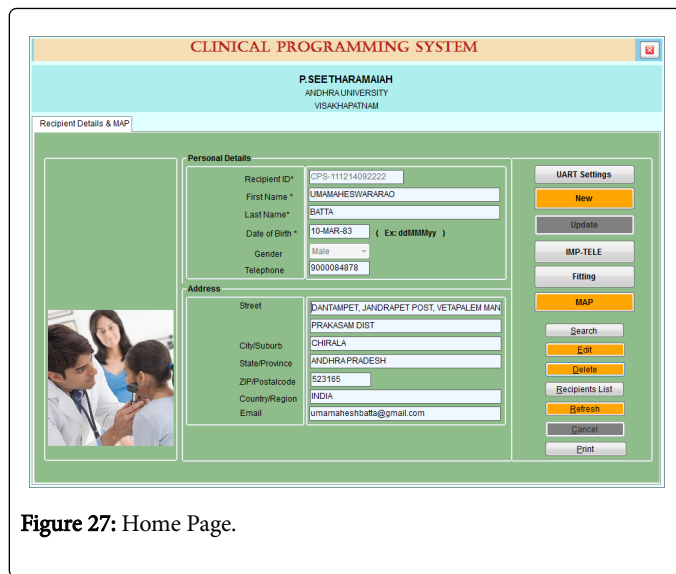


Figure 27: Home Page.

31. Click on MAP button on Home Page window and it opens Electrode THL/MCL of ID:CPS-100713050340, Name: SREENIVAS window. See Figure 28 below.

32. MAP is used to show the patient parameters and to store the parameters in Speech Processor.

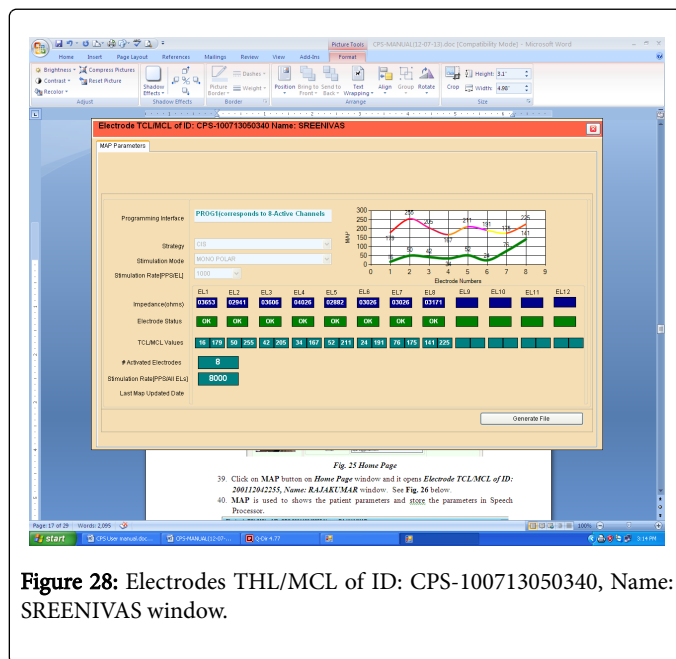


Figure 28: Electrodes THL/MCL of ID: CPS-100713050340, Name: SREENIVAS window.

33. Click on GENERATE FILE button in Electrode THLs/MCLs of ID: CPS-1112114092222, Name: umamaheswararao window. See Figure 29 below.

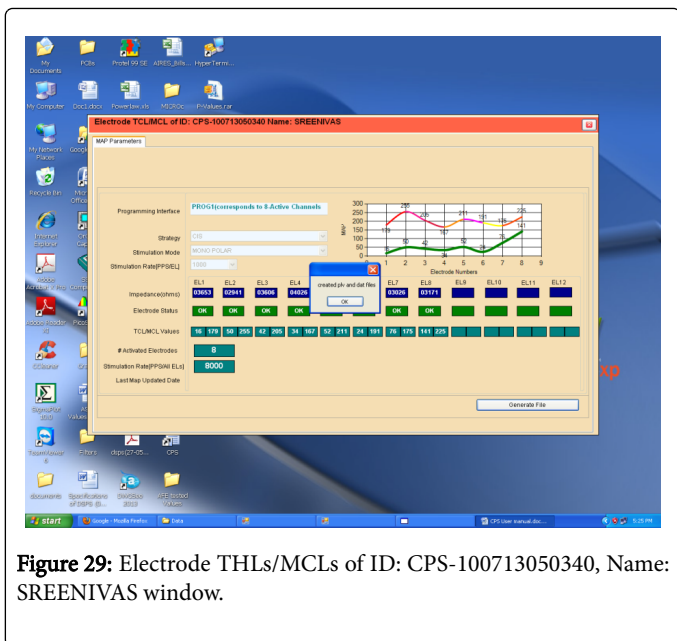


Figure 29: Electrode THLs/MCLs of ID: CPS-100713050340, Name: SREENIVAS window.

34. See Digital Speech Processor System(DSPS) window for programming the Electrodes data into the DSPS unit. See Fig. 30 below.

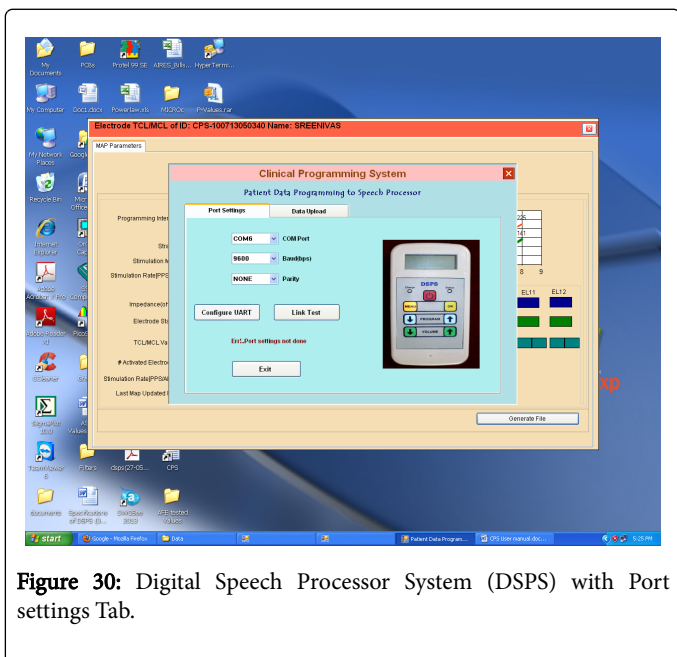


Figure 30: Digital Speech Processor System (DSPS) with Port settings Tab.

35. Disconnect the ITMS unit from PC by Unplugging Serial cable at ITMS unit. Also disconnect ITMS unit from Implant by unplugging Headset cable at ITMS unit. See Figure 31.

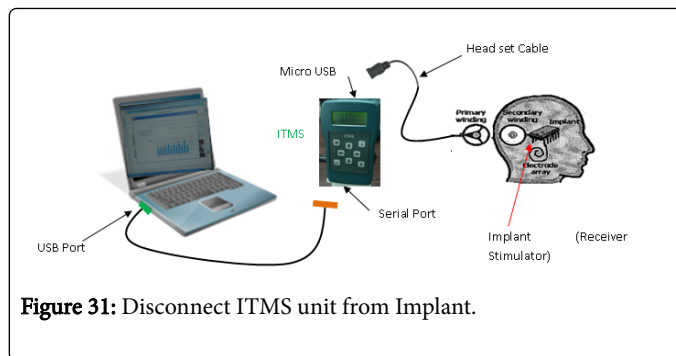


Figure 31: Disconnect ITMS unit from Implant.

36. Connect the DSPS unit to the PC with USB to Serial port cable as shown in Figure 32.

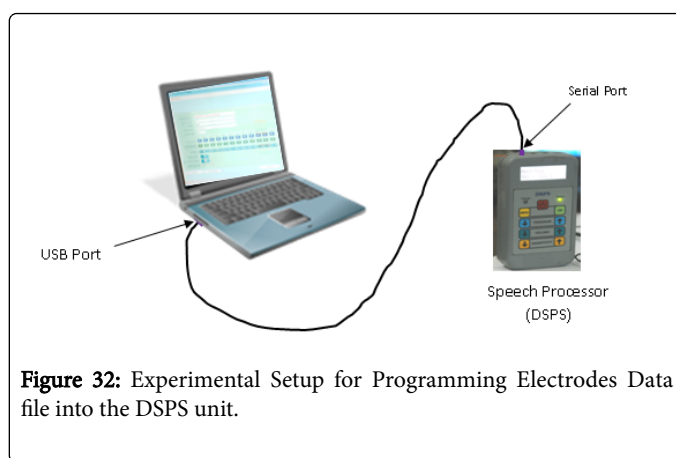


Figure 32: Experimental Setup for Programming Electrodes Data file into the DSPS unit.

37. Power ON the DSPS unit by pressing and holding Power ON switches for three seconds.

38. Enter into GUI mode from the Present Digital Speech Processor System window on PC screen by pressing MENU and OK buttons simultaneously on DSPS unit's keyboard (Figure 32) for displaying Digital Speech Processor System window as shown in Figure 33.

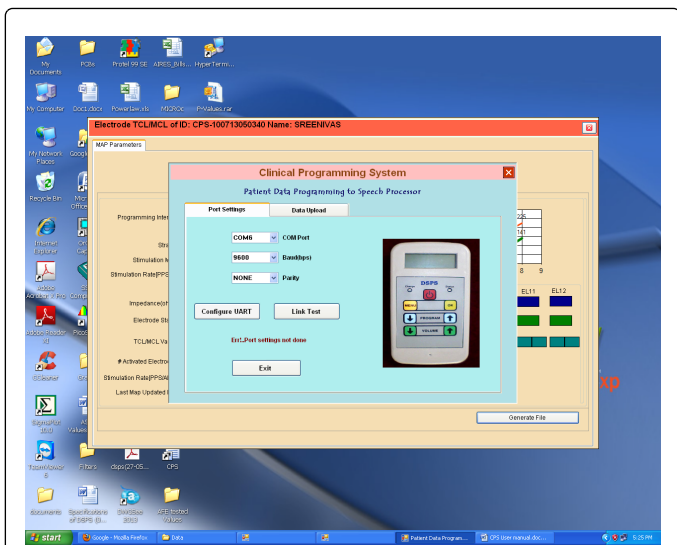


Figure 33: Digital Speech Processor System (DSPS) with activated Port settings Tab.

39. Set “Com Port” to COM1, “Baud Rate (bps)” to 9600, “Parity” to NONE.

40. Click on Configure UART button to observe COM1 port parameters as “COM1-9600-NONE-1” as shown in Figure 34 below.

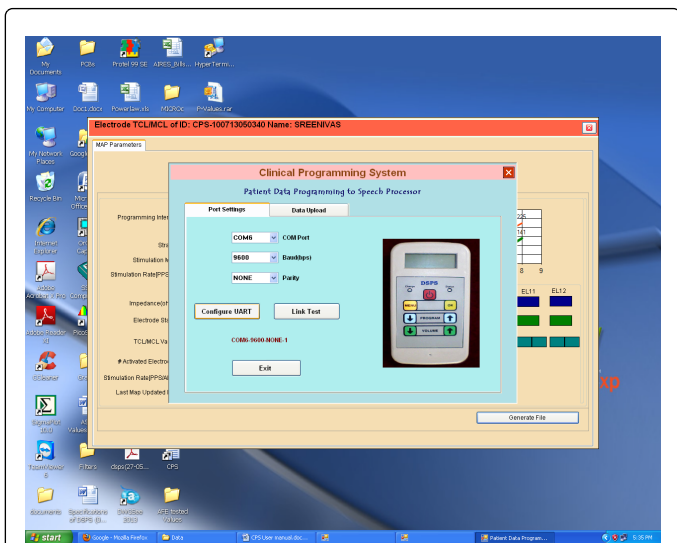


Figure 34: Digital Speech Processor System (DSPS).

41. Click on LINK TESTS Wait for UART Link is working message window and click on OK button. See Figure 35 below.

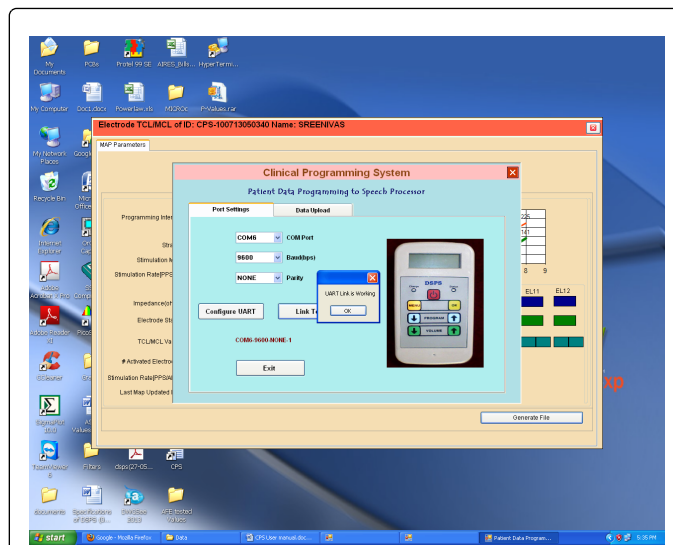


Figure 35: Digital Speech Processor System (DSPS).

42. Click on Data Upload tab and observe three buttons: PATIENT INFO., PLV Table and FILTER COEFFS are there. See Figure 36 below.

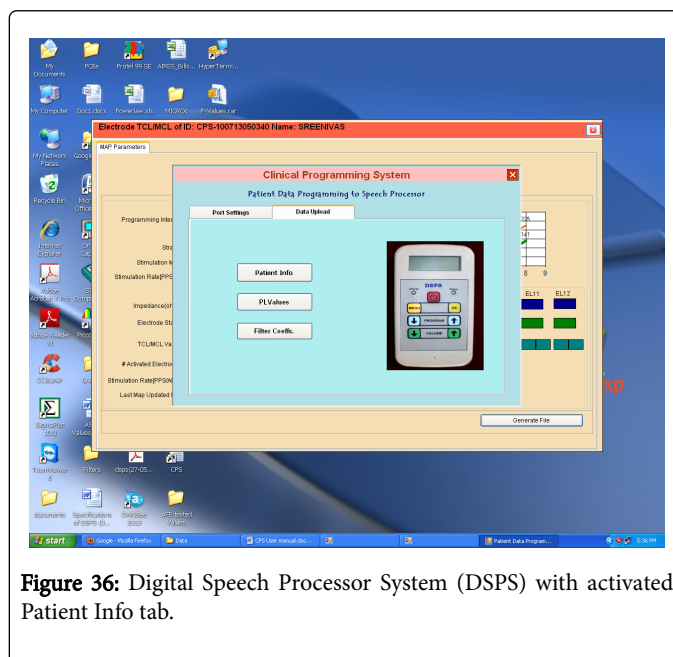


Figure 36: Digital Speech Processor System (DSPS) with activated Patient Info tab.

43. Click on Patient Info Button for uploading the patient information into the DSPS unit. Then click on OK button in Received Response window. See Figure 37 below.

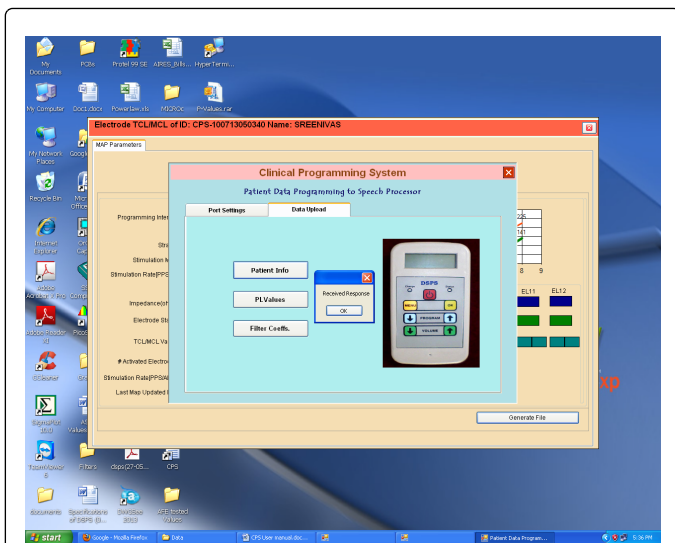


Figure 37: Digital Speech Processor System(DSPS) with activated Patient Info tab.

44. Wait for the “Transmitted the Patient Data file” message box and then click on OK. See Figure 38 below.

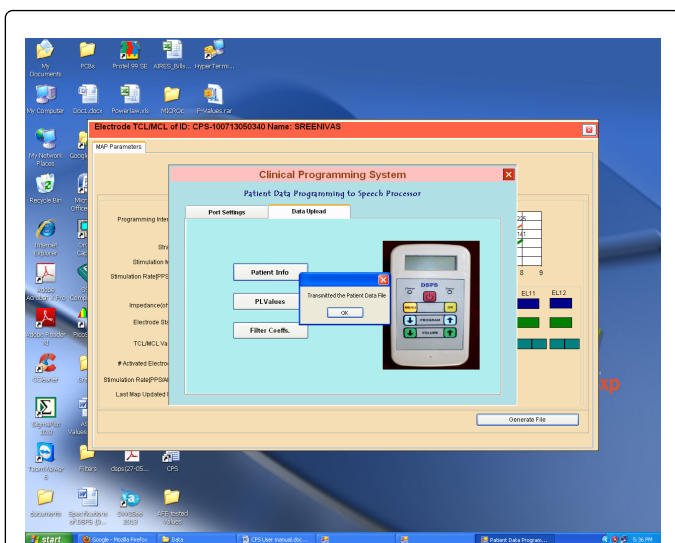


Figure 38: Digital Speech Processor System(DSPS) with activated Patient Info tab.

45. Click on PLV Table for Uploading the Power Law Values Table into the DSPS unit and click on OK button in Received Response window. See Figure 39 below.

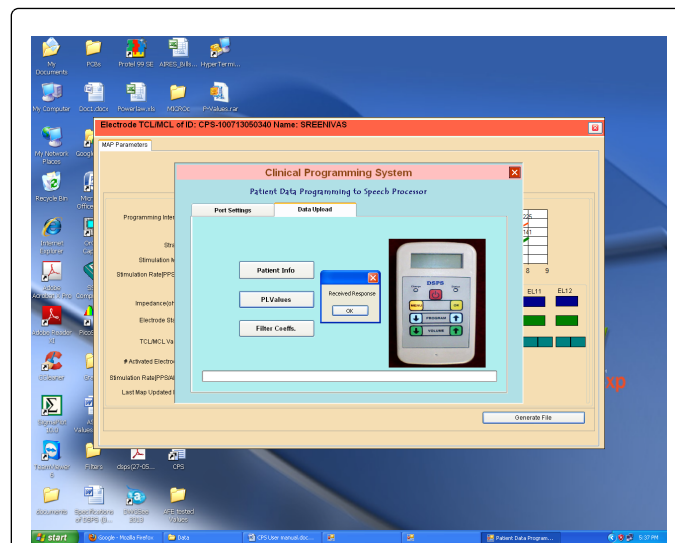


Figure 39: Digital Speech Processor System (DSPS)with activated Data Upload tab.

46. Wait (around five minutes) until we get Transmitted the PLV File window. Click OK. See Figure 40 below.

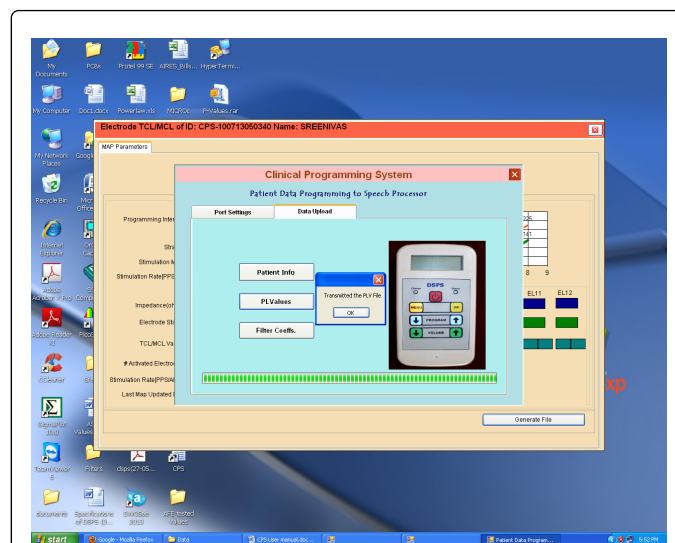


Figure 40: Digital Speech Processor System (DSPS)with activated Data Upload tab.

47. Click on Upload Filter Coeffs Button and click on OK button in Received Response window for uploading the Filter Coefficients into the DSPS unit. See Figure 41 below.

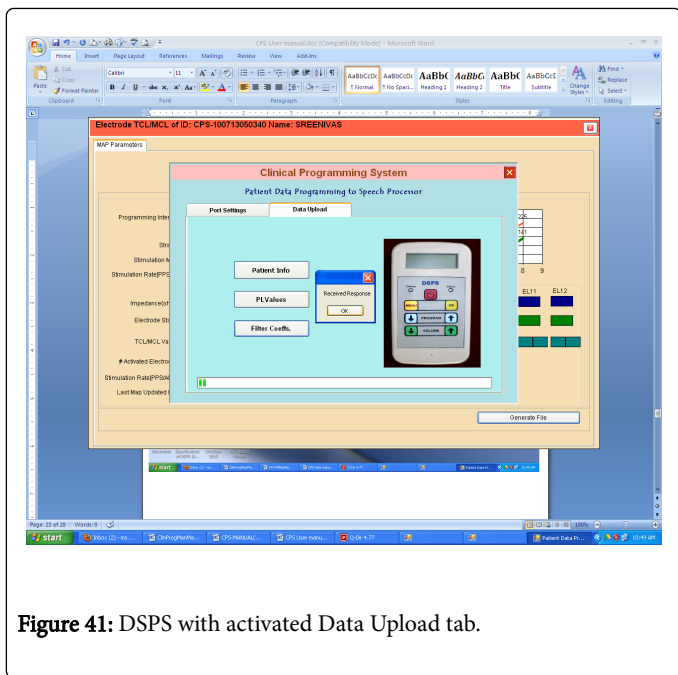


Figure 41: DSPS with activated Data Upload tab.

48. Wait for the “Transmitted the Coeffs file” message box and then click on OK. See Figure 42 below.

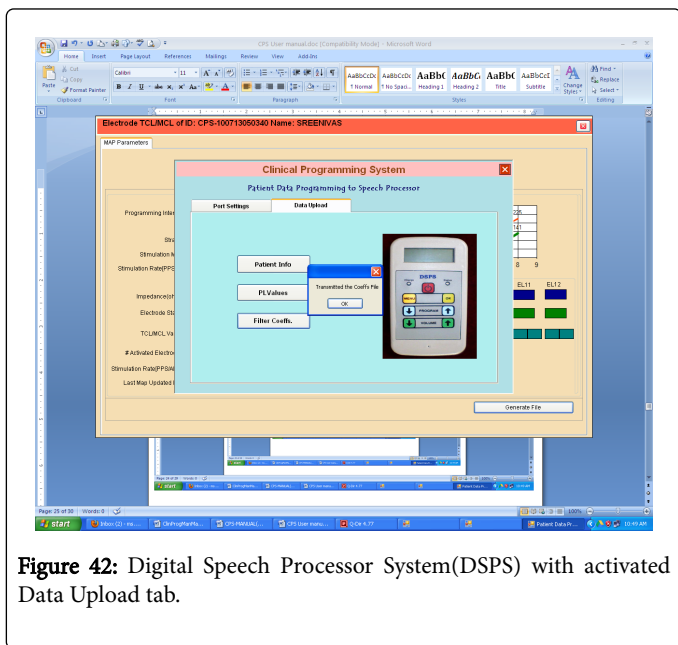


Figure 42: Digital Speech Processor System(DSPS) with activated Data Upload tab.

49. Click on Port settings and press the Exit button. See Figure 43 below.

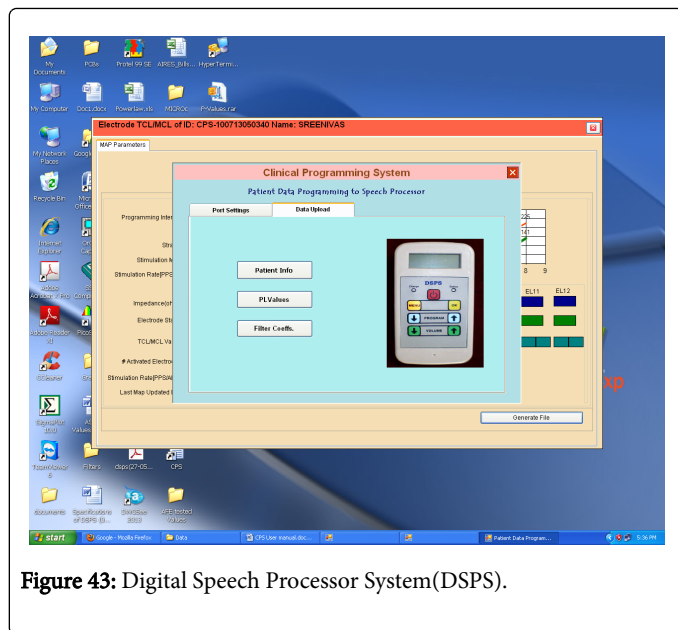


Figure 43: Digital Speech Processor System(DSPS).

50. Click on Exit button for Exiting from GUI mode in DSPS. See Figure 44 below.

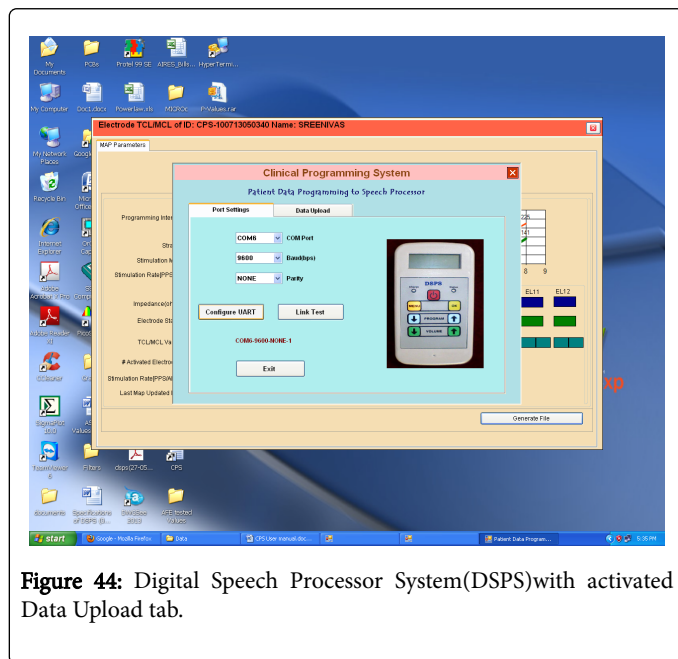


Figure 44: Digital Speech Processor System(DSPS)with activated Data Upload tab.

51. Click on OK button in Exiting DSPS GUI message window for closing the Digital Speech Processor System(DSPS) window. See Figure 45.

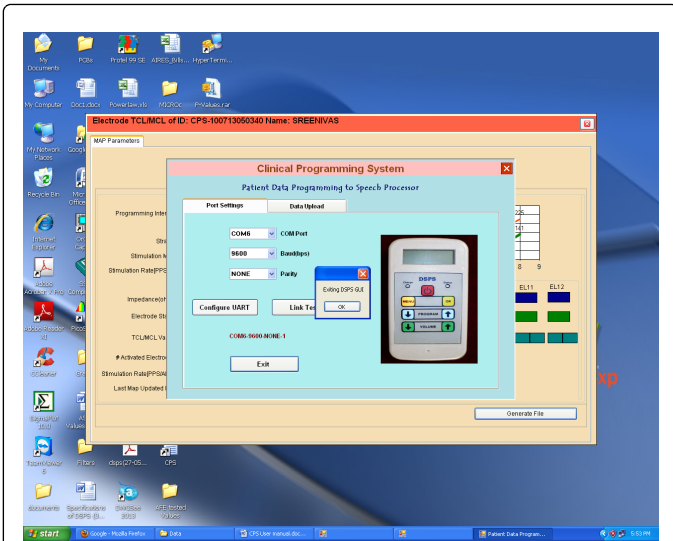


Figure 45: Digital Speech Processor System(DSPS)with activated Data Upload tab.

52. Click on Close X Symbol on Electrode TCL/MCL of ID: CPS-1112114092222, Name: umamaheswararao window and it opens the Home Page Window. See Figure 46 below.

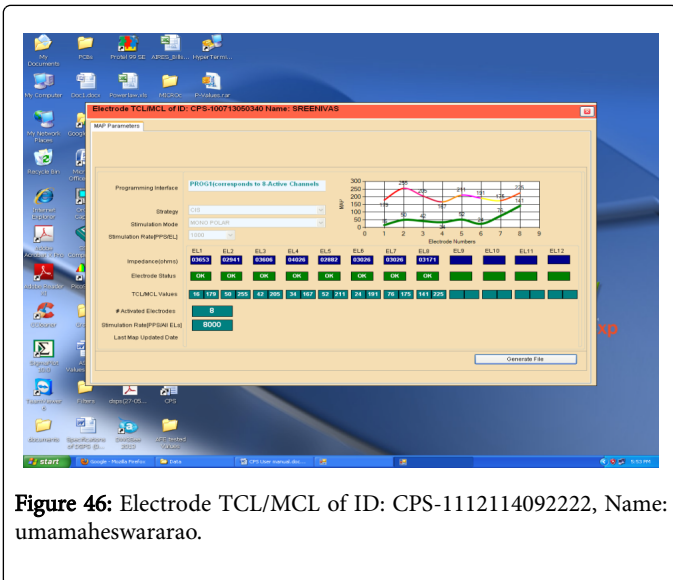


Figure 46: Electrode TCL/MCL of ID: CPS-1112114092222, Name: umamaheswararao.

53. Click on Close X Symbol on Home Page window for closing the Clinical Programming Software. See Figure 47 below.

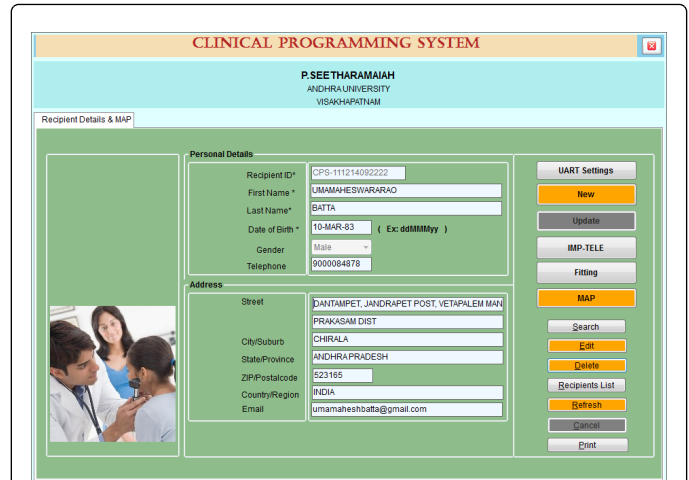


Figure 47: Home Page.

54. Disconnect the DSPS Unit from PC by unplugging USB to Serial Port cable. See Figure 48.

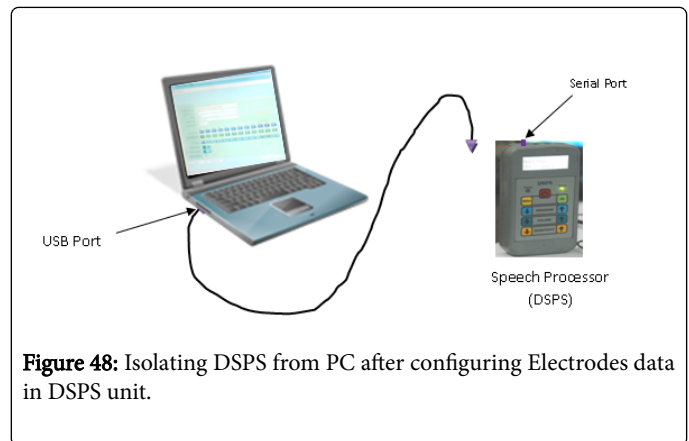


Figure 48: Isolating DSPS from PC after configuring Electrodes data in DSPS unit.

55. Connect Head-Set Cable to the DSPS unit as shown in Figure 49.

Speech processor is ready for user training

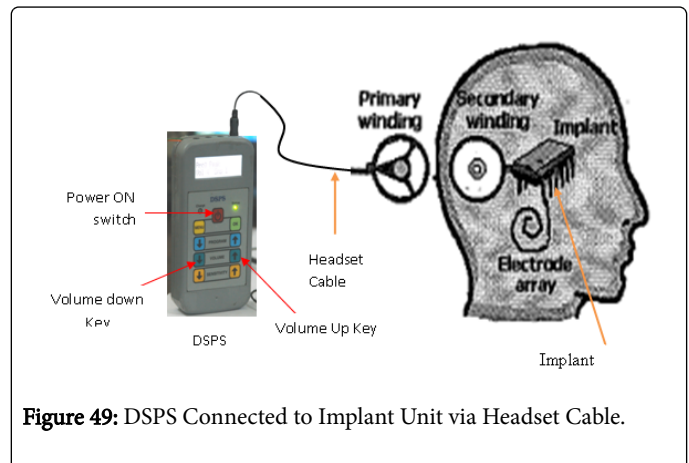


Figure 49: DSPS Connected to Implant Unit via Headset Cable.

56. Power ON the DSPS unit by pressing and holding Power ON switch for three seconds and adjust Volume setting required by the

user using Volume UP and DOWN keys for comfortable hearing levels.

Conclusion

This paper discussed a safety analysis for clinical programming systems. A software safety analysis involving a combination of FMEA and FTA techniques was conducted on the software functions of the critical system to identify potentially hazardous software faults. The safety properties of the CPS were identified by conducting the safety analysis. CPS offers a great benefit to both the audiologist and hearing impaired patients by way of balancing the channels with suitable threshold levels of hearing. These safety requirements were incorporated in the design and development of Clinical programming system of Bionic ear. Impedance telemetry software implementation details to perform resistance measurement function and also as an interface module between CPS and IRS is covered with relevant flowcharts. Clinical Programming Software is developed and implemented for DSPS and ITMS with Receiver-Stimulator as used by an audiologist for performing post-operative fitting procedure for better recognition of speech/sound.

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