Software Safety Analysis for Clinical Programming Software of Cochlear Implant System

Unamaheswararao B1 and Seetharamaiah P2

1Dept. of Computer Sciences, Andhra University, Visakhapatnam, India
2Dept. of Computer Sciences, Andhra University, Visakhapatnam, India

Corresponding author: Unamaheswararao B, Dept. of Computer Sciences, Andhra University, Visakhapatnam, India, Tel: +91 9000084878; Email: umamaheshbetta@gmail.com

Rec date: Aug 04, 2015; Acc date: Oct 06, 2015; Pub date: Oct 09, 2015

Copyright: © 2015 Unamaheswararao B, et al. This is an open-access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.

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 rare 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 external 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 incidence 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 logically 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 (Groller, 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 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).

<table>
<thead>
<tr>
<th>DATE</th>
<th>COUNTRY</th>
<th>CAUSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>June 3, 1985</td>
<td>Marietta, GA</td>
<td>Breast removal, loss of use of arm</td>
</tr>
<tr>
<td>July 26, 1985</td>
<td>Ontario, Canada</td>
<td>Total hip replacement needed</td>
</tr>
</tbody>
</table>
Techniques, data migration mistakes when new systems are applied or modified

Citation: following main areas such as Manage all required information for each incorporated from

provided, data losing from individual information without the another program when the full perspective for the information was not decoding medical information coming through an interface from CPS

processor, loading/Mapping THL/MCL of Active Electrodes into

adjust sound processing and stimulation parameters in a speech activated continually because some of the resource information was major program improvements occur,

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

Table 1: Causes of hazards.

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>Cause</th>
</tr>
</thead>
<tbody>
<tr>
<td>January 6, 1986</td>
<td>Yakima, WA</td>
<td>Minor disability and scarring</td>
</tr>
<tr>
<td>March 21, 1986</td>
<td>Tyler, TX</td>
<td>Death</td>
</tr>
<tr>
<td>April 11, 1986</td>
<td>Tyler, TX</td>
<td>Death</td>
</tr>
<tr>
<td>January 17, 1987</td>
<td>Yakima, WA</td>
<td>Death</td>
</tr>
</tbody>
</table>
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).

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

<table>
<thead>
<tr>
<th>Phenomenon</th>
<th>Cause</th>
<th>Effect</th>
<th>Probability</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Occurrence of virus in the CPS software</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) Some unknown programs running in background</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

cause software conflict damage the CPS software Marginal shut down all programs except CPI software

Telemetry measurement not possible message

<table>
<thead>
<tr>
<th>Phenomenon</th>
<th>Cause</th>
<th>Effect</th>
<th>Probability</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Logic fault</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) Interface fault</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c) Data fault</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d) Calculation fault</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>e) Memory fault</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Telemetry measurement if the calibration measurement cannot be performed successfully Other failures in power supply, loss of system operation Marginal

Control program software is corrupted

<table>
<thead>
<tr>
<th>Phenomenon</th>
<th>Cause</th>
<th>Effect</th>
<th>Probability</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Logic fault</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) Interface fault</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c) Data fault</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d) Calculation fault</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>e) Memory fault</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

a) Occurrence of virus in the CPS software b) Some unknown programs running in background

Unpredictable sequence of operations minor or Marginal

Table 2: SFMEA Analysis of CPS Software.

Software fault tree analysis (sfta) of cps

After determining the top-level failure events, a complete Software Fault Tree Analysis shall be performed to analyze the faults that can cause those failures. This is a top-down technique that determines the origin of the critical failure. The top-down technique is applied following the information provided at the design level, descending to the code modules. Figure 1 shows the sample fault tree for the top event the display of Hardware not found message.

![Fault Tree Diagram]

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, 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.

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.

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 Figure 3.

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).
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.

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.
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.

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.

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.

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

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.

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.

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

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

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.

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

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

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.

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

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.

Mapping THL/MCL of active electrodes into DSPS

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.

33. Click on GENERATE FILE button in Electrode THLs/MCLs of ID: CPS-111211409222, Name: umamaheswararao window. See Figure 29 below.
34. See Digital Speech Processor System (DSPS) window for programming the Electrodes data into the DSPS unit. See Fig. 30 below.

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.

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

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.
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.

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

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

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

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.

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

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

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

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

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

References

1. Dr Lepmets M, Dr Clarke P, Dr McCaffery F and Finnegan F Regulated Software Research Centre, Dundalk Institute of Technology.