Implantable Receiver Stimulator for Profoundly Deaf People – Cochlear Implant System-STPA Analysis of Clinical Programming Software

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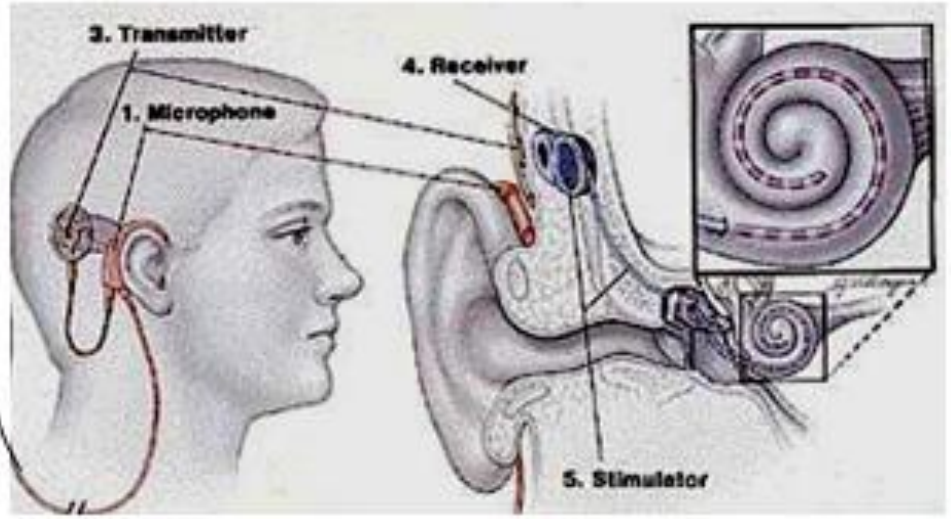
ITMS

Speech Processor (DSPS)



Implant

STAMP/STPA WORKSHOP 2017 Massachusetts Institute of Technology, Boston, USA

- Hearing impairments are clinically categorized into two major groups:

Conductive _ Problems at the external or middle ear that block or degrade sound transmission from the external ear to the cochlea are the cause of conductive hearing loss. Replacements of the middle ear bones and other sophisticated corrective procedures are available for conductive hearing loss patients.

Sensorineural Sensorineural hearing loss involves damages in the hair cells of inner ear or cochlea that result in a change in sensitivity to sound. The loss of hair cells in the cochlea due to exposure to loud sound or heavy drug treatment is the most common sensorineural impairment and also results in subsequent degeneration of the adjacent auditory neurons

- If the hair-cell and/or auditory nerve damage is excessive, the connection between the brain and the external world is lost and the person who has such level of loss is recognized as being profoundly deaf (hearing loss of more than 90 dB for Pure Tone Average (PTA) frequencies). However, some amount of living auditory neurons can still exist in the cochlea, even with extensive loss of hair cells. Direct electrical stimulus of auditory neurons can create a sound sensation in profoundly deaf people.

- The electronic neural stimulus systems for electrical stimulation of auditory nerves using a line array of electrodes inserted in cochlea, developed as bionic implants based on embedded computing approach are named as cochlear implants or cochlear prosthesis.

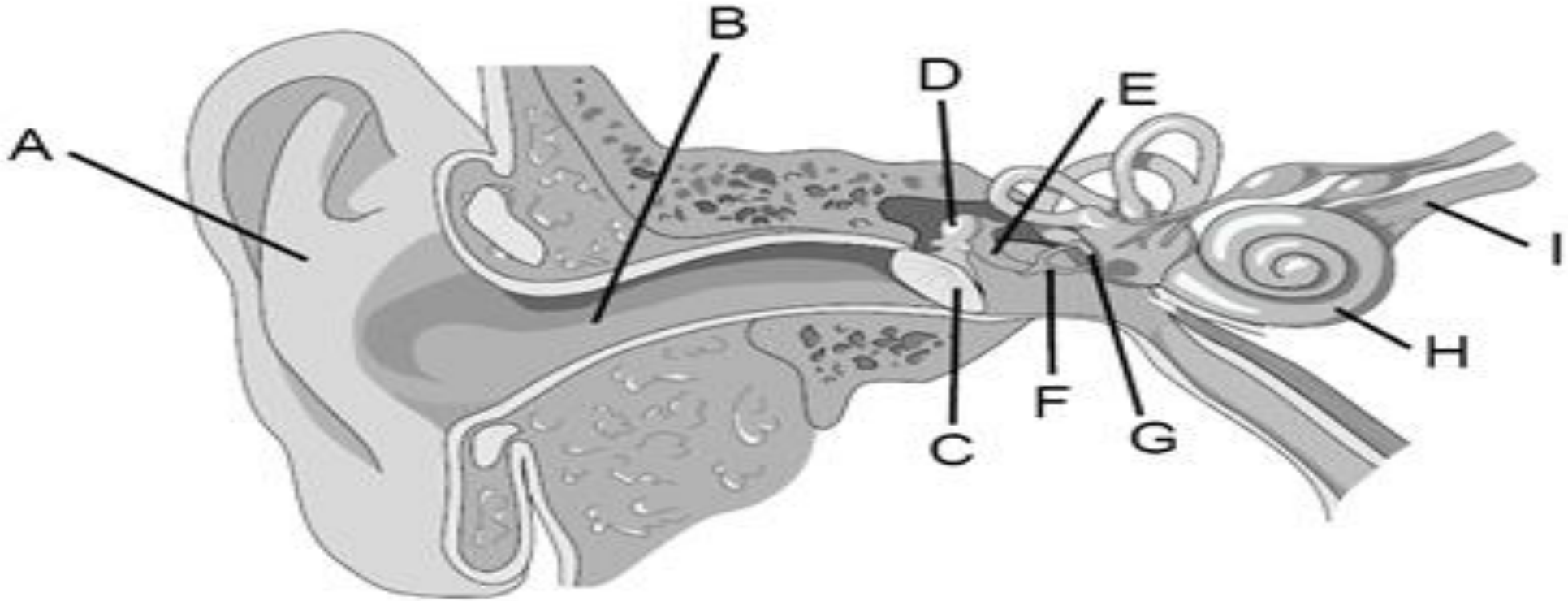
RESEARCH REQUIRED IN EMBEDDED SYSTEMS FOR DIGITAL HEALTH PRODUCTS

- **INDIGENOUS PRODUCT DEVELOPMENT**
  - **Proprietary (Patents)**
  - **Affordable Cost for use by common people**
- **BETTER PERFORMANCE**
  - **100% functionality**
- **LOW POWER CONSUMPTION**
- **DIGITAL HEALTH PRODUCT EXAMPLES**
  - **PROSTHETIC DEVICES**
    - **AUDITORY PROSTHESIS**
    - **RETINAL PROSTHESIS**

NEED FOR AUDITORY PROSTHESIS

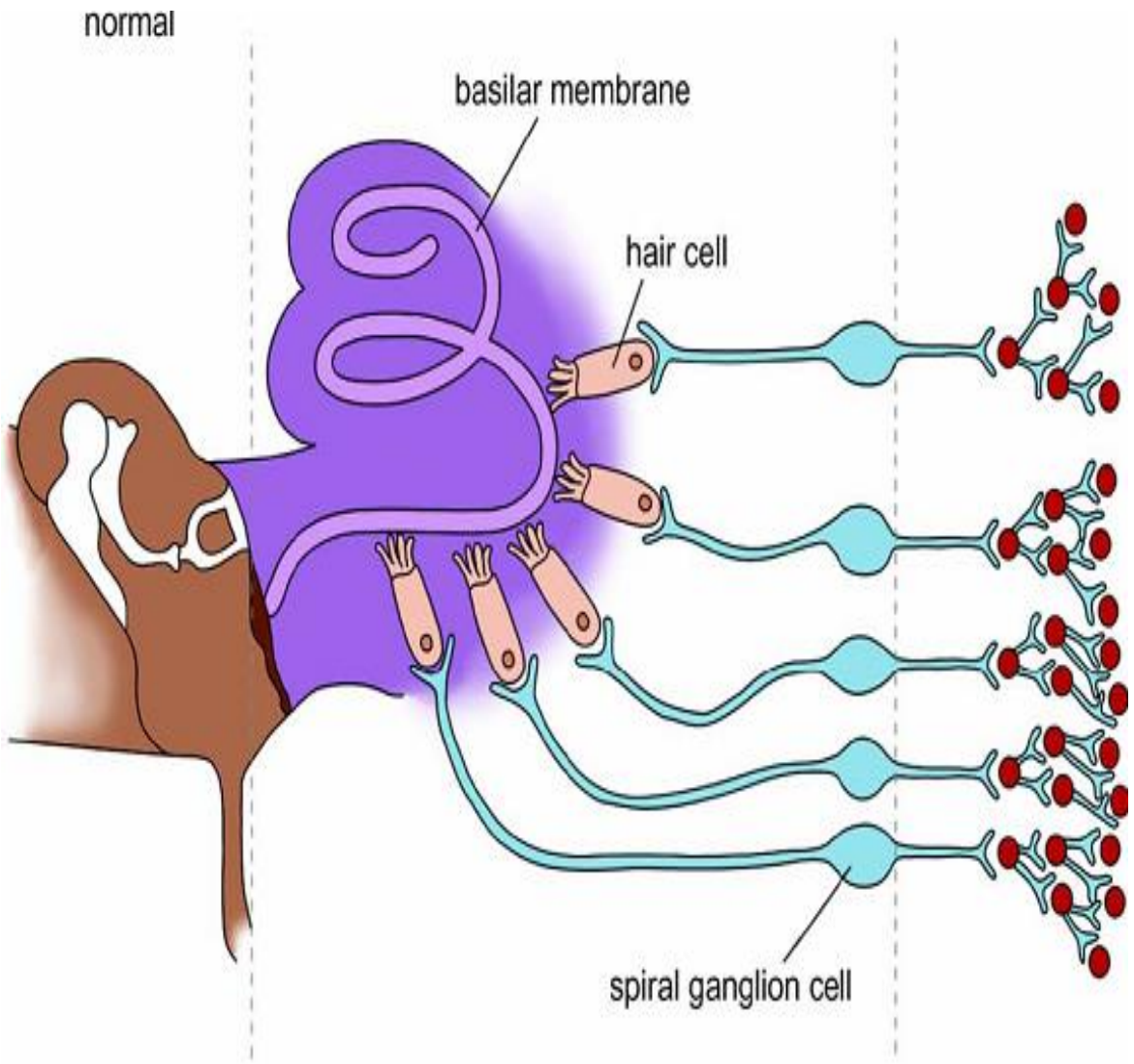
- **DEAF PEOPLE IN INDIA**
  - 1.7 MILLION BETWEEN 15 AND 59 YEARS OF AGE.(NSSO,2001)
  - 18 MILLION (THE HINDU, NEW DELHI, DECEMBER 4,2011)
  - 63 MILLION(WHO, MEGHALAYA TIMES, DECEMBER 4, 2011)
- **AUDITORY PROSTHESIS OR COCHLEAR IMPLANT**
- **COST OF COCHLEAR IMPLANT AT PRESENT**
  - AROUND RS 8 LAKHS
- **80-90% SPEECH RECOGNITION**
- **IMPROVEMENTS REQUIRED**
  - SPEECH/MUSIC/NOISY ENVIRONMENTS
  - PERFORMANCE
  - POWER , SIZE , COST
  - RELIABILITY & SAFETY

Anatomy of the human ear

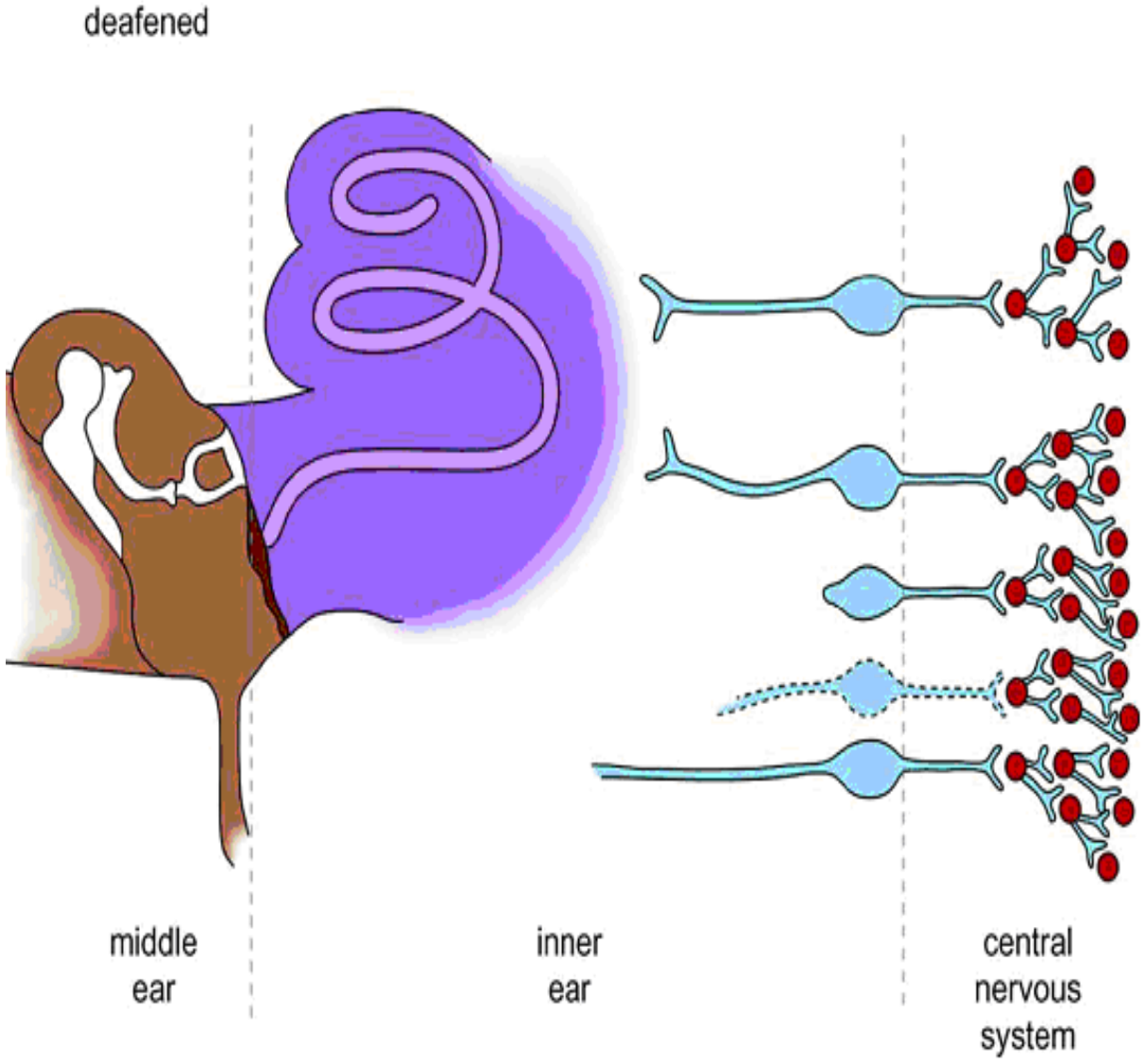


(A) pinna, (B) external auditory meatues, (C) tympanic membrane, (D) malleus, (E) incus, (F) stapes, (G) oval window, (H) cochlea , (I) auditory nerve.

Normal Hearing

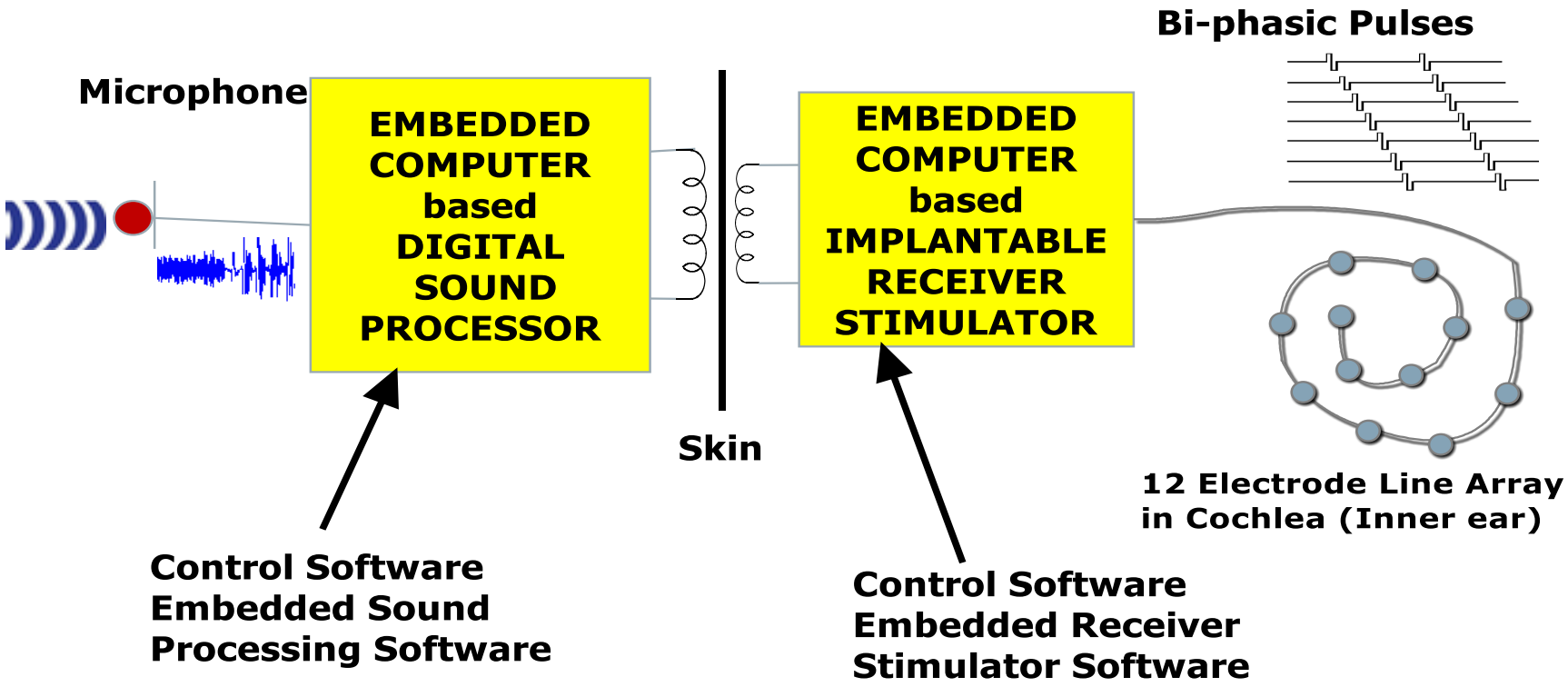


Deafened



RESEARCH PROBLEM

Development of a Embedded Computer based Cochlear Implant System a.k.a Bionic-Ear as a prototype model that is adaptable to product development.

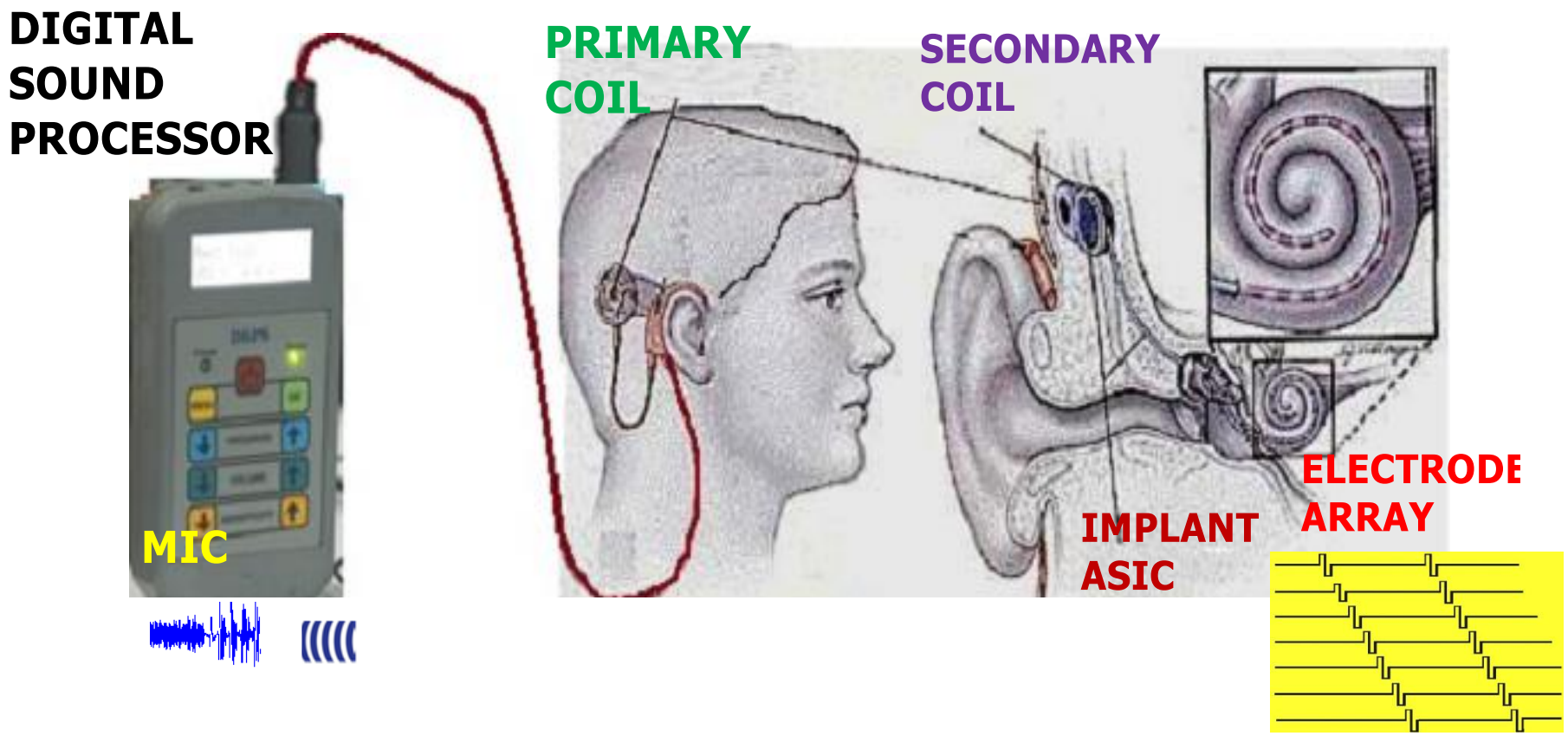


BWSP with head set

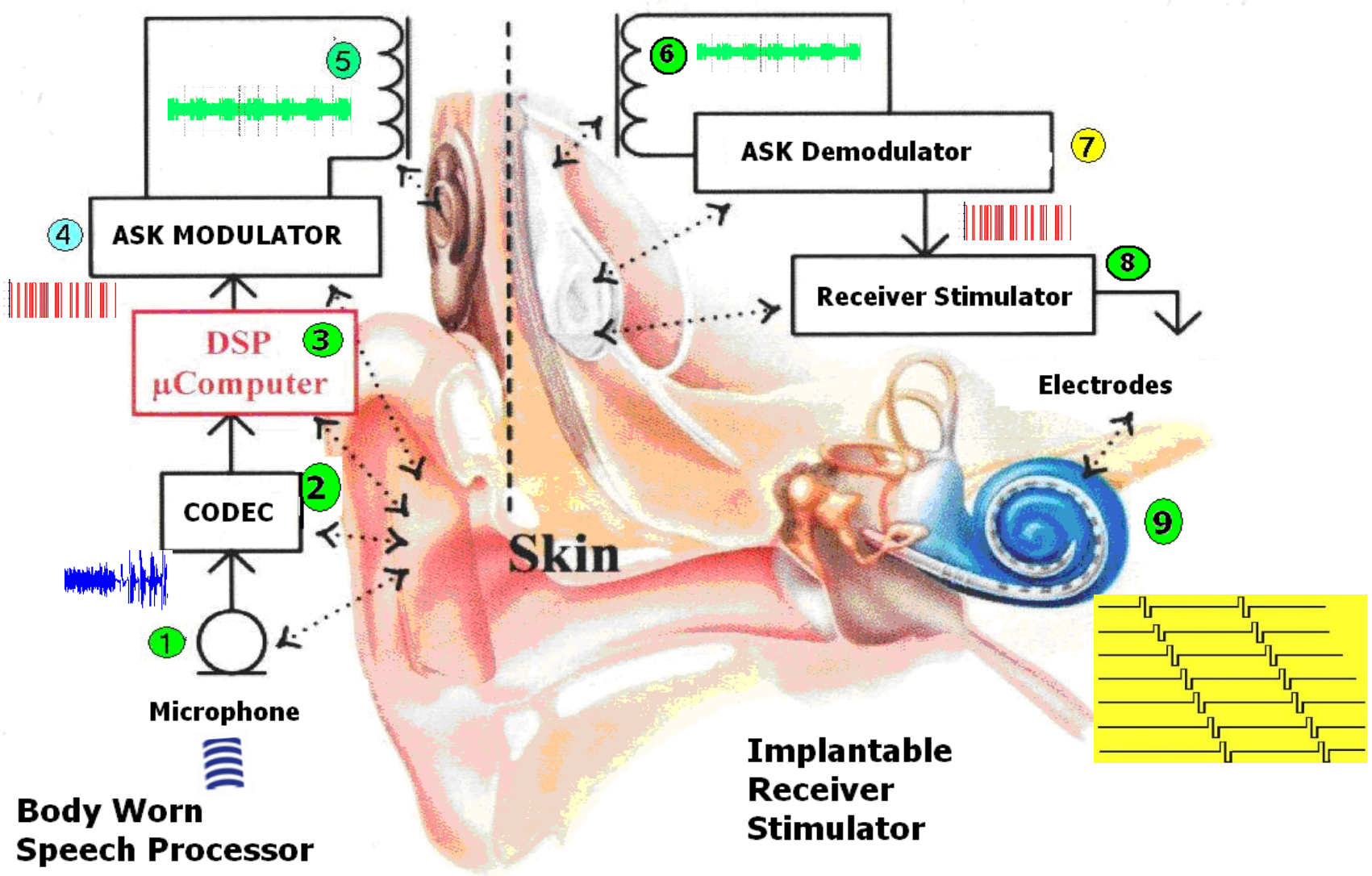
Receiver-Stimulator

ASIC Chip of Receiver Stimulator

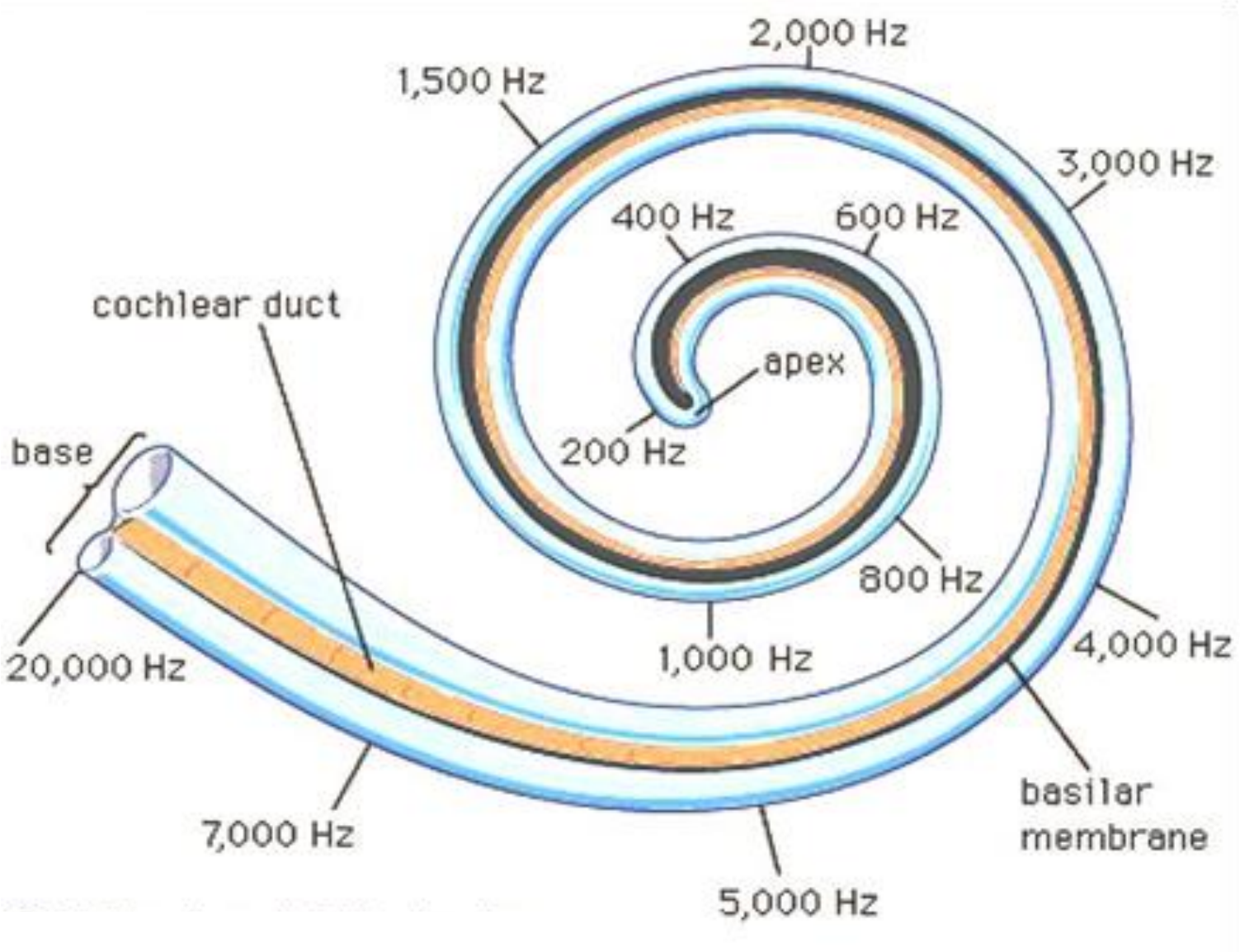
EMBEDDED COMPUTER BASED DIGITAL SOUND PROCESSOR WITH IMPLANTABLE RECEIVER STIMULATOR WITH EXPANDED VIEW



FUNCTIONAL OPERATION OF BIONIC EAR

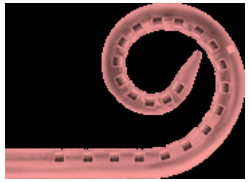


FREQUENCY ASSIGNMENT – PLACE CODING

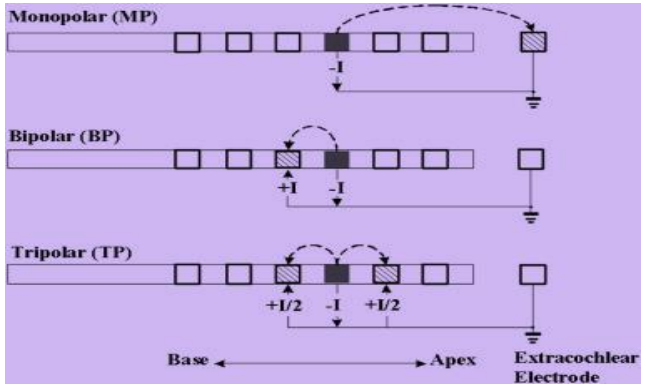


COCHLEAR IMPLANT SYSTEM DESIGN REQUIREMENTS

- **SPEECH PROCESSING ALGORITHMS**
  - CIS, SMSP, SPEAK, ACE
- **NUMBER OF SENSING ELEMENTS**
  - 12 ELECTRODES



- **ORDER OF STIMULATING THE SENSORS**
  - SEQUENTIAL
  - NON SEQUENTIAL
- **POWER AND DATA TRANSFER BETWEEN SP & RS**
  - PERCUTANEOUS
  - TRANSCUTANEOUS
- **TYPE OF STIMULATION**
  - MONOPOLAR
  - BIPOLAR
  - TRIPOLAR



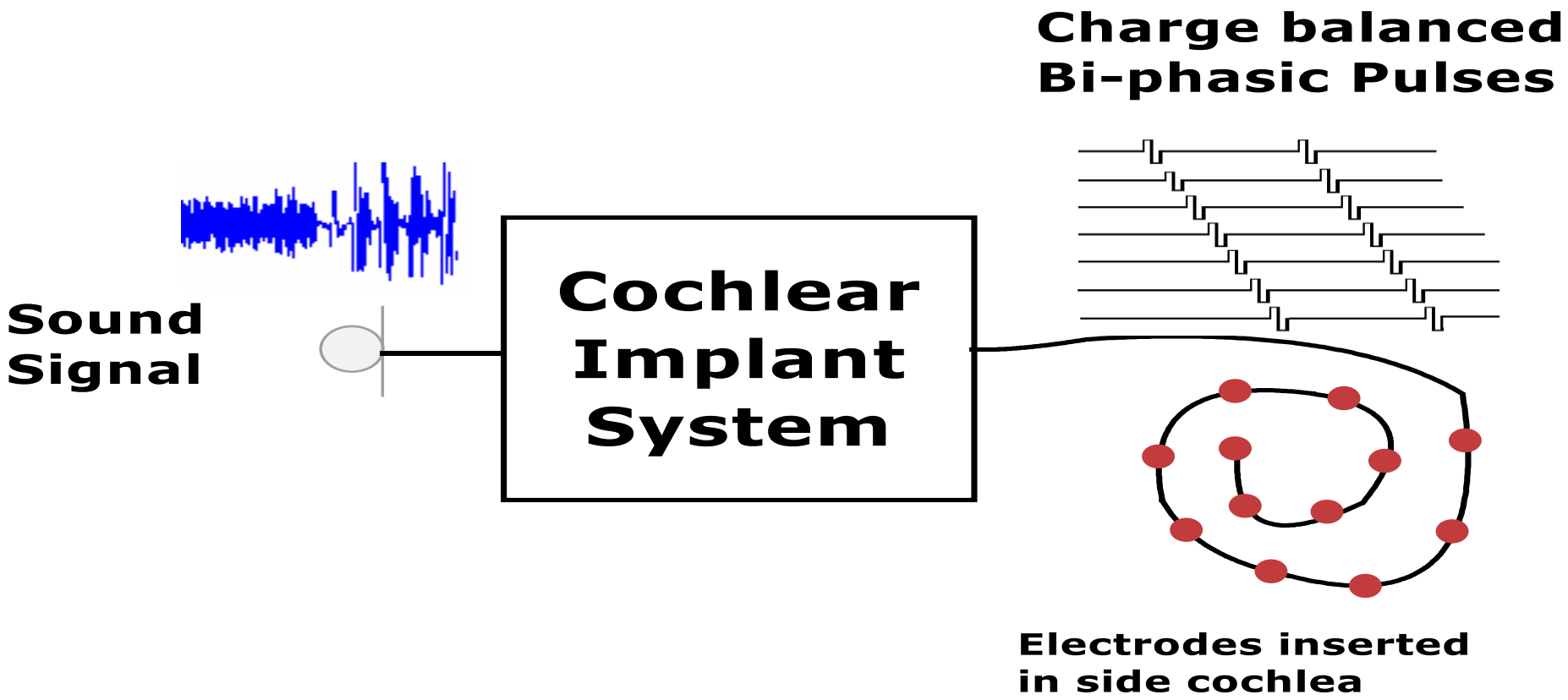
PROPOSED SOLUTION : DESIGN SPECIFICATIONS

- **MODIFIED CONTINUOUS INTERLEAVED SAMPLING (CIS) SPEECH PROCESSING ALGORITHM**
  - Programmability
  - Higher Stimulation
- **NUMBER OF ELECTRODES**
  - 12 Electrodes
- **BI-PHASIC PULSATILE STIMULATION**
  - Minimize the channel interactions
- **SEQUENTIAL STIMULATION**
  - From APEX to BASE

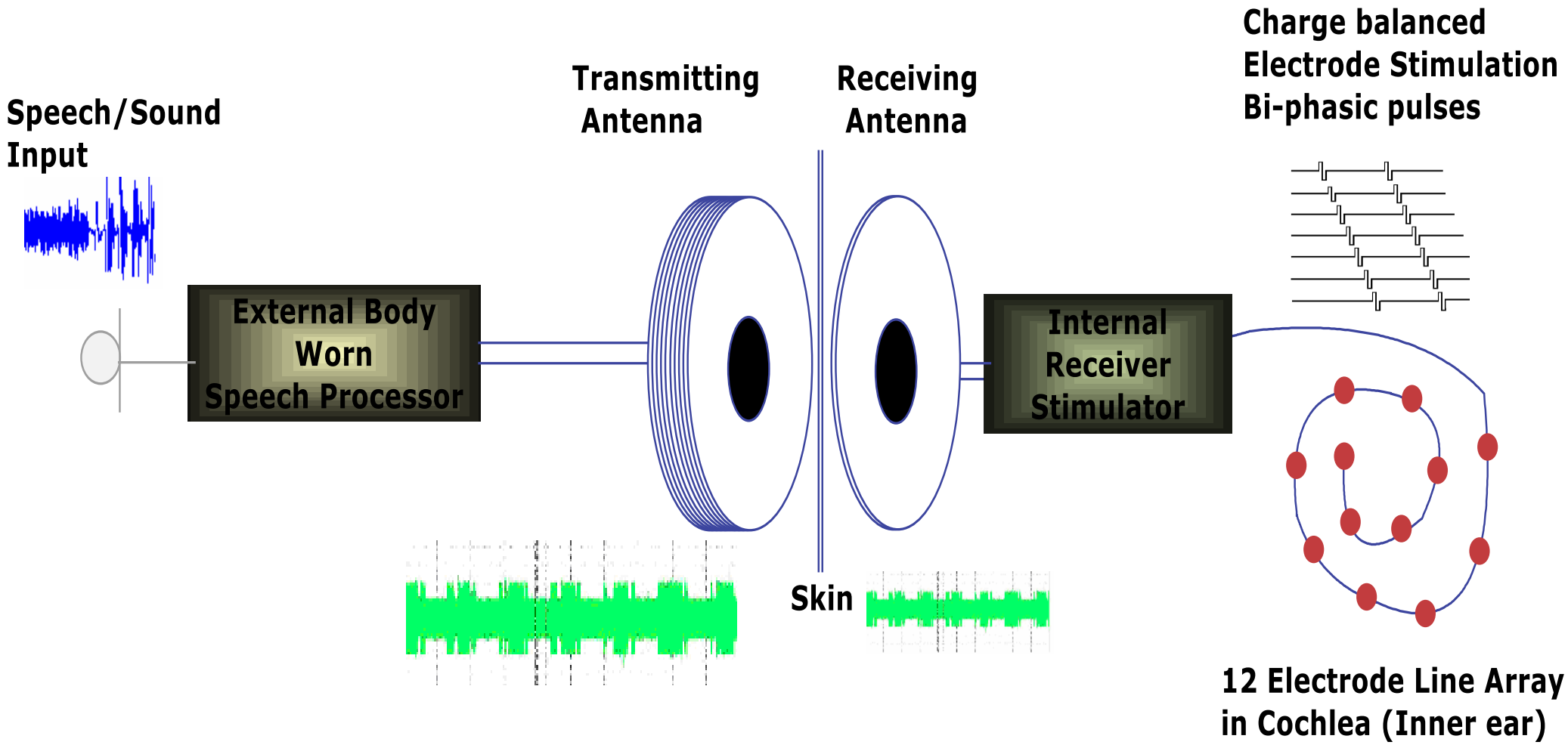
PROPOSED SOLUTION : DESIGN SPECIFICATIONS

- IMPLANT POWER AND DATA TRANSFER
- STIMULATION TYPE
  - CONSTANT CURRENT SOURCE STIMULATION
- STIMULATION RATE
  - 833 – 1000 pps/electrode/second
- COMMUNICATION PROTOCOLS
  - FCSB INSTEAD OF SEMA AND MANCHESTER

INPUT – PROCESSING – OUTPUT (IPO) REQUIREMENTS

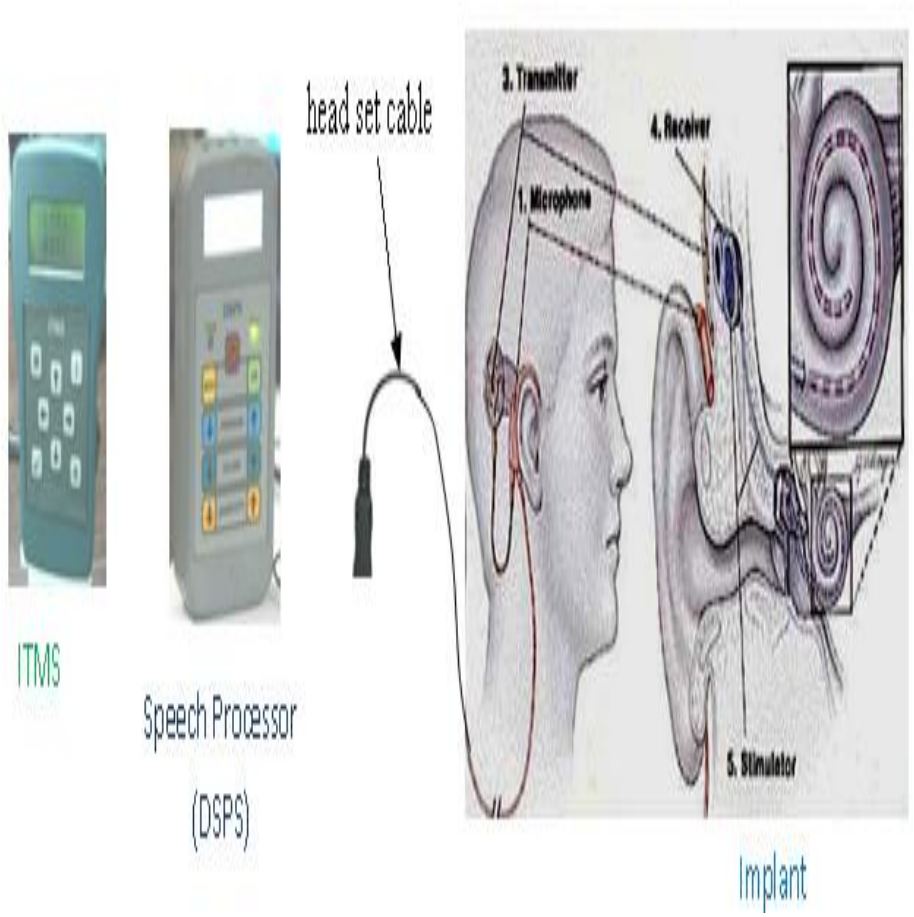


IPO REQUIREMENT OF COCHLEAR IMPLANT SYSTEM



CONTROL SOFTWARE FOR CLINICAL PROGRAMMING (CSCP) OF COCHLEAR IMPLANT SYSTEM (CIS)

- **CSCPS of CIS** - a laboratory prototype.
  - real-time, software controlled Medical Safety Critical System.
  - developed in order to validate the proposed Systems-theoretic approach.
  - consists of several software-controlled hardware components and software components.



CONTROL SOFTWARE FOR CLINICAL PROGRAMMING Modules

- Impedance Telemetry Monitoring System (ITMS)
- Digital Speech Processor System (DSPS)
- Implantable Receiver Stimulator (IRS)
- Control Software for Clinical Programming (CSCP)

IMPEDANCE TELEMETRY MONITORING SYSTEM (ITMS)

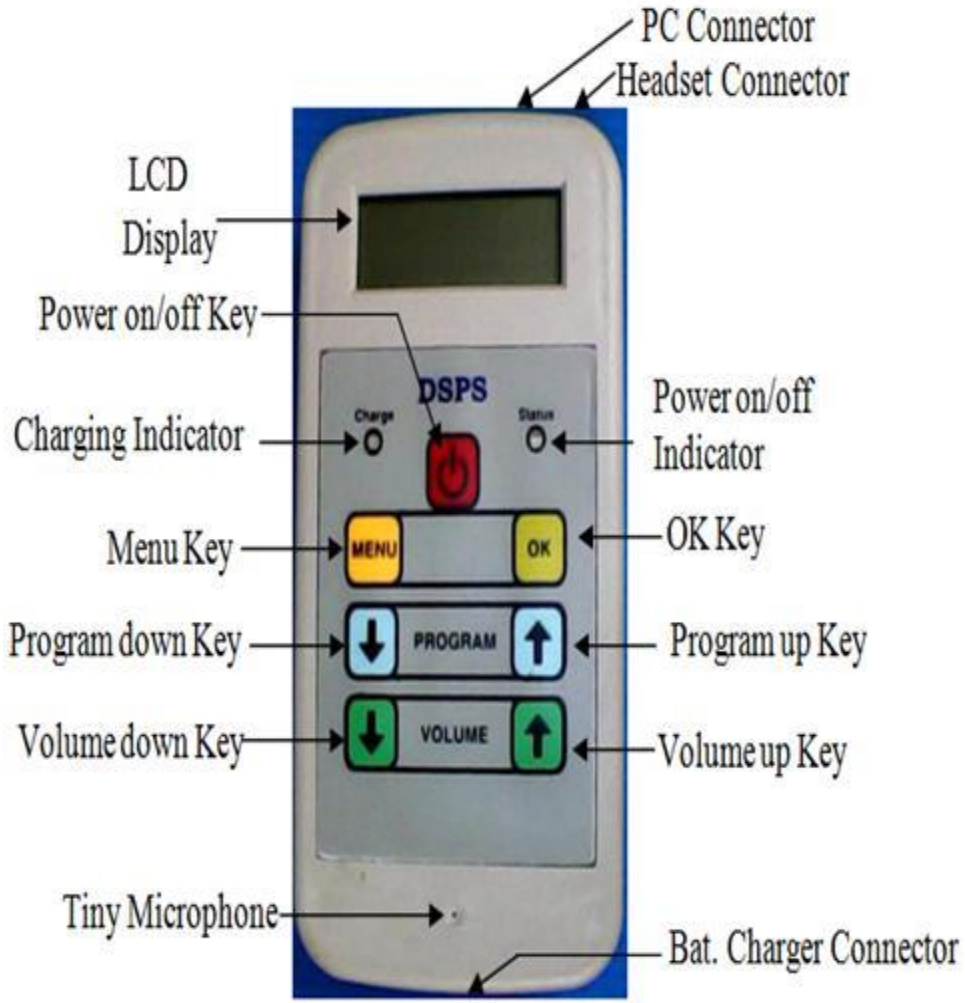
- Finding the active electrodes of electrode array of 12 Electrodes
- Measure impedances of a patient
- ITMS can operates in two modes
- Takes impedance values from patient
- Sends these impedance values to CSCP

ITMS

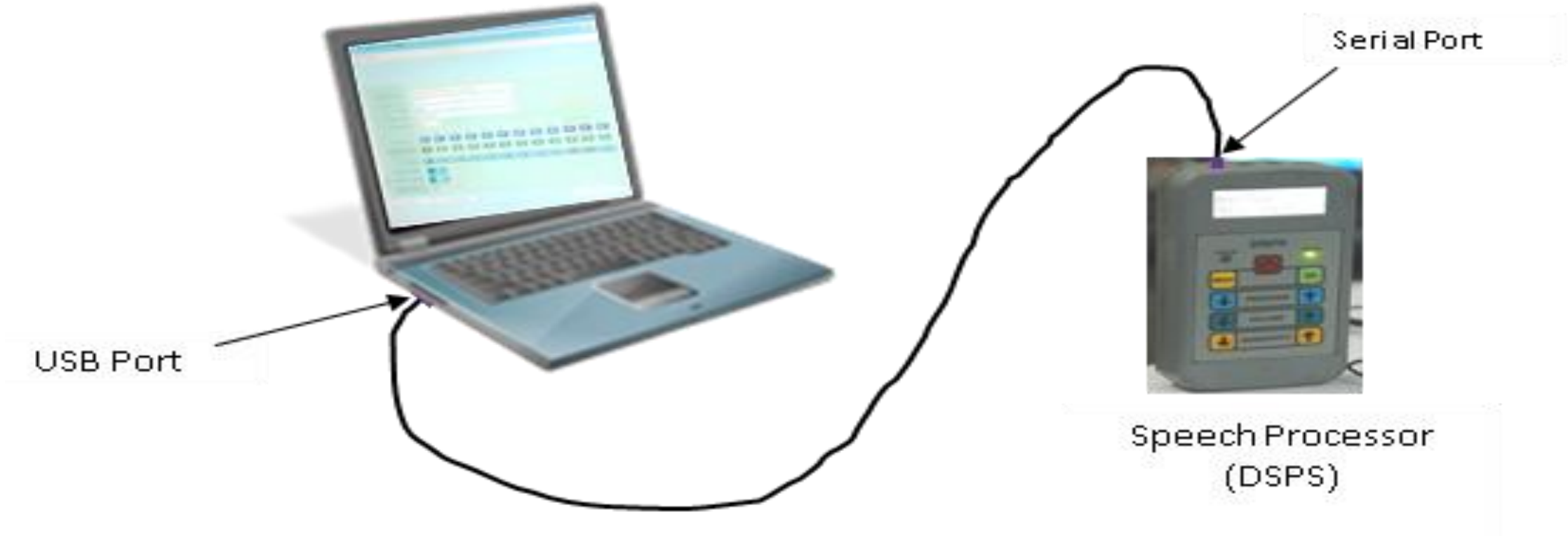
Clinical Programming Software by Audiologist

Digital Speech Processor System (DSPS)

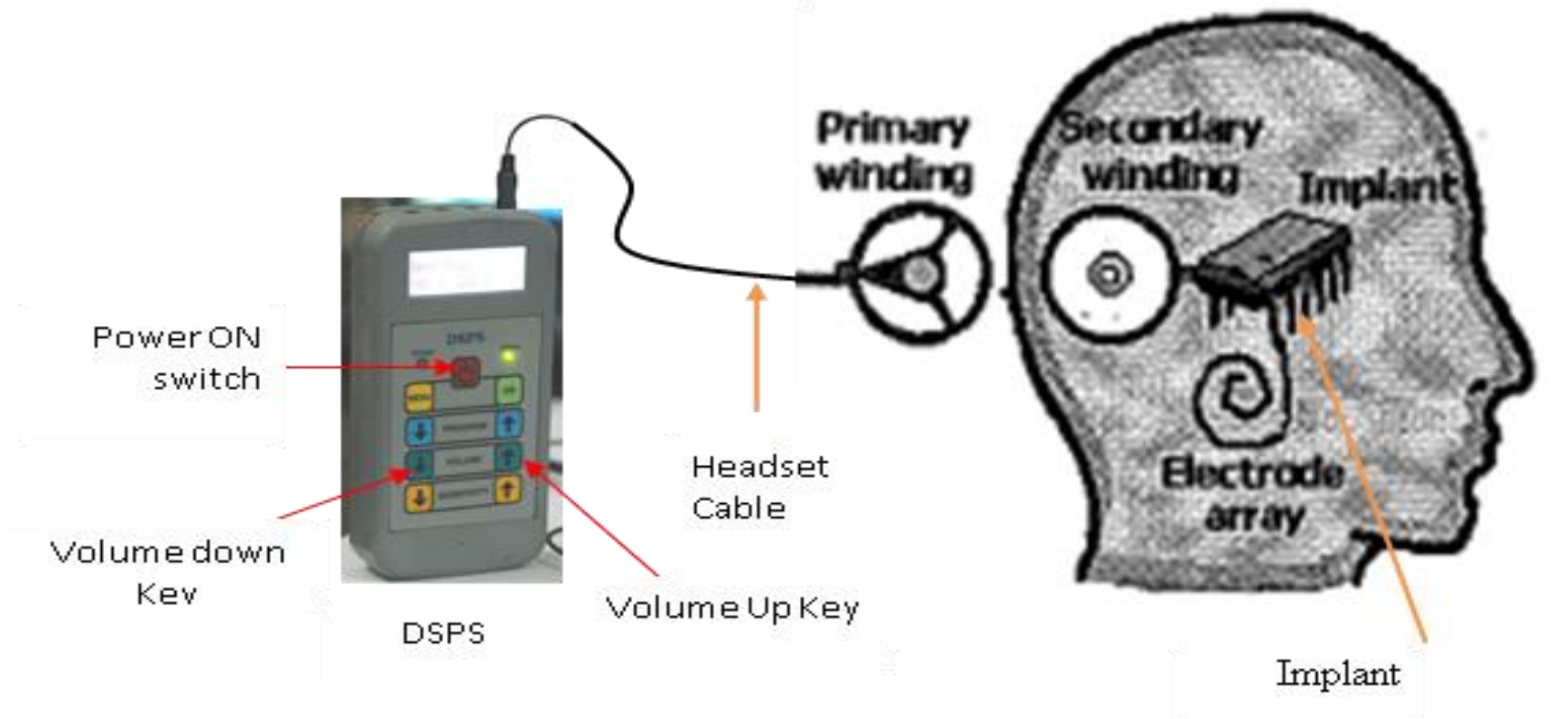
- Embedded system
- It receives sounds from a microphone,
- converts them to electrical signals and
- sends the signals to the headset
- Takes patient information from CSCP



Programming Electrodes Data file into the DSPS unit



DSPS Connected to Implant Unit via Headset Cable



IMPLANTABLE RECEIVER STIMULATOR (IRS)

- stimulate auditory nerve system with the help of electrode array placed inside the cochlea of deafened person
- embedded in the skull behind the ear

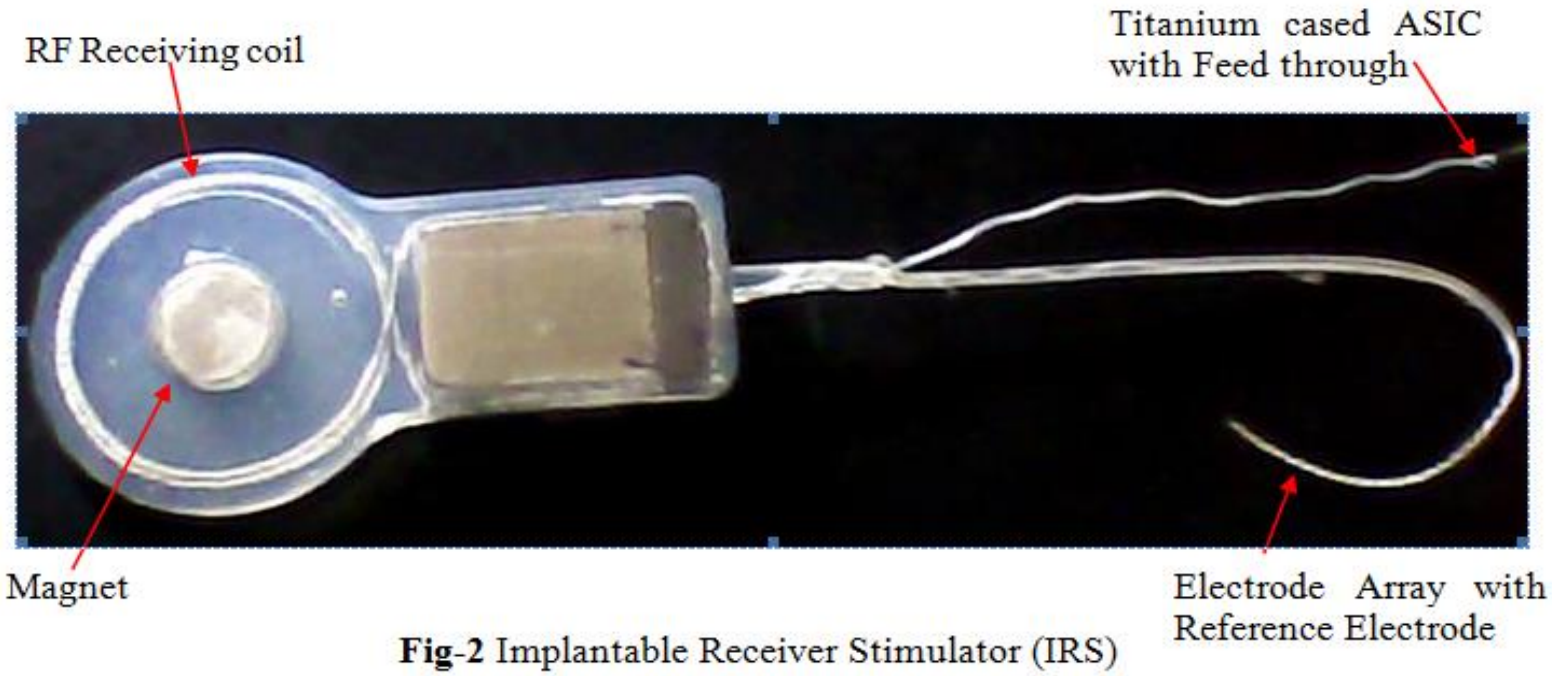
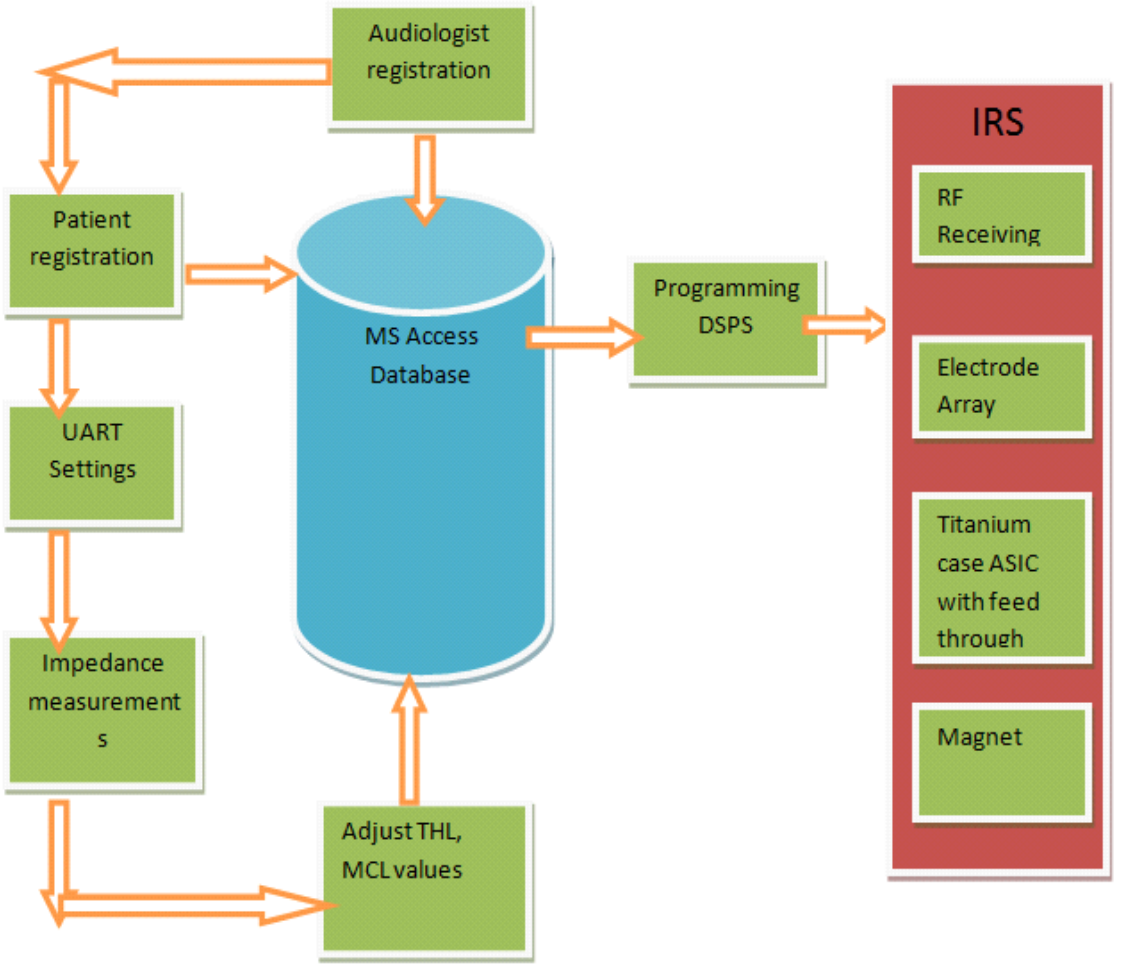


Fig-2 Implantable Receiver Stimulator (IRS)

CONTROL SOFTWARE FOR CLINICAL PROGRAMMING (CSCP)

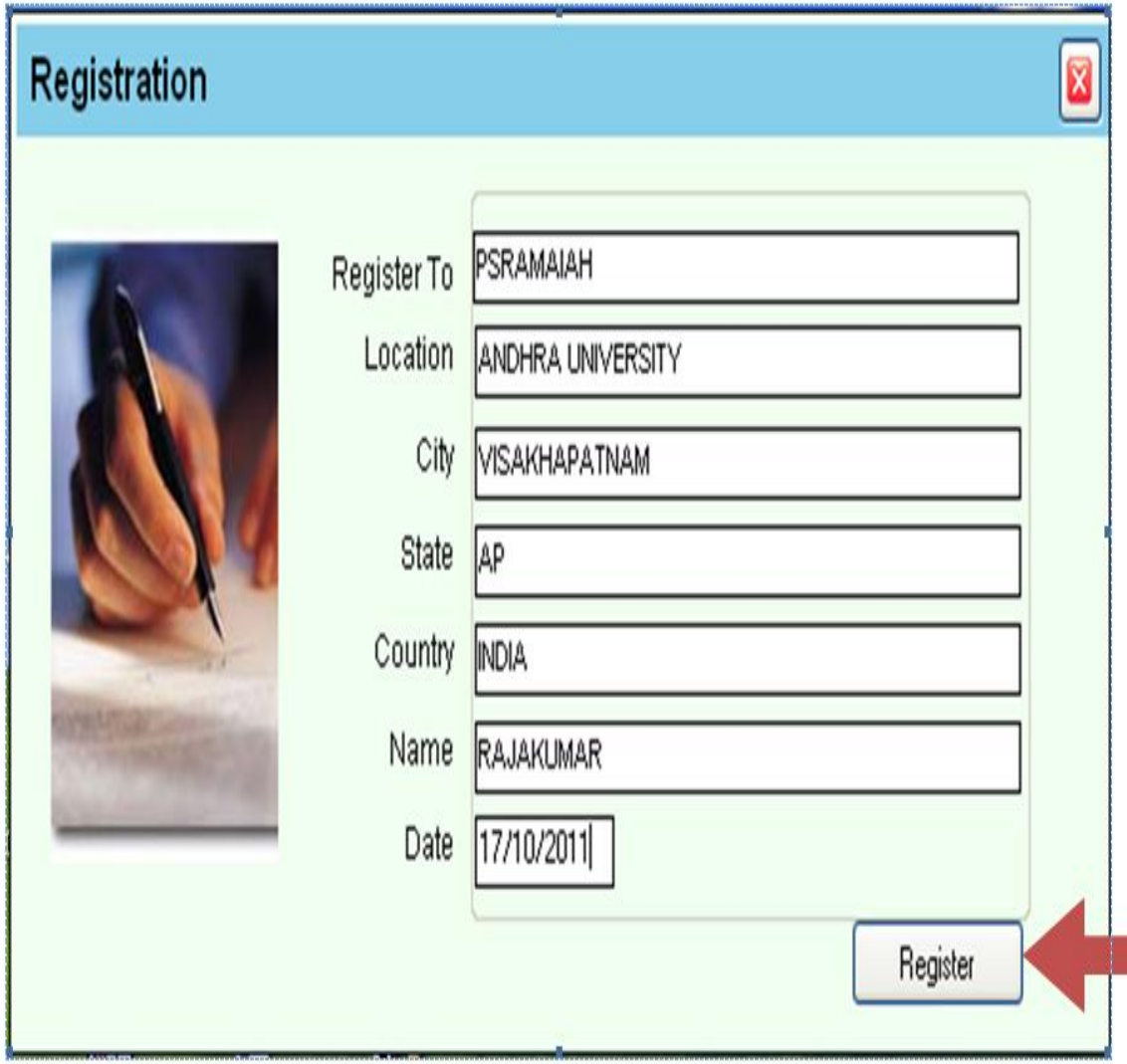
CSCP Functions
• Audiologist Registration
• Patient Registration
• Measuring Impedances from patient
• Fitting THL/MCL for each Active Electrode
• Mapping THL/MCL of Active Electrodes into Speech Processor
• Programming DSPS



Functional operation of CSCP of CIS System

CONTROL SOFTWARE FOR CLINICAL PROGRAMMING

- Audiologist is a operator
- 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 to register.



Audiologist Registration

CONTROL SOFTWARE FOR CLINICAL PROGRAMMING

CLINICAL PROGRAMMING SYSTEM

P.SEETHARAMAIAH
ANDHRA UNIVERSITY
VISAKHAPATNAM

Recipient Details & MAP

Personal Details

Recipient ID*	CPS-290415113819
First Name *	UMAMAHESWARARAO
Last Name*	BHATTA
Date of Birth *	10-03-1983
Gender	Male
Telephone	9000084878
Ear	LeftEar
Date of implantation	29-04-2015
Device SL No.	DG34

Device version No. dv45

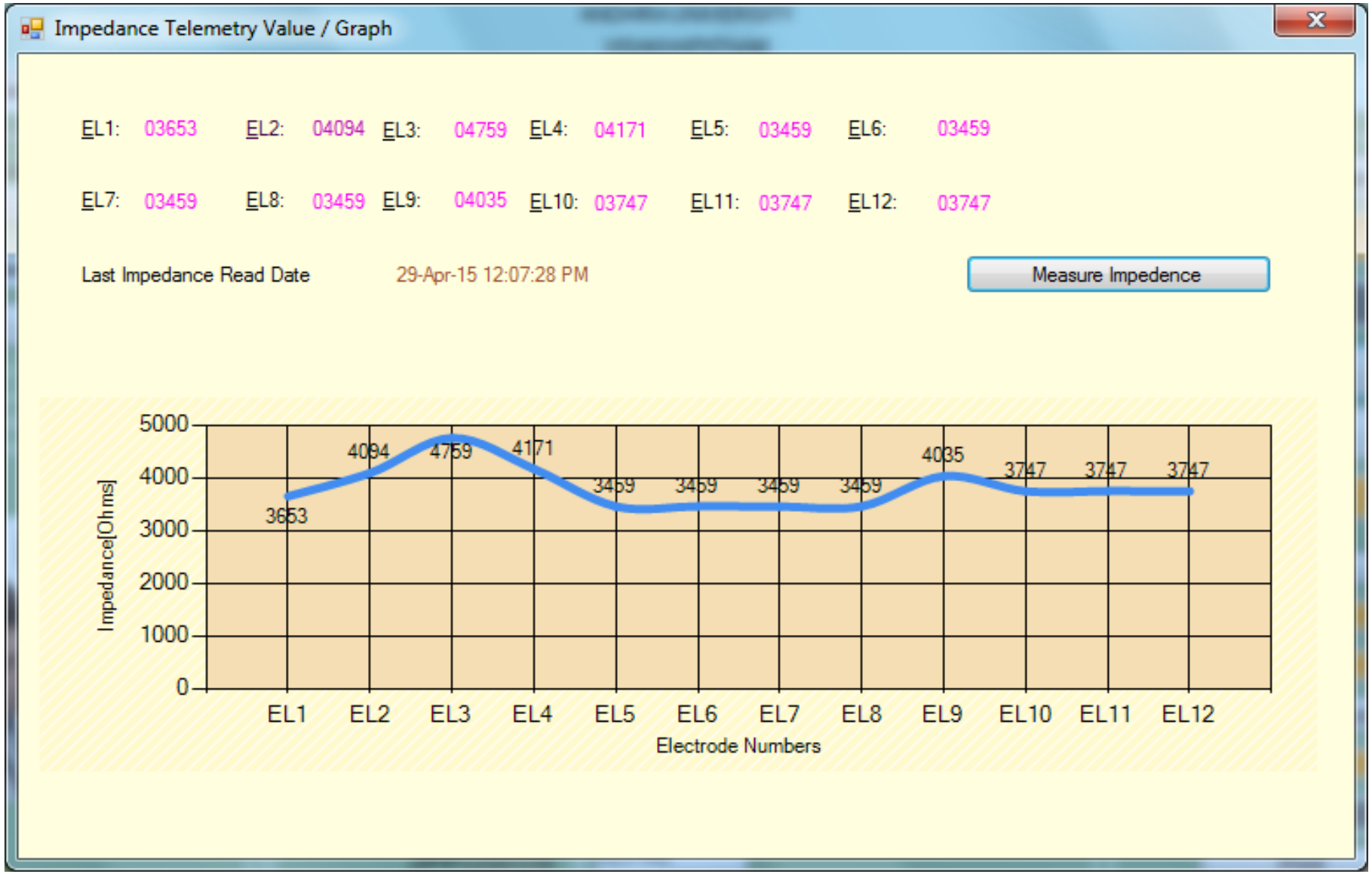
Address

Street	DANTAMPET
	JANDRAPET, VETAPALEM MANDAL
City/Suburb	PRAKASAM DIST
State/Province	ANDHRA PRADESH
ZIP/Postalcode	523165
Country/Region	INDIA
Email	umamaheshbatta@gmail.com

UART Settings
New
Update
IMP-TELE
Fitting
MAP
Search
Edit
Delete
Recipients List
Refresh
Cancel

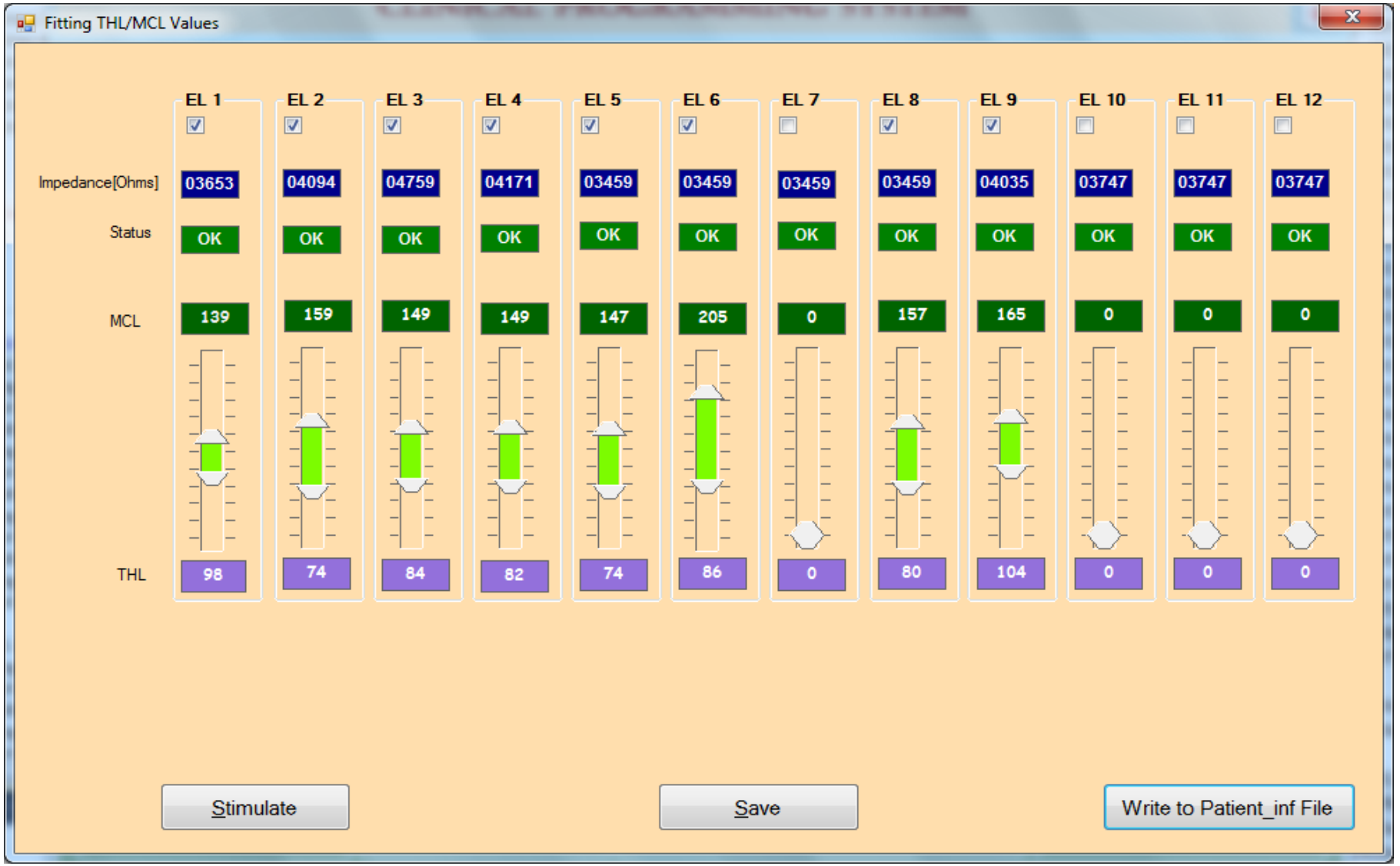
Patient Registration Form

CONTROL SOFTWARE FOR CLINICAL PROGRAMMING



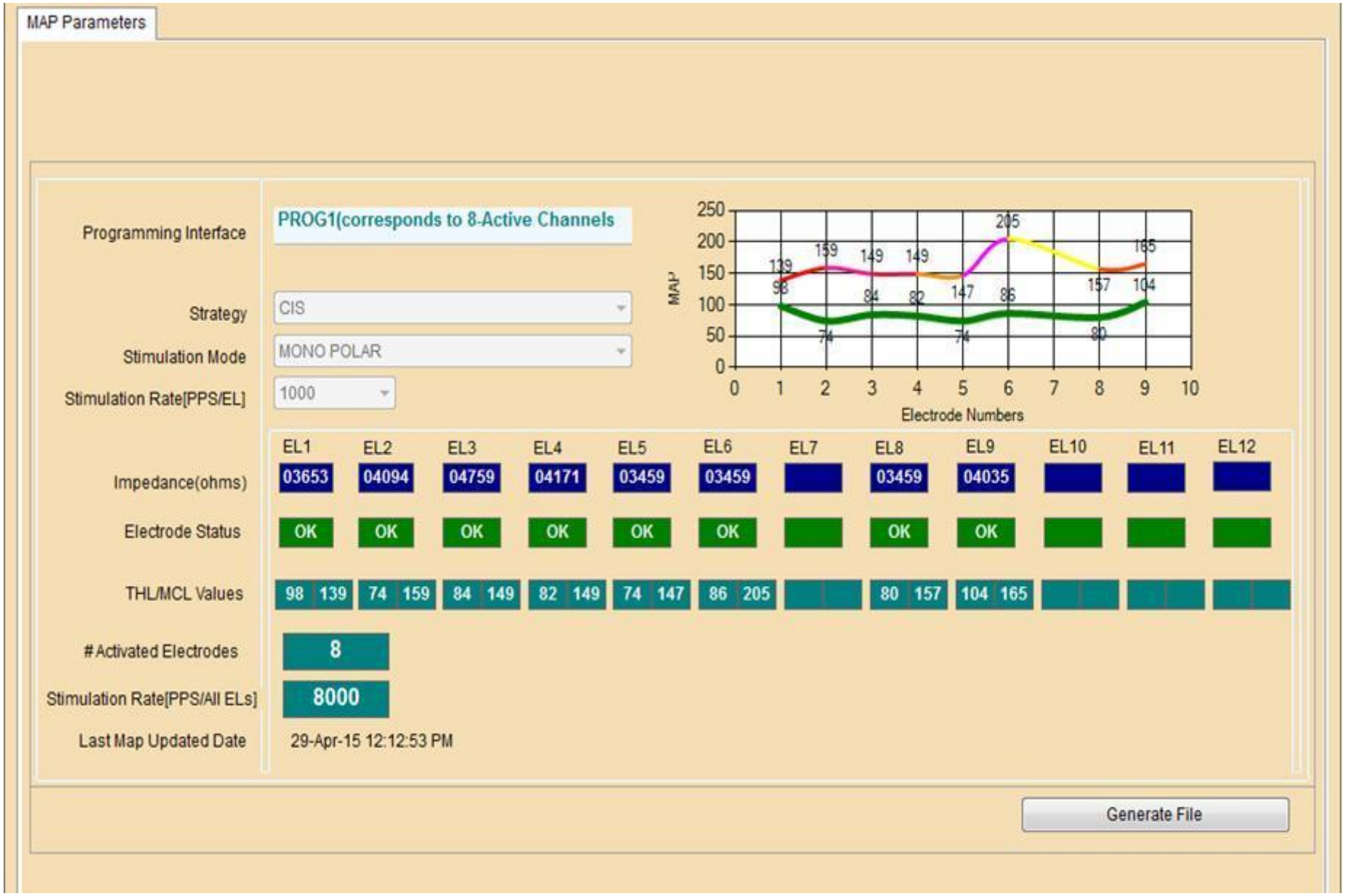
Measure impedance values

CONTROL SOFTWARE FOR CLINICAL PROGRAMMING



Fitting

CONTROL SOFTWARE FOR CLINICAL PROGRAMMING

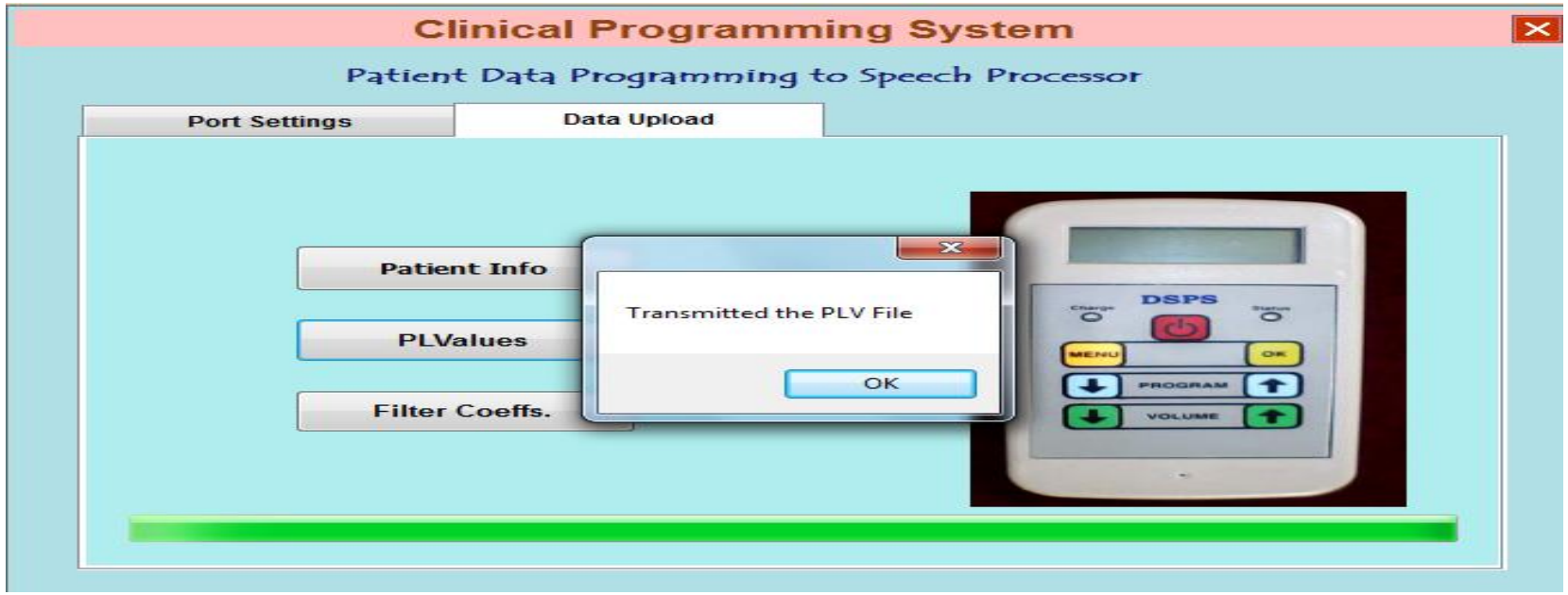


Map

CONTROL SOFTWARE FOR CLINICAL PROGRAMMING

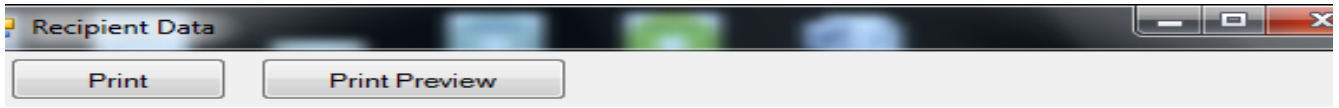
- **Speech Processor Programming**: The DA is interfaced with BWSP to program the generated files in the previous levels of assessments.
- generated programming files
- The response from the DA software

  after successful configuration of DSPS



CONTROL SOFTWARE FOR CLINICAL PROGRAMMING

- Finally, DA software generated auditory report of Bionic Ear recipient
- Patient's hearing levels and corresponding information



Recipient Data

Date :	31-Dec-13
Place :	AU-NSTL
Id :	2222
First Name :	HANUMAN KUMAR
Last Name :	V
DOB :	29-May-82 12:00:00 AM
Gender :	Male
Phone :	9032233745
Street1 :	P.COLONY
Street2 :	M.PALEM
City :	VSKP
State :	AP
Pin Code :	53003
Country :	INDIA
Email :	vhanumankumar@gmail.com
Processing Strategy :	CIS
Stimulation Mode :	MONO POLAR
Stimulation Rate :	1000pps/c
# Activated Channels :	8

ELECTRODE IMPEDANCE Values

EL1	EL2	EL3	EL4	EL5	EL6	EL7	EL8	EL9	EL10	EL11	EL12
04950	04671	04759	04026	03315	03459	03459	03459	03459	03459	03747	03459

ACTIVE CHANNEL THL/ MCL Values :

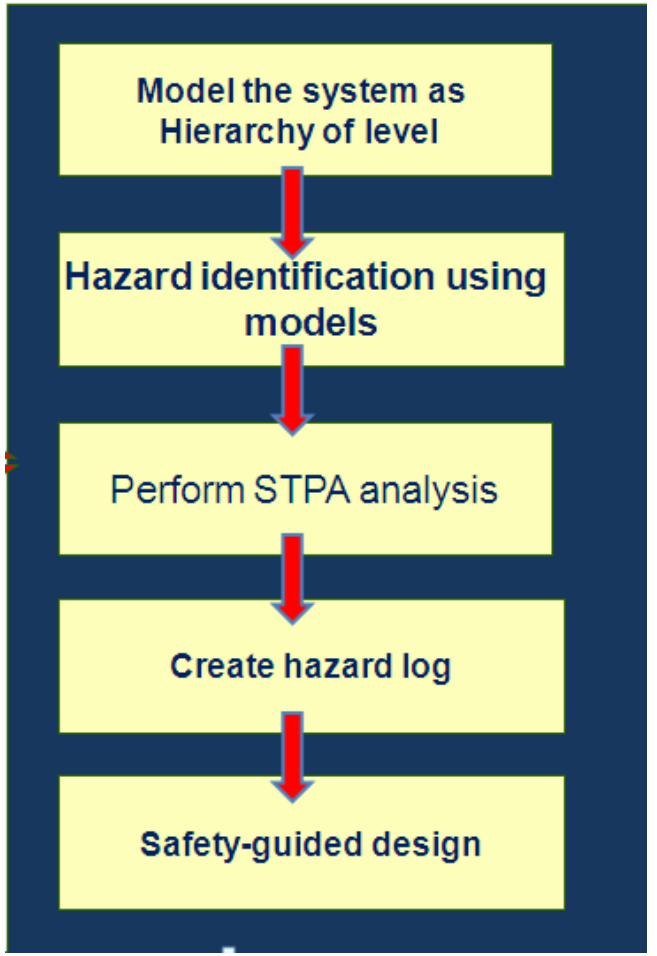
EL#	1	2	3	4	5	6	7	8	9	10	11	12
T	10	14	6	8	10	4	8	14	0	0	0	0
C	255	241	241	247	243	247	249	247	255	255	255	255

CONTROL SOFTWARE FOR CLINICAL PROGRAMMING ENVIRONMENT

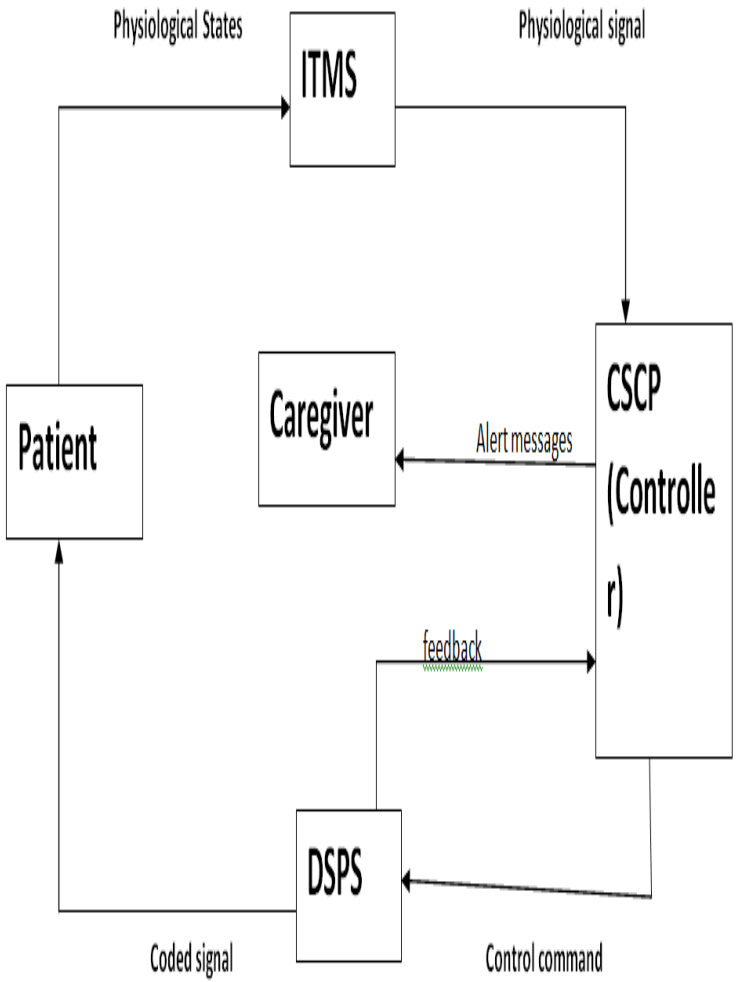
- Windows platform
- Visual studio development environment (Vb.net 2010 for clinical programming)
- C-compiler for DSPS, ITMS
- Micro Soft Access database
- UML- for model the CSCP

INTEGRATION OF PROPOSED STPA-BASED SAFETY ANALYSIS WITH CSCP OF CIS DEVELOPMENT PROCESS

1. Model the system as hierarchy levels
2. Identification of hazards
3. STPA analysis
4. Creation of hazard log
5. Safety-guided Design



1. MODEL THE SYSTEM AS HIERARCHY LEVELS



Medical Cyber-Physical System architecture

```
1  ----------------------------------------
2  -- Basic CPS of CIS system
3  -- AADL Inspector
4  -- (c) Ellidiss Technologies
5  -- Updated: January 2015
6  ----------------------------------------
7
8  PACKAGE CPSofCIS ::basic
9
10
11 DEVICES
12     dp: DSPS;
13   dt : ITMS;
14   END devices;
15
16 logicmodule
17        controller: CPS computer;
18   END logicmodule;
19
20
21
22 CONNECTIONS
23     ITMS -> CPS;
24   CPS -> DSPS;
25 END CONNECTIONS
26
27
28 END CPSofCIS;
29
```

CSCP of CIS medical architecture specification

2. IDENTIFYING HAZARDS

- Loss (accident)

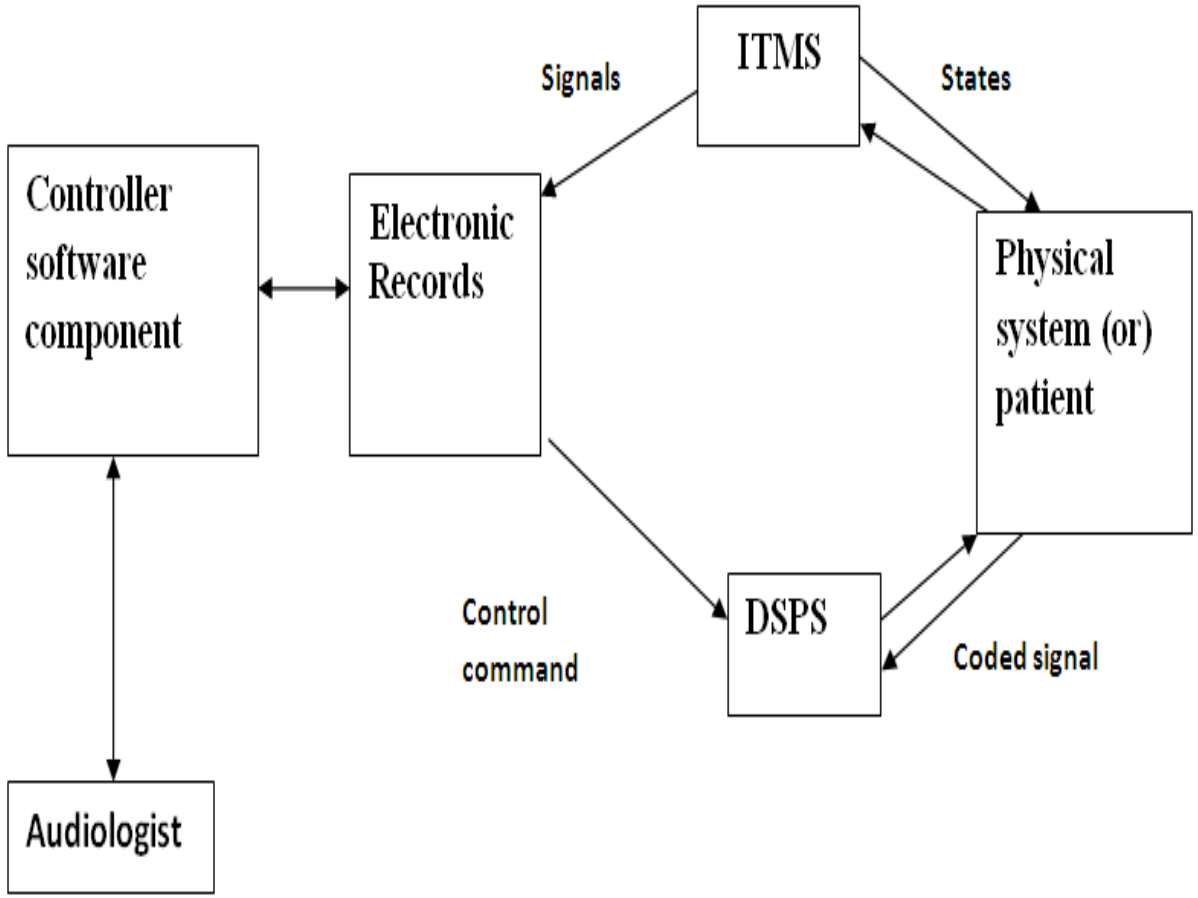
  patient is killed or seriously injured
- Hazards
- System reports fake patient’s results to the user.
- The system reports the patient’s required results from the controller too late
- CSCP provides send impedance values command when ITMS is not connected

SYSTEM SAFETY CONSTRAINT FOR CSCP

- SC1: correct patient results must be reported to the Audiologist
- SC2: Patient results must be reported to the Audiologist in a useable time frame.

CONTROL STRUCTURE OF CSCP OF CIS

- Identify major components and controllers
- Label the control/feedback arrows
- The following shows high level control structure of CSCP of CIS system



IDENTIFY UNSAFE CONTROL ACTIONS (UCAS)

Control action	Not providing causes hazard	Providing causes hazard	Incorrect Timing/ Order	Stopped Too Soon
Sends patient information	CPS provides sends patient info command when info is wrong	CPS not provides sends patient info command when info is correct	CPS provides sends patient info command too late or too early	CPS stops sends patient info command too soon or too long
Measure impedance values	CPS provides Measure impedance values command when info is wrong	CPS not provides Measure impedance values command when info is correct	CPS provides Measure impedance values command too late or too early	CPS stops Measure impedance values command too soon or too long

INADEQUATE CONTROL ALGORITHM OF CSCP OF CIS SYSTEM

Scenarios that may leads to Inadequate Control Algorithm of CSCP of CIS system and violate the safety constraints belonging to this classification are:

- Inadequate algorithm for acquiring patient sample impedance measurements
- Inadequate algorithm for impedance measurements comparison
- Inadequate algorithm for patient sample impedance measurements
- Inadequate control algorithm for upstream data transfer
- Inadequate control algorithm for downstream data transfer.

PROCESS MODEL OF CSCP OF CIS SYSTEM IS INCONSISTENT, INCOMPLETE

Scenarios which may lead to inadequate enforcement of the safety constraints are the following:

- CSCP Assume erroneous low impedance results from ITMS is accurate result
- CSCP: Assume erroneous high impedance results from ITMS is accurate result
- ITMS: Inadequate impedance result feedback
- ITMS: Assume erroneous low impedance results from controlled is accurate result
- ITMS: Assume erroneous high impedance results from controlled is accurate result
- Incorrect data transfer confirmation logic on ITMS controller

COMPONENT FAILURES OF CSCP OF CIS SYSTEM IS CHANGES OVER TIME

- DSPS: Failure of attraction of volume to CSCP
- DSPS: Contaminants gather on selective e
- DSPS: Inadequate transfer of volume to patient
- DSPS: Insufficient initial amount of volume selective CSCP
- DSPS: Physical damage of ITMS during the use life
- DSPS: ITMS delaminating of working electrode
- CSCP: Electrical interference from ITMS causing inadequate impedance recordings
- CSCP: Inadequate adaptation to DSPS
- Performance degradation over time

RESULTS ANALYSIS OF CSCP OF CIS SYSTEM

- We applied this approach on CSCPS of CIS system, following things are identified
- 134 hazards identified, 12 were found to play a contributor to the case accident
- 65 scenarios identified by FMEA
- 134 identified by STPA

NEW SYSTEM DESIGN REQUIREMENTS FOR CSCP OF CIS SYSTEM

Hazard by STPA	New System design requirements
Inadequate control of verifying abnormal impedance value results at lower level.	The system shall verify all impedance results for Deviance at lower control levels in addition to the CPS controller.
Higher CPS controller constraint of reporting patient report before lower level control loop could verify sensor integrity.	The system shall allow the sensor integrity verification in the wash cycle to complete before patient results are reported to the user

NEW DESIGN RECOMMENDATIONS FOR CSCP OF CIS SYSTEM

- Design control algorithms in the lower level controllers (Control loop f1-f2-f3-f4) to verify active and inactive electrodes in system.
- Initiate an ITMS arrangement immediately before the patient readings.
- Decrease ITMS and DSPS Calibration time.
- the control structure presented was limited to the thesis boundary.
- Continue and complete a full STPA analysis on all control loops in the CPS of CIS System.

THANK YOU