Product Name: Implantable Pulse Generator (IPG) of the CARSS System.

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1 Introduction

This document presents the software design specifications for the product.
The software architecture has 11 units based on functions, and based on the 3 states defined by SRS, the active state has 8 operating modes.

1.1 Document overview

This document describes the software architecture, software design description, software workflow and algorithm, and describes the software requirements and software design items.

1.2 References

- CAR-208 IPG Software Requirements Specification (v1.0)
- HNT-TECH-14-HPD Protocol Description (v1.0)
- IPG-schematic-layout (v1.0)
- Stimulation Circuit Overview
- Stimulation Waveforms Overview
- Impedance Measurement Strategy
- VNSb FW and HW interaction description v1.0
- XLboard Commands v1.0

2 Software Architecture overview

Operating platform:

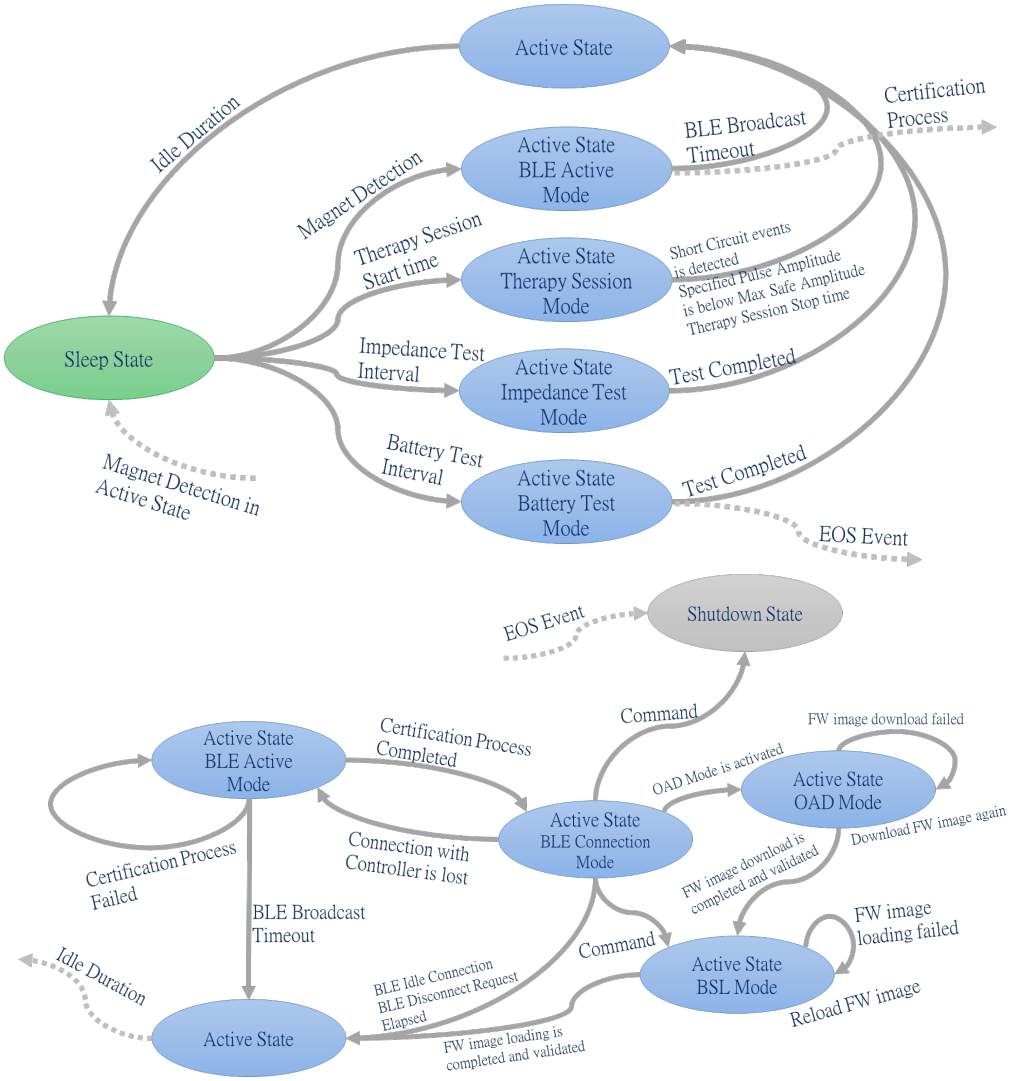
✧ Microcontroller							
Part No.	STM32U585QII6Q	SRAM	786 KB	Flash	2 MB	Package	UFBGA 132-7x7 P0.5 mm
Core	ARM Cortex M33	Clock	160 MHz	Supplier	STMicroelectronics		
✧ Embedded software							
Item		Software		Version	Supplier		
STM32 HAL Library		STM32Cube_FW_U5		1.7.0	STMicroelectronics		

✧ Microcontroller							
Part No.	nRF52810-CAAA	RAM	24 KB	Flash	192 KB	Supplier	Nordic
Core	ARM Cortex M4	Clock	64 MHz		Package	WLCSP 33-2.48x2.46 P0.5 mm	
✧ Embedded software							
Item	Software		Supplier		Version		
SDK	nRF5 SDK		Nordic		17.1.0		
	S112 SoftDevice				7.2.0		

The software architecture has 8 units based on functions

- **Authentication**
  Authentication functions related to ECDSA, such as User class authentication and image file authentication during firmware update.
- **BLE**
  Manage BLE advertising, pairing, connection, disconnection and security through communication with the BLE chip.
- **Command**
  Management of the composition, parsing and execution of commands.
- **Log**
  Manage the generation, writing, searching and reading of various log data.
- **Measurement**
  Used to control the hardware used for measurements, including enabling or disabling hardware and voltage measurement and conversion.
- **Parameter**
  Manage the reading, writing, conversion, and range determination of various parameters.
- **State Machine**
  Manages the triggering conditions for all transitions between operating states and modes of the system.
- **Stimulation**
  Management of electrical stimulation related hardware, including electrical stimulation waveform, amplitude, output channel and duration.

2.1 Workflows and algorithms



The firmware following states based on the 3 states defined by SRS, the active state has 8 operating modes. Please refer to Document "CAR-208 IPG Software Requirements Specification" for detailed definitions.

- **Shutdown State**
- **Sleep State**
- **Active State**
  - BLE Active Mode
  - BLE Connection Mode
  - Therapy Session Mode
  - Impedance Test Mode
  - Battery Test Mode
  - OAD Mode
  - BSL Mode
- DVT Mode (For testing purposes only, this document does not contain)

2.2 Software Design Specification

SDS ID	Instruction of Detailed Design Specifications	SRS ID
Shutdown State		
SD-SH01	When entering Shutdown State, the MCU disables FRAM, all serial ports, all electrical stimulation circuits, battery monitor and BLE. Finally, control the GPIO to turn off the power of the IPG.	SR-IO06
Sleep State		
SD-SL01	When entering Sleep State, the MCU disables FRAM, all serial ports, all electrical stimulation circuits, battery monitor and BLE. Then enable the timers of therapy session start (via RTC), impedance test and battery test. Then enable the function of magnetic detection. And then enable the "stop mode" of STM32U5 (refer to the datasheet).	SR-SL02 SR-SL03 SR-SL04 SR-SL05 SR-SL06 SR-IO07
SD-SL02	When waking up from Sleep State by magnetic detection, count the magnetic detection time and issue the magnet detection event. When the magnetic detection duration, spacing and times meet the SRS definition of wakeup, it enters Active State - BLE Active Mode, otherwise it returns to Sleep State. When waking up from Sleep State by the timer of therapy session start, it enters Active State - Therapy Session Mode. When waking up from Sleep State by the timer of impedance test, it enters the Active State - Impedance Test Mode. When waking up from Sleep State by the timer of battery test, it enters the Active State - Battery Test Mode. When exiting Sleep State, the MCU enables FRAM and all serial ports.	SR-SL02 SR-SL03 SR-SL04 SR-SL05 SR-SL06 SR-IO07
SD-SL03	When waking up from Sleep State by magnetic detection, count the magnetic detection time and issue the magnet detection event. When the magnetic detection duration, spacing and times meet the SRS definition of BLE reset, enable timer of BLE reset. And then it returns to Sleep State.	SR-SA11 SR-IO07

Active State		
SD-AC01	When Idle Duration is elapsed, it enters Sleep State.	SR-SL01
SD-AC02	When a magnet is detected, count the magnetic detection time and issue the magnet detection event. When the magnetic detection duration, spacing and times meet the SRS definition of BLE reset, enable timer of BLE reset. When the magnetic detection duration, spacing and times meet the SRS definition of sleep, it enters Sleep State.	SR-SL07 SR-SA11 SR-IO07
SD-AC03	If watchdog timer is reached, issue the Unresponsive Function event and reset system.	SR-SA01
SD-AC04	Timestamps are included when data for events, battery level, parameter updates, and impedance are added to the log.	SR-EV01 SR-FR01 SR-IO08
SD-AC05	Manage log writing to avoid overflow.	SR-EV02 SR-FR02 SR-FR03 SR-IO08
Active State - BLE Active Mode		
SD-BA01	When entering Active State - BLE Active Mode, the MCU enables power of BLE. Then get the current or default (determined by BLE reset timer) pairing code, whitelist setting, BLE broadcast timeout, MSD (Manufacturer-specific data, including the BLE ID, updated every sec) to enable BLE broadcasting.	SR-BA01 SR-BA02 SR-BA04 SR-SA02 SR-SA11
SD-BA02	When BLE is pairing, check the pairing code and whitelist. If correct, the connection is established. If incorrect, broadcasting continues until timeout and then enters sleep state.	SR-BA02 SR-BA03 SR-BA04 SR-SA09 SR-SA10
SD-BA03	When the BLE connection is established, start the certification process with Controller to check the ECDSA authentication and BLE ID. If correct, it enters the Active State - BLE Connection Mode, if not, continue broadcasting.	SR-BA05 SR-BA06 SR-SA10

Active State - BLE Connection Mode		
SD-BC01	When entering Active State - BLE Connection Mode, enables the timer of BLE Idle Connection. Then refresh the timer every time a command is received.	SR-BC20
SD-BC02	Start the timer of BLE Disconnect Request when the command is received.	SR-BC03
SD-BC03	When the BLE Idle Connection or BLE Disconnect Request timer times out and the Manual Therapy Session is inactive, it exits BLE Connection Mode and BLE Active Mode.	SR-BC03 SR-BC20
SD-BC04	Change to the specified State or Mode according to the received command.	SR-BC01 SR-BC02 SR-SA03 SR-SA04
SD-BC05	Control hardware based on received commands.	SR-BC04 SR-BC05 SR-BC06 SR-BC07 SR-BC08 SR-BC09 SR-BC22 SR-SA03 SR-SA04
SD-BC06	Read and write data according to the received command.	SR-BC10 SR-BC11 SR-BC12 SR-BC13 SR-BC14 SR-BC15 SR-BC16 SR-BC17 SR-BC18 SR-BC19 SR-BC22 SR-SA03 SR-SA04 SR-SA05 SR-SA06 SR-SA07 SR-SA08 SR-SA12 SR-IO08
SD-BC07	Enters BLE Active Mode when connection to the controller is lost.	SR-BC21

Active State - Therapy Session Mode		
SD-TH01	Search for short circuit events when entering Therapy Session Mode. If detected, exit Therapy Session Mode.	SR-TH01 SR-TH02
SD-TH02	Load and check stimulation parameters when initializing stimulation. Then enable the timer of therapy session stop (via RTC). The hardware is then controlled to initiate the output of the stimulus.	SR-TH03 SR-TH04 SR-TH05 SR-TH06 SR-TH07 SR-TH08 SR-TH09 SR-TH10 SR-TH11 SR-TH12 SR-TH13 SR-TH14 SR-IO01 SR-IO02 SR-IO03 SR-IO04 SR-IO05 SR-IO09
SD-TH03	When the timer for treatment session stop is reached, stop stimulation and exit Therapy Session Mode.	SR-TH14
Active State - Impedance Test Mode		
SD-IM01	When entering Active State - Impedance Test Mode, the impedance for the Cathode + Anode combination is measured.	SR-IM01 SR-IO10
SD-IM02	Determine whether to trigger Normalized Impedance and Short Circuit event based on the SRS definition.	SR-IM02 SR-IM03 SR-IM04
SD-IM03	When impedance test is completed, exit Impedance Test Mode and restart the timer of impedance test.	SR-IM05
Active State - Battery Test Mode		
SD-BT01	When entering Active State - Battery Test Mode, the battery voltage is measured.	SR-BT01
SD-BT02	Compare battery voltage with ER Level and EOS Level. Determine whether to trigger ER and EOS event based on the SRS definition. If the EOS event is triggered, enter Shutdown State.	SR-BT02 SR-BT03 SR-BT04 SR-BT05 SR-BT06
SD-BT03	When battery test is completed, exit Battery Test Mode and restart the timer of battery test.	SR-BT07

Active State - OAD Mode		
SD-OA01	Signature of the firmware image is authenticated using the ECDSA.	SR-OA01
SD-OA02	Firmware image download to FRAM.	SR-OA02 SR-FR04
SD-OA03	If the firmware image verification is valid, enter BSL mode, otherwise restart the firmware image download to FRAM.	SR-OA03 SR-OA04
Active State - BSL Mode		
SD-BS01	Start firmware image loading from FRAM to ROM.	SR-BS01
SD-BS02	If the firmware image verification is valid, enter Active State, otherwise restart the firmware image loading.	SR-BS02 SR-BS03

3 Traceability Matrix

SRS ID	SDS ID	Parameter ID	VVT ID
SR-SL01	SD-AC01	HP29	VV-UT06 VV-UT07 VV-IT07
SR-SL02	SD-SL01 SD-SL02	HP30	VV-UT06 VV-UT07 VV-IT08
SR-SL03	SD-SL01 SD-SL02	HP22 HP23	VV-UT04 VV-UT06 VV-UT07 VV-IT08
SR-SL04	SD-SL01 SD-SL02	STX1	VV-UT06 VV-UT07 VV-IT08
SR-SL05	SD-SL01 SD-SL02	HP18	VV-UT06 VV-UT07 VV-IT08
SR-SL06	SD-SL01 SD-SL02	HP19	VV-UT06 VV-UT07 VV-IT08
SR-SL07	SD-AC02	HP22 HP23	VV-UT04 VV-UT06 VV-UT07 VV-IT07
SR-BA01	SD-BA01	HP03	VV-UT02 VV-UT03 VV-UT06 VV-IT01
SR-BA02	SD-BA01 SD-BA02	-	VV-UT01 VV-IT01
SR-BA03	SD-BA02	-	VV-UT01 VV-IT01
SR-BA04	SD-BA01 SD-BA02	HP14	VV-UT06 VV-UT07 VV-IT01
SR-BA05	SD-BA03	-	VV-UT07 VV-IT01
SR-BA06	SD-BA03	-	VV-UT02 VV-UT03 VV-IT01
SR-BC01	SD-BC04	-	VV-UT03 VV-UT07 VV-IT02
SR-BC02	SD-BC04	-	VV-UT03 VV-UT07 VV-IT02
SR-BC03	SD-BC02 SD-BC03	HP16	VV-UT06 VV-UT07 VV-IT02
SR-BC04	SD-BC05	-	VV-UT03

			VV-UT08 VV-IT02
SR-BC05	SD-BC05	-	VV-UT03 VV-UT08 VV-IT02
SR-BC06	SD-BC05	STX1	VV-UT03 VV-UT06 VV-UT07 VV-IT02
SR-BC07	SD-BC05	STX2	VV-UT03 VV-UT06 VV-UT07 VV-IT02
SR-BC08	SD-BC05	-	VV-UT03 VV-UT05 VV-IT02
SR-BC09	SD-BC05	-	VV-UT03 VV-UT05 VV-IT02
SR-BC10	SD-BC06	HPXX SPXX STX1 STX2	VV-UT03 VV-UT06 VV-IT02
SR-BC11	SD-BC06	HPXX SPXX STX1 STX2	VV-UT03 VV-UT06 VV-IT02
SR-BC12	SD-BC06	-	VV-UT03 VV-UT04 VV-IT02
SR-BC13	SD-BC06	-	VV-UT03 VV-UT04 VV-IT02
SR-BC14	SD-BC06	-	VV-UT03 VV-IT02
SR-BC15	SD-BC06	-	VV-UT03 VV-IT02
SR-BC16	SD-BC06	-	VV-UT03 VV-UT05 VV-IT02
SR-BC17	SD-BC06	-	VV-UT03 VV-UT06 VV-IT02
SR-BC18	SD-BC06	-	VV-UT03 VV-UT04 VV-IT02
SR-BC19	SD-BC06	-	VV-UT03 VV-UT04 VV-IT02
SR-BC20	SD-BC01 SD-BC03	HP15	VV-UT06 VV-UT07

			VV-IT02
SR-BC21	SD-BC07	-	VV-UT02 VV-UT03 VV-UT07 VV-IT02
SR-BC22	SD-BC05 SD-BC06	-	VV-UT03 VV-UT05 VV-IT02
SR-TH01	SD-TH01	-	VV-UT04 VV-IT03
SR-TH02	SD-TH01	-	VV-UT07 VV-IT03
SR-TH03	SD-TH02	SP02 SP11	VV-UT06 VV-IT03
SR-TH04	SD-TH02	SP02 SP11	VV-UT06 VV-UT07 VV-IT03
SR-TH05	SD-TH02	SP02 SP11	VV-UT04 VV-UT06 VV-IT03
SR-TH06	SD-TH02	SP02	VV-UT06 VV-UT08 VV-IT03
SR-TH07	SD-TH02	SP03	VV-UT06 VV-UT08 VV-IT03
SR-TH08	SD-TH02	SP04	VV-UT06 VV-UT08 VV-IT03
SR-TH09	SD-TH02	SP07 SP08	VV-UT06 VV-UT08 VV-IT03
SR-TH10	SD-TH02		VV-UT08
SR-TH11	SD-TH02	SP08	VV-UT06 VV-UT08 VV-IT03
SR-TH12	SD-TH02	SP02 SP06 SP07	VV-UT06 VV-UT08 VV-IT03
SR-TH13	SD-TH02	SP07	VV-UT06 VV-UT08 VV-IT03
SR-TH14	SD-TH02 SD-TH03	STX2	VV-UT06 VV-UT07 VV-UT08 VV-IT03
SR-IM01	SD-IM01	-	VV-UT05 VV-IT04
SR-IM02	SD-IM02	-	VV-UT05 VV-IT04
SR-IM03	SD-IM02	SP12	VV-UT04

			VV-UT06 VV-IT04
SR-IM04	SD-IM02	SP11	VV-UT04 VV-UT06 VV-IT04
SR-IM05	SD-IM03	HP18	VV-UT07 VV-IT04
SR-BT01	SD-BT01	-	VV-UT05 VV-IT05
SR-BT02	SD-BT02	HP26	VV-UT06 VV-IT05
SR-BT03	SD-BT02	HP26 HP27	VV-UT06 VV-IT05
SR-BT04	SD-BT02	-	VV-UT04 VV-IT05
SR-BT05	SD-BT02	-	VV-UT06 VV-IT05
SR-BT06	SD-BT02	-	VV-UT04 VV-UT07 VV-IT05
SR-BT07	SD-BT03	HP19	VV-UT07 VV-IT05
SR-EV01	SD-AC04	-	VV-UT04
SR-EV02	SD-AC05	-	VV-UT04
SR-SA01	SD-AC03	-	VV-UT04
SR-SA02	SD-BA01	-	VV-UT01
SR-SA03	SD-BC04 SD-BC05 SD-BC06	-	VV-IT02
SR-SA04	SD-BC04 SD-BC05 SD-BC06	-	VV-IT02
SR-SA05	SD-BC06	-	VV-UT06 VV-IT02
SR-SA06	SD-BC06	-	VV-UT06 VV-IT02
SR-SA07	SD-BC06	-	VV-UT03 VV-IT02
SR-SA08	SD-BC06	-	VV-UT06 VV-IT02
SR-SA09	SD-BA02	-	VV-IT02
SR-SA10	SD-BA02 SD-BA03	-	VV-UT01 VV-IT02
SR-SA11	SD-SL03 SD-AC02 SD-BA01	HP24 HP25	VV-UT02
SR-SA12	SD-BC06	-	VV-UT02
SR-OA01	SD-OA01	-	VV-UT01 VV-IT06
SR-OA02	SD-OA02	-	VV-IT06
SR-OA03	SD-OA03	-	VV-UT01

			VV-UT07 VV-IT06
SR-OA04	SD-OA03	-	VV-IT06
SR-BS01	SD-BS01	-	VV-IT06
SR-BS02	SD-BS02	-	VV-UT01 VV-IT06
SR-BS03	SD-BS02	-	VV-IT06
SR-FR01	SD-AC04	-	VV-UT04
SR-FR02	SD-AC05	-	VV-UT04
SR-FR03	SD-AC05	-	VV-UT04
SR-FR04	SD-OA02	-	VV-IT06
SR-IO01	SD-TH02	-	VV-UT08
SR-IO02	SD-TH02	-	VV-UT08
SR-IO03	SD-TH02	-	VV-UT08
SR-IO04	SD-TH02	-	VV-UT08
SR-IO05	SD-TH02	-	VV-UT08
SR-IO06	SD-SH01	-	VV-IT09
SR-IO07	SD-SL01 SD-SL02 SD-SL03 SD-AC02	-	VV-IT07 VV-IT08
SR-IO08	SD-AC04 SD-AC05 SD-BC06	-	VV-UT04
SR-IO09	SD-TH02	-	VV-UT08
SR-IO10	SD-IM01	-	VV-UT05

REVISION HISTORY

Rev.	Date	Description
01	01/01/2026	SDS for IPG hardware version 1