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Canary Clinic Base Station (BS3)Hardware Design Document

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CONTROLLED DOCUMENT

CREATION TECHNOLOGIES

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Revision History

ECO	Revision	Description	Date	Author
100841	A0	Initial Release	03/23/2021	Dean Miller, Doug Miller

1 Table of Contents

2 Purpose

This document describes the mechanical, electrical design, and packaging for the Canary Clinic Room Base Station (BS3). The Base Station design is based on the requirements defined in the Product Requirements Document (PRD). This document describes key hardware design elements and rationale.

3 Scope

This scope of this document applies to the design of the Clinic Base Station (BS3).

Labeling content is not discussed in this document and is a responsibility of Canary Medical.

4 References

Document Number	Document Name
19005-0002	Design and Development Plan
19005-1012	Clinic Hardware Architecture Document
19005-0016	Product Requirements Document
19005-0019	Software Requirements Specification, Clinic Base Station
19005-1039	Clinic Software Architecture and Detail Design Document
19005-0115	Clinic Assembly Drawing/BOM
19005-0187	Clinic Packaged Assembly Drawing/BOM
19005-0113	Clinic PCB Assembly Schematic and BoM files

5 Definitions

The following table provides definitions of terms and acronyms.

Term	Definition
BS	Base Station
BS1	Operating Room Base Station: Device that communicates with implanted medical devices over MedRadio, and with the internet/Canary Cloud Applications over a USB-connected PC.
BS2	Home Base Station: Device that communicates with implanted medical devices over MedRadio, and with the internet/Canary Cloud Applications
BS3	Clinic Base Station: Device that communicates with implanted medical devices over the MedRadio, and with the Clinic PC Application over a wired USB connection. The base station is designed to collect large amounts of data over short time periods in a clinical setting.
CDS	Creation Design Services
CTE	Canary Tibial Extension
FW	Firmware
GUI	Graphical User Interface
HW	Hardware, consisting of electrical and mechanical components
IC	Integrated Circuit
IFU	Instructions for Use
LCD	Liquid Crystal Display
MICS	Medical Implant Communication Service
N/A	Not Applicable

Term	Definition
OTS	Off the Shelf
OR	Operating Room
PRD	Product Requirements Document
TBD	To Be Determined
SOM	System on Module

6 Base Station Overview

The three devices being developed by CDS are data transfer base stations that communicate between the CTE implant(s) or CanarE devices and different target applications depending on the base station. While the three different base stations are used in three different physical environments, much of the HW is consistent because the required operation is similar. CDS has developed the OR (BS1) and Home (BS2) Base Stations for Canary Medical as a previous effort (refer to doxuments xxxxxx). This document defines the hardware architecture of the Clinic Base Station (BS3).

The BS3 base station device contains a MICS transceiver that communicates with implanted CTEs or CanarE's via 400Mhz radio. The base station also contains HW to communicate data bidirectionally to PC applications via USB,.

6.1 Clinic Base Station (BS3)

BS3 is used in a clinic environment to capture patient kinematic data during a clinician prescribed and supervised therapy session. BS3 is a battery-powered handheld device with an LCD display, GUI, and buttons. The clinician will use the clinic PC application to create an assessment test plan for a selected patient. The test plan will then be downloaded onto the BS3 via USB. The patient CTE or CanarE data is collected while the patient is mobile, so BS3 must communicate and store CTE or CanarE data while detached from the Clinic's Host PC under battery power. There are two different BS3 user modes; 1) Host PC mode and 2) battery power mode. Figure 1 illustrates the BS3 system in Host PC mode. In this mode, the BS3 is connected to the Host PC via USB and recharges the BS3 battery, allows the clinician to create patient assessment test plans, and permits the collected CTE or CanarE data to be uploaded to the Host PC application. Figure 2 shows the BS3 system in Battery Power mode. In the Battery Power mode, the device initates data collection on the CTE or CanarE and the data is uploaded from the CTE or CanarE to the BS3.

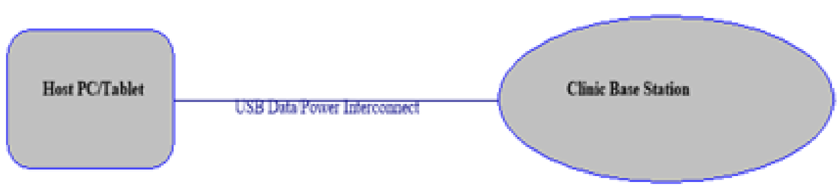


Figure 1. BS3 System Diagram – Host PC User Mode

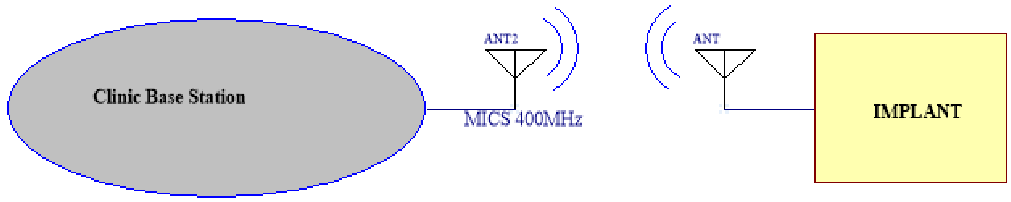


Figure 2. BS3 System Diagram – Battery Power User Mode

7 Base Station Design

The section describes the design of the Clinic base station.

7.1 Clinic Base Station Assembly

The following figure shows the major components in the 19005-0115 Clinic Base Station Assembly.

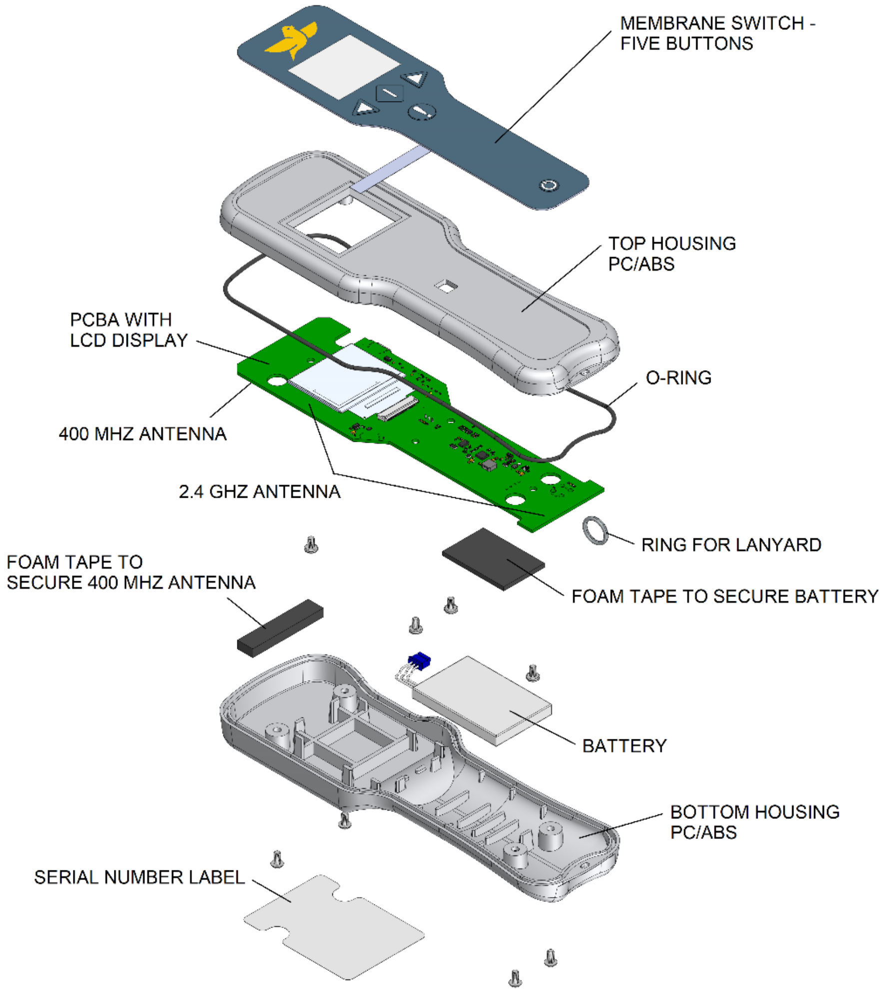


Figure 3. BS3 Mechanical Exploded View

7.1.1 BS3 Mechanical

The Clinic Base Station enclosure consists of two injection-molded polycarbonate/acrylonitrile butadiene styrene (PC/ABS) parts. The PCBA is secured to the top enclosure half with four screws. The bottom enclosure half is assembled to the top enclosure half, with the PCBA and battery, using four tamper-resistant screws. A membrane switch assembly is applied to the top cover. The membrane switch assembly includes five buttons (ON/OFF, LEFT, RIGHT, SELECT, & ALERT) and a clear window to provide viewing access to the display screen. An O-ring is assembled between the top and bottom case halves within a tongue-and-groove feature to achieve the IPX2 fluid ingress rating. The increased wall thickness required for the O-ring groove also provides the strength and stiffness required to meet the drop requirements. Foam tape is applied to the bottom enclosure's inside top surface to eliminate the audible ringing of the 400 MHZ antenna when the base station is impacted. The battery pack is secured to the PCBA with double-sided foam tape. A tag ring and lanyard will be shipped with the base station to help the user secure the device to their wrist. The serial number label will contain identifying information such as a model and serial number.

The following items influenced material selection:

- Compatibility with cleaning solutions
- Enclosure flame rating requirements
- Impact strength

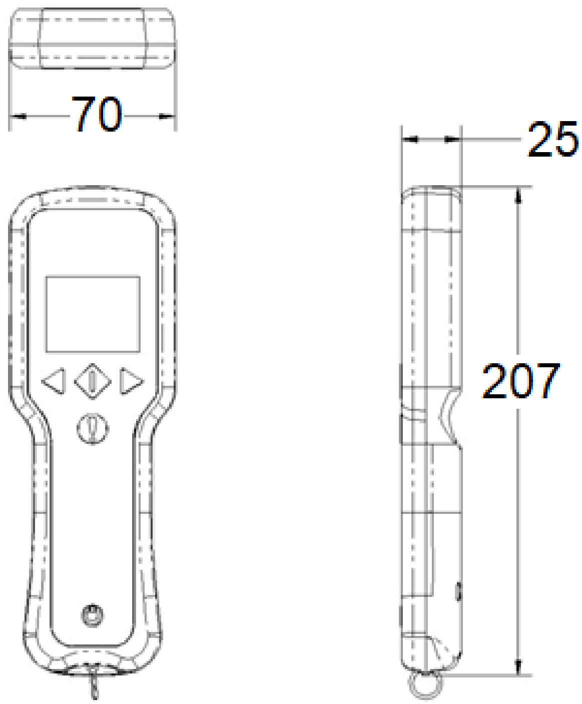


Figure 4. Clinic BS Enclosure (dimensions in mm)

7.1.2 BS3 Electrical

The BS3 electronics are implemented on a 4 page schematic, part number 19005-0113.

Sheet 1: Top-level hierarchial block. An interconnect drawing of the full system. This sheet includes 2 LEDs that are for software development only. They will not be visible in the end product.

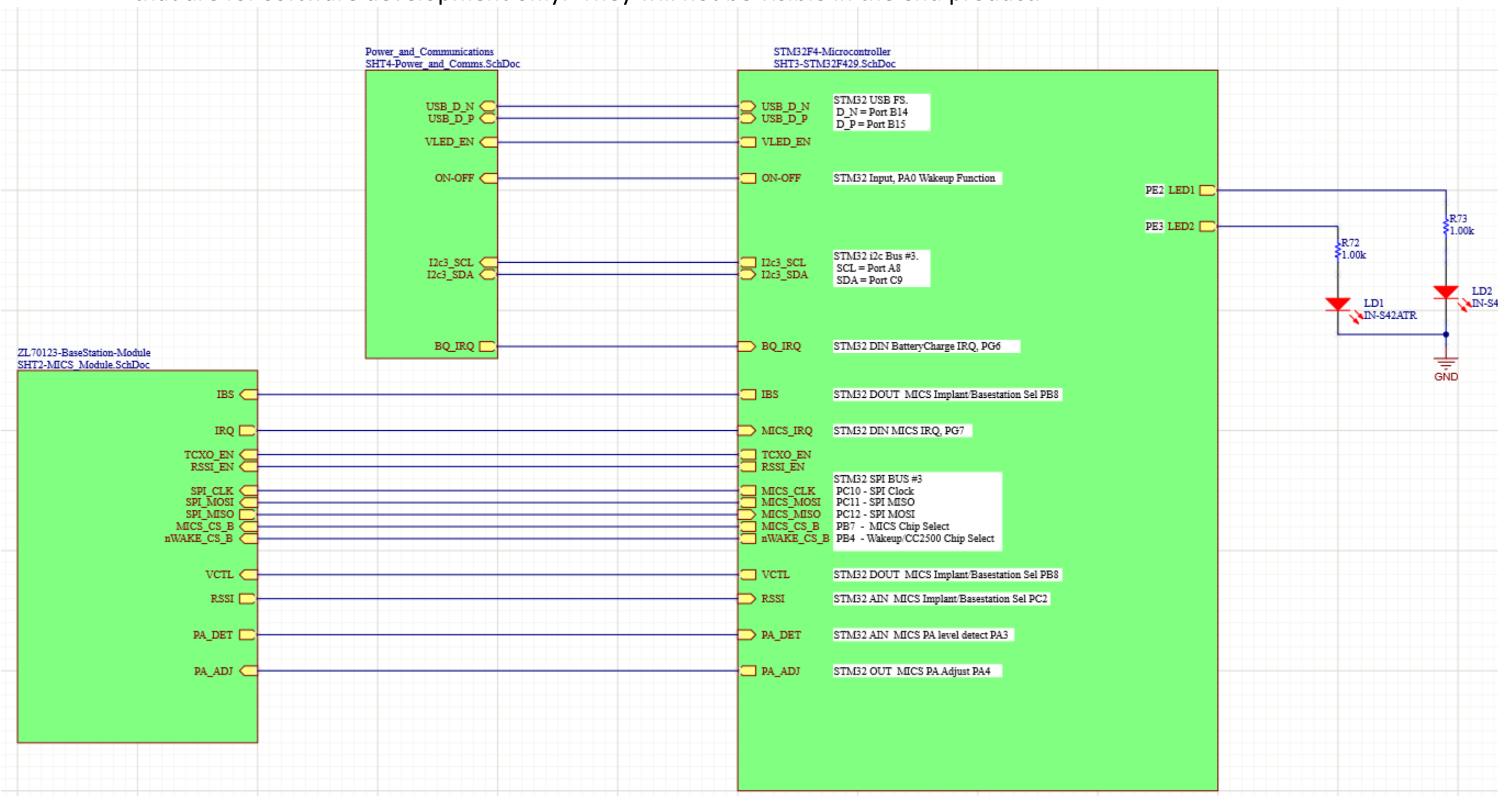


Figure 5: BS3 RevB2 Top-level Electrical Interconnect

Sheet 2: MICS subsystem. Includes Microsemi ZL70123 radio module, antennas, and RSSI circuitry.

Sheet 3: STM32F429 ARM microcontroller subsystem. The STM32F429 is an ARM Cortex M4 microcontroller. All system software resides in its internal Flash. Sheet 3 also contains RAM and Flash memory devices, OLED Display interface, overlay keypad inputs and programming connector interfaces.

Sheet 4: Power and Communications subsystem. Includes USB serial interface to an external PC, battery charging/monitoring systems, power input voltage and current protection and power regulators for 3.3 and backlight power supplies.

7.1.2.1 Sheet 2, MICS Radio Communications

The MICS subsystem main components:

- Microsemi ZL70123 SOM.
  - Microsemi ZL70103 MICS microprocessor.
    - Controls MICS 400MHz communications.
    - Communicates with system main microcontroller via SPI bus
  - TI CC2500 2.4GHz RF microprocessor.
    - Controls 2.4GHz Wake-up function

      - Communicates with system main microcontroller via SPI bus
   - 24.000MHz TCXO oscillator
- Analog Devices AD8310 LogAmp for RF Received Power measurements
- One 400MHz antenna for MICS communications
- Two 2.45GHz antennas for MICS Wakeup function.
- An RF switch between the wakeup antennas allows the system to select either antenna for wake-up attempts.

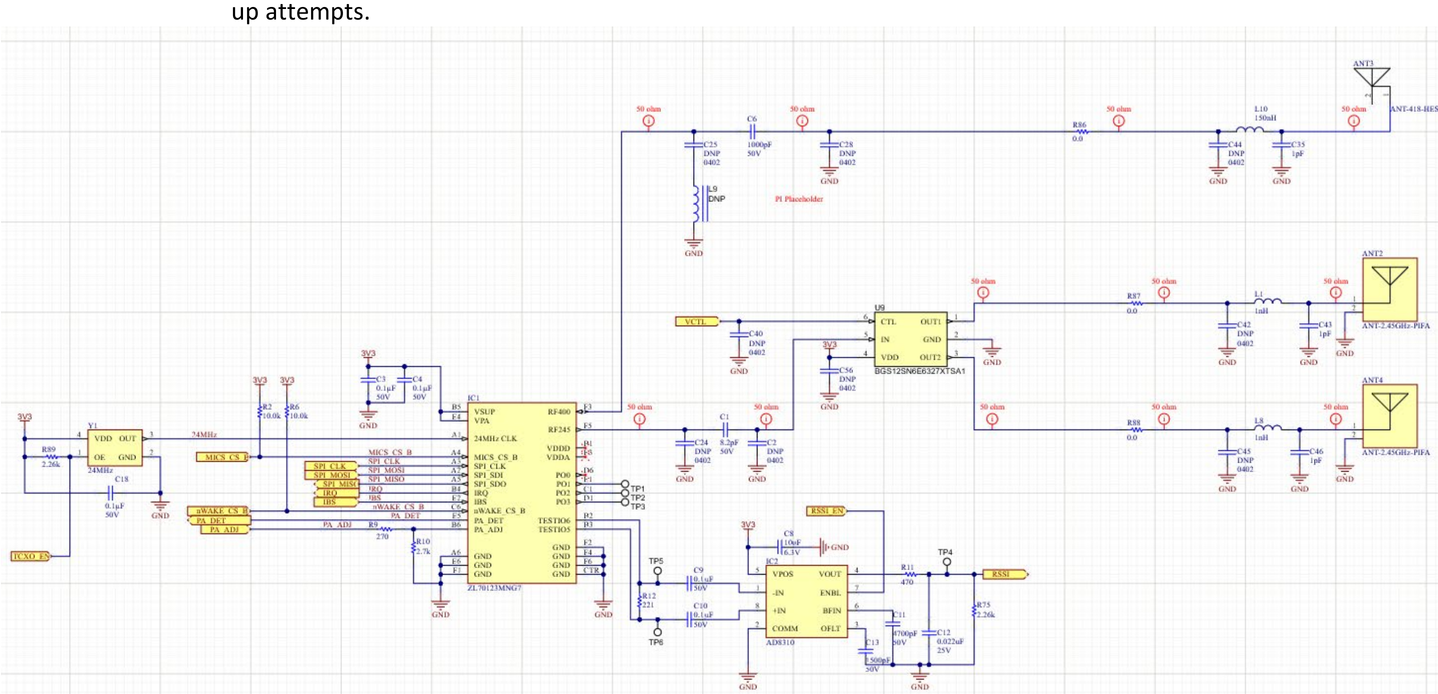


Figure 6: Microsemi ZL70123 MICS Radio and antennas

7.1.2.2 Sheet 2, RSSI Monitoring

The AD8310 logarithmic amplifier performs RSSI measurements when the ZL70123 TESTIO5 and TESTIO6 pins are configured. The output of the amplifier goes to the 12-bit ADC in the STM32F429.

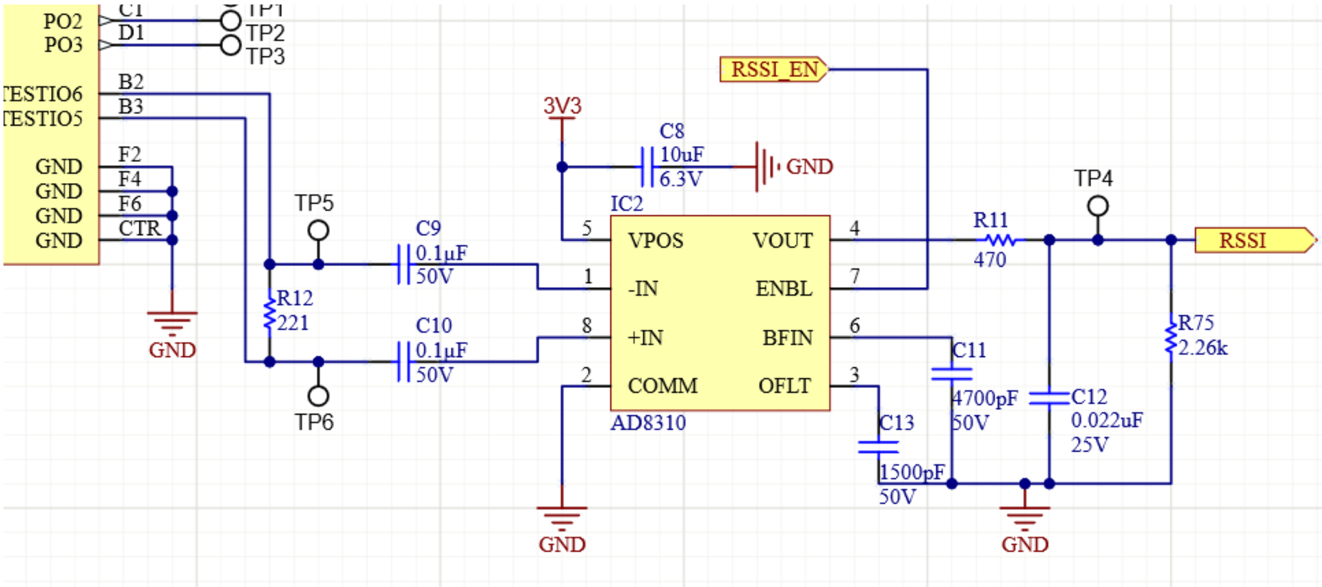


Figure 7: Log-amp RSSI for Clear Channel Detection

7.1.2.3 Sheet 3, ARM Microcontroller

The ST Microelectronics STM32F429 is a 144-pin package that contains an ARM Cortex M4 microcontroller, 2MB Flash, 260KB RAM, integrated LCD Controller and a Flexible External Memory Controller.

The software in the ARM performs all the functions defined in the BS3 software requirements, including Real-time-clock maintenance and storage of data downloaded from an implant in an on-board SPI Flash chip. The ARM initiates communication sessions with a MICS implant device, stores data received from those devices and uploads the data to the Canary Cloud application using a USB Host communications interface. There are 4 discrete button inputs to the microcontroller, and one dedicated Power On/Off button. The system can be powered ON by pressing the On/Off button located on the touch-screen overlay. The system can be powered OFF by pressing and holding the On/Off button for at least 5 seconds. Alternately, the microcontroller can shut off power by enabling the FW_SHTDN signal for at least 5 seconds.

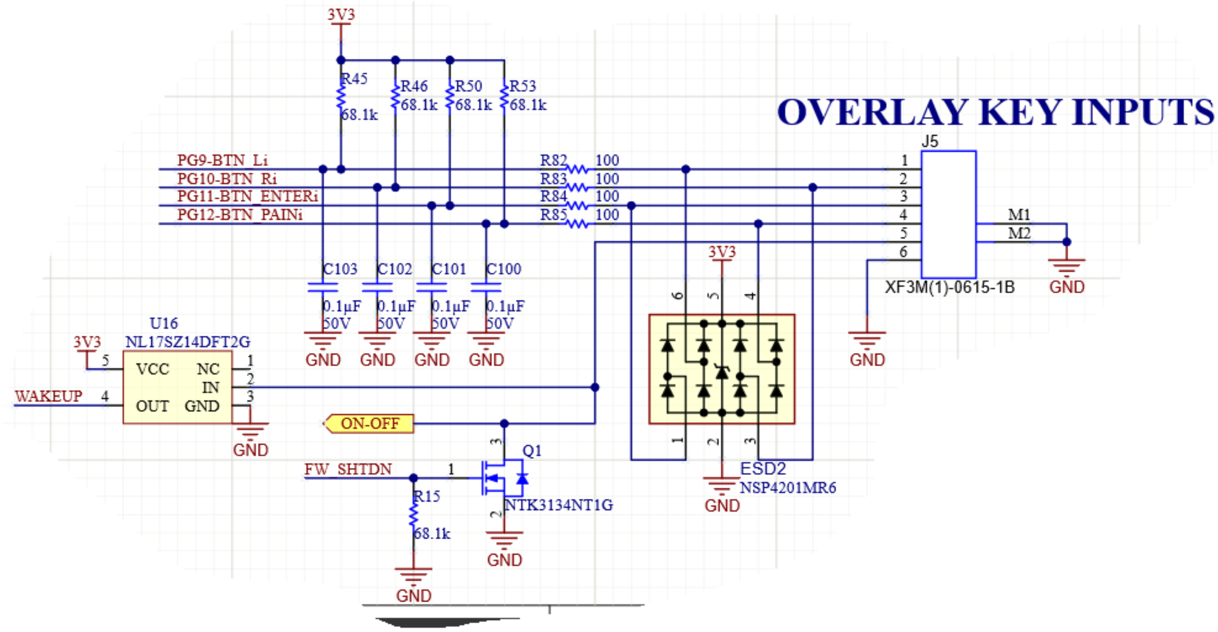


Figure 8: Key pad interface for the STM32F429.

7.1.2.4 Sheet 3, External Memory Devices

An ISSI IS42S16 SDRAM memory is attached to the STM32F429. This is a parallel bus interface device that allows 0-wait state data transfers to the microcontroller. The IS42S16 contains 8MB of storage, accessible as two banks of 2Mx16b words.

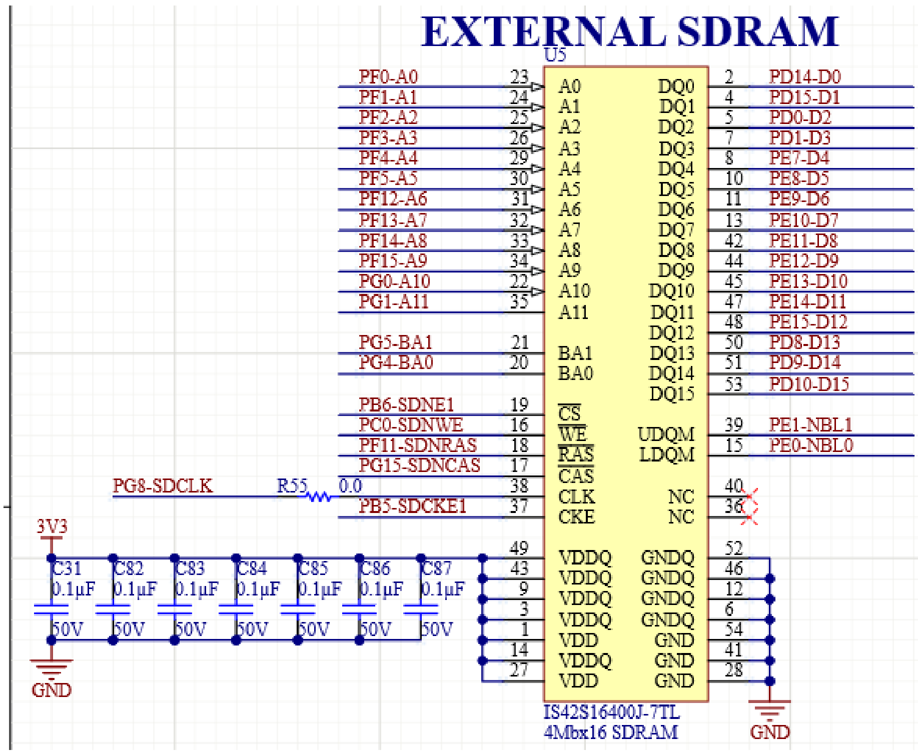


Figure 9: Microcontroller parallel-bus RAM Memory device

An ISSI IS42S16 SDRAM memory attached to the STM32F429 allows 0-wait state data transfers. The IS42S16 contains 8MB of storage.

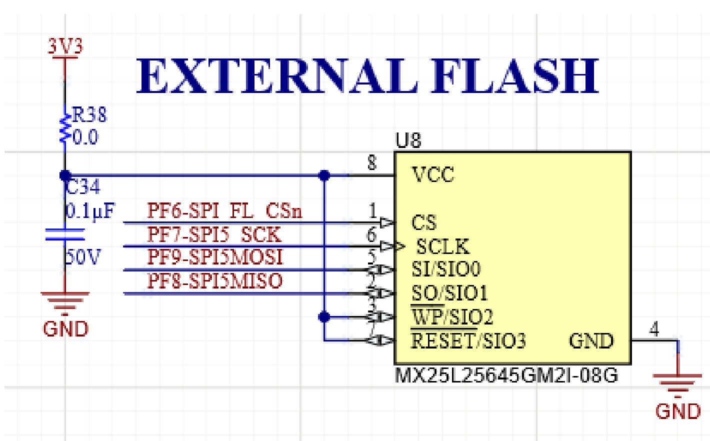


Figure 10: Microcontroller SPI-based Flash Memory devices

7.1.2.5 Sheet 3, 160x128 (Resolution) OLED Display

The BS3 connects to a 1.69" diagonal color display. The SPI2 bus from the STM32F429 connects to a Newhaven NH160128 OLED display via FFC connector J1.

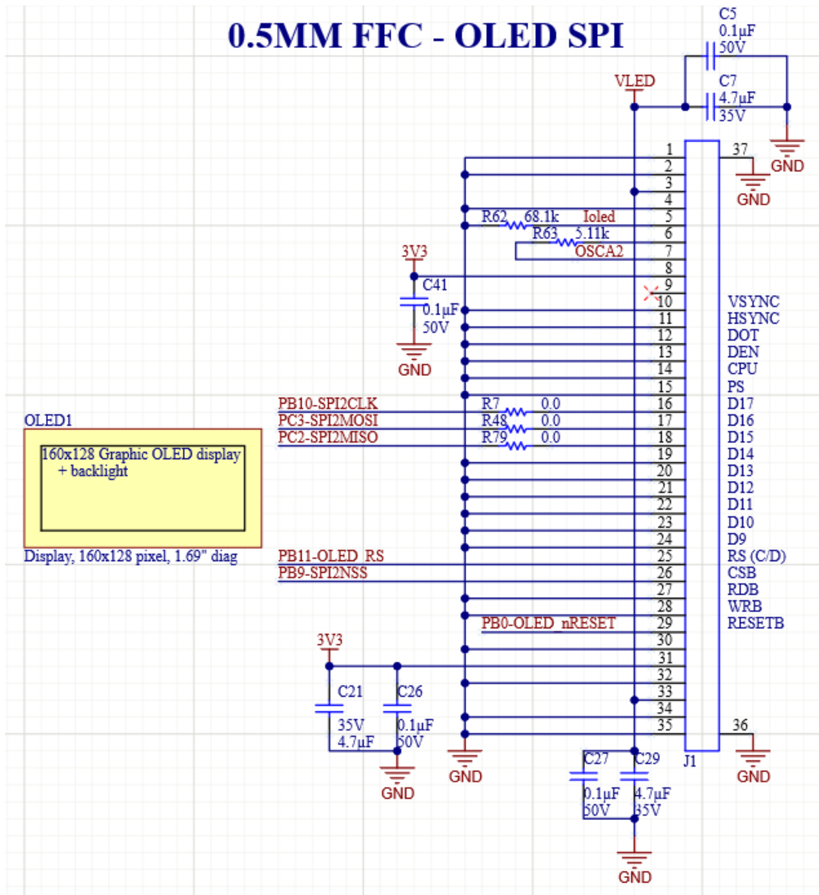


Figure 11: Microcontroller SPI-based Graphical Display Interface Connector

7.1.2.6 Sheet 4, Power and communications

The Power and Communications subsystems converts incoming power from the USB port to 3.3V for use in the base station. A TI TPS2162DS buck regulator converts the incoming USB power, nominally 5Volts, into the 3.3V power.

7.1.2.7 External Power Input

A USB 2.0 compliant microUSB connector supplies all external power to the BS3.

- Input Voltage = 5.0VDC +/- 10%
- Input current: Variable, depending on PC capability. Limited to 1.07A maximum by input protection circuitry.

The BS3 system is protected with an inline eFuse. The TI TPS25921 provides over-voltage, under-voltage, and current limit protection on the VIN power input.

Since the nominal voltage from the PC is 4.5-5.5V, the TPS25921 resistor bridge sets the limits as close as possible to 4.5 and 5.5V. Using standard, readily available resistor values the following nominal thresholds are set for over and under voltage detection:

- under-voltage threshold = 4.48V

- over-voltage threshold = 5.45V.

  Factoring in the tolerances of the 3 resistors and the 3% tolerance of the TPS25921, the variation from device-to-device can be:

- under-voltage range = 4.25 – 4.70V
- over-voltage range = 5.18 – 5.72V

  All devices in the system that are exposed to the VIN rail can tolerate these ranges.

The Maximum current limit is set by a single resistor, R8=100k, in the RevA1 units. Ilimit = .01073*R8. This limits VIN to ~1.07A.

Inrush current (SoftStart) is set with C4. When C4 = 1000pF the ramp time will be ~3milliseconds.

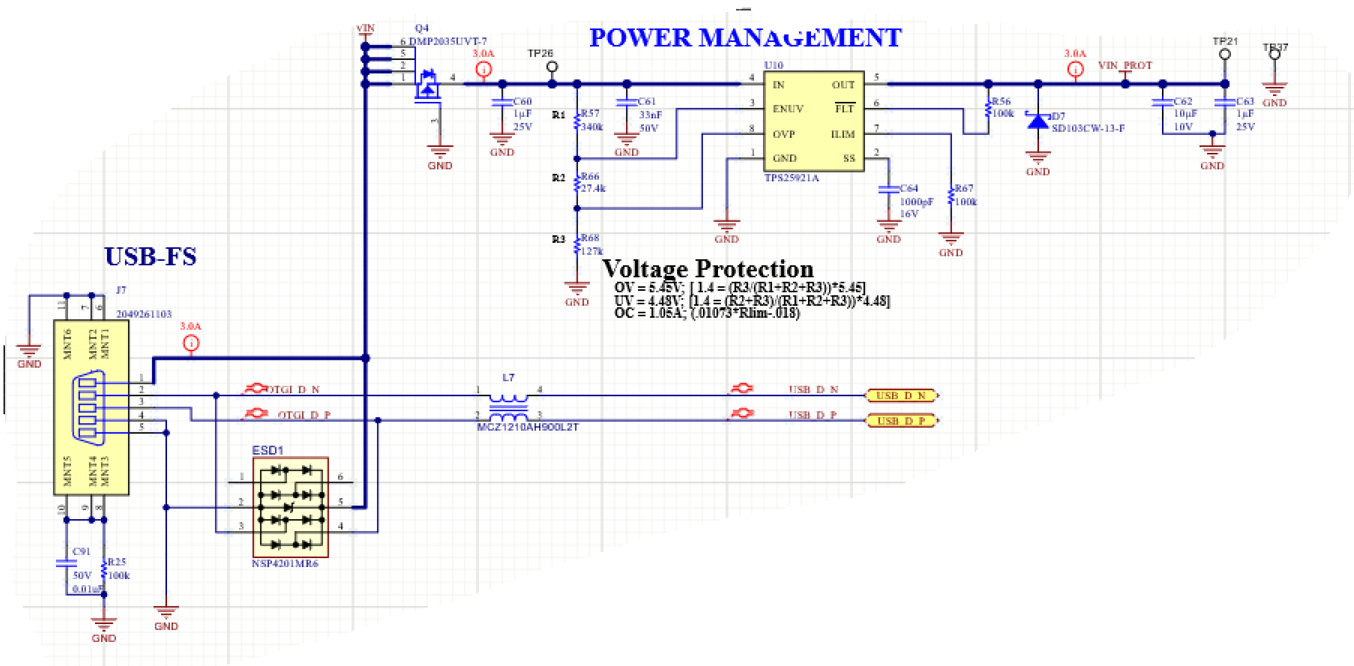


Figure 12 - Power Input Voltage/Current Monitor

7.1.2.8 Battery Charging and Charge Status Monitoring

Battery Charging is controlled by a TI BQ24193. The BQ24193 determines the source for the VSYS power rail and prevent battery overcharge by providing a maximum charge time as well as temperature and voltage monitoring.

VBAT. The battery specified for use in the Gen2 system is a single-cell Lithium battery from PHD Energy. Part Number = 523450-1S1P

Battery pack specifications:

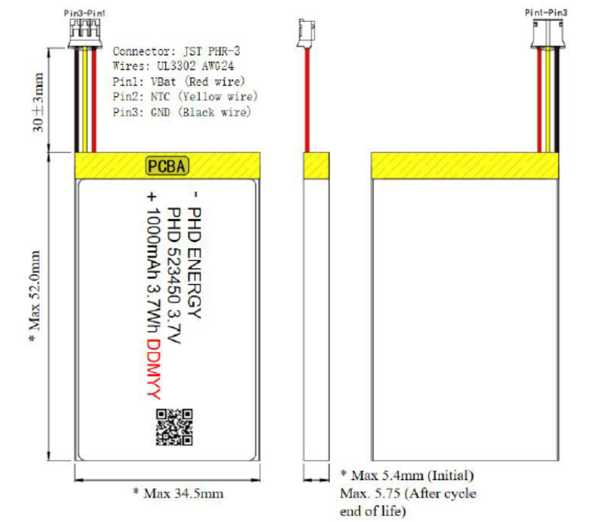
PHD ENERGY BATTERY & MANUFACTURING

PHD ENERGY INC   Rev: V0   Date: 2020.6.29

Model: 523450-1S1P

Nominal capacity	1000mAh			
Minimum capacity	≥950mAh			
Nominal voltage	3.7V			
Charge method	Operating temperature	Max. current	Max. Voltage	Cut-off current of CV
	0~15℃	0.2C	4.2V	≤0.01C
	16~45℃	1.0C	4.2V	≤0.01C
Discharge method	Operating temperature	Continuous current		Cut-off voltage
	-20~0℃	0.2C		3.0V
	0~15℃	1.0C		3.0V
Cycle life	Ambient temperature	Charge /Discharge current	Cycles	Capacity
	25±2℃	0.2C / 0.2C	500	≥80%
Dimension (T*W*L)	Max 5.4*34.5*52.0mm (Initial)			
Resistance (Discreet value)	≤180mΩ (AC 1000Hz)			
Weight	≈18.5g			

Capacity:
0.2C CC (constant current) charge to 4.2V, then CV (constant voltage) charge till charge current decline to 0.01C, rest for 10 min, discharging the battery with constant current at 0.2C till the voltage drops to 3.0V.



PCBA function:

1. Over-voltage protection;
2. Under-voltage protection;
3. Over-current protection;
4. Short circuit protection;
5. Temperature monitoring.

Figure 13 - Example Battery Spec

The battery pack has 3 wires, BAT+, BAT- and NTC. As described above, an internal temperature monitoring NTC is part of the battery. The NTC is a standard 10K ohm, B-value 3380 resistor, as specified above. This is the nominal value also required by the BQ battery charger.

Charging VBAT:

The bq24193 is an I2C controlled power path management device and a single cel Li-Ion battery charger. It integrates the input reverse-blocking FET (RBFET, Q1), high-side switching FET (HSFET, Q2), low-side switching FET (LSFET, Q3), and BATFET (Q4) between system and battery. The device also integrates the bootstrap diode for the high-side gate drive.

Below is the functional block diagram for the BQ24193.

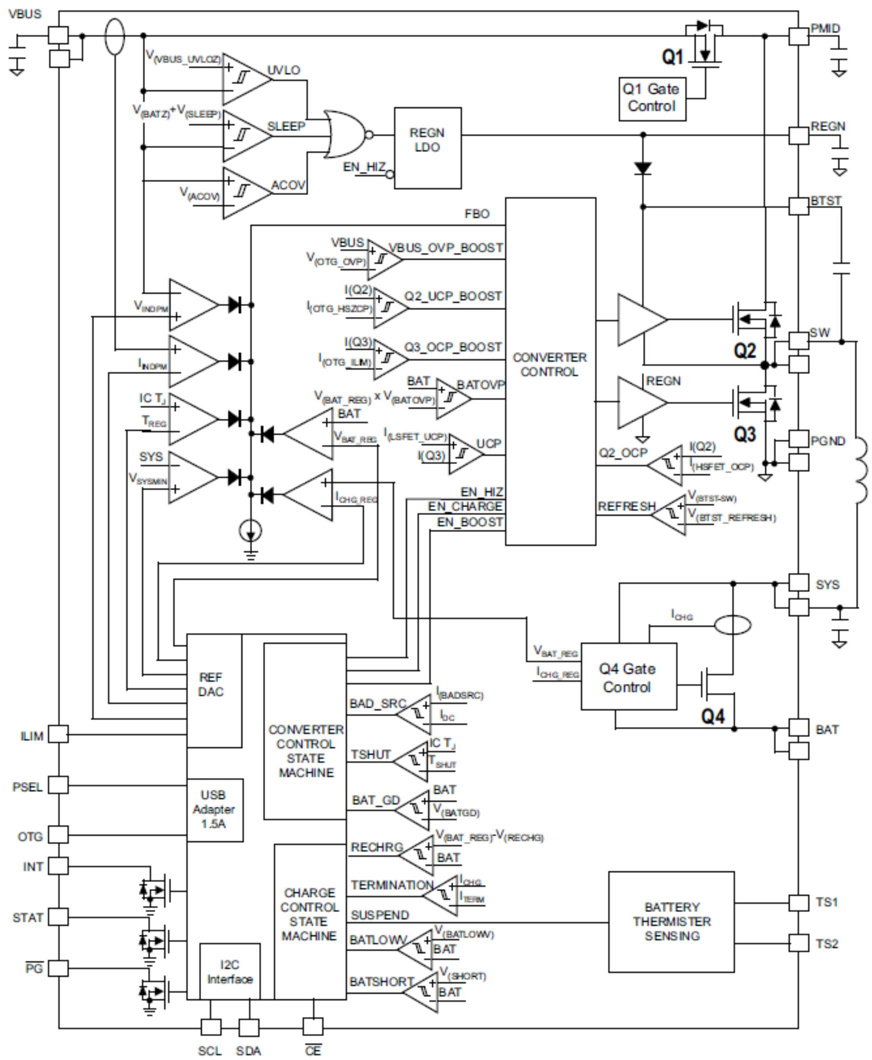


Figure 14 - TI BQ21493 Functional Block Diagram

Battery Charging Current Limit: Charging current into the battery is limited by a single resistor tied to the Ilim pin. Selecting R37 = 620 ohms sets the maximum charge current to ~800mA. This sets the recharge rate to about 0.75C. Limiting charging rate to below 1C maximizes the expected life of the battery.

Communications interface: The BQ21493 interfaces to the system STM32F429 main processor on the i2c bus

VSYS: Vsys is the main power rail in the Gen2 system. It connects to VBAT in the BQ24193 when charging voltage is not present and to Either VBUS or VBAT when the charging voltage is present.

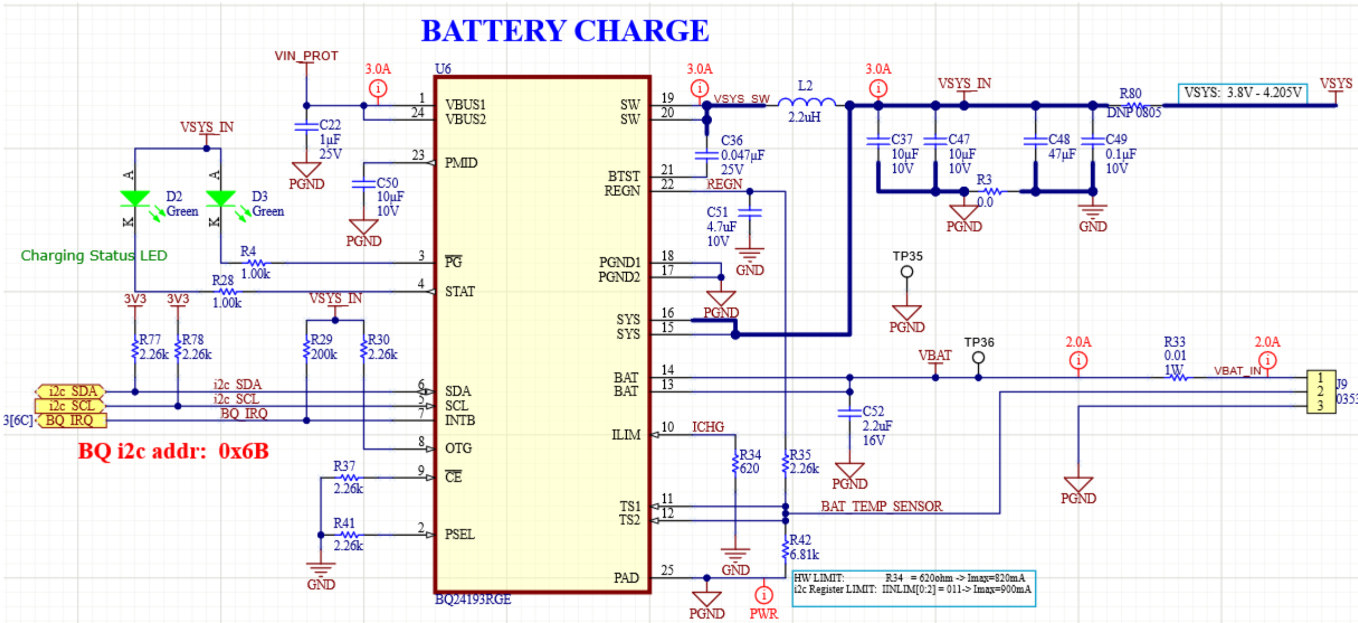


Figure 15 - Battery Charging and Safety

7.1.2.9 Battery Fuel Gauge Monitoring.

U7 continuously monitors VBAT bidirectionally (charge/discharge) through current-sense resistor R33. U402 is a TI BQ27441-G1A battery fuel gauge.

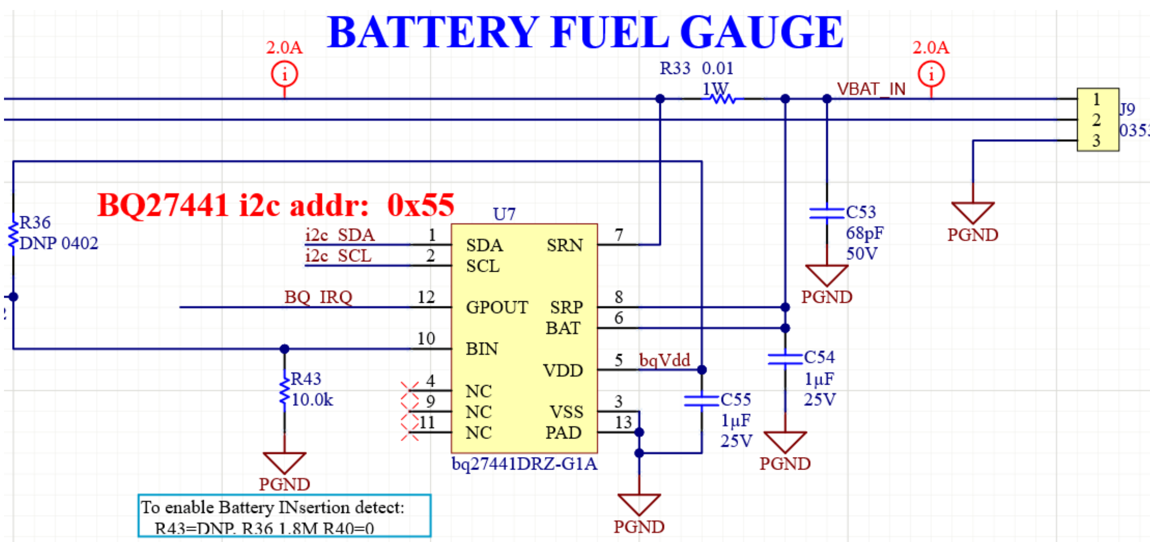


Figure 16 - Battery Connection, Smart Monitor

The bq27441-G1A battery fuel gauge accurately predicts the battery capacity and other operational characteristics of a single, Li-based, rechargeable cell. It communicates via the I2C1 bus with the system i.MX6 processor to provide cell information, such as state-of-charge (SOC). The device is orderable in two predefined, standard configurations. The Gen2 design uses the bq27441-G1A fuel gauge. It is predefined for LiCoO2-based batteries with a 4.2-V maximum charge voltage.

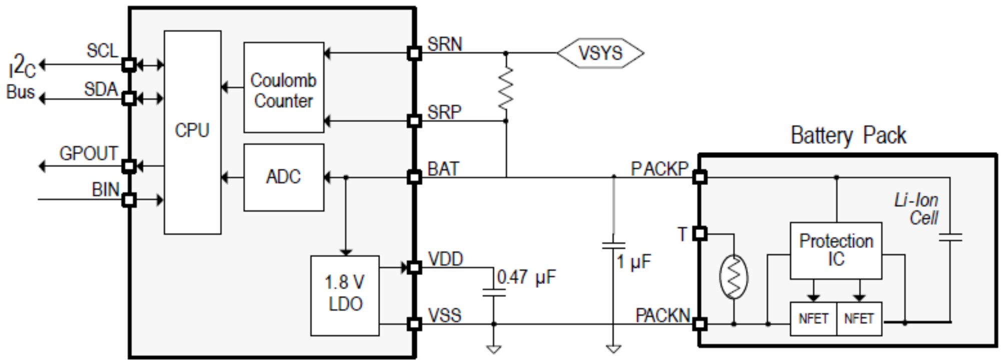


Figure 17 - TI BQ24471 Block Diagram

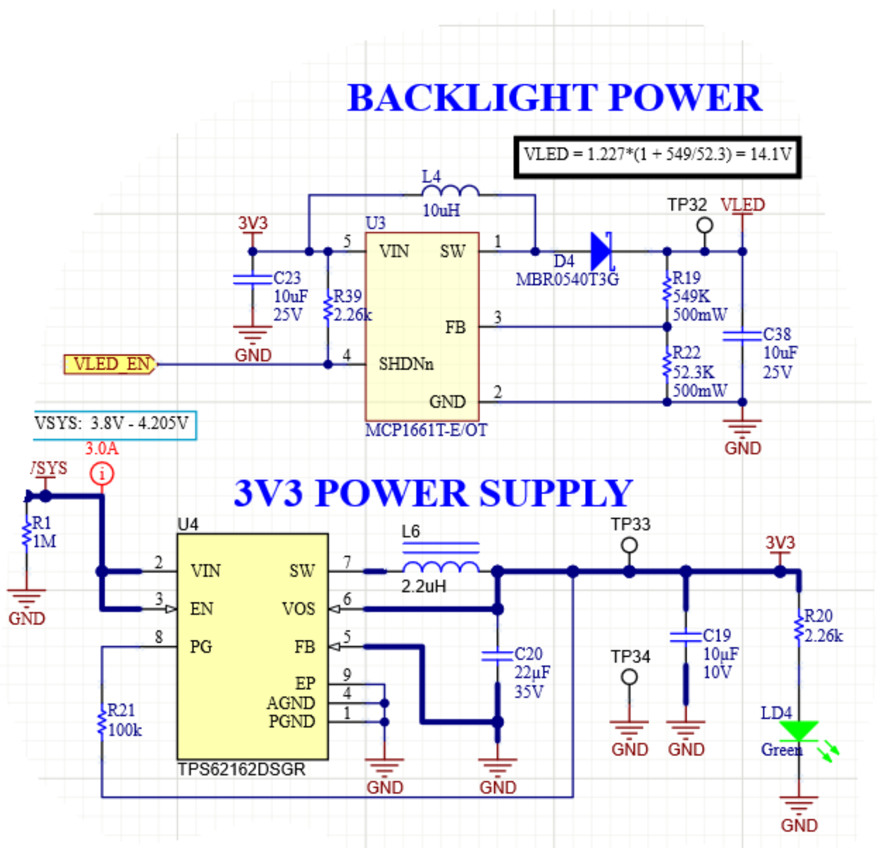


Figure 18: 3.3V system and 14V backlight Regulators

The STM32F429 microcontroller has an Full-speed, USB 2.0-compliant hardware interface. This interface is used to transfer patient data received over the MICS radio to a Clinic PC Application. The micro-USB receptacle also provides power for the Base Station, a 5V power source for battery charging and operation while connected to the PC.

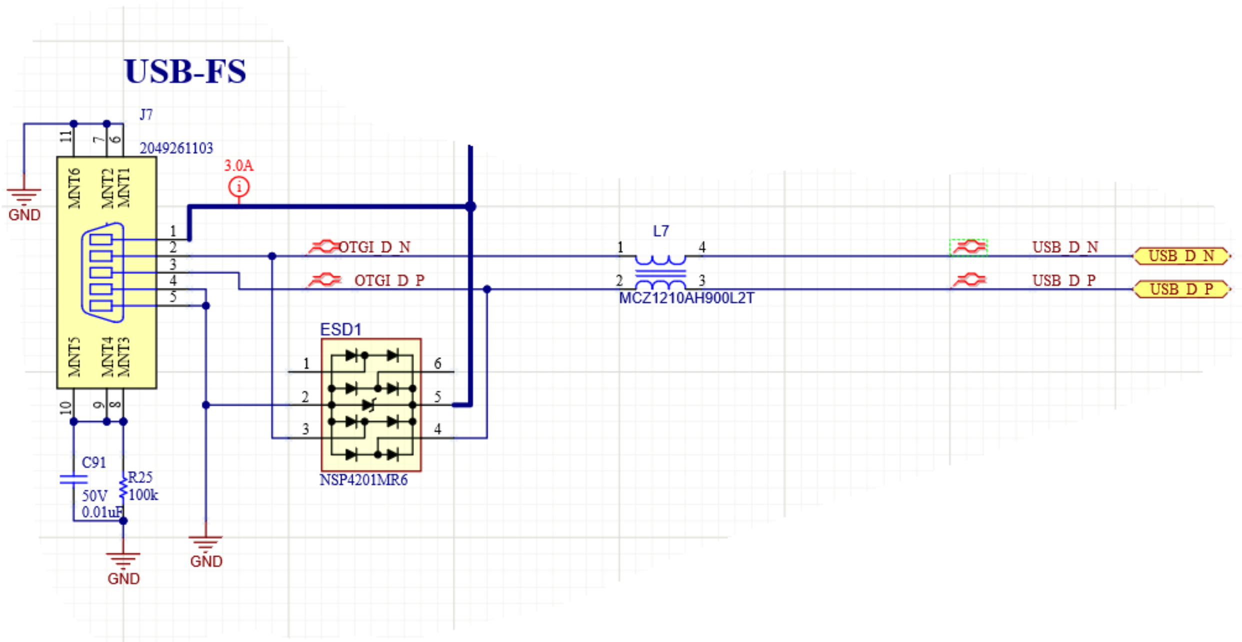


Figure 19: FS-USB microUSB connector interface.

7.2 Packaging

The BS3 packaging consists of an individual cardboard box for shipment to the clinic. The packaging will include a Quickstart guide, USB cable, USB power supply, and a Lanyard.

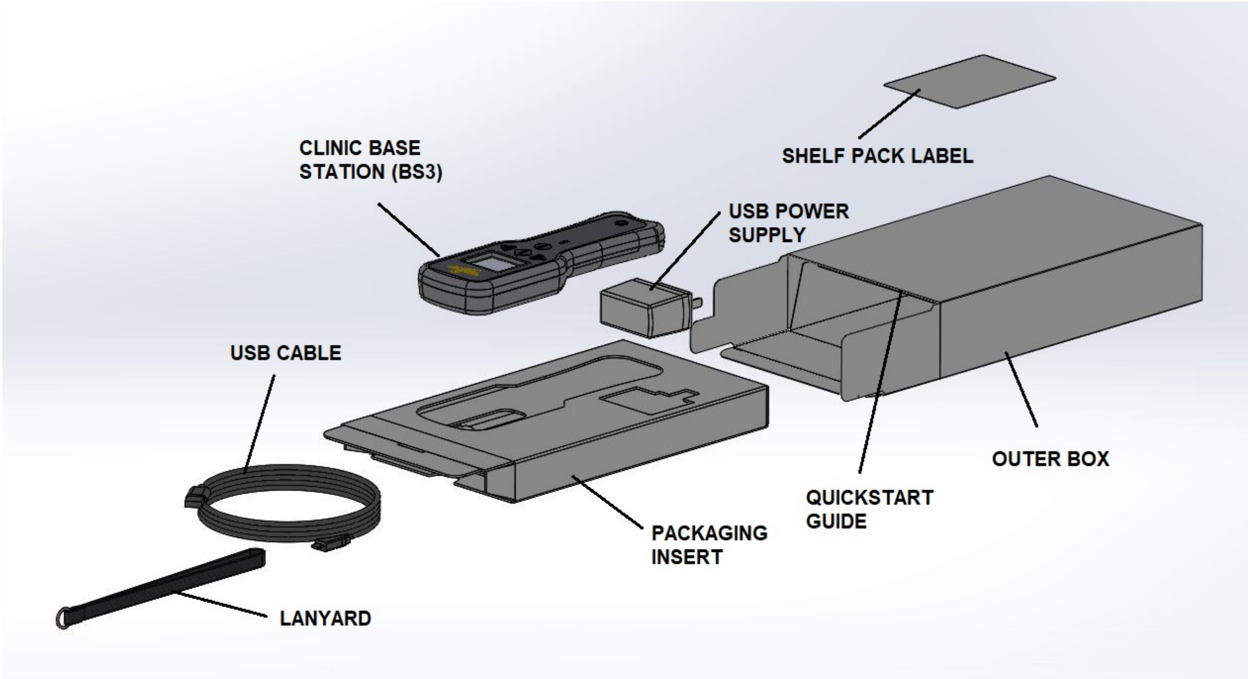


Figure 20: BS3 Packaged Assembly – Exploded View.