

Update:

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5. Retrieve 41 Lacs of data beginning from 0 and manually confirm
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8 Days Storage for Lead 7

Unit Test Case

Retrieve the Device ID from the storage and then find out the manufacturer's information and the size of the storage.

Unit program that reads the device id and reveals the same to debugger expression

2. The read and write capability of storage devices.

Store 1000 Number of random Data with Sequential Epoch Number Starting from 0 to 1000 and read the same locations in return and verify manually.

4. Retrieve 41 lacs of data, commencing from 0 and confirm manually.

Put Breakout point on loop of 1 page. Upon completion of 1 Page wait and see if correct epoch number is showing. Do these for the rest of the sequence.

5. Retrieve 41 Lacs of data beginning from 0 and manually confirm.

Store data to the Storage Starting from 0 to 41 Lacs.

Retrieve data from the storage and decode the epoch counter from 0 to 41 Lacs.

Compare the epoch counter with loop counter. If loop counter and retrieved epoch counter data is matched, then data is stored and retrieved correctly, else there is a problem/glitch, count that glitch to the program using error Counter.

3. Maintain 7 days of data for Lead 7.

Total Number of Packets for 7 days is 41 Lacs, so we store 41 Lacs data sequentially starting from 0

7. Store 1 lac data, retrieve it, and verify if you received the same information on time.

Store the 1 Lac of Data to the Storage

Write a script to compare the retrived epoch with stored epoch sequentially.

8.Store 17000 Data to the Storage and retrive the data to the web platform using Oom Patch

- 1. Connect with Oom App and Provide epoch to the patch.
- 2. Turn off the Internet / Disconnect from patch and wait for atleast 30 to 40 minutes to get data stored.
- 3. Turn on Internet and reconnect the patch.
- 4. Note down the number of data being stored to the patch.
- 4. Bring device nearby to sync the data.
- 5. wait for data to be sync.
- 6. In database check if all the data has been synced to the mongodb database.

9. Store 17000 Data to the Storage and retrieve the data to the web platform using Oom Patch

Store data to the Storage Starting from 0 to 41 Lacs.

Retrive data from the storage, and decode the epoch counter from 0 to 41 Lacs Compare the epoch counter with loop counter.

If loop counter and retrived epoc counter data is matched, then data is stored and retrived correctly, else there is a problem/glitch, count that glitches to the program using errorCounter.

10.Store and Retrieve data from the Storage using Oom Application and check if the counter getting 0 or not.

Connect Patch with the Oom Application.

Turn off the Internet and check the

Need to check

17 data getting stored in once in 1 page.

so if we are turning patch while less than 17 data collected in a queqe.

data management would require tackling these.

Need to check

Write Count and Read Count getting store along with page number and block number

ECG Straight Line

Unit Test Case

1.Straight Line – Bug

Unit program that reads the device id and reveals the same to debugger expression

- 1) Output data were compared with data 000
- 2) Output data were compared with data 0xff

2. Straight Line – Bug

Unit program that reads the device id and reveals the same to debugger expression					
1) If same data arrive multiple time, reinitialise the sensor.					

Check Sum Encryption

1 Checksum Encryption

Process->

- 1. Enable Notifications on 0x1802 Characteristic under 0x180D Service
- 2. Read 10 Byte Code Notified on 0x1802.
- 3. 10 Number Byte refreshed on every new Bluetooth connection establishment.
- 4. Take Byte Number 4 and 5 if Starting Index from 0 or take Byte Number 5 and 6 if Starting Index from 1.
- 5. Generate 10 Byte Code Using Serial Number and Epoch as usual.
- 6. Replace byte number 4 and 5 of Actual Encryption with Checksum Byte 4 and 5 and write it to the 0x1801 characteristic.
- 7. write command byte as usual to 0x1802 to start incoming ecg data.

Yes

Enter Wrong Epoch with Usual Serial Epoch Combination

ECG Spikes

change the millivolts in ascending sequence from 0.5 to 2mV and in descending sequence from 2 to 0.5mV in to the simulator and check the response if there is any spike or what.

Turn off the simulator, plug the patch and turn on the patch and check when the smartphone is getting connect, if there is any spike due to which whole waveform is getting shorter.

wear the patch on any person/user or plug the patch to the simulator and give some external noise which may create impact on voltage difference and check if there is any spike.

Battery Simulator

Power Profiler

- 1. Connect Power Profiler with Oom-Patch and set the Voltage 4.2(100%), check the power consumption.
- 2. set the voltage to 3.7(50%) check the power consumption.
- 3. set the voltage to 3.5(30%) and check the power consumption.
- 4. set the voltage to 3.3(5%) and check the power consumption.

12 Lead ECG Simulator

ECG Data Generation and Transmission.

Capture ECG Data

Lead 2 Data Plotting

Multiple data provided into custom array wave form. format is as per the below 1. Lead 2 data was in Excel, Plotted in exce graph.

2. Same data stored to array format.

- 3. Transmitted these to the patch via electrodes.
- 4. Connection matrix

Circuit 1

RA = Oom Patch RA

LA = Oom Patch LA

LL = Oom Patch LL

Circuit 2

5. Oom patch connected with smartphone and Checked data plot Same data stored to array format.

Transmitted these to the patch via electrodes.

4. Connection matrix

Circuit 1

RA = Oom Patch RA

LA = Oom Patch LA

LL = Oom Patch LL

Circuit 2

Lead 2 Data Plotting

Same value data fill inside the array and connect the simulator with oom patch to check the data weather it is correct or not with the wiring diagram Transmitted these to the patch via electrodes.

Connection matrix
Circuit 1
RA = Oom Patch RA
LA = Oom Patch LA
LL = Oom Patch LL and tested in the oom patch application in the smart phone

Implemented the code in arduino and assigning different data to the arduino and checked the data in the arduino plotter and it's plotting perfectly

Lead 2 Data Plotting

Lead 2 Data Plotting ESP 32 code developed and tested with the arduino plotter and OOM ECG app data is coming is perfect but need to find the common array size for the all data so BPM will detect in OOM app

Lead 2 Data Plotting Connect RA->Patch RA, LA-> Patch LA & LL-> Patch LL and upload the code into ESP32 and connect the Patch with the OOM app and test the data in OOM app

Lead 2 Data Plotting
Two circuit combination and each circuit have 3 teminals which are LL,LA,RA 1) First
circuit's LL -> 7 Lead oom patch LA 2) First circuit's RA -> Second circuit's RA 3) Second
circuit's RA -> 7 Lead oom patch RA 4) Second circuit's LL -> 7 Lead oom patch LL

Lead 1, Lead 2 & V5 Data Plotting

Three circuit combination and each circuit have 3 teminals which are LL,LA,RA 1) First circuit's LL -> 7 Lead oom patch LA 2) First circuit's RA -> Second circuit's RA 3) Second circuit's RA -> 7 Lead oom patch RA 4) Second circuit's LL -> 7 Lead oom patch LL 5)

Third circuit's LL -> OOM Patch V5

UART TYPE C

5 Pins are used for the Programming

JTAG_TCKC- 25 (Input Only)

JTAG_TMSC- 24 (Input and Output)

RESET - 35

VCC

GND

1) UTC

Transmit Simple Hello World Data to the Terminal with default pins of the Controller

Used Code Composer Studio Terminal to check these.

Transmit Simple Hello World Data to the Secondary Pins

Changed Support Pins from Default Pin and Transmitted to the UART and checked with USB2TTL

RX Pin Modified from

RX Pin Modified from

RX - 5 ----> TCK

TX - 4 ----> TMS

RX Pin Modified from

Connected with Type C Cable

It has 4 pins which are directly connected with the Smartphone

USB port was not showing, when connecting with cable with our USB2TTL Connector

Data Collection	
Read the Storage Flash and Collect a data to an array of 10000 bytes.	

Battery Documentation - SRS

Aim:

To write a documentation on Battery for Medical Devices.

Problem Statement:

To write a document for a battery related to medical industry.

Outline:

This section outlines the overview of the battery product and it should have a lifetime of 10 days. As we are using a PCBA Board with a two placeholders at each end to fit a small size battery in it. The battery capacity used by the company in this document is 350 MAH and 180 MAH in capacity, should be connected in parallel. The lithium polymer battery should be rechargeable. There existing design should not have any changes.

When the product is going to be used, certain assumptions must be made to ensure that it is working properly.

- I The device should have a battery reading monitoring gadget attached to it to track the battery.
- Ii Two small battery on the PCBA board should be put in the existing design volume, so it should work like a single battery.

lii No matter what port as adapter we use be it Laptop or Mobile, the capacity of the battery should not change.

Constraints:

- The accuracy of the battery calculation depends on the precision of the battery monitoring circuit.
- Ii The LED used in the board PCBA functionality depends on proper operations of the LED components being used.

When battery in the PCBA device undergoes charging for a period of full charge[approx 60 minutes], the device should be able to use it for atleast 3 days.

Warning:

Do use a proper adapter.

The device should not overheat by the environment 50 degrees and above.

Don't use power adapter above 45 Watt.

Safety

1) Quality Type:

The battery could not overcharge[the battery criteria should be 4.2+ or - 0.1 in full charge].

2) Battery should not be overheat while charging.

Other Safety Requirements:

Precise indications ensure that the users using the battery are well guided about the battery status.

Test Cases:-

a)Test Case 1:

Full charge battery upto to it's total capacity.

Verification - The different colored LEDs are always displayed when the USB is plugged in, regardless of the switch position.

Validation - Output of the system displayed should correctly match.

I Under full charge the battery should indicate Green and under charge battery should indicate Red.

b)Test Case 2:

li When battery in the PCBA is fully charged it should work for 3 days minimum.

Verification - Make sure to confidently unplug and plug in the correct USB cable.

Validation - The PCBA board should be able to display the LED status accurately.

c)Test Case 3:

If the range of voltage comes more than 4.2 Watt then the Battery is faulty.

Verification - The voltage passed must not exceed 4.2 volt.

Validation - If Battery voltage is increasing beyond certain limits it can damage the PCBA components.

d)Test Case 4:

Less than 45 Watt power, the battery should not work.

Verification - A steady supply of current is essential for full functioning of battery at optimum level.

Validation - Lipo Battery's are a good example.

e)Test Case 5:

Battery discharging test ratio should satisfy 7 to 10 days of battery backup.

Verification: after fully charged device turn it on, connect with smart phone and note start time and end time of battery discharge.

Validation : Battery should last for atleast prescribed hours duration.

Requirements

The primary requirement is to ensure the proper installation (mounting) of the battery on the PCBA board, enabling it to function without operational issues for 10 days when fully charged. Upon reaching a battery charge exceeding 20% of the total capacity, the LED is to blink once every 3 seconds. Conversely, when the battery charge falls below 20% of its capacity, the LED should blink once every second.

Verification Criteria:-

- The system that displays the output should be able to correctly match and display the battery percentage that has been utilized.
- Ii The LED used should change its color according to charging state and battery percentage(Full charge indicates by green LED)

By plugging and unplugging the correct USB cable the PCBA board should be able to detect the correct LED status change(Under charging of device is indicated by RED LED).

2) Validation:-

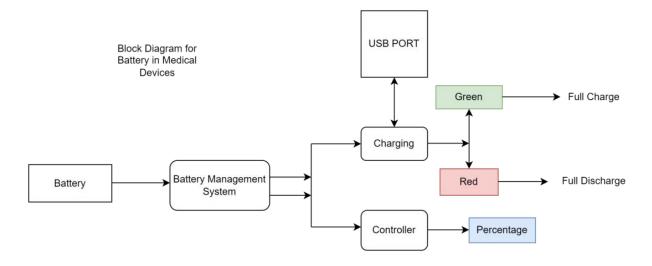
1) BMS[Battery Management Testing]:

Depending on the battery percentage, the LED indicators display different colors
when micro USB is plugged on port or switch is on.(red for charging, green for
full charge,no colour displayed means LED is faulty).

- If a USB cable is plugged in and power supply is on, the LED status changes to indicate charging.
- If the power supply is turned off or the USB cable is unplugged, the LED status indicates no charging (LED off).
- Things to be kept in Mind:
- Battery voltage monitoring should be designed in such a way so as to prevent overcharging and deep discharging which could damage the battery used in the PCBA board.
- While choosing and installing LED components safety guide lines need to be followed in order to prevent hazards.

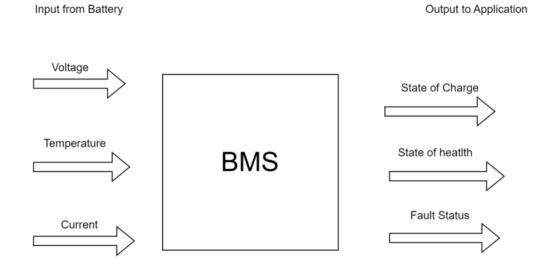
Diagrams:

Block diagram for Battery in medical devices

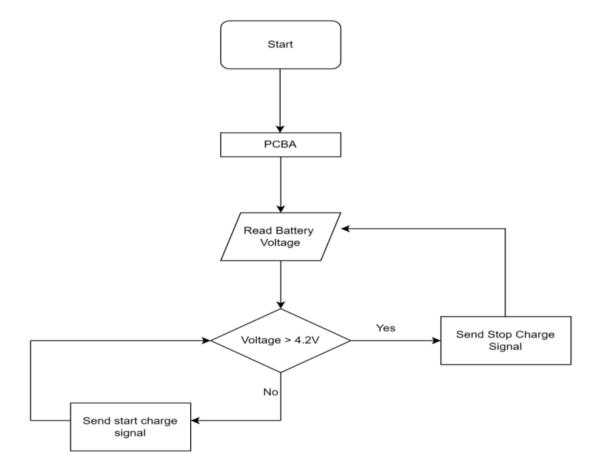


Use Case Diagram for battery in Medical Devices

Use Case Diagram of Battery



Flow Chart Diagram for Battery Control Functionalty



Battery Documentation used in Medical Devices

Types of Battery

- 1) Nickel Metal Hydride Battery Not suitable
- 2) Nickel Cadmium Battery Not Suitable
- 3) Alkaline Batteries Not Suitable
- 4) Pin-type Lithium Ion Batteries Not Suitable
- 5) Metal Iodine Batteries(MIB's) Suitable
- 6) Manganese Dioxide Batteries Suitable
- 7) Carbon Monofluoride Batteries Suitable
- 8)Lithium Silver Vanadium Dioxide Battery Suitable
 - 1) Pouch Type Battery:-

1)Battery Name - Nickel Metal Hydride Battery

Yes, Nickel Metal Hydride (NiMH) batteries are available in pouch type.

Nickel Metal Hydride batteries rely on a specific chemical reaction between the positive and negative electrodes to store and release energy.

Battery Chemistry:-

The positive electrode, known as the cathode, is composed of nickel oxyhydroxide (NiOOH), which bears resemblance to the material utilized in Nickel-Cadmium (NiCd) batteries.

The negative electrode, also known as the anode, in this particular battery type is composed of a hydrogen-absorbing alloy. This sets it apart from NiCd batteries, which utilize cadmium. These alloys can be manufactured using a variety of metals such as lanthanum, nickel, and manganese.

The electrolyte utilized is a solution of potassium hydroxide (KOH), which serves as a conduit for the movement of ions between the electrodes.

Discharge Process:-

During the discharging process, hydrogen atoms from the negative electrode react with nickel oxyhydroxide from the positive electrode, thereby storing energy. Conversely, during the recharging process, hydrogen migrates back to the negative electrode while nickel oxyhydroxide is regenerated at the positive electrode.

Recharge Process:-

The recharge ability of nickel-metal Hydride (NiMH) batteries stems from the reversible nature of the chemical reactions within them. This characteristic enables these batteries to undergo recharging hundreds to thousands of times through the controlled application of current. Essentially, the charging process reverses the discharge reaction, thereby restoring the original chemical state of the electrodes.

NiMH battery vs Lipo Battery

Capacity vs Size

Size:

Both NiMH and LiPo batteries can be easily manufactured in the specified size of 40mm x 20mm x 5mm. However, for the same capacity, a NiMH battery will inevitably be slightly larger due to its lower energy density compared to LiPo.

Standard battery used:

Specifications:

Length - 40mm

Breadth - 20 mm

Thickness - 5 mm

Battery Description: -

- NOVACELL 3.7V

+602040P 420mAh

502035/350h 202309

R-41138894

Comparison:-

With standard battery used NimH battery are slightly larger size and might be a good choice.

On the Other hand if one chooses weight and size that are critical a Lipo battery more compact and powerful choice.

Pouch Type Battery:-

Battery Name - Nickel Cadmium Battery

There are currently no commercially available battery pouches specifically designed for nickel-cadmium (NiCad) batteries.

NiCad battery are typically designed in two main Configurations:-

- I Sealed:-"These feature a welded metal shell and are not intended to be opened by the user. They do not require a pouch."
- Vented: These come with a durable plastic case equipped with a pressure relief valve.

 They are specifically engineered to remain sealed and do not need a pouch for storage.

Pouch Type Battery:-

I Battery Name - Alkaline Batteries

Alkaline batteries are never sold in battery pouches; they are typically packaged in blister packs, cardboard boxes, or plastic packaging.

Pouch Type Battery:-

Battery Name - Pin-type Lithium Ion Batteries

Pin-type lithium ion batteries do not come in battery pouches.

5)Pouch Type Battery:-

Battery Name - Iodine Batteries

Metal lodine batteries do not come in battery pouches.

Pouch Type Battery:-

Battery Name - Manganese Dioxide Batteries

Yes Manganese Dioxide Batteries come in battery pouches.

Pouch Type Battery:-

Battery Name - Carbon Monofluoride Batteries

Pouch Type Battery:-

Battery Name - Lithium Silver Vanadium Dioxide Battery

Lithium Silver Vanadium Dioxide Battery do not come in battery pouches.

Pouch Type Battery:-

Battery Name - Carbon Monofluoride Batteries

Carbon MonoFluoride Batteries Batteries

Safety

Battery Type:

The battery that is being used must be of a good quality.

Overheating:

When the battery reaches a certain charging limit[Eg:70%] it should not over heat otherwise the circuit inside the battery can melt and the battery will stop working properly.

Other Safety Requirements:

Precise indications ensure that the users using the battery are well guided about the battery status.

Test Cases:

- When battery reaches 95% charge the battery must be able to function for a maximum of 3 to 4 hours or maximum to a day depending on the usage.
- li Less than 25 Watt power, the battery should not work.
- Ii The battery must be kept in a dry place to avoid chemical properties of the battery being changed.
- lii When the battery reaches the 100% charging capacity it should not over heat.

Requirements

Test Cases:

1)Test Case 1:

I Full charge battery upto 8 days to 10 days.

I Under full charge the battery should indicate Green and under charge batter should indicate Red.

2) Test Case 2:

When battery in the PCBA is fully charged it should work for 3 days minimum.

Test Case 3:

If the range of voltage comes more than 4.2 Watt then the Battery is faulty.

Test Case 4:

Less than 45 Watt power, the battery should not work.

Constraints:

- The accuracy of the battery calculation depends on the precision of the battery monitoring circuit.
- Ii The LED used in the board PCBA functionality depends on proper operations of the LED components being used.
- When battery in the PCBA device undergoes charging for a period of full charge[approx 60 minutes], the device should be able to use it for atleast 3 days.

Test Cases:

- lii Less than 45 Watt power, the battery should not work.
- liii Full charge battery must work upto 8 days.
- liv Under full charge the battery should indicate Green and under charge batter should indicate Red.
- li If the range of voltage comes more than 4.2 Watt then the Battery is faulty.

ECG Data Acquisition

Aim:

To write a documentation of ECG data acquisition.

Problem Statement:

To identify if we are getting any spikes mixed with actual ECG data.

Outline:

This section outlines the overview of ECG data acquisition and its accuracy, via a patch which is connected to a simulator or human subject.

To test this ECG data acquisition the following ways are adopted.

1)Scenario 1

- I The patch gets attached to a simulator.
- li We are turning on the patch and connected with the smartphone.
- lii We are turning on the simulator.

If there is a spike and the ECG shows then the test fails

If there is no spike and the ECG shows then test passes.

Scenario 2

- liii The patch gets attached to a simulator.
- liv Considering patch is on simulator is on and connected with smartphone and regular data is getting relayed.
 - In this scenario an external noise is created on patch and the data gets noted.

If there is a spike and the ECG shows then the test fails

If there is no spike and the ECG shows no then test passes.

Scenario 3

- Iv The patch gets attached to a simulator.
- lvi This in turn is connected via smartphone that is used to check the data.
- lvii The simulator is turned on and the data gets noted.

- Iviii The patch and the simulator voltage readings are kept between a range from 0.5mV to 2mV.
- lix In the first step we set the voltage to 0.5mV to the patch and we check for 20 seconds and data gets noted.
- Ix Then we set the voltage to 1mV to the patch and we check for 20 seconds and the data gets noted.
- lxi We repeat the previous step and go upto 2mV to the patch and check for 20 seconds, till we note the data.

If there is a spike and the ECG shows then the test fails

If there is no spike and the ECG shows then test passes.

4)Scenario 4

- lxii The user wears the device or the patch is attached to the chest of human subject.
- Ixiii The user does extensive activities such as Running, Jogging, Walking and the data gets noted.

*NOTE:



Figure 1: ECG Graph showing Spike

The above diagram depicts when the patch(device) is connected to the simulator, or any other device say a smartphone. The following things need to be noted.

- While testing if there is any spike or noise as shown in the first ECG Acquisition diagram, the test case failed.
- li Subsequently, if there is no spike of the ECG acquired wave form, the test case has passed.

Result:

Spike comes -> Test case fail

Spike does not come -> Test case Pass