

USER MANUAL

Wearable Health Monitoring System

(MODEL : S-PATCH3)

Document No. : S-UM-01 (Rev. 0.2)

Samsung Electronics Co., Ltd.

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Revision History

Revision Number	Issue Date	Contents of revision
Rev.0.0	2016.12.28	Established by Manufacturer's User Manual Policy
Rev.0.1	2017.1.5	5.1 Label Update
Rev.0.2	2017.2.9	5.1 Label Update
<u>Rev.0.2</u>	<u>2017.2.9</u>	<u>4.2.1 Spec Update</u>

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1. Product Introduction

1.1 Introducing S-PATCH3

This product is intended to measure, transfer and record electrocardiogram signal. The viewer on mobile device may display ECG wave form, Heart Rate, Respiration Rate, Heart Rate Variability and other information. The product consists of S-PATCH3 body signal sensing module, ECG electrodes and mobile app viewer to monitor the signals.

- Product Type– Ambulatory electrocardiographic systems
- Name– S-PATCH3 Wearable Health Monitoring System
- Serial Number– SP3-1612-0041
- Manufacturer–SAMSUNG ELECTRONICS Co., Ltd.
1-1, Samsungjeonja-ro, Hwaseong-si, Gyeonggi-do, 18448 Korea

1.2 Indication for Use

The S-PATCH3 Wearable Health Monitoring System is intended to record, transfer and store single channel electrocardiogram signals. The S-PATCH3 signal sensing module transmits data through wireless communication to mobile device. The product is not intended for pediatric use.

The S-PATCH3 wearable health monitoring system monitors and displays:

- Heart Rate
- ECG signal
- Heart Rate Variability
- Respiration Rate

2. Cautions

2.1 General

- 1) DO NOT store in extremely hot, cold, humid, or wet conditions.
- 2) Since this product is a medical device, instructions are required to properly dispose of it. Contact the deputy or manufacturer for such instructions. Improper disposing of this device can lead to legal consequences.
- 3) Contact the manufacturer if the product functions abnormally, problematically, or not at all. Any attempt to repair without the manufacturer's guide is not recommended.
- 4) Reuse of the electrodes is prohibited in any circumstances due to the infection.
- 5) Use of electrodes sticker may cause a skin irritation or reaction.
- 6) DO NOT expose to strong electromagnetic fields.
- 7) Too much body hair may cause an unsuccessful recording.
- 8) DO NOT use to diagnose heart related conditions.
- 9) No warranty for any data or information that is collected erroneously by the device, or misuse or malfunction as a result of abuse, accidents, alteration, misuse, neglect, or failure to maintain the products as instructed.

2.2 Safety

- 1) Before treatment, the doctor must explain cautions to the patient.
- 2) Operate the product in the correct order as described in this manual.
- 3) Use this device under doctor's prescription.
- 4) Beware of the polarity of the Coin battery when exchange and insert the battery.
- 5) DO NOT use during magnetic resonance imaging (MRI) or external defibrillation procedures.

- 6) DO NOT drop or bump with excessive force.
- 7) DO keep components out of reach of children.
- 8) DO NOT swallow the device or wind the cable around the neck.

2.3 Contra-Indication

- 1) Patients with artificial cardiac pacemaker, cardioverter defibrillator, or other implantable electric devices.
- 2) Pregnant or breast-feeding mothers
- 3) A current sign or medical history of skin cancer, rash, skin disorder, keloid, and/or any injury.

2.4 Usage and Storage Conditions

2.4.1 Conditions for Usage

- 1) Temperature: 0°C-45°C (32°F to 113°F)
- 2) Relative humidity: 10%-95% (non-condensing)
- 3) Atmospheric pressure: 700hPa-1060hPa

2.4.2 Conditions for Storage

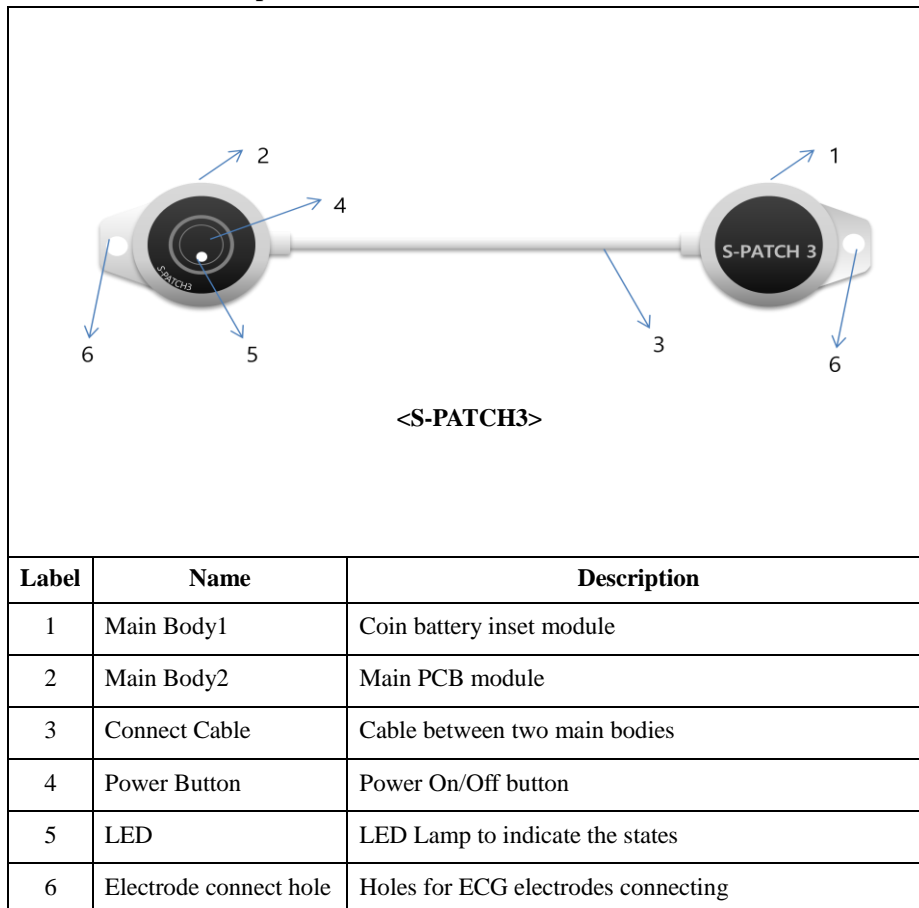
- 1) Temperature: -20°C-70°C (-4°F to 158°F)
- 2) Relative humidity: 10%-95% (non-condensing)
- 3) Atmospheric pressure: 400hPa-1500hPa
- 4) Keep the device in the case when it doesn't use.

2.4.3 Cleaning Condition

- 1) Clean the device with soft, dry cloth
- 2) Equipment failure may occur due to dust and debris during long-term use of the equipment.

3. Components and Installation of S-PATCH3

3.1 Main Device Components



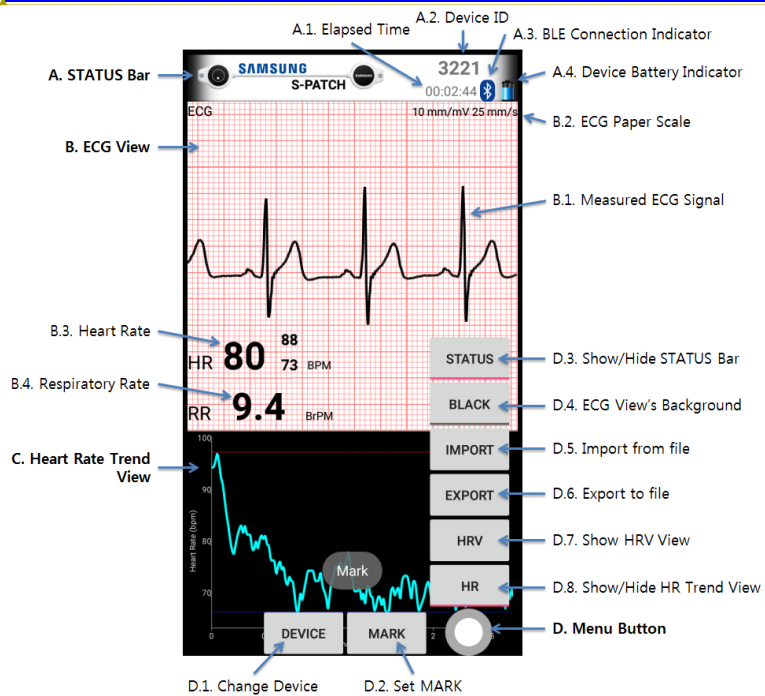
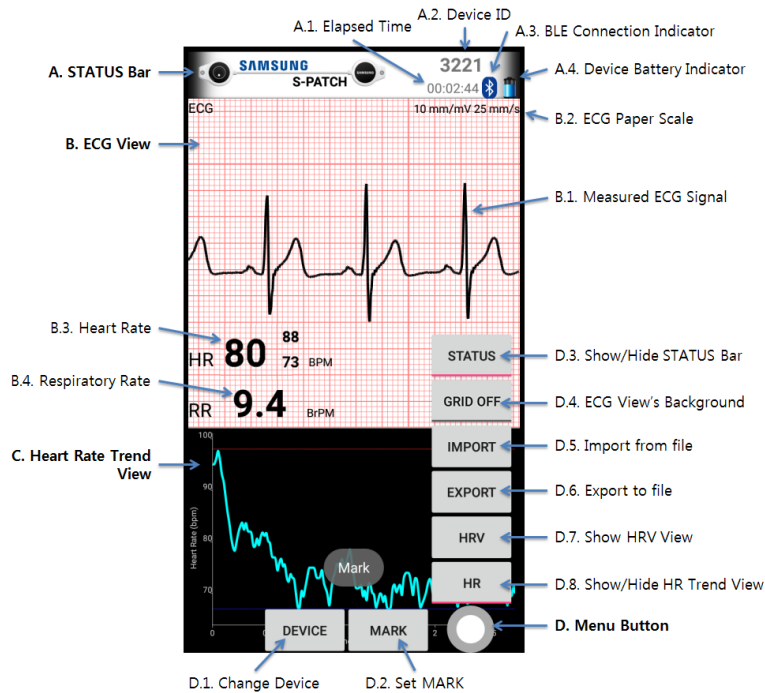
3.2 Accessory Components

<div><p><Electrode></p><p><Battery></p></div>		
Label	Name	Description
1	Electrode	Multi-purpose monitoring electrodes with sticky gel feature (high performance adhesive and foam backing) Note: Use the FDA registered Electrode.
2	Battery	Power supply for S-PATCH3. DC 3V Coin Battery.

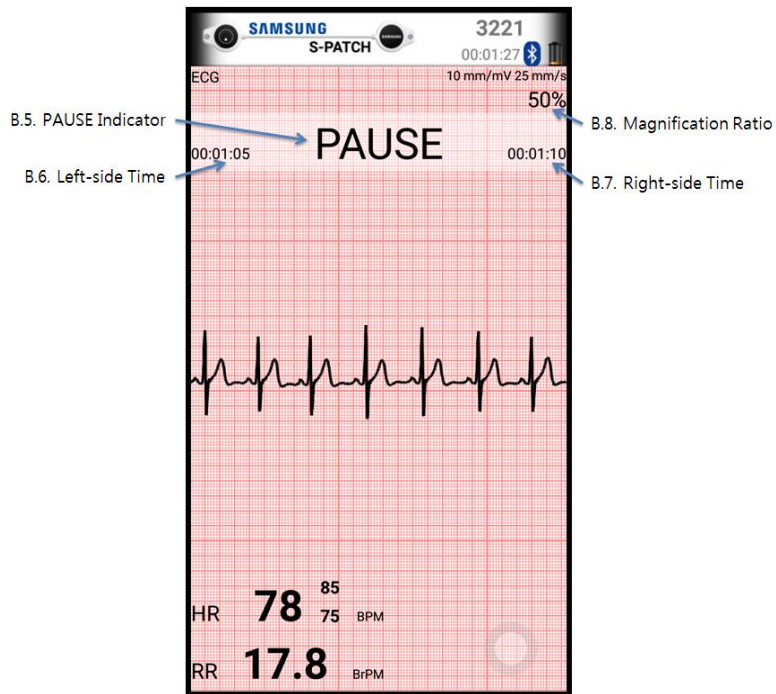
The Applied Parts are main device and electrode

3.3 Display viewer

1) Main Display of S-PATCH3 App

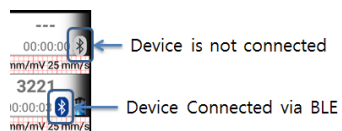


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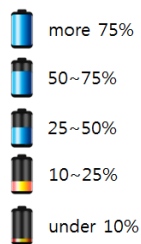


A. STATUS Bar

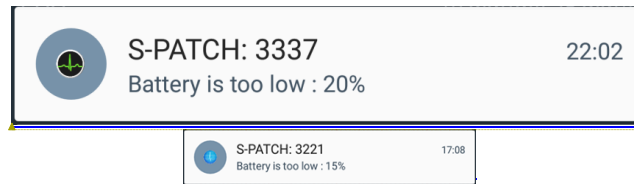
- A.1. Elapsed Time: The elapsed time from the first signal receiving time
- A.2. Device ID: Connected S-PATCH Device's ID
- A.3. BLE Connection Indicator: Bluetooth Low Energy Connection State



- A.4. Device Battery Indicator: Remained battery state of the connected device

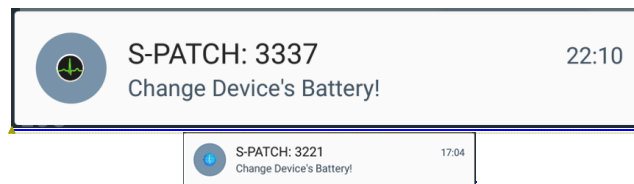


In the case of the ratio is lower than 25%, "Battery is too low" Notification will appear.



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In the case of the ratio is lower than 10%, “Change Device’s Battery!” Notification will appear.

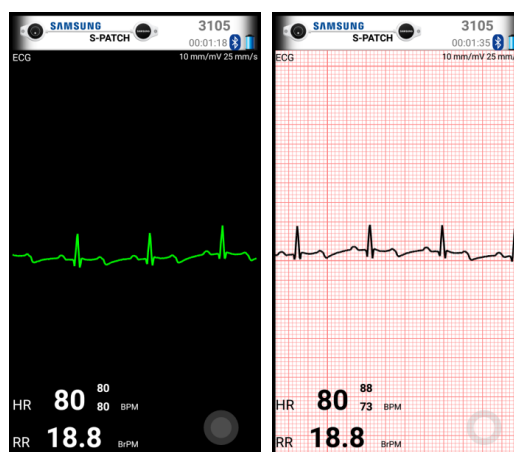


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- B. ECG View
 - Double Tapping on ECG View will toggle MONITORING and PAUSE mode.
 - In PAUSE mode, it's enabled that Scrolling by swipe gesture on ECG Graph. Scaling (magnification ratio changing 50 ~ 150%, by 10%) by zooming gestures is able for both modes.
 - B.1. Measured ECG Signal: Measured ECG signals
 - B.2. ECG Paper Scale: Scale of ECG Paper. It's same as actual size in case of the magnification ratio is 100%
 - B.3. Heart Rate: Current Measured Heart Rate and Maximum/Minimum HR
 - B.4. Respiratory Rate: Measured Respiratory Rate. The unit of the respiratory rate is BrPM (Breath per minute). Actual range of the respiratory rate is from 9 BrPM to 30 BrPM. The resolution is 0.96 BrPM.
 - ** During measure the Respiratory Rate, minimize move.
 - B.5. PAUSE Indicator: PAUSE mode indicator. Even in PAUSE mode, received signal will be stored.
 - B.6. Left-side Time: The elapsed time of the left-side signal
 - B.7. Right-side Time: The elapsed time of the right-side signal
 - B.8. Magnification Ratio: The magnification ratio of the ECG signal and ECG Paper. It's invisible in case of the ratio is 100%
- C. Heart Rate Trend View: Heart rate trend graph for 1 Hour.
- D. Menu Button: It's translucent. Touching the button makes it opaque and show menu buttons. Nothing selected until 3 seconds then it backs to translucent and menu buttons will be disappeared.
 - D.1. Change Device: Device Select View will appear
 - D.2. Set MARK: add User event mark
 - D.3. Show/Hide STATUS Bar: show/hide STATUS Bar



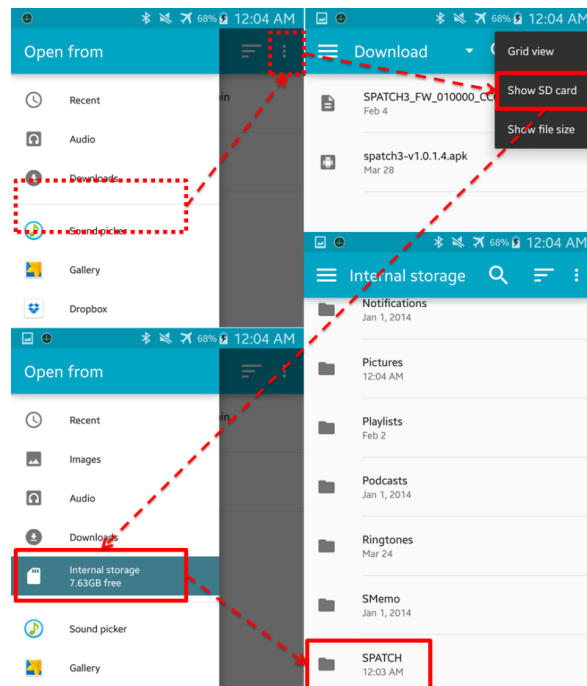
D.4. ECG View's Background:
 BLACK: black background, green signal
 PAPER: ECG Paper background, black signal



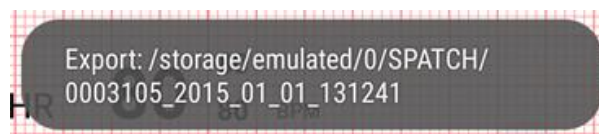
D.5. Import from file: read signal data from stored file. S-PATCH format(*.sp) and MIT BIH format(.hea/.dat, 16 format - only for exported by this app) can be loaded.

0003105 2015-01-01 134143.sp	13:41
0003105 2015-01-01 134422.sp	13:44
0003105_2015_01_01_131241.dat	13:14
0003105_2015_01_01_131241.hea	13:14

If there is no folder stored signal files, check your system options like below. In case of Android OS, Internal Storage would be hidden.



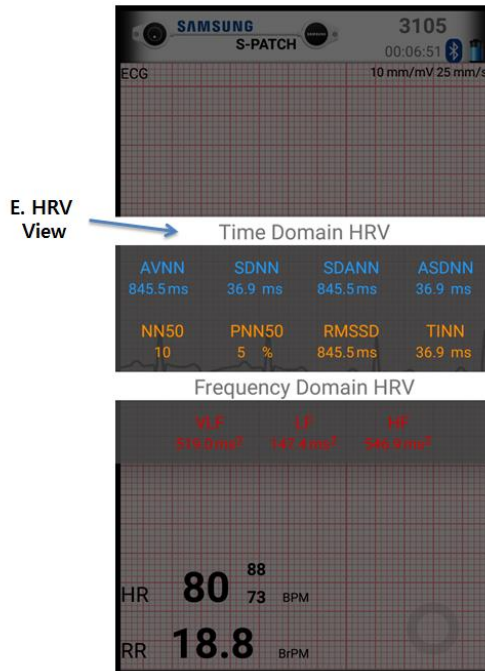
D.6. Export to file: Received Signal data automatically stored to device's storage as formatted .sp (S-PATCH format). This button makes MIT BIH format file. The file name is automatically generated by based on the Device Number and the first connection time.



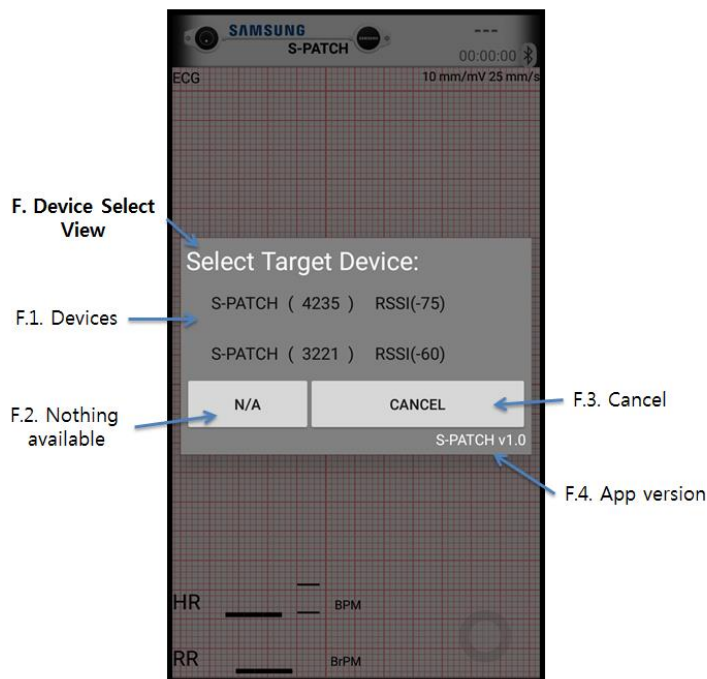
D.7. Show HRV View: shows HRV information view

D.8. Show/Hide HR Trend View: show/hide HR Trend View

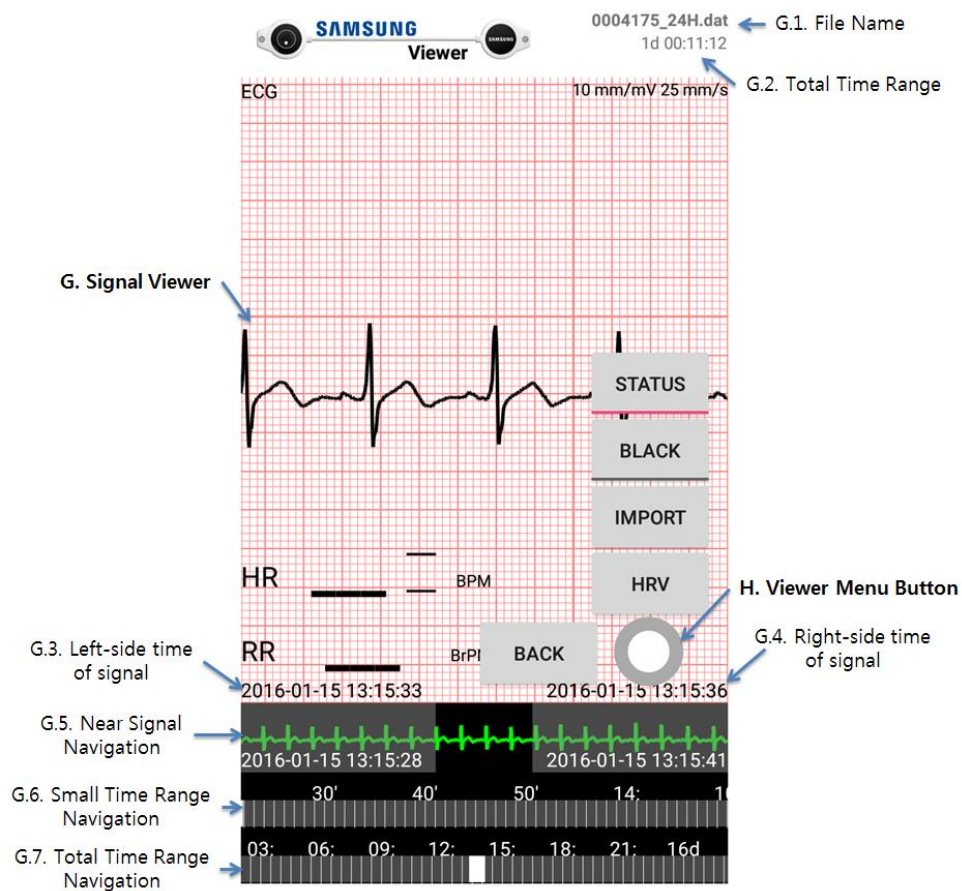
HR Trend View shows HR trend and minimum/maximum HR for 1 Hour.



- E. HRV View: shows HRV information
 - E.1. Time Domain HRV
 - E.1.1. AVNN: mean of all the intervals in ms
 - E.1.2. SDNN: standard deviation all RRIs over the complete test duration in ms
 - E.1.3. SDANN: standard deviation of the 5 min means in ms
 - E.1.4. ASDNN: mean of the 5 min standard deviation in ms
 - E.1.5. NN50: the number of RRI difference of successive RRIs greater than 50ms
 - E.1.6. PNN50: NN50 as a percentage of all allowed RRIs
 - E.1.7. RMSSD: root mean square of successive differences in ms
 - E.1.8. TINN: triangular index interval is the baseline width of the distribution measured as a base of a triangle approximating the RRI distribution
 - E.2. Frequency Domain HRV
 - E.2.1. VLF: very low frequency power (0.00333 Hz to 0.040 Hz)
 - E.2.2. LF: low frequency power (0.040 Hz to 0.150 Hz)
 - E.2.3. HF: high frequency power (0.150 Hz to 0.400 Hz)
- ** During measure the HRV, minimize move.

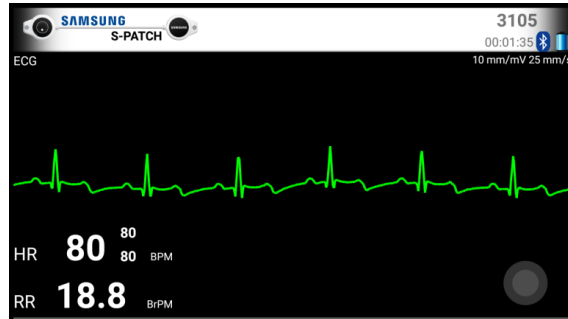


- F. Device Select View: scanning S-PATCH devices nearby and show IDs.
- F.1. Devices: Scanned S-PATCH devices are shown. One of them is selected then connection will be tried. The number in bracket after S-PATCH name is the Device ID. RSSI is Received signal strength indication in a wireless environment, in arbitrary units. It could be used to calculate distance of the S-PATCH and the host device.
- F.2. Nothing available: This will disconnect connected device and stay without any connection
- F.3. Cancel: This will back without any changes
- F.4. App version: This shows App's version



- G. Signal Viewer
- G.1. File Name: Loaded File Name
 - G.2. Total Time Range: Stored total signal's range
 - G.3. Left-side time of signal: Signal Viewer's left side time
 - G.4. Right-side time of signal: Signal Viewer's right side time
 - G.5. Near Signal Navigation: This shows signals of larger range than Signal Viewer. Swipe gesture will scroll the time range.
 - G.6. Small Time Range Navigation: This supports specific time selection in small time range by touch. If total time range is too small, this will disappear.
 - G.7. Total Time Range Navigation: This supports the selection of the Small Time Range Navigation's range on the total time range.
- H. Viewer Menu Button
- "BACK" button supports return of previous window as like as Android Device's Cancel button.
- Other buttons are same as S-PATCH real-time signal display state.

The app shows as Landscape orientation as following as device's orientation.



3.4 How to Install S-PATCH3

3.4.1 Installing S-PATCH

- 1) Download the S-PATCH App from Google Play Store (Android KitKat or later). The device must support Bluetooth Low Energy.
- 2) Install the downloaded file on user's mobile device.
- 3) Insert battery to main body 1 of S-PATCH3.



Insert a coin battery (CR2032, 3V) as shown.

- 4) Connect Electrodes to electrode connect hole in each side of S-PATCH3.



3.5 Precautions

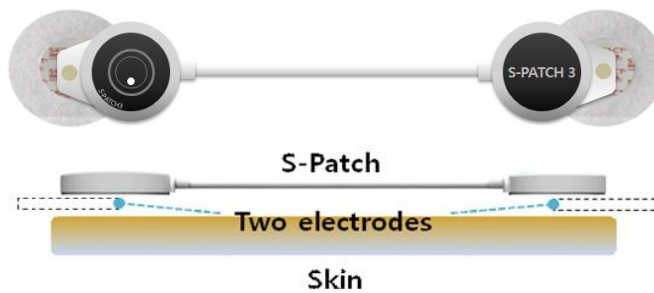
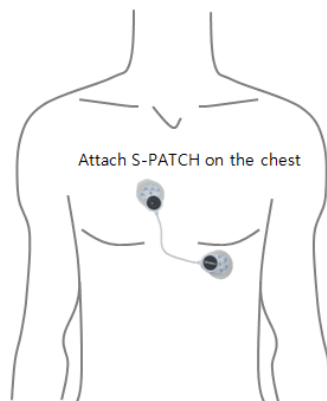
- 1) The electrodes and coin battery are disposable. Please observe local laws for disposal of electrodes and coin battery.
- 2) Please ensure user's hands are clean and dry when handle the S-PATCH3
- 3) The body hair possibly causes contact problem which results a fault detection of physiological data.
- 4) After using the device, wipe dust and other foreign substances using a dry cloth.
- 5) This product must not be disposed of with your other household waste. Instead, it is your responsibility to dispose of your waste equipment by handing it over to a designated collection point for the recycling of waste electrical and electronic

equipment. The separate collection and recycling of your waste equipment at the time of disposal will help to conserve natural resources and ensure that it is recycled in a manner that protects human health and the environment. For more information about where you can drop off your waste equipment for recycling, please contact your local city office, your household waste disposal service or the shop where you purchased the product.

4. Using and Operating S-PATCH3

4.1 How to Use S-PATCH3

- 1) After connect the electrodes with S-PATCH3, peel the plastic on the backside of the electrodes.
- 2) Attach the S-PATCH3 on recommended position as drawn.



- 3) Push the power button longer than 3 seconds.

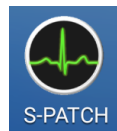


- 4) Confirm that the LED is ON and OFF 3 times.

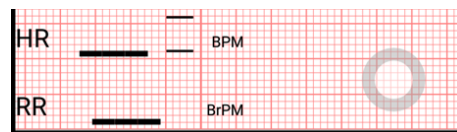


5) Put the Bluetooth mode to “ON” mode of user’s mobile device.

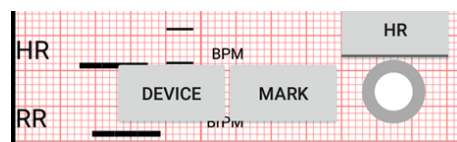
6) Please execute S-PATCH App.



7) Please touch the Menu Button located right bottom side like as below.



8) Menu Buttons will appear then touch “DEVICE” button



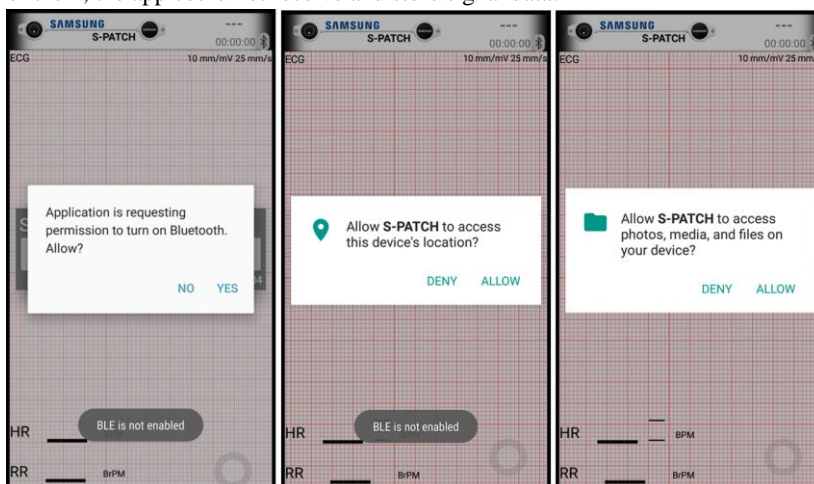
Buttons will disappear if there is no selection for 3 seconds.

9) Connectable S-PATCH Devices will be added to the list.

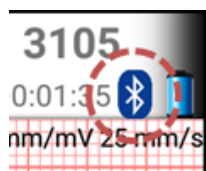


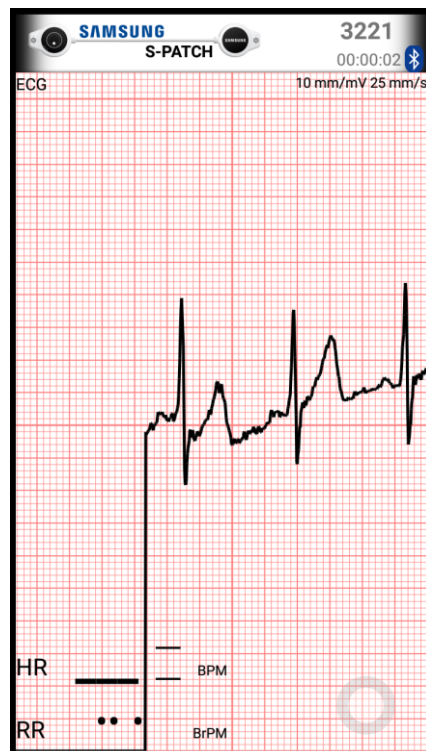
If the app has not yet proper permission to access the host device's BLE, permission requesting messages will be shown like below.

S-PATCH app uses BLE and storage of the host device. And BLE needs Location Permission, so, BLE, Location and Storage permissions are requested. If it's denied one of them, the app could not receive and store signal data.

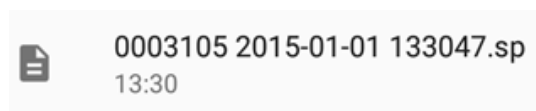


- 10) Select the device to be connected.
- 11) After pairing S-PATCH device, top-right side's connection indicator will be updated, and ECG Signals will be shown as following as BLE transmission.



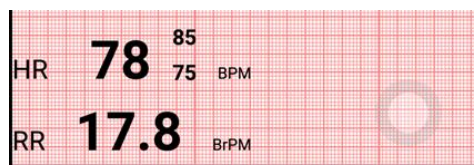


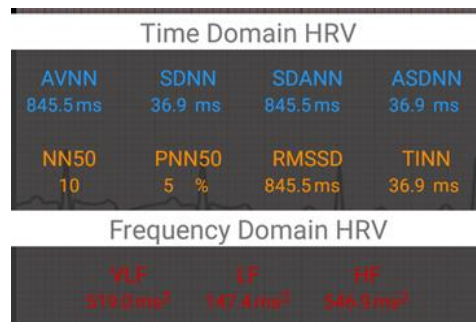
Received signal data is automatically stored to the host device's storage as file under /SPATCH folder. The file and folder name is generated by S-PATCH device number and connection time.



Above example means S-PATCH (3105) device's signals are received since 2015 year January 1st day PM 1:30:47. Same name's folder has detail data.

Algorithm Result (Heart rate, Respiratory Rate and Heart rate variability) will be updated after valid signals are received for required time range for each algorithm.

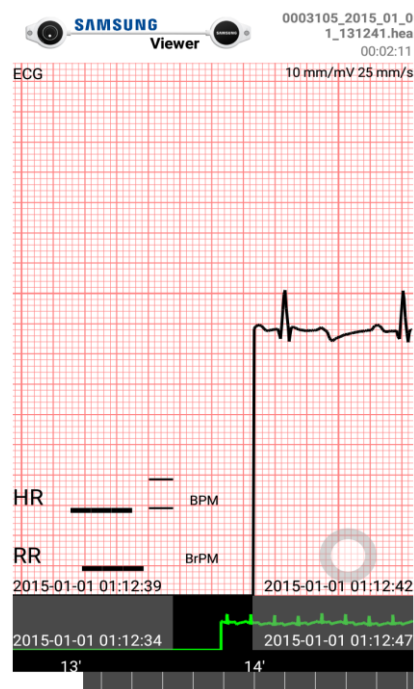




- 12) Select “N/A” to finish recording on Device Selection



- 13) To load a stored signal, select “IMPORT” button through Menu-Button and choose the file. Then it will be loaded like below.

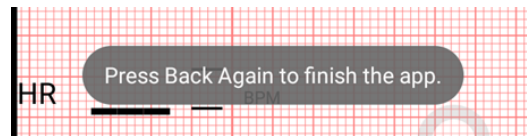


Bottom navigation and swiping on signal graphs are able to move on the showing time. And HR, RR and HRV values are updated as following as the time.

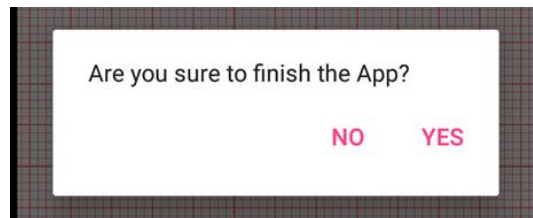
If the S-PATCH device is connected, received signal will be stored in background.

“BACK” button of Menu Buttons will back.

- 14) To finish S-PATCH app, push “BACK” button of Android device.
To prevent unintended finish, below message is shown.



If “BACK” button is pressed again during 1 second, one more confirmation is required.



“YES” will terminate the app. “NO” will not.

In case of using iOS, just push “HOME” button.

4.2 Specifications

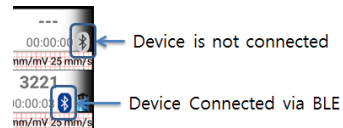
4.2.1 S-PATCH3 Specifications

Classification	Name	Description
Performance	Type	CF-Type
	Channel	Single channel
Circuitry	Communication with Mobile device	Bluetooth
	DC Offset Tolerance	+/- 300mV
	ADC Resolution	12 bits
	ADC Sampling Rate	1000 Samples/Second
	Input Impedance	>100 MΩ
Power Requirements	Power Supply	DC 3V , Coin Battery (CR2032)
	Battery Life	>48 Hr.
Software	F/W version	V1.00
	CPU	S1SBP6A (Cortex-M4F microprocessor)
	BLE	Dialog DA14583(ARM Cortex-M0)
	App(Android)	Kitkat(API19) or later
Physical Characteristics	Weight (Exc. Battery)	6g
	Dimension(Main Body1,2)	38*27*5 (mm), 38*27*3 (mm)[W*D*H]
	Dimension(Connect Cable)	110 ± 5 (mm)

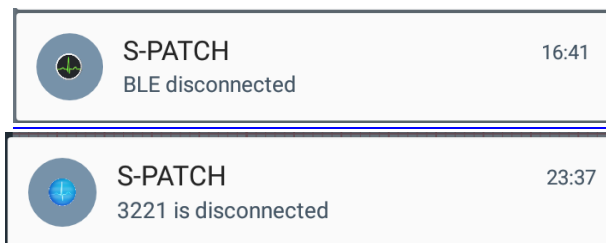
4.3 Error Message and Alarm

4.3.1 Device Disconnection

If the BLE is disconnected on receiving signal, BLE connection indicator is updated.



And notification will appear with alarm or vibration as user's setting.
(Mute setting would not make any alarm sound and vibration)

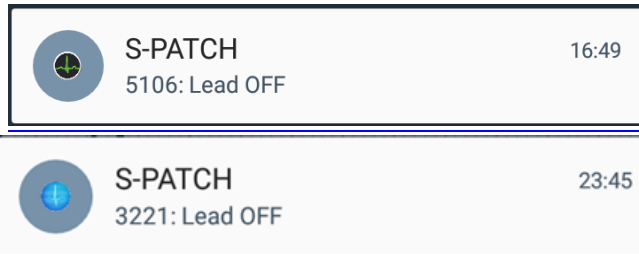


4.3.2 Abnormal signal detect

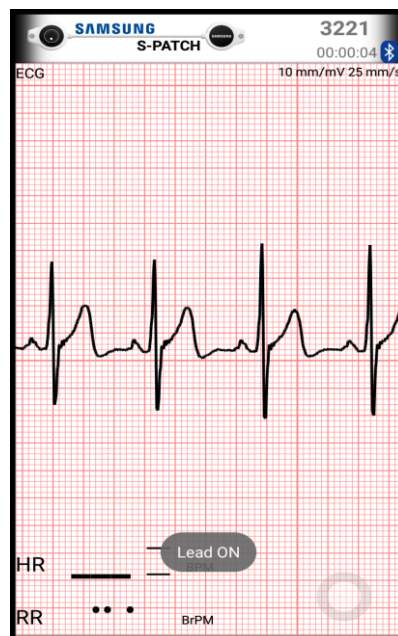
In case of algorithm detects invalid signal, assume LEAD OFF state and show below.



And alarm like below. All algorithms are not available.

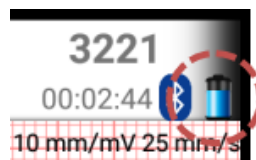


After valid signal is detected, it's changed to LEAD ON state and algorithms are restarted.

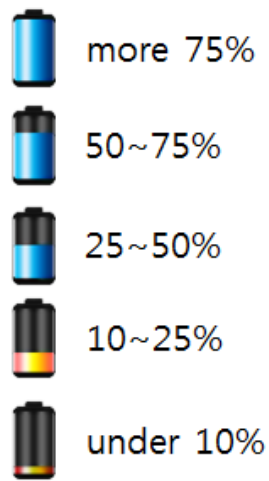


4.3.3 Low Battery mode

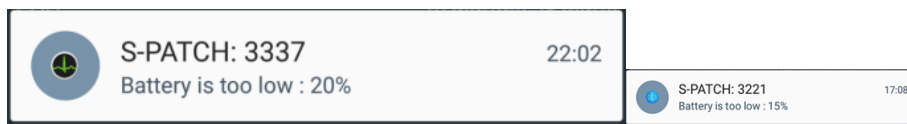
Battery state is updated on top-right of the STATUS bar.



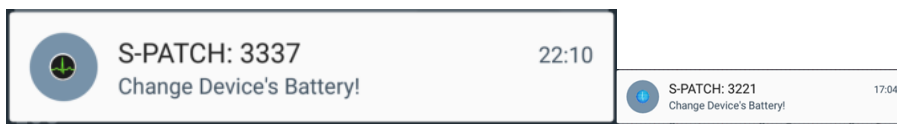
Battery Icon's meaning is like below.



In the case of the ratio is lower than 25%, "Battery is too low" Notification will appear.

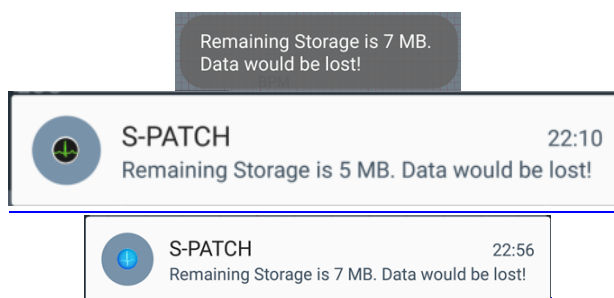


In the case of the ratio is lower than 10%, "Change Device's Battery!" Notification will appear.



4.3.4 Low Remaining Storage

If the remaining storage is under 10MB, caution will appear.



Then make some more remaining storage. If not, signal would be lost.

4.4 Maintenance

For cleaning, gently wipe with a soft dry cloth after using the S-PATCH 3. Please attempt to keep S-PATCH3 dust free. S-PATCH is waterproof. But it should be kept dry. This device does not have serviceable components.









Do not disassemble, crush, puncture, short external contacts or circuits, dispose of in fire or water.

|

5. Labels and Packaging

5.1 Labels










5.1.1 Label for Packaging

DEVICE NAME	Wearable Health Monitoring System		
MODEL NAME	S-PATCH3		
SUPPLY VOLTAGE	3. Vd.c. (Lithium coin battery)	FCC ID	A3LSPATCH3
Dimension (Main Body1, 2)	38 * 27 * 5 (mm), 38 * 27 * 3 (mm) [W * D * H]		
Dimension (Connect Cable)	110 ± 5 (mm)	IP Grade	IP22
 Serial Number		 Date of manufacture	
<div>  CAUTION - Electric shock " To avoid electrical shock, do not disassemble the device " </div> <div>  Please read the user's manual carefully before use </div> <div>   Only CF Type </div>			
 Manufacturer : Samsung Electronics Co., Ltd. 1-1, Samsungjeonja-ro, Hwaseong-si, Gyeonggi-do, 18448 Korea Tel) +82-31-8037-3533 E-mail) s.patch@samsung.com			 WEEE MADE IN KOREA

5.1.2 Label for module



- Descriptions on the visual symbols of the label

Label	Symbol	Description
1		The serial number that identifies the object.
2		Date of manufacture
3		Manufacturer
4		Caution / Warning
5		Instruction for User Manual
6		Type of applied part
7		Prescription only
8		WEEE Mark
9		Temperature limitation

5.2 Packaging

5.2.1 Package List

Classifications	Components	Quantity
Main Box	S-PATCH3 module	1
	Electrodes	4
	Battery	1
	Manual	1

5.2.2 Package Units

- 1) S-PATCH3 module
Main module.
- 2) Electrodes
4 Electrodes are in the 1 plastic bag.
- 3) Battery
1 Coin Cell battery is shipped at package.
- 4) Manual

6. Information on EMC

6.1 Guidance and Manufacturer's Declaration – Electromagnetic Emissions

- The EUT is intended for use in the electromagnetic environment specified below. The customer or the user of the EUT should assure that it is used in such an environment.

Immunity test	Compliance	Electromagnetic environment - Guidance
RF Emissions CISPR 11	Group 1	The EUT uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF Emissions CISPR 11	Class B	The EUT is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / Flicker emissions IEC 61000-3-3	Complies	

6.2 Guidance and Manufacturer's Declaration – Electromagnetic Immunity

- The EUT is intended for use in the electromagnetic environment specified below. The customer or the user of the EUT should assure that it is used in such an environment.


Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV Contact ±8kV air	±6kV Contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ± 1kV for input/output lines	±2kV for power supply lines ± 1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U _T (>95% dip in U _T) for 0.5cycle 40% U _T (60% dip in U _T) for 5 cycle 70% U _T (30% dip in U _T) for 25 cycle <5% U _T (<95% dip in U _T) for 5 s	<5% U _T (>95% dip in U _T) for 0.5cycle 40% U _T (60% dip in U _T) for 5 cycle 70% U _T (30% dip in U _T) for 25 cycle <5% U _T (<95% dip in U _T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the EUT image intensifier requires continued operation during power mains interruptions, it is recommended that the EUT image intensifier be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U _T is the A.C. Mains voltage prior to application of the test level.			

6.3 Guidance and Manufacturer's Declaration – Electromagnetic Immunity

- The EUT is intended for use in the electromagnetic environment specified below. The customer or the user of the EUT should assure that it is used in such an environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80MHz	3 Vrms 150 kHz to 80MHz	Portable and mobile RF communications equipment should be used no closer to any part of the EUT, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5GHz	3 V/m 80MHz to 2.5GHz	$d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3.5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$

			<p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b Interference may occur in the vicinity of equipment marked with the following symbol :</p> 
<p>NOTE 1) At 80MHz and 800MHz, the higher frequency range applies.</p> <p>NOTE 2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the EUT is used exceeds the applicable RF compliance level above, the EUT should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the EUT.</p> <p>^b Over the frequency range 150kHz to 80MHz, field strengths should be less than $[V_1]$ V/m.</p>			

6.4 Recommended separation distances between portable and mobile RF communications equipment and the EUT

- There is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the EUT can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the EUT as recommended below, according to the maximum output power of the communications equipment.


Rated maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m]		
	150kHz to 80MHz $d = [\frac{3.5}{V_1}] \sqrt{P}$	80MHz to 800MHz $d = [\frac{3.5}{E_1}] \sqrt{P}$	800MHz to 2.5GHz $d = [\frac{7}{E_1}] \sqrt{P}$
	$V_1=3V_{rms}$	$E_1=3V/m$	$E_1=3V/m$
0.01	0.116	0.1166	0.2333
0.1	0.368	0.3687	0.7378
1	1.166	1.1660	2.3333
10	3.687	3.6872	7.3785
100	11.660	11.6600	23.333
<p>For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.</p> <p>NOTE 1) At 80MHz and 800MHz, the separation distance for the higher frequency range applies.</p> <p>NOTE 2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

6.5 Immunity and Compliance Level

Immunity test	IEC 60601 Test Level	Actual Immunity Level	Compliance Level
Conducted RF IEC 61000-4-6	3Vrms 150kHz to 80MHz	3Vrms	3Vrms
Radiated RF IEC 61000-4-3	3Vrms 80MHz to 2.5GHz	3V/m	3V/m

6.6 Guidance and Manufacturer's Declaration – Electromagnetic Immunity

- The EUT is intended for use in the electromagnetic environment specified below. The customer or the user of the EUT should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80MHz	3 Vrms 150 kHz to 80MHz	The EUT must be used only in a shielded location with a minimum RF shielding effectiveness and, for each cable that enters the shielded location with a minimum RF shielding effectiveness and, for each cable that enters the shielded location
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5GHz	3 V/m 80MHz to 2.5GHz	Field strengths outside the shielded location from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than 3V/m. ^a Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
NOTE 2) It is essential that the actual shielding effectiveness and filter attenuation of the shielded location be verified to assure that they meet the minimum specification.			
^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength outside the shielded location in which the EUT is used exceeds 3V/m, the EUT should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as relocating the EUT or using a shielded location with a higher RF shielding effectiveness and filter attenuation.			

7. FCC Compliance Statement

This device complies with part 15 of the FCC rules. Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference, and
- (2) This device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment on and off, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antennae
- Increase the separation between the equipment and the receiver
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

FCC RF Exposure Statement

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. End users must follow the specific operating instructions for satisfying RF exposure compliance. The antenna used for this transmitter must not transmit simultaneously with any other antenna or transmitter, except in accordance with FCC multi-transmitter product procedures.

FCC Caution

Any changes or modifications to the equipment not expressly approved by the party responsible for compliance could void user's authority to operate the equipment.

8. Product Life time and Warranty

8.1 Product Life time

- S-PATCH3 is guaranteed to last for a minimum of two years.

8.2 Product Warranty

- The warranty covers a year.
However, the conditions excluded by the warranty are as follows.
 - Natural aging of the product from daily usage

- Product damage due to improper storage
- Product damage due to improper usage

9. Company Introduction

9.1 Company Name and Address

Company name: Samsung Electronics Co., Ltd.

Address: 1-1, Samsungjeonja-ro, Hwaseong-si, Gyeonggi-do, 18448 Korea

Tel : +(82) 31-8037-3533

e-mail: s.patch@samsung.com