

USER MANUAL

Wearable Health Recording System

(MODEL: S-PATCH)

Caution: Federal law restricts this device to sale by or on the order of a physician.

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Samsung Electronics Co., Ltd.

1-1, Samsungjeonja-ro, Hwaseong-si, Gyeonggi-do, South Korea

Revision History

Revision Number	Issue Date	Contents of Revision
Rev.0.0	2020.01.20	Established by Manufacturer's User Manual Policy
Rev.0.1	2020.01.28	Section 5.6, Updated specification of external device connection
Rev.0.2	2020.02.07	Section 4.2, Deleted applied part description Section 5.3, Updated BLE specification
Rev.0.3	2020.02.14	Section 8, Added FCC SDoC information

Table of Contents

1.	Product Introduction	5
1.1.	Introduction.....	5
1.2.	Indications for Use & Intended Use.....	5
1.3.	Contraindication.....	5
2.	Cautions	6
2.1.	General	6
2.2.	Safety	6
2.3.	Usage and Storage Conditions.....	7
2.3.1.	Conditions for Usage	7
2.3.2.	Conditions for Storage.....	7
2.3.3.	Cleaning Condition.....	7
3.	Warning.....	7
4.	Components and Installation of S-PATCH	7
4.1.	Main Device Components.....	7
4.1.1.	Sensor device	7
4.1.2.	Cradle	8
4.1.3.	PC software	9
4.1.4.	Mobile app	10
4.2.	Accessory Components.....	10
4.3.	How to Start S-PATCH.....	11
4.3.1.	Required Environment.....	11
4.3.2.	System Initialization.....	11
4.3.3.	Sensor device Setup.....	14
4.4.	Precautions	15
5.	Using and Operating S-PATCH	15
5.1.	How to Use S-PATCH	15
5.1.1.	Attachment to the patient body and Power On.....	15
5.1.2.	Connection to the Mobile app.....	16
5.1.3.	Completion of recording	19
5.1.	Daily Usage.....	19
5.2.	Data download and management.....	19
5.2.1.	ECG Data Download and Display	19
5.2.2.	ECG Data Import and Export.....	20
5.3.	Specifications.....	21
5.4.	Error Message.....	22
5.4.1.	Device Disconnection.....	22
5.4.2.	Abnormal Signal Detect	22
5.4.3.	Low Battery Mode	22
5.4.4.	Low Remaining Recording Time.....	22
5.5.	Maintenance	23
5.6.	Specification of External Device connection.....	23
5.7.	Heart Rate Algorithm.....	24
6.	Labels and Packaging.....	25
6.1.	Labels.....	25
6.1.1.	Label for Packaging.....	25
6.1.2.	Label for the Sensor device.....	25
6.1.3.	Label for the Cradle.....	25
6.1.4.	Descriptions of the visual symbols of the label.....	26
6.2.	Packaging.....	26
7.	Electromagnetic Environment	27
7.1.	Guidance and Manufacturer's Declaration – Electromagnetic Emissions.....	27

7.2.	Guidance and Manufacturer's Declaration – Electromagnetic Immunity	27
7.3.	Guidance and Manufacturer's Declaration – Electromagnetic Immunity	28
7.4.	Recommended separation distances between portable and mobile RF communications equipment and the S-PATCH.....	29
7.5.	Immunity and Compliance Level	29
8.	FCC Compliance Statement	30
9.	Expected Service Life time and Warranty	31
9.1.	Expected Service Life Time.....	31
9.2.	Product Warranty	31
10.	Company Name and Address.....	31

1. Product Introduction

1.1. Introduction

The S-PATCH Wearable health recording system is an electrocardiogram(ECG) recording system designed to record, transfer and display ECG data collected from devices worn on adult patient's body. The system consists of a Sensor device, a Cradle, PC software, a Mobile app and associated accessories (electrodes, coin battery, USB cable, installation USB flash drive). The Sensor device records the ECG signals continuously from the patients. The recorded data is then transferred to the physician's Windows PC via the Cradle for cardiac rhythm interpretation. The patients can monitor the Sensor device status via the Mobile app installed on their smartphone.

- Product Name - Wearable Health Recording System
- Model Name - S-PATCH
- Manufacturer - SAMSUNG ELECTRONICS Co., Ltd.
1-1, Samsungjeonja-ro, Hwaseong-si, Gyeonggi-do, 18448 Korea

1.2. Indications for Use & Intended Use

The S-PATCH Wearable health recording system is indicated for use on adult patients prescribed by physicians as an ECG data recorder for cardiac rhythm interpretation.

The S-PATCH Wearable health recording system is intended to record, transfer and display the single-channel electrocardiogram (ECG) data including heart rate and ECG signals. It allows physicians to analyze the cardiac rhythm. The system is not intended for pediatric use.

1.3. Contraindication

- 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. 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.
- 10) If there is a change in the performance of a medical device, contact the manufacturer for action.
- 11) the Keep the smart phone with you to check the Sensor device status.
If the S-PATCH has no remaining storage memory or the coin cell battery drains, the Sensor device will not continue to collect your data.

2.2. Safety

- 1) Before use, 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, and the battery certified to IEC 60086-4 or UL1642 should be used.
- 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.
- 9) Do NOT allow the cable to twist or bend.
- 10) Make sure that all electrodes are connected to the patient correctly before operation.
- 11) Conductive parts of electrodes and associated connectors for type CF applied parts, should not contact other conductive parts including earth;
- 12) Do not wear device over excessive body hair in the torso area. Excessive body hair should be removed several hours before use.
- 13) Do not use any lotions, oils, or powders on your chest area before or during use.
- 14) S-PATCH is intended to be used with FDA cleared silver/silver chloride (Ag/AgCl) ECG electrodes supplied to a patient by a physician or recording center. ECG electrodes not FDA cleared may cause a patient's skin to react with irritation or reddening.

2.3. Usage and Storage Conditions

2.3.1. Conditions for Usage

- 1) Temperature: 5 °C - 40 °C (41°F to 104°F)
- 2) Relative humidity: 10%-95% (non-condensing)
- 3) Atmospheric pressure: 700hPa-1060hPa

2.3.2. Conditions for Storage

- 1) Temperature: -25 °C - 70 °C (-13°F to 158°F)
- 2) Relative humidity: 10% to 95% (non-condensing)
- 3) Atmospheric pressure: 700hPa-1060hPa
- 4) Keep the device in the case when it doesn't use.

2.3.3. 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. Warning

MR-unsafe!

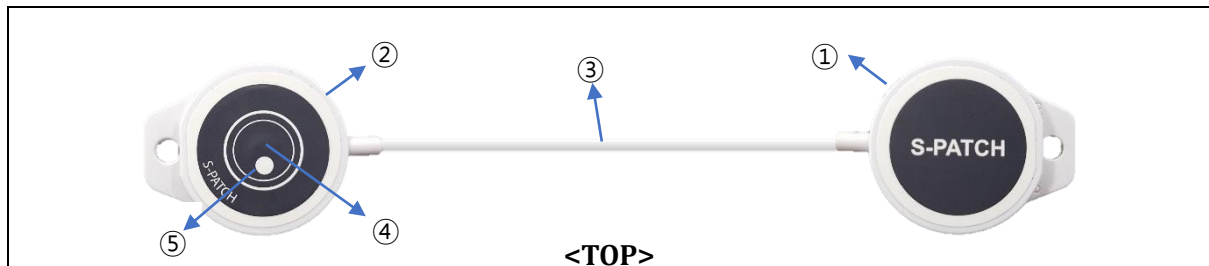
Do not expose the device to a magnetic resonance (MR) environment.

- 1) The device may present a risk of projectile injury due to the presence of ferromagnetic materials that can be attracted by the MR magnet core.
- 2) Thermal injury and burns may occur due to the metal components of the device that can heat during MR scanning.
- 3) The device may generate artifacts in the MR image.

4. Components and Installation of S-PATCH

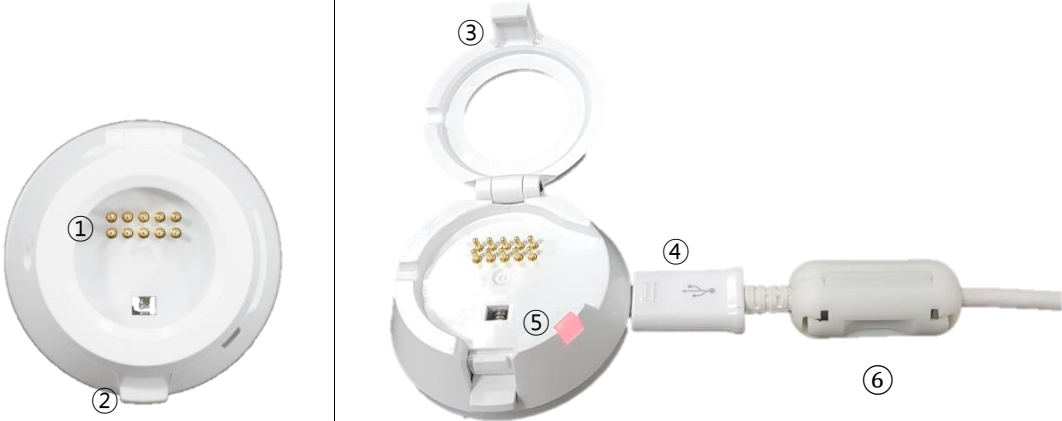
4.1. Main Device Components

4.1.1. Sensor device



 <BOTTOM>		
Label	Name	Description
①	Battery module	Coin battery inset module
②	Sensing module	ECG Sensing module
③	Connect Cable	Connection between Battery module and Body2
④	Power Button	Power On/Off button
⑤	LED	LED Lamp to indicate the device states
⑥	Electrode connect hole	Holes for ECG electrodes connecting
⑦	Product code	Product Serial Number & QR code
⑧	Cradle connection pins	10-pins for connecting to Cradle

4.1.2. Cradle

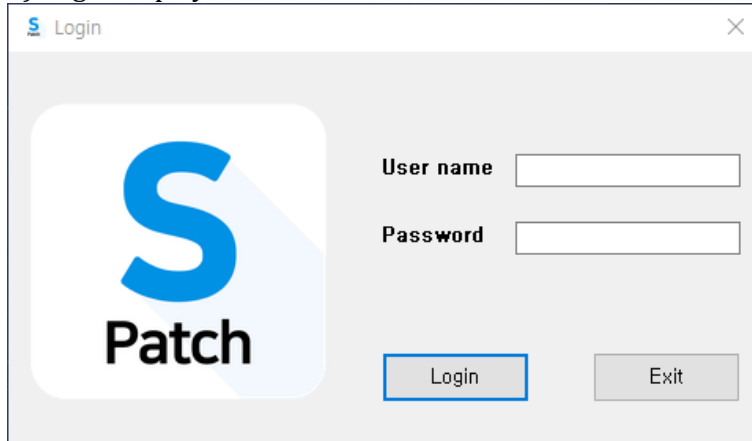
		
Label	Name	Description
①	Module connection pins	10 pogo pins for connecting to S-Patch module
②	Push button	Locking door open button
③	Locking door	Locking door to fasten S-Patch module to the Cradle
④	USB cable	Micro type B USB Cable
⑤	LED	LED Lamp to indicate the cradle state
⑥	Ferrite core	Electromagnetic Interference blocking material



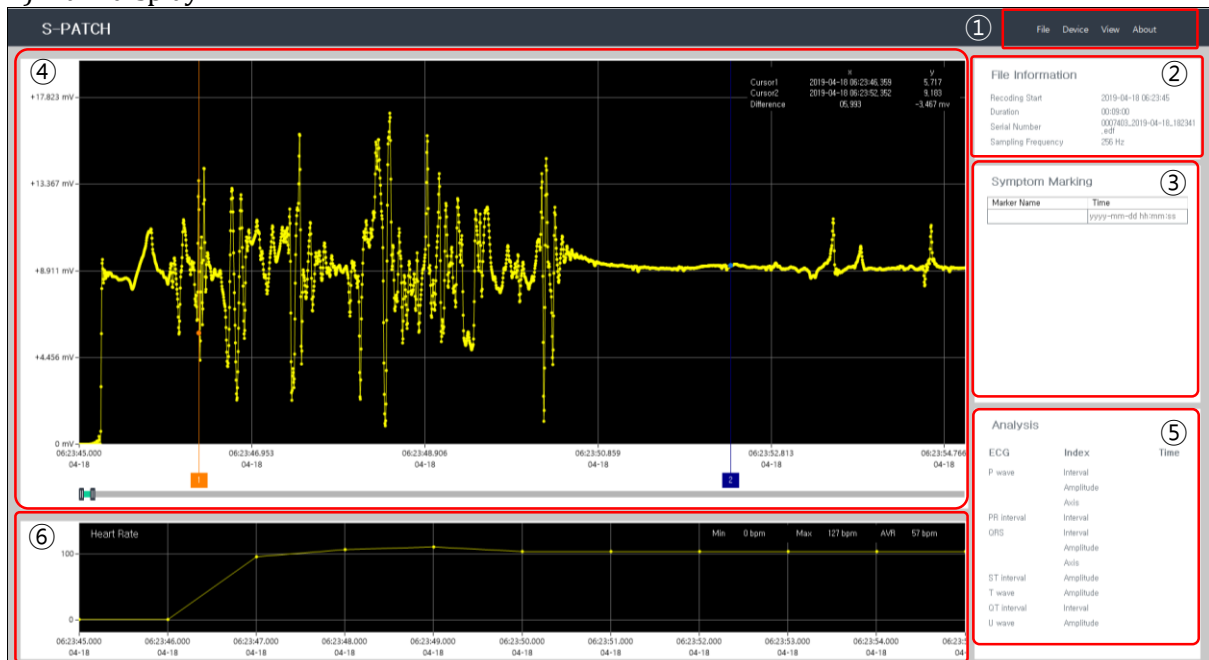
; Do not remove ⑥ Ferrite core from the USB cable. It may cause EMI(Electromagnetic Interference) problem

4.1.3. PC software

1) Login display



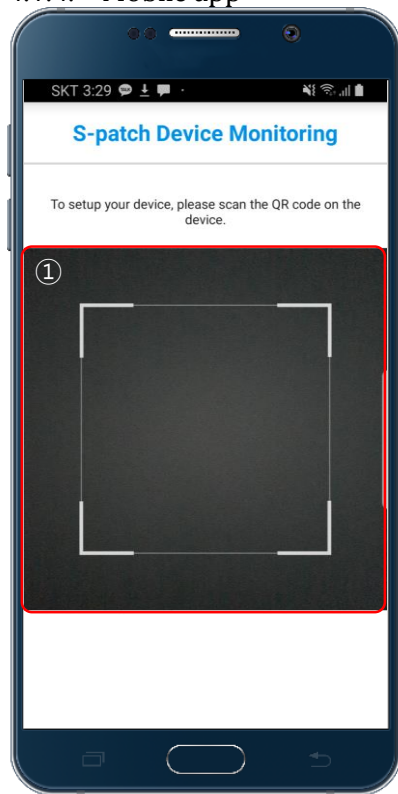
2) Main display



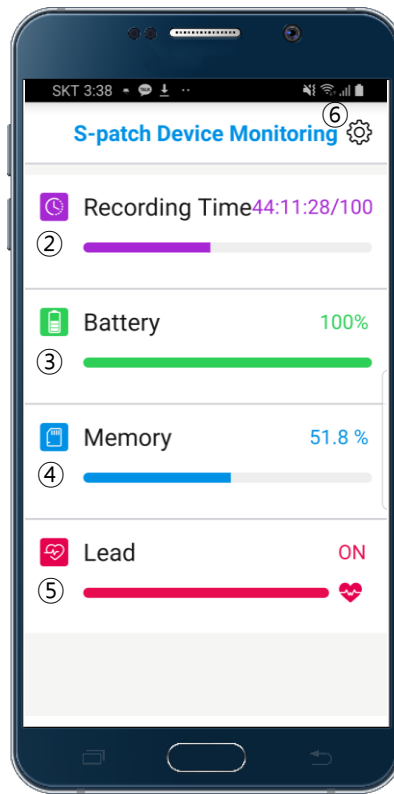
Label	Name	Description
①	Menu	File / Device / View / About
②	File Information	Recording Start Time : DD MM YYYY hh:mm Duration : hh:mm:ss Serial number : 8byte Sampling Frequency : 256Hz
③	Symptom Marking	Input abnormal symptom time recorded by the

		Patient
④	ECG signal Graph	ECG signal graph chart display - Zoom In/Out, Cursor, Marker
⑤	Analysis	Heart Rate Table
⑥	Heart Rate Graph	Heart rate graph chart display

4.1.4. Mobile app



[Device connection on]



[Device connected]

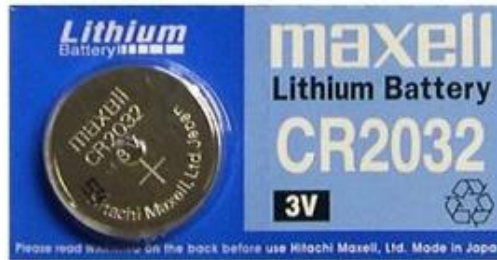
Label	Name	Description
①	QR code scanning	QR code scanning to connect Bluetooth
②	Recording Time	Recording time among the total recordable time
③	Battery	Remaining battery level
④	Memory	Storage memory usage level
⑤	Lead on/off	Indication of module attachment on the patient body
⑥	Setting	Device disconnection, Alarm per each display item

4.2. Accessory Components

--



<Electrode>



<Battery>

Label	Name	Description
①	Electrode	Multi-purpose recording electrodes with sticky gel feature (high performance adhesive and foam backing) Note: Use the FDA registered Electrode.
②	Battery	Power supply for S-PATCH. DC 3V Coin Battery. Note: Use the certified battery by IEC 60086-4 or UL1642

4.3. How to Start S-PATCH

4.3.1. Required Environment

- Windows 10 installed PC
 - 200MB free disk space or greater
 - Minimum High Speed USB 2.0
- PC software
 - Installation file (USB flash drive)
- Sensor device
- Cradle and USB cable

4.3.2. System Initialization

1) PC software installation

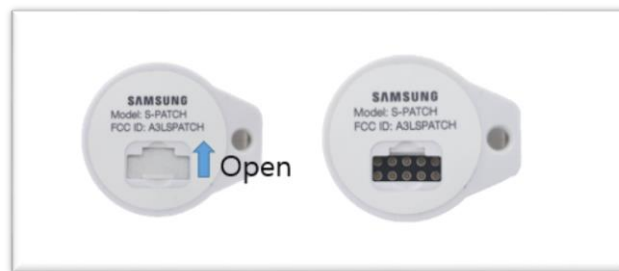
- Install setup file (S-Patch PC software setup.exe) on the USB flash drive
- Open the Spatch Management.exe

2) Connect the Cradle to the PC USB Port. Then the LED of the Cradle will turn red color



3) Plug the Sensor device into the Cradle

- Open the sliding door on the bottom of the Sensing module to connect the Cradle



- Attach the Sensing module to the Cradle. Then the LED of the Cradle will turn green color



4) Execute S-PATCH management (S-PATCH.exe) in the Desktop or PC software installed folder

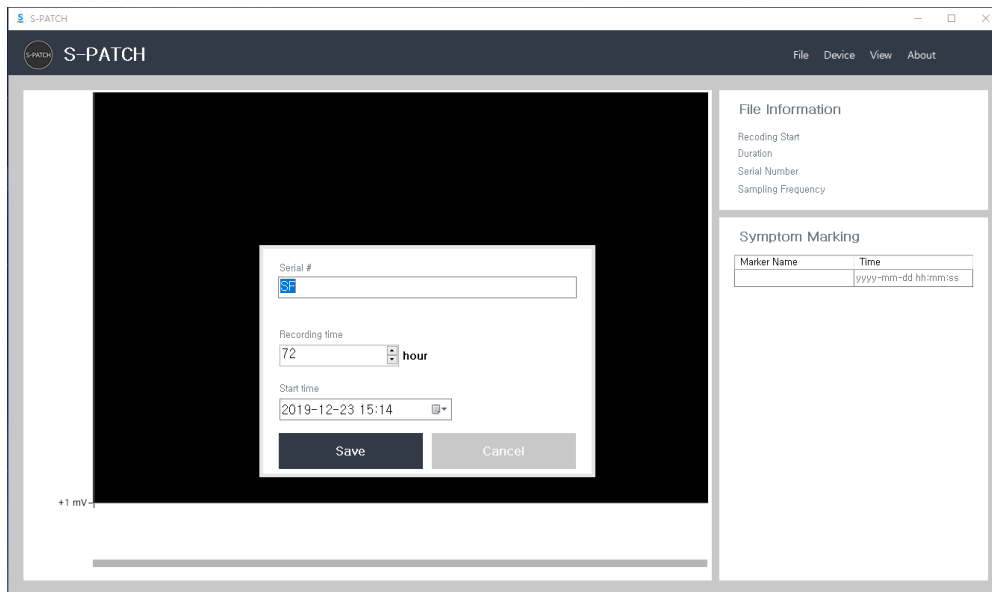
5) Create User account

- [illegible]

The screenshot shows a 'Login' window with a light gray background. On the left side, there is a large blue 'S' logo with the word 'Patch' in black text below it. On the right side, there are two input fields. The first is labeled 'User name' and contains the text 'new account'. The second is labeled 'Password' and contains seven asterisks. At the bottom of the window, there are two buttons: 'Login' and 'Exit'.

8) Device-Initialize will be activated in the Menu and Click 'Initialize'

- 9) Click 'Device-Disconnect' in the Menu



4.3.3. Sensor device Setup

1) Insert battery to the battery module of Sensor device

First, release the screw on the battery module using screw driver.
Second, open the upper case of battery module and insert the battery.
Lastly, close the case and lock the screw.



;

Do not replace the battery at extreme environment condition (Extremely high temperature, high pressure, high humidity and Etc...).

Please contact to the manufacturer, if you need more information to replace the battery.

The battery certified to IEC 60086-4 or UL1642 should be used.

2) Connect Electrodes to electrode connect hole in each side of the Sensor device



4.4. Precautions

- 1) The electrodes and coin battery are disposable. Please observe local laws for disposal of electrodes and coin battery.
- 2) To remove the battery if the Sensor device is not likely to be used for long time.
- 3) Please ensure user's hands are clean and dry when handle the Sensor device
- 4) The body hair possibly causes contact problem which results a fault detection of physiological data. Excessive body hair should be removed several hours before use.
- 5) After using the device, wipe dust and other foreign substances using a dry cloth.
- 6) 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 where you purchased the product.

5. Using and Operating S-PATCH

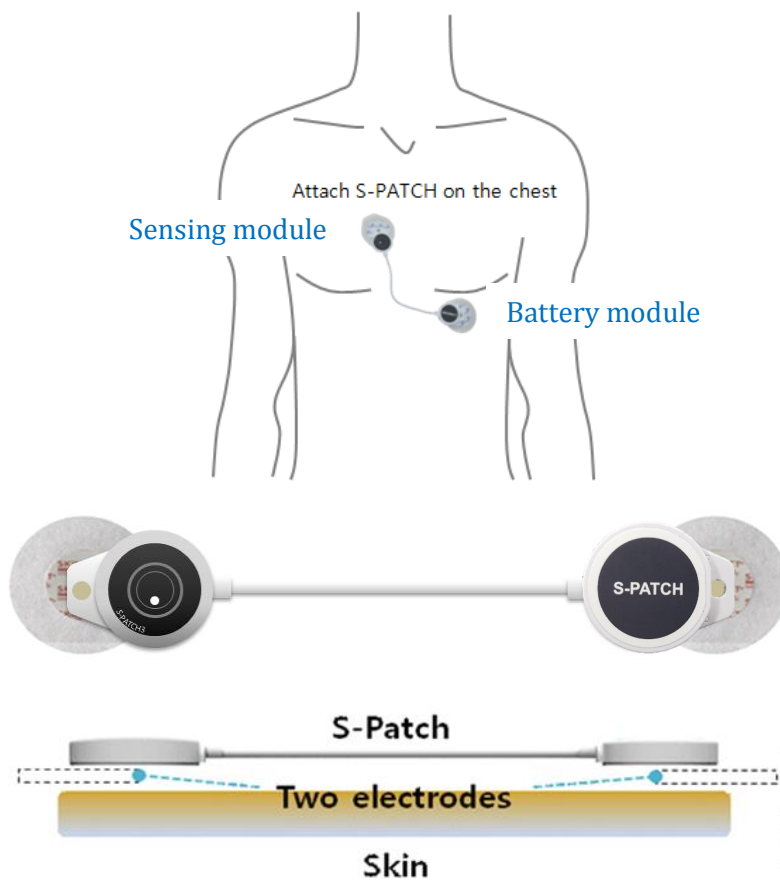
5.1. How to Use S-PATCH

5.1.1. Attachment to the patient body and Power On

- 1) After connecting the electrodes with the Sensor device, peel the plastic on the backside of the electrodes.
- 2) Attach the Sensor device on recommended position as drawn.



; Make sure that all electrodes are connected to the patient correctly before operation.



- 3) When press the power button, LED is On. And hold the power button until LED is Off.



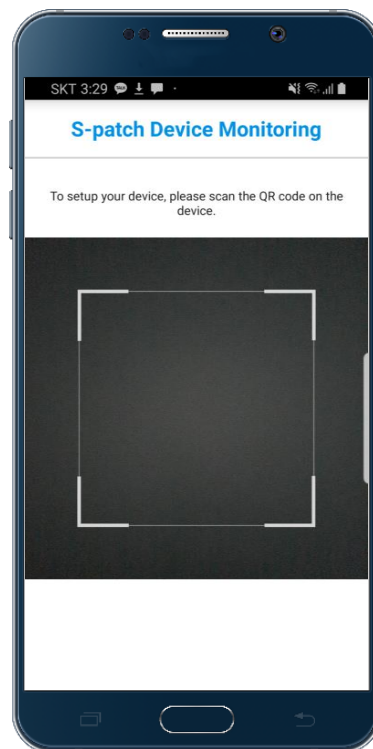
5.1.2. Connection to the Mobile app

- 1) Copy the Mobile app (S-PATCH mobile app.apk) from the USB flash drive to the patient's smart phone.
- 2) Install the Mobile app (S-PATCH mobile app.apk) on the smart phone.

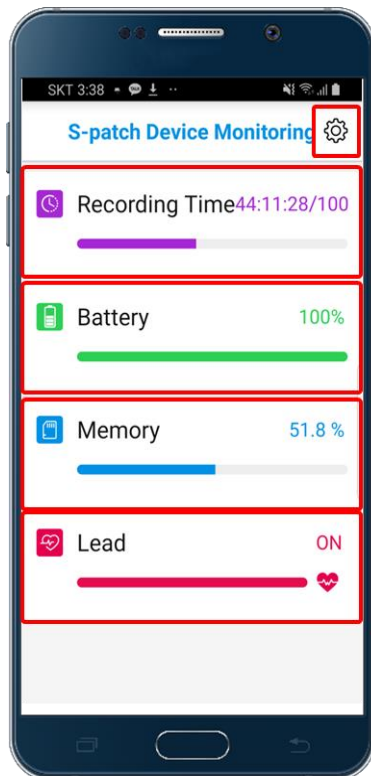
- 3) Execute the Mobile app.



- 4) QR code scanning on the packing box for Bluetooth pairing
(If lose the box, refer to the QR code in the Sensor device bottom side.)

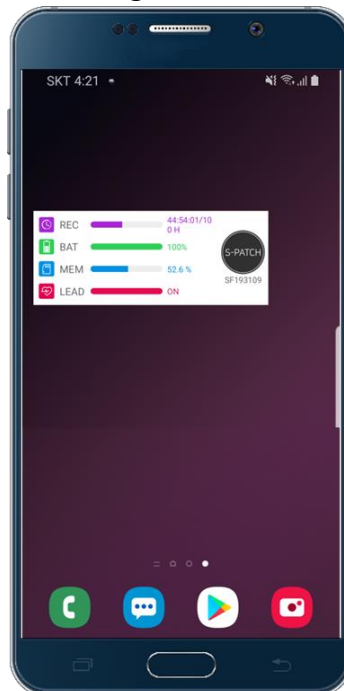


- 5) After completing pairing, S-Patch Device Monitoring display will appear



- Setting
- Recording Time
Data recording time among the total recordable time set in the module
- Battery
To display remaining battery level as a percentage
- Memory
To display storage memory usage as a percentage
- Lead
Lead on: monitoring ECG signal normally
Lead off: detecting lead-off

- 6) If adding S-PATCH widget in Home screen of mobile device, Recording Time / Battery / Memory / Lead states will be monitoring in Home screen.



If the connection is interrupted due to an abnormal condition, Mobile app will display “S-Patch is disconnected” and “S-Patch is not working”

S-PATCH Mobile 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 Mobile app could not receive the status data.

5.1.3. Completion of recording

When the recording time is over, remove the Sensor device from the patient's chest and dispose of the used electrodes

5.1. Daily Usage

Wear this S-PATCH as you go about your normal daily activities, as well as at night while you sleep. However, you need to remove the Sensor device when:

- Showering, bathing, or swimming
 - Traveling on aircraft
 - Undergoing an MRI
- 1) To finish the Mobile app, press "BACK" button on the Android device or touch "Multi-tasking" button on the Android device and close the app.
 - 2) Remove the Sensor device from the chest.
 - 3) When you are ready to put the Sensor device back on, attach the Sensor device on the recommended position. Turn on the Mobile app and resume monitoring the Sensor device status.

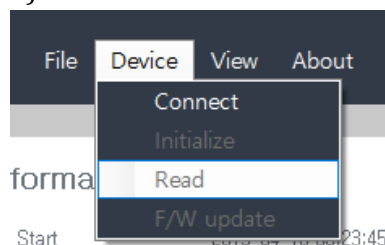
5.2. Data download and management

5.2.1. ECG Data Download and Display

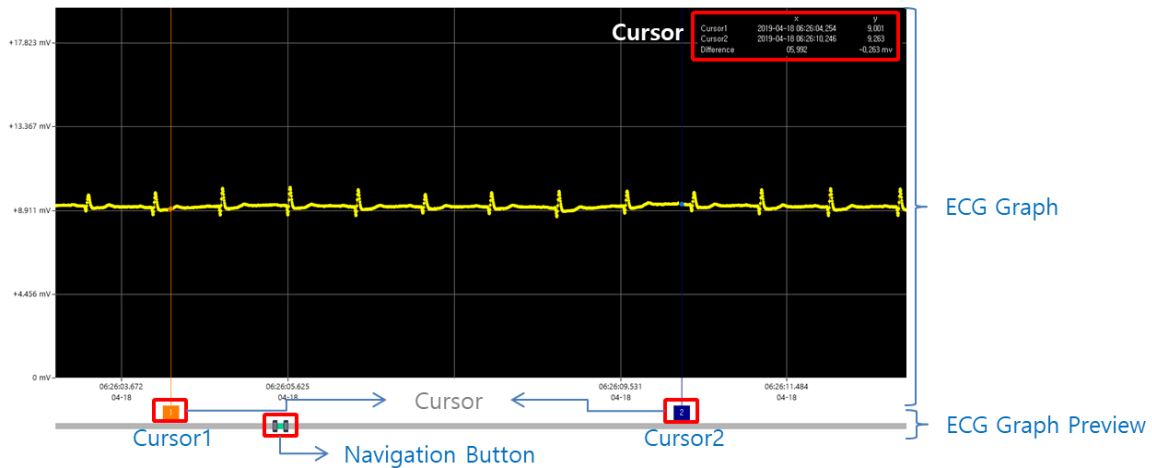
1) Connect the Sensor device and Cradle to the Personal Computer

2) Open the PC software and Login with User name & Password created in the System initialization step

3) Device connect and Read data in Menu bar



4) After reading data, ECG graph will appear in ECG signal graph window



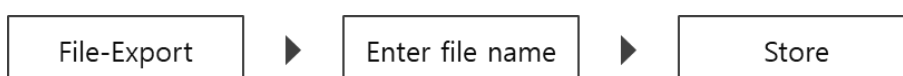
- ECG Graph Preview
 - Navigation Button: Move recorded data along X-axis of time
- ECG Graph
 - Zoom
 - Mouse scroll: X/Y axis simultaneous zoom in/out
 - Alt + mouse scroll: Y axis zoom in/out
 - Ctrl + mouse scroll: X axis zoom in/out
 - Shift + mouse left click area selection: selected area zoom in/out
 - Zoom in limit area: X axis – 1sec / Y axis – 2mV
 - Zoom out limit area: X axis – Full recorded time / Y axis – 100mV
 - Cursor
 - Create Cursor: Menu-View-Cursor
 - Cursor1, 2 and difference will be displayed
 - Marker
 - Place the mouse pointer over the graph and right click → 'Symptom Marking Add'
 - Create Marker entering Marker time name and time
 - Created Markers will be displayed Symptom Marking window

Symptom Marking

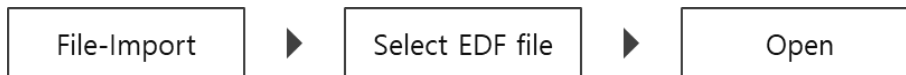
Marker Name	Time
marker1	2019-11-30 08:09:42,387
marker2	2019-11-30 08:09:43,402
marker3	2019-11-30 08:09:44,414
	yyyy-mm-dd hh:mm:ss

5.2.2. ECG Data Import and Export

1) Export: To save a loaded ECG data including Markers. Following



2) Import: To load a stored EDF file and display ECG graph



5.3. Specifications

S-PATCH 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	256 Samples/Second
	Input Impedance	>100 MΩ
Power Requirements	Power Supply	3Vd.c. (Lithium coin battery)
	Battery Life	Up to 72 Hr.
Software	F/W version	V1.00
	CPU	S1SBP6A (Cortex-M4F microprocessor)
	BLE	Dialog DA14583 (ARM Cortex-M0)
	App(Android)	Android version 9 or later
Physical Characteristics	Weight (Exc. Battery)	8g
	Dimension (Battery module,2)	29*5.5 (mm), 29*4.4 (mm) [D*H]
	Dimension (Connect Cable)	110 ± 10 (mm)
Communication	Bluetooth	Max. 10 Meters
	Radio Modulation	GFSK
	Radio Frequency	2,402 MHz ~ 2,480 MHz
	Max. RF Output Power	0 dBm

5.4. Error Message

5.4.1. Device Disconnection

If the BLE is disconnected on the mobile device, Mobile app will display “S-Patch is disconnected” message, Figure 1

5.4.2. Abnormal Signal Detect

In case of Mobile app detects an invalid signal, assume LEAD OFF state and an error notification pop-up will appear, as shown below in Figure 2. Press “OK” to turn off the pop-up. After valid signal is detected, it's changed to LEAD ON state.

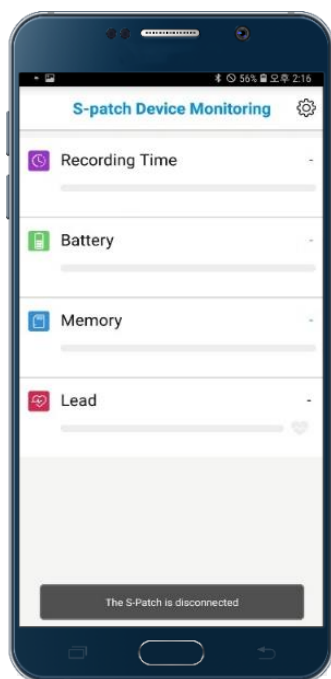


Figure 1

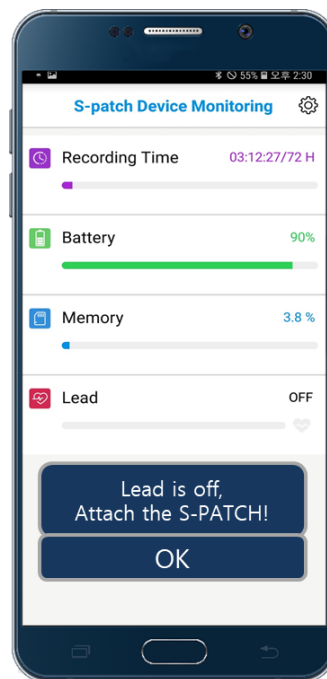


Figure 2

5.4.3. Low Battery Mode

If the battery level is less than 10%, you will get a notification that "Battery is too low", Figure 3. Press OK to turn off notifications.

When the battery runs out, you will get a notification that “Change the Battery!”, Figure 4. Press OK to turn off notifications. And then you need to change the battery.

5.4.4. Low Remaining Recording Time

When the recording time is finished, “Recording time is over, visit the hospital” notification will appear, as shown below in Figure 5.

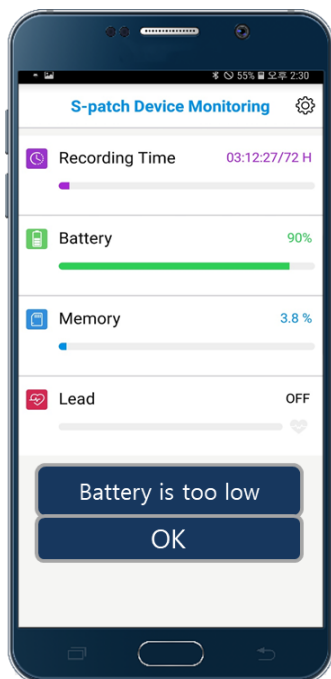


Figure 3

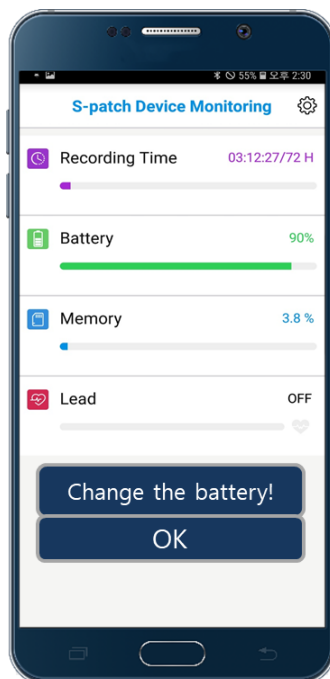


Figure 4

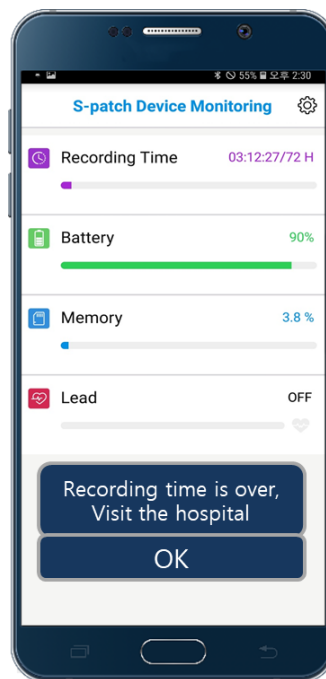


Figure 5

5.5. Maintenance

For cleaning, gently wipe with a soft dry cloth after using the Sensor device. Please attempt to keep the Sensor device dust free. The Sensor device is water resist. 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.

5.6. Specification of External Device connection

The Sensor device is connected to the Android Application. The data indicating the status of the device is transmitted to the application from the device.

A. The required specification of the interface and IT -Network that combines PEMS

1) Sensor device / Mobile App interface

- Data format: Bluetooth
- Mobile Application: Application on based Android
- Device status information
 - Device information (Bringing information when connecting to BLE)
 - Battery information (Receiving information periodically)

B. Technical specification about network connection of PEMS including security features.

- 1) Mobile Application is designed to not-affect by an external virus infiltration. But if infected with virus, Operating System may be a loss of storage data. Therefore, in the case of virus infection it should be operated by an antivirus program.

2) Specification of Network connection

Communication protocol: the protocol between the Sensor device and the Mobile app is a BLE central (Mobile) – peripheral (Sensor device) communications and they communication with security requirements defined in the BLE Protocol Stack.

C. Responsibility Organization

- Connection of the PEMS to an IT-Network that includes other equipment could result in previously unidentified risks to patients, operators or third parties;
- The responsible organization should identify, analyze, evaluate and control these risks;
- Subsequent changes to the IT-Network could introduce new risks and require additional analysis; and
- Changes to the IT-Network include:
 - changes in the IT-Network configuration;
 - connection of additional items to the IT-Network;
 - disconnecting items from the IT-Network;
 - update of equipment connected to the IT-Network; and
 - upgrade of equipment connected to the IT-Network.

5.7. Heart Rate Algorithm

The ECG signals converted to the digital values after the analog front-end blocks. The digital signals are filtered to reduce the noise such as electrical motion, AC power noise (50/60 Hz), and motion artifacts. After enhancing the quality of the ECG signals, the R peaks in the QRS complex are detected and the interval (henceforth referred to as RRI) between every R peak is calculated in the Sensor device. The data are transmitted to the smart phone via BLE. In the host mobile application of the smart phone, the HR and HRV algorithms are estimated on data received from the Sensor devices.

$$HR = \frac{1}{RRI_{avg}} \times 60$$

The “RRI Estimation” block calculates differences between each pair of QRS indexes. Ectopic beats results in a sharp transient of R-R interval. The “Ectopic Beat Removal” block detects these abnormal beats and the values are replaced by the average value of adjacent R-R intervals.

6. Labels and Packaging

6.1. Labels

6.1.1. Label for Packaging

PRODUCT NAME	Wearable Health Recording System		
MODEL NAME	S-PATCH		
RATED VOLTAGE	3.0 V d.c. (Lithium coin battery)	FCC ID	A3LSPATCH
Dimension (Sensing module)	29 x 5.25 mm [Diameter x Height]	IP Grade	IP22
Dimension (Battery module)	29 x 5.8 mm [Diameter x Height]	SN Serial Number (Sensor device)	
Dimension (Connect cable)	110 ± 10 mm	SN Serial Number (Cradle)	
Dimension (Cradle)	44.5 x 19.4 mm [Diameter x Height]	Date of manufacture	
 CAUTION - Electric shock " To avoid electrical shock, do no disassemble the device "  Please read the user's manual carefully before use  CF Type  Only Prescription only  Keep Dry			
 Manufacturer : Samsung Electronics Co., Ltd. 1-1, Samsungjeonja-ro, Hwaseong-si, Gyeonggi-do, 18448 Korea Tel) +82-31-8096-7012 E-mail) s.patch@samsung.com		 WEEE   MADE IN KOREA	

6.1.2. Label for the Sensor device



6.1.3. Label for the Cradle

Wearable Health Recording System		S-PATCH Cradle	
SN	SF 193129		Please read the user's manual carefully before use.
			Samsung Electronics Co.,Ltd.

6.1.4. Descriptions of the visual symbols of the label

No.	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 CF applied part
7		Prescription only
8		WEEE Mark
9		Keep Dry
10		Non-ionizing radiation
11		MR unsafe

6.2. Packaging

Identification	Components	Quantity
Main Box	Sensor device	1
	Electrodes	4
	Battery	1
	Quick guide	1
Sub Box	Cradle	1
	USB cable	1
	USB flash drive	1

7. Electromagnetic Environment

7.1. Guidance and Manufacturer's Declaration – Electromagnetic Emissions

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

Immunity test	Compliance	Electromagnetic environment - Guidance
RF Emissions CISPR 11	Group 1	The S-PATCH 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 S-PATCH is suitable for use in ail establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes

7.2. Guidance and Manufacturer's Declaration – Electromagnetic Immunity

- The S-PATCH is intended for use in the electromagnetic environment specified below. The customer or the user of the S-PATCH 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	±8kV Contact ±2,4,8,15 kV air	±8kV Contact ±2,4,8,15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

7.3. Guidance and Manufacturer's Declaration – Electromagnetic Immunity

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

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - Guidance
Radiated RF IEC 61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the S-PATCH, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.166\sqrt{p} \quad 150\text{kHz to } 80\text{MHz}$ $d = 1.166\sqrt{p} \quad 80\text{MHz to } 800\text{MHz}$ $d = 2.333\sqrt{p} \quad 800\text{MHz to } 2.5\text{GHz}$ 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). 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 : 
NOTE 1) At 80MHz and 800MHz, the higher frequency range applies. NOTE 2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

^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 S-PATCH is used exceeds the applicable RF compliance level above, the S-PATCH should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the S-PATCH.

^b Over the frequency range 150kHz to 80MHz, field strengths should be less than $[V_1]$ V/m.

7.4. Recommended separation distances between portable and mobile RF communications equipment and the S-PATCH

- There is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the S-PATCH can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the S-PATCH 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 $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$	80MHz to 800MHz $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$	800MHz to 2.5GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
	$V_1=3V_{rms}$	$E_1=3V/m$	$E_1=3V/m$
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
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. NOTE 1) At 80MHz and 800MHz, the separation distance for the higher frequency range applies. NOTE 2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

7.5. Immunity and Compliance Level

Immunity test	IEC 60601 Test Level	Actual Immunity Level	Compliance Level
Radiated RF IEC 61000-4-3	10V/m 80MHz - 2.7GHz 80 % AM at 1 kHz	10V/m	10V/m

8. 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.

Supplier's Declaration of Conformity

47 CFR § 2.1077 Compliance Information

Unique Identifier: RD28

Responsible Party – U.S. Contact Information

Company: Samsung Semiconductor Inc.

Street Address : 3655 N 1st St

City, State : San Jose, CA

Zip Code : 95134

Contact information : Kevin Lee / email : lee.kevinj@samsung.com / phone : +1-408-544-4000

9. Expected Service Life time and Warranty

9.1. Expected Service Life Time

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

9.2. 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

10. Company Name and Address

Company name: Samsung Electronics Co., Ltd.

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

Tel : +(82) 31-8096-7012

e-mail: s.patch@samsung.com