

USER MANUAL

Wearable Health Monitoring System

(MODEL: S-PATCH3-Cardio)

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



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Samsung SDS Co., Ltd.

125, Olympic-ro 35-gil, Songpa-gu, Seoul, Republic of Korea

Revision History

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Contents

1. Product Introduction	5
1.1 Introducing S-PATCH3-CARDIO	5
1.2 Indication for Use	5
2. Cautions	5
2.1 General	5
2.2 Safety	5
2.3 Contra-Indication	6
2.4 Usage and Storage Conditions	7
2.4.1 Conditions for Usage	7
2.4.2 Conditions for Storage.....	7
2.4.3 Cleaning Condition	7
3. Components and Installation of S-PATCH3-CARDIO	8
3.1 Main Device Components.....	8
3.2 Accessory Components	9
3.3 How to Install S-PATCH3-CARDIO	10
3.3.1 Installing S-PATCH	10
3.4 Precautions	11
4. Using and Operating S-PATCH3-CARDIO.....	12
4.1 How to Use S-PATCH3-CARDIO	12
4.2 Specifications	17
4.2.1 S-PATCH3-CARDIO Specifications	17
4.3 Error Message	18
4.4 Maintenance	18
4.5 Specification of External Device connection.....	18
5. Heart Rate Algorithm	19
5.1 HR calculation per beat.....	19
5.2 Average HR calculation of a section	19

6.	Labels and Packaging	20
6.1	Labels.....	20
6.1.1	Label for Packaging	20
6.1.2	Label for module.....	20
6.2	Packaging.....	21
6.2.1	Package List.....	21
6.2.2	Package Units	21
6.	Information on EMC.....	22
6.1	Guidance and Manufacturer’s Declaration – Electromagnetic Emissions	22
6.2	Guidance and Manufacturer’s Declaration – Electromagnetic Immunity.....	22
6.3	Guidance and Manufacturer’s Declaration – Electromagnetic Immunity.....	23
6.4	Recommended separation distances between portable and mobile RF communications equipment and the EUT	24
6.5	Immunity and Compliance Level	25
6.6	Guidance and Manufacturer’s Declaration – Electromagnetic Immunity.....	26
7.	FCC Compliance Statement.....	27
8.	Expected Service Life time and Warranty	27
8.1	Expected Service Life Time	27
8.2	Product Warranty	27
9.	Company Introduction.....	28
9.1	Company Name and Address.....	28

1. Product Introduction

1.1 Introducing S-PATCH3-CARDIO

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-CARDIO body signal sensing module, ECG electrodes and mobile app viewer to monitor the signals.

- Product Name– Wearable health Monitoring System
- Model Name– S-PATCH3-CARDIO
- Manufacturer–SAMSUNG SDS Co., Ltd.

1.2 Indication for Use

This product is intended to measure, transfer and record electrocardiogram signal. The viewer on mobile device may display ECG wave form, Heart Rate and other information. The product consists of S-PATCH3-CARDIO body signal sensing module, mobile application and web portal of electrocardiogram analysis for physician.

The S-PATCH3-CARDIO signal sensing module transmits data through wireless communication to mobile device.

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

- Heart Rate
- ECG signal
- The connection between S-PATCH3-CARDIO and mobile device is using Bluetooth communication.

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.

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.

- 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) Conductive parts of electrodes and associated connectors for type CF applied parts, should not contact other conductive parts including earth;

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

2.4.2 Conditions for Storage

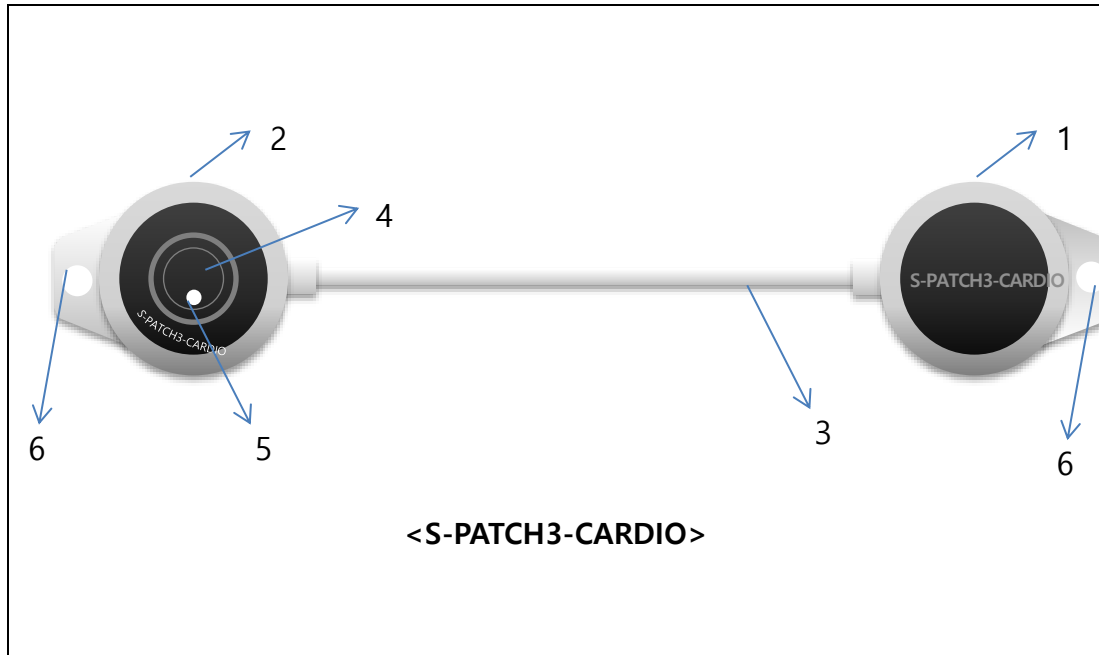
- 1) Temperature: -25 °C - 70 °C (-13 °F to 158 °F)
- 2) Relative humidity: 10%-95% (non-condensing)
- 3) Atmospheric pressure: 700hPa-1060hPa
- 4) Keep the device in the case when it doesn't use.

2.4.3 Cleaning Condition

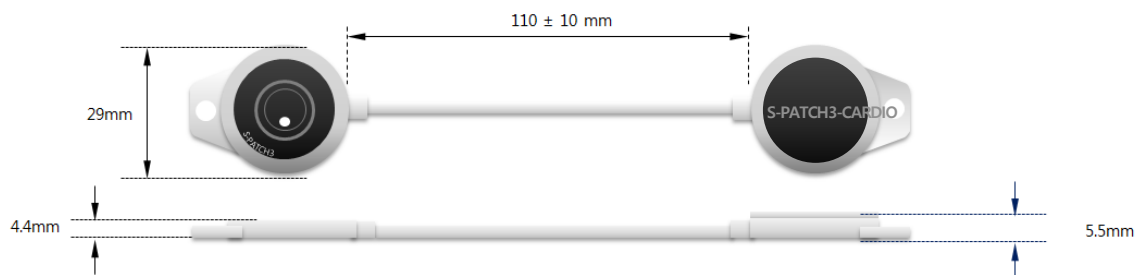
- 1) Clean the device with soft, dry cloth
- 2) Equipment failure may occur due to dust and debris during long-term use of the equipment.

3. Components and Installation of S-PATCH3-CARDIO

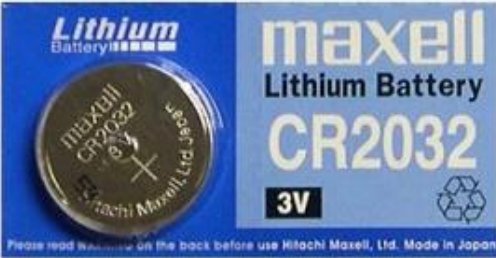
3.1 Main Device Components



Label	Name	Description
1	Main Body1	Coin battery inset module
2	Main Body2	Main PCB module
3	Connect Cable	Cable between two main bodies
4	Power Button	Power On/Off button
5	LED	LED Lamp to indicate the states
6	Electrode connect hole	Holes for ECG electrodes connecting



3.2 Accessory Components

<p><Electrode></p>  <p><Battery></p>		
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-CARDIO. DC 3V Coin Battery.

The Applied Parts are main device and electrode

3.3 How to Install S-PATCH3-CARDIO

3.3.1 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-CARDIO.



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

First, release the screw on main body1 using screw driver.
Second, open the upper case of main body1 and insert the battery.
Lastly, close the case and lock the screw.

⚠ Caution ;

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.

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



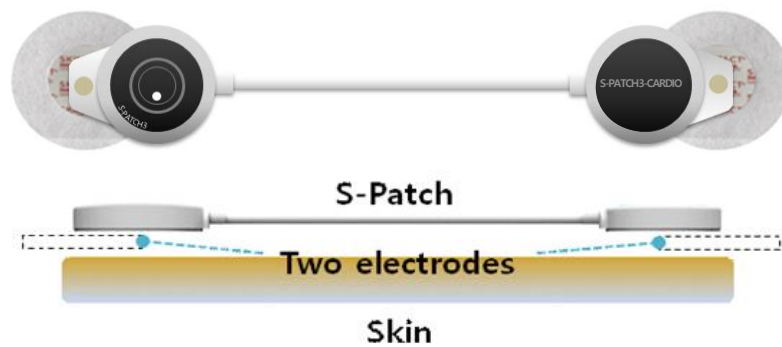
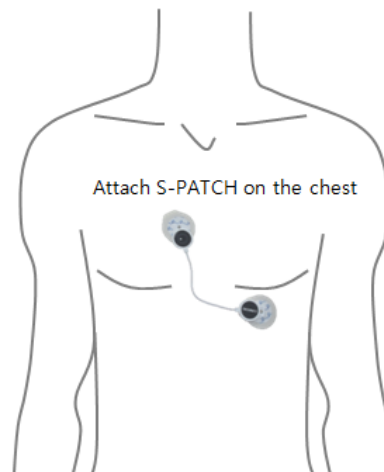
3.4 Precautions

- 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 S-PATCH3-CARDIO is not likely to be used for some time.
- 3) Please ensure user's hands are clean and dry when handle the S-PATCH3-CARDIO
- 4) The body hair possibly causes contact problem which results a fault detection of physiological data.
- 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 the shop where you purchased the product.

4. Using and Operating S-PATCH3-CARDIO

4.1 How to Use S-PATCH3-CARDIO

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



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



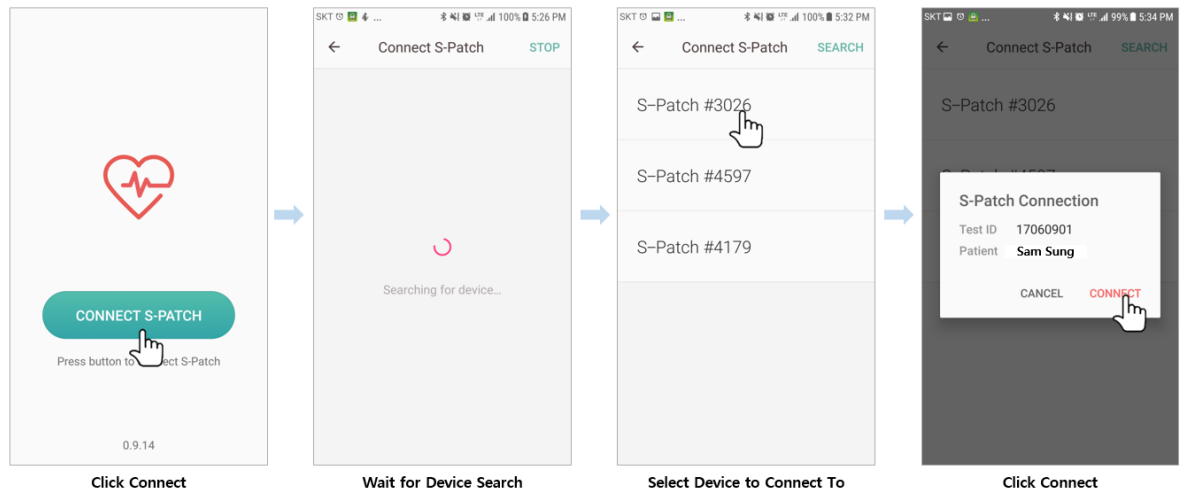
- 4) Confirm that the LED is ON and OFF 3 times.



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

6) Please execute S-PATCH App

6-1) Open the App to see following sequence of screens:



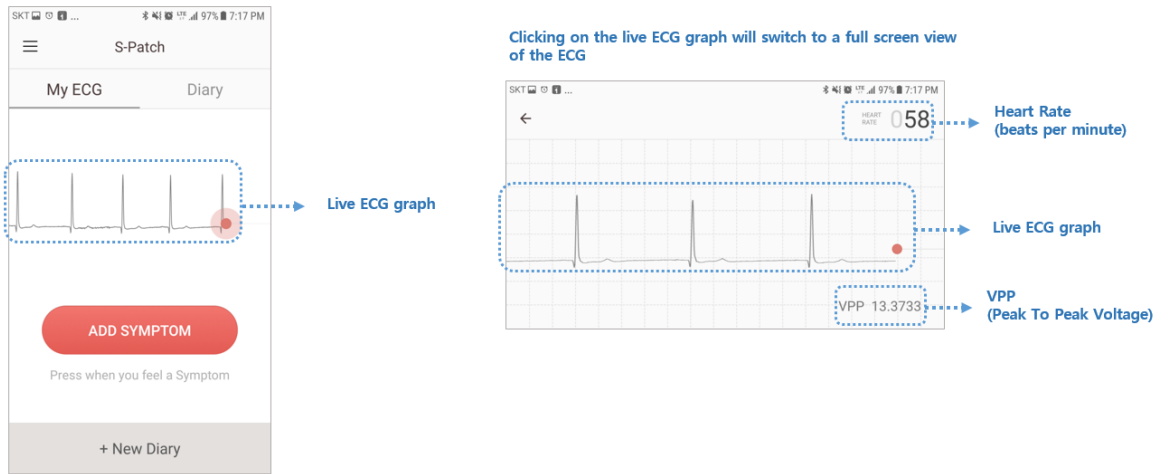
6-2) Press “Connect S-Patch” button on lower center of screen.

6-3) Wait while the app searches for device.

6-4) Select device to connect.

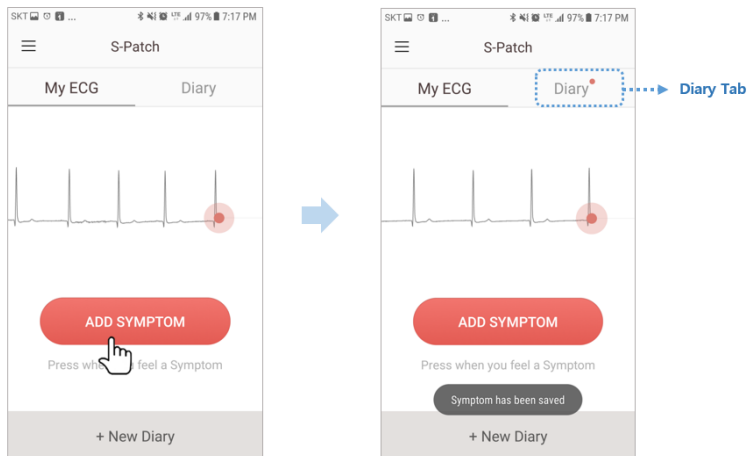
6-5) Press “Connect” after confirming test sequence(test ID) and patient name (patient ID).

6-6) User's ECG graph can be viewed from screen.

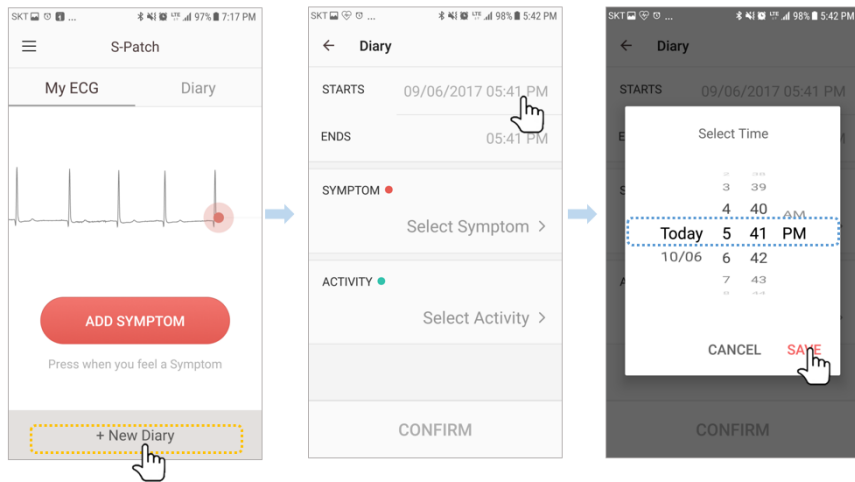


Clicking on the live ECG graph will pull up vertical screen for full screen view of ECG.

6-7) Press “Add Symptom” button to record any symptoms instantly. This button will save a “not specified” symptom on diary tab to which user can add details at a later time.



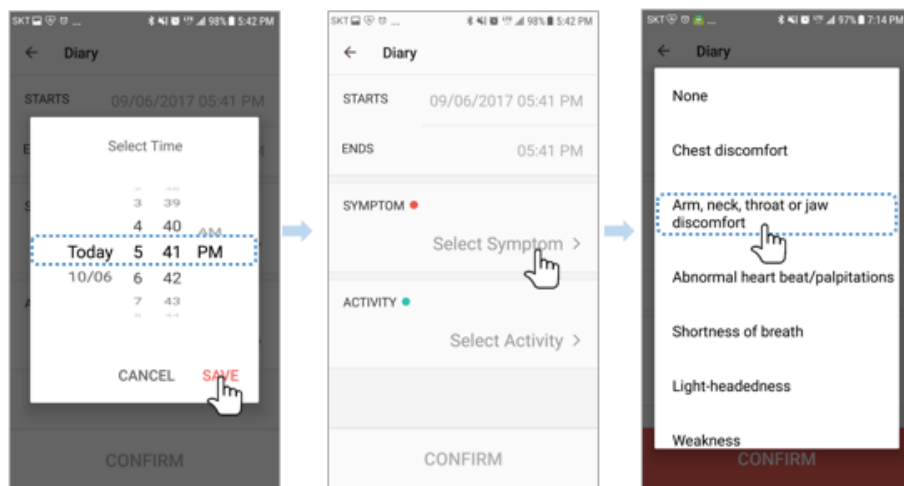
After button is pressed “Symptom has been saved” message appears momentarily at bottom of screen.



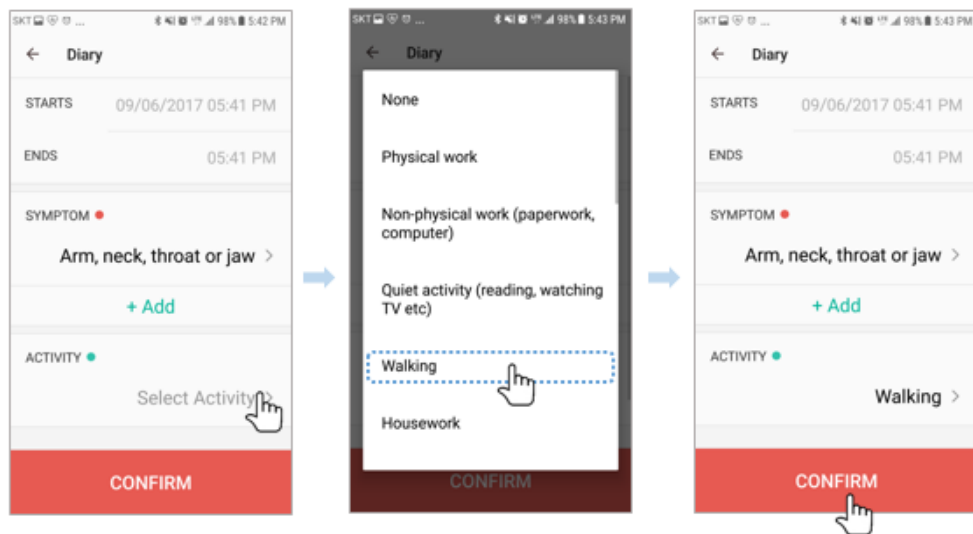
6-8) Press “+ New Diary” to create a new diary entry.

6-9) Enter start date and time of symptom.

6-10) Enter end date and time of symptom.



6-11) Press “Select Symptom” and select a symptom from list.



6-12) Press “Select Activity” and select an activity from list.

6-13) Press “Confirm” to save the new diary entry.

6-14) When the duration of test is over, test will automatically upload to cloud, but in case user desires to end the test early press the menu button on upper left of screen.



6-15) Press “End Test” on the bottom of menu options.

6-16) An “End test” message will appear and user can press “End” to end the test.

6-17) When manually ending the test, the test data also requires manual sending. After the test is ended, screen will change to send data screen.



6-18) Press “Send Data” button on lower center of screen (requires internet connection).

6-19) Wait for app to finish transmitting data.

6-20) Click “Reset Application” to prepare the app for next S-Patch test.

4.2 Specifications

4.2.1 S-PATCH3-CARDIO 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	3 Vd.c. (Lithium coin battery)
	Battery Life	120 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)	8g
	Dimension(Main Body1,2)	29*5.5(mm), 29*4.4(mm) [Diameter* Height]
	Dimension(Connect Cable)	110 ± 10 (mm)

4.3 Error Message

Error Message	Situation	Solution
The server encountered an error	When an error has occurred at server and the mobile request cannot be executed	Contact service desk and enquire.
No data to send	When no data has been recorded because there is an error with time of gateway device and the test ends as soon as it has been started	Reinstall App
Failed to connect to service	When mobile device cannot access server due to network error	Re-try after moving to area with LTE or Wifi connection

4.4 Maintenance

For cleaning, gently wipe with a soft dry cloth after using the S-PATCH 3. Please attempt to keep S-PATCH3-CARDIO 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.

4.5 Specification of External Device connection

The S-Patch3 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) Main 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)

Data to Device – Data Channel

Transmits the data to the device

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 main unit and the mobile app is a BLE central (Mobile) – peripheral (main unit) 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

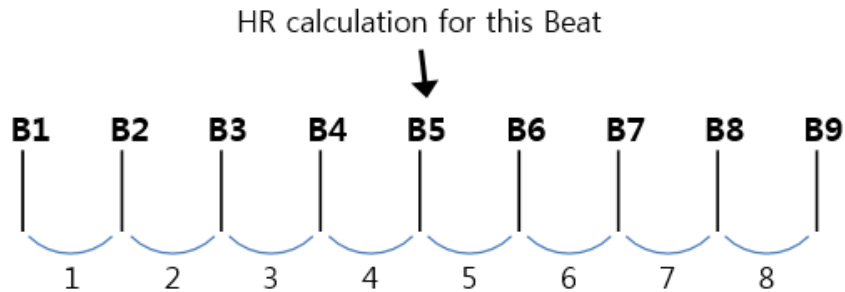
– changes to the it-network include:

- 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. Heart Rate Algorithm

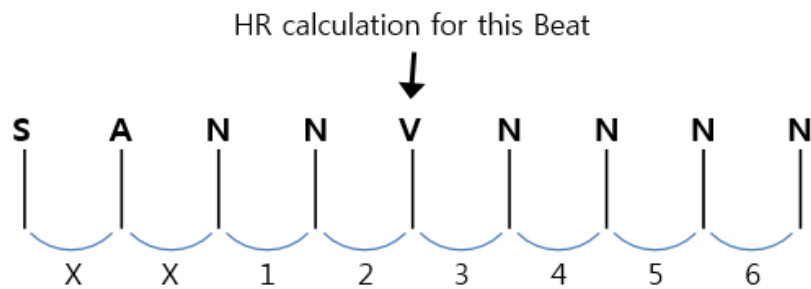
5.1 HR calculation per beat

When calculating HR of each beat, 9 beats including previous 4 beats and following 4 beats are required.



$$\text{Number of effective sections} / ((\text{time of B9} - \text{time of B1}) / 60)$$

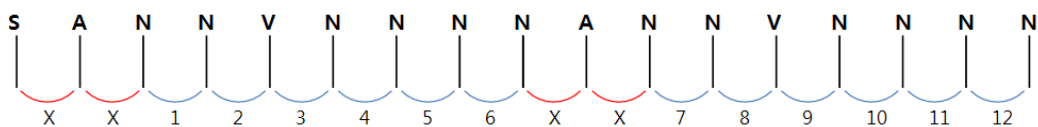
Definition of “section” is the interval between consecutive beats such as B1 and B2, and in case 1 of the 2 beats is A (Artifact), exclude it from effective section. If there are less than 5 effective sections, no calculation.



As the above picture, if beats S A N N V N N N N are within a section of 5 seconds and the excluded section is 1 second, the V beat in the center will have HR value of $6 / ((5-1) / 60) = 91$ bpm.

5.2 Average HR calculation of a section

Average HR of a section is calculated with the beats included in the section.



If the above data is within a 20 second frame, the average HR is calculated as follows:

$$\text{Number of effective sections} / ((\text{Total length of effective sections}) / 60)$$

At this time, “section” refers to the interval between consecutive beats such as B1 and B2, and in case 1 of the 2 consecutive beats is A (Artifact), exclude it from effective section before calculation.









Therefore, there are 12 effective sections, and if the total length of invalid sections is 2 seconds, the average is calculated as follows:

$$12 / ((20-2) / 60) = 40 \text{ bpm}$$

6. Labels and Packaging

6.1 Labels

6.1.1 Label for Packaging

PRODUCT NAME		Wearable Health Monitoring System		
MODEL NAME		S-PATCH3-Cardio		
SUPPLY VOLTAGE		3. V d.c. (Lithium coin battery)	FCC ID	WQRSPATCH3
Dimension (Main Body1, 2)		29 * 5.5 (mm), 29 * 4.4 (mm) [Diameter * Height]		
Dimension (Connect Cable)		110 ± 10 (mm)		
SN	Serial Number		Date of manufacture	
	CAUTION - Electric shock " To avoid electrical shock, do not disassemble the device "			
	Please read the user's manual carefully before use		CF Type	 Keep dry
	Manufacturer : Samsung SDS Co., Ltd. 125, Olympic-ro 35-gil, Songpa-gu, Seoul, Republic of Korea Tel) +82-2-6155-3114		 WEEE MADE IN KOREA	

6.1.2 Label for module












Front- side 2 Labels



Rear-side 2 Labels

- 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		Keep Dry

6.2 Packaging

6.2.1 Package List

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

6.2.2 Package Units

- 1) S-PATCH3-CARDIO 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

7. Information on EMC

7.1 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 S-PATCH3 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-PATCH3 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 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	±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 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 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	<p>Portable and mobile RF communications equipment should be used no closer to any part of the S-PATCH3, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3,5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$
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	<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</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol :</p> 

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 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.

^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 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 $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$	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

7.6 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
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz</p> <p>10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz</p>	<p>3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz</p> <p>10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz</p>	<p>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</p> <p>Field strengths outside the shielded location from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than 3V/m.^a</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> <p>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.</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 outside the shielded location in which the EUT is used exceeds 3V/m, the EUT should be observed to verify normal operation.</p> <p>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.</p>			

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.

9 Expected Service Life time and Warranty

9.1 Expected Service Life Time

- S-PATCH3-CARDIO 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 Introduction

10.1 Company Name and Address

Company name: Samsung SDS Co., Ltd.

Address: 125, Olympic-ro 35-gil, Songpa-gu, Seoul, Republic of Korea

Tel: +82-2-6155-3114

10.2 EC Representative

Name: Samsung SDS Europe

Address: KT13 0NY, 1st Fl. No. 5, The Heights, Brooklands Weybridge
Surrey, United Kingdom

Contacts:

- Phone: +44-7825-035-687
- Fax: N/A