USER MANUAL

Wearable Health Monitoring System

(MODEL: S-Patch Ex)

Document No: WS-UM-01 (Rev. 0.1)

Wellysis Corp.

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1 Product Introduction

1.1 Introducing S-Patch Ex

The S-Patch Ex is a light-weight electrocardiogram (ECG) and heart rate (HR) monitoring device with accompanying software. The S-Patch Ex operates wirelessly, and due to its compact size it is unobtrusive during daily activity. The S-Patch Ex continuously measures ECG and HR signals, and streams the digitized signals to a mobile gateway device equipped with S-Patch Ex App. At the end of each ECG recording session, patients can upload their data to a secure cloud portal via their mobile device connection. After the data upload takes place, physicians can access and review their patients' ECG data remotely via the S-Patch Ex Web. The S-Patch Ex is intended to be used with direction from trained medical professionals in accordance with the user manual.

- Product Name: Wearable health Monitoring System
- Model Name: S-Patch Ex
- Manufacturer: Wellysis Corp.

1.2 Indication for Use

Intended Use	The S-Patch Ex is a wearable health monitoring system for measuring and analyzing patient electrocardiogram (ECG) waveforms and heart rate (HR). The product consists of bio-signal sensing device, mobile application and web portal of electrocardiogram analysis for physician. The S-Patch Ex is intended for use in the diagnosis of patients with suspected cardiac symptoms such as but not limited to: Abnormalities of heartbeat, abnormalities of breathing, lightheadedness, dizziness, chest pain, sweating, pre-syncope, syncope, fatigue, or anxiety. The device has not been tested specifically for pediatric use.

1.3 Marks and Symbols

Label	Symbol	Description
1	SN	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	Rx Only	Prescription only

8		WEEE Mark
9		Keep Dry
10		Temperature limit
11		Humidity limitation
12	EC REP	Authorized European Representative address
13	CE 0068	The CE symbol indicates that this product complies with the European Directive for Medical Devices 93/42/EEC as amended by 2007/47/EC as a class IIa device.
14		Non-ionizing radiation
15	MR	MR unsafe

1.4Target treatment group and diseases

No	Contents	Description
1	Indications	Detection of cardiac arrhythmia and diagnostic evaluation of patients who may be asymptomatic or who may suffer from transient symptoms such as, but not limited to abnormalities of heartbeat, abnormalities of breathing, lightheadedness, dizziness, chest pain, sweating, pre-syncope, syncope, fatigue, or anxiety.
2	Age	Adults and adolescents at physician's discretion
3	Weight	Not limited
4	Health	1. Not recommended for use on patients with artificial cardiac pacemaker, cardioverter defibrillator, or other implantable electric devices. 2. Not recommended for use with pregnant women or breast-feeding mothers 3. To be used at physician's discretion on patients with current symptoms or medical history of skin cancer, rash, skin disorder, keloid, and/or any skin injury.
5	Nationality	Not limited
6	Condition	Not limited

2 Cautions

2.1 General

1) Store in climate controlled environments (parameters specified in section 1.4)
2) Since this product is a medical device, instructions are required to properly dispose of it. Contact the distributor or manufacturer for such instructions
3) Contact the manufacturer if there are any problems with product functionality.
4) Reuse of the electrodes is prohibited in any circumstances due to the risk of infection.
5) Prolonged use of electrodes may cause skin irritation. Discontinue use and consult your physician if skin irritation occurs.
6) DO NOT expose the device to strong electromagnetic fields.
7) No warranty is provided for any erroneous data collected by the device due to misuse or malfunction as a result of abuse, accidents, alteration, neglect, or failure to maintain the products as instructed.
8) Contact the manufacturer if there is a change in the performance of the device.
9) DO NOT place the device on top of excessive body hair. Body hair should be removed prior to placement of the device.
10) This device can be operated in at least one Member State without infringing applicable requirements on the use of radio spectrum.

2.2 Safety

1) A healthcare professional should explain the proper use of the device to a patient
2) Use this device under doctor's prescription.
3) Make sure the coin battery is inserted in the correct orientation
4) DO NOT use during magnetic resonance imaging (MRI) or external defibrillation procedures.
5) DO NOT drop or bump with excessive force.
6) Keep components out of reach of children.
7) 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 women or breast-feeding mothers.
3) Patients with current symptoms 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 Conditions for Cleaning

1) Disinfect by wiping with standard hospital disinfectant
2) DO NOT immerse device in liquid

2.4.4 Conditions for Usage and Storage of Electrode

1) Temperature: −10°C- 40°C (14°F to 104°F)

2.5 Use of Device

1) The electrodes and coin battery are disposable. Please observe local laws for disposal of electrodes and coin battery.
2) Remove the battery if the device is not likely to be used for an extended period of time.
3) Please ensure hands are clean and dry when handling the S-Patch Ex
4) Excessive body hair may cause noise in the recording.
5) Clean and disinfect the device by wiping with standard hospital disinfectant. Do not immerse the device in liquid.
6) This product must not be disposed of with household waste. Please recycle with other electrical equipment.

2.6 Use of Electrodes

2.6.1 Storage

1) Store electrodes according to manufacturer recommendations

2.6.2 Patient Preparation

1) Get the electrode ready for treatment.
   Wash the target area of the body and dry out the region. If necessary, shave the area for a better adhesion of the electrode to the skin.

2.6.3 Electrode Placement Precautions

1) Do not use the electrode in fracture region, neck, face or region around the heart.
2) Do not use this electrode to the patient who has a pacemaker and/or any kinds of transplantations inside his or her body.
3) Do not use this electrode while taking a shower, bathing or swimming.
4) Dried out electrodes should not be used
5) Electrodes should not be reused

2.7 Warning

2.7.1 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

2.7.2 FCC

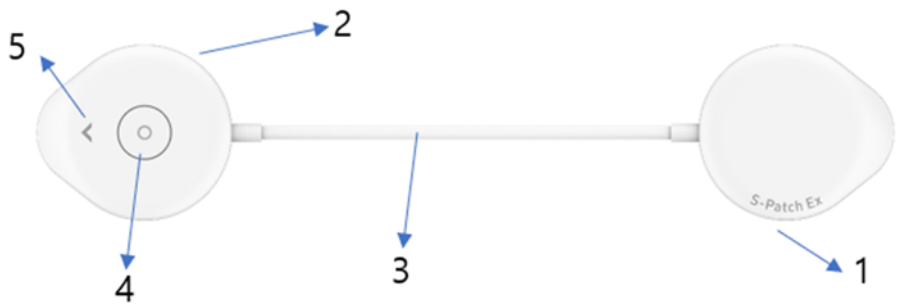
1) This equipment has been tested and found to comply with the limits for a class B digital device, pursuant to Part 15 of the FCC Rules.
These limits are designed to provide reasonable protection against harmful interference in a residential installation.
This equipment generates uses and can radiate 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 or television
reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and 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.

2) This device comply with part15 of FCC rules.
Operation is subject to the following two conditions:
- This device may not cause harmful interference.
- This device & its accessories must accept any interference received, including interference that may cause undesired operation.

3) This equipment may generate or use radio frequency energy.
Changes or modifications to this equipment may cause harmful interference unless the modifications are expressly approved in the instruction manual.
This user could lose the authority to operate this equipment if an unauthorized change or modifications is made.

3 Components and Installation of S-Patch Ex

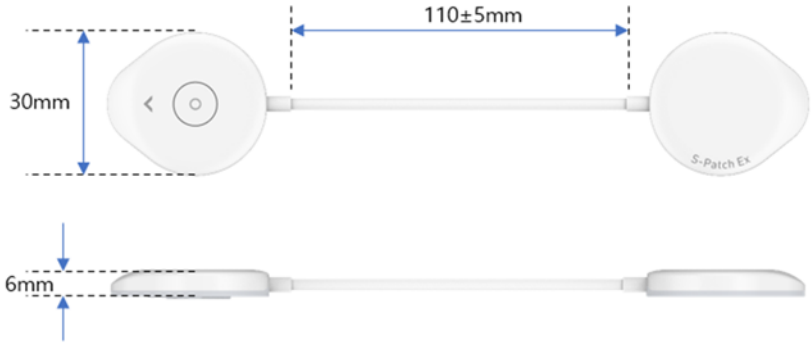
3.1 Main Device Components



< Front of S-Patch Ex >

< Rear of S-Patch Ex >

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

<Electrode>

<Battery>

Label	Name	Description
1	Electrode(single use)	Model name: HR-OP42 Dimension: 43Ø Multi-purpose monitoring electrodes with sticky gel feature (high performance adhesive and foam backing)
		Material: PE foam, Ag/AgCl sensor, Nickel plated brass, Solid hydro gel
2	Battery	Power supply for S-Patch Ex. DC 3V Coin Battery. Battery is replaceable.
3	S-Patch Ex Web	The S-Patch Ex Web is a cloud-based server which stores the encrypted ECG data

3.3 Material

No.	Title	Material	Grade
1	Exterior of Signal Detection Module	PVC	V-0
2	Connection cable	PVC	V-0

3.4 How to Install S-Patch Ex

3.4.1 Installing S-Patch Ex

1) Download the S-Patch Ex App (Android 8 and above /iOS 12 and above) from S-Patch Ex mobile app download link (https://play.google.com/store/apps/details?id=com.wellysis.spatchcardio.app&hl=en_US&gl=US or https://apps.apple.com/kr/app/s-patch-cardio/id1496099268?l=en). 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-Patch Ex (Check the polarity of the battery and insert it correctly).

First, Open the Battery cover on main body 1.
Second, Insert the battery.
Lastly, close the battery cover and turn it clockwise.

⚠ Caution ;

Do not expose the battery to extreme environmental conditions (Extremely high temperature, high pressure, high humidity and etc.)

4 Using and Operating S-Patch Ex

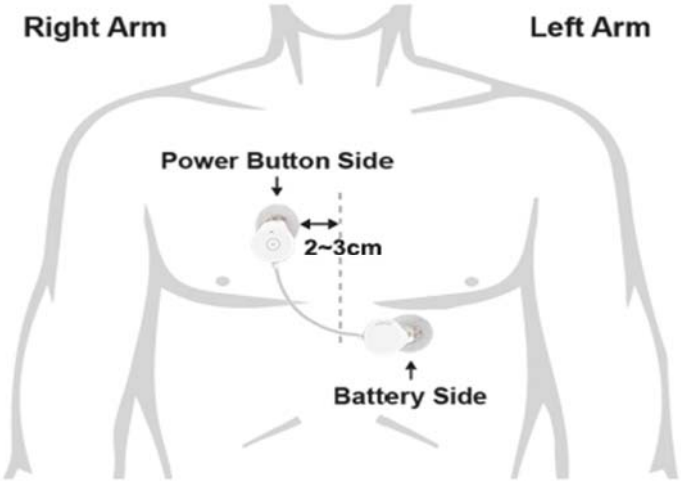
4.1 Turning S-Patch Ex on and Positioning it on Body

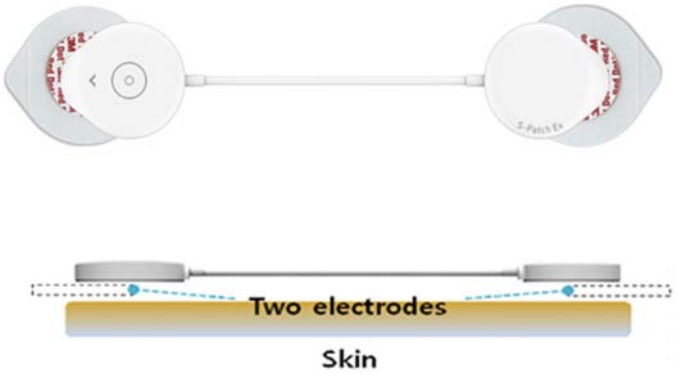
1) Push and hold the power button for 3 second.

2) Confirm that the LED blinks ON 1 time and OFF for 5 seconds.

On Off

3) Make sure Bluetooth is enabled on the mobile device.
4) After connecting the electrodes with S-Patch Ex, peel off the plastic covers from the backside of the electrodes.
5) Attach the S-Patch Ex according to the recommended position as shown below.





4.2 S-Patch Ex ECG Test with Smart Phone

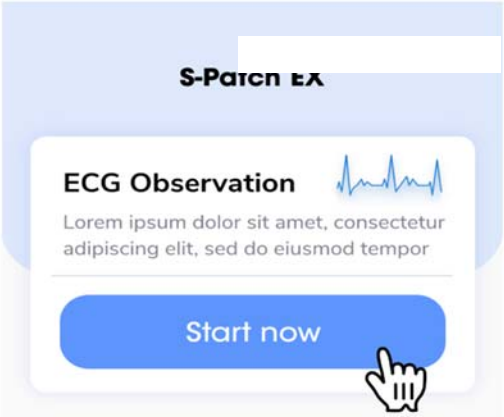
1) Connecting S-Patch Ex Device to the App.

1-1) Start S-Patch Ex App from the mobile device.

1-2) Enter the Organization Code as shown below to connect S-Patch Ex to the mobile device.

a. Select Region and entering Organization Code and Device S/N

b. Connecting S-Patch Ex Device



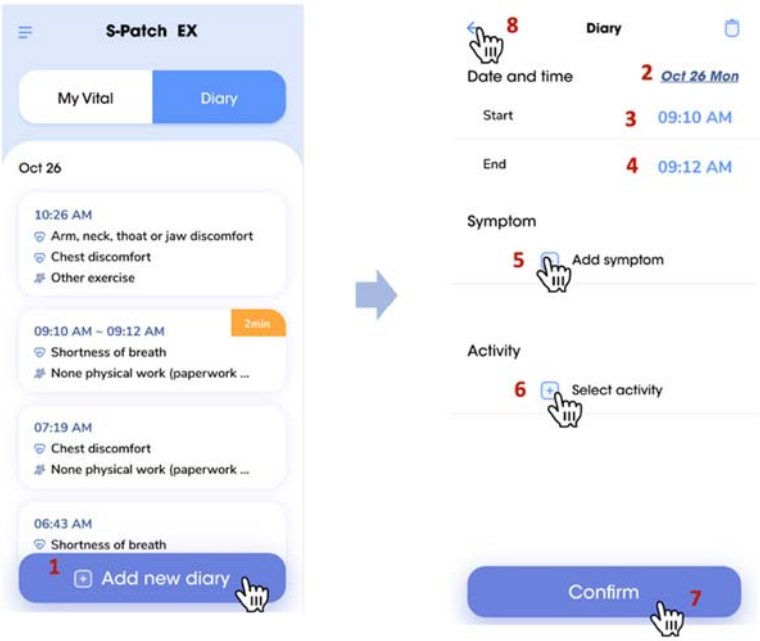
Note: Contact the system administrator if the Organization Code is unknown
Note: S-Patch device number is printed on the back of the device

1-3) Verify that User's ECG graph, HR and HRV can be viewed on the screen.

2) Logging Symptoms

2-1) Click on ADD SYMPTOM button to log symptoms into Patient Diary.

2-2) Entering Patient Diary



(1) Click on Add new diary button to create a new Patient Diary.

(2) Enter start and end date of the diary event.

(3) Enter start date/time of the diary event.

(4) Enter end date/time of the diary event.

(5) Click on "Add symptom" button to choose a symptom from the list.

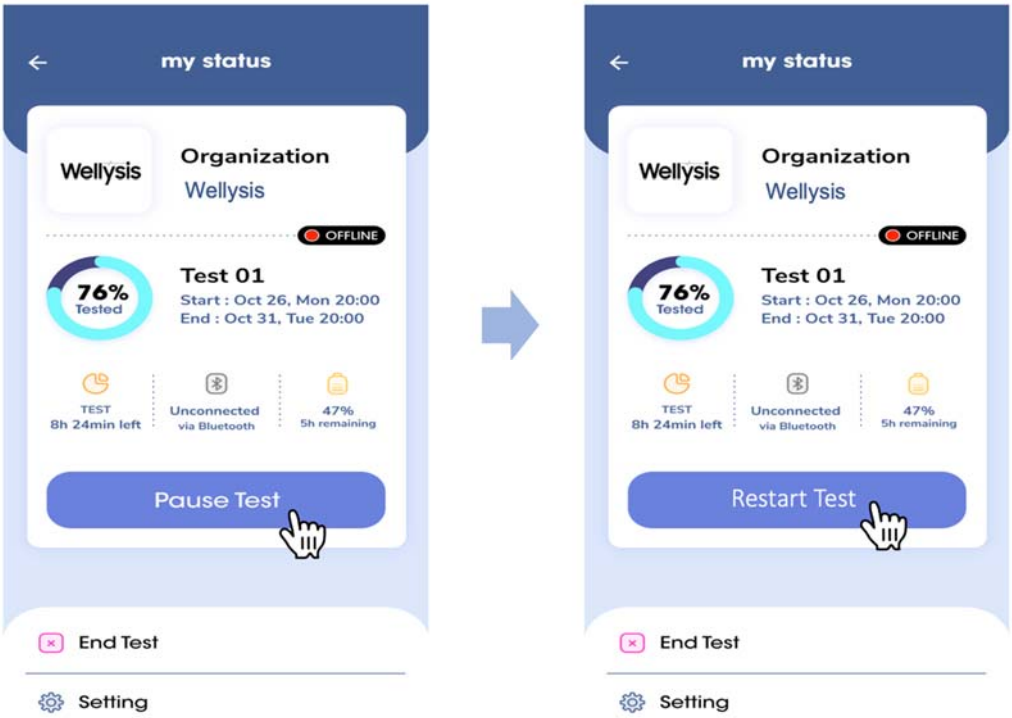
(6) Click on "Select activity" button to specify what activity was being performed when the symptom occurred.

(7) Click Confirm button to save the new Patient Diary.

3) Pausing and Resuming Test

3-1) Click on the "Pause Test" button in my status page to temporarily pause the test.

3-2) Click "Restart Test" to resume.



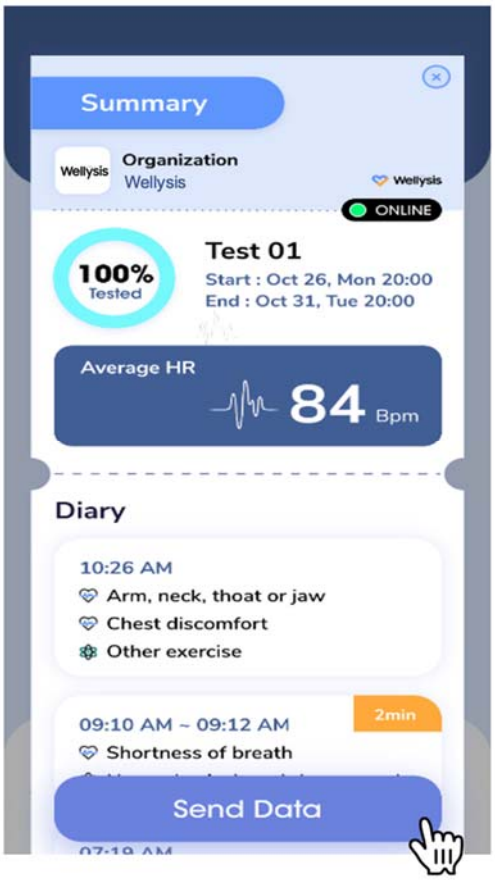
4) Completing Test

Click on the "End Test" button in my status page to complete the test.

5) Sending Data

For analysis of the test the ECG data needs to be sent to S-Patch Ex Web.

5-1) Click Send Data button.



4.3 Specifications

4.3.1 S-Patch Ex 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	DC 3V, Coin Battery (CR2032)
	Battery Life	100 Hr. (replaceable)
Hardware/ Software	F/W version	V1.5.0
	CPU	S1SBP6A (Cortex-M4F microprocessor)
	BLE	Nordic nRF52833(ARM Cortex-M4)

	IMU	ICM-42605
	Memory	W25M02GVZEIG (256MB)
	App(Android/iOS)	8 and above / 12 and above
	Language	English, Korean
	Optimized mobile devices	iPhone - 6, 6Plus, 6s, 6sPlus, 7, 7Plus, 8, 8Plus, XR, SE, SE2, 11, 11Pro, 12, 12Pro Samsung – Galaxy A7, A9, A9Pro, A30, A50, A21, A31, A51, A90-5G, Note9, Note10, Note10Plus, Note20, Note20Ultra, S9, S9Plus, S10, S10Plus, S20, S20Plus, S20Ultra
Physical Characteristics	Weight(Exc. Battery)	9g
	Dimension(Main Body1,2)	30*6(mm), 30*6(mm) [Diameter* Height]
	Dimension(Connect Cable)	110 ± 5 (mm)
Technical Characteristics	Heart Rate Range	30 ~ 240bpm
	Heart Rate Accuracy	30 ~ 120 ± 2bpm 120 ~ 240 ± 3bpm
	Linearity and Dynamic Range	± 10%
	Input impedance	≥10MΩ
	Gain accuracy	± 10%
	Gain stability	± 3%
RF	RF Information	2402 ~ 2480 HMz
	Max RF output Power	- 4.57 dBm

4.4 Error Message

Error Message	Situation	Solution
The server encountered an error. Please try again later. * Contact email : spatch.cardio@ wellysis.com	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. Please check your	When mobile device cannot access server due to network error	Re-try after moving to area with LTE or Wifi connection

network status		

4.5 Maintenance

For cleaning, gently wipe the S-Patch Ex with medical grade disinfectant. DO NOT immerse the S-Patch Ex in liquid. The S-Patch Ex is water resistant, but should be kept dry. This device does not have user serviceable components.
Do not disassemble, crush, puncture, short external contacts or circuits, dispose of in fire or water.

4.6 Specification of External Device Connection

The S-Patch Ex connects to an application running on a mobile device

A. S-Patch to Application Interface

1) Main Device / Mobile App interface
   Data format: Bluetooth
   Mobile Application: Android/iOS Application
   Device status information
   Device information (Bringing information when connecting to BLE)
   Battery information (Receiving information periodically)
   Data to Device – Data Channel
   Transmits data to the device

B. Solution Network Security

1) The Mobile Application has been tested to be secure against all currently known threats
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 the communication with security requirements defined in the BLE Protocol Stack.

C. User Responsibility for Security

– Connection of the S-Patch Solution to an unsecure IT-Network could result in previously unidentified risks to patients, operators or third parties;
– The responsible organization should identify, analyze, evaluate and control these risks;
– 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.

4.7 Daily Use

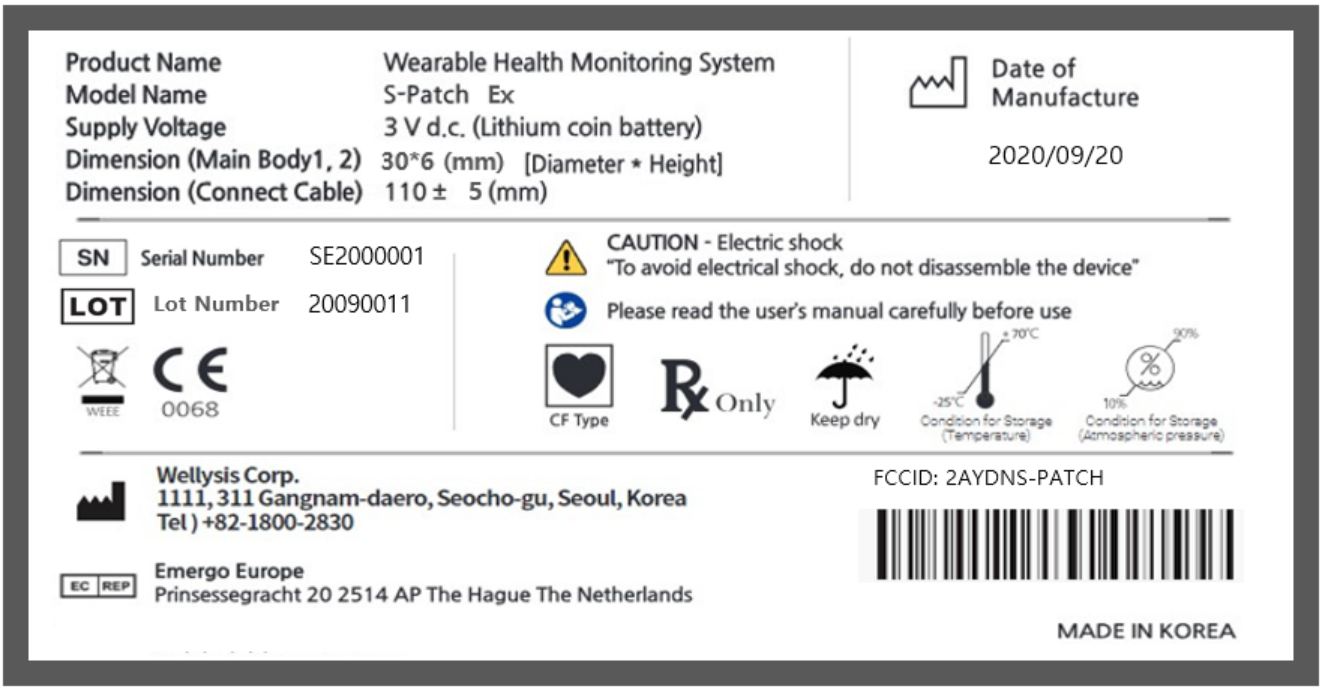
The S-Patch Ex is meant to be worn during normal daily activities, as well as at night while sleeping. However, the S-Patch Ex needs to be removed before the following activities:
-Showering, bathing, or swimming
-Traveling on aircraft
-Undergoing an MRI

1) To finish S-Patch app, push "BACK" button of Android or iOS device.
2) If "BACK" button is pressed again during 1 second, one more confirmation is required.
3) Tap "YES" to terminate the app.
4) Remove the S-Patch Ex and push the power button longer than 20 seconds to turn off the device.
5) When you are ready to put the monitor back on, attach the S-Patch Ex on recommended position. On the mobile phone application, resume monitoring

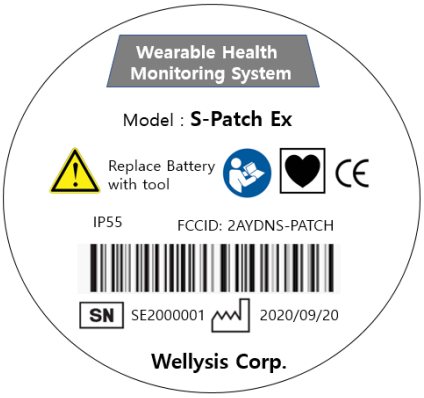
5 Labels and Packaging

5.1 Labels

5.1.1 Main Label (location: under the back of the box) (Size: 100 x 55 mm)



5.1.2 Label for module (Size: Φ26mm)



<Rear-side Label>

5.2 Packaging

5.2.1 Package List

Classifications	Components	Quantity
Main Box	S-Patch Ex module	1
	Electrodes	4 (4 Electrodes are in the 1 plastic bag)
	Quick Manual	1

5.2.2 Package Units

1) S-Patch Ex module
   Main module.
2) Electrodes
   4 Electrodes are in the 1 plastic bag.
3) Manual
   Korean or English
   ** If users request, the wellysis can provide the user manual in the requested language

5. Information on EMC

5.1 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-Patch Ex 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 Ex 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

5.2 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%.

5.3 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
			Portable and mobile RF communications equipment should be used no closer to any part of the S-Patch Ex, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
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	**Recommended separation distance** $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 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	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 deter-mined 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 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.

5.4 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=3Vrms	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.

5.5 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

5.6 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 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	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	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	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.

6. Expected Service Life time and Warranty

6.1 Product Warranty

- The product is guaranteed to be free of manufacturing defects and has a limited warranty for 1 year from the date of purchase.

  Damage or malfunction of the device to the following conditions are excluded from the warranty:
  - Normal wear and tear of the product from normal daily usage
  - Product damage due to improper storage
  - Product damage due to improper usage

7. Manufacturer Information

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