P94A000001A

AT-Patch

User Manual



This product is a disposable medical device.
Reuse is prohibited.

DUG-02-EU-EN Rev 1.0

08/2022

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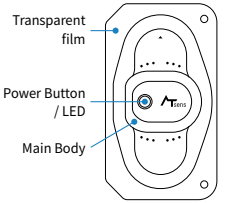
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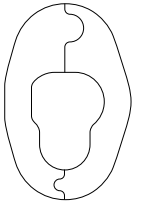
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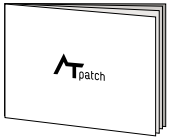
Product Components



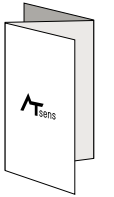
ATP-C130 (1EA)



Sub Patch (1EA)



Manual (1EA)



Symptom Note (1EA)

App



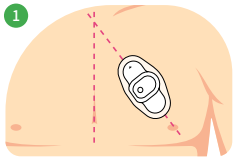
AT-Note

PC S/W (AT-Report) & Accessories Sold separately

PC S/W	Accessories	
		
AT-Report (ATR-C130) USB Memory (1EA)	Dedicated USB cable / ATCBL-120 (2EA)	BLE Dongle (1EA)

1) For a detailed description of the AT-Report, refer to the PC S/W user manual.
2) The PC S/W manual is in the USB Memory.

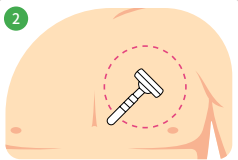
1



Checking the area to attach the device

Draw an imaginary line between the middle of the two clavicles and left nipple, and check the position to ensure the device is attached to the center of the area.

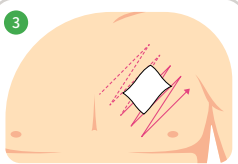
2



Shaving and exfoliating the device attachment area

If there is a lot of chest hair in the area where the device will be attached, use a razor to remove the chest hair and remove foreign substances such as dead skin cells.

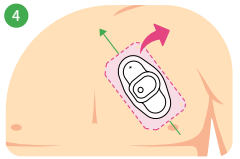
3



Cleaning the area where the device will be attached with alcohol

1) Clean the attachment area with an alcohol swab for at least 1 minute.
2) Clean with alcohol and dry for at least 2 minutes.

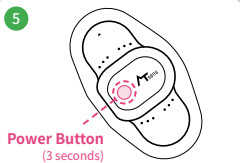
4



Detaching the Film & Attaching the device

Detach the device from the transparent protective film. And attach the device with the side marked with "▲Up" facing upwards.

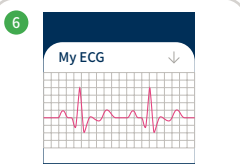
5



Turning on the power

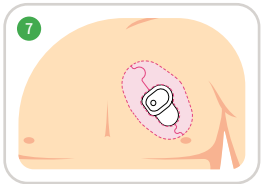
Press the power button of the device for more than 3 seconds and the color of the button will change to green, flash 3 times, and make a sound.

6



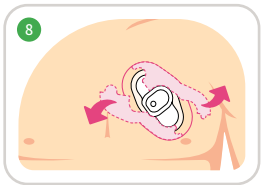
Checking the ECG signal

1) After attaching, check the signal status in AT-Note App.
(Reattachment 1~2 times possible if the signal would be poor.)
2) After confirming the signal, press the entire area of the device for at least 10 seconds so that the device adheres well.



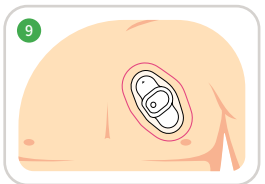
Attaching the Sub Patch

Put the Sub Patch on top of the attached device in the correct direction. After attaching the Sub Patch, press firmly on the entire surface of the device for at least **1 minute** to improve adhesion. Attach Sub Patch correctly at once. Reattachment can not be possible.



Removing protective tape

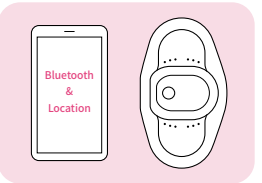
After attaching the Sub Patch, detach the protective tape from the base film slowly.



Checking the attachment of the device

Check if the device and the Sub Patch are attached well without loose areas. If there are unattached areas on the skin, press the base film with finger smoothly to be attached well.

Connect to App to record ECG signal



1. Bluetooth & Location service

Check if the Bluetooth and location service functions are activated to connect the device.

2. Connecting with the smartphone App (AT-Note) ⚠

After attaching the device, connect the device with the smartphone App (AT-Note) to check the ECG signal. **Must check the start of recording ECG signal.**

Turning off the power



Once the initial connection is checked, device is not terminated for the duration of use.

- It is impossible to physically turn it off. After the operation time, the button color turns red and the power turns off automatically after 3 beeps.

  * ATP-C130 : 14 days

- After use, the device must be returned to the hospital.
- The working status of the device can be checked through the App's real-time live Viewer.

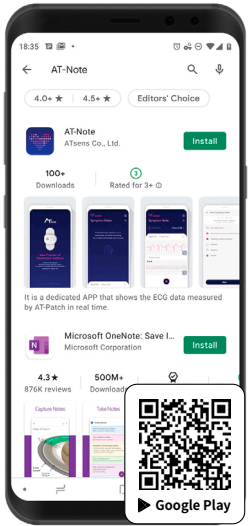
How to install the App

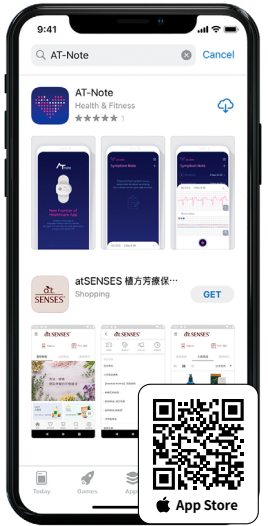
AT-Note
ATsens Co., Ltd.

For Android™ users :
Google play™ (https://play.google.com/store)

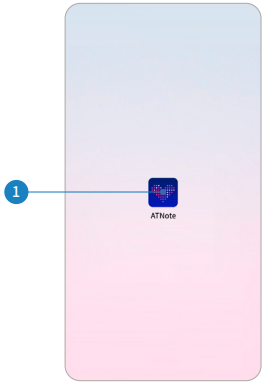
For iPhone® users :
App Store℠ (https://www.Apple.com/ios/App-store/)

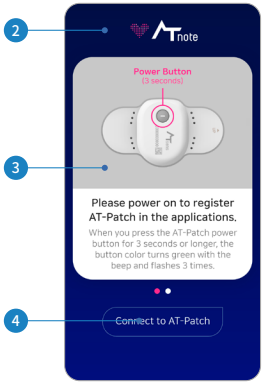
1. Please search “AT-Note”, “ATsens”, “AT note” in your usual Google Play™ Store or App Store℠, or scan the QR code
2. Install the App.
3. Complete the registration steps, then start using the App.
   - Supports : Android 5.0 or later / iOS 11.0 or later

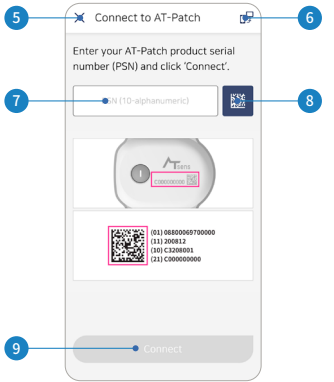




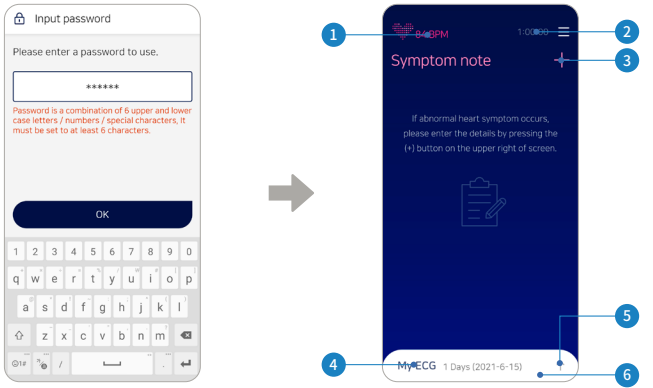
Screen with the App (AT-Note) Icon & Initial Run Screen



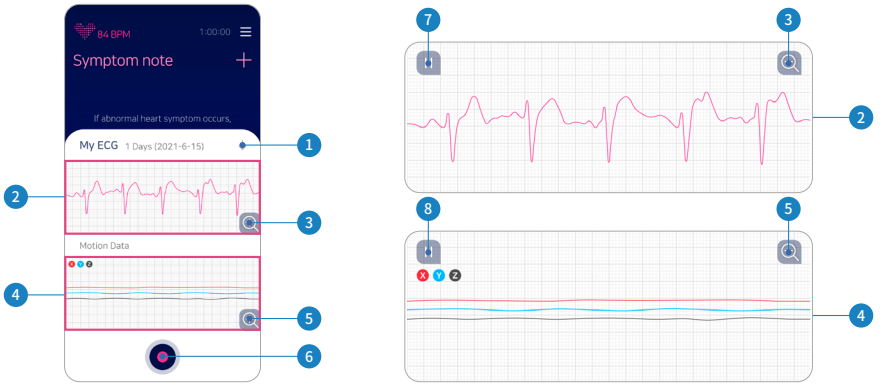




No	Description	No	Description	No	Description
1	App (AT-Note) Icon	4	Move to "Connect to device screen" button	7	PSN information input field
2	Intro screen	5	Cancel connecting to device icon	8	Scan data matrix icon
3	A guide to device connection	6	Symptom Note transmission icon	9	Connect to device button

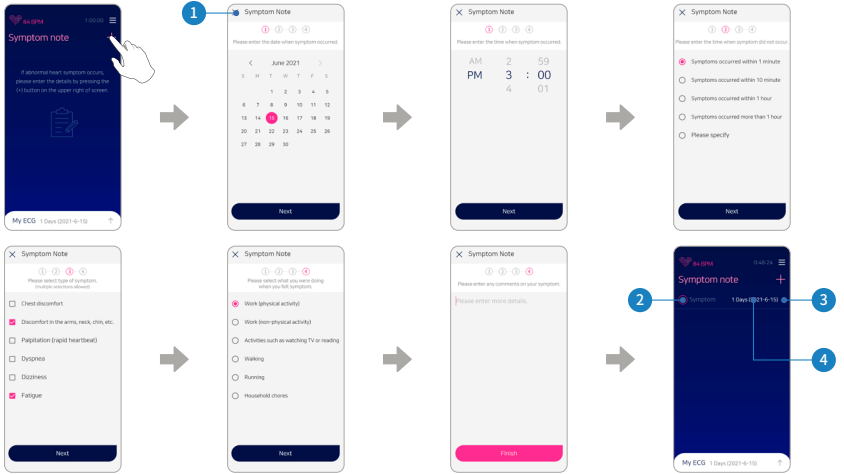


No	Description	No	Description
1	A section displaying heart rate (BPM) data output	4	A section displaying the Day number of using the App (AT-Note) and current date
2	Live on function can be used for 60 minutes per day	5	Icon to generate real-time ECG and 3-axis data output as graphs
3	Icon that leads to the Symptom Note entry screen	6	A section displaying the ECG and 3-axis data output through graphs in real time



No	Description	No	Description	No	Description
1	Stop generating real-time ECG and 3-axis data output icon	4	3-axis data graph output section	7	Pause ECG data graph icon
2	ECG data graph output section	5	3-axis data graph zoom-in icon	8	Pause 3-axis data graph icon
3	ECG data graph zoom-in icon	6	Record real-time data icon		

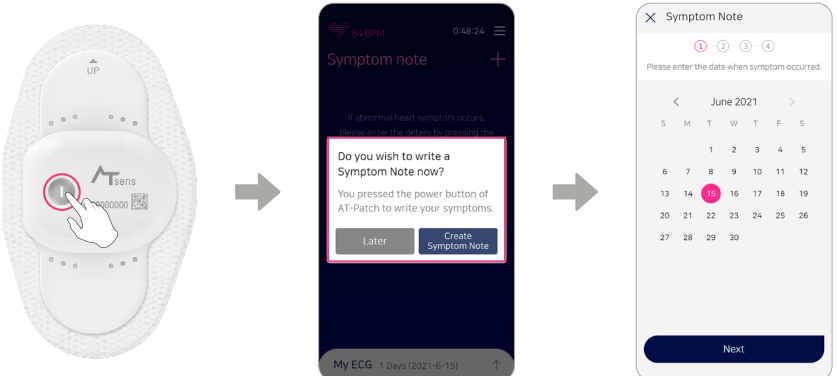
Making Symptom Note Entries Using the App (AT-Note)



No	Description	No	Description
1	Quit making Symptom Note entry icon	3	Symptom Note details icon
2	Symptom Note entry count	4	The Day number of using the App

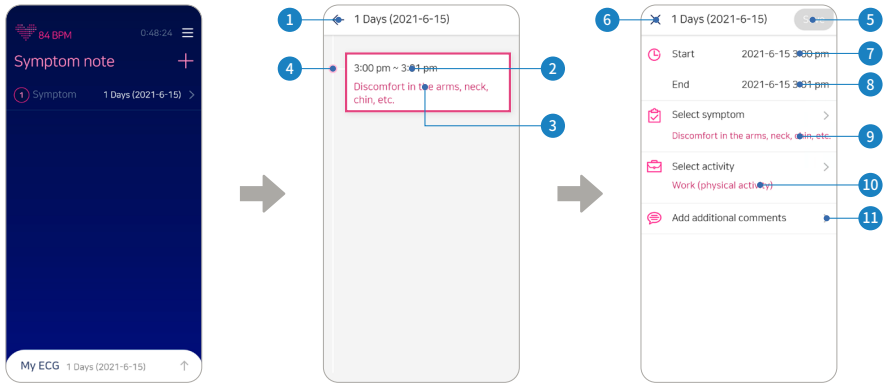
Making Symptom Note Entries Using the Device

Once the power button on the device is pressed for about 0.2 seconds causes the color of button to change and sound, and the App receives the event information from the device and a dialog box is displayed to ask whether to record the symptoms immediately in a pop-up window. If the “Later” is tapped, the Symptom Note entry count on the main page increases, but no new screen shows up. Once the “Create Symptom Note” is tapped, the first screen for making Symptom Note entry is displayed.



Press for about 0.2 seconds

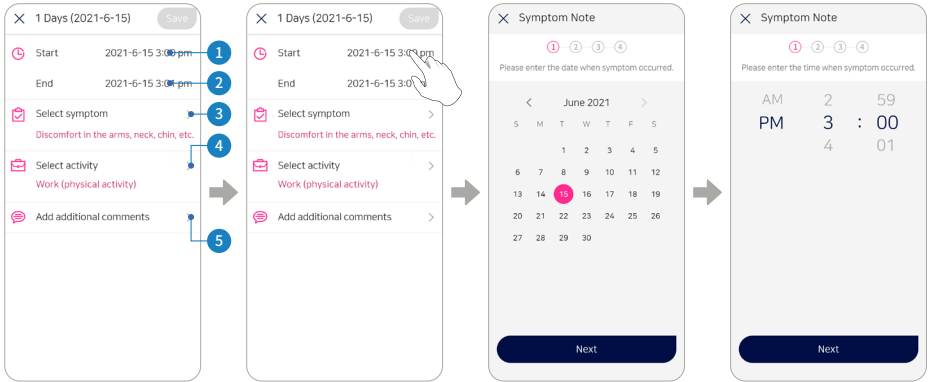
Viewing Details of Symptom Notes Registered at the App (AT-Note)



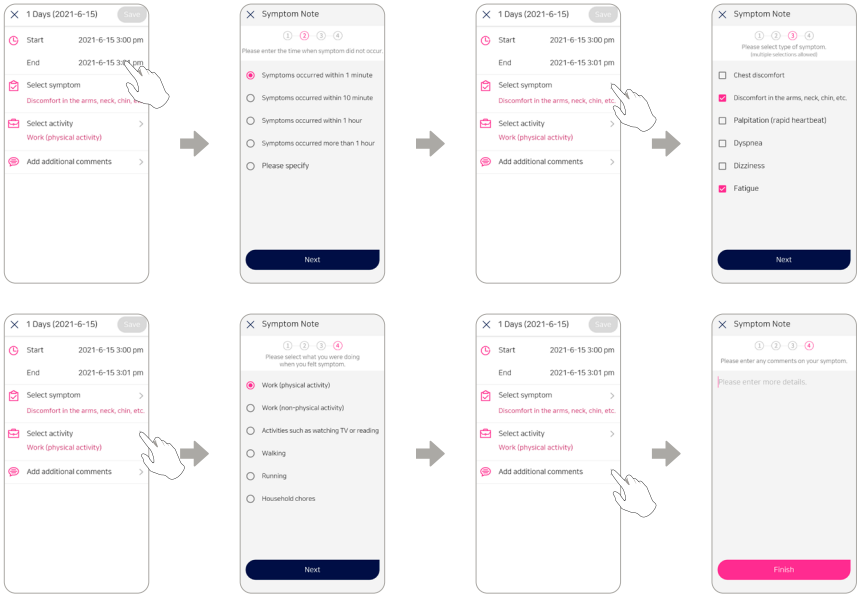
No	Description	No	Description	No	Description
1	Go Back icon	5	Save Symptom Note revision icon	9	Symptom type
2	Start time and End time of Symptom	6	Close Symptom Note details icon	10	Activity type
3	Symptom type	7	Start time of Symptom	11	Other explanation
4	Symptom Note entry completed / incomplete, and recorded ECG data display	8	End time of Symptom		

Symptom Note Revision Screen

Upon tapping each revision icon or revision icon area on a single entry of Symptom Note, the previously selected values for the items are displayed on the screen. Empty values of the Symptom Note entries through the device have to be entered by tapping the revision icon or revision icon area.

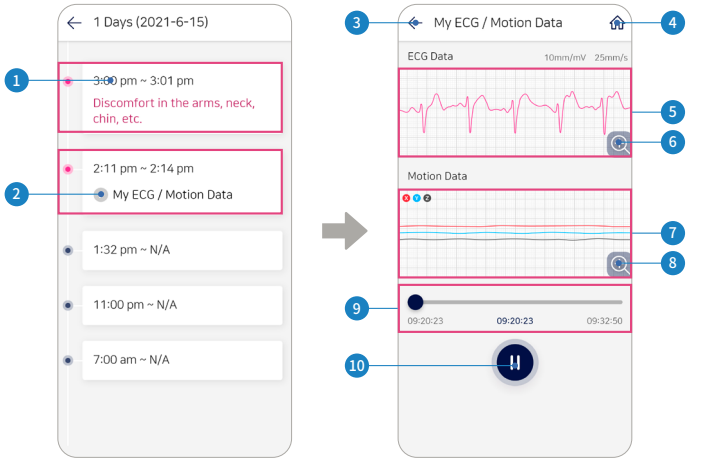


No	Description	No	Description
1	Start time of Symptom revision icon area	4	Activity type revision icon
2	End time of symptom revision icon area	5	Add other explanation icon
3	Symptom type revision icon		



Viewing Recorded Data

As shown in the red rectangular section, the recording data can be accessed through the screen that lists the registered Symptom Note entries for a Day number of using the App. The ECG recording data does not include Symptom Note contents, only ECG data. The ECG recording data viewing screen is displayed upon tapping the red rectangular section.



No	Description
1	ECG recording start time and end time
2	Move to ECG recording data viewing screen icon
3	Go Back icon
4	Move to Main Screen icon
5	ECG data graph output section
6	ECG data graph zoom-in icon
7	3-axis data graph output section
8	3-axis data graph zoom-in icon
9	Play Controller
10	Play / Pause

Contraindications

1) Do not use if you have current symptoms or medical history of skin cancer, rash, dermatosis, keloids, wounds, etc.

Adverse Event

Physician should advise patients to seek medical attention if either of the following occurs.

1) Mild rash
2) Allergic reaction
3) Skin irritation
4) Itchiness

Warnings

1) This product is for single use only. Reuse is prohibited. Reusing it may lead to malfunction and inaccurate results.
2) DO NOT attach to any other place than the recommended bodily location of Application.
3) Only authorized technicians are allowed to repair or disassemble Device.
4) Make sure to be fully aware of how to use the product, through sufficient training, before using it.
5) Avoid use at locations where wireless communication interference may occur (e.g., places where metallic hardware or electronic devices are frequently found).
6) This product cannot be simultaneously used with a defibrillator.
7) DO NOT expose to strong electromagnetic fields.
8) The device should not be used adjacent to or stacked with other equipment.
9) The device may be interfered with by other equipment, even if that other equipment complies with CISPR EMISSIONS requirements.
10) Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device. Otherwise, degradation of the performance of this equipment could result.
11) Cautions should be communicated to the patient.
12) All serious accidents related to the medical devices should be reported to the health authorities of the Member State where the manufacturer, user and patient are located.
13) This device is not intended for use by infants weighing less than 10 kg.

Precaution

1) Inappropriate Application and use of the sensor may result in inaccurate measurements, please avoid the below.
   - Excessive movement of the patient.
   - Application outside the recommended bodily locations.
   - To prevent signal abnormalities due to the state of the patient's skin, sufficient notice of use from physician must be obtained before use.
2) The following persons should consult physician before using the device.
   - Patients with sensitive skin or skin allergy.
   - Patients with wounds on the skin that contact the device.
   - Patients with cardiac pacemakers, cardiac defibrillators or other implantable electrical devices.
   - Pregnant women, breastfeeding mothers, infants or children.
3) Take caution to avoid getting liquid in the device, and also avoid the following.
   - Long-term exposure to water such as baths, swimming, etc.
4) Avoid letting the device come into contact with organic compounds like thinners or benzene.
5) Beware of strong shocks and vibrations.
6) Once the product is detached from the body, do not reattach it.
7) The smartphone on which the App is run must be one with a test report or a certificate issued by national or accredited offices.
8) The device needs special precautions regarding EMC and needs to be utilized according to the EMC information provided in the Electrical safety and compatibility section.
9) Portable and mobile RF communications equipment can affect medical electrical equipment.
10) If the device stops in the middle, see physician.
11) Measures to be taken when a cybersecurity issue occurs.
   - The manufacturer should be consulted if a cybersecurity issue occurs.
   ATsens Co., Ltd. : Tel. +82 70 5220 0220 / Fax. +82 70 8270 0738 / E-mail. sales@atsens.com

Clinical information

Intended Purpose

Device is intended to measure, analyze, and report electrocardiogram (ECG) information for long-term monitoring (up to 14 days) by attaching to the skin surface. It is used for patients with heart disease such as arrhythmia or patients with suspected heart disease. Reported ECG metrics include single lead analysis in beats, heart rate measurement and rhythm analysis. Used by patients as prescribed by physician or medical personnel.

Target Treatment Group

- Patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, presyncope, syncope, fatigue, or anxiety.
- Patients with heart disease such as arrhythmia.

Target User

The patient (AT-Note & Device)

Clinical Benefit

It measures patient electrocardiogram (ECG) information for a long-term monitoring, analyzes and reports measured data, and helps physician or medical personnel prescribe it.

Product Disposal

Disposal of Device and battery must comply with local waste disposal regulations. Non-compliance with waste disposal regulations may result in environmental pollution.
NOTE : The data stored within the device must be taken care of before disposal.

Conditions for use and Storage

Conditions for Use

1) Temperature range : 10°C ~ 45°C
2) Relative humidity range : 10% ~ 95%, non-condensing
3) Atmospheric range : 700hPa ~ 1060hPa

Conditions for Storage

1) Temperature range : -20°C ~ 55°C
2) Relative humidity range : 0% ~ 95%, non-condensing
3) Atmospheric range : 700hPa ~ 1060hPa
4) Keep dry and keep away from sunlight.

Specifications

	Item	Description
ECG	Type of Applied Part	BF type
	Sampling Rate	250 sample / sec
	Input Offset Dynamic Range	± 300mV
	Channel	1 channel
	ADC Resolution	10 bits
	Input Impedance	>10MΩ
	Frequency Response	0.67Hz to 40Hz
Electrode	AC impedance	Less than 3KΩ (10Hz)
RF	RF communication	2.4GHz BLE 4.2
	Effective Radiated Power	< 1mW
	RF Frequency Band of TX	2.4GHz
	Bandwidth of the Receiver	2400 ~ 2480MHz
Power Requirement	Power Supply	DC 3V, Coin Battery (CR2032)
Physical Characteristics	IP Classification	IP 57
	Total Size (L x W x H : mm)	84 x 48.8 x 8.5
	Main Body Size (L x W x H : mm)	31 x 39 x 7.8
	Sub Patch Size (L x W x H : mm)	104 x 68.8 x 0.05
	Weight (g)	Main Body : Below 12g Sub Patch : Below 1g

Electrical Safety and Compatibility

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The device 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 device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
Immunity Test	IEC 60601 Test and Compliance Level		Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV/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 %.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz		Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Radiated RF IEC 61000-4-3	Test Frequency	Level	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 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, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol :
	80 MHz - 2,7GHz 80% AM at 1 kHz	10 V/m	
	385MHz (Pulse Modulation 18Hz)	27 V/m	
	450MHz (FM ±5 kHz deviation 1 kHz sine)	28 V/m	
	710, 745, 780 MHz (Pulse Modulation 217Hz)	9 V/m	
	810, 870, 930 MHz (Pulse Modulation 18Hz)	28 V/m	
	1720, 1845, 1970, 2450 MHz (Pulse Modulation 217Hz)	28 V/m	
	5240, 5500, 5785 MHz (Pulse Modulation 217Hz)	9 V/m	
	30 kHz (CW)	8 A/m	
	134.2 kHz (Pulse Modulation 21.1 kHz)	65 A/m	
	13.56 MHz (Pulse Modulation 50 kHz)	7.5 A/m	

Symbols

Symbol	Description	Symbol	Description	Symbol	Description	Symbol	Description
	Manufacturer		MR unsafe	IPXX	Ingress Protection		Caution
KR	Date of manufacture and country of manufacture (made in Korea)		Atmospheric pressure limitation		Type BF Applied part		Separate collection for EEE
UDI	Unique Device Identifier		Humidity limitation		Direct Current	MD	Medical Device
#	Model number		Temperature limit	Rx only	Prescription Only Professional Use Only Not available without a doctor's prescription		Do not re-use
SN	Serial number		Keep away from sunlight		Use by It can be used up to the date stated by the manufacturer		Keep dry
	Refer to instruction manual / booklet		Do not use if package is damaged and consult instructions for use	CE	CE Marking of Conformity	EC REP	Authorized representative in the European Community / European Union
	Non-ionizing radiation						

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