Model: J21A

"Chiline" Blood Pressure Monitor

Instruction Manual

MOHW-MD-No. 000000

Please read the instruction manual carefully before using the product.

“This product involves the collection, processing and use of personal data, and shall comply with the regulations of the Personal Data Protection Act.”

1. Product Description

The Chiline Blood Pressure Monitor has an integrated system design in which a cellphone App is used to display measured results, and to search, manage and analyze data. To ensure accuracy, it is recommended to calibrate the device every two years. This product is compiled with IEC 80601-2-30: 2017, EN 1060-1, and EN 1060-3 standards.

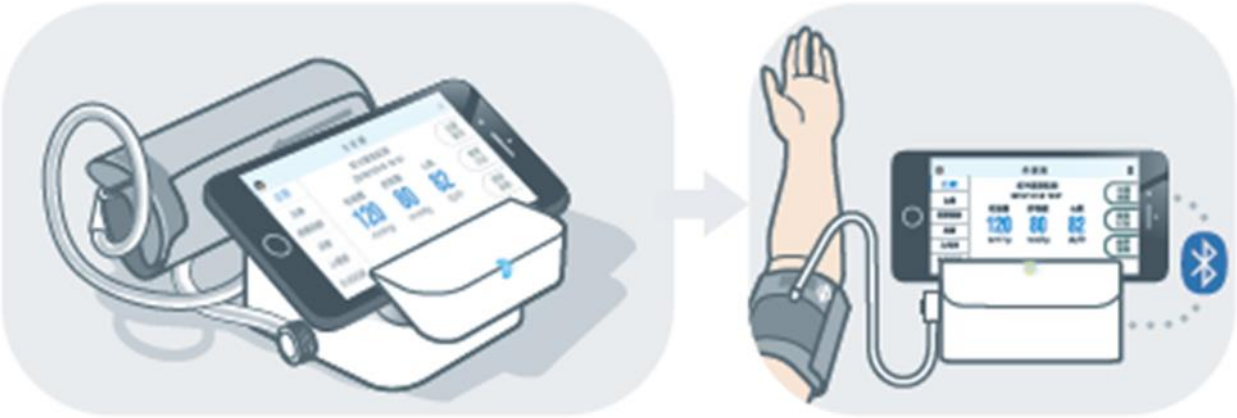
2. Product Features

1. Integrated system design: The device is connected with a cellphone app through which measured results and related information are displayed.
2. Suspected Atrial Fibrillation (AFib) detection: Atrial fibrillation is the irregular contraction of the upper chambers of the heart (atria). During this situation, blood might flow irregularly and lead to blood clots, which accompanies an irregular heartbeat. The device is equipped with the function of suspected AFib detection, when a suspected atrial fibrillation is detected during the measurement process, it will be displayed AFib reminder symbol in the measurement result.

   ※Note: If AFib reminder symbol prompt frequently when measuring blood pressure, it is strongly recommended that you seek medical attention as soon as possible for further examination.
3. Automatic cuff inflation: The cuff automatically inflates to an appropriate level based on the user's systolic blood pressure and the circumference of the arm. This feature prevents over inflation that causes discomfort.
4. Cuff detection: The cuff detection feature checks if the cuff is appropriately fastened. A cuff that is too loose or too tight may lead to inaccurate results.
5. Movement detection: The movement detection feature notifies the user that the result may be inaccurate when movement of the arm is detected.

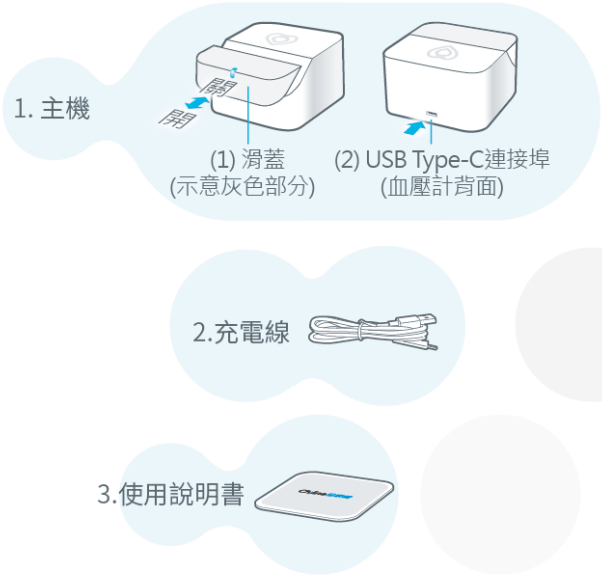
3. Application

Chiline Blood Pressure Monitor is a non-invasive blood pressure monitoring system. It uses the oscillometric method to measure an adult's systolic and diastolic blood pressure and heart rate and has a built-in detection function for suspected atrial fibrillation (AFib).



4. Contents

1. Chiline Blood Pressure Monitor main unit
   (1) Slider (gray in image)
   (2) Micro USB port (back of the unit)
2. Charging cable
3. Instruction manual



■ Arm cuff (optional wearing)

(1) Arm cuff (L)
Model: CD-2101

(2) Arm cuff (M)
Model: CD-2102

(3) Arm cuff (S)
Model: CD-2103

(4) Arm cuff (L) without D-ring
Model: CM-2101

(5) Arm cuff (M) without D-ring
Model: CM-2102

(6) Arm cuff (S) without D-ring
Model: CM-2103

5. Warnings

1. ***Do not adjust medications based on the results of this device. Take medications according to your physician's prescription. Only physicians are qualified to diagnose and treat hypertension.***
2. ***Do not use this device on an arm that is injured or under treatment.*** (***For example: mastectomy or lymphadenectomy)***
3. ***Do not use the arm cuff during an IV administration or blood transfusion. Do not wear the arm cuff when you have other medical electronic devices on your arm, or the device may not function properly.***
4. ***Do not use this device near any high-frequency surgical instruments, in an area where MRI or CT scan is present, or in an oxygen-enriched area.***
5. ***Do not use this product in flammable anesthetic gases mixed with air or in flammable anesthetic gases mixed with oxygen or nitrous oxide.***
6. ***Do not use this device on children under 12 or on anyone who is not able to express his or her thoughts.***
7. ***Do not use this device to measure anything other than blood pressure.***
8. ***Do not disassemble the device or the arm cuff, as doing so may lead to inaccurate readings.***
9. ***Do not forcefully bend the arm cuff or air tube. During measurement, do not press the air tube to avoid disturbing the bloodstream.***
10. ***Do not use the device outside of the intended conditions listed in "Product Specifications", as doing so may lead to inaccurate readings.***
11. ***Do not take a measurement right after smoking or drinking alcohol.***
12. ***Do not take a measurement when feeling exhausted.***
13. ***When removing the air cuff from the main unit, pull from where the air plug connects with the device. Do not forcefully pull at the cord itself.***
14. ***Do not inflate the air cuff when it is not wrapped around the arm.***
15. ***Movement of the body or having cold chills during measurement may lead to inaccurate readings.***
16. ***Only use the arm cuff provided. Using an arm cuff from a different brand may lead to inaccurate readings.***
17. ***The device may not be used in an area that is humid or near the water. Using it in such conditions may result in malfunction.***
18. ***Do not take a measurement immediately after having a meal. Wait for at least an hour before doing so.***
19. ***Do not take a measurement when the body temperature is above 38 degrees Celsius.***
20. ***Relax before taking a measurement. It is advised to rest for 15 minutes prior to taking a measurement. Keep an interval of 5 minutes between measurements for accurate readings.***
21. ***During the measurement, please relax and sit with your arms on the table and your back straight against the back of the chair. Do not cross your feet, sit up straight with your feet flat.***
22. ***Taking blood pressure too often may cause harm due to blood flow disturbance. Before using this device repeatedly, please confirm that the operation of the product will not cause long-term damage to blood circulation.***
23. ***It is forbidden to alter the frequency, boost the power, or alter the features and capabilities of the original design without the manufacturer's consent.***

6. Instructions

6.1 Before measuring

(1) It is recommended to charge the blood pressure monitor for more than 3 hours before first use.

(2) Download the free Chiline app (scan the QR code on the packaging or on the back of the instruction manual).

(3) Go to “Settings” in your cellphone to turn on Bluetooth.

(4) Slide the top slider to turn on the device.

(5) Open the Chiline app (main screen will look similar to the image on the right).

Main screen of the ChilineHo me Care App

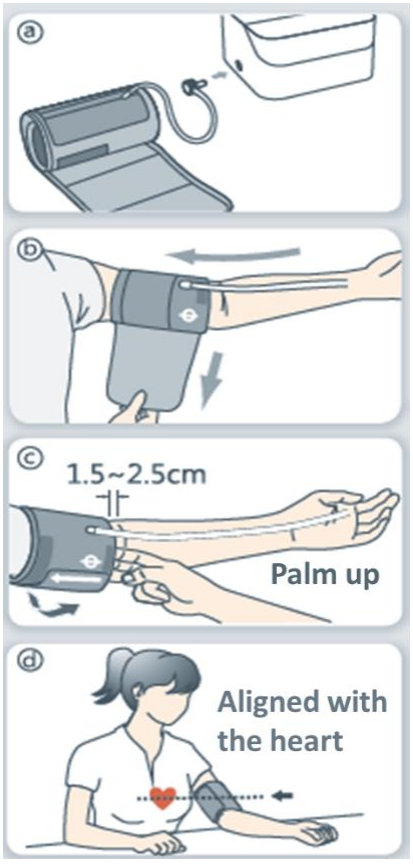
(6) Apply the arm cuff correctly as shown on the right image:

a. Insert the air plug in the main unit. Make sure it is securely plugged in.

b. Apply the cuff to the left arm with the palm facing upward. Make sure the air tube sits in the center of the arm.

c. Keep the bottom of the cuff 1.5 to 2.5 cm above the elbow. Leave a space wide enough to slide one to two fingertips underneath.
(Note: if you need an arm cuff with a different size, please contact the seller.)

d. Make sure the cuff is at heart level.



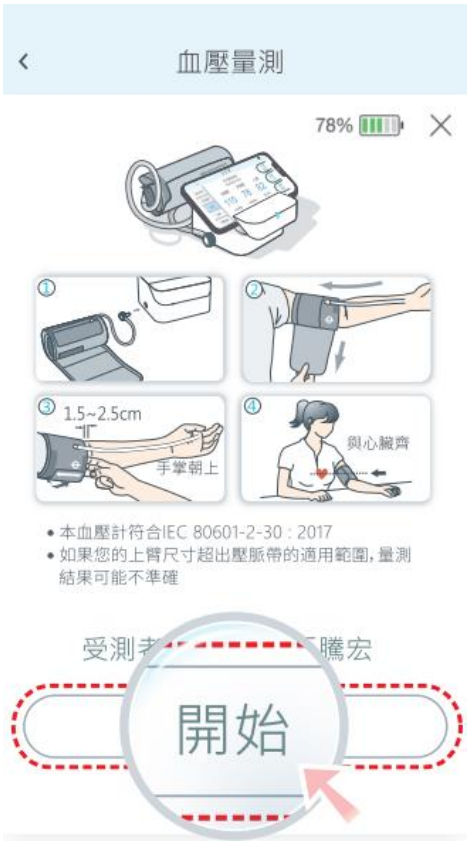
6.2 Begin measuring

(1) Make sure the arm cuff is correctly worn.

(2) Open the Chiline HomeCare App, then tap “Measure Blood Pressure” (bottom left image).

(3) The app will automatically search for the blood pressure monitor. The blue light on the monitor will remain on when the Bluetooth connection is successful.

(4) Tap “Start” (bottom right image) in the app to begin blood pressure measurement.



(5) The blood pressure monitor will automatically detect the user’s systolic blood pressure to determine the extent of cuff inflation. This feature avoids over inflation that can cause discomfort and lead to inaccurate readings.

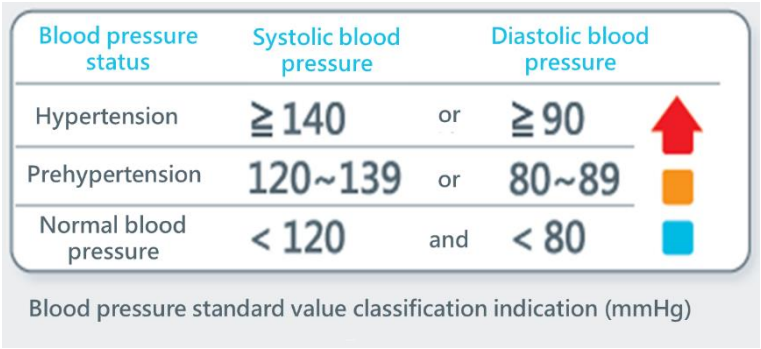
(6) After measuring, systolic and diastolic blood pressure readings as well as heart rate will be shown on the screen (bottom left image). The data will also be saved automatically.

(7) When finish measuring, slide back the slider to turn off the device (the device will turn off automatically after 3 minutes of inactivity).

Please note:

If there is an emergency anytime during the measurement, simply slide back the slider or tap "Stop" on the screen. The arm cuff will deflate immediately. If the app is closed or the cellphone is turned off, the device will still complete the measurement.

(8) The blood pressure guidelines issued by the Health Promotion Administration are as follows:



Disclaimer: The measurement data of this product is for medical diagnosis and analysis only. Any medical act should be performed by medical professionals and should be used after following the doctor's recommendation.

7. Product Specifications

Product Model	J21A
Product	Wireless Bluetooth Blood Pressure Monitor (wireless Bluetooth 4.1)
Blood Pressure Monitor Size	90mm(L) x 90mm(W) x 50mm(H)
Weight	310 g±5g
Power Supply	1.Lithium battery (2600mAh) 2. Power adapter(5V/2A DC，USB Type-A) Model: ADAPTER TECHNOLOGY CO., LTD. ATM012T-W050VU (optional purchase)
Arm Cuff /Model (Support size)	Arm Cuff (L) / CD-2101 (32~43 cm) Arm Cuff (M) / CD-2102 (22~32 cm) Arm Cuff (S) / CD-2103 (17~22 cm) Arm cuff (L) without D-ring) / CM-2101 (33~47 cm) Arm cuff (M) without D-ring) / CM-2102 (25~35 cm) Arm cuff (S) without D-ring) / CM-2103 (18~26 cm) **Choose the appropriate arm cuff : T The wrong arm cuff size may produce inaccurate measurement results.** - The appropriate upper arm size is marked on each arm cuff. (The upper arm dimension is the upper arm's external measurement from shoulder to elbow.) -To let you know if you're wearing the right cuff, the cuff is tagged with an indication label and the appropriate cuff range.
Storage Conditions/Transport Conditions	Temperature:-10°C ~ 60°C (14°F~140°F) Humidity:10% ~ 90%
Operation Conditions	Temperature: 10°C –40°C Humidity: 15%–85%
Atmospheric pressure range	700~1060 hPa
Blood Pressure Reading Range	30~260 mmHg
Blood Pressure Reading Error	±3 mmHg
Heart Rate Reading Range	40–199 bpm
Heart Rate Reading Error	±5%
product life cycle	2 year

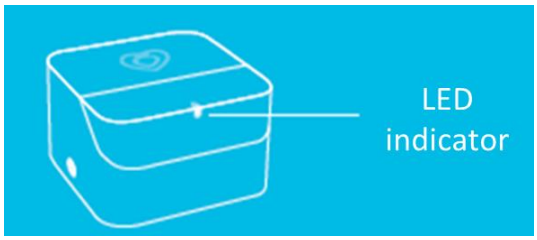
Note: Please use a transformer and charging cable that meet the regulations for charging.
This product uses built-in lithium battery. Users cannot replace the battery on their own.

Please recycle waste batteries

8. Device Notifications and Solutions

8.1 Duo-color LED indicator light

The LED indicator light (location per image below) provides two colors for indication: blue and green.



(1) When Bluetooth connection is on, blue light remains on.
(2) If the device is on while charging, green light flashes every 1.5 seconds (on for 0.5 second, off for 1 second). If the device is on when fully charged, green light remains on.
(3) If the device is off while charging, green light flashes every 3.5 seconds (on for 0.5 second, off for 3 seconds). If the device is off when fully charged, green light shuts off.
(4) Green light remains on when the slider is open, indicating that the device is on.
(5) Green light shuts off when the device is off.

8.2 Troubleshooting

Please follow the below solutions for each problem.

Displayed message and solutions	Causes
No device found. Please ensure the device is turned on. (If this error persists, please read the manual or contact customer service.)	1) Device is off. 2) Device has been inactive for more than 3 minutes. 3) The distance between device and cellphone is out of range of connection. 4) Bluetooth is off.
The device has been disconnected. (If this error persists, please read the manual or contact customer service.)	
Unable to connect to the device (If this error persists, please read the manual or contact customer service.)	
Due to the following reason, it is recommended to measure again: Lower end of the cuff and the tube are not positioned correctly near the bend of the elbow.	Error during measurement. Position the cuff correctly around the arm. Make sure the air plug is securely plugged in.
Due to the following reason, it is recommended to measure again: -Blood pressure values beyond device range (30-260 mmHg) -Heart rate value beyond device range (40-199 bmp)	Measured value beyond device range
Due to the following reason, it is recommended to charge the device and measure again: Low battery. Measurement cannot be completed.	Low battery. Measurement cannot be completed.

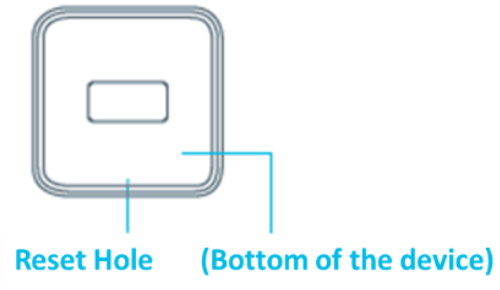
8.3 Technical issues

Please follow the below solutions for each technical issue.

Displayed message and solution	Cause
Error: **E1** Air leak in the cuff. Contact customer service.	Air circuit abnormality
Error: **E2** Inflation error. Contact customer service.	Inflation over 300 mmHg
Error: **E3** Unable to save data. Contact customer service.	Memory parameters error of the device
Error: **E4** Device error. Contact customer service.	Persistent error of the device

8.4 Reset

When there is a malfunction and the above solutions do not work, use a needle-like object to press into the reset hole (right image). The LED light will disappear for one second then reappear. If the problem persists after resetting, please contact customer service. Do not disassemble the device on your own. The warranty is void if the device has been disassembled



9. Other

9.1 Cleaning methods: Please clean this product as follows before each use.

Part	method
Main unit	For daily cleaning, please use a dry wipe or 75% alcohol or 1:50 diluted Bleach to wipe the surface of this product.
Arm cuff	For daily cleaning, please use a soft cloth with water or 75% alcohol or 1:50 diluted bleach to wipe the inner part of the cuff (in contact with the skin), and then air dry the cuff.

9.2 About the battery

(1) This product is a built-in, non-replaceable lithium battery, users should not replace or repair it by themselves, which may lead to product safety hazards.

a) To avoid the risk of fire or burns, do not disassemble, impale, crash, or dispose of the battery in fire or water; the battery may rupture, explode, or release dangerous chemicals.

b) When the battery is not being charged properly, gives a foul odor, or has a change in shape, stop using the battery and return the device to the manufacturer. Only authorized engineers are permitted to disassemble the device. Rechargeable lithium battery with the same model as the one provided by the original manufacturer must be used.

(2) It requires about 3 hours to charge the device battery from 0% to 100%.

9.3 Symbols

Symbol	Description
	Carefully read the instruction manual before using the product.
	Protection level : BF
	National Communication Commission (NCC)
	Recycling information. This product contains electronics and electronic components that may harm the environment. Do not dispose of the product with other general waste. Recycle the product following applicable local laws and regulations.
	Radiofrequency radiation hazard warning symbol
	Serial number
	Direct current
	Manufacturing date
	Manufacturer

Note:

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.

9.4 Manufacturer statement

9.4.1 Guidance and manufacturer's declaration—electromagnetic emissions

The device is intended for use in the electromagnetic environment specified below. The user must ensure that the device is used in such environment.

Emission test	Compliance	Electromagnetic environment—guidance
Radiofrequency 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.
Radiofrequency 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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	N/A	

9.4.2 Recommended distance between portable/mobile RF communications equipment and Chiline Blood Pressure Monitor

Chiline Blood Pressure Monitor is intended for use in an environment in which radiated RF disturbances are controlled. The user can help prevent electromagnetic interference by maintaining a minimum distance between portable/mobile RF communications equipment and the Blood Pressure Monitor as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Distance according to frequency of transmitter (m)		
	150 kHz–80 MHz $d = 1.2\sqrt{P}$	80 MHz–800 MHz $d = 1.2\sqrt{P}$	800 MHz–2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum not listed, the recommended distance d in meters (m) can be determined 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:

- At 80 MHz and 800 MHz, the distance for the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

9.4.3 Guidance and manufacturer's declaration—electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The user must ensure that the device is used in such environment.

Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment—guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2, 4, 8, 15 kV air	±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%. Try to use the device in the environment specified. If the condition of the environment cannot be determined, other preventive measures must be taken, such as using an antistatic device, discharging static electricity from the

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment—guidance
			body or wearing antistatic clothing.
Electrical fast transient/burst IEC 61000-4-4	±2 kV ±1 kV for input/output	±2 kV ±1 kV for input/output	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5, 1 kV line(s) to line(s);	±0.5, 1 kV line(s) to line(s);	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T for 0.5 cycle (1 phase) 0% U_T for 1 cycles 70% U_T for 25/30 cycles (50/60 Hz) 0% U_T for 250/300 cycles (50/60Hz)	0% U_T for 0.5 cycle (1 phase) 0% U_T for 1 cycles 70% U_T for 25/30 cycles (50/60 Hz) 0% U_T for 250/300 cycles (50/60Hz)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power interruption, it is recommended that the device is powered by an uninterruptible power source or a battery.
Power frequency (50/60 Hertz) magnetic field IEC 61000-4-8	30 A/m (50 or 60 Hz)	30 A/m at 50 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: UT is the AC mains voltage prior to application of the test level.			

9.4.4 Guidance and manufacturer's declaration—electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The user must ensure that the device is used in such environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment—guidance
Conducted RF IEC 61000-4-6	3 Vrms at 0.15 – 80 MHz & 6V at ISM Frequency	3 Vrms (V1=3) at 0.15 – 80 MHz & 6V at ISM Frequency	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** $E = \frac{6}{d}\sqrt{P}$
Radiated RF IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz 80% AM at 1kHz	10V/m 80 MHz to 2.7 GHz 80% AM at 1kHz	Recommended 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 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 80 MHz and 800 MHz, the higher frequency range applies.
Notes 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 and AM and FM radio broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment from fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures are required, such as reorienting or relocating the device.

[b]Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

9.5 FCC Statements

1. Note: 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 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. Any changes or modifications not expressly approved by the party responsible for compliance could void your authority to operate the equipment.

3. This product is based on SAR assessment and the user manual must have the following warnings “This device meets the government’s requirements for exposure to radio waves. This device is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy set by the Federal Communications Commission of the U.S. Government.

The exposure standard employs a unit of measurement known as the Specific Absorption Rate, or SAR. The SAR limit set by the FCC is 1.6 W/kg. Tests for SAR are conducted using standard operating positions accepted by the FCC with the EUT transmitting at the specified power level in different channels. The FCC has granted an Equipment Authorization for this device with all reported SAR levels evaluated as in compliance with the FCC RF exposure guidelines. SAR information on this device is on file with the FCC and can be found under the Display Grant section of www.fcc.gov/oet/ea/fccid

Installation Requirements:

Cellphone requirements:

Android operating system
Supports low-power Bluetooth data transfer
Android 10 or later

Apple iOS
Supports low-power Bluetooth data transfer
iOS 13 or later

※ For a list of mobile devices that work with it, please visit the official website.www.chilinemd.com.tw

※ Users download and install the "Chiline Home Care APP", and must electronically sign the user agreement and privacy policy consent form before using it.

Data transfer
Bluetooth mode: This product (main unit) will transfer data via Bluetooth to the Chiline mobile app. The app will then upload data to the Chiline Health Management Platform (a cloud platform).

Wi-Fi mode: This product (main unit) will transfer data via Wi-Fi directly to the Chiline Health Management Platform (a cloud platform).

Product Owner and Address:
Inventec Appliances Corporation
1F, No. 37, Wugong 5th Road, New Taipei Industrial Park,Wugu District, New Taipei City, Taiwan, R.O.C.

Physical Manufacturer and Address:
Inventec Appliances Corporation
4F, No. 37, Wugong 5th Road, New Taipei Industrial Park,Wugu District, New Taipei City, Taiwan, R.O.C.
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