

User Manual

Holter Monitor

Model name : mobiCARE-MC200M
mobiCARE-MC200ML
mobiCARE-MC200M7
mobiCARE-MC200ML7



seers

Doc. No. : ST-UM-MC200Ms-HA[E]

Vev. No. : 1.0v

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1. Product Introduction

1.1. Intend of Use

- mobiCARE-MC200M/mobiCARE-MC200ML/ mobiCARE-MC200M7/ mobiCARE-MC200ML7 (hereinafter "mobiCARE-MC200M series") is a light-weight electrocardiogram (ECG) and heart rate (HR) monitoring device with accompanying software. The mobiCARE-MC200M series operates wirelessly, and due to compact size is unobtrusive during daily activity. The mobiCARE-MC200M series continuously measures ECG and HR signals and measures the change in impedance for respiration rate and electrode status. And also, if necessary, measures the change in movement of the person with the product attached using the IMU sensor, and then stores measured data on the memory. Simultaneously, mobiCARE-MC200M series streams digitized signals to a mobile gateway device equipped with the mobiCARE Cardio Hospital App /mobiCARE Cardio Diary App.

At the end of ECG recording, they upload measured data to a secure cloud portal via PC uploader program. After data upload takes place, physicians can access and review their patients' ECG data remotely via the mobiCARE Cardio Web.

The difference between four models is length of the 'Connect Cable' and size of the 'Coin Battery'. The length and size of the mobiCARE-MC200M is 180mm & CR2450R, mobiCARE-MC200ML is 250mm & CR2450R, mobiCARE-MC200M7 is 180mm & CR2477, mobiCARE-MC200ML7 is 250mm, CR2477, Others are both same.

Model name	Cable length	Battery size
mobiCARE-MC200M	180mm	CR2450R
mobiCARE-MC200ML	250mm	CR2450R
mobiCARE-MC200M7	180mm	CR2477
mobiCARE-MC200ML7	250mm	CR2477

[Model difference]

The mobiCARE-MC200M series is intended to be used with direction from trained medical professionals in accordance with the user manual.

- Product name : Cardiac Monitoring System
- Model name : mobiCARE-MC200M / mobiCARE-MC200ML /

- Manufacturer : Seers Technology Co., Ltd.

1.2. Intended purpose of the device

Intended Use

The mobiCARE-MC200M series is a Heart/Cardiovascular Disease 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.

Indication for use

Arrhythmia

1.3. Marks and Symbols

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
10		Temperature limit
11		Humidity limitation
12		Authorized European Representative address
13		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 unsafe

1.4. Intended Patient population

- 1) Age : ALL
- 2) Weight : ALL
- 3) Health :
 - (1) Do not use Patients with artificial cardiac pacemaker, cardioverter defibrillator, or other implantable electric devices.
 - (2) Do not use for pregnant women or breast-feeding mothers
 - (3) To be used at physician discretion on patients if patient presents current sign or medical history of skin cancer, rash, skin disorder, keloid, and/or any injury.
- 4) Nationality : Not limited
- 5) Patient state : Not limited

1.5. Intended part of the body or type of tissue applied to or interacted with

- 1) Intended part of the body : Near Heart on the BODY
- 2) Type of tissue : Skin

1.6. Intended user profile

1) Education

- Minimum :

(1) Main unit / Application : Patient with at least 10 years education can use the product alone, and patient without at least 10 years education (ex, child, etc.) or patient who need help (ex, senior) can use it under the care of their parents or guardian

(2) Web software : Those who have a professional license

- Maximum : No maximum

2) Knowledge

- Minimum : It is necessary to understand the numerical values and the overall description in Korean or English manual for ECG main unit and Mobile App. Medical knowledge for Web software to analysis

- Maximum : No maximum

3) Language understanding

- Be able to understand the numerical values and general technical information presented in the user manual written in Korean or English

4) Experience

- No special experience needed and no maximum for ECG main unit and Mobile App.

- Experience need to analyze the cardiac monitoring

5) Permissible impairment

- Mild reading vision impairment or vision corrected to log MAR 0.2(6/10 or 20/32)

- Impaired by 40% resulting in 60% of normal hearing at 50Hz to 2kHz

6) Others

(1) At least the electrocardiogram graph must be confirmed

(2) At least you need to install the app on your phone and use the installed app

- (3) At a minimum, the viewer program must be installed on the computer and the installed program must be available.

1.7. Use environment

1) Environment

- General : Home, Hospital environment, Indoor, Outdoor

- Physical

(1) Temperature : 5 ~ 40°C

(2) Relative Humidity : 10-95%

(3) Atmospheric pressure : 700-1060hPa

2) Frequency of use

- 24hours per a day (continuously)

3) Mobility

- Portable(Hand-held) equipment

1.8. Operating principle

mobiCARE-MC200M series records every heartbeat. mobiCARE-MC200M series automatically detects an arrhythmia, the mobiCARE Cardio App transmits information to mobiCARE Cardio Web for analysis

2. Medical Safety

2.1. General

- 1) Store in climate controlled environments (parameters specified in section 1.4)
- 2) This product is a medical device that contains electronics and batteries. Please dispose of it according to local regulations. Contact the distributor for more information..
- 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, misuse, 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) Use of accessories other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

2.2. Safety

- 1) A healthcare professional should explain the proper use of the device to a patient
- 2) Use this device under a health professional'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.
- 8) DO NOT modify this equipment without authorization of the Seers Technology Co., Ltd. Any repair or maintenance service performed by non-authorized personnel immediately voids all warranty and liability claims. Maintenance services performed improperly can cause system malfunctions that may put the operator and patients at risk.
- 9) There is possibility that infant or child may be strangled by cable. Please keep the device away from reach of infant or child.
- 10) Please be aware that children may be choked by swallowing the small parts. Please keep the device away from reach of infant or child.
- 11) If the cable continues to be twisted, you may get inaccurate results. Recommend to check whether the tubing is kinked before use.
- 12) Patients with artificial cardiac pacemaker, cardioverter defibrillator, or other implantable electric devices.
- 13) Do not use the case that a current sign or medical history of skin cancer, rash, skin disorder, keloid, and/or any injury.

2.3. Contra-Indication

- 1) Do not use for patients with symptomatic episodes where variations in cardiac performance could result in immediate danger to the patient
- 2) Do not use for patients with known history of life threatening arrhythmias
- 3) Do not use in combination with external cardiac defibrillators or high frequency surgical equipment near strong magnetic fields or devices such as MRI
- 4) Do not use on patients with neuro-stimulator, as it may disrupt the quality of ECG data
- 5) Do not use on patients who do not have the competency to wear the device for the prescribed monitoring period.

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) -25 °C to + 5 °C , and
- 2) +5 °C to + 35°C at a relative humidity up to 90%, non-condensing;
- 3) >35°C to 70°C at a water vapour pressure up to 50hPa

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.

2.4.4. Conditions for Usage and Storage of Electrode

- 1) According to Manufacturer inspection of Electrode

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. If the battery is left unused for a long time, there is a danger of battery leakage.
- 3) Please ensure hands are clean and dry when handling the mobiCARE-MC200M series
- 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 Electrode

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
- 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

2.6.4. How to supply

- 1) Manufacturer recommends to use the electrode introduced in this document
- 2) If use the replacement, manufacturer recommends to use the CE Marked electrode.

2.7. Warning

MR-unsafe!

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

- 1) The device may present a risk of projectile injury due to the presence of ferromagnetic materials that can be attracted by the MR magnet core.
- 2) Thermal injury and burns may occur due to the metal components of the device that can heat during MR scanning.
- 3) The device may generate artifacts in the MR image
We are not intended to be used together with other product, and that is not assessed about safety. Therefore, we recommend to use the device as manufacturer's requirement.

Warnings

- 1) Do not use on patients with known allergic reaction to adhesives or hydrogels or with family history of adhesive skin allergies. Patient may experience skin irritation.
- 2) Do not reuse on multiple patients. It is a single patients use device. Reuse will cause incorrect patient data and patient may experience skin irritation.
- 3) Do not use on patients residing in areas with limited to no cellular reception.
- 4) No modification of this equipment is allowed.

Precaution

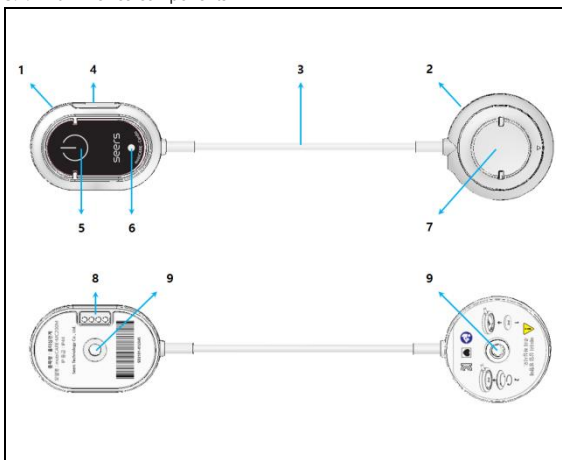
- 1) The system includes temperature and humidity limitations. If exposed, patients may experience degradation of adhesive performance causing the device to slip or fall off during the patient wear duration.
- 2) The system has a shelf life date. Use of expired device may cause a degradation of ECG signal quality and/or low battery condition.
- 3) Do not use the system if package is damaged. Device may not perform as intended.
- 4) Safety and effectiveness of the system on pediatric patient (younger than 18 years old) has not been established.
- 5) Keep device and packaging away from young children. Contents may be harmful if swallowed. Patch contains button cell batteries that are not accessible during normal use but, if exposed, are known choking hazards and may cause severe tissue injury if ingested.
- 6) Safety and effectiveness on patients receiving any form of pacing therapy has not been established. Paced cardiac rhythms may not be accurately detected and may be incorrectly classified
- 7) Registration errors may result in limited functionality or erroneous ECG reporting. Utmost caution should be applied to ensure that patient registration is accurate and complete.

2.8. Side-Effect

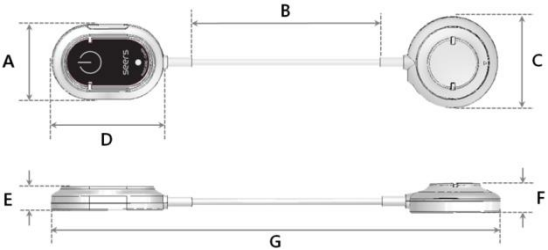
Skin reaction.

3. Components and Installation

3.1. Main Device components

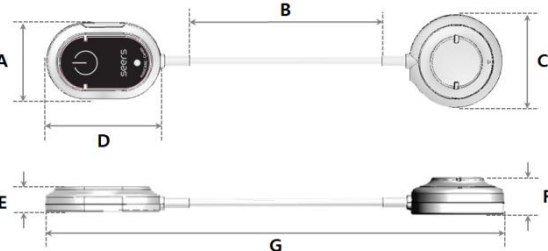


Label	Name	Description
1	Main body	A body including the mainboard
2	Battery body	A body to insert the battery
3	Connecting cable	Connecting cable between two bodies It differs between two model; mobiCARE-MC200M : 180mm mobiCARE-MC200M7 : 180mm, mobiCARE-MC200ML : 250mm mobiCARE-MC200ML7 : 250mm
4	SOCKET	A socket for Memory card
5	Button	Power on/off and additional function (Symptom, BLE advertising) button
6	Status indicating LED	Flashing LED lamp indicating the status
7	Battery cover	Battery cover
8	Insert pin	Terminal for downloading data
9	Electrode mounting hole	Hole for connecting ECG electrodes

								
모델명	A	B	C	D	E	F	G	중량
	단위 : mm							단위 : g
mobiCARE-MC200M	32	180	39	48	10	12.8	285	20
mobiCARE-MC200ML	32	250	39	48	10	12.8	355	22

(Without Battery)

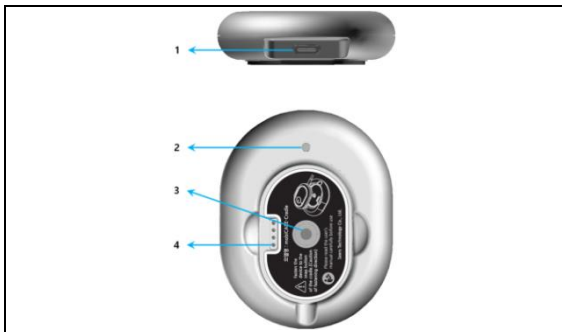
(tolerance $\pm 10\%$)

								
모델명	A	B	C	D	E	F	G	중량
	단위 : mm							단위 : g
mobiCARE-MC200M7	32	180	39	48	10	15.5	285	21
mobiCARE-MC200ML7	32	250	39	48	10	15.5	355	23

(Without Battery)

(tolerance $\pm 10\%$)

3.2. Cradle



Label	Name	Description
1	USB CONNECTOR	USB Connector to connect to PC
2	Power LED	Displays the USB power connection status
3	DEVICE mounting area	A part to mount the body Mount with the cable direction at the bottom
4	DOWNLOAD pin	A terminal to download data by contacting the insert pin of the main body

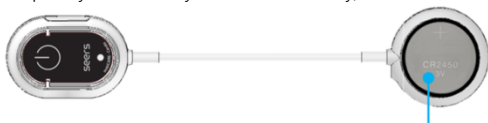
3.3. Component

 <Battery>		 <Battery>	 <Open Tool>
Label	Name	Description	
1	Battery	Power supply for mobiCARE-MC200M series. DC 3V Coin Battery. Battery is replaceable. mobiCARE-MC200M : CR2450R	

		mobiCARE-MC200ML : CR2450R mobiCARE-MC200M7 : CR2477 mobiCARE-MC200ML7 : CR2477
2	Open Tool	Used to open the Battery Cover

3.4. How to install mobiCARE-MC200M series

- 1) Download the Seers mobiCARE Cardio Hospital/Diary App from Seers Technology mobile app download link
(Please access the download URL provided by your service provider to download the mobile app.) The device must support Bluetooth Low Energy.
- 2) Install the downloaded file on user's mobile device.
- 3) Insert battery to Battery body of mobiCARE-MC200M series (Check the polarity of the battery and insert it correctly).



Insert the coin battery (CR2450R or CR2477, 3V) as shown

First, release the Battery cover on Battery body using Tool.

Second, open the Battery cover of Battery body and insert the battery.

Lastly, close the Battery cover and lock the Battery cover.



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.

3.5. Precautions before use

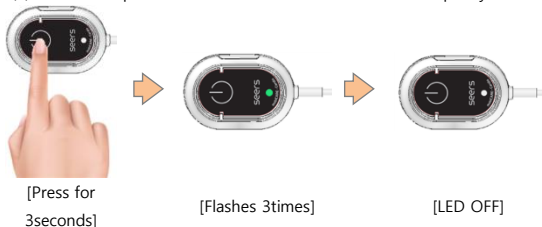
- 1) Before operating this product, please read the user manual.
- 2) Confirm that there are no problems with using the product according to the product precautions.
- 3) This device can be used for everyday activities as well as during sleep. However, you should stop using and remove the device if;
 - Bath or swim
 - Aircraft boarding
 - Taking MRI
 - Taking CT, X-ray

4. How to use mobiCARE-MC200M series

4.1. How to use

1) mobiCARE-MC200M series ON

- (1) With mobiCARE-MC200M series turned off, press the power button for about 3 seconds.
- (2) Release the power button when the status LED flashes quickly 3 times.



2) mobiCARE-MC200M series attachment

(1) Attaching electrodes

- ① Prepare a disposable electrode with a diameter of 4mm
- ② Attach disposable electrodes to each side of the body as shown below

Attaching electrodes

Attaching electrodes



(2) Attaching main body

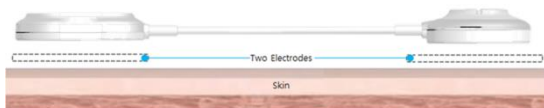
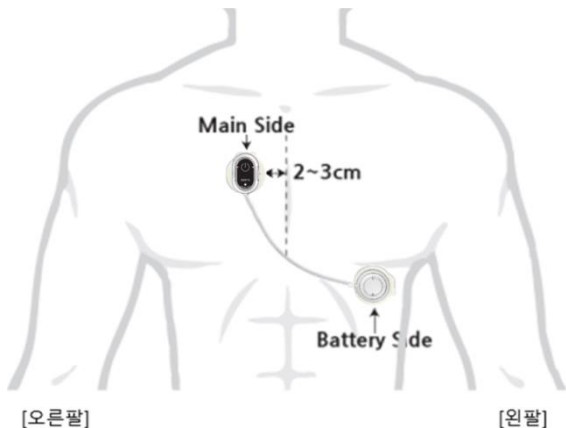
- ① Remove the release paper on the contact surface of the electrode.
- ② Attach the body to the patient's body as shown in the figure below.

Note : After attaching the MAIN part first as shown in the figure, attach the battery part diagonally from the MAIN part under the chest as shown in the figure.

When attaching, keep adequate spacing between the electrodes to avoid over tightening the wires.

Be careful not to reverse the attachment positions of the main and battery parts.

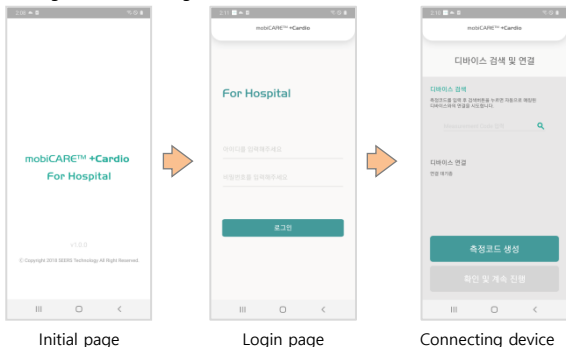
- ③ In case of poor electrode attachment, the LED flashes periodically.



3) mobiCARE-MC200M series connecting device and APP

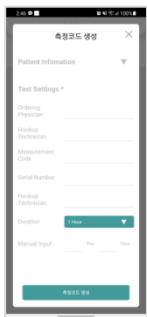
- (1) Launch the mobiCARE Cardio For Hospital App on your mobile device.
- (2) Enter your ID and password to log in. The ID and password are the same as the web software login information.
- (3) After entering the measurement code, click Search to connect to the device.

① Login and connecting the device



- Generating measurement code

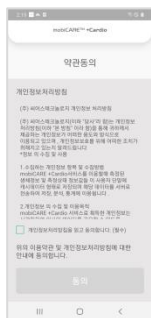
If the measurement code is not generated, you can click the Generate Measurement Code button to generate the measurement code. When the measurement code generation is complete, press the measurement code generation button at the bottom and enter the generated measurement code to connect it with the device.



Measurement code
generating page 1

Measurement code
generating page

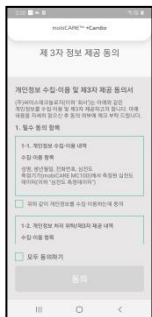
- (4) After checking the patch connection status, battery level, and patch signal in the app, the measurement start button will be activated. After pressing the measurement start button, check the contents of the third party information provision agreement, and select consent to activate the consent button at the bottom. Click Agree to see the user's ECG graph on the screen,



Checking device
status

Checking device
status completed

Agreement to terms
and conditions



Third party information provision agreement



Live ECG graph to display

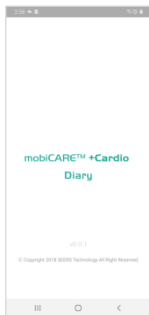
- (5) After confirming that the ECG Data is displayed normally, click the End button to close the mobiCARE Cardio For Hospital App.



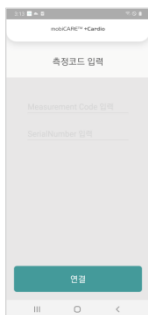
Closing App

4) mobiCARE-MC200M series Connecting the device and diary app

- (1) Launch the mobiCARE Cardio Diary App on the mobile device.
- (2) Press and hold the device's Power button for more than 3 seconds to change to the advertising mode.
- (3) Enter the measurement code and device number to connect to the device.



Initial page



Device connection



Connection
completed

5) Write a heart diary

- (1) Click the "+" button to write the heart diary.
- (2) Click to select symptoms and activities.
- (3) Enter the start time and end time and click the complete button to record the heart diary.



Add the symptoms
and activities



Select the
symptoms and
activities



Enter the start
time/end time
Click complete

- Checking real-time ECG data

Click the graph tab in the upper center to display ECG data for 30 seconds. When the display time is over, the screen changes to the heart diary.



Click the graph



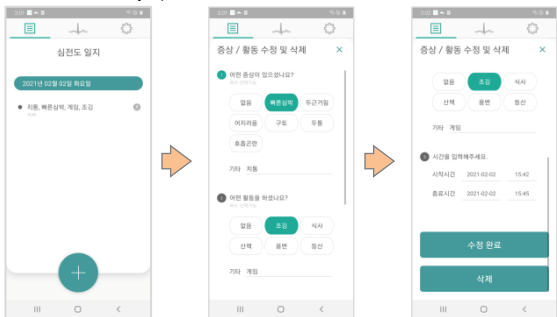
Displays the ECG for
30seconds



Heart diary

6) Edit the heart diary

- (1) Select the item that needs to be corrected in the heart diary.
- (2) Click and edit symptoms and activities, then save or delete the contents.



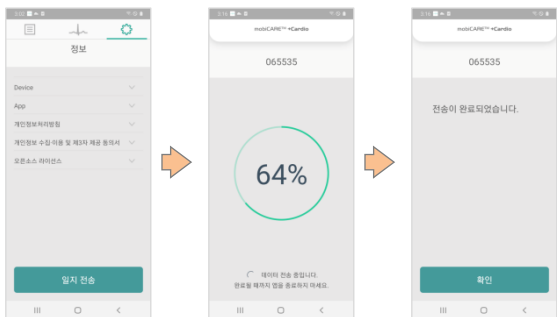
Select item

Edit the symptoms
and activities

Complete editing or
delete

7) Transfer the heart diary

- (1) Click Transfer diary button in Settings. A pop-up window will appear.
- (2) Click Transfer diary button in the pop-up window.
- (3) When data transmission is completed, click OK to move to the heart diary page.



Click Transfer diary
button

Click Transfer diary
button

Click OK to move to
the heart diary page

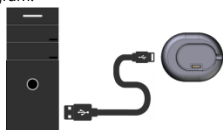
- (4) App termination proceeds with the app termination process of each OS.

8) Data upload

- 1) When the test is completed, open the battery cover, remove the battery, and close the cover.
- 2) Run the Data upload program on the PC.
- 3) Connect PC and cradle with USB cable for data transmission.
- 4) After mounting the main body on the cradle, check if the main body is connected to the data upload program.
(Please pay attention to the orientation when attaching the body to the cradle. If the body is still operating without removing the battery, it may take several seconds longer)
- 5) Click upload in Data upload program.
- 6) When data transmission is completed, remove the main unit from the cradle and close the data upload program.



Run the program



Connect the Cradle and the PC with the cable



Mount the main body on the Cradle



Data download



Data upload



Data transmission completed and close the program

4.2. Specifications

Model	mobiCARE-MC200M / mobiCARE-MC200ML / mobiCARE-MC200M7 / mobiCARE-MC200ML7	
	MAIN body : 32mm x 49mm (t=10mm)	
	BATTERY Body	
Size	1) mobiCARE-MC200(M/ML) : Φ 39mm (t=12.8mm)	
	2) mobiCARE-MC200(M7/ML7): Φ 39mm (t=15.5mm)	
	Main body connection line	
	1) mobiCARE-MC200M, mobiCARE-MC200M7: 180mm	
	2) mobiCARE-MC200ML, mobiCARE-MC200ML7: 250mm	
	Cradle : 76mm x 60mm (t=17.4mm)	
Weight	1) mobiCARE-MC200M : 20g (without battery)	
	2) mobiCARE-MC200M7 : 21g (without battery)	
	3) mobiCARE-MC200ML : 22g (without battery)	
	4) mobiCARE-MC200ML7 : 23g (without battery)	
	5) mobiCARE-Cradle : 200g	
Monitoring Time	1) mobiCARE-MC200M, mobiCARE-MC200ML : Min. 7 days (continuously)	
	2) mobiCARE-MC200ML, mobiCARE-MC200ML7 : Min. 10 days (continuously)	
Expected service life	About 2 years	
Signal Measurement	Sampling	256 Samples/Second
	Range of filter	0.05~55Hz
	Continuous measurement time	mobiCARE-MC200(M/ML): 7 days mobiCARE-MC200(M7/ML7): 10days (replaceable)
	Consumption power	1.4mW
Power	Main unit	3VDC (coin type)
	Battery	mobiCARE-MC200(M/ML):CR2450R mobiCARE-MC200(M7/ML7):CR2477
	Protective degree	Internal powered, CF type
Communication	Data communication	Bluetooth 5.1 (Bluetooth Smart)
	Transfer distance	10m [LOS(Line of sight) condition]

Software	Device Firmware	mobiCARE Firmware (v1.0.0)	
	App software	mobiCARE Cardio Hospital (v1.0.0)	
		mobiCARE Cardio Diary (v1.0.0)	
Minimum specification of Smart device	Web software	mobiCARE Web Service (v1.0.0)	
	OS	Android 7.0 (over)	
		iOS 12.0 (over)	
		RAM	2GB
Component	Inside Memory	16GB	
	mobiCAREC-MC200M / mobiCAREC-MC200ML /		
	mobiCARE-MC200M7 / mobiCARE-MC200ML7, Coin Battery 1EA, Manual, Open Tool		
Operating Environment	Operation		Storage/Transport
	Temperature	5 ~ 40℃	-25 °C to + 5 °C , and
	Humidity	10 ~ 95%R.H (Non-condensing)	+5 °C to + 35℃ at a relative humidity up to 90%, non-condensing;
		Atmospheric pressure	700 ~ 1060 hPa
	IP grade	IP44	
Technical Characteristic	Heart Rate Range	30 ~ 280bpm	
	Heart Rate	≤30 ~ ≤120 ± 2bpm	
	Accuracy	<120 ~ ≤280 ± 3bpm	
RF	Frequency	2.4 GHz band	
	RF Output Power	Max. 0 dBm	
Manufacturer/country		Seers Technology Co., Ltd / KOREA	

4.3. Maintenance

For cleaning, gently wipe the mobiCARE-MC200M series with medical grade disinfectant. DO NOT immerse the mobiCARE-MC200M series 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.

4.4. Specification of External Device connection

The mobiCARE-MC200M series is connect to the Android & iOS Application. The data indicating the status of the device is transmitted to the application from the device.

The required specification of the interface

- Main Device / Mobile App interface
- Data format : Bluetooth
- Mobile Application : Application on based Android & iOS
- Device status information
- Device information (Bringing information when connecting to BLE)
- Battery information (Bringing information when connecting to BLE)
- Data to Device – External memory
- Transmits the data to server

4.5. Error Message & Troubleshooting

4.5.1. Error Message & LED Display

Message & LED	Description	Solution
Check the status of the device	Can't connect to a patch	Check the patch connection status . Check the battery level and replace it if it is insufficient. Check the signal strength and replace the device if the error continues.
Battery status	Battery remaining less than 100%	Replace the battery.
Patch signal status	No ECG Signal	Check if the electrode is properly connected and make sure that the attachment is correct.
Orange LED lights up during measurement	External memory error	Check if the external memory is properly installed in the product socket and the installation status is correct.
Orange LED blinks during measurement	No ECG Signal	Check if the electrode is properly connected and make sure that the attachment is correct.
Green LED	Bluetooth	If the distance between the

blinks periodically during measurement	disconnected	product and the mobile device is far, the Bluetooth signal weakens and the connection can be lost. When writing a heart diary, it is recommended that the product and mobile device be kept close each other.
Battery level is low.	Battery remaining less than 10	Recommended to replace the battery.

4.5.2. Troubleshooting

Problem	Cause	Solution
If the device does not work even if you press the power button for more than 3 seconds	Battery	Replace the battery
If the battery cover does not close	Battery mounting	Check the mark on the part to be fastened with the battery cover, connect it correctly, and then fasten again.
When searching for mobiCARE-MC200M series in mobile APP, and mobiCARE-mobiCARE-MC200M series is not found	mobiCARE-MC200M series Power and status	Check if the power of mobiCARE-MC200M series is turned on. or check if mobiCARE-mobiCARE-MC200M series is in Advertising mode. If not in Advertising mode, mobiCARE-MC200M series will not be searched.
Mobile app says there is no measurement code	Unregistered measurement code	Verify that the entered measurement code is generated.
An error occurs while sending the heart diary	Network	Check if the current network environment is normal. If the Wi-Fi signal

		is weak, we recommend turning off Wi-Fi and using LTE or 3G, or moving to an area with a strong Wi-Fi signal to transmit.
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5. Labels and Packaging

5.1. Labels

5.1.1. Device Label



MAIN BODY BOTTOM



MAIN BODY TOP



BATTERY BODY BOTTOM

(1) Barcode format

A	B	C	D	E	F	-	GHIJKL
Name of identification		2-digit production year		2-digit production month		-	SN

- AB : 2-digit Name of identification (mobiCARE-MC200M series → SD)
- CD : 2-digit production year. (2021 year → 21)
- EF : 2-digit production month (January → 01, April → 04, October → 10, November → 11, December → 12)
- GHIJKL : Convert the back five digits of the MAC Address into a decimal number and use the back six digits as the device number.

ex) mobiCARE-MC200M series January 2021 Products produced by Seers Technology + Mac Address (08:D5:C0:70:74:23) → SD2101-029731

5.1.2. Gift Box label

(1) mobiCARE-MC200M

Product Name Model Name Supply Voltage Dimension (Main Body) Dimension (Battery Body) Dimension (Connect Cable) IP Grade	Cardiac Monitoring System mobiCARE-MC200M = 3V 32*49*10(mm) (Width * Length * Height) Φ39*12.8(mm) (Width * Length * Height) 180mm ± 10% IP Grade : IP44	 Date of Manufacture 2021. 01
 (01)08800096400007 (10)SD2101 (21)029731	SN 029731 LOT SD2101	 CAUTION - Electric shock "To avoid electrical shock, do not disassemble the device"  Please read the user's manual carefully before use  CF Type  Rx Only  Keep dry  -25℃ ~ +70℃  10% ~ 90%  WEEE
 Seers Technology Co., Ltd. (Sangdaewon-dong, techcenter 1314) 124, Sagimakgol-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea Tel) +82-31-8023-9811 Fax) +82-31-8023-9812	 Inter KOTRA GmbH Kurfürstenplatz 34 D-60486 Frankfurt am Main Germany Phone) +49 (0)69 - 71675855 / Fax) +49 (0)69 - 778918 Mobile) +49 (0)173 - 3085294 / E-mail) pauluskwon@interkotra.de	 2764 MADE IN KOREA

(2) mobiCARE-MC200ML

Product Name Model Name Supply Voltage Dimension (Main Body) Dimension (Battery Body) Dimension (Connect Cable) IP Grade	Cardiac Monitoring System mobiCARE-MC200ML = 3V 32*49*10(mm) (Width * Length * Height) Φ39*12.8(mm) (Width * Length * Height) 250mm ± 10% IP Grade : IP44	 Date of Manufacture 2021. 01
 (01)08800096400007 (10)SD2101 (21)029731	SN 029731 LOT SD2101	 CAUTION - Electric shock "To avoid electrical shock, do not disassemble the device"  Please read the user's manual carefully before use  CF Type  Rx Only  Keep dry  -25℃ ~ +70℃  10% ~ 90%  WEEE
 Seers Technology Co., Ltd. (Sangdaewon-dong, techcenter 1314) 124, Sagimakgol-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea Tel) +82-31-8023-9811 Fax) +82-31-8023-9812	 Inter KOTRA GmbH Kurfürstenplatz 34 D-60486 Frankfurt am Main Germany Phone) +49 (0)69 - 71675855 / Fax) +49 (0)69 - 778918 Mobile) +49 (0)173 - 3085294 / E-mail) pauluskwon@interkotra.de	 2764 MADE IN KOREA

(3) mobiCARE-MC200M7

Product Name Model Name Supply Voltage Dimension (Main Body) Dimension (Battery Body) Dimension (Connect Cable) IP Grade	Cardiac Monitoring System mobiCARE-MC200M7 = 3V 32*49*10(mm) (Width * Length * Height) Φ39*15.5(mm) (Width * Length * Height) 180mm ± 10% IP Grade : IP44	 Date of Manufacture 2021. 01
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 (01)08800096400007 (10)SD2101 (21)029731	SN 029731 LOT SD2101	 CAUTION - Electric shock "To avoid electrical shock, do not disassemble the device"  Please read the user's manual carefully before use  CF Type  Rx Only  Keep dry  -25°C ~ +70°C  10% ~ 90%  WEEE
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 Seers Technology Co., Ltd. (Sangdaewon-dong, techcenter 1314) 124, Sagimakgol-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea Tel) +82-31-8023-9811 Fax) +82-31-8023-9812	EC REP Inter KOTRA GmbH Kurfürstenplatz 34 D-60486 Frankfurt am Main Germany Phone) +49 (0)69 - 71675855 / Fax) +49 (0)69 - 778918 Mobile) +49 (0)173 - 3085294 / E-mail) pauluskwon@interkotra.de	 2764 MADE IN KOREA
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(4) mobiCARE-MC200ML7

Product Name Model Name Supply Voltage Dimension (Main Body) Dimension (Battery Body) Dimension (Connect Cable) IP Grade	Cardiac Monitoring System mobiCARE-MC200ML7 = 3V 32*49*10(mm) (Width * Length * Height) Φ39*15.5(mm) (Width * Length * Height) 250mm ± 10% IP Grade : IP44	 Date of Manufacture 2021. 01
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 (01)08800096400007 (10)SD2101 (21)012345	SN 0123456 LOT SD2101	 CAUTION - Electric shock "To avoid electrical shock, do not disassemble the device"  Please read the user's manual carefully before use  CF Type  Rx Only  Keep dry  -25°C ~ +70°C  10% ~ 90%  WEEE
--	--	--

 Seers Technology Co., Ltd. (Sangdaewon-dong, techcenter 1314) 124, Sagimakgol-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea Tel) +82-31-8023-9811 Fax) +82-31-8023-9812	EC REP Inter KOTRA GmbH Kurfürstenplatz 34 D-60486 Frankfurt am Main Germany Phone) +49 (0)69 - 71675855 / Fax) +49 (0)69 - 778918 Mobile) +49 (0)173 - 3085294 / E-mail) pauluskwon@interkotra.de	 2764 MADE IN KOREA
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※ The barcode label on the gift box is the same as the barcode on the product label

(5) Barcode Format

A. Product identifier code

AB	C	DEF	GHIJK	LMNO	P
Application Identifier	Logistics identifier	Country code	Company code	Product code	Parity bit

- AB : 01 (2-digit Application Identifier code)
 - C : 0 (1-digit Logistics identifier code)
 - DEF : 880 (Country code)
 - GHIJK : 00964 (Company code)
 - LMNO : 4-digit product code
 - P : 1-digit parity bit
- ① Serial numbers are assigned from right to left including check digits.
 - ② Add up all the even numbers.
 - ③ Multiply the result of step 2 by 3.
 - ④ Sum all the remaining numbers (odd number excluding check digits).
 - ⑤ Sum the result of step 3 and the result of step 4.
 - ⑥ The maximum value added to the result of step 5 to be a multiple of 10 is the check digit. Here, if the result of step 5 is a multiple of 10, the check digit is 0.

B. Lot number

A	B	C	D	E	F	G	H
Application Identifier		Name identification		production year		production month	

- AB : 10 (2-digit Application Identifier code)
- CD : 2-digit Name of identification (mobiCARE-MC200M series → SD)
- EF : 2-digit production year. (2021 year → 21)
- GH : 2-digit production month.(January → 01, September → 09, November → 11, December → 12)

C. Serial number

A	B	C	D	E	F	G	H
Application Identifier		Serial number					

- AB : 21 (2-digit Application Identifier code)

- CDEFGH : Convert the back five digits of the MAC Address into a decimal number and use the back six digits as the device number.

5.2. Packaging

5.2.1. Packing List

Classifications	Components	Quantity
Gift Box	mobiCARE-MC200M / mobiCARE-MC200ML / mobiCARE-MC200M7 / mobiCARE-MC200ML7 product	1
	Battery	1
	Manual	1
	Open Tool	1
	Cradle	1

5.2.2. Packing Unit

- 1) mobiCARE-MC200M / mobiCARE-MC200ML / mobiCARE-MC200M7 /
mobiCARE-MC200ML7 product

Main Product

- 2) Battery

1 Coin Cell battery is shipped at package

- 3) Manual

- 4) Open Tool

- 5) Cradle

6. Expected Service Life time and Warranty

6.1. Product Warranty

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

	Seers Technology Co., Ltd. (Sangdaewon-dong, techcenter 1314), 124, Sagimakgol-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea Tel) +82-31-8023-9811 Fax) +82-31-8023-9812
	Inter KOTRA GmbH Kurfurstenplatz 34 D-60486 Frankfurt am Main Germany Phone +49 (0)49-71675855 / Fax +49 (0)49-778918 Mobile +49 (0)173-3085294 / E-mail) pauluskwon@interkotra.de

8. Declaration of Conformity

8.1. Electromagnetic Compatibility

It has been independently tested and it manufactured in compliance with the following EMC standard IEC 60601-1-2:2014

Guidance and manufacturer' declaration – electromagnetic emissions		
The mobiCARE-MC200M series is intended for use in the electromagnetic environment specified below. The customer or the user of the mobiCARE-MC200M series should assure that it is used in such an environment		
Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The mobiCARE-MC200M series use 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 mobiCARE-MC200M series must be used only in a shielded location with a minimum RF shielding effectiveness and, for each cable that exists the shielded location, a minimum RF filter attenuation of 13dB from 30MHz to 1000MHz The mobiCARE-MC200M series, when installed in such a shielded location, is suitable for use in all establishments other than domestic 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	-	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	-	

Guidance and manufacturer' declaration – electromagnetic immunity

The mobiCARE-MC200M series is intended for use in the electromagnetic environment specified below. The customer or the user of the mobiCARE-MC200M series assure that it is used in such an environment

Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC 610 00-4-2	± 8 kV contact $\pm 2, 4, 8, 15$ kV air	± 8 kV contact $\pm 2, 4, 8, 15$ 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%
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines	-	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	-	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply lines IEC6100-4-11	$< 5\%$ UT ($> 95\%$ dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT	-	Mains power quality should be that of a typical commercial or hospital environment If the user of the mobiCARE-mobiCARE-MC200M series requires

	(30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 seconds		continued operation during power mains interruptions, it is recommended that the mobiCARE-MC200M series be powered from an uninterruptible power supplied or a battery
Power frequency (50/60Hz) Magnetic field IEC61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

Note UT is the a.c. mains voltage prior to the application of the test level

Guidance and manufacturer' declaration – electromagnetic immunity

The mobiCARE-MC200M series is intended for use in the electromagnetic environment specified below. The customer or the user of the mobiCARE-MC200M series should assure that it is used in such an environment

Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment-guidance
Conductive RF IEC61000-4-6	3Vrms 150kHz to 80MHz	- 10V/m	Portable and mobile RF communications equipment should be no closer to any part of the mobiCARE-MC200M series Including cables, than the recommended distances calculated from the equation applicable to the

Radiated RF IEC61000-4-3	10V/m 80MHz to 2,700MHz		frequency of the transmitter Recommended separation distance $d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3,5}{E_1} \right] \sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$ 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 metres(m). Field strengths from fixed RF transmitters, as determined by an electromagnetic surveya should be less than the compliance level in each frequency rangeb 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 transmitted, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM			

and FM radio broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment in the location due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the mobiCARE-MC200M series is used exceeds the applicable RF compliance level above, the mobiCARE-MC200M series should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating mobiCARE-MC200M series b Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile communication equipment and the mobiCARE-MC200M series

The mobiCARE-MC200M series is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the mobiCARE-MC200M series can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and mobiCARE-MC200M series 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 $d = [\frac{7}{E_1}] \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1.0	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitter 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 of the transmitter in watts (W) according to the transmitter manufacturer.

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.

FCC Part
15.105

The mobiCARE-MC200M series 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.

The mobiCARE-MC200M series 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 mobiCARE-MC200M series 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.

FCC Part
15.19(a)

The mobiCARE-MC200M series 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.
FCC Part 15.21	The mobiCARE-MC200M series may generate or use radio frequency energy. Changes or modifications to mobiCARE-MC200M series may cause harmful interference unless the modifications are expressly approved in the instruction manual. This user could lose the authority to operate mobiCARE-MC200M series if an unauthorized change or modifications is made.
Wireless Tx/Rx frequency information	2402-2480 MHz
CE	The mobiCARE-MC200M series can be operated in at least one Member State without infringing applicable requirements on the use of radio spectrum.

Seers Technology



MANUFACTURER

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