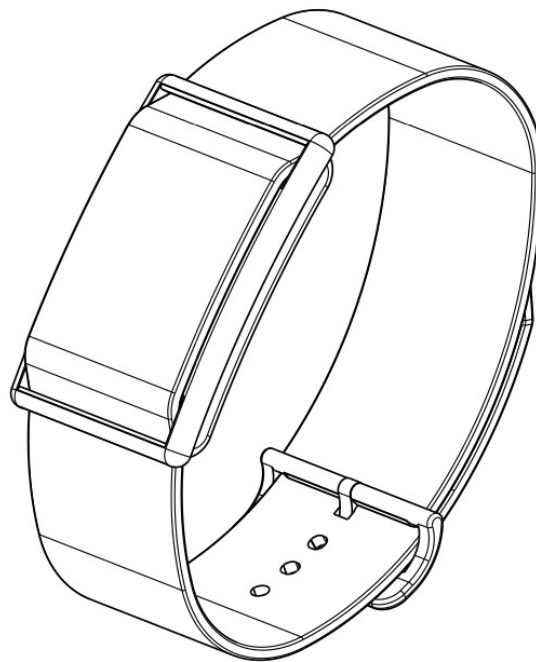


EN



CardioWatch 287-1

Bracelet & Corsano Trials

Instruction Manual

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2 INTRODUCTION

Thank you for purchasing the 287 CardioWatch. Corsano CardioWatch not only analyses heartbeat, but also and especially heart rhythm - simple and at any time. The bracelet has been validated in clinical studies and detects irregular heartbeats (e.g. extrasystoles) as well as the presence of absolute arrhythmia with suspected atrial fibrillation (AF). However, irregular heartbeats (e.g. extrasystoles) and atrial fibrillation can only be diagnosed in accordance with the guidelines with an ECG of the thoracic wall, generally carried out by cardiologists.

If you or your patient are feeling unwell or experience other troubling symptoms, please seek medical advice immediately.

3 SAFETY INSTRUCTIONS

This instruction manual provides you with important information about the Corsano 287 CardioWatch Bracelet. To ensure the safe and proper use of this bracelet, READ and UNDERSTAND all of the safety and operating instructions. If you do not understand these instructions or have any questions, contact info@corsano.com before attempting to use this bracelet. For specific information about your own heartbeats, consult with your physician.

Although clinical studies have shown that the bracelet in combination with a suitable heart rhythm interpretation service is able to identify arrhythmias (such as atrial fibrillation) with a very high accuracy level the slight possibility of a miscalculation still exists. Therefore, the results provided should under no circumstances replace the personal diagnosis, consultation, care or treatment by medical or medically trained staff.

In case any serious incident has occurred in relation to the device it has to be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

3.1 Intended Use

This device is a digital bracelet intended for use in measuring pulse rate and activity in adult patient population. The device provides the data for further cardiovascular, respiratory, and sleep analysis in order to provide a warning signal in case of the appearance of irregular heartbeats during measurement.

Environments of Use: Hospital and Home Patient Population: Adult

3.2 Receiving and Inspection

Remove this bracelet and other components from the packaging and inspect for damage. If this bracelet or any other components is damaged, DO NOT USE and contact +31-12345678.

Read the Important Safety Information in this instruction manual before using this bracelet. Follow this instruction manual thoroughly for your safety.

Keep for future reference. For specific information about your own heartbeats, CONSULT WITH YOUR PHYSICIAN.

- DO NOT use this bracelet on infants, toddlers, children or persons who cannot express themselves.
- DO NOT adjust medication based on readings from this bracelet. Take medication as prescribed by your physician. ONLY a physician is qualified to diagnose and treat high or irregular heartbeats.
- DO NOT use this bracelet on an injured arm or an arm under medical treatment.
- DO NOT use this bracelet in areas containing high frequency (HF) surgical equipment, magnetic resonance imaging (MRI) equipment, computerized tomography (CT) scanners. This may result in incorrect operation of the bracelet and/or cause an inaccurate reading.
- DO NOT use this bracelet in oxygen rich environments or near flammable gas.
- Consult with your physician before using this bracelet if you have common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation; arterial sclerosis; poor perfusion; diabetes; pregnancy; pre-eclampsia or renal disease. NOTE that any of these conditions in addition to patient motion, trembling, or shivering may affect the measurement reading.
- NEVER diagnose or treat yourself based on your readings. ALWAYS consult with your physician.
- To help avoid strangulation, keep the charger cable away from infants, toddlers or children.
- This product contains small parts that may cause a choking hazard if swallowed by infants, toddlers or children.

3.3 Data Transmission

This product emits radio frequencies (RF) in the 2.4 GHz band. DO NOT use this product

in locations where RF is restricted, such as on an aircraft or in hospitals. Turn off the Bluetooth® feature in this bracelet and remove batteries and/or unplug the charger when in RF restricted areas. For further information on potential restrictions refer to documentation on the Bluetooth usage by the FCC.

3.4 Charger Handling and Usage

- DO NOT use the charger if this bracelet or the charger cable is damaged. If this bracelet or the cable is damaged, unplug the charger immediately.
- Plug the charger into the appropriate USB outlet. DO NOT use in a multi-outlet plug.
- NEVER plug in or unplug the charger from the electric outlet with wet hands.
- DO NOT disassemble or attempt to repair the charger.

3.5 Handling and Usage

- Stop using this bracelet and consult with your physician if you experience skin irritation or discomfort.
- Consult with your physician before using this bracelet on an arm where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present because of temporary interference to blood flow, which could result in injury.
- Consult with your physician before using this bracelet if you have severe blood flow problems or blood disorders.
- DO NOT use this bracelet for any purpose other than measuring heartbeats.
- During measurement, make sure that no mobile device or any other electrical device that emits electromagnetic fields is within 12 inches (30 cm) of this bracelet. This may result in incorrect operation of the bracelet and/or cause an inaccurate reading.
- DO NOT disassemble or attempt to repair this bracelet or other components. This may cause an inaccurate reading.
- DO NOT drop or subject this bracelet to strong shocks or vibrations.
- DO NOT use this bracelet with other medical electrical (ME) equipment simultaneously. This may result in incorrect operation of the bracelet and/or cause an inaccurate reading.
- Ensure that this bracelet has acclimated to room temperature before taking a measurement. Taking a measurement after an extreme temperature change could lead to an inaccurate reading.









3.6 Charger Handling and Usage

- Fully insert the USB plug at the end of the charger into the USB outlet.
- When unplugging the charger from the outlet, be sure to safely pull from the USB outlet. DO NOT pull from the charger cable.
- When handling the charger cable:

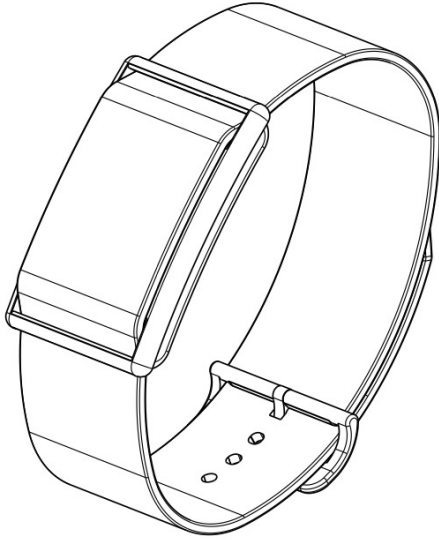
DO NOT damage it. DO NOT break it.
DO NOT tamper with it.
DO NOT forcibly bend or pull it. DO NOT twist it.
DO NOT use it if it is gathered in a bundle. DO NOT pinch it.
DO NOT place it under heavy objects.
- Wipe any dust off of the charger.
- Unplug the charger when not in use.
- Unplug the charger before cleaning this bracelet.

4 SYMBOLS

These instructions for use contain the following symbols (color and size may vary):

Symbol	Meaning
	Indicates the investigative device manufacturer
	Warning Indicates the need for the user to consult the instructions for use for important information such as warnings and cautions. A warning is always related to safety.
	Note Indicates the need for the user to consult the instructions for use
	Indicates the manufacturer's catalogue number so the device can be identified
	Indicates the manufacturer's serial number so that a specific device can be identified
	CE marking indicates that a product complies with applicable European Union regulations
	FCC marking indicates the electronic device, which sold in the United States, is certified and the electromagnetic interference from the device is under the limits that are approved by Federal Communications Commission
	Indicates a product should not be disposed of in a landfill; the black bar indicates that the equipment was manufactured after 2005

5 CONTENTS / PRODUCT INCLUDES



Bracelet (CS-287BR)



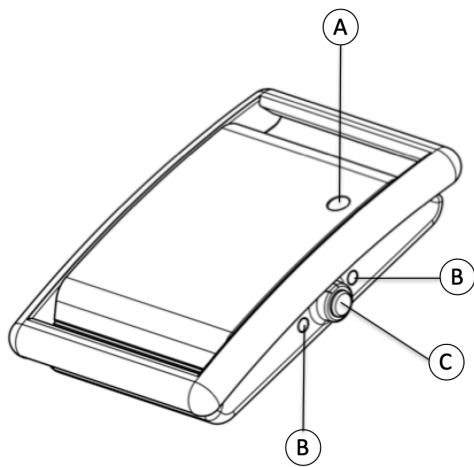
Charger (CS-287CH-1)



Instruction Manual (CS-287IFUEN-1)

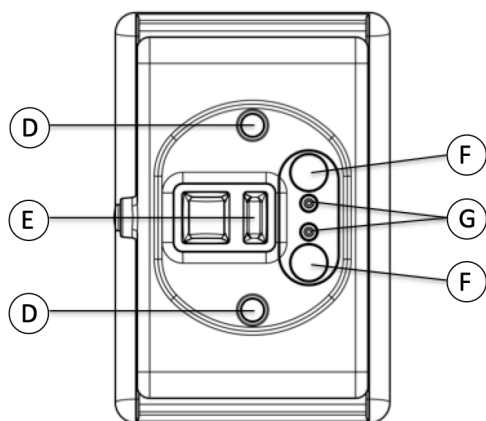
6 KNOW YOUR BRACELET

6.1 Front of the bracelet



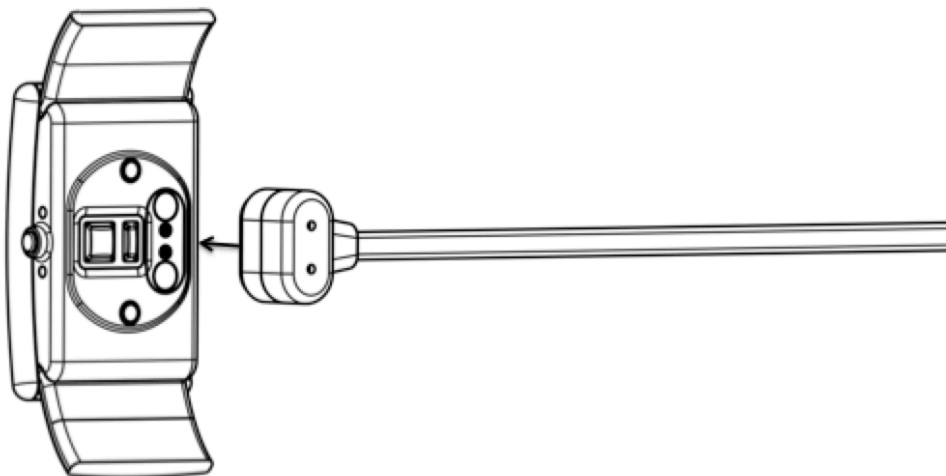
- (A) Ambient Temperature Sensor
- (B) LEDs
- (C) Pusher button

6.2 Back and bottom of the bracelet

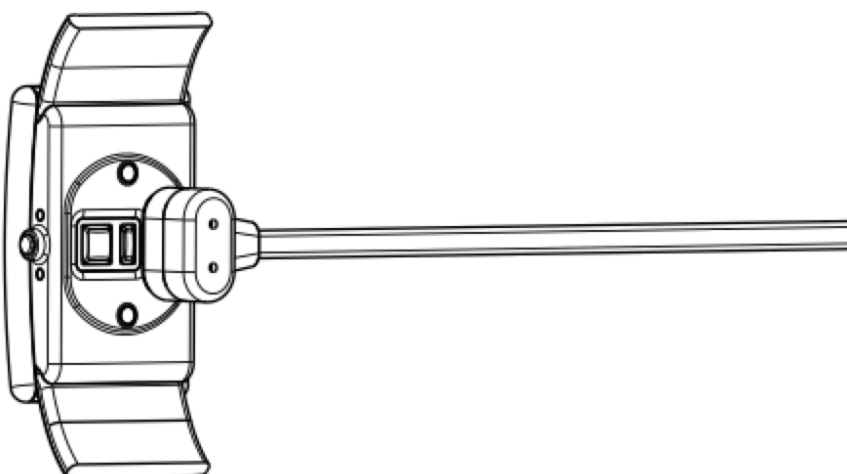


- (D) Temperature Sensors
- (E) PPG Sensor
- (F) Magnets
- (G) Charge Contacts

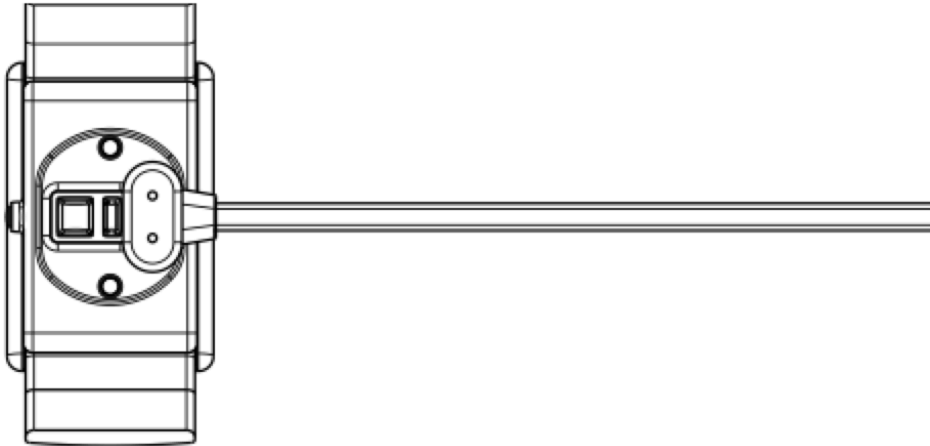
6.3 Charging the bracelet



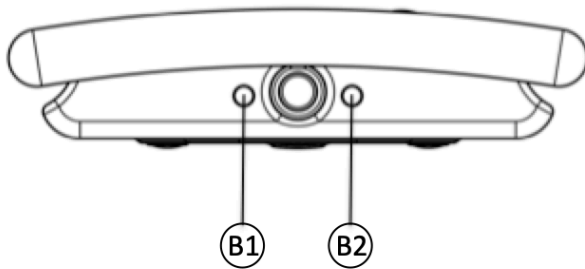
Attach the charger cable to the backside of the bracelet. The magnets will pull the charger head to the bracelet.



The Magnets will click the charger into position. The LEDS will light up to indicate that charging has started.



The polarity of the magnets in the bracelet and the charger will ensure that the charger contacts will align.



LED	Pattern	State
Green (B1)	Flashing	Bracelet charging
Green (B1)	OFF	Bracelet fully charged or not on charger

7 USING YOUR BRACELET WITH A SMART DEVICE

7.1 Download and install the “CORSANO TRIALS” app onto your smart device.

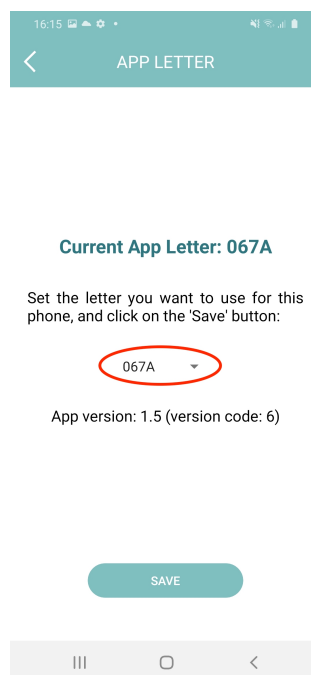
The “CORSANO TRIALS” app is currently available only via AppTester. You need to inform the email address to which we should send the invitation. Minimum requirements for use of the app, currently available for Android only:

- Android: version 8.0 or higher

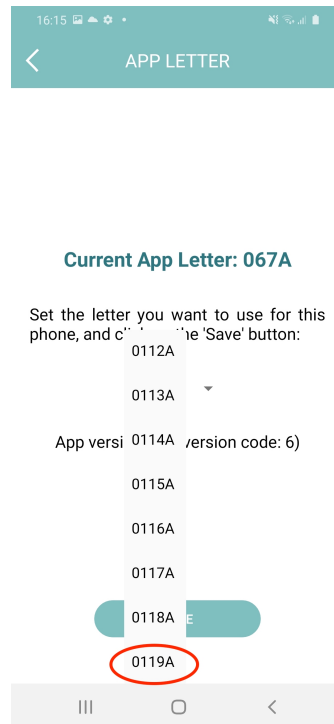
Please check latest list: [Compatible smartphone characteristics](#)

7.2 Set the name of your Bracelet on the app

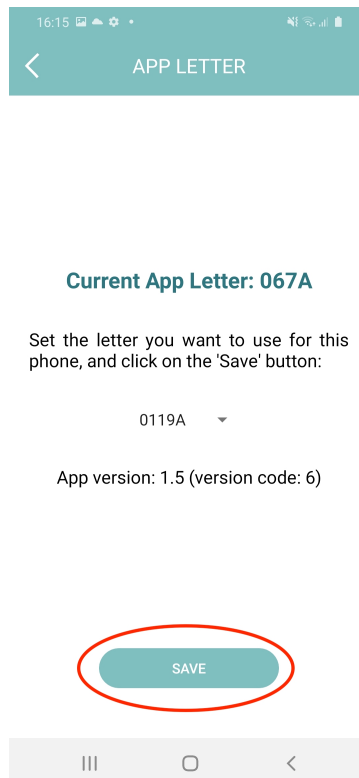
When you first open the app, you will be asked to set the name of your bracelet. Click on the picker:



Identify your bracelet's name on its strap, and select it in the menu:



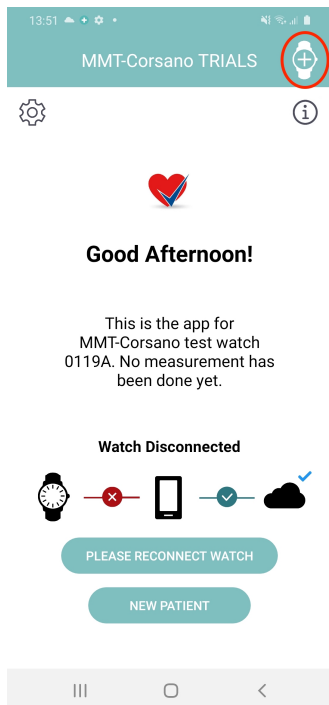
Click on the button "SAVE":



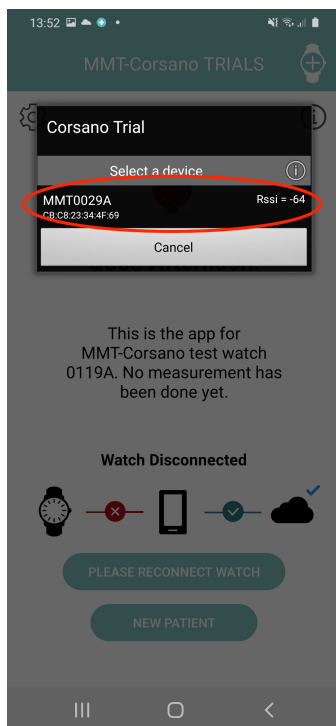
7.3 Pairing Your Bracelet with a Smart Device

Press the pusher on the bracelet. The orange LED will flash: the bracelet is waiting for pairing.

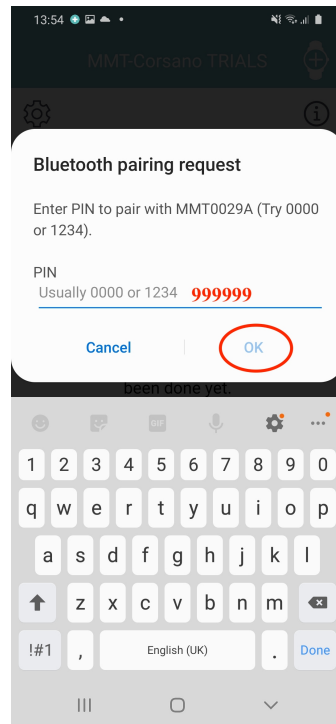
Click on the upper right hand corner icon:



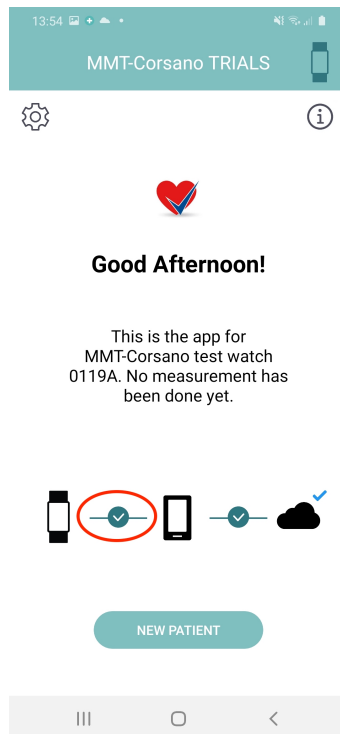
Click on the name of your device:



Enter the password 999999 and click on “OK”:

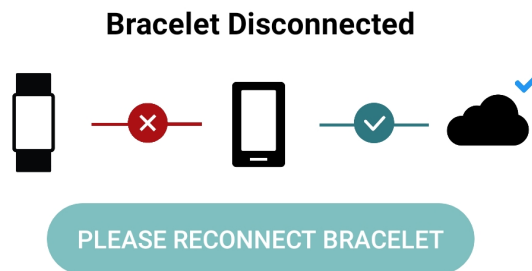


When your bracelet is connected successfully to your smart device, the green “V” symbol appears on the screen:



7.4 Troubleshooting the Bluetooth Connection

If the connection between the bracelet and app is lost, a red “X” will appear:



Click on the button Please Reconnect Bracelet and follow instructions:

1. Make sure your phone is nearby
2. Check if watch is charged
3. Check if GPS is on (Android only)
4. Force quit the app on your phone
5. Turn your phone's Bluetooth off and on again
6. Re-open the app

If these steps did not reconnect, please proceed:

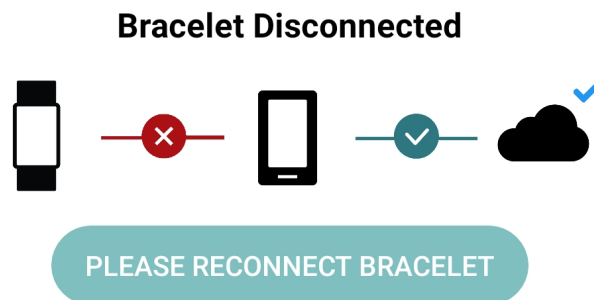
1. Shut down your phone (do not do restart; completely shut the phone off and turn it back on). This will fully reset the Bluetooth system in the phone
2. Turn your phone on again
3. Re-open the app

If none of the above did not resolve, you will need to re-pair your bracelet:

1. Go to watch settings: Remove/Clean old pairing
2. Go to Bluetooth settings, find 287, 286, 284 > Click Forget Device/Unpair
3. Force quit the app on your phone
4. Re-open the app
5. Press the (+) inside the watch icon in upper right corner
6. Follow pairing instructions

7.5 Troubleshooting the Cloud Connection

If the connection between the app and the cloud is lost, a red “X” will appear:



Click on the button Please Reconnect To Cloud and follow instructions:

1. Make sure your phone is connected to internet
2. Force quit the app on your phone
3. Turn your phone’s Airplane Mode off and on again
4. Re-open the app

If these steps did not reconnect, please proceed:

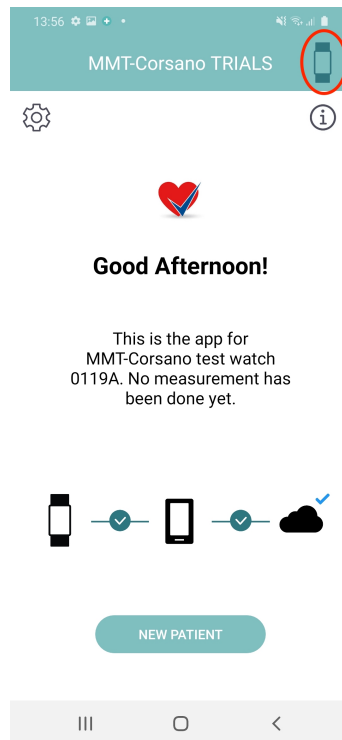
1. Shut down your phone (do not do restart; completely shut the phone off and turn it back on). This will fully reset your phone
2. Turn your phone on again
3. Re-open the app

If none of the above did not resolve, you will need to to logout and login again to the cloud:

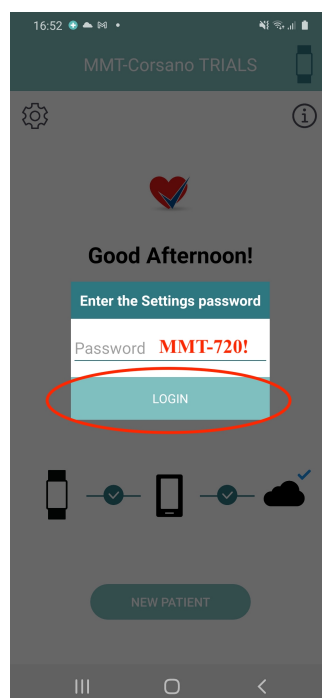
1. Go to profile settings and log out
2. Force quit the app on your phone
3. Re-open the app
4. Enter user and password
5. Follow instructions

7.6 Verify that your device is up to date

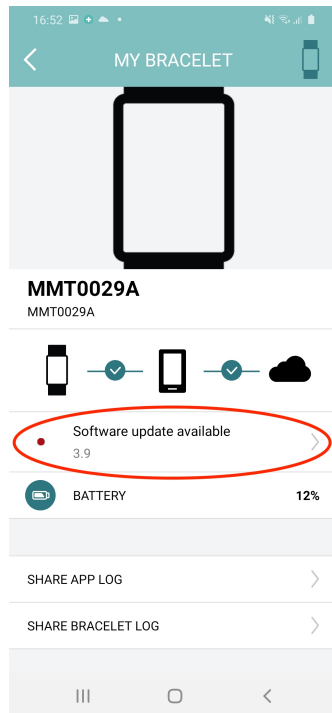
Click on the upper right hand corner logo:



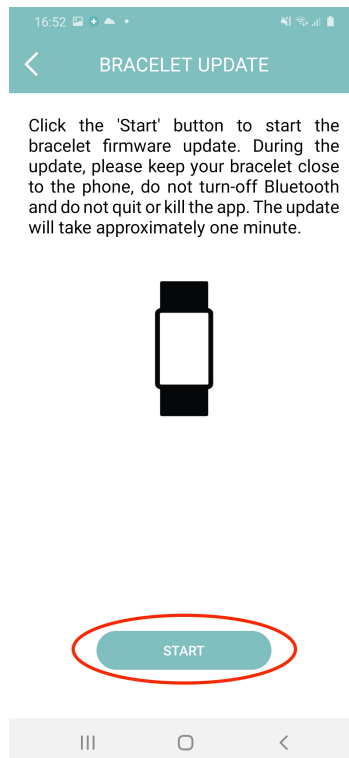
Put the password MMT-720! And click on “Login”:



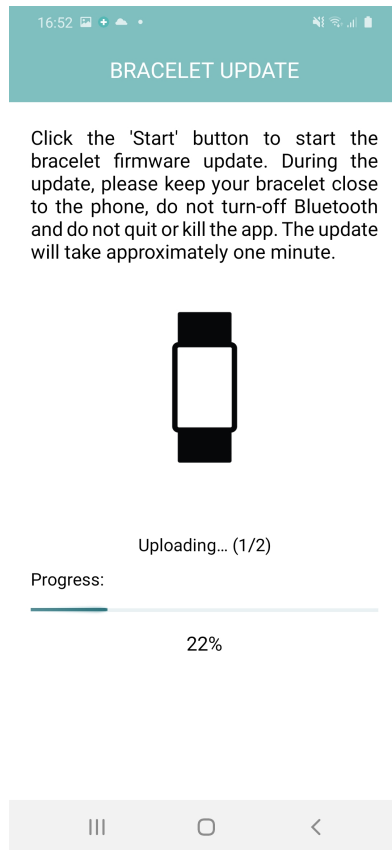
If the app indicates that a software update is available, click on it:



Click on "Start":

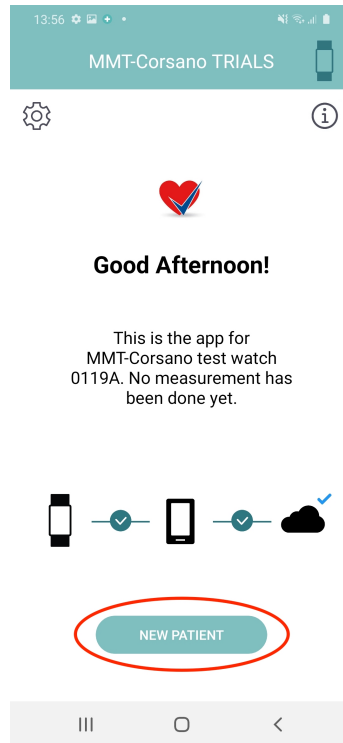


During the update, keep your bracelet close to your phone. The update will take approximately one minute. When the update is done, click on “Done”.



8 RECORD PATIENTS

Click on “New Patient”:

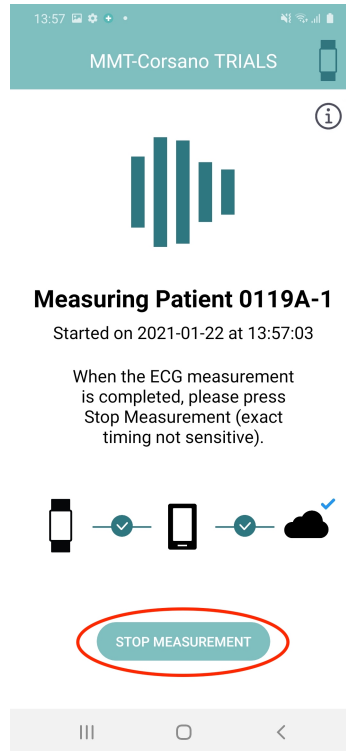


Click on “Start Measurement”:

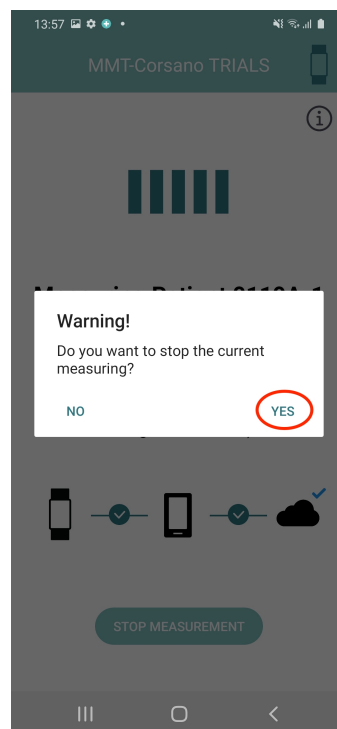


During the measurement, please do not remove the app from multitasking. The screen of the phone can be locked. Please keep an internet connection on the phone while measuring. Please keep the phone close to the bracelet (few meters maximum) when measuring.

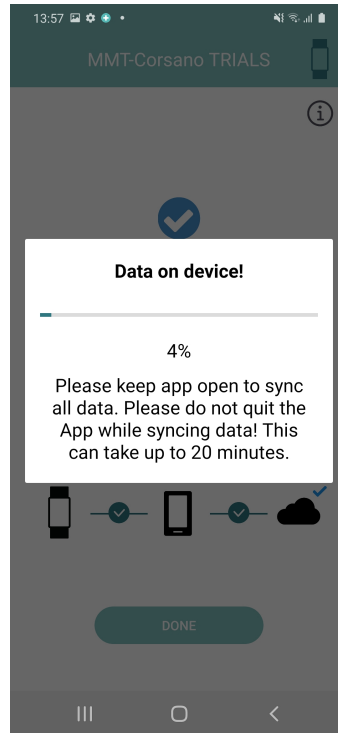
When you want to stop the measurement, click on “Stop Measurement”:



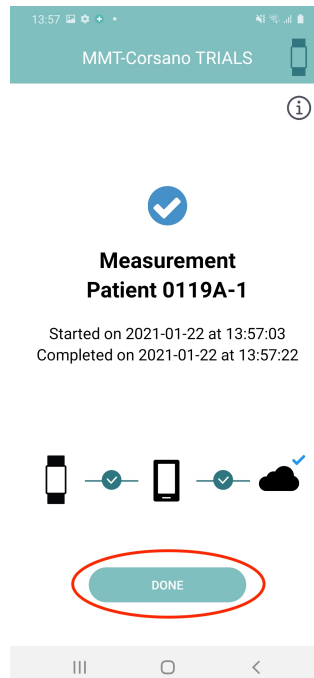
Confirm the stopping of the measurement by clicking on “Yes”:



The app will automatically download the data. During the download, please do not quit the app, and please keep the bracelet as close as possible to the phone:



Click on “Done”:



You can start these steps again to record other patients.

9 SPECIFICATION

PPG Sensor Characteristics

PPG	Single Channel
PPG LEDs number	2
PPG LEDs Peak wavelength.....	525 nm
PPG LEDs max current.....	30 mA
PPG sampling resolution.....	19 bits

Motion Sensor Characteristics

Type	3-axis
Acquisition noise	1.3 mg RMS
Sensor range	±16 g full scale

Data Acquisition

PPG sampling rate	25 Hz
Motion sampling rate.....	100 Hz
Flash Memory Size.....	64 Mbit
Recording	Continuous

Power Requirements

Battery type	Rechargeable
Technology.....	Lithium Polymer
Battery capacity (Bracelet)	93 mAh
Autonomy (Bracelet).....	up to 1 week

Dimensions

Length x Width x Height	20mm x 32mm x 9mm
-------------------------------	-------------------

Environmental Specifications

Operational Temperature	+10 to +45 degrees C
Storage Temperature	-10 to +50 degrees C
Operational Humidity.....	10% to 80%
Storage Humidity	10% to 80%

Interface

Wireless Communication.....	BLE 5.0
Display LEDs.....	1 green, 1 orange
User action	pusher button

Measuring accuracy

Heart Rate	+/- 3 BPM compared to ECG
RR interval.....	+/- 50ms compared to ECG

PPG sensor are exposed on the back of the Corsano bracelet. The PPG sensor makes contact with the user's skin.


10 ELECTRICAL SAFETY AND ELECTROMAGNETIC COMPATIBILITY

Guidance and manufacturer's declaration - electromagnetic emissions		
<p>The Corsano Bracelet is intended for use in the electromagnetic environment specified below. The customer or the user of Corsano Bracelet should assure that it is used in such an environment.</p>		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	<p>The Corsano Bracelet uses RF energy only for its internal function. Therefore, RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</p>
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	<p>The Corsano Bracelet 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.</p>

Guidance and manufacturer's declaration—electromagnetic immunity			
Corsano bracelet is intended for use in the electromagnetic environment specified below. The customer or the user of Corsano bracelet should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	<u>±6 kV contact</u> <u>±8 kV air</u>	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 61000-4-5	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-6	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	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.

Guidance and manufacturer’s declaration—electromagnetic immunity

Corsano bracelet is intended for use in the electromagnetic environment specified below. The customer or the user of Corsano bracelet should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p>	<p>3 Vrms</p> <p>3 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of Corsano bracelet, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance (m)</p> <p>$d = 1.2 \sqrt{P}$</p> <p>$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz</p> <p>$d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz</p> <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a, should be less than the compliance level in each frequency range^b.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

NOTE 1—At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Corsano bracelet is used exceeds the applicable RF compliance level above, Corsano bracelet should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating Corsano Bracelet.

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

Recommended separation distances between portable and mobile RF communications equipment and Corsano Bracelet

Corsano Bracelet is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Corsano bracelet can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Corsano bracelet 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)		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 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 output power not listed above, the recommended separation 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 1—At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

11 DISPOSAL OF THE DEVICE

Once your bracelet has reached its end of life it has to be properly recycled so that the material can be reused and will not end up in the environment. Preferably bring your device to a recycling service for Waste Electrical and Electronic Equipment.



12 CORSANO CONTACT INFORMATION

Corsano Health B.V.
Isaac da Costalaan 20
1401BH Bussum
The Netherlands

www.corsano.com

