Viatom Checkme O2 Recorder

Instructions for Use
with the SleepImage System

Viatom Checkme™ O2 Wireless Wrist Pulse Oximeter
Distributed by MyCardio LLC for use with the SleepImage System
Issued May 5, 2020 REF D-6.00283 Rev 1
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Table of Contents

Symbol	Description
(person figure)	Type BF-applied part
(factory)	Manufacturer
CE0197	CE Marking indicating conformance to EC Directive No. 93/42/EEC
(MR crossed out)	MRI Unsafe. Presents hazards in all MR environments as recorder contains strongly ferromagnetic materials
(WEEE bin)	Indicates separate collection for electrical and electronic equipment (WEEE)
IP22	Protected against spraying water and against access to hazardous parts with a tool, per IEC 60529
(instructions icon)	Follow Instructions for Use
(warning triangle)	Warning and Caution
SN	Serial Number
(bell crossed out)	No alarm system

Disclaimer

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Introduction

This user manual explains how to use the Viatom Checkme O2 recorder with the [SleepImage App](#). In order to use the recorder, the user must have been provided with a unique Patient ID from a licensed healthcare provider who has an account with SleepImage as well as a mobile device with Bluetooth capability and an internet connection. Please consult with your healthcare provider to get access to the analyzed data output.

Included in Box

       Checkme O2 Unit x 1
       Ring Sensor x 1
       USB Charging Cable x 1

Using the Recorder with the SleepImage System

This recorder is intended to be used with the SleepImage System for measuring, displaying and streaming data from the recorder via Bluetooth to the [SleepImage App](#) (available for Android and iOS). To use with SleepImage, fist download the App from either the iOS App Store, or the Google Play Store, then pair the recorder.

iOS: App Store	Download on the App Store
Android: Google Play	GET IT ON Google Play

Manufacturer Warnings and Cautionary Advices

- DO NOT squeeze the sensor or apply excessive force on the sensor & cable
- Never submerge the recorder in water or other liquids.
- Do not clean the recorder with acetone or other volatile solutions.
- Do not place this recorder in pressure vessels or gas sterilization device.
- Consult your doctor immediately if you experience symptoms that could indicate acute disease.
- This recorder has no output displayed other than during recordings, it displays pulse rate (BPM) and oxygen saturation (SpO2) as confirmation of an ongoing recording. Do not use this information for self-diagnosing a condition or disease.
- Use only cables, sensors and other accessories specified in this manual.
- This recorder and its accessories are intended to record during sleep. Prolonged continuous use of the sensor may increase the risk of undesirable skin irritation, reddening, blistering or burns. Patient sensitivity varies depending on medical status or skin condition. For patients with sensitive skin or poor peripheral blood circulation, inspect the sensor placement more frequently.
- Functional tester cannot be used to assess the accuracy of the sensor or the recorder.
- This recorder is designed to record data using a light emitting sensor. Factors that may degrade the performance of the sensor or affect the accuracy of the recorded data include the following:
  - Excess ambient light
  - Excessive motion
  - Electrosurgical interference
  - Blood flow restrictors (arterial catheters, blood pressure cuffs, infusion lines, etc.)
  - Moisture in the sensor
  - Improperly applied sensor
  - Incorrect sensor type or size
  - Poor pulse quality
  - Venous pulsations
  - Anemia or low hemoglobin concentrations
  - Cardiogreen and other intravascular dyes
  - Carboxyhemoglobin
  - Methemoglobin
  - Dysfunctional hemoglobin

Maintenance

Cleaning the Recorder

Use a soft cloth moistened with water or alcohol wipe to clean the device surface and sensor. The recorder display module can be removed from the rubber wrist band which can be cleaned in warm water with mild soap. DO NOT clean the display module with water or soap.

Charging the Recorder

Charge the recorder before using. Connect the recorder to a USB port of a computer or USB charging adapter using the charging cable provided. While charging, a battery indicator will flash on the screen. After the recorder is fully charged, the battery indicator will disappear. The rechargeable battery is expected to last for approximately 10 hours of continuous recording. To keep the battery in good condition, charge the battery every 6 months when not in use.

Display

During use, the recorder displays time, remaining battery capacity, pulse rate and blood oxygen saturation (SpO_2).

Power ON/OFF

To Power ON: Press and hold the button until the recorder display turns on.

To Power OFF: Recorder turns off automatically 2 minutes after the sensor is removed from finger, or if connection to the SleepImage App is lost. It can be turned off manually by pressing the on/off button for about 2 seconds.

Pairing the Recorder

Pair the Recorder to a phone using Bluetooth that is controlled through the SleepImage App using the following steps:
- Ensure the recorder screen is on to enable the Bluetooth visibility in the SleepImage App
- Ensure the mobile device has Bluetooth enabled
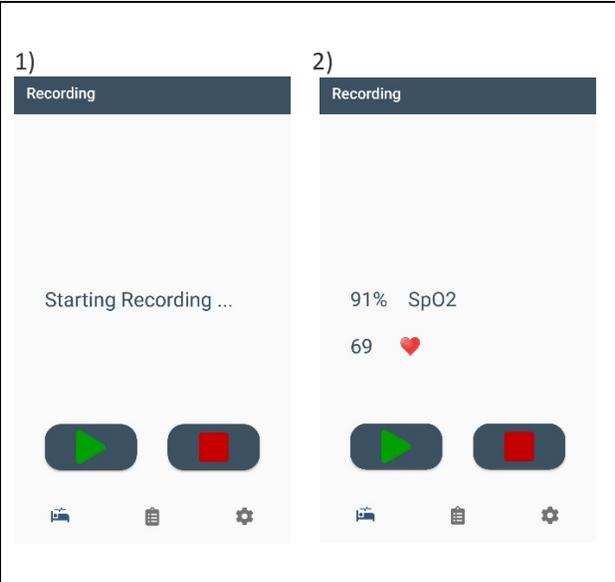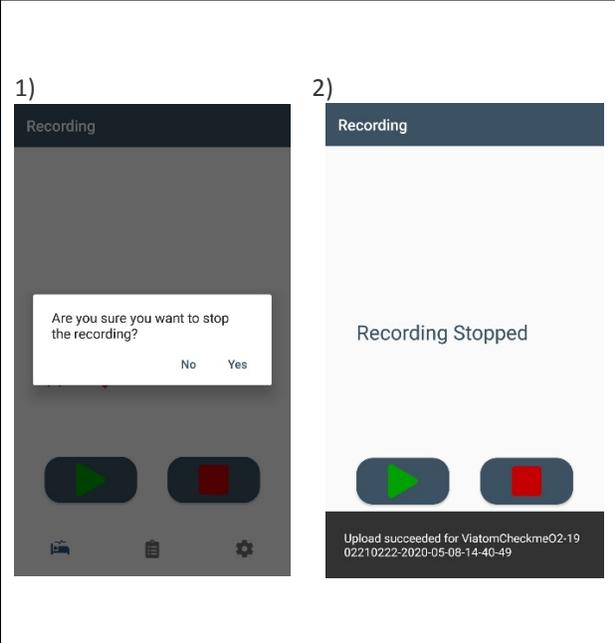- Follow instruction prompts in the SleepImage App to pair the recorder

See separate SleepImage App Instructions for Use document

Note: DO NOT PAIR the recorder with the mobile device using the 'Settings' on the phone.

Performing a SleepImage Study

To begin a SleepImage Study, you will first need to have charged the recorder, and paired it with the SleepImage App

START:	
Connect the sensor to the recorder, attach the strap around the wrist and place ring sensor around thumb or index finger. For good signal quality, the sensor needs to be tight. **Avoid having it too tight or too loose.** Turn on the recorder with the SleepImage App open (see separate App Instructions for Use) and press the Play button in the App to start a recording (image 1). Confirm that the pulse rate and SpO_2 display both on the device display and the SleepImage App (image 2). Keep the phone near your bed, then go to sleep.	1) Recording — Starting Recording … 2) Recording — 91% SpO2, 69 ♥
STOP:	
After waking up, open the SleepImage App, confirm that the pulse rate and SpO_2 are displayed both on the device display and the SleepImage App. Press the Stop button in the App to stop a recording. Press Yes to confirm (Image 1) An Upload Succeeded message will appear at the bottom of the App window (Image 2) Remove the sensor from the finger and disconnect the sensor from the recorder. The recorded data will be automatically uploaded to the Clinician's SleepImage account (see separate App Instructions for Use).	1) Recording — Are you sure you want to stop the recording? No Yes 2) Recording — Recording Stopped — Upload succeeded for ViatomCheckmeO2-19 02210222-2020-05-08-14-40-49

Successful data collection in progress is indicated by SpO2 and Pulse Rate values being displayed in the app. During this time, the screen on the recorder will display SpO2 and Pulse Rate values as well. If you notice that the screen is off during the recording period, click (do not hold) the power button so that the screen turns back on.

Specifications

Classifications		
EC Directive	MDD 93/42/EEC	
	R&TTE 1999/5/EC	
	ROHS 2.0 2011/65/EU	
Protection against electrical shock	Type BF	

Environmental		
Item	**Operating**	**Storage**
Temperature	5 – 40 ℃ (41 – 104 ℉)	-25 – 70 ℃ (-13 – 158 ℉)
Relative humidity (noncondensing)	10% – 95%	10% – 95%
Barometric	700 – 1060 hPa	700 – 1060 hPa
Dust & Water resistance	IP22	

Physical	
Weight	12 g (main unit)
Display	OLED
Wireless	Bluetooth 4.0 BLE

Power Supply	
Charge Input	DC 5V ± 10%
Battery type	Rechargeable lithium-polymer
Charge time	2 – 3 hours
Storage Capacity	4 records total (~10 hours each) 5th record will overwrite memory

SpO$_2$	
Standards	ISO 80601-2-61
SpO$_2$ Range	70% – 100%
SpO$_2$ Accuracy	80% – 100% ±2% | 70% – 79% ±3%
Wavelength	660 – 940nm
Output Power	Red / Infrared: 3mW max. avg.

Electromagnetic Compatibility

The recorder meets the requirements of EN 60601-1-2. EMC table information is listed on the manufacturer's website: https://api.viatomtech.com.cn/documents/2017/emc_en.pdf

EMC Warnings and Cautions

- Using accessories other than those specified in this manual may result in increased electromagnetic emission or decreased electromagnetic immunity of the equipment.
- The recorder or its components should not be used adjacent to or stacked with other equipment.
- The recorder needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.
- Other devices may interfere with the recorder even though they meet the requirements of CISPR.
- When the signal input is below the minimum amplitude provided in technical specifications, erroneous measurements could result.
- Portable and mobile communication equipment may affect the performance of the recorder.
- Other devices that have RF transmitter or source may affect the recorder (e.g. mobile phones, tablets and personal computers with wireless function).

Recorder specifications cautions and warnings have been provided by the manufacturer. For information about potential applications of using this recorder other than with the SleepImage System please contact the manufacturer.

Troubleshooting

Problem	Possible Cause	Possible Solution
Recorder does not turn on or is not responsive	Battery may be low	Charge battery and try again
	Unexpected software condition	Press & hold button for 10 seconds to reset
SleepImage App cannot connect with recorder	Bluetooth on phone is OFF	Turn on Bluetooth on phone
	Recorder is OFF	Turn on the recorder

If your issue persists, please email support@sleepimage.com with the following info: User Name, SleepImage Account Name, Serial Number of Recorder, App version, and a description of the issue encountered. Include screenshots/pictures, if applicable.