mCVInsight® User Guide

InteloMed, Inc.

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General Information

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About mCVInsight®

Product Description

Every time a patient's heart beats, the resultant pulse of blood emits a blush under the skin that is invisible to the naked eye but recognizable by a camera. Armed with this understanding and using only the camera and processing power already inherent in a common device such as a smartphone or tablet, the use of Intelomed's mCVInsight telemedicine tool permits a physician to measure empirical patient health information such as pulse rate and respiration rate. Because this examination no longer requires contact with the patient, these measurements can be captured and transmitted remotely, maximizing the comfort and convenience of the patient while minimizing exposure to infection for both patient and caregiver.

Intended Use

The mCVI MCP application is a non-invasive, no contact method to measure and record pulse rate and respiration rate.

Indications for Use

The Indication for Use statement is based on the primary predicate device (Intelomed CVI K120052). The mobile CVInsight system is comprised of a pulse oximeter and a software application installed and operating on a mobile phone. The pulse oximeter device is indicated for use in measuring, displaying, and storing pulse rate and respiration rate of adult patients. It is intended for spot-checking and/or data collection and recording of patients who are well or poorly perfused. The intended use environments are Hospitals, Medical Facilities, Ambulatory, Sub-Acute, and Home use. mCVInsight measures, displays, and stores pulse rate and respiration rate.

Safety and Performance Warnings

WARNING: Do not self-diagnose or self-medicate on the basis of the measurements. Always consult your doctor.

WARNING: Check the following to prevent inaccurate (or no) readings:

- The patient does not have any medical conditions that might interfere with readings.
- Contact your physician if you have concerns.

WARNING: Inaccurate respiration rate (RRp) measurements may be caused by:

- Low arterial perfusion
- Motion

CAUTION: Avoid using the mCVInsight app under bright light sources and direct sunlight to minimize interference that may result in no or inaccurate readings.

Contraindications

mCVInsight is not for use in the following situations:

1. Unsuitable lighting conditions that are either too bright (should not be used outside), or too dark, or unstable (flashing artificial lighting).

2. Patients under 18 years of age

3. Patient has an arrhythmia

4. The patient has their face obstructed with topical substance or skin disease. For example, makeup, tattooing, burns, scarring, and severe acne in the area of interest

5. In a Magnetic Resonance (MR) environment

6. In the presence of flammable anesthetics or gases

WARNING: Investigational device. Limited by Federal (or United States) law to investigational use.

WARNING: This device is intended only as an adjunct device in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.

NOTE: Please contact healthcare professionals if Respiration Rate is <7 or >24 respirations per minute

CAUTION: Federal law (USA) restricts this device to be sold by or on the order of a licensed practitioner.

R̠ ONLY

Symbols

Symbol	Instruction	Definition
Pulse Rate	Pulse Rate Display	Indicates the pulse rate value displayed by the mCVInsight application in beats per minute
Respiration Rate	Respiration Rate Display	Indicates the respiration rate value displayed by the mCVInsight application in breaths per minute
R̠ ONLY	Prescription Use Only	For use with a prescription only

mCVInsight® Description

Parts List

mCVI® application

Android Rev 0.20.187.391c0e2

Apple Rev 0.20.190.eb023aa

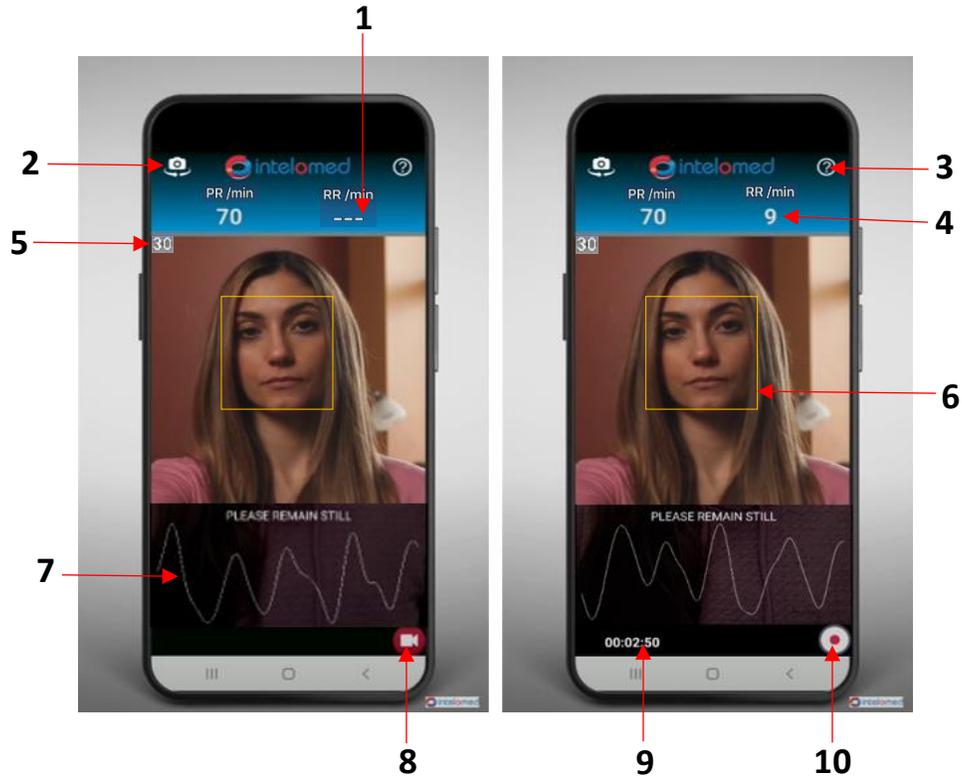A device with the following minimum hardware specifications:

	OS	Processor	Memory (RAM)
Android	9.0	Octa-core 2.35 GHz	4 GB
iOS	14.4	Quad-core 2.34 GHz	2 GB

mCVI Controls and Indicators

The table below describes the mCVI controls and indicators

Screen Controls/Indicators	Screen Graphic	Comments
Information Icon		Displays quick start, manufacturer information, troubleshooting, link to user guide, and software version
Camera Flip		Alternates the camera view between front and back
Pulse Rate Display	PR /min	Displays pulse rate per minute
Respiration Rate Display	RR /min	Displays respiration rate per minute
Start Session Button		Begins saving session data when pressed
End Session Button		Ends the saving session and prompts saving and sending options
Frames per Second (fps)	30	Displays video frame rate per second (fps)
iPPG Waveform Graph		Displays live iPPG waveform
Session Time	00:02:50	Tracks time elapsed during a single saving session

mCVI Features

Item	Description	Function
1	No Value Dashes	Indications that values have yet to be determined or a loss of values due to motion, lighting, or device position changes
2	Camera Flip	Alternates the camera view between front and back
3	Information Icon	Displays quick start, manufacturer information, troubleshooting, link to user guide, and software version
4	Pulse Rate and Respiration Rate Display	Displays pulse rate and respiration rate per minute
5	Frames per Second	Displays video frame rate per second (fps)
6	Face Detection Box	Displays a box around the subject's face when detected **Note:** This is NOT facial recognition
7	iPPG Waveform Graph	Displays live iPPG waveform
8	Start Session Button	Begins saving session data when pressed
9	Session Time	Tracks time elapsed during a single saving session
10	End Session Button	Ends the saving session and prompts saving and sending options

Setup

1. Turn on Wi-Fi enabled device
2. In device settings:
    i. Verify Wi-Fi is connected
    ii. Verify automatic date and time is turned on
    iii. Check for software update. If update is available, follow prompts to download and install prior to mCVInsight application use
3. Purchase and install mCVInsight application from Apple or Google store
4. Open mCVInsight after installation and follow the prompts, ensuring to give permissions for the device to have access to the camera, microphone, and photos

Usage

- Hold camera steadily at an arm's length in good lighting
- Press record to start a session
- Press stop to end session
- Enter email information to send file to desired recipients

Example of using back camera

Example of using front camera
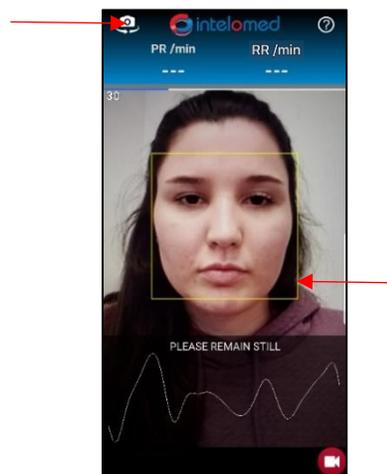
Step-by-Step Usage and Tips

1. Open the mCVI app

   NOTE: For best results when using mCVI, the subject should refrain from wearing glasses, avoid wearing face lotions or foundation make up, and keep hair pulled back, away from forehead and face

2. Subject should be sitting in chair at table with plain background behind them, ensuring there are no light sources behind them

   NOTE: Ensure overhead lighting or well-lit area in front of subject with equal brightness across entirety of subject's face. Inconsistent light sources on the face could result in no or unreliable readings.

3. Place device in stand, or in steadied hands, so that device sits upright and is within an arm's length from the subject's face

4. Use the front camera to capture the subject's face when subject is using mCVI independently, and use the back camera when another user is using mCVI on the subject. Flip the camera position by using the camera flip option in the upper left corner, ensuring that the subject's face is centered and the detection box is capturing their face
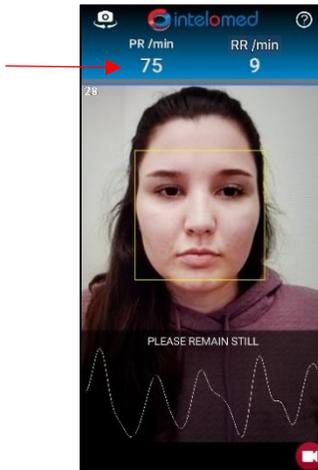

   NOTE: Ensure device has sufficient charge for the length of session.

5. Once face detection box is clearly on subject's face, the subject is to remain still, looking straight at the camera to ensure that their face and the detection box remains centered
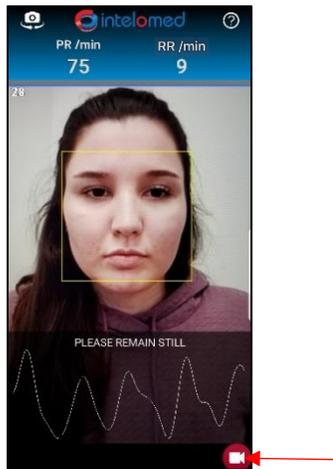
   NOTE: Refrain from moving or talking to ensure accurate readings

6. Pulse rate should appear in approximately 15 seconds and respiration rate should appear in approximately 45 seconds.

   NOTE: If these values do not appear or are not accurate, refer to the "Troubleshooting" section
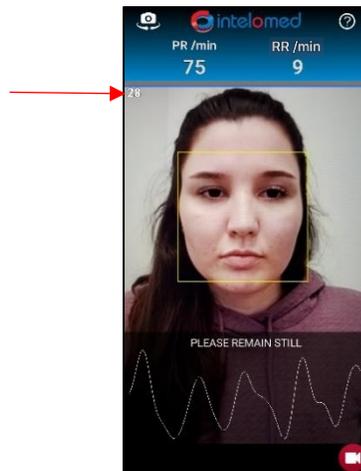

7. To begin a data saving session, simply tap the start session icon and remember to remain still
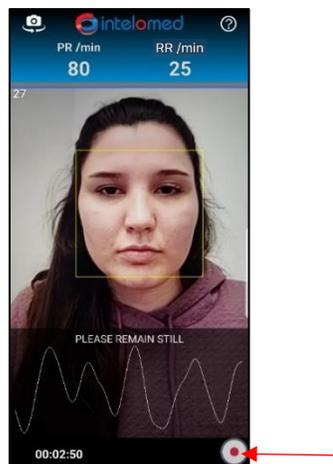
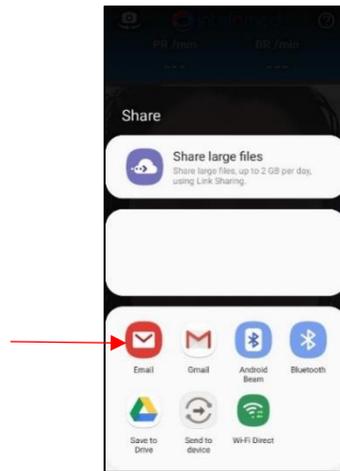8. Ensure that the frame rate is >20 fps

   NOTE: If frame rate is <20 fps, refer to Troubleshooting

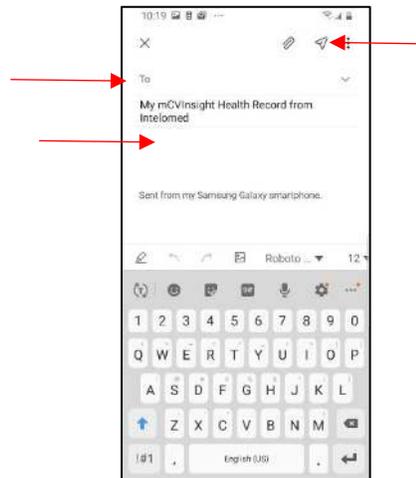9. To end the session, simply tap the end session icon

10. When end session button is pressed, you will be prompted to send the data via email

11. Add text to the body of the message and email recipients as desired
12. Send the email

13. To close out of the mCVInsight application completely, follow the instructions below for the device being used:

- Android:

At the Home screen, or while in the mCVInsight app, tap the Recent Apps on-screen key, which is left of the on-screen Home key. Scroll up or down to see all open apps. Find the mCVInsight app and swipe from the left or right to close the app. This will clear the app and remove it from your screen. Tap the on-screen Home key to return to the Home screen.

- Apple iPhone with physical button:

At the Home screen of the iPhone, or while in the mCVInsight app, double-click on the Home button to access the App Switcher and then swipe up on the mCVInsight to close. If you are not immediately brought to the Home screen after closing the app, press the Home button a single time to return to the Home screen.

- Apple iPhone without physical button:

At the Home screen of the iPhone, or while in the mCVInsight app, swipe up from the bottom of the screen and pause while still pressing the screen. When the App Switcher comes up, swipe left and right through the different app cards to find the mCVInsight app that you want to close. Use a quick swipe upwards to close the app. If you are not immediately brought back to the Home screen after closing the app, tap anywhere in the gray area around the edge of the App Switcher screen to return to the Home screen.

Maintenance

Mobile CVInsight is a downloadable application for iOS and Android devices. Updates will occur either manually or automatically, at the user's discretion.

Troubleshooting

Problem	Possible Cause	Possible Solution
Pulse Rate and Respiration Rate are not displayed	Poor Lighting (10 lux < good lighting > 5000 lux)	Ensure uniform lighting preferably from above and not behind
	Lighting has changed	Place hand to block camera view for 2 seconds then resume
	Excessive movement	Remain still during monitoring
	Device position	Hold device steady, at arm's length, with full face visible
Face Detection Box fails to appear on screen	Poor Lighting (10 lux < good lighting > 5000 lux)	Ensure uniform lighting preferably from above and not behind
	Excessive movement	Remain still during monitoring
	Device position	Hold device steady, at arm's length, with full face visible
Grainy video Low fps (<20 fps) Video lag	Minimum OS requirements have not been met	Perform device updates. Consult minimum Android/iOS device requirements for app operation
Email not sent/received	Inappropriate closure of email utility	Email is saved as draft. Check drafts and resend.
	Internet/cellular connectivity unavailable	Ensure connectivity is established and resend drafts. Connect device to computer and download data files directly for transmission.

Glossary

- **Caregiver** – A caregiver is a general term used to define an individual who may be monitoring a patient. Monitoring by a second party infers using the device rear camera.

- **iPPG** – Imaging Photoplethysmography. This signal is derived from the consecutive image data of the patient and is analogous to the signal that comes from the pulse oximeter.

- **MCP –** Mobile Computing Platform

- **mCVI or mCVInsight®** – Mobile CVInsight. The product that is described in this document.

- **Session data** – The data collected by mCVI application from the moment the start session button is pressed and a valid iPPG signal is captured until the end session button is pressed.