Vital-Trac™ User Manual

UM- 1: Rev. 4.0
Mindset Medical

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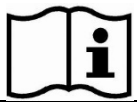
Glossary of Symbols

Symbol	Symbol Title	Symbol Description
	Consult Instructions for Use	Indicates the need for the user to consult the Instructions for Use.
	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	Manufacturer	Indicates the medical device manufacturer.
Rx ONLY	Prescription Use Only	Caution: Federal (US) law restricts this device to sale by or on the order of a physician. Indicates the product is indicated for professional use only.

1. Getting Started

What is Vital-Trac?

Vital-Trac is an application developed by Mindset Medical to measure your vital signs using the camera on your smartphone, tablet, laptop, or desktop computer. Vital-Trac can be configured as a General Wellness application and/or prescribed by your healthcare provider as a Software as a Medical Device (SaMD).

Icon	Product Use	Description
	Prescribed by Healthcare Provider (Rx Only)	**Vital-Trac SaMD:** You can tell if you are using the prescription product by looking for the icon on the results page. These results were generated using the SaMD product and will be sent directly to your healthcare provider.
	General Wellness (non-prescription)	**Vital-Trac:** You can tell if you are using the non-prescription product by looking for the General Wellness icon on the results page. These results are for your information only and are not always automatically shared with your healthcare provider. These measurements are intended to promote a healthy lifestyle and do not replace medical advice.

Vital-Trac is not available in app stores. You will receive a secure link to access the app directly or through another digital application. Vital-Trac works with the camera on your smartphone, tablet, or computer.

How it Works

Each time your heart beats, your face shows tiny color changes, which are invisible to the human eye. Similarly, each time you breathe, your shoulders and torso move slightly. Vital-Trac uses your camera to detect subtle changes in facial coloration and shoulder motion to calculate vital signs (e.g., pulse and respiratory rate) in real time.

Installation

- Click the secure link sent by your provider within 72 hours
- Open the link in your browser
- Enter your birth date to confirm identity
- Agree to the Terms and Conditions and Consent to Measure Vitals
- Allow camera access

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2. Instructions for Use

See full prescribing information for Vital-Trac. Read the manual carefully and pay attention to the warnings and cautions throughout.

Device Description

Vital-Trac is a software application that utilizes existing optical camera technology embedded in a smartphone, tablet, or computer to estimate vital signs such as pulse and respiratory rate from a video recording.

Indications for Use

Vital-Trac is intended for non-invasive spot measurement of pulse and respiratory rate of adult patients in home use, hospitals, clinics, and long-term care settings.

Vital-Trac is indicated for use on adults 22 years of age or older who do not require critical care or continuous vital signs monitoring.

Vital-Trac is not intended to direct therapy independently.

Contraindications

The following facial conditions are contraindicated with Vital-Trac and may impact the ability to measure your vital signs. Check with your healthcare provider if you have any of the following:

- Scars or burns
- Port wine stains or large birthmarks
- Tattoos or henna
- Rosacea, eczema, and rashes
- Bruising

Warnings and Precautions

WARNING: Vital-Trac should be used under the care of your physician. Always consult your physician regarding clinical decisions. Do not rely on Vital-Trac as the only basis for medical decisions; pulse and respiratory rate measurements alone are not intended to direct medical care.

CAUTION: To ensure the proper operation of the device, avoid distractions. Don't use Vital-Trac while driving, walking, or participating in any activity requiring your full attention.

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

- Keep your face still and follow the on-screen guide during measurement. Don't eat, drink, or talk while during measurements.
- Other apps should not be running simultaneously when using Vital-Trac.
- Make sure you are not near other devices (e.g., microwaves, cordless phones, Wi-Fi routers, or other signal/radio wave emitting devices) that may interfere with Vital-Trac operation.
- Vital-Trac must have permission to use your device's camera to work properly.
- Ensure your device's camera is not cracked or dirty, which could obstruct measurement.
- Don't use other camera-interfacing apps (like social media or video conferencing apps) while using Vital-Trac.
- Ensure a stable Internet connection for Vital-Trac to function and transmit results.
- Vital-Trac is for individual use and communicates directly with your healthcare provider. Don’t share the app with someone else; it could compromise care.
- Not following instructions as displayed on the screen could result in no readings.

Note: Vital-Trac will only report readings when there is high confidence in the measurement accuracy, but this is not guaranteed. Vital-Trac may provide recommendations to improve the conditions, where possible, for the next session. If readings cannot be generated after multiple sessions, Vital-Trac ends the measurement session and notifies the prescribing physician that the measurement was unsuccessful.

Vital-Trac detects subtle color changes in the face as part of heart rate evaluation. Testing has shown that the report rate will be lower (i.e., no readings displayed) for darker skin tones where color changes are harder to detect.

CAUTION: Inaccurate heart rate measurements may also be caused by:

- Low arterial perfusion (reduced blood flow)
- Excessive motion

- Low lighting or rapid changes in the light environment
- Loss of data transmission from the camera device
- Elevated heart rate greater than 103 beats per minute

NOTE: Further, clinical data used to support the safety and effectiveness of the device did not include subjects with elevated pulse rates, so accuracy may be reduced when the subject has a pulse rate greater than 103 beats per minute. Other patient conditions that may affect the device's performance are listed in the labeling.

CAUTION: Inaccurate respiratory rate measurements may be caused by excessive motion.

CAUTION: Maintain your camera in a fixed position utilizing an external aid (e.g., device stand), as camera motion may prevent the respiratory rate from being reported (i.e., no readings displayed).

CAUTION: Partial or full obstruction of the face, neck, or shoulders from the camera may prevent the respiratory rate from being reported (i.e., no readings displayed).

Specifications

Expected Performance

Heart Rate Measurement	
Declared Range (Represents Error Level or A_{RMS})*	50 to 103 (+/-3) beats per minute
Displayed Range*	40 to 120 beats per minute
Measurement Window	60 seconds
Measurement Location	Face
Breathing Rate/Respiratory Rate Measurement	
Displayed Range (Represents Error Level or A_{RMS})	8 to 30 (+/-3) breaths per minute
Measurement Window	60 seconds
Measurement Location	Face, neck, and shoulders

*Definitions and calculations per ISO 80601-2-61 Medical electrical equipment —Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

Data Analysis

Vital-Trac measures shoulder movement as a part of the respiratory rate evaluation. Consequently, testing has shown that the report rate will be lower (i.e., no readings) if a user is “belly breathing.” Belly breathing, also known as diaphragmatic breathing, involves contracting the diaphragm, the muscle located between the chest and abdomen, as the primary means for inhaling and exhaling. As such, the shoulders and thorax move less, making it difficult for Vital-Trac to measure breathing rate.

In addition, check with your healthcare provider if you have any of the following which may cause abnormal (low or high) readings:

- cough/cold or other infections
- hiccups
- tremor/shaking
- asthma/chronic obstructive pulmonary disease (COPD)
- issues maintaining posture
- certain medications
- exercise, dehydration, stress, nervousness, or arrhythmia

Limitations

- Vital-Trac is not intended to be the sole method of checking the physical health of a patient. Healthcare providers are responsible for reviewing all measurements.
- Not for arrhythmias: Vital-Trac doesn't detect arrhythmias or irregular heartbeats.
- Not for continuous monitoring: the app is not designed for ongoing vital signs monitoring.
- Unstudied Conditions: the app hasn't been tested in people with movement disorders (such as Parkinson's disease, multiple sclerosis, tardive dyskinesia, etc.). Consult your healthcare provider if you're unsure about your condition and its impact on using Vital-Trac.
- Unauthorized tampering: any unapproved changes to Vital-Trac software may prevent it from working correctly.

Before You Start

- Use the app indoors in even lighting
- Sit comfortably with your back supported, legs uncrossed, and feet flat
- Avoid wearing face makeup or sunscreen
- Ensure your face, neck, and shoulders are clearly visible (i.e., no hats, masks, or bulky clothing)
- Relax for 5 minutes before starting
- Keep the background simple and still
- Avoid flashing lights, TVs, and movement behind you

During Measurement

- Position your face in the guide
- Remain still and avoid talking, eating, or moving
- Wait for the app to complete the scan and show your results
- Your results will automatically be sent to your healthcare provider.

NOTE: Session(s) timeout after 5 minutes of inactivity. If this occurs, you'll need to restart the session by re-entering your date of birth.

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Troubleshooting Alerts

If Vital-Trac doesn't work on your device, please contact your healthcare provider for an alternative method to measure your vitals. Other troubleshooting alerts may include:

- Red guide: adjust lighting or remain still
- Unable to measure vitals: let your healthcare provider know that Vital-Trac may not work for you with your current device

Additional troubleshooting information is available in Section 5.

3. Devices and Operating Systems Compatibility

Device/Camera Requirements

- Resolution: 640x480 pixels or higher
- Frame rate: 20 fps minimum
- RAM: 6.0 GB+

Check Compatibility

- iOS: Settings > Camera > Record Video > at least 720p 30 fps
- Android: Settings > Camera > Front picture size ≥ 2448x2448

Compatible Browsers

Supported Browsers	Versions
Safari	16 or higher
Google Chrome	114 or higher
Microsoft Edge	123 or higher
Samsung Internet	27 or higher

Note: Due to issues with Mozilla Firefox, this browser is not recommended for use with Vital-Trac.

Supported Operating Systems

Operating System (OS)	Versions
Android	Android 12 or higher
iOS	iOS 18 or higher
iPad OS	iPad 17 or higher
Mac OS	13.7.3 (Ventura) or higher
Microsoft Windows	Windows 11 or higher

Note: Some devices running on these operating systems may not be compatible with Vital-Trac. If you have any technical difficulties, please contact vtsupport@mindsetmedical.com.

Vital-Trac may not work on all camera-equipped smartphones, tablets, or computers. If Vital-Trac doesn't work on your device, seek an alternative method to measure your heart and respiratory rates.

4. Cybersecurity & Privacy

Stay Secure

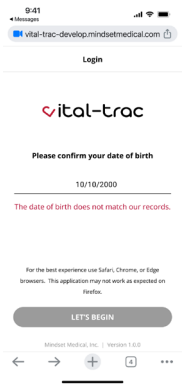
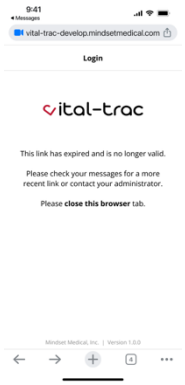
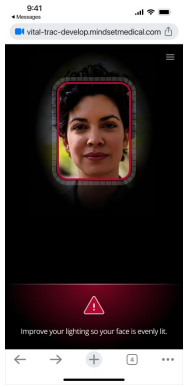
- Only click on links from your healthcare provider
- Never enter personal information outside the official app link
- Use private, secure internet (avoid public Wi-Fi)
- Enable security features on your device (PIN, biometrics)
- Keep your software and apps up to date with the latest security updates

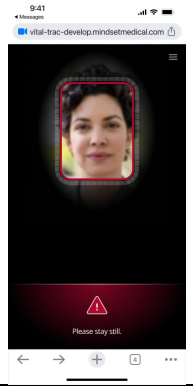
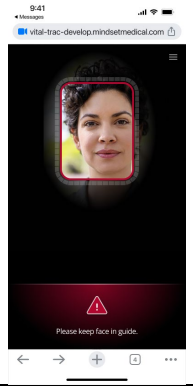
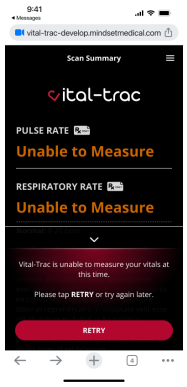
Your Data

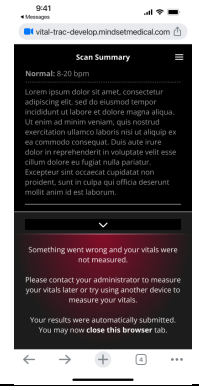
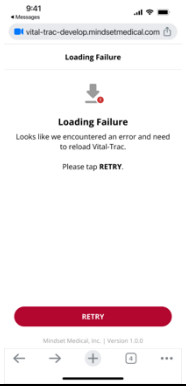
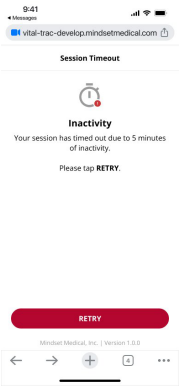
- Your health data is encrypted during transmission and is not stored on your device
- The app closes when you exit the browser
- Only your birth date is used for identity confirmation

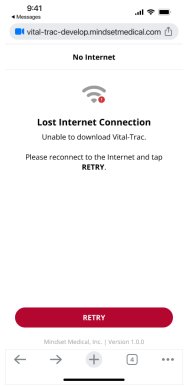
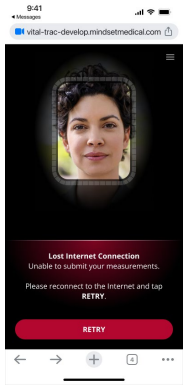
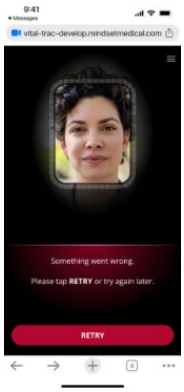
Need Help? If you encounter issues or have questions, contact your healthcare provider or email Mindset Medical support at vtsupport@mindsetmedical.com

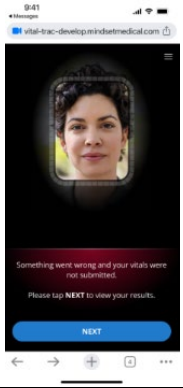
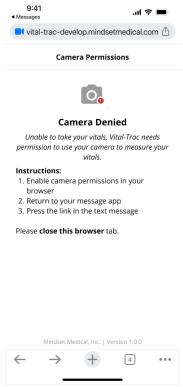
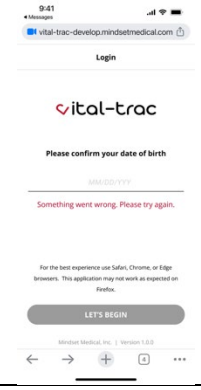
5. Error Messages

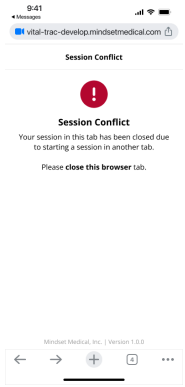
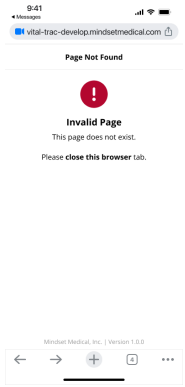
Vital-Trac Screen	Error Message
	**Incorrect Date of Birth** **What it Means:** The date of birth entered doesn't match the date of birth on file in the patient record with your healthcare provider. If an incorrect Date of Birth is entered five (5) times in a row, there will be a delay period of 15 minutes. After the expiration of the 15-minute delay period, you'll be able to try again. If the Date of Birth is incorrect five (5) more times, there will be a delay period of 60 minutes. If the Date of Birth is incorrect five (5) more times, you won't be able to use Vital-Trac. This is designed to keep your information safe. **Fix:** Contact your healthcare provider to verify your Date of Birth and request a new link.
	**Expiration of URL** **What it Means:** The link included in the SMS message sent by your healthcare provider will expire 72 hours after you receive it. During that 72-hour period, you will receive a reminder SMS message if you haven't used Vital-Trac. **Fix:** If the link is expired, contact your healthcare provider, and request a new link.
	**Poor Lighting Conditions** **What it Means:** The lighting isn't ideal for Vital-Trac to work properly. **Fix:** Adjust lighting to remove shadows or bright spots for even lighting on your face.

Vital-Trac Screen	Error Message
	**Too Much Movement** **What it Means:** Your phone or head is moving too much. **Fix:** Hold your phone and head steady. Make sure your face is centered in the guide.
	**Face Outside Guide** **What it Means:** Your face has moved out of the required position. **Fix:** Realign your face to the center, focusing on remaining within the guide.
	**Unable to Measure Vitals** **What it Means:** A vital sign could not be measured. **Fix:** Attempt the measurement again. You can try to measure your heart/respiratory rate three (3) times during each measurement session before you receive a Continuous Error.

Vital-Trac Screen	Error Message
	**Continuous Error** **What it Means:** Vital-Trac has tried to measure your vital sign(s) three (3) times in a row. The device used may not be compatible with Vital-Trac, or poor conditions are preventing Vital-Trac from working properly. **Fix:** Consider using a different device that is compatible with Vital-Trac. Consider using an alternative means to measure your vital signs.
	**Loading Failure** **What it Means:** There was an error loading Vital-Trac onto your device. **Fix:** Make sure you have an Internet connection and try restarting it.
	**Inactivity** **What it Means:** Vital-Trac will automatically close if there is no interaction for more than 5 minutes. **Fix:** Conduct your measurement within 5 minutes after starting Vital-Trac.

Vital-Trac Screen	Error Message
	**Lost Internet Connection – Unable to Download** **What it Means:** You need an Internet connection to download Vital-Trac. Your device is currently offline. **Fix:** Check and restore your Internet connection.
	**Lost Internet Connection – Unable to Submit** **What it Means:** You need an Internet connection to submit your results to your healthcare provider. Your device is currently offline. **Fix:** Check and restore your Internet connection.
	**Failed Submission Screen** **What It Might Be:** Loss of server connection when attempting to submit your results two (2) times in a row. **Fix:** Attempt to submit your vitals one (1) more time or try again later using the URL in your text message.

Vital-Trac Screen	Error Message
	**Continuous Error (Failed Submission)** **What It Might Be**: Loss of server connection when attempting to submit your results after three (3) attempts. **Fix:** Try again later using the URL in your text message.
	**Camera Access Denied** **What it Means:** The Vital-Trac can't use your device's camera. **Fix:** Change your device settings to allow camera access for the Vital-Trac
	**Something Went Wrong** **What it Means**: The Vital-Trac was not able to connect with the backend servers to confirm your date of birth. **Fix:** Try again later.

Vital-Trac Screen	Error Message
	**Session Conflict** **What it Means:** The App was opened in two (2) separate browser windows. The error will appear in the first browser window. **Fix:** Close the browser window with the error screen and use Vital-Trac as instructed.
	**Invalid Page Screen** **What it Means:** You have attempted to navigate back into Vital-Trac after submitting a measured result, attempted to reload a screen during an active measurement session, or used the browser's history to return to a screen in the App. **Fix:** Restart Vital-Trac by tapping on the original URL received

6. Customer Support and Contact Information

Need Help? If you encounter issues or have questions, contact your healthcare provider or email Mindset Medical support at vtsupport@mindsetmedical.com.

Manufacturer

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