Model Details

Basic info:

Presage vitals by video analysis generates pulsatile metrics such as aggregate pulse rate from a 30s video clip containing a subject's face. An API has also been developed to allow users easy access to compute this metric for commercial and scientific applications.

Organization developing model: Presage Technologies

Model date: 20250428t162129

Model version: 1.1.0

Model type: A deterministic computer vision model with two primary stages. The first identifies and tracks key feature points on the subject's face, and aggregates the image intensity into a set of means for specific regions of interest. The second stage uses signal processing to analyze the temporal fluctuations of these means to isolate and quantify the aggregate pulse rate.

License: The algorithm is currently proprietary, and licenses are granted with predefined agreement.

Where to send questions: Questions can be sent to: support@presagetech.com

Intended Use

Model uses:

Aggregate pulse rate models were intended for use by qualified clinicians, polygraphers and researchers for the analysis and non-diagnostic utility of pulsatile flow quantification and derivative metrics. It was intended to be used with a video from a stationary device (such as a handheld, mobile or laptop camera), that contains the subject's face in view, and be of 30 consecutive seconds in length and acquired at a minimum of 25 frames per second. The user's face must be visible and unobstructed for at least 15 consecutive seconds within the video, and the user must not make sudden large motions or move their face beyond 90 degrees of optical axis during this time. It is only intended to measure pulse rate values in the range of 40-180 bpm.

Out-of-scope uses:

The Presage pulse rate model is not intended for diagnostic purposes. Do not self-diagnose or self-medicate on the basis of the measurements. No alarms are provided, and it is not an arrhythmia detection or monitoring model. It is currently not intended for use in highly dynamic environments, or with a highly moving camera. We ensure all users have acknowledged and agreed to our license agreement and terms of service for usage prior to use.

Factors

The pulse metrics model first requires Mediapipe's face detection algorithm to identify the face and 468 key feature points on the face (mesh model). Thus, if these features are not identifiable by Mediapipe's algorithm, then pulse metrics will not be calculable. Reference the Mediapipe model cards can be found here: <u>Full Range Face detection model card</u> and <u>lite pose detection</u>:

- User's face orientation must be within angular parameters for detection by Mediapipe, off axis view decreases model's detection abilities. User's face and chest must be sufficiently visible, illuminated and positioned within the imaging window. User's face and body must be clear, and not blurry due to excessive motion or camera system. Users are instructed to maintain a fixed position.
- Environment: Model is developed on images with various lighting, noise and motion conditions and with diverse augmentations. However, its quality can degrade in extreme conditions.

These factors can affect model performance:

- Lighting: Sufficient illumination as well as temporal changes in lighting can affect the ability to correctly measure pulse rate and plethysmogram or return rate.
- User: User demographics, including skin tone and facial hair, may impact return rate. Darker skin tone will require a higher threshold on illumination intensity to produce accurate results, which if not met may reduce return rate. Facial hair or other facial obstructions will reduce the area of analysis, which may affect return rate.

• Motion: High degrees of user motion are not tolerated by the pulse rate algorithm. It is recommended to users that both the camera be mounted and the user maintains a fixed position before acquiring measurement.

Other factors:

• **Instrumentation:** Several cameras, including mobile (Android), USB (Econ) and webcam (Logi) based devices with varying sensitivities and image resolutions have been tested for efficacy. The biggest factor with respect to instrumentation is the importance of locking camera parameters during acquisition, including exposure, gain and white balance, while also operating on the uncompressed video stream. The SDK accounts for these factors, as well as variance in image size, resolution, and aspect ratio. When evaluating on pre-recorded videos, the biggest factor to consider is the codec, which can incorporate intraframe or interframe compression, both of which may impact accuracy.

Metrics

- 1. RMSD of point estimate of pulse rate: root mean square deviation between all aggregate measured values evaluated over a 30 second period of pulse rate and ground truth measurements. This is used because it is an aggregated measure of error that can be easily evaluated against alternative devices. For reference, the predicate device Oxehealth claims 1.81 bpm.
- 2. MAE of point estimate and 95% CI of pulse rate: median absolute error or deviation of aggregate measurements as compared to ground truth. Unlike RMSD, MAE allows for interpretability of error and distribution of error and is more robust to outliers than mean evaluations.
- 3. Mean proportion of returned values of pulse rate: for every 30 seconds of video, a single weighted measurement can be measured. Of all possible sets of 30 second clips within a video, this is a measure of the proportion of them that returned a valid measurement of pulse rate. The pulse rate model must be evaluated for accuracy and reliability. For reference, the predicate device Oxehealth claims 58% (95% CI 51% 65%).

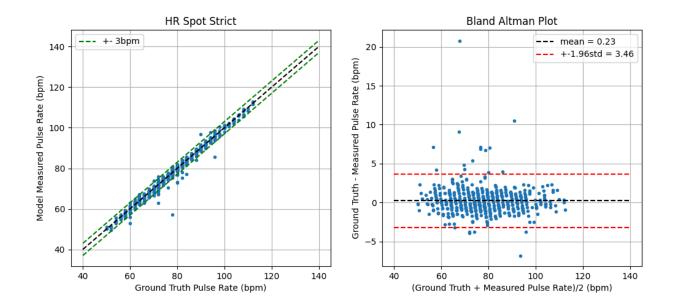
Evaluation Data

The evaluation data consists of a set of 236 videos. Corresponding quantities of pulse rate were measured from a Biopac research grade pulse oximeter. A clip of 30s from each video was run through the Presage aggregate pulse rate model for evaluation, leading to a total number of 826 samples. Videos were acquired on users covering a range of demographic variability, including age, gender and Fitzpatrick scale.

Quantitative Data

- 1. RMSD of point estimate of pulse rate: 1.78 bpm
- 2. MAE of point estimate and 95% CI of pulse rate: 1.11 bpm with 95% CI of [0.99, 1.23]
- 3. Mean proportion of returned values of pulse rate and 95% CI: 0.71

Distribution of error figures:



Skin Tone (Fitzpatrick)	% of Dataset (num samples)	RMSD	MAE [95% CI]	Mean Return Rate
1	0.17 (138)	2.56	1.26 [0.83, 1.68]	0.91
2	0.14 (116)	1.23	1.00 [0.78, 1.23]	0.99
3	0.08 (69)	1.37	1.06 [0.74, 1.38]	0.99
4	0.15 (125)	1.49	1.10 [0.84, 1.37]	0.69
5	0.13 (104)	1.81	1.19 [0.84, 1.54]	0.55
6	0.15 (123)	2.15	1.16 [0.78, 1.54]	0.28

Sex	% of Dataset (num samples)	RMSD	MAE [95% CI]	Mean Return Rate
Μ	0.35 (286)	2.15	1.20 [0.95, 1.44]	0.76
F	0.47 (389)	1.56	1.07 [0.92, 1.23]	0.69

Camera Type	% of Dataset (num samples)	RMSD	MAE [95% CI]	Mean Return Rate
Android	0.46 (381)	1.55	1.09 [0.94, 1.25]	0.84
Econ	0.54 (444)	2.01	1.14 [0.95, 1.32]	0.60
Logi	0.00 (1)	nan	nan [nan, nan]	0.00

Ethical Considerations

As a remote sensing device, the risks posed to the subjects in the trial are minimal, including the association of each subject with corresponding biometric data. Mitigation of these risks include de-identifying all subject data, including videos, prior to saving it. Additionally, all data is securely stored in a HIPPA compliant database with access to a select number of trained researchers.

The model is not intended for human life-critical decisions, diagnostics or prognostication.

Limitations and Tradeoffs

- Works best in stationary conditions (subject and measurement device are stationary)
- Requires at least 10 seconds of uninterrupted and unobstructed view of subject's face and chest area
- Currently only measures a single subject at a time