feebris

PLETHAI-v2.1.0 Electronic Instructions for Use

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Intended Purpose

PlethAI app analyses photoplethysmogram (PPG) signals from approved pulse oximeters to provide a numerical reading of Breathing Rate (BR) and Pulse Rate (PR) and to identify episodes of irregular heart rhythms suggestive of atrial fibrillation (AFib). PlethAI is intended to be installed into third-party healthcare mobile applications which can input a PPG signal generated by a medically certified pulse oximeter and can display the output of PlethAI.

Device Description

PlethAI is a software library that is to be installed and run within a 3rd party Healthcare Database/Monitoring Mobile Application with its outputs visible in a HealthCare Professional's work station and is intended to be used on adults who require monitoring as part of their care pathway in a inpatient-level care at home services, such as virtual wards and hospital at home setting under clinical oversight.

PlethAI is a software library that extracts three features from a photoplethysmography (PPG) signal, generated by a certified pulse oximeter and does not provide a user interface and is designed to be accessed through its application programming interface (API) by the Healthcare Database/Monitoring Software that displays the output processed by PlethAI.

The three features are:

1. **Breathing Rate Calculation**: predicts breathing rate, in breaths per minute, of a patient between 8 bpm and 35 bpm

2. **Heart rhythm Detection**: aids in the identification of regular rhythm and irregular rhythms suggestive of atrial fibrillation.

3. **Pulse rate Calculation**: predicts pulse rate, in beats per minute, of a patient between 30 bpm and 180 bpm

Target Population

18 years and above

Indications for Use

Patients who are appropriate for remote or community based care pathways, in particular at risk of respiratory and cardiovascular diseases or deterioration. These are patients who have been in a general clinical state that has been assessed by a clinician to be stable enough to be considered for remote monitoring out of hospital environments.

This covers patients who are pre or post diagnosis, pre or post presentation of symptoms, or early-late stage in condition progression which includes:

- Long term condition monitoring - for example, patients with chronic illness such as COPD/asthma, diabetes, hypertension or heart diseases.
- Outpatient assessment - for example, patients that have been referred/walked-in to a hospital/clinical environment for a consultation.
- Monitoring post hospital discharge - for example, patients who have recently been discharged from the hospital and need ongoing remote monitoring.
- Monitoring to inform the need for hospital admission - for example, patients whose condition can be treated/managed at home with remote monitoring and escalated into the hospital, if the clinical state of the patient exacerbates.
- Community assessment - for example, patients receiving routine health checks to check to assess risk and inform the need for further escalation.

PlethAI is not to be used as a sole form of monitoring on patients, it should not be used to replace traditional methods of diagnosis and treatment.

PlethAI is intended as an adjunct to assist in the monitoring of a condition whose treatment is normally not expected to be time critical.

Intended Users

- Healthcare professional - Practitioners, including physicians, nurses, pharmacists, respiratory therapists, physical therapists, technologists, or any other practitioners or allied health professionals that have a role in using a device for human use.
- Installation Engineer - Software Engineering experience in C++ or Java / Swift, sufficient to follow PlethAI installation and testing instructions

Contraindications

- Patients requiring ventilation (Non-Invasive Ventilation (NIV));
- Contraindication: Patients with disordered breathing (e.g. diagnosed obstructive/central apnoeas, breathing pattern disorders, panic attacks);
- Contraindication: Patients with pacemakers, implantable cardioverter-defibrillator (ICD) or any other intra-cardiac device;
- Contraindication: Patients younger than 18 years

Warning

- PlethAI Heart Rhythm detection may be less accurate in patients with severe cardiovascular disease;
- PlethAI Heart Rhythm detection on Non-AF Irregular Rhythms patients may Be Classified as AF;
- The PlethAI Heart detection output should be taken under careful consideration when there is a history of clinically significant premature ventricular contractions (PVCs), as this may influence the output. In such situations, additional clinical assessment is advised;
- PlethAI Heart Rhythm Detection should not be considered a gold standard for the assessment of PVC burden;
- Rare AF and electrical conduction deficit PlethAI Heart Rhythm may output Regular Rhythm;
- The outputs of PlethAI should not be used as a sole means of diagnosis; it should not be used to replace traditional methods of diagnosis and treatment
- In rare situations, the PlethAI breathing rate may output a value that is half the true breathing rate for the patient

Precautions

- Precaution: In rare situations, the PlethAI breathing rate may output a value that is double the true breathing rate for the patient.;
- Precaution: Only input signals generated by CE-marked pulse oximeter devices into PlethAI;
- Precaution: PlethAI Breathing Rate Calculation should not be used on patients exhibiting erratic breathing patterns or those who are hyperventilating;
- Precaution: PlethAI may abstain from results-certain instances of inherent limitations, technical issues, or unique patient factors
- Precaution: PlethAI may provide a breathing rate prediction of 8 or 9 breaths per minute when a patient is breathing under the intended range of 8 to 35 breaths per minute. If it is suspected that the patient is breathing below 8 breaths per minute and they receive a prediction of 8 or 9 breaths per minute, further health assessment or clinical intervention may be required.

Limitations

- PlethAI breathing rate does not apply to breathing rate values less than 8 breaths per minute and greater than 35 breaths per minute.
- PlethAI pulse rate does not apply to pulse rate values less than 30 beats per minute and greater than 180 beats per minute.

- PlethAI heart rhythm is not intended to be used as a sole diagnostic tool for heart rhythm abnormalities.
- PlethAI is not tested for and therefore should not be used on people younger than 18 years.

Clinical Benefits

- The clinical benefit for PlethAI Breathing Rate is the non-invasive measurement of Breathing Rate using existing certified pulse oximetry devices.
- The clinical benefit for PlethAI Pulse Rate is the non-invasive measurement of Pulse Rate using existing certified pulse oximetry devices.
- The clinical benefit for PlethAI Heart Rhythm is the non-invasive assessment of Heart Rhythm using existing certified pulse oximetry devices.

Performance Characteristics

Breathing Rate
Range: 8-35 breaths per minute Step size: 1 breaths per minute Accuracy: +/- 3 breaths per minute
Pulse Rate
Range: 30-180 beats per minute Step size: 1 beats per minute Accuracy: +/- 3 beats per minute
Heart Rhythm
Classifications: Regular rhythm, irregular rhythm suggestive of atrial fibrillation Sensitivity > 94.6% and Specificity > 92.9% of the irregular class

Note: PlethAI can also return an 'Abstention' result for a biomarker if the biomarker cannot be determined. In such cases, please refer to the 'Troubleshooting section'

Installation Package Contents

PlethAI needs to be installed by an installation engineer following the link provided by Feebris Ltd that is part of the Installation package. In case you need a copy of the installation guide, please reach out to support@feebris.com

The content of the PlethAI installation package is as follows:

- PlethAI-v_x.y.z.zip
  - packages/plethai-vx.y.z-Android/ containing the following items:
    - share/ - a folder containing package configuration and cmake files for subdependencies
    - lib/ - a folder containing all necessary .a static libraries, including for the PlethAI C++ static library, as well as extra configuration files for some subdependencies
    - include/ - a folder containing all necessary .h header files for each package used by PlethAI, include the header files of PlethAI itself
- PlethAI-v_x.y.z-githash.sha256 - a checksum hash to verify the integrity of PlethAI-v_x.y.z.zip
- PlethAI-v_x.y.z-githash-PlethAITestHarnessApp.zip - a sample application to accompany the installation guide.

Maintenance

There is no maintenance activities required. The PlethAI software is a one-shot installation software library, containing a set of algorithms. As such it does not require any routine maintenance such as security patching. The contained machine learning algorithms are pre-trained and fixed and do not involve any continuous learning or online learning.

Hardware requirements

PlethAI shall be compatible with

- Mobile Phone (Operating System: Android 12 to 15)
- Processor Architecture: ARM64
- Memory Size: 4GB+

Software requirements

Mobile phone Operating System Requirements:

- Operating System: Android 12 to 15

Installation Requirements:

- CMake minimum version required is 3.22.1.
- Android NDK minimum version required is 25.

Accessory

PlethAI is validated to be used with the following Pulse Oximeters Hardware devices:

- *Viatom CheckMe O2*
- *Shanghai Berry BM2000A*
- *Nonin WristOx2 3150*

Recommendations

It is recommended to use a CE-marked pulse oximeter (sample rate range 75 Hz to 125 Hz) for recording signals while using PlethAI. Ensure that the patient is not excessively in motion when recording a signal using the CE-marked approved pulse oximeters.

Decommissioning

- Open the source-code for the host mobile application.
- Navigate to the `./app/src/main/cpp` directory
- Remove all PlethAI files (i.e. the `pleth-ai-jni-bridge.cpp` file, the CMake build instructions and the packages sub-directory)
- Navigate to the JAVA application source code: `.app/src/main/java/` and remove all files in the `com.feebris` package.
- Remove all references to the PlethAI classes, and the PlethAI helper classes from the application source code.
- Rebuild the host mobile application.
- Release the host mobile application.

Troubleshooting

- The signal quality is too low - Ensure that the patient is not moving excessively. Please follow the instructions to use the pulse oximeter as recommended by the manufacturer
- Predicted breathing rate is greater than 35 - PlethAI Breathing Rate calculation ranges from 8 -35 breaths per min. Repeat the measurement and if the same error is generated, use an alternative method for evaluation of breathing rate
- PlethAI abstained from giving a prediction with enough confidence - In the event of the absence of results, please first repeat the measurement. If the problem persists, please revert to standard clinical practices. This could be due to inherent limitations, technical issues, or unique patient factors.

- Predicted pulse rate is greater than 180 or Predicted pulse rate is less than 30 - PlethAI Pulse Rate calculation ranges from 30 - 180 beats per min. Repeat the measurement and if the same error is generated, use an alternative method for evaluation of pulse rate.
- Signal too short - PlethAI aborted before it could produce results. Please ensure a full reading is obtained.
- Refinement error (Pulse Rate) - PlethAI wasn't confident enough to provide a prediction. Please retake the measurement.

Note: Always check the version of the PlethAI is the latest version by the Manufacturer.

Serious incident reporting

Any **serious incident**[1] that occurs in relation to the use of this to PlethAI should be reported to the manufacturer (Feebris) at qara@feebris.com and support@feebris.com and the competent authority of the Member State in which the user and/or patient is established.

[1]A serious incident is defined as any incident that directly or indirectly led, might have led, or might lead to any of the following:

- *Death of a patient, user, or other person*
- *Serious deterioration in health*
- *Serious public health threat*

Support and Complaints

Please ensure that you include all relevant details regarding your issue or complaint to assist us in providing you with prompt and effective support.

For any support inquiries or to report a complaint related to PlethAI, please contact us via email at support@feebris.com.

Manufacturer

Feebris Ltd.

Registered Address: Newfrith House, 21 Hyde Street, Winchester, Hampshire, SO23 7DR, United Kingdom

Operational Address: Office 408, 4th Floor, Telephone House, 69-77 Paul Street, London, EC2A 4NW, United Kingdom

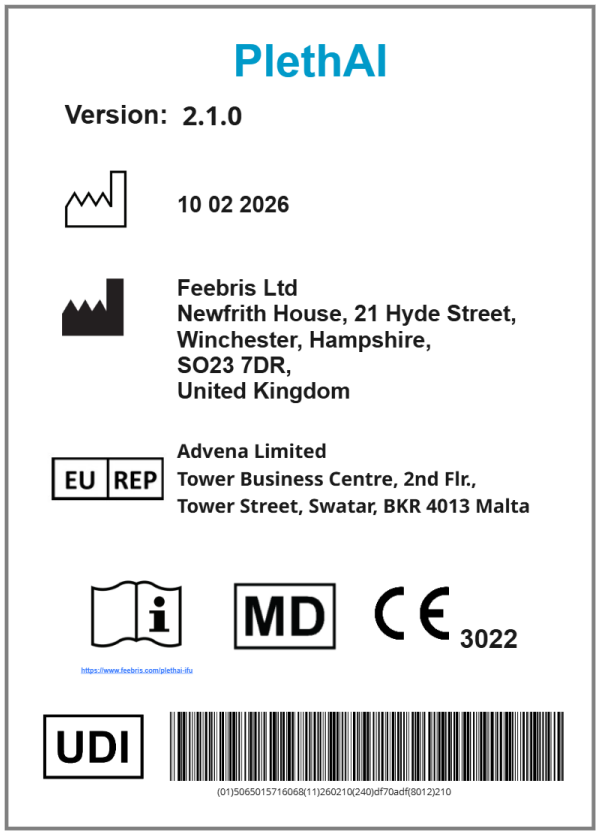
https://www.feebris.com
Contact: support@feebris.com

European Authorised Representative

EU REP Advena Ltd

Tower Business Centre, 2nd Flr, Tower Street, Swatar, BKR 4013, Malta.

Device Label



Accessing the IFU

This is an *electronic instructions for use* and is available online at https://www.feebris.com/plethai-ifu. If a paper copy is required, it can be requested free of charge by contacting our support team on support@feebris.com

Symbols

	Manufacturer
EU REP	European Authorised Representative
CE	Signifies European technical conformity
	Consult electronic instructions for use

MD	Medical Device
UDI	UDI - Unique Identification Number

Revision History

Version	Effective Date	Version Notes
1	2026-02-06	Initial Release - eIFU PlethAI v2.1.0.