Object

This document presents the user manual of LibCardio.

Scope of application

This document applies only to the medical device LibCardio.

Revision history

Version	Date	Changes in the record	Editor
01	29/12/2022	Creation	Idriss FOUODJI
02	27/02/2023	Update information about Arrhythmia	Mélaine GAUTIER
03	17/07/2023	Add labeling & frequency information. Add list of compatible oximeters Add residual risks information	Mélaine GAUTIER
04	29/08/2023	Add the circumstances in which the user should consult a healthcare professional, and reference standards used for writing this document.	IDRIS PACHA Nour
05	18/09/2023	Added goals and target audiences, as well as solutions for identified risks, and added warnings.	IDRIS PACHA Nour

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1. References and related documents

External documents :

Standard:

- ISO 15223-1 :2017 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: general requirements.
- EN 1041:2008+A1:2013 Information supplied by the manufacturer of medical devices.
- COMMISSION IMPLEMENTING REGULATION (UE) 2021_2226

Directive:

- MDR 2017/745

Others:

- BM1000B&D pulse oximeter operation manual 20210429-V3.2 (downloadable there https://www.sensoriaanalytics.com/en/libcardio-documentation/)

2. General description

Cardiovascular disease kills 1 in 3 people worldwide, without warning. The heart carries signs of trouble and by detecting them with new technologies, many of these deaths could be avoided. If detected early enough, most of these diseases are reversible. For this to happen, everyone must be able to control their heart in a simple, portable and reliable way, whenever they want.

Current prevention solutions do not detect the majority of cardiovascular diseases that lead to death: prevention campaigns consist in minimizing risk factors (tobacco, hypertension, obesity, etc.). However, more than a quarter of the people who die are not due to these factors. Cardiac check-ups are done by cardiologists or specialized hospitals on an ad hoc basis. Half of the deceased have no prior symptoms, and therefore have no reason to consult.

3. Operating principle
3.1. Intended purpose

LibCardio is a medical device designed to be integrated into a software application for the prevention and detection of cardiovascular, respiratory, and stress-related diseases using signal processing analysis and artificial intelligence.

It is used in conjunction with an accessory device (such as an oximeter) and employs advanced signal processing and artificial intelligence techniques to provide reliable information.

3.2. Intended Users

Companies operating in the field of medical devices and wellness, seeking to incorporate a wider range of real-time signals related to respiration, the cardiovascular system, and stress, can integrate this library into their medical device software applications.

Intended patient population: The medical device provided by Sensoria Analytics aims to be used for screening purposes by providing common vital signs that are useful cross pathologies. It can be used on adults seeking a global check-up, it is for the general population with the same restriction than oximeter devices (adults). It also targets the subjects with Allergy or Asthma that want to track their respiratory situation through these vital signs.

An input quality signal indicator is provided to ensure the reliability of the signal and analysis.

3.3. Indications

The library has been designed for integration into various software applications used in the context of medical devices. These applications are primarily dedicated to routine medical examinations, including home monitoring, use in telehealth kiosks, or by healthcare professionals. Additionally, this library can be used for preventive examinations that may not necessarily be planned in advance, providing significant flexibility in its utilization.

3.4. Contraindications

It is recommended not to use the LibCardio solution to measure subjects with poor blood circulation due to a condition such as Raynaud's disease, or patients with a pacemaker, as well as limitations related to the use of the accessory device (oximeter).

The product is intended for use only in adults. Do not use the product for children, infants, and newborns.

3.5. Conditions of use

For optimum, reliable oximeter readings, the subject must be in a static position.

He/she should insert his/her finger (index or middle finger preferred) into the oximeter tip, without creating pressure on the sensor, and should not move during the measurement.

It is advisable not to have any nail polish on the measuring finger, to not create an artifact in the measurement.

3.6. How does the product work?

The LibCardio library has input and output elements.

The input elements of the library include:

- Raw data: the fundamental data are: the photoplethysmography signal (PPG), the Heart rate (HR), the Pulse Oxygen Saturation (SpO2), Inter-Beat Interval (IBI). These data are accepted by the library provided that they respect the configurations required (data format...) by the library;
- Data from a certified medical device (such as an oximeter, a connected watch...), tested and validated to ensure the accuracy of the results provided by the library. The connection with the library can be done by sending data packets in the required format or a Bluetooth or USB device recognized by the library.
  The input device currently used is an oximeter from the supplier Berry using a private protocol;
- An internally generated file that already has the data and configurations required by the library.

The data received by the library are then processed as they are acquired and the different algorithms are applied to generate the output data (instantaneous and at the end of the recording) among which, in addition to the input data, we have: signal quality, RMSSD, cardiac amplitude, cardiac variability, respiratory rate.

The LibCardio library is intended to be used in association with another application (middleware) which is considered as the user interface. It is in this application that the output data of the library will be interpreted according to the need. Thus, we will be able to have information such as cardiac rigidity, arterial elasticity, blood pressure, respiratory rate...
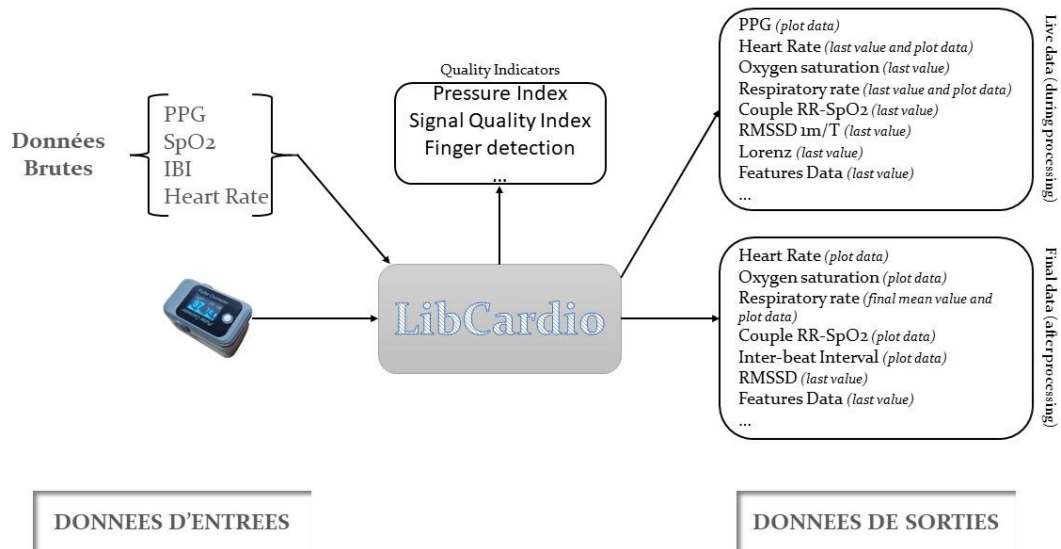
Principe de fonctionnement LibCardio

3.7. Compatible oximeters

Oximeters validated and compatible with LibCardio:

- BM1000B/BM1000D
- BM3000B

A firmware update towards our proprietary protocol is necessary if the device is not sent by us.

3.8. Safety information
3.8.1. Risks and measures to be taken

There are several risks that can lead to misinterpretation by the application or the user, resulting in undesired incorrect diagnoses or experiment failures, leading to wasted time and/or misinterpretation.

HAZARDS	CAUSES	SOLUTIONS
Usability		
Presence of artifacts in the signal that can lead to unreliable results.	Movement of the person or environmental issues (e.g., sunlight, nail polish).	Readjust the position of the subject's finger, then take a new measurement.
Reliability of results compromised due to low signal intensity.	Low blood perfusion (Raynaud's phenomenon, cold hands).	The subject does not correspond to LibCardio target audience. If the disease is not strong try to warm the finger and improve the finger blood circulation before to take a new measurement
Inconsistency or loss of data.	Electromagnetic interference disrupting measurements.	Make sure you are in a place where the accessory will not be exposed to interference.
Use of personal data as input leading to inconsistent results.	Missing or incorrect personal data.	Please submit or correct personal information.
Unreliable results due to data loss.	Missing input packets (e.g., interference or BLE transmission).	Take new measurement. If the problem persists or is recurring, please contact SENSORIA ANALYTICS.
Loss of output data caused by a library crash.	Internal failure during the calculation process (algorithms).	Please contact SENSORIA ANALYTICS and provide a description of the sequence of event that leads to the crash and all the useful data that you help to solve the issue.
Result errors caused by algorithm	Algorithm instability.	Please contact SENSORIA

errors.		ANALYTICS and provide a description of the sequence of event that leads to the issues and all the useful data that you help to solve the issue.
Maintenance		
Application instability or crash following platform (OS) or external library update.	The update removes an obsolete function used by the library, causing the library to fail.	Please contact SENSORIA ANALYTICS and provide the previous and current version of the library.
Inconsistent data after input protocol update.	Input protocol update.	Please contact SENSORIA ANALYTICS and provide the installed protocol and current version of the library.
update of output leading to data access loss.	switch of data.	Please contact SENSORIA ANALYTICS and provide the previous and current version of the library.

During the development, solutions were implemented to reduce these risks, we kindly request you to carefully follow the precautions and usage limitations of the Libcardio library to ensure an optimum usage of it.

3.8.2. Precautions and warnings

- LibCardio serves as a supplement to patient assessment. Its use should be combined with the observation of clinical signs and symptoms. It is not intended for therapeutic purposes.

- EXPLOSION RISK: Do not use the accessory in the presence of explosive substances, vapors, or flammable liquids.

- The person using LibCardio and its accessories must have the adequate skills for its use (e.g. oximeter) and the interpretation of the output signals.

- When connecting the accessory, be sure to do it with caution to avoid any risk of strangulation of the patient.

- Ensure not to use LibCardio and its accessories during MRI (Magnetic Resonance Imaging) or CT (Computerized Tomography) scans, as induced current can potentially cause burns.

- When using LibCardio and its accessories with electric surgical equipment, the user must exercise caution and ensure the safety of the subject.

- Store LibCardio accessories in a secure location to prevent the risk of being bitten by pets or intrusion by pests. Keep accessories and small parts like batteries out of the reach of children to avoid accidents.

4. Library Integration Platform

The compiler used must support at least C++17.

The integration of the library can be done on PC or on a mobile application.

The acquisition frequency are 50, 100 or 200 Hz (recommended).

On PC, the library is by default provided in C and C++ and can be integrated in other languages depending on the need of the application manufacturer. It works on the following environments:

- Linux (64 bits)
- Windows (64 bits)
- iOS (64 bits)

On mobile application, the library is provided in C++ and works on the following environments:

- Android (64 bits)
- iOS (64 bits)

The integration procedure is detailed in the LibCardio integration document.

5. The different input data of the library
5.1. Mandatory data
5.1.1. The PPG signal

Photoplethysmography (PPG) is a non-invasive optical method that measures changes in skin tone associated with simultaneous changes in blood volume in subcutaneous blood vessels during the cardiac cycle. PPG sensors use optical pulses generated by a red or near-infrared light source (light-emitting diode) and receive light reflected from a photodetector. This is a signal that contains several pieces of information about the cardiovascular system.

5.1.2. Heart Rate

This is the heart rate estimated by the number of contractions (beats) of the heart per minute (bpm).

5.1.3. Oxygen saturation rate (SpO2)

This is the fraction of oxygen-saturated hemoglobin to total hemoglobin (unsaturated + saturated) in the blood.

5.1.4. Inter-Beat Interval (IBI)

IBI is a scientific term used to refer to the time interval between heartbeats. It is also sometimes called the cardiac period. When using the ECG series, it is defined as the time between successive R peaks. It is expressed in milliseconds.

5.2. Optional data
5.2.1. Personal data

The calculation of some parameters is influenced by personal data such as heart rate. However, they are main optional for the library.

5.2.2. Input quality indicator

This data, which depends on the device used as input to the library, gives information on the quality of the signal. For example, in the case of the oximeter, it indicates whether the finger is detected or not.

5.2.3. Perfusion index (PI)

The PI is the ratio of pulsatile to non-pulsatile static blood flow in a patient's peripheral tissue, such as the fingertip, toe or earlobe. It is an indication of the pulse intensity at the sensor site.

6. The different output data of the library
6.1. Heart rate (HR)

This instantaneous value is an average over a time window: 1 second by default. At the end of the recording, the median value of the whole recording and a list of RH values versus time are provided.

Heart rate interval	Accuracy

0-30 bpm	undefined
30-240 bpm	+/- 2 bpm

For an healthy adult, it is recommended to consult a healthcare professional if the heart rate at rest is consistently above 100 bpm or below 35 bpm (look for literature for more detailed information).

6.2. Oxygen saturation rate

The value of this parameter is provided instantaneously. It is an average over a time window: 1 second by default.

The median value of the entire recording and a list of SpO2 values versus time are also provided at the end of the recording.

Oxygen saturation interval	Accuracy
<70%	undefined
70%~79%	+/- 2 %
80%~100%	+/- 3 %

If the oxygen level is below 90% for an adult in standard condition, it is recommended to consult a healthcare professional. Some parameters like altitude can change this minimum reference value.

6.3. The PPG signal

It is provided instantaneously as raw and filtered data, in the form of a list of values over a given period of time (usually 1 second).

6.4. Inter-Beat Interval (IBI)

The IBI value is provided at the end of the recording as a list of raw and filtered values. It is filtered to remove artifacts and other ectopic values before being processed for heart rate variability analyses.

Sum of IBI	Accuracy
Recording time	+/-2%

6.5. Input quality indicator

The value of this parameter will allow to know if the finger is present on the current signal (case of an oximeter).

It is also important for the stability of the data because it will allow to know at any time if each of the values of a data set is in the desired range.

6.6. Respiratory rate (RR)

It is the number of breaths/respirations per minute (rpm) or, more formally, the number of movements indicating inspiration and expiration per unit of time. The first value is calculated as a moving average after 30s and then a new value is proposed every 3 seconds. This is the instantaneous value. The median value of the whole recording and the list of RR values versus time are also provided at the end of the recording.

Respiratory rate interval	Accuracy
0-80 rpm	< +/- 2 rpm

For an adult, if the respiratory rate at rest exceeds 20 rpm, it is advisable to consult a healthcare professional.

6.7. The RMSSD (Root Mean Square of Successive Differences)

This parameter is used to detect irregularities. It is calculated at the moment and at the end of the recording. The value calculated at the end of the recording corresponds to the last value of the recording that has been filtered.

RMSSD interval	Accuracy
0-400	+/- 10 (dependent on IBI calculation)

6.8. Instantaneous Pulse Rate Variability (PRV)

It is the instantaneous representation of the pulse variability in real time. At each instant, a coordinate point (x, y) is given.

A list of values is also provided at the end of the record.

6.9. Pulse wave characteristics (Features)

The characteristics of the pulse wave are interesting for the calculation of certain parameters. They mainly consist in identifying the value of the inflection points of each wave and their positions. The calculation is done at the end of the recording.

6.10. Heart rate variability (HRV)

It is a distribution of the intervals between two heartbeats over a period of time. It is considered to reflect the activity of the sympathetic and vagal components of the autonomic nervous system (ANS).

The HRV parameters are a set of statistical measures that provide information about cardiac activity in the time, frequency and non-linear domains. It is a set of 59 values that contain a lot of information.

6.11. Arrhythmia

Arrhythmias are abnormalities of the heart rhythm. In instantaneous, it is calculated at each tick (1 if the algorithms have detected something abnormal otherwise 0).

The end of the recording corresponds to a list of probabilities (presence of arrhythmia, no presence of arrhythmia) as well as an indication value of potential arrhythmia: 0 unlikely arrhythmia, 1 Potential arrhythmia, 2 Good probability of presence of an arrhythmia.

This value is calculated from the final list (if less than 40% of the values indicate an arrhythmia, 0 is returned, if between 40% and 60%, 1 is returned, otherwise 2 is returned).

For an adult, if you have at each recording a potential or a good probability of presence of an arrhythmia, it is strongly recommended to consult a healthcare professional to do complementary analysis.

6.12. Stress

Stress is a major problem in our society, as it is the cause of many health problems such as cardiovascular diseases. To prevent it from becoming chronic and causing irreversible damage, it is necessary to detect it in its early stages.

The library outputs 3 stress values (and the percentage associated with each value) to determine the stress state of an individual.

6.13. Heart rate amplitude

The cardiac amplitude plays an important role on the cardiorespiratory system. Thus, its increase has a positive effect on cardiorespiratory diseases.

As for the library, it gives in output (at the end of the recording) the percentage of high, average and low cardiac amplitudes, a global score of the amplitudes and the list of the amplitudes at each second (in the form of vector).

Heart rate amplitude Interval	Accuracy
0-100 %	+/- 2 %

7. Maintenance and update of the library

Maintenance of the library is provided for the entire warranty period by contacting support@sensoriaanalytics.com.

Updates for corrections to the library are provided automatically to the customer throughout the warranty period in the format the customer uses via a downloadable link.

If a significant error is identified, an update to correct the error will be provided to all customers, whether under warranty or not, to ensure product safety and performance.

8. Paper version and update of the user manual

A paper version of the user manual is supplied to our customers on request in 7 days.

For online access to the latest versions of the user manual, please use the link below:

https://www.sensoriaanalytics.com/en/libcardio-documentation/

9. Reporting serious incidents

We would like to draw your attention to the importance of reporting any serious incident involving Libcardio. If you encounter a serious problem or notice a malfunction, it is crucial that you report it to the competent authority in your country.

By reporting any incident, you help us to continually improve our product and protect the health of our users.

If you have any questions or need assistance with reporting, please do not hesitate to contact our services.

10. Label

10.1. Label symbols

This symbol represents Sensoria Analytics's e-mail address. You can use this e-mail address to contact us if you have any questions or concerns, or to obtain additional information about using Libcardio.

This symbol represents Sensoria Analytics's telephone number. You can use this number to contact us for technical support, to report problems or to get quick answers to urgent questions about using LibCardio.

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10.2. Label content

End of the document