# Product sheet

Gabi Pediarity for research

## What is Gabi Pediarity?

Gabi Pediarity is a comprehensive solution to record and collect health data from the pediatric population from 0-12 years old. While initially designed for pediatrics, the solution works on older children and on adults.

Gabi Pediarity is composed by:

* The Gabi Band: A sensor to collect and interpret biometric signals and send over Bluetooth Low Energy to Gabi Monitor. The Gabi Band is fitted on the upper-arm of the participant.
* The Gabi Monitor: A dedicated tablet with the Gabi Monitor App to collect the data from the Gabi Band and send it over WiFi on the Gabi Cloud.
* The Gabi Cloud: A secured cloud environment to store and consolidate the collected data.
* The Gabi Analytics: A web portal to visualize the collected data and the trends.

## What’s in the box?

The Gabi kit is composed by:

* The Gabi Band (the sensor unit).
* 4 textile bracelets (S, M, L and XL) to adapt to the different morphology.
* The Gabi Monitor tablet with the Gabi Monitor App pre-installed.
* 2x USB cables (for the band and the tablet).
* 2x USB charger for power outlet.

## Health data collected

|  |  |  |  |
| --- | --- | --- | --- |
| **Vital signs** | **Range** | **Accuracy** | **Frequency** |
| Pulse rate | 25 to 250 bpm | ±3 bpm RMSE (\*) | 1 data point per sec |
| SpO2 | 50 to 100% | ±3.5% RMSE (\*) | 1 data point per sec |
| Respiratory rate | 3 to 70 BrPM | ± 3 BrPM RMSE | 1 data point per sec |
| Skin temperature | 0 to 50°C | ± 0.01°C | 1 data point per 5 sec |
| Actigraphy | 0 to 2G | ±0.001G | 3 data points (X, Y, Z) per 100 ms |

(\*) FDA cleared signal processing algorithm

## Battery life

The Gabi Band is designed to record and stream data for 18+ hours. However, the Gabi Band has been tested for up to 60+ hours. It takes about 1 hour to recharge a fully depleted Gabi Band.

The Gabi Monitor tablet is designed to record data for 8+ hours. However, the Gabi Monitor tablet has been tested for up to 19+ hours. It takes about 4 hours to recharge a fully depleted Gabi Tablet. During the recording, it is preferable to keep the tablet plugged on the power outlet.

## Wireless communication

The Gabi Band sends the collected data by streaming to the Gabi Monitor tablet. The data is sent over Bluetooth Low Energy (BLE) 4.2. The range is about 23 feets (7 meters).

The Gabi Monitor tablet sends the collected data at the end of the recording to the Gabi Cloud. The data is sent over WiFi 2.4 GHz. The range is the classic WiFi 2.4 GHz range.

## Offline data storage

The Gabi Band is able to store 8 hours of data without Bluetooth connectivity. This local offline storage is designed for recovery purposes only, not for normal operating conditions.

The Gabi Monitor tablet is able to store 250+ nights without Internet connectivity.

## Data transfer & export

All data is stored safely on Gabi cloud during the length of the study.

There is one archive per participant per month or per day in the export.

A exported file is a compressed archive composed by 4 files:

* dm.json: Meta data file containing general information about the archive.
* plx.csv: CSV file containing vital signs with a reliability flag per vital sign.
* temperature.csv: CSV file containing the skin temperature.
* accs.csv: CSV file containing the actigraphy.

The files can be sent over email or through drop on a cloud bucket (AWS, Azure, Google Cloud, etc).

One night of recording represents approximately 0.25MB/hour compressed (2.5MB/hour uncompressed). All timestamps in the files are stored in UTC format.

## Tests & certifications

|  |  |
| --- | --- |
| **Category** | **Standard** |
| Biocompatibility - Cytotoxicity | ISO 10993-5:2009 |
| Biocompatibility - Sensitization | ISO 10993-10:2021 |
| Biocompatibility - Irritation | ISO 10993-23:2021 |
| Electrical Safety | IEC 60601-1:2005/Amd2:2021 |
| Electrical Safety | IEC 60601-1-6:2010 |
| Electrical Safety | ISO 80601-2-61:2017 |
| EMC Safety | IEC 60601-1-2:2014/Amd1:2021 |
| Software | ISO 62304:2006/Amd1:2015 |
| Usability | IEC 62366-1:2015/Amd1:2020 |
| Performance - Accuracy of pulse oximeters | ISO 80601-2-61:2017 |

## Data privacy & security

Gabi Pediarity is GDPR and HIPAA compliant.

Vulnerability scanning is performed every week. All components are tested through penetration testing by an independent company at least once a year.

All data is encrypted at rest and during transit according to state-of-the-art standards.

At the first demand, all data concerning the study is deleted.