
	Release Note for PEDIARITY 1.1	
	GD00169 v2	PEDIARITY™

PEDIARITY™ v1.1 Release Note


Version	Date	Change description
0	13-MAR-2024	Initial version
1	06-JUN-2024	Add features, technical changes and bug fixes compared to previous version 1.0.1
2	10-JUL-2024	Update target version of the components

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2. Definitions & abbreviations


ACCS	Accelerometers
DPO	Data Protection Officer
HCP	Healthcare professional
IFU	Instructions for use
PR	Pulse rate
RR	Respiratory rate
SpO2	Peripheral oxygen saturation

3. Related documents

GD00001	PEDIARITY User Needs
GD00008	PEDIARITY Design requirements
GD00021	PEDIARITY Caregiver IFU
GD00022	PEDIARITY HCP IFU

4. Reference documents & norms

IEC 62304:2006	Medical device software – Software life cycle processes
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5. Introduction

This document is the release note of PEDIARITY™ v1.1. It covers:

- the versions of the subsystems included in the version
- the change log compared to the previous version
- the known issues in the software.

This document is communicated to the end user of the system.


6. Version of subsystems

Subsystem	Component	Version
Gabi Band	Hardware	GSC2 rev. B
	Firmware	1.6.8
	Including Signal processing algorithm	1.4.9
Gabi Monitor App	Application	1.12.12+179
Gabi Analytics	Analytics	0.10.20
	Privacy	0.10.20
Gabi Cloud	Backend	1.14.18

7. Change log

7.1. New features or updated features

Biometrics monitoring	<ul style="list-style-type: none"> • Display SpO2 values below 70% (old range from 70% to 100%, new range from 50% to 100%) • Improve the detection of the reliability of the measurements • Allow the user to select the sensibility of the cardiac events' detection • Improve biometrics scrollbar to identify the type of events
Patient's dashboard	<ul style="list-style-type: none"> • Revamp the patient's list into the patient's dashboard with a preview of the last recording data • Support the program selection to display only relevant information in the dashboard according to the specialty of the HCP in Gabi Analytics


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Health report	<ul style="list-style-type: none"> • Separate the display of cardiac events (below and above thresholds are displayed individually) • Offer tab visualization “last recording”, “last 7 nights”, “last 30 nights” and “last 90 nights” • Remove heatmap from the health report • Add event list based on threshold
Patient management	<ul style="list-style-type: none"> • Remove the note feature from Gabi Analytics • Support gender information for the caregiver • Support note about the health condition and the tags
HCP management	<ul style="list-style-type: none"> • Support gender information for the HCP • Support selection of the specialty to adapt the UI
Mobile App	<ul style="list-style-type: none"> • Improve onboarding of the caregiver on Gabi Monitor • Add troubleshooting helpers for the caregiver on Gabi Monitor • Support Spanish language for caregivers and patients • Add information pane to explain what’s is going on with the sensor (e.g. calibration in progress) • Add manufacturer test screen to allow end-of-line testing by the tablet manufacturer
Misc	<ul style="list-style-type: none"> • Add links to the policies in the Help menu • Update logo and color to the new brandbook • Add support for exporting the raw data of a study (only available to Gabi SmartCare team)

The detailed features are defined in GD00001 (User needs) and GD00008 (Requirements).

7.2. Bug fixes

Gitlab ID	Description
cna-app#310	Pairing not possible on Gabi Monitor App after reset and change of band with the same tablet
cna-app#304	After resetting the Gabi Monitor App, the user cannot use the same QR-code during the onboarding
gabi-file#22	When no live data for more than 8 hours, the timestamp on the recovery timestamp may be incoherent.
gabi-hcp-web#379	The selection of a specific day closes unexpectedly when the user selects a day older than the last month.
cna-app#255	After update of the firmware, if the user clicks too fast, the app requests to update

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	again.
cna-app#199	Two status widgets are still in English. The French label is not applied.
gabi-hcp-web #243	If the thresholds are crossed on two biometrics and a part of one of them is not reliable, the segments are still marked in red in the timeline.
cna-app#163	After letting the app on the screen "Scan QR-code" with camera on for a while, the tablet crashed
cna-app#324	During the onboarding, if the internet connection is temporarily down during the linking of the band with the patient, the onboarding is blocked.
gabi-hcp-web #333	The account is blocked after 3 failed login attempts. However, it is well locked on the 4th attempt.
cna-app#240	Incoherence between Gabi Analytics and Gabi Monitor about the 13-years old warning message.
gabi-hcp-web #387	In the privacy screen, the "Next" button should be "Save" for the sake of clarity.
gabi-hcp-web #395	Heatmap in Gabi Analytics shows a double empty day when changing from summer time to winter time
cna-app#238	The checking of the app version isn't performed properly during the onboarding. It is done only after the end of the onboarding process.

7.3. Technical changes

Data processing	The recording processing chain has been updated to support other devices in the future.
Availability	The call to the backend by the frontend are using a dedicated load balancer instead of the integrated load balancer of Firebase Hosting.
Dependency updates	The dependencies have been updated due to vulnerabilities found in some of the dependencies

8. Known issues

The known issues are classified into 4 categories:

- Safety issues: All known issues that have an impact on the safety of the patient.

- Blocker issues: Known issues for which there is no known workaround.
- Minor: Other known issues that have no impact on the safety or the performance.
- Cosmetic: Issues that don't impact the usage of the system (e.g. typos, etc). Cosmetic issues have no impact on safety or performance.


The issues are planned for resolution in a future release.

8.1. Safety issues

8.2. Blocker issues

8.3. Minor issues

Gitlab ID	Description	Workaround
gabi-hcp-web #394	When HCP updates the language of the user, the mobile app keeps the language selected by the user during the onboarding	Be aware that as soon as you proceeded to on-boarding of the Gabi Monitor App, you can change your language in the App settings. The HCP will not be able to update it from his platform.
gabi-hcp-web #253	The cursor of the scrollbar is misaligned on Safari.	If using Safari, the cursor allowing you to navigate through the recording may respond slowly. You can use another browser to ease your navigation.

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8.4. Cosmetic issues

Gitlab ID	Description	Workaround
cna-app#351	The reminder to start the recording briefly appears when the data are already uploaded to the cloud.	
gabi-hcp-web#386	In the privacy screen, the tab name overlap with the ">" on low resolution screen	