gabi SMARTCARE	Release Note for Pediarity 1.1	
	GD00169 vB	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
3	15-JUL-2024	Add list of known issues
4	16-JUL-2024	Add new known issue cna-app#533
A	16-JUL-2024	Target version
A0	29-AUG-2024	Issue backend#608 is fixed, adjustment of latest version with infrastructure hotfix
B	06-SEP-2024	Target version

Role	Name	Date	Signature
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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 (v1.0.1)
- 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	1.6.10
	Including Signal processing algorithm	1.4.9
Gabi Monitor App	Application	1.13.6+186
Gabi Analytics	Analytics	0.10.21
	Privacy	0.10.21
Gabi Cloud	Backend	1.14.23

7. Change log
7.1. New features or updated features

Biometrics monitoring	- 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 and the periods with reliable data
Patient's dashboard	- 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	● 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	● Remove the note feature from Gabi Analytics ● Support gender information for the caregiver ● Support note about the health condition and the tags
HCP management	● Support gender information for the HCP ● Support selection of the specialty to adapt the active patients list display
Mobile App	● Improve onboarding of the caregiver on Gabi Monitor ● Add troubleshooting helpers for the caregiver on Gabi Monitor ● Support Spanish language for caregivers ● Add information pane to explain what's is going on with the sensor (e.g. calibration in progress)
Misc	● Add links to the policies in the Help menu ● Update logo and color to the new brandbook

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 updating the firmware, if the user clicks too quickly, the app requests to update again.
cna-app#199	Two status widgets are still in English. The French label is not applied.

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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 highlighted 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.

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The issues are planned for resolution in a future release.

8.1. Safety issues

None

8.2. Blocker issues

None

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 proceed 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.
gabi-hcp-web #715	In the daily biometrics view, when zooming starts in the middle of an event, the event is not displayed in the zoom windows.	Thresholds are displayed in the zoom. If more precision is required, you can start the zoom before the event.
pediarity#69	The biometric is tagged as not reliable in case of flapping. The implementation is considering 28 seconds included instead of 30 seconds not included to define the duration for a stable signal.	None. This is a small update in the definition of the flapping.
gabi-firmware #151	Raw data recovery may be stuck when multiple disconnections during the recovery.	Instruct the user to keep the band close enough to the tablet during a recording.
gabi-hcp-web #684	The sorting of the patients' list is case sensitive on the last name of the patient	When entering the data of the patient, stay consistent with the cases. You can update the casing afterwards by updating the patient's data.
gabi-hcp-web	On unstable connectivity, the error 502 could	When the error appears, reload

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#664	appear (Bad Gateway) which could lead to missing information in the GUI.	the web page.
gabi-hcp-web #641	During the creation of the patient, the user may be logged out for inactivity and receive an error message.	When the error appears, reload the web page.
cna-app#502	Sometimes, forced firmware update doesn't work at the first attempt	Shutdown the tablet, unplug the band, start the tablet, plug the band on power and retry the forced update
cna-app#533	If the band is disconnected, the "I need help" message doesn't mention that the band should not be plugged while worn by the child.	The band cannot be worn while plugged on a power plug.
backend#621	The trend indicator in the patient's list and in the health report may be inconsistent due to rounding.	If there is a doubt, always look carefully at the values.

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.	None
gabi-hcp-web#386	In the privacy screen, the tab name overlap with the ">" on low resolution screen	None
gabi-hcp-web#718	There is a link "See full change log history" at the end of the change log which is not needed and inactive	None
gabi-hcp-web#711	The first time indicated in the preview of an event is shifted.	None
gabi-hcp-web#707	When sorting the patients' list, the GUI doesn't differentiate "no data" and "0 events". It leads to mixed sorting for those data.	None
gabi-hcp-web#704	Broken image of sitting fox when requesting a date in daily biometrics for the demo patient and for which there is no data.	None
gabi-hcp-web#703	Data is not available for the patient demo when selecting the date before 01-JAN-2021.	None
gabi-hcp-web#688	When there is no data in the last column of the patients' list, the hint popup appears outside of the screen (cropped)	None

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gabi-hcp-web#674	On low resolution, some parts are not fully displayed in the title bar (HCP name, Analytics version and logout menu).	Scroll horizontally to access to the cropped information
gabi-hcp-web#656	The label "12h" is not displayed in the last available night health report in events' chart while it is displayed properly in the aggregated chart.	None
gabi-hcp-web#650	On last available night health report, the display of the sorting of events has 3 statuses displayed (1 arrow up, 1 arrow down, 2 arrows up & down). The sorting cycle should alternate between up & down.	Click on the arrows to have the expected sorting and ignore the "2 arrows up & down" status.
gabi-hcp-web#645	The logo of Gabi displayed in the "Too small screen message" is the old one.	None
pediarity#59	During the onboarding on the mobile app, the first name and the band S/N are displayed when the link with the patient is done; not when the link with the band is done.	None
cna-app#492	Gabi logo doesn't appear on the foreground notification	None
gabi-hcp-web#593	After moving the guided tour window and resizing the browser window, the guided tour window may be outside of the visible window.	Shrink the browser window until you get the error message "Too small screen" and enlarge it again. The guided tour will reappear properly.
gabi-hcp-web#572	When expanding the health condition and the patient info at the same time, the patient's info superpose the health condition.	Open health condition and patient info independently.
cna-app#351	The reminder to start the recording briefly appears on a regular basis	None