
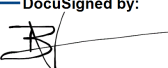


	GD00138 Release Note	
	Pediarity™ v1.0.1	Version A / 15-NOV-2023

# Release Note

## *Pediarity™ v1.0.1*


Version	Nature of change	Date
1	Initial version	08-NOV-2023
2	Add dependencies updates	10-NOV-2023
A	Target version	15-NOV-2023

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	Medical device software – Software life cycle processes
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## 5. Introduction

This document is the release note of Pediarity™ v1.0.1. 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	1.6.7
	Including Signal processing algorithm	1.4.8
Gabi Monitor App	Application	1.9.15+147
Gabi Analytics	Analytics	0.5.6
	Privacy	0.5.6
Gabi Cloud	Backend	1.9.9

## 7. Change log

### 7.1. New features or updated features

Biometrics monitoring	<p>The respiratory rate is not monitored anymore. Therefore:</p> <ul style="list-style-type: none"> <li>• Gabi Monitor App doesn't display the respiratory rate on the real time display nor on the charts from last recording.</li> <li>• Gabi Analytics doesn't display the respiratory rate on the health report nor on the daily biometrics.</li> </ul>
Target population age	<p>The target population is only infants and children (28 days to 12 years old). Therefore:</p> <ul style="list-style-type: none"> <li>• Gabi Monitor App displays a warning if the patient age is below 28 days.</li> <li>• Gabi Analytics displays a warning if the patient age is below 28 days.</li> </ul>

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Online IFU	The IFUs are available on the domain <a href="https://help.gabismartcare.com">https://help.gabismartcare.com</a> instead of <a href="https://gabi.help">https://gabi.help</a> .
Labelling	The icon “Alarm inhibit” (IEC60417) has been added in the legal mentions of Gabi Monitor App. The icon “MRI unsafe” has been added on the kit label.

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

## 7.2. Bug fixes

No bug fixes.

## 7.3. Technical changes

Environment configuration	The software components have been adapted to be able to deploy on an additional internal test environment named “preprod”.
Cybersecurity configuration	The configuration of software components has been adapted following penetration testing to address the medium risks.
Dependency updates	The dependencies have been updated due to a high critical vulnerability found in one dependency.

## 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

None


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## 8.2. Blocker issues


None

## 8.3. Minor issues

Gitlab ID	Description	Workaround
<a href="#">cna-app#310</a>	Pairing not possible on Gabi Monitor App after reset and change of band with the same tablet	If during the on-boarding process, the pairing between the Gabi Band and the Gabi Monitor Tablet is impossible, please restart the tablet
<a href="#">gabi-hcp-web #394</a>	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.
<a href="#">cna-app#304</a>	After resetting the Gabi Monitor App, the user cannot use the same QR-code during the onboarding	If you reset the Gabi Monitor App, you will not be able to proceed to on-boarding of your patient with the same QR-code. Please request a new one to your HCP.
<a href="#">gabi-file#22</a>	When no live data for more than 8 hours, the timestamp on the recovery timestamp may be incoherent.	If the Gabi Monitor Tablet loses the connection with the Gabi Band for more than 8 hours during a recording, the data older than 8 hours are lost and the timing linked to the data may be switched.
<a href="#">gabi-hcp-web #379</a>	The selection of a specific day closes unexpectedly when the user selects a day older than the last month.	In the patient's daily biometrics view, when using a small screen, the date is displayed as selected date and not on a calendar view. If you open the calendar to select another day, you can navigate through the months via left/right arrows. If you press the right arrow when being on the before last month, the calendar window closes unexpectedly. In this case, come back to the

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		health report and select the wanted day of the last month from there.
<a href="#">cna-app#255</a>	After update of the firmware, if the user clicks too fast, the app requests to update again.	If you face this issue, please be wait around 30 seconds before acknowledging the firmware update.
<a href="#">cna-app#199</a>	Two status widgets are still in English. The French label is not applied.	Please restart the Gabi Monitor Tablet.
<a href="#">gabi-hcp-web #253</a>	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.
<a href="#">gabi-hcp-web #243</a>	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.	When two biometrics are highlighted, please review carefully the data of both biometrics.
<a href="#">cna-app#163</a>	After letting the app on the screen "Scan QR-code" with camera on for a while, the tablet crashed	In case the Gabi Monitor Tablet crashes, please restart it. When restarting the on-boarding process, prepare your QR-code so that you don't keep the camera ON for too long.
<a href="#">cna-app#324</a>	During the onboarding, if the internet connection is temporarily down during the linking of the band with the patient, the onboarding is blocked.	If during the on-boarding process, the link between the Gabi system and the patient is impossible, please restart the tablet
<a href="#">gabi-hcp-web #333</a>	The account is blocked after 3 failed login attempts. However, it is well locked on the 4th attempt.	If you enter three times a bad password on Gabi Analytics, your account will be blocked. But you will only be notified on the fourth try, even if entering the correct password. You will receive an email inviting you to redefine your password.
<a href="#">cna-app#240</a>	Incoherence between Gabi Analytics and Gabi Monitor about the 13-years old warning message.	On the 13th anniversary of the patient, a warning (out of intended use) will be displayed on Gabi Analytics. This warning will be displayed on Gabi Monitor App only the

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		day after.
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## 8.4. Cosmetic issues

Gitlab ID	Description	Workaround
<a href="#">cna-app#351</a>	The reminder to start the recording briefly appears when the data are already uploaded to the cloud.	
<a href="#">gabi-hcp-web#387</a>	In the privacy screen, the “Next” button should be “Save” for the sake of clarity.	
<a href="#">gabi-hcp-web#386</a>	In the privacy screen, the tab name overlap with the “>” on low resolution screen	
<a href="#">gabi-hcp-web#395</a>	Heatmap in Gabi Analytics shows a double empty day when changing from summer time to winter time	
<a href="#">cna-app#238</a>	The checking of the app version isn’t performed properly during the onboarding. It is done only after the end of the onboarding process.	