



VERSION REPORT

Doc: GF160

Version: 5.0

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VERSION REPORT:

FibriCheck iOS

1.1.4

Application: FIBRICHECK IOS
Version number: 1.1.4
Software Safety Class: B

SOFTWARE VERSION CHECKLIST
Do the changes have effect on the following?

| | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|----|
| Application specifications | Yes | No |
| Labelling | Yes | No |
| Instructions for use | Yes | No |
| Risk Management Report: | Yes | No |
| Does the changes affect the performance specification of the MD? | Yes | No |
| Does the changes affect materials of the MD? | Yes | No |
| Does the changes introduce new hazards which have not been previously addressed? | Yes | No |
| Does the changes affect the risks associated with existing hazards? | Yes | No |
| Does the changes alter the details on compliance with the essential requirements given in the design / type approval dossier submitted to the Notified Body? | Yes | No |
| Does the changes alter the details on intended use given in the design / type approval dossier submitted to the Notified Body? | Yes | No |
| Does the changes mean that the device will have different end users or be used in a different manner? | Yes | No |
| Does the changes mean that the clinical data/performance evaluation data for the original device is not sufficient to confirm conformity of the changed device with the required characteristics and performance? | Yes | No |
| Is the changes a direct result of actions taken related to concerns arising from incidents/recalls/complaints? | Yes | No |

If No, provide a justification why not:

This version includes small improvements and bug fixes. This version has an improved finger detection system.

Required Approvals: Signature(s)/Date

Date: 26/06/2017

Quality Manager:



RELEASE FORM

Is the following information available?

| | | |
|----------------------------------------------------------------------------------|-----|----|
| An updated version of the user needs, requirements and technical specifications? | Yes | No |
| An updated version of the product anomaly list (PAL) ? | Yes | No |
| An updated version of the product SOUP list ? | Yes | No |
| Unit test results (if applicable) | Yes | No |
| Software system & integration test results | Yes | No |
| Updated version of the Risk Management Report (if required) | Yes | No |

If No, provide a justification why not:

Not required.

Release Git Information:

Release commit number: **8716d01**

Previous version number: **1.1.3**

Previous master commit **aa40cb8**

* Changes and corresponding JIRA issues are available as commit messages in the GIT repository of the project. The changes between the project versions release commit and the previous master commit represent all changes to the application.

Required Approvals: Signature(s)/Date

Date: 26/06/2017

Project Manager:





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ANNEX A (optional)

SOFTWARE VERSION CHANGE REQUESTS (JIRA ISSUES)

| Key | Description | Status |
|------------|-----------------------------------------------------------|--------|
| FIBIOS-443 | App begint te meten zonder vinger op camera | Closed |
| FIBIOS-449 | Log connected user with crashlytics | Closed |
| FIBIOS-450 | Improve the finger detection algorithm | Closed |
| FIBIOS-451 | Bug where you can't measure twice | Closed |
| FIBIOS-457 | AlertView crashing. Statistics from Crashlytics | Closed |
| FIBIOS-461 | Make Notification & Location onboarding screens optional. | Closed |
| | | |



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ANNEX B (informative)

SOFTWARE UNIT TEST RESULTS

| Key | Description | Status |
|------------------|----------------|--------|
| BeatListenerTest | Heartrate test | Passed |
| | | |