Alert-iT Care Alarms

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| | | **Dated:** | 21/01/2022 |
| | | **Our Reference:** | BT1005 |

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Your Reference:

Technical Bulletin

Product(s) Affected;

Pulse Companion (P194B).

Wireless Heart Rate Sensors (P195).

How to Identify;

All Pulse Companions running firmware v3.0.0 and below. The firmware version can be checked using the Alert-iT app under "Advanced Settings > Info".

All P195 sensors are affected (Rhythm 24 and Rhythm+ 2.0).

Problem;

Excessive "Armband Lockup" faults being raised. (Fault 18).

Cause;

If the wireless heart rate sensor is pressed very firmly into the skin, the blood flowing underneath the sensor can be reduced and the sensor may struggle to read the users heart rate correctly. The sensor may continue to provide a constant heart rate reading that does not reflect the users actual heart rate.

This problem typically occurs when the user rolls over and compresses the sensor against the skin during the night, but can be caused by the adjustable strap being fitted too tightly in extreme cases.

Mitigation;

Changing the position where the sensor is fitted is usually enough to resolve this issue.

Please see new recommendations on sensor placement/positioning and fitment guidance in latest handbook.

UH1482A Pulse Companion Handbook v12. [Page 16];

"It is recommended to fit the sensor in a position where it is unlikely to be pressed into the skin if the user rolls over during the night. Suggested positions are the upper arm or calf, with the sensor positioned on the inside of the arm or calf so that the user can lie on either side without pressing the sensor into the skin."

The Pulse Companion already includes a safety feature that raises a fault if the sensor reading doesn't change for an extended period of time to mitigate against this foreseen event. However, it was decided during this risk review that the default delay before the fault condition is raised could be reduced.

Product being recalled? No.

After review of the Pulse Companions risk management file, it was deemed that the existing control measures offered sufficient protection against this situation going unnoticed.

The Pulse Companion software has been updated moving forwards to reduce the risk even further by dropping the lockup timeout to 3 minutes. See attached risk assessment for further details.

Consequences/risks of continued unchanged use;

Possibility of the user not being monitoring during the period before the "Armband Lockup" fault is raised by the Pulse Companion.

The "Armband Lockup" timeout is 15 minutes for Pulse Companion Firmware v1.0.3 (30/09/19).

The "Armband Lockup" timeout is 3 minutes for Pulse Companion Firmware v4.0.0 (19/01/22).

Any available changes and how to obtain them;

The Pulse Companions firmware has been updated (v4.0.0) to reduce the default "Armband Lockup" timeout to 3 minutes in order to further minimise any risks. The latest firmware does allow users to increase this timeout via the app if they decide it is safe to do so.

Customers who wish to get this update can contact their equipment provider. The update is free of charge providing the equipment is returned to the manufacturer.

Related Change Notes: CN431

Related Risk Assessments: TF4 P194B Risk Analysis Report 20220119

Related NCR: NCR10834

Yours Sincerely,

Name: Tony Bullars   Position: Sales and Support Director