Header

Project Name: Firmware Update Triggering False High-Priority Alerts
Product Line: Sleep Therapy Devices
Platform: Respironics Platform C
Primary Team: R&D (Software)
Supporting Teams: Quality, Post Market Surveillance, Regulatory Affairs, Service
Project Phase: Design → Verification → Post-Market Monitoring
Timeline:

- Change Request & Impact Assessment: Q1 2023
- Development & Internal Testing: Q2 2023 – Q3 2023
- Verification & Validation: Q4 2023
- Market Release: Q1 2024
- Post-Market Issue Identification & Remediation: Q2 2024 – Q4 2024
  Document Type: Project History
  Keywords: firmware update, false alerts, alarm sensitivity, field performance, verification gap, real-world usage

---

Section 1 – Objective

Release a firmware update to improve device responsiveness and enhance alert detection sensitivity for specific therapy conditions, while maintaining compliance with alarm performance standards.

Section 2 – Current Status

Firmware patch released to address false high-priority alerts in affected markets.
Verification protocol updated to include expanded real-world simulation scenarios.
Post-market monitoring shows significant reduction in false alert complaint rate.

Section 3 – What Went Well

- Rapid root cause analysis after complaint trend identification.
- Cross-functional coordination between Software, Quality, and Post Market Surveillance.
- Clear rollback plan for affected regions.
- Structured communication to field service teams and distributors.
- Improved traceability between software change request and verification documentation.

Section 4 – What Went Wrong

- Increased alarm sensitivity triggered unintended high-priority alerts under certain real-world usage conditions.
- Verification scenarios did not fully replicate user behaviour variability.
- Field environment data was not incorporated early into simulation modelling.
- Complaint signals were initially interpreted as isolated user error.
- Alert fatigue risk was underestimated during risk assessment.

Section 5 – Approaches Attempted

1. Threshold recalibration within firmware logic.
2. Expanded simulation testing incorporating varied breathing pattern datasets.
3. Review of alarm classification logic to reduce unnecessary escalation.
4. Temporary field guidance to service teams pending software patch.
5. Enhanced complaint monitoring for early detection of similar patterns.

Threshold recalibration combined with expanded scenario testing produced stable performance without compromising detection capability.

Section 6 – Outcome

Firmware patch approved following additional verification cycles.
False high-priority alert rate reduced to below pre-update baseline.
Alarm verification protocol permanently expanded to include real-world variability scenarios.
Risk assessment templates updated to explicitly evaluate alert fatigue impact.

Section 7 – Key Lessons

- Software sensitivity changes can introduce disproportionate downstream behavioural effects.
- Verification must incorporate realistic usage variability beyond laboratory baselines.
- Early post-market signals should not be dismissed as isolated incidents.
- Alarm-related risk must consider user fatigue and behavioural adaptation.
- Firmware changes require rigorous scenario-based validation prior to release.