HeartLink Health LLC – Algorithm v4.1-CL (ASE 1.3)

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# Post‑Market Monitoring Plan (PMP)

## Purpose

Define methods for ongoing performance monitoring and user feedback review post‑release.

## Monitoring Activities

• Quarterly algorithm drift review using anonymized user data.  
• Feedback log review from provider portal.  
• Re‑validation triggered if >5 % deviation from baseline metrics.

## Responsibilities

QA Lead oversees review; CTO authorizes any re‑validation cycle.

## Record Keeping

All feedback and corrective actions logged in the Post‑Market Surveillance Register, retained ≥ 5 years.

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