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

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# Clinical Evaluation Summary

This document summarizes the clinical rationale and evidence supporting the HeartLink Adaptive Stability Engine (ASE) version 1.3, integrated as algorithm v4.1‑CL.

Clinical Basis: HeartLink follows American Heart Association (AHA), American College of Cardiology (ACC), and Heart Failure Society of America (HFSA) guidance for symptom monitoring and early detection of decompensation.

Intended Use: To support home health monitoring and remote care coordination by identifying worsening symptom patterns indicative of heart failure decompensation.

Validation Summary: Performance across validation trials T1.0–T1.9 demonstrated mean accuracy 93%, AUC 0.96, and false‑alert rate 0.28%.

Conclusion: The algorithm demonstrates clinical plausibility, strong analytical validity, and suitability for non‑diagnostic patient monitoring applications.

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