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April 2026

RE: i-STAT 1 analyzer software version JAMS261A, JAM2261A and CLEW A52

The i-STAT® System Software was developed within the Abbott Point of Care Quality Management System. The quality system defines the organizational structure, procedures, processes, and resources needed to meet the requirements of global medical device regulations and standards. The impact of the changes within the release of software version JAMS261A, JAM2261A and CLEW A52 were evaluated, and the evaluation did not identify any changes that would impact the quality of the reported results on the i-STAT system. Changes were reviewed and approved prior to implementation. Approved changes were documented, verified, and tracked to closure. Verification activities, traced to approved specifications, all met acceptance criteria. The documentation supporting the development and testing of the i-STAT System software resides in a controlled location at the APOC Princeton Facility.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Linda Maczuszenko'.

Linda Maczuszenko
Director, Product Quality Assurance
Abbott Point of Care