



Abbott Point of Care
400 College Road East
Princeton, NJ
08540

T: +1 609 454 9000

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RE: i-STAT 1 analyzer software version JAMS260A, JAM2260A and CLEW A51

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 JAMS260A, JAM2260A and CLEW A51 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 'Maczuszenko', is written over a light blue horizontal line.

Linda Maczuszenko
Director, Product Quality Assurance
Abbott Point of Care