

## Evaluation of the Next Generation i-STAT® Point-of-Care Instrument using a Sodium Test \*

\*submission pending FDA review

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**Introduction:** The next generation i-STAT instrument is a handheld, *in vitro* diagnostic analytical device designed to run i-STAT test cartridges. The system is designed for use at or near point of patient care, by trained medical professionals (e.g. nurses and respiratory therapists) and is for prescription use only.

An update of the i-STAT 1 wireless analyzer, the next generation i-STAT system is comprised of the instrument, rechargeable battery, base station, electronic simulator, control material, printer and i-STAT test cartridges. The next generation i-STAT instrument features a barcode scanner, user interface with touch screen display and wireless capability. The instrument reports quantitative results within approximately 2 minutes. The principle governing operations associated with measurement and generation of test results remains unchanged.

The next generation i-STAT instrument provides a 5 inch diagonal color touch screen through which the operator inputs data, views instructions and accesses information such as patient results and test status. From the screen the operator can perform a new test, review information from a previous test or perform administrative activities such as quality control. The touch screen display is designed to be used while wearing gloves. To facilitate use, the instrument provides audio and visual prompts. Visual prompts may notify the operator of patient results, battery status or quality check code. Audio prompts may notify operator that the barcode was successfully scanned or patient results are ready.

**Methods:** The analytical functioning of the next generation i-STAT instrument was demonstrated using the i-STAT sodium (Na) test. Analytical evaluation included multi day precision, linearity, analyte recovery, limit of quantitation (LoQ), interference from potential substances, and robustness to cleaning and disinfecting. Clinical evaluations were also completed and included total precision in blood, total precision in aqueous materials, and correlation to the currently marketed FDA cleared i-STAT 1 wireless analyzer.

**Results:** The within-laboratory (total) precision ranged from 0.32 mmol/L to 0.96 mmol/L. A linearity beyond the reportable range of the test was demonstrated and the mean % recovery ranged from 99.9% to 100.6%. The observed LoQ was below 100 mmol/L. No new interferences were found after testing 19 species. After 10, 950 instrument cleaning and disinfecting cycles, instrument appearance, instrument functionality and i-STAT Na test accuracy were all demonstrated.

**Conclusion:** The studies demonstrate that the next generation i-STAT system offers precise and accurate test results and is an updated version of the currently marketed, and FDA cleared i-STAT 1 wireless analyzer.

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