

K961579

**IX. SAFETY AND EFFECTIVENESS SUMMARY**

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The STA Compact® instrument is a fully automated laboratory analyzer designed to perform tests which aid in the diagnosis of coagulation abnormalities or in monitoring anticoagulant therapy. Once samples and test reagents are loaded onto the instrument, sample handling, reagent delivery, analysis and reporting of test results are performed automatically, making the STA Compact® instrument a true walkaway system. A central processing unit controls instrument functions, including management of patient results, quality control, scheduling of instrument maintenance and workload organization.

The instrument utilizes Diagnostica Stago (France) reagents, and is open to adaptation of other reagents currently available from third-party manufacturers. Barcoding of test reagents, calibrators and controls facilitates their use on the system and makes reagent management simple. Manual entry of reagent information enables the use of non-barcoded reagents.

The instrument performs multiple test methodologies in random access (as selected by the user); these include clot-based tests and photometric assays at predetermined wavelengths.

Sample-to-sample carryover has been demonstrated to be very low, being of the order of 5/100th of 1% (i.e., 0.05%).

The STA Compact® instrument is substantially equivalent to the commercially available full-size STA® analyzer that received FDA 510(k) clearance under K942117.