

## Assessing of the Ease of Use and Graphical User Interface Functionality of the ProTime InRhythm by Untrained Users

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**Background:** Point-Of-Care (POC) assays should be simple enough to be performed with accuracy by untrained users, using only the manufacturer's written labeling materials. The ProTime InRhythm™ System (InRhythm) provides quantitative measurement of Prothrombin Time / International Normalized Ratio (PT/INR) from capillary whole blood or fresh venous whole blood collected with no additives. The test system is used in the management of patients treated with oral vitamin K antagonist (VKA) therapy. The InRhythm System consists of the InRhythm instrument and disposable PT reagent cuvettes. The instrument is a small, portable, handheld device with a barcode scanner and Wired Ethernet that is POCT-1A compliant. The system utilizes a user friendly state-of-the-art Graphical User Interface (GUI). At start up the instrument main menu displays four touch screen activated icons, for Patient Test, External Liquid Quality Control (LQC), Search Records, and Instrument Set-up. The InRhythm database stores 1200 patient and/or LQC results with associated information, such as patient or operator identification number, user notes and cuvette lot information. The InRhythm cuvette requires one drop of blood (13 µl) to perform duplicate patient and on-board quality control test.

**Objective:** The objective of this study was to evaluate the clinical applicability of the InRhythm system with respect to ease of use, usability of GUI and clarity of labeling by untrained healthcare professionals using only written instructions in the product labels without receiving additional training (e.g. verbal, coaching or prompting).

**Methods:** The survey was completed at the conclusion of a clinical study designed to evaluate the clinical performance of the InRhythm by untrained professionals (untrained operators). The study was executed at 3 different clinical sites and a minimum of 3 untrained operators participated from each site. The operators performed duplicate PT/INR testing of Fingerstick and Venous Whole Blood samples from 135 VKA patients and 15 healthy donors at each site following written instructions in the InRhythm Quick Reference Guide and the User Manual. The PT/INR tests were equally distributed between operators at each site as possible. Additionally, the operators performed external LQC testing at two levels on the day of patient sample testing. The questionnaire included 15 questions on the ease of use and knowledge assessment and 46 questions on different GUI functionalities. Agreement was on a 1 to 5 scale; 1= strongly disagree and 5= strongly agree. The study is considered successful if  $\geq 90\%$  of questions has an average score of 3 or higher (Neutral- Strongly Agree) for the ease of use evaluation and if  $\geq 90\%$  of the total responses are answered as Neutral to Very Easy (score 3 or higher) for the GUI evaluation.

**Results:** A total of 10 untrained operators participated in this study and completed questionnaires at the conclusion of the study. Average years of work experience of the participating operators was 2.4 yrs (range: 1 – 7 yrs). Their level of education was: some college (n= 3), associate degree (n= 2) Bachelor degree (n= 2) and graduate degree (n= 3). Average score of each of the 10 questions evaluating the ease of use was very high ranging between 4.2 to 4.6 and 100% of all scores was 3 or higher suggesting that the InRhythm PT/INR test is simple enough to be performed by untrained operators. Answers of knowledge assessment (5 true/false questions) resulted in 90% agreement with the correct answers. Evaluation of the GUI questionnaire (n= 46 questions) showed 100% of scores were 3 or higher (Neutral to Very Easy) and the range of average score of each individual question was 3.6 to 4.6 confirming the clarity of instructions in the labeling materials.

**Conclusion:** Data from this evaluation demonstrates that the InRhythm system is simple to use and possesses effective GUI features which facilitate usage by untrained and/or inexperienced healthcare professionals.