

A PERFORMANCE ANALYSIS COMPARING THE ENHANCED PROTIME®
MICROCOAGULATION SYSTEM AND THE ORIGINAL PROTIME

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ABSTRACT

A performance analysis comparing the results obtained with the new and the original ProTime® Microcoagulation Systems was completed to verify the clinical equivalence of the two systems' INR results as obtained by existing ProTime customers, both professional and patient self-testers. A features evaluation was also performed to assess the enhanced capabilities of the new ProTime.

Paired INR data (n=137) were collected using both versions of the ProTime. Participants answered a questionnaire regarding their opinion of the new features. All results were recorded.

The overall correlation coefficient between the two device types was 0.94. The average feature score was 0.4 on a scale of -1.0 to 1.0.

The data from this study indicate that the new enhanced ProTime provides equivalent results to the traditional ProTime instrument. The new features added are considered an improvement to the system by current ProTime customers.

INTRODUCTION

The ProTime Microcoagulation System is a portable, battery operated, PT/INR testing instrument designed to allow healthcare professionals and patients to safely manage oral anticoagulation therapy. The ProTime system consists of the ProTime instrument, the reagent cuvette with built-in quality control, and the Tenderlett® Plus sample collection system. The instrument and cuvette quality controls function together to ensure correct sample size, collection technique, test procedure, device functionality and reagent integrity. This helps healthcare professionals and patients ensure accurate results each time the test is performed.

The new ProTime system has several new instrument and software features designed to enhance user ease and convenience, increase results-reporting efficiency and reduce transcription errors. The software has been updated to include the ability to auto-send results quickly and easily to a printer or a computer. Results can be transmitted to a laboratory through a clinical interface. The new ProTime also accepts and stores patient and/or operator ID (PID/OID), and the operator can identify the test as a patient result or a QC test. The error code numbers have been replaced with simple error messages. Key design enhancements include an easy-to-read back-lit display and an operator rechargeable and replaceable battery.

The Tenderlett Plus and Tenderlett Plus LV cups have been slightly modified to provide a more secure fit with the new ProTime. The new collection cups can be used with both ProTime systems.

METHODS

Eight current ProTime users (four professional [PRO] and four patient self-testers [PST]) were asked to participate in a clinical evaluation of the enhanced ProTime. Participants included both ProTime (5-channel cuvette) and ProTime3 (3-channel cuvette) users. All participants were asked to perform duplicate fingerstick measurements of INR on the traditional and new ProTime units and were asked to complete an evaluation form. No patient identification was supplied to the study sponsor. Patients were assigned sequential numbers for study participation. The traditional ProTime INR served as the control for each patient's new ProTime INR result.

Inclusion Criteria

Professional sites: Patients presenting for routine oral anticoagulation therapy management were offered the opportunity to participate in this trial. Participants were all 18 years of age or older and signed the Informed Consent. Each participating study center evaluated at least one of the feature enhancements included for professional use.

Data Exclusion

Patient samples in which duplicate INR results were not available were excluded from the correlation analyses.

RESULTS

Figure 1 shows the results from eight separate clinical evaluations (four professional sites and four patient self-testers). The slope of the regression is very close to 1.0, indicating uniformity in the results obtained from the two systems. Both systems were tested using the ProTime 3-channel cuvettes and the ProTime 5-channel cuvettes. The two systems proved to be comparable when using either type of cuvette as the correlation coefficient equaled 0.94 for both the 3-channel and the 5-channel cuvette (Table 1).

Data Set	Slope	Intercept	R
ProTime PRO	0.91	0.26	0.95
ProTime3 PRO	0.94	0.06	0.95
All PST	0.88	0.52	0.88
All ProTime	0.91	0.31	0.94
All ProTime3	0.97	0.04	0.94
All data combined	0.96	0.10	0.94
INR 8.0 excluded	0.96	0.11	0.93

Table 1

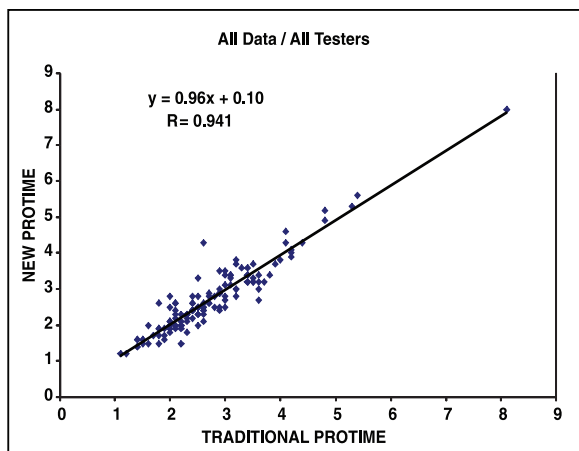


Figure 1

Features were scored on a scale from -1 (worse) to 1 (better), with zero being the same. Overall, the new instrument was considered superior to the older version with the average feature score being 0.4 (Table 2).

Features evaluation: 1 = better than original; 0 = equivalent; -1 = worse	
Features Evaluated	Grand Average
Case design	0.8
Soft keys	0.6
Placement of Tenderlett Plus	0.4
Back-lit display	0.8
Main Menu sequence	0.1
Wait time to sampling	0.4
Clarity of error messages	0.3
View Data History	0.7
Enable PID/OID	0.6
Follow PID/OID prompts	0.5
Confirmation screen displayed after entering PID/OID?	0.4
Select LQC NOR/ABN	1
Scroll through other results	0
Able to store up to 50 results	0.7
Change default password (PRO only)	0.5
Enter password to access the Program Mode (PRO only)	0.5
Set INR limits	1
Set ISI values (PRO only)	1
Clear Memory (PRO only)	0.5
Set beep to ON/OFF	0.4
Set language	0.3
Set time/day	0.1
Change battery	0
Set month/year (PRO only)	0.3
Grand average across sites	0.37

Table 2

DISCUSSION

The clinical comparison of the two ProTime systems demonstrates their equivalence. This study demonstrated that both ProTime systems enable users to have confidence that the INR results obtained from the enhanced system are equivalent to its predecessor.

The enhanced features of the new ProTime were assessed and considered to be equivalent or better than the original ProTime system. An Operator's Manual and a training CD are included with the new ProTime system. These educational items were generally considered to be helpful and easy to use. The CD was found to be clear and the evaluators agreed that the CD would be very beneficial to new users.

The data from this study indicate that the new enhanced ProTime provides accurate results and is considered an improvement by current ProTime customers.



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