

# Reliability of patient self-testing and point-of-care testing with the Harmony™ INR Monitoring System: a two-year study

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## Introduction

LifeScan, Inc. (Milpitas, CA), a Johnson & Johnson company, has developed the Harmony™ INR Monitoring System for PT-INR (Prothrombin Time - International Normalized Ratio) monitoring of patients on oral anticoagulation therapy (OAT). The Harmony system is intended for both patient self-testing (PST) and point-of-care (POC) testing. The accuracy of the Harmony system in the hands of OAT patients<sup>1</sup> and POC personnel<sup>2</sup> has been demonstrated in clinical studies. In one of these studies,<sup>1</sup> OAT patients with no prior PT-INR self-testing experience received approximately one hour of training in the use of the Harmony system from POC personnel at one of four study sites. Patients then performed PT-INR self-tests at two- and four-week intervals over a 12-week period. Each PST result was compared to a monitor result obtained by POC personnel and a reference result from the hospitals' laboratories (all tests performed within a 4-hour interval); strong correlations ( $r \geq 0.94$ ) were seen between these results.

The current study, a continuation of the 12-week study at one of the four sites, was designed to assess the reliability of PST from three perspectives:

### Long-term training retention

Are OAT patients able to perform reliable PST with the Harmony system over an extended period of time with minimal initial training and no retraining?

### Time in target therapeutic range

Is there a relationship between frequent (weekly) PST with the Harmony system and time in target range (i.e., the percentage of PST results falling within the patients' target ranges)?

### Self-reporting of PST results

Can OAT patients reliably report PST results using a customized Interactive Voice Response (IVR) system?

## Materials and methods

All 103 subjects who began the current study (see Table 1) were OAT patients who participated in the 12-week accuracy study at VAMCLL. Patients received no supplemental PST training for the current study. In addition to following the anticoagulation monitoring schedules prescribed by their physicians (typically, a monthly clinic visit for an INR test with the clinic's monitoring instrument), patients participated in the following study-related activities:

- On a weekly basis (including the days when clinic visits were scheduled), each patient performed PST at home with the Harmony system, recorded the result on a case report form, and reported the result to the clinic using the IVR system.
- During the regularly scheduled clinic visits, POC personnel performed a Harmony PT-INR test on each patient within four hours of the patient's self-test.

## Materials and methods (continued)

**Table 1**

### Subject demographics and diagnoses

Total subjects = 103

		Years	
		<i>n</i>	%
Age	Mean (SD)	64.6 (11.4)	
	Median	66.2	
	Range	33 to 88	
Demographic factors		<i>n</i>	%
Gender	Female	12	11.7
	Male	91	88.3
Ethnicity	African American	5	4.9
	Caucasian	85	82.5
	Hispanic/Latino	12	11.7
	Other	1	1.0
Education	K–8	7	6.8
	High school	30	29.1
	1–4 years college	54	52.4
	> 4 years college	12	11.7
Primary diagnosis	Atrial fibrillation	40	38.8
	Heart valve	24	23.3
	Phlebitis	6	5.8
	Cerebrovascular accident	8	7.8
	Myocardial infarction	4	3.9
	Pulmonary embolism	3	2.9
	Other	18	17.4

All testing with the Harmony system was performed according to the following procedure:

1. Turn the monitor ON by pressing the power/select button (Figure 1).
2. Compare the code numbers on the monitor display and the test strip vial; use the option change buttons to adjust.
3. Insert a test strip into the monitor's test strip holder; wait for the system to warm up ( $\approx$  30 seconds).
4. Apply a drop of fresh capillary (fingerstick) blood to the test spot on the test strip.
5. After a 90-second countdown, read the INR result on the monitor display.

Patients reported their self-test results using an IVR system<sup>3</sup> developed by InterClin, Inc. (Loma Linda, CA). This dial-in system asks the patient a series of questions, including PST result; the patient responds by pressing the appropriate keys on the phone pad. The system includes features for verifying patients' responses, notifying patients of out-of-range results, and preventing continued use of the IVR system (after an out-of-range result) without staff approval. Patient training on the IVR system was limited to a five-minute description and a one-page handout.

The study began in December 1999. Results are current through March 2002. Most patients completed at least 24 months of testing; 71 patients continue to participate in this on-going study.

### Results were analyzed as follows:

#### Long-term training retention

Paired results (Harmony PST vs. Harmony POC test on the same day) were subjected to orthogonal regression analysis. Slope, y-intercept, correlation coefficient (*r*), and standard error of the estimate ( $S_{y,x}$ ) were calculated for the set of paired results. The degree to which PST and POC INR results are in statistical agreement is taken as the measure of training retention.

## Materials and methods *(continued)*

### Time in target therapeutic range

For each month of the study, the percentage of PST results (all subjects and time points) that fell within the subjects' target therapeutic ranges was calculated.

### Self-reporting of PST results

All IVR results ( $n = 7,117$ ) were compared to the corresponding PST values recorded by the patients. The percentage of IVR results that exactly matched the corresponding patient-recorded results was calculated.

## Results and discussion

### Long-term training retention

Figure 2 illustrates the relationship between PST and POC results (1,251 pairs), which produced the following orthogonal regression statistics: slope = 1.02; y-intercept =  $-0.05$ ;  $r = 0.96$ ;  $S_{y,x} = 0.16$ . PST results were within  $\pm 0.5$  units of POC results 96.9% of the time. These statistics show strong agreement between PST and POC results, indicating that patients can perform reliable Harmony INR tests with minimal initial training and no retraining.

### Time in target therapeutic range

The percentage of patient self-tests that were within their therapeutic ranges increased steadily from about 40% to about 60% over the first four months of the study and remained at about 60% thereafter (Figure 3).

### Self-reporting of PST results

A comparison of patient-recorded results and results in the IVR database indicates that 6,910 of the 7,117 IVR results (97.1%) matched those recorded by the subjects.

## Results and discussion *(continued)*

Figure 1

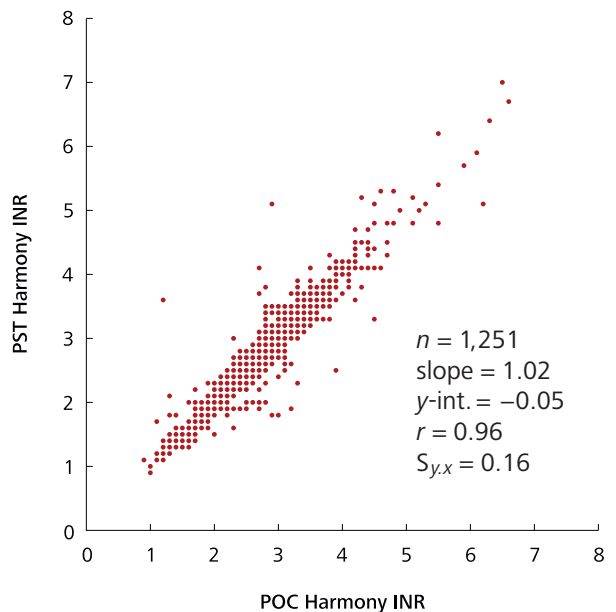
### LifeScan Harmony INR Monitoring System



Figure 2

### Orthogonal regression analysis

*PST Harmony INR vs. POC Harmony INR*

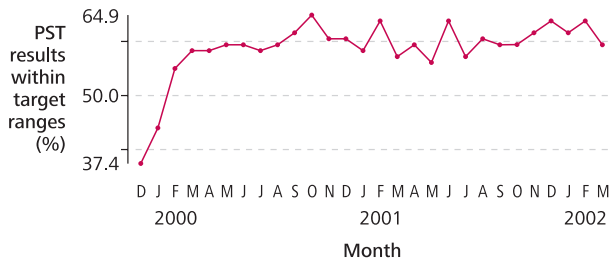


## Results and discussion (continued)

**Figure 3**

### Time in target therapeutic range

All PST Harmony INRs for each month of study



Target therapeutic ranges	# Subjects
2.0–3.0	85
2.5–3.5	8
Other	10

## Conclusion

These results demonstrate 1) a high degree of patient training retention and low degree of operator dependence; 2) improved times in target therapeutic range associated with weekly self-testing; and 3) reliable patient self-reporting, an important component of PST. These findings support the reliability of PST and POC testing with the Harmony system.

### References

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2. Earp BC, Hambleton JS, Jacobson A, Spencer F. Accuracy and precision of the LifeScan INR monitoring system in point-of-care settings. *Clinical Chemistry*, 2001 (suppl.), 47:175.
3. Jacobson AK, Scott RD, Peckham, NH, Earp, B. Reliability of patient self-reporting of self-test results to a central database utilizing a computerized interactive voice response system. *Thrombosis and Haemostasis 2001* (suppl.), Abstract OC2454.