# Clinical Evaluation for

# Embrace No Code Blood Glucose Monitoring System

Applicant: Apex Biotechnology Corp.

Test Date: 2007/8/28~2007/9/21

Clinical Site: SCHMIDT Group Practice Clinic
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# 1. Scope and Objective

The **primary objective** of this study is to verify the performance of testing on Embrace No Code system as compared to an accepted standard method of blood glucose analysis (the Yellow Springs Instrument [YSI]).

The assessment of each user's ability could understand and perform the operation of the systems while obtaining accurate results, and to assess the ease to be understanding of the User's manual, ease of use of the devices, and the acceptance degree of the voice feature.

# 2. Materials

(1) Embrace No Code Blood Glucose Monitoring System:
- Meters (6 sets): S/N TK0000000014 ~ 19
- Test strips: 3 lots, lot No. FS002i, FS002J, FS002K, at least 500 pieces (10 vials) each lot
- Embrace level 1 & 2 Control Solutions
- User Manual

(2) YSI 2300 Glucose Analyzer, reagents, and controls

(3) Linearity control check solution: an NIST traceable NERL 1343 Standard Glucose Solution

(4) Capi-ject capillary blood collection tubes

(5) Micro-centrifuge for HCT detection

(6) Lancing devices and Lancets

(7) Case Report Forms, Data Logs and Questionnaires (Appendix 1)
- Form A: Informed Consent and Subject Information
- Form B: YSI and Meters Quality Control Log
- Form C: Test Data Log
- Form D~F: Questionnaires: User Manual Questionnaire, Ease-of-Use Questionnaire and Voice Feature Questionnaire

# 3. Subjects

(1) Total of 152 volunteers whose HCT is in the range of 30~55% participated in the study.   The only exclusion criteria were bleeding diathesis or coagulation disease.

(2) All volunteers filled the Subject Information and signed Consent before

testing.

(3) The age distribution is 20 - 81 years old and the sex percentages are around 50% to 50%.

(4) Eighty two (82) diabetics are included, twenty (20) are type I and sixty two (62) are type II.   Forty five (45) diabetics are impaired visual, including the severe presbyopia, retinopathy, cataract or glaucoma.   Except forty seven (47) diabetics, most participants are without the experience of performing self-monitoring blood glucose.

(5) Education levels are junior high school to post graduate, and with at least 3 years English experience.   The averaged English learning experience is 8.3 years.   All the participants can read and speak English. They operated the Meter and performed blood glucose tests after reading the English User Manual.

## 4. Evaluation Site and Personnel

Investigation was conducted at SCHMIDT Group Practice Clinic, Hsinchu, Taiwan, directed by three clinicians.   The project director is majored in Gastroenterology and Internal Medicine.   Both co-investigators are majored in Endocrine and Metabolism and Neurology and Internal Medicine.   The investigator responded to evaluate the qualified participants, answer to any questions regarding the study and control the proper participants numbers of different glucose levels.

Three trained technicians were also involved, two from ApexBio and one from SCHMIDT clinics to run YSI analyzer, meters tests and data collection. Healthcare Professional Tests were performed by the physicians or trained technicians.

## 5. Method

5.1 Device-Familiarization Period

The participants were familiar with the meter operation and sample adsorption after reading the Embrace No Code User's Guide.   Only the English instructions and questionnaires were provided on study.   The participants were confirmed be able to read and understand the English language.   After the familiarization period, the participants performed the Control Solution (Level 1

and Level 2) tests to verify their operating techniques. Record the test readings of Control Solution and check with the Control Ranges labeled on the strip bottle.

5.2 Sample Collection & Meter testing

(1) Participant washed hands with warm, soapy water or alcohol wipes. Hands are thoroughly rinsed and dried.

(2) Participants performed finger stick to obtain Capi-ject collection for duplicate measurements with YSI reference analyzer. At least 250 μL should be collected. Duplicate YSI measurement should take place within 10 minutes of collection.

(3) With no assistance or guidance (other than from Participant's own reading of User's Manual), the Participant:

- Conducted self-test on Embrace No Code meter #1.

(4) Healthcare Professional conducted:

- Embrace No Code meter test with Meter #1.
- Embrace No Code meter test with Meter #2.

Healthcare Professional recorded the time of both the tests of Participant and Professional and recorded observations, such as Participant errors or error messages requiring repeat self-testing.

(5) Second finger stick performed by Professional to obtain Capi-ject collection for duplicate measurements with YSI reference analyzer and hematocrit determination. At least 250 μL should be collected.

Healthcare professional made additional finger sticks as needed to obtain blood for YSI or hematocrit determination.

Healthcare professional interrogated meter memories and compared results from meter memory to results on Test Data Log. Study Coordinator indicated memory was checked on Test Data Log and recorded any discrepancies.

(6) Alternate site testing (AST)

- Participant conducts self-test on palm.

- Professional conducts palm sampling.

- Participant conducts self-test on forearm.

- Professional conducts forearm sampling.

Participants performed alternate site testing started from palm or forearm

according to the advice of Study Coordinator.   One half of Participants started AST testing with palm, ½ with forearm.   One half of palm sampling was done on thenar, ½ on hypothenar.   Professional tested same part of palm as Participant.   Healthcare professional kept a running log to control the proper numbers of test sites started.

(7) Third finger stick performed by Professional to obtain Capi-ject collection for duplicate measurements with YSI reference analyzer.   At least 250 $\mu$L should be collected.

(8) The Professional documented all blood glucose results on Test Data Log.

(9) Professional collected additional one tube (EDTA anticoagulant) of finger stick capillary blood from some participants with low glucose level.   These blood samples were incubated for about 3-4 hours allow glucose hydrolyzed to adequate low levels (< 50mg/dL), which were tested by professional only.

5.3 User Questionnaires

After the meters testing, participants refer to User Manual Sections that are referenced in the questionnaires while completing the following questionnaires.

- User Manual Questionnaire

- Ease-of-Use Questionnaire

- Voice Feature Questionnaire.

## 6. Measurement Procedures

6.1  Quality Control Check of YSI 2300 Analyzer

Daily quality control for the linearity checks of YSI 2300 analyzer was performed and recorded before testing and every two hours during testing period.

The NERL 1343 Standard Glucose Solutions were used for this study. Glucose levels of the NERL standards are 50 mg/dL, 100 mg/dL, 200 mg/dL, 400 mg/dL and 750 mg/dL.

Accuracy – mean results of duplicate tests should be within 5 mg/dL of the target glucose value at levels < 100 mg/dL or within 5% of the target glucose value at levels $\geqq$ 100 mg/dL.

6.2   Quality performance confirm for Embrace No Code meters

The Embrace No Code systems (meters and strips) were run the Control Solution tests to confirm their performance each day before testing.

Test result should be within the control ranges labeled on the strip bottle.

6.3    Finger stick capillary blood collection: after hand cleaning, each participant performed a finger stick by himself.

6.4    Record the testing time by healthcare professional.

6.5    The first capillary blood sample for YSI analyzer was collected and measured by healthcare professional. Record the sampling time.

6.6    Test on Embrace No Code meter following the User's Guide by the participant himself.

6.7    Test the same capillary sample on another 2 Embrace No Code meters by healthcare professional.

6.8    After the meters testing, perform a second fingerstick and collect the second fingerstick capillary blood sample for YSI analyzer.   Record the sampling time.   The time period for both YSI samples collected should not be longer than 10 minutes.

6.9    Collect a blood sample into a centrifuge with 12000 rpm for 5 minutes to measure the hematocrit (HCT).

6.10 The participant cleaned and dried through the palm and forearm.

6.11 According to the Healthcare Professional, Participant performed sticks on either palm or forearm in first and tested on meter, and then the other site.

6.12 Using the same stick, healthcare professional tested the AST sample on meter.

6.13 Healthcare Professional recorded the stick time and the measuring results of Participants and Professionals on the Test Data Logs.

6.14 After finishing the blood test, the participants were required to fill up designed Questionnaires to evaluate their understanding the User's Manual and the satisfactory of the system.


# 7.  Statistical Analysis

Participant Information sheets are reviewed by Study Coordinators to determine

if the subject is taking a medication that may yield false results with the Embrace No Code system. Only results from Participants who have hematocrits between 30% and 55% will be used in determining the Embrace No Code system's performance. Data from pilot Participants will not be analyzed.

**Steady state evaluation**

Calculate the change percentage <u>between the first and second fingerstick</u> YSI results. Participants with changes larger than 10% are lack of steady state. Exclude non-steady state results for the System Accuracy Evaluation.

Calculate the change percentage <u>between the second and third fingerstick</u> YSI results to determine steady state for AST testing. Exclude any participant's outside 10% limits for steady state.

**Test serial of palm and forearm and sampling site of palm**

Count the number of subjects started from palm and count the number of puncture on Thenar.

## 7.1 Accuracy Evaluation

### 7.1.1 Correlation

Compare <u>averaged</u> duplicate YSI of first fingerstick vs. professional's both tests on meters for the System Accuracy Evaluation. The professional's meters value will be plotted on the vertical axis against the mean of the two YSI values on the horizontal axis. Using linear regression, the data of the individual Embrace No Code meter results versus YSI results will be analyzed. The slope, y-intercept and correlation coefficient will be noted on the scatter plot.

### 7.1.2 Bias analysis

(1) Calculate bias (mg/dL) if glucose level < 75 mg/dL or %bias if glucose level $\geqq$ 75 mg/dL between Embrace No Code meter's readings and YSI 2300.

(2) Use readings from YSI 2300 as X-axis and the calculated bias to be Y-axis. Plot the bias with +/- 20% as the control limits at glucose level higher than 75mg/dL and +/- 15mg/dL at glucose level lower than 75mg/dL.

(3) Count the numbers outside the acceptable control limits.

### 7.1.3 Error Grid Analysis

Count the numbers fall within Zone A~Zone E.    100% of the test data of Embrace No Code must be fall within zone A and B.

(1) Zone A – glucose values deviating from the reference method by less than 20%

(2) Zone B – deviation greater than 20%, leading to benign or no treatment error

(3) Zone C – resulting in over-correcting acceptable blood glucose levels.

(4) Zone D – dangerous failure to detection and treatment.

(5) Zone E – erroneous treatment error.

## 7.2 User performance evaluation

7.2.1 Control Solution Test Evaluation

Control Solution test results from the users are recorded and compare with the Control Ranges on Strip labels to evaluate the user can get correct control solution results.

7.2.2 Blood Glucose Value Comparison

Blood glucose value obtained from fingerstick of untrained user is compared to results obtained from YSI Analyzer and fingerstick results obtained from professional.    Calculate and compare the followings:

(1) Compare participant's self-test vs. Professional's first meter test

(2) Compare participant's self-test vs. averaged duplicate YSI of first fingerstick

## 7.3 For AST Evaluation

7.3.2 AST vs. Fingerstick Evaluation

Blood glucose values obtained form alternate sampling sites (palm and forearm) are compared to fingerstick results obtained from physician.    Plot the results of forearm and palm on the vertical axis against the fingerstick results on the horizontal axis.    Perform the linear regression analysis, note the slope, y-intercept and correlation coefficient on the scatter plots.    Compare the followings:

(1) Compare Professional's first meter test on fingerstick vs. Participant self-test on palm

(2) Compare Professional's first meter test on fingerstick vs. Professional's test on palm

(3) Compare Professional's first meter test on fingerstick vs. Participant self-test on forearm

(4) Compare Professional's first meter test on fingerstick vs. Professional's test on forearm

## 7.4 User Questionnaires Evaluation

Data obtained from the three Questionnaires will be summarized and presented with the data analysis. The mean of the numerical responses for each statement and overall mean will be calculated and plotted as bar charts. Users' suggestions and comments will be summarized and discussed.

# 8. Results

## 8.1 Data Sheet

Total of 158 blood samples were tested, including 152 fresh capillary blood samples meet the hemmatocrit criteria of 30~55% and additional 6 glucose hydrolyzed incubated blood samples.

Change percentages of the 152 fresh samples are during -8% ~ 7% between the first and second fingerstick YSI results and -9% ~ 5% between the second and third YSI results. They meet in the steady state blood glucose criteria of within +/- 10%.

All the results from the qualified 158 samples are included in the meters accuracy evaluation by Healthcare Professional and only the 152 fresh blood samples are included in User and AST performance evaluations.

Three strip lots were used for testing of 158 samples randomly and almost equally during the study period. Forty nine (49) of blood samples were tested with strip lot FS002i, fifty sixty (56) with lot FS002J and fifty three (53) with lot FS002K.

For AST testing, half (76) of 152 participants started from palm, another half started from forearm. Half punctured palm on Thiner and another half on Hypothenar.

Re Appendix 2 for the Clinical Evaluation Worksheets

## 8.2 Accuracy Evaluation

### 8.2.1 Correlation between Embrace No Code against YSI

Re Exhibit 1 of Appendix 3 for the Correlation of Embrace No Code against YSI.  The slope, y-intercept and correlation coefficient of linear regression are summarized on the table and noted on the scatter plot.

### 8.2.2 Bias Analysis

Re Exhibit 2 of Appendix 3 for the Bias Counts and Bias Plot of Embrace No Code against YSI.  100% of the 158 test samples fall within the acceptance criteria.

### 8.2.3 Clark Error Grid Analysis

Re Exhibit 3 of Appendix 3 for the Error Grid Analysis of Embrace No Code against YSI.  100% of the 158 test samples fall within Zone A, which is the acceptance area.

## 8.3 User Performance

### 8.3.1 Control Solution Test Evaluation

Re Exhibit 1 of Appendix 4 for the Control Solution Test evaluated by Lay Users.  Total of 152 untrained lay users perform the correct Control Solution Tests.  100% of the test results of both the Level 1 and Level 2 Control Solution fall within the control ranges labeled on strip label.  All the 152 users could perform the correct Control Solution tests after reading the User's Manual.

### 8.3.2 Blood Glucose Value Comparison

Re Exhibit 2 of Appendix 4 for the Comparison of participant's self-test vs. Professional's first meter test and Exhibit 3 of Appendix 4 for the Comparison of participant's self-test vs. averaged duplicate YSI of first fingerstick.

The slope, y-intercept and correlation coefficient of linear regression are summarized on the table and noted on the scatter plot.

## 8.4 For AST Evaluation

Re Exhibit 1 ~ 4 of Appendix 5, the followings are evaluated.  The slope, y-intercept and correlation coefficient of linear regression are summarized on

the tables and noted on the scatter plots.

- Compare Professional's first meter test on fingerstick vs. Participant self-test on palm

- Compare Professional's first meter test on fingerstick vs. Professional's test on palm

- Compare Professional's first meter test on fingerstick vs. Participant self-test on forearm

- Compare Professional's first meter test on fingerstick vs. Professional's test on forearm

8.5 **User Questionnaires Evaluation**

8.5.1 Utility and Clarity of User's Guide

Re Exhibit 1 of Appendix 6 for the averaged rating score of the questionnaires for Utility and Clarity of User's Guide.   Scores for all the 12 questions are averaged over 4.   Most the users understand the indication on the User's Guide easily.

8.5.2 Ease of Use of Embrace No Code

Re Exhibit 2 of Appendix 6 for the averaged rating score for Ease of Use of Embrace No Code.   Scores for all the 12 questions are averaged of 4.3 ~ 4.7. Design and performance of Embrace No Code are acceptable by most the users.   The lowest score items are the setting the meter and perform the AST sampling.

8.5.2 Acceptance Degree of Voice Feature

Re Exhibit 3 of Appendix 6 for the averaged rating score for Acceptance Degree of Voice Feature.   Scores for all the 5 questions are all over 4.5. Users with impaired visual agree that the accessory voice function is user friendly, to assistant for testing.   Users with normal sight like the voice function because of the smart and innovation design.

# 9. Conclusion

According to the clinical study, as compared to the reference method YSI 2300 analyzer, the GlycoSure Voice show good correlation, 100% of the 158

test samples fall within the acceptance criteria of bias analysis, and 100% fall within the Zone A of Clark Error Grid analysis.

For the AST tests, both the trained professional and untrained user can get the accurate results, correlated well to YSI.   According to the clear indication on the User's Guide, users can perform the correct sampling and testing to generate the accurate results.

After reading the User's Manual, even the untrained lay users can operate the Embrace No Code meter correctly to get the accurate blood glucose value, correlated to trained healthcare professional.

Most users understand the indication on User's Guide and can operate the meter without assistants.   The most satisfied feature of the new system is the Voice function, because it helps to remind for the test results.


## 10. REFERENCE

10.1 FDA, ICH Harmonized Tripartite Guideline, Guideline for Good Clinical Practice, 1 May 1996.

10.2 ISO 15197, In vitro diagnostic test system – Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus. First edition, May 2003.

10.3 AdvaMed Draft Guidance Document – Review Criteria for Assessment of Portable Blood Glucose Monitoring In Vitro Diabetic Devices.

10.4 Draft Guidance for Industry and FDA Staff - Total Product Life Cycle for Portable Invasive Blood Glucose Monitoring Systems -- APPENDIX 1. <u>ALTERNATIVE SAMPLE SITE TESTING (AST)</u>.

10.5 Clarke WL, Cox D, Gonder-Frederick LA, Carter W, Pohl SL: Evaluating clinical accuracy of systems for self-monitoring of blood glucose. Diabetes Care 10:622–628, 1987.

# Appendix 2


# Clinical Evaluation Worksheets

Meter:  Embrace No Code                              Test Date:8/28/~9/21/2007

Lot no:  FS002i, FS002J, FS002K                       Temp.oC: 23.1 ~25.5

                                                      RH%:     45 ~ 65 %

| Test No. | HCT | Fingertip-YSI Test | | | | | | Change (%) | | Fingertip | | | Palm | | Forearm | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | YSI-1st Finger Stick | | YSI-2nd Finger Stick | | YSI-3rd Finger Stick | | 1st vs. 2nd | 2nd vs. 1st | User | Professional | | User | Professional | User | Professional |
| | | Test 1 | Test 2 | Test 1 | Test 2 | Test 1 | Test 2 | | | Meter 1 | Meter 1 | Meter 2 | | | | |
| 1 | 41 | 333 | 334 | 333 | 333 | 333 | 334 | 0% | 0% | 340 | 344 | 347 | 349 | 349 | 351 | 347 |
| 2 | 43 | 214 | 214 | 214 | 211 | 213 | 214 | -1% | 0% | 222 | 223 | 210 | 218 | 216 | 194 | 188 |
| 3 | 49 | 234 | 233 | 234 | 233 | 234 | 234 | 0% | 0% | 215 | 226 | 226 | 207 | 203 | 188 | 219 |
| 4 | 37 | 457 | 457 | 454 | 456 | 457 | 459 | 0% | 1% | 424 | 422 | 443 | 472 | 447 | 423 | 461 |
| 5 | 45 | 48.8 | 46 | 44.7 | 44.1 | 46 | 45 | -6% | 2% | 65 | 62 | 55 | 62 | 62 | 58 | 60 |
| 6 | 45 | 389 | 386 | 385 | 384 | 386 | 386 | -1% | 0% | 367 | 372 | 382 | 372 | 382 | 358 | 370 |
| 7 | 45 | 272 | 270 | 271 | 268 | 270 | 271 | -1% | 0% | 243 | 251 | 262 | 248 | 261 | 281 | 274 |
| 8 | 41 | 194 | 196 | 197 | 195 | 195 | 197 | 1% | 0% | 182 | 187 | 198 | 209 | 226 | 178 | 201 |
| 9 | 40 | 290 | 288 | 291 | 288 | 289 | 290 | 0% | 0% | 292 | 263 | 305 | 324 | 310 | 270 | 274 |
| 10 | 48 | 222 | 219 | 225 | 223 | 223 | 222 | 2% | -1% | 208 | 198 | 201 | 186 | 221 | 198 | 229 |
| 11 | 42 | 366 | 364 | 363 | 362 | 364 | 364 | -1% | 0% | 389 | 378 | 367 | 364 | 386 | 344 | 325 |
| 12 | 43 | 208 | 206 | 210 | 210 | 209 | 208 | 1% | -1% | 194 | 199 | 210 | 199 | 228 | 200 | 218 |
| 13 | 43 | 234 | 233 | 241 | 241 | 238 | 237 | 3% | -1% | 219 | 211 | 213 | 206 | 208 | 222 | 245 |
| 14 | 43 | 319 | 317 | 331 | 332 | 326 | 324 | 4% | -2% | 326 | 343 | 318 | 334 | 373 | 294 | 353 |
| 15 | 36 | 362 | 363 | 364 | 361 | 362 | 364 | 0% | 0% | 370 | 352 | 405 | 337 | 413 | 362 | 418 |

| Test No. | HCT | Fingertip-YSI Test | | | | | | Change (%) | | Fingertip | | | Palm | | Forearm | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | YSI-1st Finger Stick | | YSI-2nd Finger Stick | | YSI-3rd Finger Stick | | 1st vs. 2nd | 2nd vs. 1st | User | Professional | | User | Profess ional | User | Profes sional |
| | | Test 1 | Test 2 | Test 1 | Test 2 | Test 1 | Test 2 | | | Meter 1 | Meter 1 | Meter 2 | | | | |
| 16 | 48 | 417 | 417 | 426 | 424 | 420 | 421 | 2% | -1% | 399 | 408 | 407 | 389 | 429 | 383 | 424 |
| 17 | 43 | 215 | 215 | 215 | 214 | 215 | 215 | 0% | 0% | 210 | 211 | 229 | 203 | 254 | 224 | 220 |
| 18 | 45 | 245 | 245 | 243 | 242 | 244 | 244 | -1% | 1% | 237 | 238 | 222 | 245 | 259 | 239 | 248 |
| 19 | 45 | 270 | 268 | 270 | 268 | 269 | 269 | 0% | 0% | 249 | 262 | 261 | 272 | 253 | 258 | 260 |
| 20 | 38 | 356 | 354 | 358 | 354 | 355 | 356 | 0% | 0% | 368 | 373 | 377 | 348 | 360 | 362 | 348 |
| 21 | 47 | 413 | 416 | 413 | 414 | 414 | 415 | 0% | 0% | 403 | 392 | 420 | 382 | 409 | 390 | 400 |
| 22 | 36 | 405 | 403 | 406 | 407 | 406 | 405 | 1% | 0% | 429 | 411 | 393 | 414 | 428 | 420 | 432 |
| 23 | 43 | 253 | 252 | 256 | 253 | 253 | 254 | 1% | 0% | 242 | 228 | 254 | 268 | 259 | 251 | 234 |
| 24 | 43 | 51.2 | 49.3 | 52.9 | 51.6 | 51.4 | 51.1 | 4% | -2% | 56 | 50 | 57 | 54 | 50 | 60 | 62 |
| 25 | 43 | 451 | 449 | 453 | 452 | 451 | 451 | 1% | 0% | 456 | 475 | 457 | 424 | 450 | 410 | 464 |
| 26 | 38 | 386 | 385 | 387 | 387 | 387 | 386 | 0% | 0% | 358 | 407 | 393 | 370 | 384 | 379 | 376 |
| 27 | 49 | 245 | 244 | 244 | 243 | 244 | 244 | 0% | 0% | 240 | 228 | 228 | 213 | 240 | 226 | 242 |
| 28 | 35 | 478 | 476 | 479 | 479 | 478 | 478 | 0% | 0% | 491 | 499 | 504 | 473 | 487 | 465 | 468 |
| 29 | 38 | 196 | 198 | 197 | 195 | 196 | 198 | -1% | 1% | 201 | 194 | 211 | 184 | 192 | 189 | 188 |
| 30 | 38 | 254 | 253 | 261 | 257 | 256 | 257 | 2% | -1% | 257 | 277 | 270 | 232 | 248 | 248 | 252 |
| 31 | 37 | 320 | 318 | 319 | 317 | 319 | 319 | 0% | 0% | 308 | 325 | 331 | 330 | 310 | 339 | 323 |
| 32 | 44 | 253 | 251 | 254 | 252 | 253 | 253 | 0% | 0% | 249 | 241 | 252 | 269 | 269 | 226 | 228 |
| 33 | 44 | 196 | 193 | 195 | 192 | 194 | 194 | -1% | 0% | 192 | 204 | 189 | 195 | 208 | 203 | 223 |

| Test No. | HCT | Fingertip-YSI Test | | | | | | Change (%) | | Fingertip | | | Palm | | Forearm | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | YSI-1st Finger Stick | | YSI-2nd Finger Stick | | YSI-3rd Finger Stick | | 1st vs. 2nd | 2nd vs. 1st | User | Professional | | User | Professional | User | Professional |
| | | Test 1 | Test 2 | Test 1 | Test 2 | Test 1 | Test 2 | | | Meter 1 | Meter 1 | Meter 2 | | | | |
| 34 | 52 | 315 | 316 | 317 | 314 | 315 | 317 | 0% | 0% | 292 | 289 | 299 | 283 | 296 | 268 | 312 |
| 35 | 42 | 352 | 353 | 354 | 353 | 353 | 354 | 0% | 0% | 373 | 343 | 371 | 364 | 352 | 335 | 341 |
| 36 | 40 | 377 | 379 | 378 | 378 | 378 | 379 | 0% | 0% | 376 | 364 | 370 | 376 | 389 | 388 | 385 |
| 37 | 41 | 231 | 228 | 235 | 234 | 233 | 232 | 2% | -1% | 233 | 227 | 238 | 244 | 230 | 221 | 241 |
| 38 | 42 | 368 | 367 | 375 | 375 | 371 | 371 | 2% | -1% | 361 | 378 | 389 | 374 | 383 | 387 | 376 |
| 39 | 41 | 274 | 273 | 274 | 275 | 274 | 274 | 0% | 0% | 261 | 271 | 269 | 251 | 278 | 246 | 267 |
| 40 | 39 | 174 | 173 | 176 | 176 | 175 | 174 | 1% | -1% | 187 | 171 | 174 | 166 | 168 | 169 | 175 |
| 41 | 36 | 470 | 472 | 472 | 471 | 471 | 472 | 0% | 0% | 509 | 503 | 498 | 480 | 451 | 505 | 457 |
| 42 | 43 | 182 | 181 | 181 | 182 | 182 | 181 | 0% | 0% | 170 | 175 | 175 | 178 | 170 | 178 | 176 |
| 43 | 37 | 277 | 276 | 275 | 276 | 276 | 276 | 0% | 0% | 292 | 275 | 267 | 276 | 276 | 248 | 269 |
| 44 | 44 | 191 | 194 | 194 | 194 | 192 | 194 | 1% | -1% | 176 | 192 | 187 | 178 | 189 | 179 | 179 |
| 45 | 41 | 170 | 168 | 165 | 163 | 167 | 167 | -3% | 2% | 170 | 160 | 156 | 149 | 166 | 161 | 159 |
| 46 | 43 | 163 | 162 | 163 | 162 | 163 | 163 | 0% | 0% | 163 | 149 | 162 | 154 | 153 | 140 | 146 |
| 47 | 46 | 183 | 182 | 184 | 183 | 183 | 183 | 1% | 0% | 166 | 176 | 171 | 170 | 168 | 169 | 175 |
| 48 | 49 | 177 | 176 | 181 | 179 | 178 | 179 | 2% | -1% | 171 | 173 | 159 | 163 | 193 | 166 | 160 |
| 49 | 43 | 139 | 138 | 138 | 136 | 138 | 138 | -1% | 1% | 134 | 139 | 148 | 128 | 143 | 123 | 154 |
| 50 | 39 | 123 | 122 | 123 | 122 | 123 | 123 | 0% | 0% | 135 | 119 | 126 | 131 | 124 | 144 | 123 |
| 51 | 43 | 262 | 261 | 263 | 259 | 261 | 262 | 0% | 0% | 256 | 251 | 250 | 242 | 263 | 246 | 259 |

| Test No. | HCT | Fingertip-YSI Test | | | | | | Change (%) | | Fingertip | | | Palm | | Forearm | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | YSI-1st Finger Stick | | YSI-2nd Finger Stick | | YSI-3rd Finger Stick | | 1st vs. 2nd | 2nd vs. 1st | User | Professional | | User | Profess ional | User | Profes sional |
| | | Test 1 | Test 2 | Test 1 | Test 2 | Test 1 | Test 2 | | | Meter 1 | Meter 1 | Meter 2 | | | | |
| 52 | 42 | 275 | 273 | 278 | 273 | 274 | 276 | 1% | 0% | 279 | 259 | 280 | 247 | 254 | 256 | 290 |
| 53 | 42 | 159 | 158 | 157 | 156 | 158 | 158 | -1% | 1% | 161 | 139 | 152 | 166 | 151 | 155 | 165 |
| 54 | 39 | 181 | 181 | 184 | 183 | 182 | 183 | 1% | -1% | 171 | 169 | 167 | 190 | 181 | 186 | 187 |
| 55 | 43 | 301 | 302 | 299 | 299 | 301 | 300 | -1% | 1% | 293 | 291 | 290 | 291 | 300 | 303 | 303 |
| 56 | 39 | 178 | 179 | 178 | 177 | 178 | 178 | -1% | 0% | 171 | 175 | 179 | 182 | 166 | 188 | 186 |
| 57 | 38 | 164 | 165 | 168 | 164 | 165 | 166 | 1% | 0% | 176 | 179 | 168 | 165 | 180 | 164 | 167 |
| 58 | 37 | 74.7 | 75.1 | 78.4 | 76.3 | 75.7 | 76.6 | 3% | -2% | 85 | 78 | 85 | 84 | 87 | 88 | 80 |
| 59 | 48 | 188 | 189 | 180 | 179 | 184 | 184 | -5% | 3% | 197 | 202 | 205 | 207 | 199 | 201 | 199 |
| 60 | 42 | 79.5 | 79.9 | 80.7 | 79.6 | 79.8 | 80.1 | 1% | 0% | 81 | 85 | 75 | 70 | 75 | 76 | 77 |
| 61 | 42 | 91.9 | 92.4 | 93.8 | 91.6 | 92 | 92.9 | 1% | 0% | 83 | 92 | 90 | 86 | 79 | 89 | 81 |
| 62 | 48 | 186 | 187 | 188 | 184 | 185 | 187 | 0% | 0% | 172 | 169 | 181 | 186 | 176 | 161 | 174 |
| 63 | 41 | 99.6 | 101 | 105 | 104 | 103 | 102 | 4% | -2% | 85 | 87 | 90 | 90 | 90 | 85 | 95 |
| 64 | 43 | 240 | 241 | 240 | 241 | 241 | 240 | 0% | 0% | 248 | 267 | 270 | 238 | 262 | 219 | 256 |
| 65 | 50 | 177 | 178 | 181 | 180 | 191 | 179 | 2% | 2% | 183 | 179 | 185 | 175 | 180 | 184 | 174 |
| 66 | 42 | 190 | 191 | 191 | 191 | 191 | 191 | 0% | 0% | 193 | 215 | 205 | 195 | 195 | 182 | 181 |
| 67 | 46 | 81 | 81.5 | 82 | 80.2 | 80.9 | 81.5 | 0% | 0% | 95 | 94 | 92 | 84 | 81 | 91 | 83 |
| 68 | 48 | 74.1 | 74.6 | 75.3 | 73 | 73.8 | 74.7 | 0% | 0% | 67 | 80 | 81 | 69 | 81 | 62 | 84 |
| 69 | 46 | 314 | 315 | 315 | 313 | 314 | 315 | 0% | 0% | 327 | 313 | 302 | 309 | 314 | 287 | 309 |

| Test No. | HCT | Fingertip-YSI Test | | | | | | Change (%) | | Fingertip | | | Palm | | Forearm | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | YSI-1st Finger Stick | | YSI-2nd Finger Stick | | YSI-3rd Finger Stick | | 1st vs. 2nd | 2nd vs. 1st | User | Professional | | User | Profess ional | User | Profes sional |
| | | Test 1 | Test 2 | Test 1 | Test 2 | Test 1 | Test 2 | | | Meter 1 | Meter 1 | Meter 2 | | | | |
| 70 | 46 | 73.7 | 76.6 | 81.2 | 78.3 | 77.5 | 77.5 | 6% | -3% | 88 | 82 | 86 | 78 | 88 | 85 | 83 |
| 71 | 52 | 139 | 139 | 132 | 133 | 136 | 136 | -5% | 3% | 126 | 124 | 124 | 119 | 119 | 115 | 123 |
| 72 | 42 | 139 | 141 | 133 | 136 | 138 | 137 | -4% | 2% | 119 | 125 | 120 | 141 | 128 | 131 | 124 |
| 73 | 45 | 113 | 114 | 112 | 111 | 113 | 113 | -2% | 1% | 107 | 106 | 110 | 114 | 109 | 113 | 95 |
| 74 | 46 | 86.9 | 87.7 | 86.3 | 86.5 | 87.1 | 86.6 | -1% | 1% | 90 | 92 | 102 | 104 | 98 | 92 | 96 |
| 75 | 45 | 106 | 106 | 106 | 106 | 106 | 106 | 0% | 0% | 97 | 93 | 89 | 94 | 95 | 92 | 93 |
| 76 | 42 | 88.2 | 88.3 | 87.7 | 87.6 | 87.9 | 88 | -1% | 0% | 88 | 82 | 88 | 93 | 90 | 76 | 86 |
| 77 | 45 | 196 | 196 | 194 | 194 | 195 | 195 | -1% | 1% | 198 | 191 | 191 | 204 | 196 | 178 | 183 |
| 78 | 38 | 82.4 | 83.3 | 82.5 | 82.3 | 82.8 | 82.5 | -1% | 0% | 86 | 82 | 77 | 89 | 84 | 82 | 77 |
| 79 | 42 | 82.1 | 80.8 | 79.4 | 78.9 | 79.9 | 80.8 | -3% | 2% | 82 | 70 | 81 | 85 | 72 | 76 | 76 |
| 80 | 41 | 174 | 174 | 186 | 187 | 171 | 170 | 7% | -9% | 181 | 178 | 163 | 171 | 177 | 185 | 181 |
| 81 | 48 | 92.9 | 91.2 | 88.8 | 87.3 | 89.3 | 90.9 | -4% | 2% | 96 | 88 | 82 | 85 | 89 | 79 | 97 |
| 82 | 44 | 136 | 134 | 131 | 129 | 123 | 123 | -4% | -5% | 124 | 138 | 131 | 135 | 129 | 130 | 127 |
| 83 | 47 | 102 | 101 | 96.4 | 97.3 | 94.2 | 94.2 | -5% | -3% | 98 | 97 | 85 | 85 | 86 | 90 | 91 |
| 84 | 42 | 92.7 | 91 | 88.8 | 88 | 89.5 | 90.8 | -4% | 2% | 89 | 87 | 78 | 87 | 77 | 75 | 82 |
| 85 | 43 | 90.9 | 87.5 | 89.8 | 87.7 | 87.6 | 90.3 | -1% | 0% | 81 | 82 | 93 | 80 | 76 | 87 | 78 |
| 86 | 41 | 288 | 287 | 284 | 285 | 286 | 286 | -1% | 1% | 300 | 294 | 287 | 293 | 291 | 292 | 296 |
| 87 | 49 | 87 | 85.9 | 83.4 | 84.4 | 80.2 | 80.2 | -3% | -4% | 88 | 81 | 77 | 72 | 86 | 70 | 83 |

| Test No. | HCT | Fingertip-YSI Test | | | | | | Change (%) | | Fingertip | | | Palm | | Forearm | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | YSI-1st Finger Stick | | YSI-2nd Finger Stick | | YSI-3rd Finger Stick | | 1st vs. 2nd | 2nd vs. 1st | User | Professional | | User | Profess ional | User | Profes sional |
| | | Test 1 | Test 2 | Test 1 | Test 2 | Test 1 | Test 2 | | | Meter 1 | Meter 1 | Meter 2 | | | | |
| 88 | 41 | 144 | 143 | 143 | 142 | 143 | 143 | -1% | 0% | 134 | 128 | 133 | 150 | 144 | 142 | 136 |
| 89 | 44 | 164 | 164 | 162 | 162 | 163 | 163 | -1% | 1% | 159 | 156 | 141 | 141 | 169 | 137 | 161 |
| 90 | 53 | 181 | 180 | 185 | 185 | 183 | 183 | 2% | -1% | 162 | 172 | 175 | 152 | 177 | 168 | 167 |
| 91 | 44 | 73.9 | 73.7 | 76 | 76.1 | 79.9 | 80 | 3% | 5% | 68 | 66 | 76 | 75 | 68 | 70 | 65 |
| 92 | 47 | 155 | 154 | 154 | 152 | 154 | 154 | -1% | 1% | 168 | 160 | 160 | 169 | 147 | 159 | 159 |
| 93 | 45 | 138 | 136 | 139 | 137 | 138 | 138 | 1% | 0% | 129 | 152 | 137 | 137 | 136 | 131 | 139 |
| 94 | 51 | 142 | 142 | 139 | 139 | 141 | 141 | -2% | 1% | 142 | 137 | 151 | 117 | 140 | 124 | 136 |
| 95 | 44 | 183 | 185 | 184 | 183 | 183 | 185 | 0% | 0% | 184 | 172 | 177 | 169 | 176 | 178 | 189 |
| 96 | 40 | 178 | 178 | 175 | 176 | 177 | 177 | -1% | 1% | 175 | 166 | 161 | 166 | 167 | 173 | 159 |
| 97 | 44 | 82.4 | 81.6 | 84.4 | 84.3 | 83 | 83.4 | 3% | -1% | 85 | 82 | 75 | 82 | 84 | 77 | 91 |
| 98 | 42 | 177 | 176 | 179 | 179 | 178 | 178 | 1% | -1% | 168 | 169 | 163 | 171 | 179 | 177 | 173 |
| 99 | 47 | 178 | 175 | 179 | 177 | 178 | 177 | 1% | 0% | 181 | 181 | 165 | 178 | 174 | 169 | 189 |
| 100 | 50 | 161 | 160 | 162 | 162 | 162 | 161 | 1% | 0% | 162 | 158 | 160 | 158 | 164 | 147 | 170 |
| 101 | 45 | 78.8 | 78.7 | 72.9 | 74.6 | 76.7 | 75.9 | -6% | 3% | 71 | 72 | 69 | 68 | 80 | 65 | 79 |
| 102 | 42 | 79.3 | 78.4 | 80.7 | 80.9 | 79.7 | 80 | 2% | -1% | 76 | 77 | 86 | 77 | 76 | 76 | 81 |
| 103 | 47 | 385 | 383 | 377 | 376 | 380 | 380 | -2% | 1% | 371 | 372 | 377 | 380 | 375 | 366 | 370 |
| 104 | 48 | 75.3 | 74.2 | 77.4 | 77.2 | 75.7 | 76.3 | 3% | -2% | 82 | 75 | 84 | 76 | 79 | 64 | 81 |
| 105 | 45 | 189 | 189 | 194 | 194 | 191 | 192 | 3% | -1% | 170 | 170 | 169 | 179 | 166 | 166 | 158 |

| Test No. | HCT | Fingertip-YSI Test | | | | | | Change (%) | | Fingertip | | | Palm | | Forearm | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | YSI-1st Finger Stick | | YSI-2nd Finger Stick | | YSI-3rd Finger Stick | | 1st vs. 2nd | 2nd vs. 1st | User | Professional | | User | Profess ional | User | Profes sional |
| | | Test 1 | Test 2 | Test 1 | Test 2 | Test 1 | Test 2 | | | Meter 1 | Meter 1 | Meter 2 | | | | |
| 106 | 45 | 74.2 | 73.5 | 73.1 | 72.3 | 72.9 | 73.7 | -2% | 1% | 79 | 78 | 83 | 73 | 88 | 68 | 82 |
| 107 | 43 | 452 | 450 | 445 | 445 | 447 | 448 | -1% | 1% | 474 | 431 | 426 | 460 | 483 | 443 | 481 |
| 108 | 46 | 261 | 260 | 266 | 265 | 263 | 263 | 2% | -1% | 262 | 257 | 260 | 256 | 281 | 238 | 276 |
| 109 | 45 | 137 | 136 | 140 | 140 | 139 | 138 | 3% | -1% | 127 | 153 | 135 | 133 | 139 | 116 | 141 |
| 110 | 44 | 148 | 147 | 145 | 144 | 146 | 146 | -2% | 1% | 147 | 159 | 141 | 156 | 147 | 137 | 142 |
| 111 | 48 | 187 | 185 | 185 | 184 | 186 | 185 | -1% | 1% | 193 | 172 | 181 | 184 | 185 | 190 | 188 |
| 112 | 41 | 195 | 194 | 193 | 192 | 193 | 194 | -1% | 1% | 194 | 192 | 198 | 185 | 200 | 190 | 185 |
| 113 | 41 | 137 | 135 | 138 | 136 | 137 | 137 | 1% | 0% | 128 | 125 | 126 | 146 | 136 | 133 | 137 |
| 114 | 47 | 148 | 147 | 148 | 148 | 148 | 148 | 0% | 0% | 127 | 149 | 151 | 131 | 138 | 149 | 142 |
| 115 | 47 | 151 | 152 | 152 | 151 | 151 | 151 | 0% | 0% | 161 | 158 | 145 | 140 | 150 | 136 | 146 |
| 116 | 43 | 76.7 | 76 | 75.9 | 76.1 | 76.1 | 76.3 | 0% | 0% | 82 | 79 | 84 | 70 | 74 | 62 | 75 |
| 117 | 45 | 77.6 | 77.2 | 76.5 | 75.7 | 76.5 | 77.1 | -2% | 1% | 82 | 86 | 76 | 87 | 88 | 76 | 81 |
| 118 | 47 | 127 | 126 | 129 | 127 | 127 | 128 | 1% | 0% | 117 | 141 | 121 | 114 | 121 | 138 | 139 |
| 119 | 47 | 84 | 83.6 | 78.5 | 77.9 | 80.8 | 81.3 | -7% | 4% | 80 | 78 | 82 | 74 | 90 | 83 | 83 |
| 120 | 46 | 79.7 | 78.6 | 73.1 | 72 | 75.3 | 76.4 | -8% | 5% | 81 | 83 | 80 | 83 | 83 | 76 | 90 |
| 121 | 43 | 170 | 169 | 166 | 166 | 167 | 168 | -2% | 1% | 161 | 170 | 179 | 180 | 174 | 175 | 176 |
| 122 | 46 | 75.4 | 75.1 | 77.6 | 77.8 | 76.5 | 76.5 | 3% | -2% | 75 | 76 | 82 | 77 | 77 | 79 | 78 |
| 123 | 42 | 132 | 129 | 131 | 129 | 129 | 131 | 0% | 0% | 130 | 145 | 136 | 140 | 130 | 127 | 130 |

| Test No. | HCT | Fingertip-YSI Test | | | | | | Change (%) | | Fingertip | | | Palm | | Forearm | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | YSI-1st Finger Stick | | YSI-2nd Finger Stick | | YSI-3rd Finger Stick | | 1st vs. 2nd | 2nd vs. 1st | User | Professional | | User | Profess ional | User | Profes sional |
| | | Test 1 | Test 2 | Test 1 | Test 2 | Test 1 | Test 2 | | | Meter 1 | Meter 1 | Meter 2 | | | | |
| 124 | 44 | 74 | 72.9 | 77.5 | 76.1 | 79.5 | 80.8 | 5% | 4% | 81 | 82 | 80 | 84 | 78 | 82 | 72 |
| 125 | 43 | 101 | 99 | 98.5 | 97.7 | 98.4 | 100 | -2% | 1% | 110 | 114 | 111 | 107 | 106 | 117 | 95 |
| 126 | 43 | 77.8 | 77.1 | 79.2 | 78.2 | 77.7 | 78.5 | 2% | -1% | 89 | 85 | 89 | 87 | 90 | 90 | 88 |
| 127 | 48 | 87.3 | 87.5 | 82.6 | 82.9 | 85.2 | 85 | -5% | 3% | 79 | 85 | 81 | 78 | 92 | 79 | 77 |
| 128 | 42 | 94 | 93.9 | 94.7 | 93.6 | 93.8 | 94.5 | 0% | 0% | 102 | 101 | 105 | 100 | 88 | 98 | 91 |
| 129 | 46 | 92.7 | 93.8 | 94.4 | 94.8 | 94.3 | 93.6 | 1% | -1% | 92 | 96 | 91 | 86 | 88 | 85 | 83 |
| 130 | 42 | 83.7 | 83.6 | 85.5 | 84.2 | 83.9 | 84.6 | 1% | -1% | 92 | 87 | 84 | 95 | 95 | 85 | 92 |
| 131 | 40 | 79.6 | 80.6 | 77.4 | 79.2 | 79.9 | 78.5 | -2% | 1% | 78 | 77 | 80 | 70 | 72 | 73 | 73 |
| 132 | 44 | 90.6 | 91.4 | 90.2 | 90.7 | 91.1 | 90.4 | -1% | 0% | 76 | 77 | 76 | 78 | 81 | 78 | 79 |
| 133 | 42 | 83.9 | 83.5 | 86.6 | 88 | 85.8 | 85.3 | 4% | -2% | 97 | 90 | 90 | 82 | 86 | 87 | 78 |
| 134 | 40 | 76.7 | 78.7 | 78 | 78.3 | 78.5 | 77.4 | 1% | 0% | 81 | 85 | 91 | 91 | 84 | 93 | 91 |
| 135 | 41 | 65.6 | 66.4 | 66.2 | 66.3 | 66.4 | 65.9 | 0% | 0% | 74 | 73 | 74 | 79 | 74 | 76 | 71 |
| 136 | 44 | 80.7 | 81.7 | 80.8 | 80.7 | 81.2 | 80.8 | -1% | 0% | 68 | 75 | 77 | 80 | 89 | 76 | 77 |
| 137 | 44 | 201 | 203 | 199 | 197 | 199 | 200 | -2% | 1% | 196 | 197 | 198 | 201 | 194 | 190 | 197 |
| 138 | 44 | 91.4 | 92.2 | 90.5 | 91 | 91.6 | 91 | -1% | 1% | 93 | 100 | 103 | 97 | 85 | 96 | 92 |
| 139 | 41 | 116 | 118 | 117 | 117 | 118 | 117 | 0% | 0% | 99 | 107 | 98 | 107 | 108 | 102 | 105 |
| 140 | 48 | 84.5 | 86.1 | 82.7 | 82.3 | 84.2 | 83.6 | -3% | 2% | 85 | 84 | 89 | 74 | 80 | 71 | 77 |
| 141 | 49 | 74.9 | 74.8 | 77.4 | 75.9 | 75.4 | 76.2 | 2% | -1% | 82 | 79 | 79 | 85 | 82 | 80 | 74 |

| Test No. | HCT | Fingertip-YSI Test | | | | | | Change (%) | | Fingertip | | | Palm | | Forearm | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | YSI-1st Finger Stick | | YSI-2nd Finger Stick | | YSI-3rd Finger Stick | | 1st vs. 2nd | 2nd vs. 1st | User | Professional | | User | Profess ional | User | Profes sional |
| | | Test 1 | Test 2 | Test 1 | Test 2 | Test 1 | Test 2 | | | Meter 1 | Meter 1 | Meter 2 | | | | |
| 142 | 41 | 78.1 | 77.8 | 80 | 78.3 | 78.1 | 79.6 | 2% | 0% | 82 | 83 | 84 | 88 | 79 | 80 | 76 |
| 143 | 47 | 78.9 | 78.3 | 77.7 | 77.6 | 78 | 78.3 | -1% | 1% | 75 | 80 | 80 | 66 | 84 | 78 | 76 |
| 144 | 43 | 81.2 | 81.2 | 77.7 | 79.2 | 80.2 | 79.5 | -3% | 2% | 92 | 95 | 82 | 89 | 83 | 91 | 88 |
| 145 | 45 | 81.1 | 83.4 | 83.3 | 83.2 | 83.3 | 82.2 | 1% | -1% | 79 | 78 | 79 | 81 | 81 | 76 | 75 |
| 146 | 41 | 90.9 | 91.2 | 93.6 | 92 | 91.6 | 92.3 | 2% | -1% | 96 | 103 | 101 | 95 | 96 | 100 | 105 |
| 147 | 46 | 74.1 | 74.2 | 72.3 | 71.8 | 73 | 73.2 | -3% | 1% | 80 | 80 | 86 | 87 | 86 | 78 | 77 |
| 148 | 45 | 85.2 | 83.4 | 83.4 | 82 | 82.7 | 84.3 | -2% | 1% | 71 | 81 | 89 | 78 | 83 | 80 | 77 |
| 149 | 41 | 251 | 252 | 255 | 253 | 252 | 253 | 1% | -1% | 248 | 255 | 251 | 222 | 252 | 224 | 244 |
| 150 | 44 | 79.2 | 77.1 | 79.7 | 78.2 | 72.7 | 74.5 | 1% | -7% | 86 | 83 | 80 | 80 | 80 | 78 | 85 |
| 151 | 42 | 90.2 | 90.8 | 91.4 | 90.5 | 90.7 | 90.8 | 0% | 0% | 79 | 81 | 85 | 78 | 79 | 82 | 78 |
| 152 | 41 | 80.3 | 81 | 80.9 | 80.4 | 80.7 | 80.6 | 0% | 0% | 83 | 86 | 93 | 71 | 79 | 90 | 78 |
| 153* | | 44.2 | 43.6 | | | | | | | | 52 | 54 | | | | |
| 154* | | 39.6 | 41.2 | | | | | | | | 48 | 45 | | | | |
| 155* | | 47.5 | 47.6 | | | | | | | | 53 | 57 | | | | |
| 156* | | 41.3 | 40.5 | | | | | | | | 50 | 53 | | | | |
| 157* | | 47.6 | 48 | | | | | | | | 52 | 59 | | | | |
| 158* | | 34.3 | 35.8 | | | | | | | | 46 | 49 | | | | |

*: Glucose hydrolyzed samples for blood glucose level of <50mg/dL.

# Exhibit 1 of Appendix 3


Correlation of Embrace No Code vs. YSI

# Accuracy - Correlation

## Linear Regression Data:

| Embrace No Code Meter vs. YSI 2300 PLUS STAT analyzer | | | |
|---|---|---|---|
| *n* | Slope | Intercept | r value |
| 158 | 0.996 | 0.644 mg/dL | 0.995 |

## Scatter Plot:

Professional - Fingertip mean vs. YSI

y = 0.996x + 0.644
r = 0.995
n = 158

Meter glucose concentration (mg/dL) vs. YSI Reading (mg/dL)

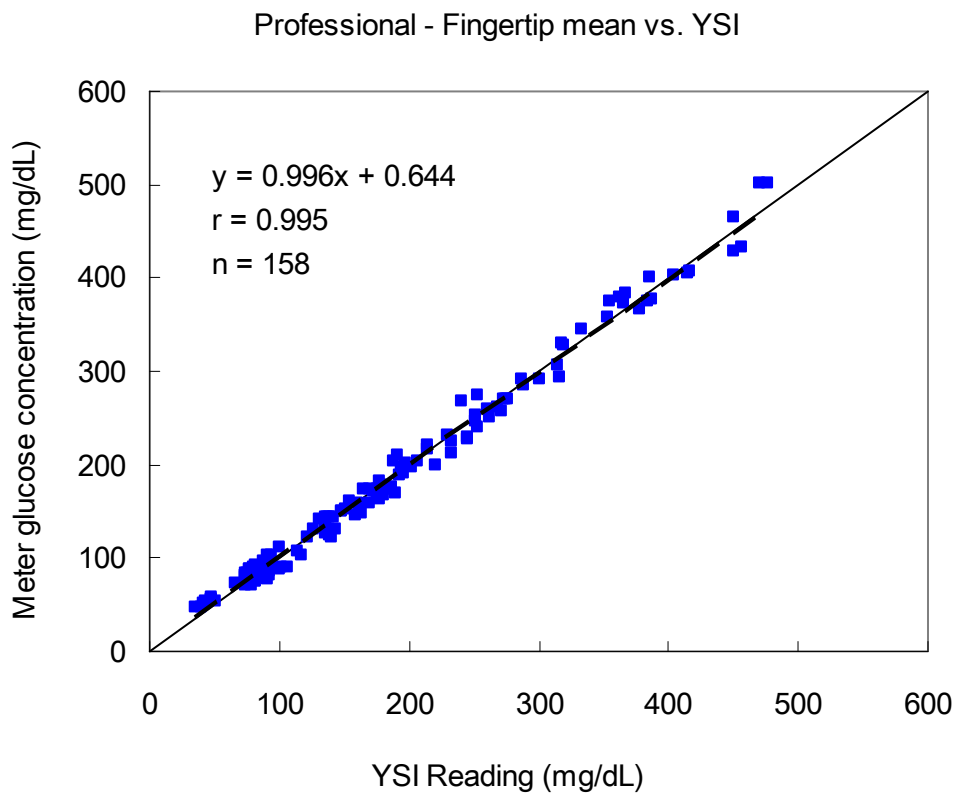# Exhibit 2 of Appendix 3

## Bias Analysis of

## Embrace No Code vs. YSI

# Accuracy – Bias Analysis

## Bias Counts:

| Bias | Embrace No Code | |
|---|---|---|
| | No. | Ratio (%) |
| Glucose level ≧75 mg/dL | | |
| < 5% | 87 | 55% |
| 5-10% | 40 | 25% |
| 10-15% | 16 | 10% |
| 15-20% | 1 | 0.6% |
| Sum of ≧75 mg/dL | 144 | 91% |
| Glucose level ＜75 mg/dL | | |
| < 15mg/dL | 14 | 9% |
| > 15mg/dL | 0 | 0% |
| Sum of ＜75 mg/dL | 14 | 9% |
| Total | 158 | 100% |

Acceptance criteria:

For glucose level ≧75 mg/dL: +/- 20% of YSI

For glucose level ＜75 mg/dL: +/- 15mmg/dL

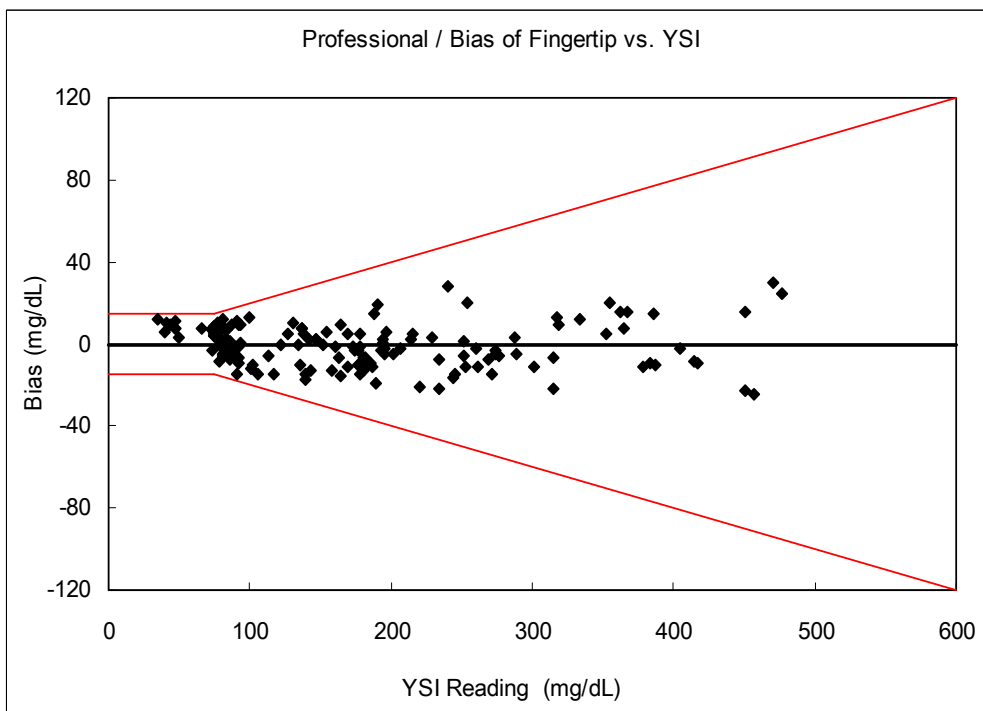## Bias Plot:

# Exhibit 3 of Appendix 3

## Clark Error Grid Analysis of

## Embrace No Code vs. YSI

# Accuracy - Clark Error Grid Plot

## Embrace No Code vs. YSI
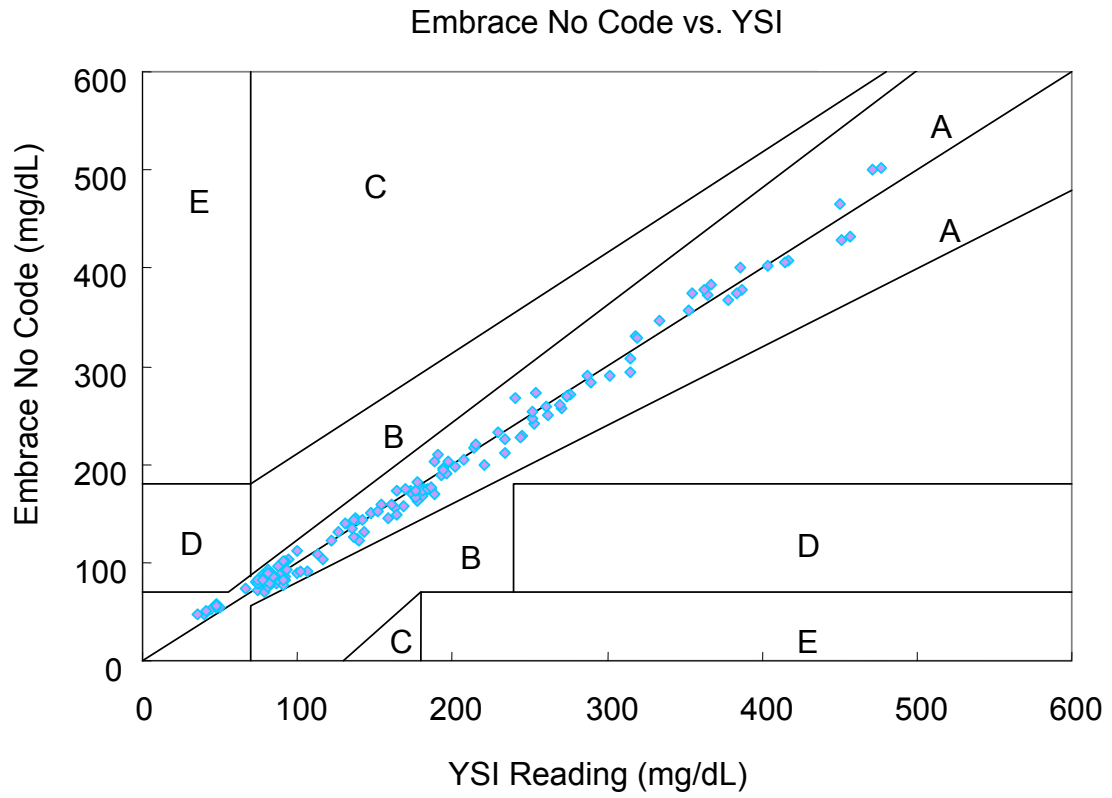
**Exhibit 1 of Appendix 4**

Control Solution Test Results

Evaluation of Lay User

# Evaluation of Control Solution Test Results of Lay Users

## Control Solution Test Result of Users:

|  | Level 1 | Level 2 |
|---|---|---|
| Readings of tests | 62~88 mg/dL | 138~189mg/dL |
| # of within range | 152 | 152 |
| Percentage | 100% | 100% |

Participant No.: 152

Lot # of test strip: FS002E

Control Range  - Level 1: 59~89mg/dL

             - Level 2: 138~206mg/dL

Lot # of control solution:

             - Level 1: TC960707M

             - Level 2: TC960701H

**Exhibit 2 of Appendix 4**

Comparison of Participant's

Self-test vs. Professional's Test

# Comparison of Participant's Self-test vs. Professional's Test - Fingertip

## Linear Regression Data:

| n | Slope | Intercept | r value |
|---|---|---|---|
| User vs. Professional of Fingertip | | | |
| 152 | 1.002 | -0.445 mg/dL | 0.994 |

## Scatter Plot of User vs. Professional:

**User vs. Professional - Fingertip**

$y = 1.0019x - 0.4454$
$r = 0.994$
$n = 152$

User Reading (mg/dL)

Professional Reading (mg/dL)
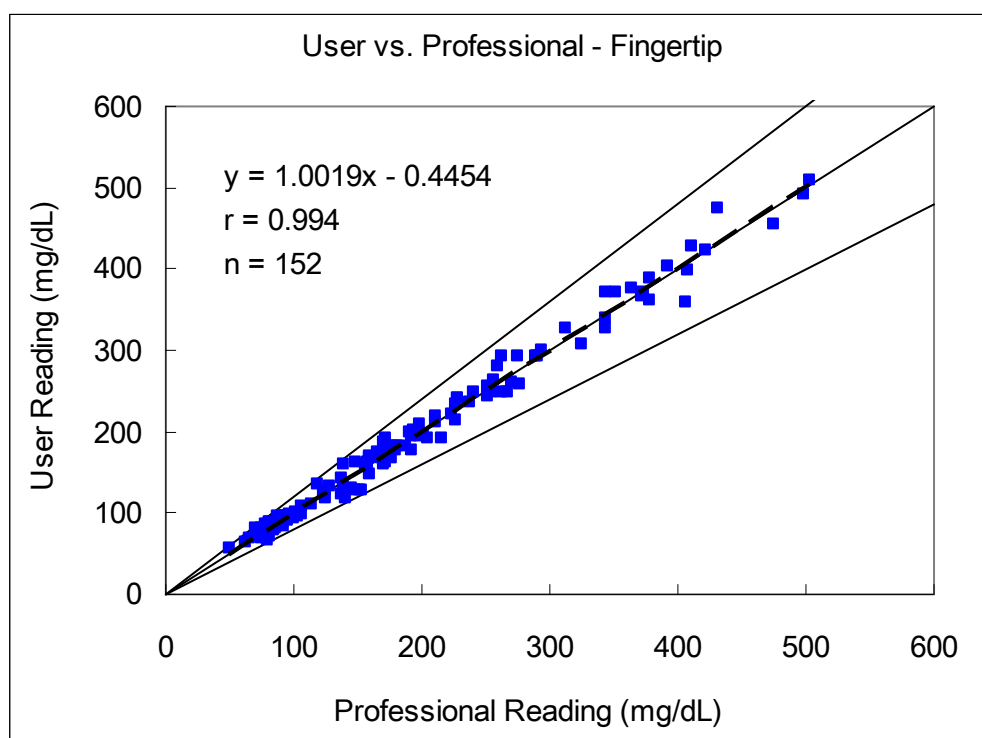
**Exhibit 3 of Appendix 4**


Comparison of User's Self-test vs. YSI

# Comparison of Participant's Self-test vs. YSI - Fingertip

## Linear Regression Data:

| User's Fingertip vs. YSI Analyzer | | | |
|---|---|---|---|
| *n* | Slope | Intercept | r value |
| 152 | 1.000 | -1.381 mg/dL | 0.994 |

## Scatter Plot:

User - Fingertip vs. YSI

y = 0.9995x - 1.3809
r = 0.994
n = 152

Meter Reading - Fingertip (mg/dL)

YSI Reading (mg/dL)

# Exhibit 1 of Appendix 5

## Comparison of Professional's Fingerstick vs. Participant's Palm

# Comparison of Participant's Self-Palm Test vs. Professional's Fingertip Test

## Linear Regression Data:

| | User's Palm vs. Professional's Fingertip | | |
|---|---|---|---|
| *n* | Slope | Intercept | r value |
| 152 | 0.981 | 1.530 mg/dL | 0.990 |

## Scatter Plot:

User's Palm vs. Professional's Fingertip

y = 0.981x + 1.5299
r= 0.990
n = 152

User's Palm Reading (mg/dL)

Professional's Fingertip Reading (mg/dL)

# Exhibit 2 of Appendix 5

## Comparison of Professional's Fingerstick vs. Professional's Palm

# Comparison of Palm Test vs. Fingertip Test of Professional

## Linear Regression Data:

| Palm vs. Fingertip of Professional | | | |
|---|---|---|---|
| n | Slope | Intercept | r value |
| 152 | 1.015 | -0.623 mg/dL | 0.993 |

## Scatter Plot:

Professional - Palm vs. Fingertip

$$y = 1.0147x - 0.6231$$
$$r = 0.993$$
$$n = 152$$

Professional's Palm Reading (mg/dL)
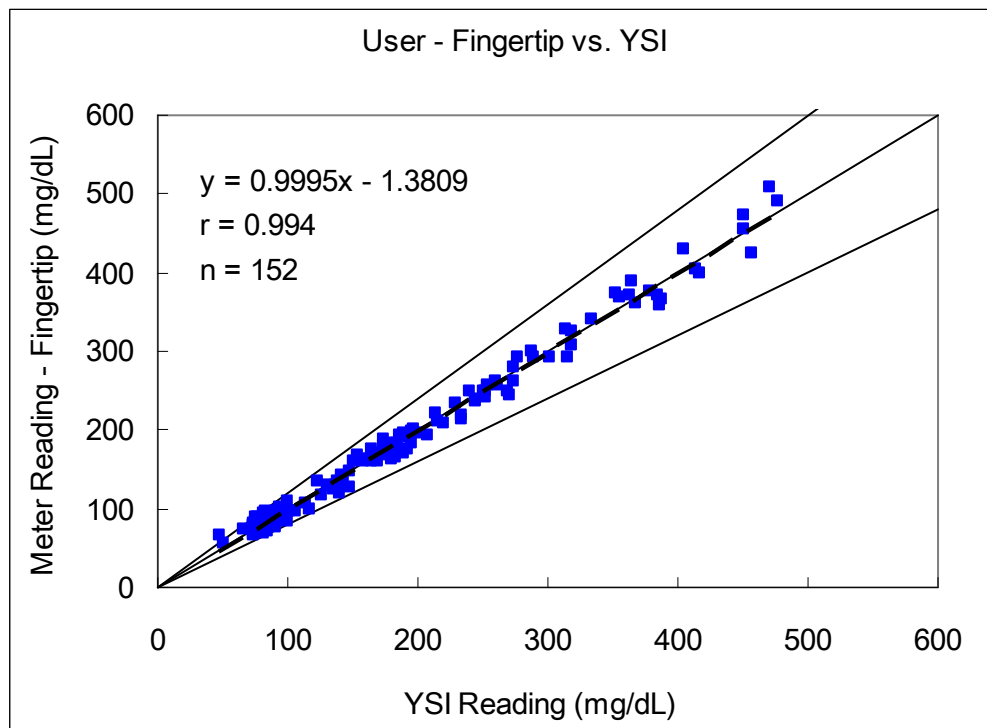
Professional's Fingertip Reading (mg/dL)
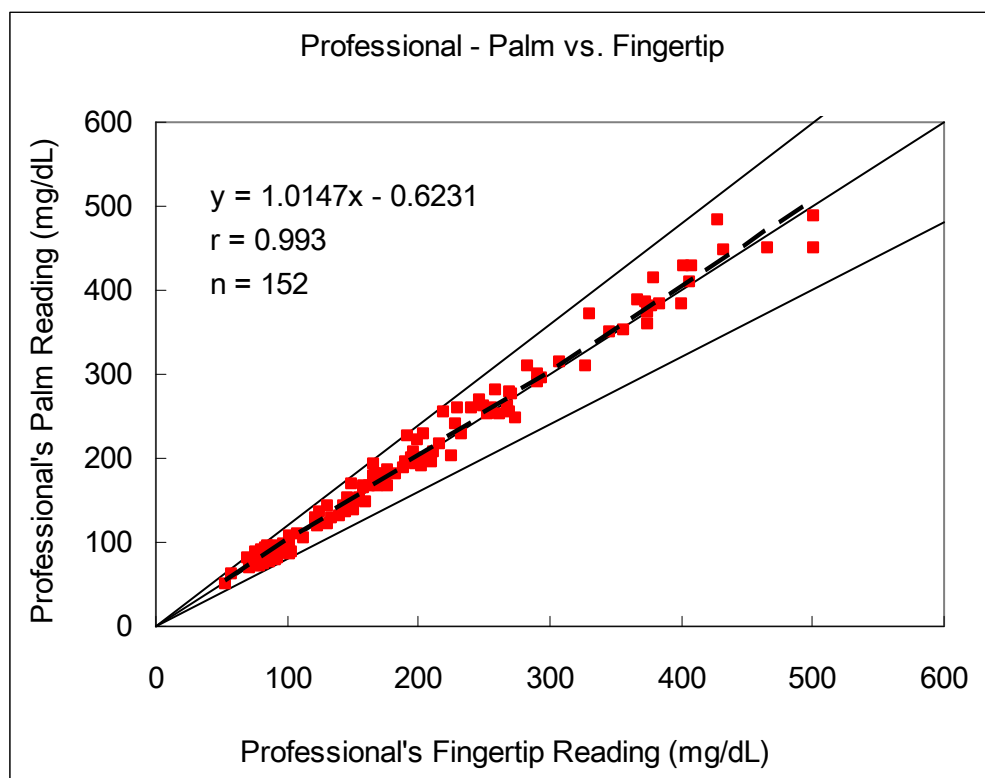
# Exhibit 3 of Appendix 5

## Comparison of Professional's

## Fingerstick vs. Participant's Forearm

# Comparison of Participants' Forearm Test vs. Fingertip Test of Professional

## Linear Regression Data:

| User's Forearm vs. Professional's Fingertip | | | |
|---|---|---|---|
| n | Slope | Intercept | r value |
| 152 | 0.968 | 0.668 mg/dL | 0.991 |

## Scatter Plot:



User's Forearm vs. Professional's Fingertip

$y = 0.968x + 0.668$
$r = 0.991$
$n = 152$

User's Forearm Reading (mg/dL)

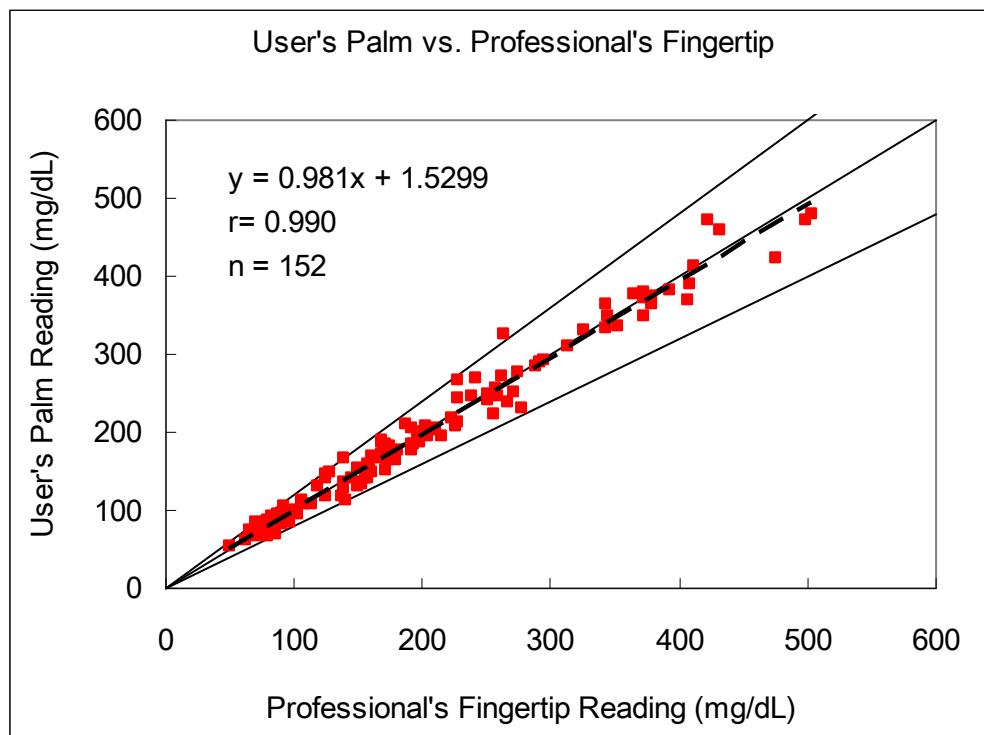Professional's Fingertip Reading (mg/dL)
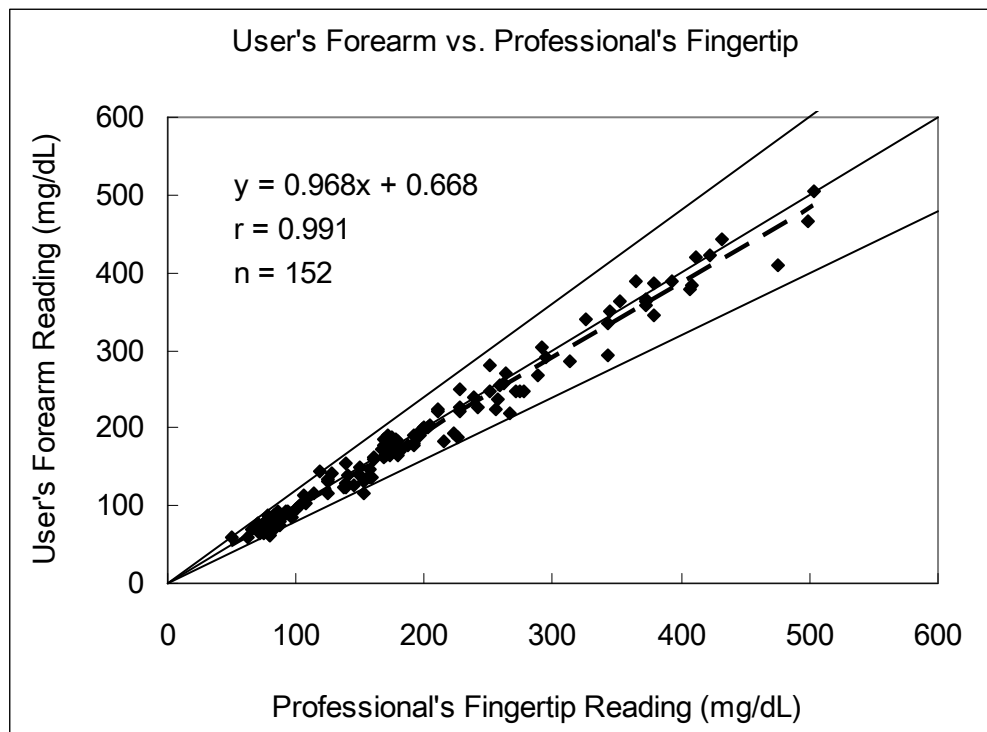
**Exhibit 4 of Appendix 5**


Comparison of Professional's

Fingerstick vs. Professional's Forearm

# Comparison of Palm Test vs. Fingertip Test of Professional

## Linear Regression Data:

| Forearm vs. Fingertip of Professional | | | |
|---|---|---|---|
| n | Slope | Intercept | r value |
| 152 | 1.002 | -0.334 mg/dL | 0.992 |

## Scatter Plot:



Professional - Forearm vs. Fingertip

y = 1.0018x - 0.3336
r = 0.992
n = 152

Professional's Forearm (mg/dL) vs. Professional's Fingertip (mg/dL)
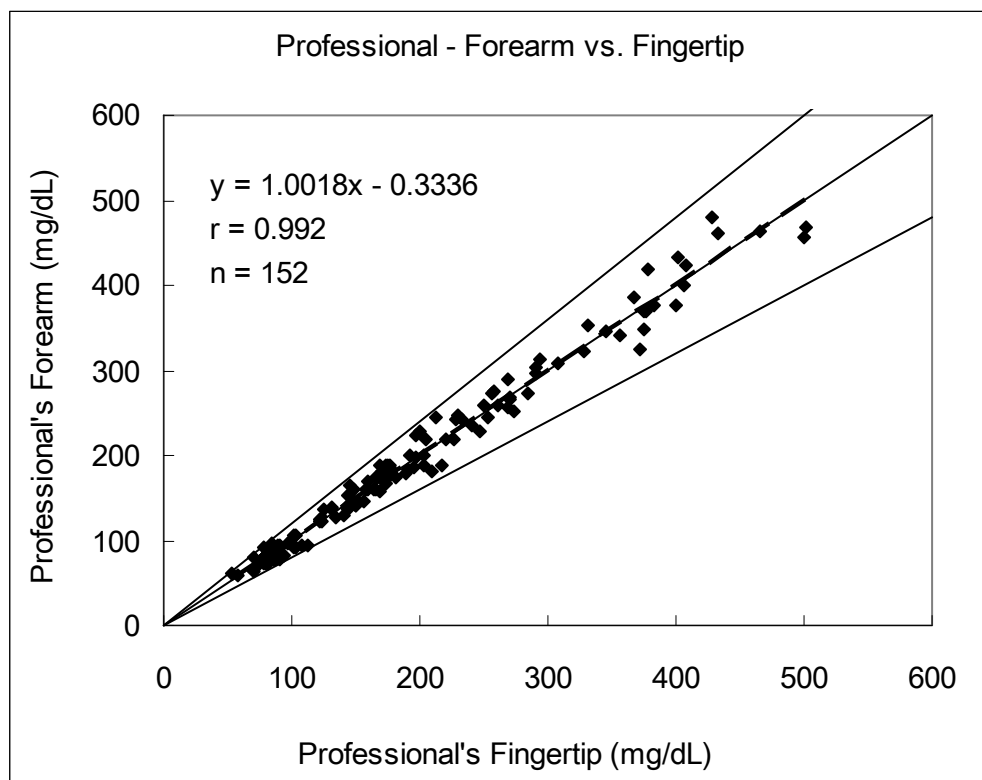
# Exhibit 1 of Appendix 6

Utility and Clarity of User's Manual

# Questionnaire for Utility and Clarity of User's Guide

## Utility and Clarity of the Embrace No Code User's Guide

| Question No. | | Rating Score |
|---|---|---|
| Q1 | Reading "Understanding your new blood glucose kit" (4.5) | |
| Q2 | Reading "Coding the Meter" (4.4) | |
| Q3 | Reading "Setting up your new system" (4.3) | |
| Q4 | Reading "Voice function table" (4.4) | |
| Q5 | Reading "Control solution testing" (4.3) | |
| Q6 | Studing and performing "Testing your blood glucose" (4.3) | |
| Q7 | Reading "Important information on Alternate Site Testing" (4.3) | |
| Q8 | Study "Understanding your blood glucose test results" (4.4) | |
| Q9 | Reading "Viewing your meter's memory" (4.3) | |
| Q10 | Reading "Caring for the meter" (4.5) | |
| Q11 | Reading "Solving problems" (4.4) | |
| Q12 | The illustration of diagrams allows the meter operated easily and quickly (4.4) | |

Rating Score: 0.0 0.5 1.0 1.5 2.0 2.5 3.0 3.5 4.0 4.5 5.0

# Exhibit 2 of Appendix 6

Ease of Use of Embrace No Code

# Questionnaire for Ease of Use of Embrace No Code

**Ease of Use of the Embrace No Code**

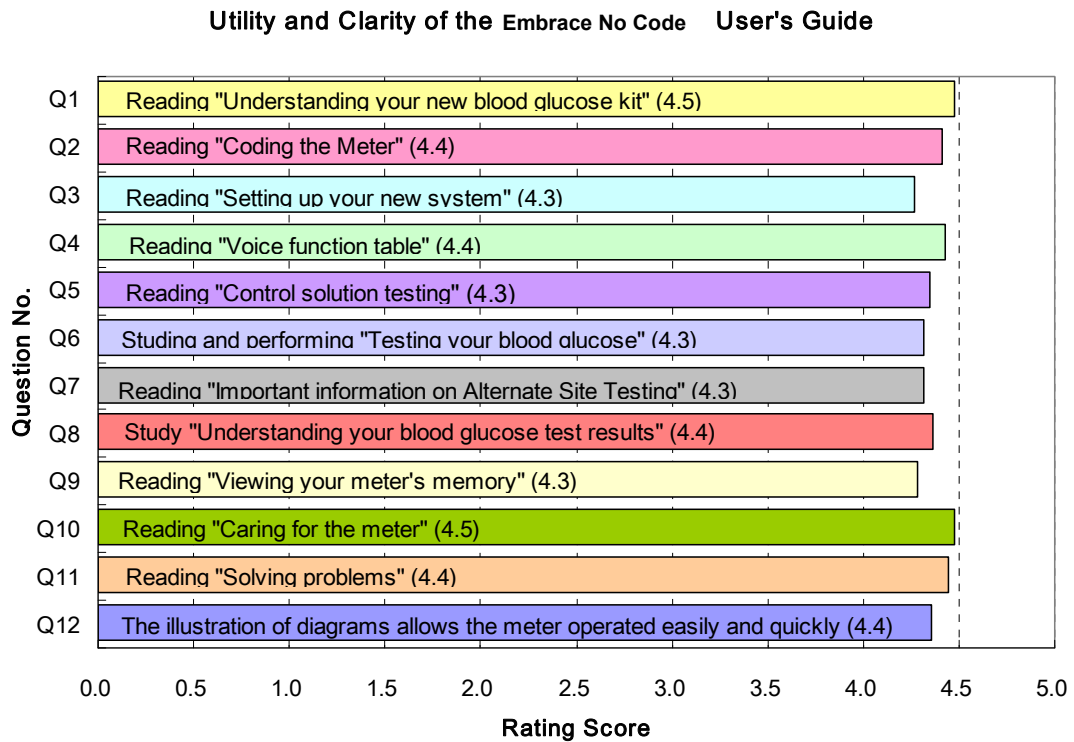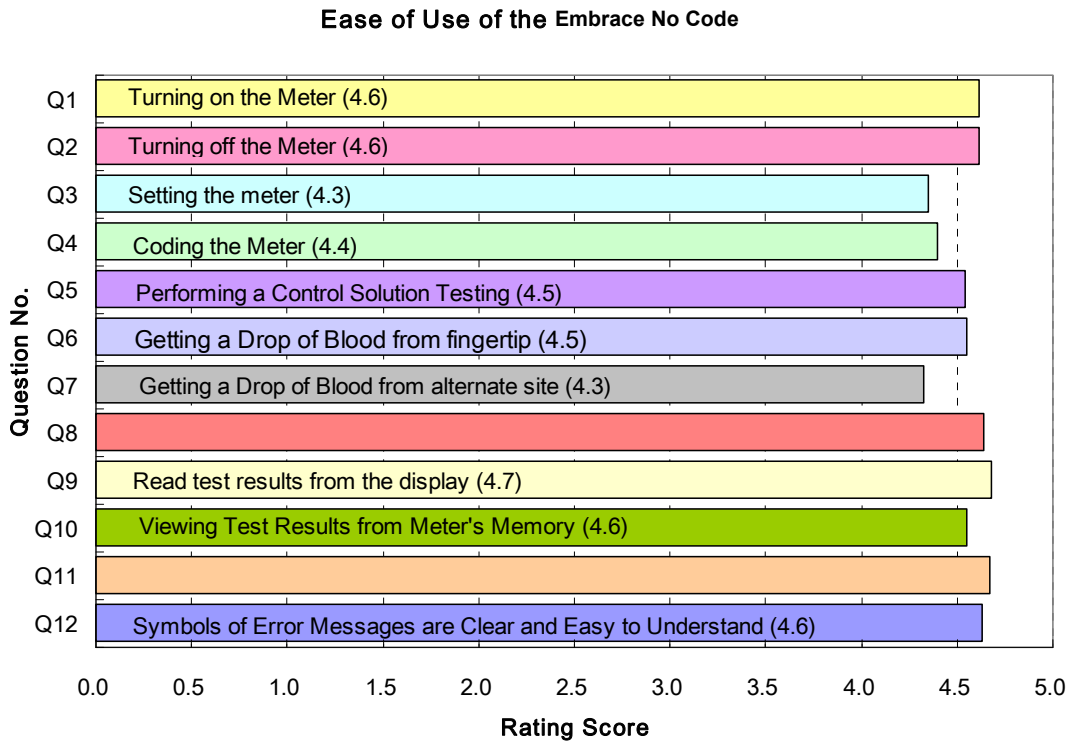| Question No. | Description | Rating Score |
|---|---|---|
| Q1 | Turning on the Meter (4.6) | 4.6 |
| Q2 | Turning off the Meter (4.6) | 4.6 |
| Q3 | Setting the meter (4.3) | 4.3 |
| Q4 | Coding the Meter (4.4) | 4.4 |
| Q5 | Performing a Control Solution Testing (4.5) | 4.5 |
| Q6 | Getting a Drop of Blood from fingertip (4.5) | 4.5 |
| Q7 | Getting a Drop of Blood from alternate site (4.3) | 4.3 |
| Q8 | | |
| Q9 | Read test results from the display (4.7) | 4.7 |
| Q10 | Viewing Test Results from Meter's Memory (4.6) | 4.6 |
| Q11 | | |
| Q12 | Symbols of Error Messages are Clear and Easy to Understand (4.6) | 4.6 |

*Rating Score axis: 0.0 to 5.0*

**Exhibit 3 of Appendix 6**

Voice Feature of Embrace No Code

# Questionnaire for Acceptance Degree of Voice Feature

**Voice Feature of the Embrace No Code**



| Question No. | |
|---|---|
| Q1 | The sound is loud enough (4.7) |
| Q2 | The sound is clear enough to understand (4.7) |
| Q3 | The voice information is easy to understand (4.6) |
| Q4 | Speech speed and tone is satisfied (4.6) |
| Q5 | The speech is helpful for testing (4.7) |

Rating Score: 0.0  0.5  1.0  1.5  2.0  2.5  3.0  3.5  4.0  4.5  5.0