

 http://www.allmedicus.com	Performance Evaluation	Ref. No.	AM-TF-G8-06
		Rev. No.	02
	Blood Glucose Monitoring System	Issue Date	2014.02.26

System accuracy evaluation

Evaluation of the system accuracy of the Embrace PRO, AGM-4000

2014. 02. 26

Prepared by Kim, Young-Tae Researcher

Reviewed by Jung, Hye Sook Manager

Approved by Oh, Byung Do Director



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System accuracy evaluation

Test Period	2014.02.17 ~ 21	Investigator	Kim, Young-Tae
Measurement Condition	20.1~25.9℃, 31.3~43.7%(RH)	Coordinator	Jung, Hye Sook
No.	Step	Description	
1	General	<p>The International Standard ISO 15197:2013 was a revision of EN ISO 15197:2003. According to the standard, to determine the system accuracy of the Embrace PRO system in capillary blood, a system accuracy evaluation is performed. This performance is to evaluate Embrace PRO system in actual condition of use; the evaluation protocol complies with ISO 15197:2013. Through the evaluation, a routine glucose measurement procedure could be validated for precision and trueness by comparison to reference measurement (YSI 2300 STAT Plus).</p>	
2	Samples	<p>The system accuracy evaluation is performed with 600 fresh capillary blood samples (200 patients, 3Lots), each with sufficient volume to be measured by two different meters and reference measurement.</p> <p>Capillary blood samples are collected by finger-prick using sterilized lancet. It is necessary, in some cases, to prick finger twice in order to obtain sufficient sample volume. It is normally difficult to obtain extremely high and low glucose concentration blood samples.</p> <p>For extreme-high glucose concentration blood samples (>400 mg/dL), the glucose concentration of blood samples are adjusted by supplementing an aqueous glucose solution in the sample. These spiked samples are allowed to stand for 15 minutes before use. Otherwise, to achieve lower glucose concentration (<50 mg/dL), anti-coagulated(EDTA-anticoagulant capillary tube) blood samples are allowed to age until the glucose is depleted to the desired level. The glucose concentration for the evaluation is specified in Table 1.</p>	

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Table 1. Glucose concentrations of samples for system accuracy evaluation

Bin #	Glucose concentration (mg/dL)	Evaluation samples		ISO15197:2013
		No. of Samples	Percentage of samples (%)	Percentage of samples (%)
1	≤ 50	*10	5	5
2	> 50 - 80	30	15	15
3	> 80 - 120	40	20	20
4	> 120 - 200	60	30	30
5	> 200 - 300	30	15	15
6	> 300 - 400	20	10	10
7	> 400	10	5	5
Total		200	100	100

*: It is the interval in which the concentration was adjusted.

3	Reagent system	600 reagent system units (Embrace PRO Test strips) are prepared from 24 vials (containing 25 strips in each vial) from 3 Lots (A14A02271, A14A13271, A14B03271).
4	Meters	3 meters (Embrace PRO meter) are prepared. (2013.07.04, EG13F01571~ EG13F01573)
5	Environment	The measurement of blood samples are performed at 20.1~25.9℃, 31.3~43.7%(RH). The collection and measurement of capillary blood samples are performed at Ahn's hospital, Seoul, South Korea.
6	Evaluation procedure	<p>The following procedure is the experimental design for evaluating system accuracy. (Please refer to Traceability Chain (AM-TF-G00-00))</p> <ol style="list-style-type: none"> a) Assign numbers to the vials b) Confirm the code of Embrace PRO meters with the code of test strips. c) Obtain a sample of fresh capillary blood by fingerstick skin puncture. d) Remove an aliquot of the sample (more than 140ul) for at least duplicate glucose measurements by reference chemical analyzer (YSI 2300 STAT Plus). The reference chemical analyzer is designed for plasma samples, the plasma preparation

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		<p>procedure(e.g. centrifugation at 1 000 g for 10 min to remove cells) be performed for each sample.</p> <p>e) Measure each sample using YSI 2300 STAT Plus, Record the result.</p> <p>f) Take one reagent system units out of each vial and measure the glucose concentration of the sample using three different meters. and record the result. Change vials every ten subjects and ensure that test strips from all vials are used in the evaluation.</p> <p>g) Repeat e) step.</p> <p>h) Cleaning and disinfection the test meter/lancing device, using a moist (not wet) cloth or tissue with isopropyl alcohol or mild detergent with water.</p> <p>i) Evaluate the results from YSI2300 STAT Plus to verify sample stability. If the change between the first and last results > 4 % at glucose > 100 mg/dL or > 4 mg/dL at glucose ≤ 100 mg/dL, the results under such condition are not included.</p> <p>j) Repeat steps c) to i) for all samples in the study.</p>
7	Acceptance criteria	<p>The minimum acceptable accuracy for results produced by a glucose monitoring system shall be as follows: 95 % of the measured glucose values shall fall within either ± 15 mg/dL of the average measured values of the reference measurement procedure at glucose concentrations < 100 mg/dL and within ± 15 % at glucose concentrations ≥ 100 mg/dL. Moreover at least 99 % of individual glucose measured values shall fall within zones A and B of the Consensus Error Grid for type 1 diabetes.</p> <p>Bias Analysis:</p> <ol style="list-style-type: none"> 1. For reference analyzer glucose values less than 100 mg/dL, subtract the reference value from the monitor value. <i>Meter Value (mg/dL) – Reference Value (mg/dL) = Difference (mg/dL)</i> 2. For reference analyzer glucose values greater than or equal to 100 mg/dL, subtract the reference value from the monitor value. Divide the difference by the reference value. Multiply the result by 100 to obtain the % difference. <i>[Meter Value (mg/dL) - Reference Value (mg/dL)] / Reference Value (mg/dL) X 100 = Difference (%)</i>

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Data analysis and
Presentation

The system accuracy for the Embrace PRO system is evaluated by using capillary blood samples from 200 patients.

Table 2. System accuracy results for glucose concentration < 100mg/dL

	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
A14A02271	33 / 51 (64.7%)	48 / 51 (94.1%)	51 / 51 (100.0%)
A14A13271	34 / 51 (66.7%)	48 / 51 (94.1%)	51 / 51 (100.0%)
A14B03271	36 / 51 (70.6%)	48 / 51 (94.1%)	50 / 51 (98.0%)
Total	103 / 153 (67.3%)	144 / 153 (94.1%)	152 / 153 (99.3%)

Table 3. System accuracy results for glucose concentration ≥ 100mg/dL

	Within ± 5 %	Within ± 10 %	Within ± 15 %
A14A02271	93 / 149 (62.4%)	139 / 149 (93.3%)	149 / 149 (100.0%)
A14A13271	90 / 149 (60.4%)	134 / 149 (89.9%)	148 / 149 (99.3%)
A14B03271	97 / 149 (65.1%)	139 / 149 (93.3%)	149 / 149 (100.0%)
Total	280 / 447 (62.6%)	412 / 447 (92.2%)	446 / 447 (99.8%)

Table 4. Overall result within accuracy limits

	Within ± 5 mg/dL and %	Within ± 10 mg/dL and %	Within ± 15 mg/dL and %
A14A02271	126 / 200 (63.0%)	187 / 200 (93.5%)	200 / 200 (100.0%)
A14A13271	124 / 200 (62.0%)	182 / 200 (91.0%)	199 / 200 (99.5%)
A14B03271	133 / 200 (66.5%)	187 / 200 (93.5%)	199 / 200 (99.5%)
Total	383 / 600 (63.8%)	556 / 600 (92.7%)	598 / 600 (99.7%)

Figure 1. System accuracy plot

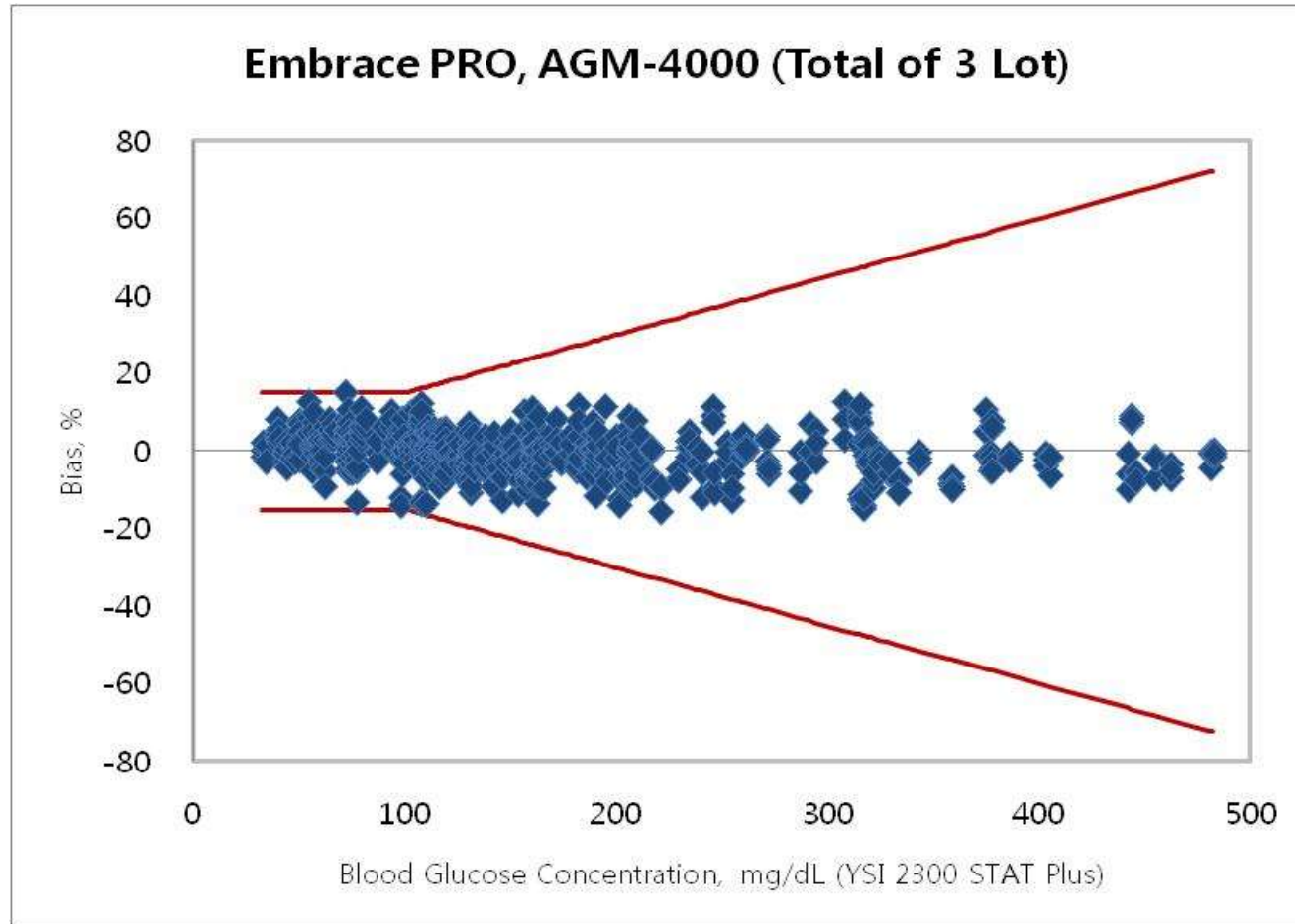
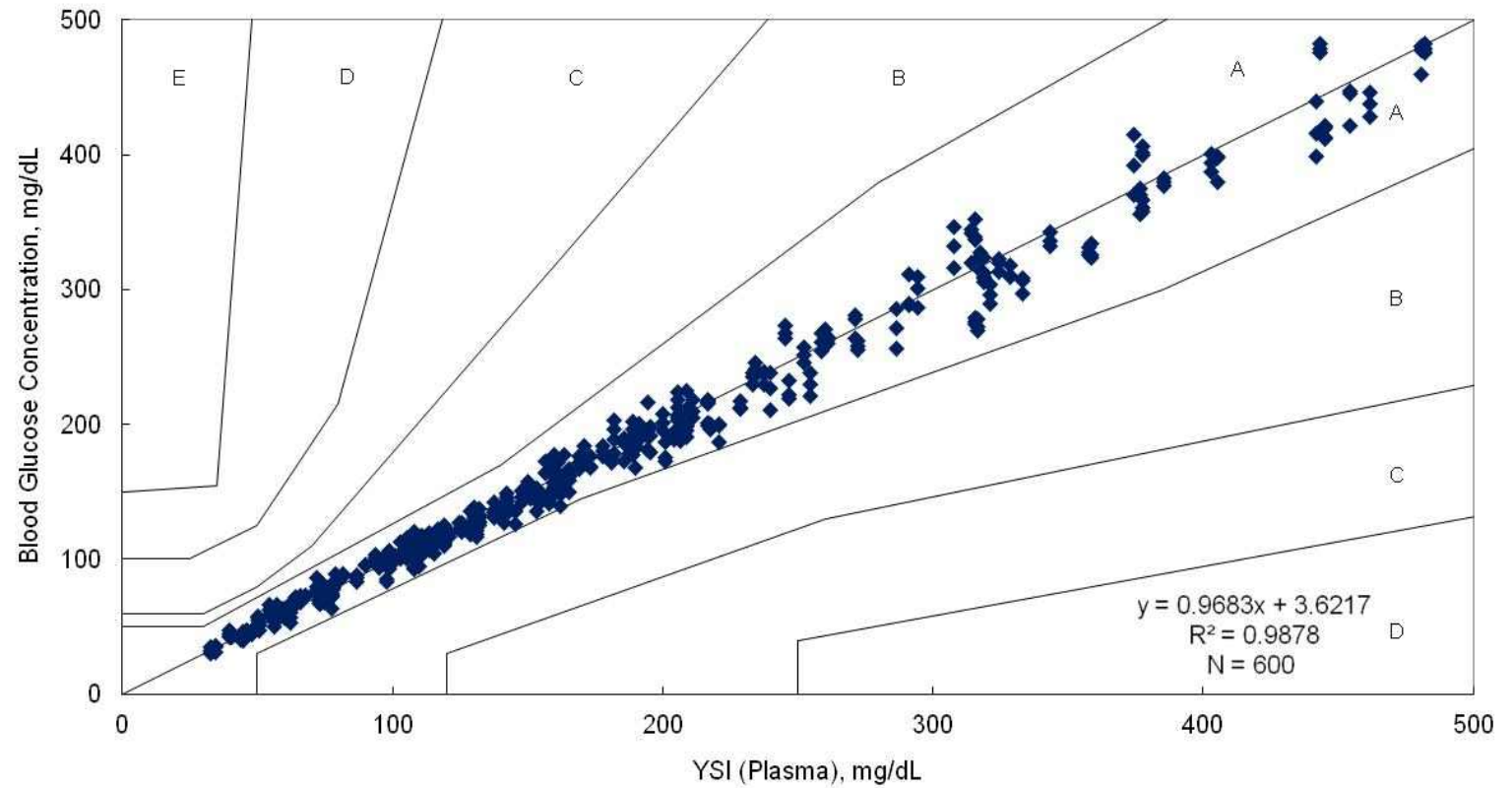


Figure 2. Regression plot

Consensus Error Grid Analysis: Embrace PRO, AGM-4000 (Total of 3 Lot)



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Table 4. Raw data of system accuracy results

	Gender	YSI Plasma				A14A02271		A14A13271		A14B03271	
		1st Results, mg/dL	2nd Results, mg/dL	Diff., mg/dL and %	Avg. , mg/dL	Results1, mg/dL	Bias	Results, mg/dL	Bias	Results, mg/dL	Bias
1	M	132	130	1.5	131	122	-6.9	132	0.8	119	-9.1
2	F	104	106	-1.9	105	103	-1.8	116	10.6	101	-3.7
3	M	215	220	-2.3	218	200	-8.1	197	-9.5	201	-7.6
4	M	127	131	-3.1	129	119	-7.6	136	5.6	120	-6.8
5	F	115	115	0.0	115	110	-4.7	119	3.1	105	-9.0
6	M	170	172	-1.2	171	176	3.0	185	8.2	171	0.0
7	M	210	212	-0.9	211	205	-2.8	210	-0.4	219	3.8
8	F	289	298	-3.0	294	287	-2.4	310	5.4	301	2.3
9	M	195	194	0.5	195	199	1.9	192	-1.7	180	-7.9
10	M	231	234	-1.3	233	239	2.5	236	1.2	230	-1.3
11	F	161	161	0.0	161	162	0.7	172	6.9	165	2.5
12	M	160	162	-1.2	161	162	0.7	162	0.7	152	-5.6
13	F	162	164	-1.2	163	160	-1.9	178	9.1	153	-6.2
14	F	194	193	0.5	194	193	-0.6	217	11.7	191	-1.7
15	F	102	103	-1.0	103	103	0.4	113	10.2	101	-1.5
16	M	199	203	-2.0	201	176	-12.4	187	-6.9	173	-13.9
17	F	380	374	1.6	377	400	6.0	407	7.8	402	6.5
18	M	183	186	-1.6	185	173	-6.7	190	2.5	186	0.3
19	F	322	325	-0.9	324	323	-0.3	320	-1.3	314	-3.1



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20	M	219	213	2.8	216	202	-6.7	216	-0.2	200	-7.6
21	M	160	162	-1.2	161	151	-6.2	164	1.9	153	-4.9
22	F	151	150	0.7	151	153	1.4	149	-1.3	146	-3.3
23	M	133	129	3.1	131	131	0.0	117	-10.7	126	-3.8
24	F	129	130	-0.8	130	136	4.7	129	-0.7	127	-2.2
25	F	292	289	1.0	291	312	7.3	289	-0.6	290	-0.3
26	M	242	234	3.4	238	238	0.2	230	-3.2	240	1.0
27	F	155	151	2.6	153	146	-4.7	136	-11.2	146	-4.7
28	F	145	145	0.0	145	136	-6.5	127	-12.7	136	-6.5
29	F	206	205	0.5	206	199	-3.6	189	-8.5	188	-8.9
30	M	230	228	0.9	229	213	-6.8	218	-4.7	212	-7.3
31	M	110	111	-0.9	111	113	1.8	105	-5.4	113	1.8
32	M	155	153	1.3	154	150	-2.8	142	-8.0	143	-7.3
33	F	318	309	2.9	314	320	1.9	345	9.8	342	8.9
34	F	189	187	1.1	188	189	0.8	179	-4.6	188	0.2
35	M	249	242	2.9	246	223	-9.5	220	-10.7	233	-5.4
36	M	173	172	0.6	173	177	2.2	168	-3.0	169	-2.4
37	F	315	315	0.0	315	338	7.2	339	7.5	353	12.0
38	F	65.2	66.4	-1.2	65.8	69	3.2	70	4.2	73	7.2
39	F	244	246	-0.8	245	268	9.2	274	11.7	264	7.6
40	M	264	258	2.3	261	265	1.6	261	0.1	263	0.8
41	M	124	124	0.0	124	128	3.0	123	-1.1	123	-1.1
42	M	190	189	0.5	190	185	-2.5	168	-11.5	189	-0.4
43	F	120	121	-0.8	121	120	-0.8	117	-3.3	121	0.0
44	F	192	188	2.1	190	186	-2.0	183	-3.6	186	-2.0



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45	F	120	118	1.7	119	126	6.1	113	-4.9	115	-3.2
46	F	241	239	0.8	240	227	-5.3	239	-0.3	211	-12.0
47	M	110	111	-0.9	111	116	4.7	118	6.5	116	4.7
48	M	222	220	0.9	221	200	-9.5	187	-15.3	201	-9.0
49	F	98.6	96.8	1.8	97.7	86	-11.7	84	-13.7	96	-1.7
50	F	97.5	99.5	-2.0	98.5	104	5.5	107	8.5	107	8.5
51	F	269	273	-1.5	271	281	3.8	279	3.0	264	-2.5
52	M	259	261	-0.8	260	264	1.6	260	0.1	271	4.3
53	M	441	443	-0.5	442	416	-5.8	399	-9.7	440	-0.4
54	F	156	158	-1.3	157	165	5.4	173	10.5	165	5.4
55	F	160	160	0.0	160	152	-4.9	162	1.4	157	-1.8
56	M	254	254	0.0	254	222	-12.7	239	-6.0	231	-9.3
57	F	204	203	0.5	204	189	-7.5	195	-4.5	192	-6.0
58	M	167	163	2.5	165	150	-9.3	167	1.0	159	-4.2
59	F	184	180	2.2	182	189	3.8	204	12.1	197	7.9
60	F	160	160	0.0	160	149	-6.8	167	4.5	158	-1.2
61	F	204	206	-1.0	205	204	-0.7	207	0.8	206	0.1
62	F	110	110	0.0	110	95	-13.5	109	-0.8	102	-7.2
63	F	130	129	0.8	130	133	2.4	139	7.0	136	4.7
64	F	185	179	3.4	182	179	-1.7	179	-1.7	179	-1.7
65	M	290	282	2.8	286	257	-10.3	286	-0.1	272	-5.2
66	M	211	207	1.9	209	199	-4.6	225	7.8	212	1.6
67	F	121	117	3.4	119	120	1.0	125	5.2	123	3.1
68	F	136	140	-2.9	138	131	-4.8	143	3.9	137	-0.5
69	F	209	209	0.0	209	191	-8.5	200	-4.2	196	-6.3



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70	M	141	140	0.7	141	128	-9.2	141	0.0	135	-4.6
71	M	200	199	0.5	200	196	-1.9	208	4.1	202	1.1
72	F	181	181	0.0	181	175	-3.3	172	-4.9	174	-4.1
73	M	161	163	-1.2	162	163	0.6	162	0.0	163	0.3
74	F	131	133	-1.5	132	128	-3.1	138	4.5	133	0.7
75	M	251	253	-0.8	252	258	2.4	246	-2.4	252	0.0
76	F	109	107	1.9	108	94	-12.7	93	-13.6	94	-13.2
77	F	233	235	-0.9	234	237	1.2	246	5.0	242	3.1
78	F	191	187	2.1	189	178	-5.7	190	0.7	184	-2.5
79	F	142	144	-1.4	143	136	-5.0	139	-2.9	138	-4.0
80	M	273	271	0.7	272	256	-5.9	262	-3.7	259	-4.8
81	F	118	119	-0.8	119	121	1.9	119	0.2	120	1.0
82	F	130	128	1.6	129	126	-2.1	124	-3.7	125	-2.9
83	M	193	194	-0.5	194	182	-6.3	182	-6.3	182	-6.3
84	M	217	215	0.9	216	219	1.2	217	0.3	218	0.7
85	M	108	107	0.9	108	115	6.8	118	9.6	117	8.2
86	F	259	259	0.0	259	255	-1.4	268	3.6	262	1.1
87	M	154	152	1.3	153	146	-4.7	153	-0.1	150	-2.4
88	M	442	444	-0.5	443	476	7.5	483	9.1	480	8.3
89	F	179	177	1.1	178	177	-0.3	185	4.2	181	1.9
90	M	193	188	2.7	191	189	-1.0	198	3.7	194	1.4
91	F	109	110	-0.9	110	108	-1.7	115	4.7	112	1.5
92	F	159	157	1.3	158	149	-5.5	147	-6.7	148	-6.1
93	M	161	163	-1.2	162	140	-13.6	156	-3.7	148	-8.7
94	F	102	102	0.0	102	103	0.9	104	1.8	104	1.4



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95	M	190	188	1.1	189	191	1.2	203	7.6	197	4.4
96	F	194	188	3.2	191	201	5.3	201	5.3	201	5.3
97	M	157	159	-1.3	158	147	-6.7	147	-6.7	147	-6.7
98	F	116	117	-0.9	117	118	1.2	123	5.5	121	3.4
99	F	113	113	0.0	113	117	3.3	120	6.0	119	4.7
100	M	109	107	1.9	108	121	12.4	117	8.7	119	10.5
101	F	94.7	92.6	2.1	93.7	100	6.3	104	10.3	102	8.3
102	F	89.5	89.9	-0.4	89.7	96	6.3	96	6.3	96	6.3
103	F	131	129	1.6	130	128	-1.8	131	0.9	124	-4.5
104	F	205	205	0.0	205	219	6.4	213	3.7	224	9.1
105	F	160	159	0.6	160	171	7.0	164	2.6	178	11.4
106	M	116	114	1.8	115	117	0.9	119	3.1	114	-1.2
107	F	112	112	0.0	112	114	1.7	111	-1.0	117	4.4
108	M	124	126	-1.6	125	125	-0.7	128	2.0	121	-3.5
109	M	131	133	-1.5	132	129	-2.7	126	-4.6	131	-0.8
110	M	63.1	61.3	1.8	62.2	57	-5.2	53	-9.2	61	-1.2
111	M	73.1	72.9	0.2	73.0	78	5.0	76	3.0	80	7.0
112	F	62.2	61.4	0.8	61.8	66.5	4.7	65	3.2	68	6.2
113	F	74.8	74.7	0.1	74.8	78	3.2	77	2.2	79	4.2
114	F	78.9	78.6	0.3	78.8	83.5	4.7	84	5.2	83	4.2
115	F	72.7	72.6	0.1	72.7	70	-2.7	68	-4.7	72	-0.7
116	F	57.7	56.0	1.7	56.9	64.5	7.6	62	5.1	67	10.1
117	F	169	169	0.0	169	172	1.9	167	-1.0	177	4.9
118	F	149	147	1.4	148	147	-0.4	143	-3.1	151	2.3
119	M	158	158	0.0	158	144	-8.6	142	-9.9	146	-7.4

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121	F	138	137	0.7	138	134	-3.0	132	-4.1	135	-1.9
122	F	111	113	-1.8	112	113	0.8	109	-2.8	117	4.4
123	F	150	149	0.7	150	155	3.4	158	5.4	152	1.4
124	F	97.2	97.4	-0.2	97.3	102	4.2	100	2.7	103	5.7
125	F	99.1	99.0	0.1	99.1	100	0.4	96	-3.1	103	3.9
126	F	97.8	99.5	-1.7	98.7	96	-2.7	93	-5.7	99	0.3
127	F	101	100	1.0	101	103	2.1	103	2.1	103	2.1
128	M	119	118	0.8	119	111	-6.5	110	-7.4	112	-5.7
129	F	119	121	-1.7	120	119	-0.7	119	-0.7	119	-0.7
130	F	104	106	-1.9	105	107	1.9	105	0.4	108	3.3
131	F	172	169	1.8	171	174	1.5	171	0.0	176	3.0
132	F	86.4	86.5	-0.1	86.5	87	0.0	84	-2.5	89	2.5
133	F	94.7	94.6	0.1	94.7	96	0.8	96	1.3	95	0.3
134	M	164	166	-1.2	165	163	-1.7	162	-2.0	163	-1.4
135	M	110	109	0.9	110	110	-0.5	108	-1.8	111	0.9
136	M	206	206	0.0	206	210	1.5	208	0.7	211	2.2
137	F	119	116	2.6	118	118	0.3	116	-1.4	120	2.0
138	M	389	380	2.4	385	380	-1.3	383	-0.6	377	-2.1
139	F	142	141	0.7	142	147	3.1	144	1.4	149	4.9
140	F	113	112	0.9	113	112	-1.5	108	-4.6	115	1.6
141	F	54.9	56.8	-1.9	55.9	55	-1.4	51	-4.9	58	2.1
142	M	61.0	60.2	0.8	60.6	59	-2.1	56	-4.6	61	0.4
143	F	77.2	77.0	0.2	77.1	74	-3.1	75	-2.1	73	-4.1
144	F	74.5	74.3	0.2	74.4	71	-3.4	69	-5.4	73	-1.4



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145	F	64.8	62.8	2.0	63.8	70	5.7	72	8.2	67	3.2
146	F	77.7	77.6	0.1	77.7	79	1.3	80	2.3	78	0.3
147	F	76.4	76.3	0.1	76.4	76	-0.4	80	3.6	72	-4.4
148	M	72.0	73.9	-1.9	73.0	81	8.0	84	11.0	78	5.0
149	F	76.5	74.5	2.0	75.5	78	2.0	76	0.5	79	3.5
150	F	108	106	1.9	107	112	4.8	109	2.0	115	7.6
151	M	94.5	94.8	-0.3	94.7	96	0.8	94	-0.7	97	2.3
152	F	82.5	80.4	2.1	81.5	89	7.5	88	6.5	90	8.5
153	F	61.0	58.8	2.2	59.9	58	-1.9	59	-0.9	57	-2.9
154	F	67.5	67.4	0.1	67.5	73	5.5	73	5.5	73	5.5
155	M	71.8	71.7	0.1	71.8	78	5.7	75	3.2	80	8.2
156	F	73.0	73.6	-0.6	73.3	71	-2.3	68	-5.3	74	0.7
157	F	54.3	54.1	0.2	54.3	63	8.7	59	4.7	67	12.7
158	F	375	372	0.8	374	393	5.1	371	-0.8	415	10.9
159	F	107	109	-1.8	108	110	1.5	107	-0.8	112	3.8
160	M	60.0	59.7	0.3	59.9	61	0.6	58	-1.9	63	3.1
161	F	105	108	-2.8	107	102	-4.9	102	-4.9	102	-4.9
162	M	60.4	58.3	2.1	59.4	63	3.6	62	2.6	64	4.6
163	F	70.5	73.2	-2.7	71.9	77	5.1	76	4.1	87	15.1
164	F	330	335	-1.5	333	307	-7.8	309	-7.2	298	-10.5
165	F	314	316	-0.6	315	280	-11.2	275	-12.8	277	-12.1
166	M	319	313	1.9	316	273	-13.7	270	-14.7	279	-11.8
167	F	483	481	0.4	482	483	0.3	476	-1.2	479	-0.6
168	F	481	480	0.2	481	460	-4.3	481	0.1	478	-0.5
169	F	375	377	-0.5	376	357	-5.1	376	-0.1	371	-1.4



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170	M	375	379	-1.1	377	361	-4.3	367	-2.8	358	-5.1
171	M	78.6	79.0	-0.4	78.8	90	11.2	82	3.2	85	6.2
172	F	343	343	0.0	343	333	-2.9	343	0.0	337	-1.7
173	M	322	320	0.6	321	290	-9.6	297	-7.4	304	-5.2
174	F	318	316	0.6	317	328	3.3	325	2.4	315	-0.8
175	F	309	305	1.3	307	347	12.9	333	8.3	317	3.1
176	M	321	317	1.3	319	306	-3.9	309	-3.0	313	-1.7
177	M	50.5	50.1	0.4	50.3	53	2.7	48	-2.3	52	1.7
178	M	44.5	47.0	-2.5	45.8	48	2.2	48	2.2	44	-1.8
179	F	40.5	38.4	2.1	39.5	48	8.5	45	5.5	43	3.5
180	F	51.0	48.9	2.1	50.0	58	8.1	57	7.1	55	5.1
181	F	47.9	47.5	0.4	47.7	48	0.3	47	-0.7	45	-2.7
182	M	35.4	33.3	2.1	34.4	35	0.6	36	1.6	32	-2.4
183	F	319	318	0.3	319	313	-1.7	324	1.7	310	-2.7
184	M	330	328	0.6	329	311	-5.3	310	-5.6	319	-2.9
185	F	356	358	-0.6	357	328	-8.2	332	-7.1	326	-8.8
186	F	360	358	0.6	359	335	-6.6	326	-9.1	324	-9.6
187	F	400	410	-2.4	405	398	-1.8	380	-6.2	399	-1.5
188	F	402	404	-0.5	403	401	-0.5	395	-2.0	388	-3.7
189	F	455	453	0.4	454	422	-7.0	448	-1.3	446	-1.8
190	F	460	464	-0.9	462	447	-3.2	429	-7.1	438	-5.1
191	M	445	445	0.0	445	420	-5.6	413	-7.2	421	-5.4
192	M	445	444	0.2	445	414	-7.0	422	-5.2	413	-7.2
193	F	77.1	77.0	0.1	77.1	64	-13.1	72	-5.1	73	-4.1
194	M	31.5	33.5	-2.0	32.5	31	-1.5	33	0.5	35	2.5



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195	F	44.8	43.8	1.0	44.3	45	0.7	40	-4.3	47	2.7
196	F	44.3	42.4	1.9	43.4	43	-0.4	41	-2.4	43	-0.4
197	F	40.7	40.3	0.4	40.5	46	5.5	43	2.5	44	3.5
198	M	40.7	38.6	2.1	39.7	43	3.3	44	4.3	43	3.3
199	F	56.5	58.8	-2.3	57.7	59	1.3	58	0.3	57	-0.7
200	F	55.1	57.0	-1.9	56.1	57	0.9	58	1.9	57	0.9

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Conclusion

According to the results, Embrace PRO systems fell between 100% and 99.5% of the individual glucose measurement results that is within ± 15 mg/dL of the results of the reference measurement procedure at glucose concentrations < 100 mg/dL and within $\pm 15\%$ at glucose concentration ≥ 100 mg/dL. And 100 % of results fell within zones A and B of the Consensus Error Grid. Therefore Embrace PRO system is pleased to 6.3.3 minimum criteria of the provisions of ISO15197:2013.