

Blood Glucose Systems											
Blood Glucose Systems	Precision, CV (%)		Bias (mmol/L)			Accuracy	Lots bias (mmol/L)			Hct Interference	User-friendliness
	under standardised and optimal conditions	user-evaluation among diabetes patients	<7 mmol/L	7-10 mmol/L	>10 mmol/L		Lot 1	Lot 2	Lot 3		
SKUP/2017/112	1.5-2.6	1.8-3.9	-0,1	-0,3	-0,8	The quality goal in ISO 15197:2003 was fulfilled	agreement	agreement	agreement	not affected by values from 31-50%	The user frindliness was rated as satisfactory
SKUP/2014/105	2,4-4,3	4,3-6,0	-0,2	-0,57	-0,8	The quality goal in ISO 15197:2003 and ISO 15197:2013 was fulfilled	agreement	agreement	agreement	not affected by values from 34-51%	Easy to operate. The user-friendliness was rated as "satisfactory"
SKUP/2013/100	1,9-3,2	3,5-4,5	agreement	agreement	agreement	The quality goal in ISO 15197:2003 and ISO 15197:2013 was fulfilled	agreement	agreement	agreement	slightly affected by values from 32-52%	Easy to operate. The user-friendliness was rated as "satisfactory"
SKUP/2013/99*	3,0-4,2	-	agreement	agreement	agreement	The quality goal in ISO 15197:2003 was fulfilled	-0,38	agreement	+0,25	-	-
SKUP/2013/98*	2,8-4,5	-	-0,15	-0,33	-0,68	The quality goal in ISO 15197:2003 was fulfilled	agreement	agreement	agreement	-	-
SKUP/2013/87	3,5-5,1	5,7-6,0	Lab: '-0,27 Diabetes: agreement	Lab: '-0,71 Diabetes: '-0,43	Lab: '-1,315 Diabetes: -0,74	The Hospital Laboratory fulfilled most likely the quality goal for the precision, the diabetes didn't fulfilled the quality goal for precision proposed in ISO 15197:2003. bOth Hospital Laboratory and the diabetes fullfileed the quality goal for accuracy proposed in ISO 15197:2003	agreement	agreement	agreement	slightly affected by values from 35-49%	The user-friendliness was rated as satisfactory
SKUP/2013/85	Lab: 3 Wards: 5,0-7,2	-	Lab: +0,28 Wards: 0,32	Lab: 0,14 Wards: 0,34	Lab: 0,20 Wards: 0,54	Hospital Laboratory fulfilled the quality goal proposed in ISO 15197 <sup>1</sup> . Hospital Wards didn't fulfilled the precision quality goal proposed in ISO 15197 <sup>1</sup> , and only one ward fulfilled the accuracy quality goal proposed in ISO 15197 <sup>1</sup>	agreement	agreement	agreement	not affected by values from 20-47%	Easy to operate but several operators find that the devices requires too many procedure steps
SKUP/2012/95	2,8-4,1	2,5-5,2	-0,11	-0,22	-0,37	Quality goal proposed in ISO 15197 <sup>1</sup> was obtained	agreement	agreement	agreement	slightly affected by values from 31-48%	Approximately 2/3 of the particpants did not find the meter easy to operate
SKUP/2012/94	1,8-3,3	1,5-4,2	+0,27	+0,24	agreement	Quality goal proposed in ISO 15197 <sup>1</sup> was obtained.	+0,26	+0,28	+0,19	not affected by values from 34-49%	Easy to operate but someone had problems with the meter during the evaluation period
SKUP/2011/93*	2,9-4,1	-	agreement	agreement	-0,51	Quality goal proposed in ISO 15197 <sup>1</sup> was obtained	-0,28	agreement	-0,41	-	Easy to operate

SKUP/2011/86	3	4,5	+0,27	+0,24	agreement	Quality goal proposed in ISO 15197 <sup>1</sup> , the "adjusted ISO-goal" <sup>2</sup> and quality goal suggested by NOKLUS (<10%) were obtained.	agreement	agreement	agreement	not affected by values from 30-49%	Easy to operate but several commented that the size of the booklet was too large
SKUP/2010/89*	<3	-	agreement	-0,2	-0,95	Quality goal proposed in ISO 15197 <sup>1</sup> and quality goal suggested by NOKLUS (<10%) were obtained	-0,35	agreement	-0,65	-	-
SKUP/2010/81*	2	-	-0,6	-0,9	-1,4	Quality goal proposed in ISO 15197 <sup>1</sup> was obtained. Quality goal suggested by NOKLUS (<10%) was not obtained	-1,14	-0,97	-1,16	-	-
SKUP/2009/75	4	4	agreement	agreement	-0,5	Total Error: 10%; Quality goal proposed in ISO 15197 <sup>1</sup> and quality goal suggested by NOKLUS (<10%) were obtained	agreement	-0,3	agreement	not affected by values from 27-49%	Easy to operate
SKUP/2009/74	<3	4	+0,3	+0,2	agreement	Quality goal proposed in ISO 15197 <sup>1</sup> and "adjusted ISO-goal" <sup>2</sup> were obtained	+0,4	+0,4	agreement	slightly affected by values from 27-49%	Easy to operate but someone had problems related to opening the tip cover.
SKUP/2009/71	4,5	6	+0,45	agreement	-0,4	Quality goal proposed in ISO 15197 <sup>1</sup> and "adjusted ISO-goal" <sup>2</sup> were obtained	agreement	agreement	agreement	not affected by values from 30-49%	Easy to operate
SKUP/2008/66	3	3-6	+0,1	agreement	-0,6	Quality goal proposed in ISO 15197 <sup>1</sup> and "adjusted ISO-goal" <sup>2</sup> were obtained	-0,4	agreement	agreement	slightly affected by values from 30-47%	Easy to operate but someone had problems related to test strips
SKUP/2007/64	2-3	4	agreement	-0,3	-0,8	Quality goal proposed in ISO 15197 <sup>1</sup> and "adjusted ISO-goal" <sup>2</sup> were obtained	-0,4	-0,35	+0,25	not affected by values from 31-48%	Easy to operate
SKUP/2007/59	3	3-5	agreement	agreement	-0,3	Quality goal proposed in ISO 15197 <sup>1</sup> and "adjusted ISO-goal" <sup>2</sup> were obtained	agreement	agreement	agreement	seem to be affected by values from 33-50%	Easy to operate
SKUP/2005/51*	2,7-5	2,7-5	-	-	-	Quality goal proposed in ISO 15197 <sup>1</sup> and "adjusted ISO-goal" <sup>2</sup> were obtained	-	-	-	-	-
SKUP/2006/50	5	6	agreement	agreement	-0,6	Quality goal proposed in ISO 15197 <sup>1</sup> and "adjusted ISO-goal" <sup>2</sup> were obtained	agreement	-0,6	-0,4	seem to be affected by values from 32-51%	Easy to operate
SKUP/2006/49*	6	5	+0,2	+0,4	+0,3	Quality goal proposed in ISO 15197 <sup>1</sup> and "adjusted ISO-goal" <sup>2</sup> were obtained	+0,5	agreement	+0,3	not affected by values from 35-49%	Easy to operate
SKUP/2006/48	3	2-6	+0,1	+0,2	+0,3	Quality goal proposed in ISO 15197 <sup>1</sup> and "adjusted ISO-goal" <sup>2</sup> were obtained	+0,3	agreement	+0,2	not affected by values from 35-50%	Easy to operate
<b>goal: &lt;5%</b>											

<sup>1</sup> ISO 15197, minimum acceptable accuracy: 95% of the individual glucose results shall fall within  $\pm 0,83$  mmol/L of the results of the comparison method at glucose concentrations  $< 4,2$  mmol/L and within  $\pm 20\%$  at glucose concentrations  $\geq 4,2$  mmol/L.

<sup>2</sup> "Adjusted ISO-goal", quality demands adjusted to the diabetes patients self-measurements: 95% of the individual glucose results shall fall within  $\pm 1,0$  mmol/L of the results of the comparison method at glucose concentrations  $< 4,2$  mmol/L and within  $\pm 25\%$  at glucose concentrations  $\geq 4,2$  mmol/L.

\* Supplementary Evaluation