

Appendix 5

PRECISE II Study accuracy results using the new glucose determination algorithm (“SW-602” algorithm) with SMBG comparator method

CGM System agreement to SMBG comparator, organized by SMBG ranges

These tables show the rate at which the Eversense CGM System agreed with SMBG measurements obtained by PRECISE II study subjects during the at-home portions of the study, when using the new “SW-602” glucose determination algorithm. The tables are organized by SMBG glucose ranges, and they tabulate the percent of CGM system measurements that were within a given range of paired SMBG measurements. The ranges included below are 15, 20, 30, 40, and greater than 40. For CGM values below 80 mg/dL, the units of the range value are mg/dL. For CGM values above 80 mg/dL, the units of the range value are percent. The data which are tabulated in these tables was collected by study subjects. SMBG measurements are less accurate than the laboratory comparator method used during the in-clinic accuracy assessments. This SMBG accuracy data is therefore more useful for observing general trends in accuracy over the lifetime of the Eversense sensor, rather than assessing point accuracy.

Table 1 - CGM System agreement (15/15%) to SMBG organized by SMBG glucose ranges

		Percent of CGM System Readings within 15/15% of SMBG						
		Day Ranges						
SMBG Range	N	1-7	8-14	15-29	30-44	45-59	60-74	75-90
<40	73	50.0%	75.0%	69.2%	50.0%	78.6%	38.5%	63.6%
40-60	1224	74.7%	82.5%	89.4%	87.4%	82.7%	80.5%	82.8%
61-80	2275	72.8%	71.3%	81.0%	83.4%	79.8%	74.8%	75.9%
81-180	18879	66.9%	71.1%	76.1%	79.5%	79.4%	79.0%	78.8%
181-300	10504	75.6%	78.1%	82.5%	85.2%	86.7%	88.5%	83.8%
301-350	1105	82.3%	83.9%	78.3%	84.1%	81.7%	89.7%	83.4%
351-400	432	75.8%	73.2%	71.4%	72.1%	73.8%	79.8%	73.7%
>400	168	53.3%	44.4%	43.8%	46.2%	46.7%	33.3%	67.7%

Table 2 - CGM System agreement (20/20%) to SMBG organized by SMBG glucose ranges

		Percent of CGM System Readings within 20/20% of SMBG						
		Day Ranges						
SMBG Range	N	1-7	8-14	15-29	30-44	45-59	60-74	75-90
<40	73	57.1%	75.0%	69.2%	50.0%	92.9%	53.8%	63.6%
40-60	1224	85.3%	90.3%	92.5%	90.4%	89.9%	86.2%	89.2%
61-80	2275	85.6%	81.3%	91.4%	91.9%	90.5%	85.0%	88.3%
81-180	18879	79.8%	82.0%	87.4%	89.4%	88.9%	88.2%	88.4%
181-300	10504	84.3%	88.5%	91.8%	93.2%	94.2%	95.2%	92.3%
301-350	1105	94.7%	92.5%	86.9%	93.8%	90.9%	95.9%	92.8%
351-400	432	90.9%	80.5%	80.0%	83.8%	91.8%	93.3%	87.7%
>400	168	60.0%	66.7%	53.1%	73.1%	63.3%	60.0%	71.0%

Table 3 - CGM System agreement (30/30%) to SMBG organized by SMBG glucose ranges

		Percent of CGM System Readings within 30/30% of SMBG Day Ranges						
SMBG Range	N	1-7	8-14	15-29	30-44	45-59	60-74	75-90
<40	73	78.6%	75.0%	92.3%	75.0%	92.9%	76.9%	63.6%
40-60	1224	92.6%	96.1%	95.6%	95.5%	93.3%	90.8%	97.8%
61-80	2275	94.6%	94.3%	96.5%	98.4%	97.3%	97.0%	94.3%
81-180	18879	91.8%	93.1%	95.6%	96.8%	96.7%	96.5%	96.5%
181-300	10504	94.6%	96.7%	97.9%	98.5%	99.0%	99.0%	98.1%
301-350	1105	99.1%	97.8%	97.1%	98.3%	99.5%	97.2%	97.8%
351-400	432	97.0%	95.1%	95.7%	95.6%	98.4%	97.8%	94.7%
>400	168	80.0%	100.0%	81.3%	88.5%	96.7%	80.0%	90.3%

Table 4 - CGM System agreement (40/40%) to SMBG organized by SMBG glucose ranges

		Percent of CGM System Readings within 40/40% of SMBG Day Ranges						
SMBG Range	N	1-7	8-14	15-29	30-44	45-59	60-74	75-90
<40	73	92.9%	75.0%	100.0%	75.0%	92.9%	84.6%	63.6%
40-60	1224	95.8%	96.1%	97.3%	98.0%	94.7%	94.4%	99.5%
61-80	2275	97.0%	98.1%	98.0%	99.0%	99.5%	98.1%	97.5%
81-180	18879	96.8%	97.3%	98.7%	98.9%	98.8%	98.7%	98.9%
181-300	10504	97.9%	99.4%	99.4%	99.7%	99.7%	99.6%	99.5%
301-350	1105	100.0%	100.0%	99.4%	100.0%	100.0%	97.9%	99.4%
351-400	432	97.0%	97.6%	95.7%	98.5%	100.0%	97.8%	98.2%
>400	168	80.0%	100.0%	93.8%	96.2%	100.0%	93.3%	96.8%

Table 5 – CGM System agreement (>40/40%) to SMBG organized by SMBG glucose ranges

		Percent of CGM System Readings beyond 40/40% of SMBG Day Ranges						
SMBG Range	N	1-7	8-14	15-29	30-44	45-59	60-74	75-90
<40	73	7.1%	25.0%	0.0%	25.0%	7.1%	15.4%	36.4%
40-60	1224	4.2%	3.9%	2.7%	2.0%	5.3%	5.6%	0.5%
61-80	2275	3.0%	1.9%	2.0%	1.0%	0.5%	1.9%	2.5%
81-180	18879	3.2%	2.7%	1.3%	1.1%	1.2%	1.3%	1.1%
181-300	10504	2.1%	0.6%	0.6%	0.3%	0.3%	0.4%	0.5%
301-350	1105	0.0%	0.0%	0.6%	0.0%	0.0%	2.1%	0.6%
351-400	432	3.0%	2.4%	4.3%	1.5%	0.0%	2.2%	1.8%
>400	168	20.0%	0.0%	6.3%	3.8%	0.0%	6.7%	3.2%