Appendix 4

PRECISION Study accuracy results using the new glucose determination algorithm ("SW-602" algorithm) with laboratory comparator method

Contents

CGM System agreement to YSI comparator, organized by CGM ranges

These tables show the rate at which the Eversense CGM System agreed with a laboratory comparator method when using the new "SW-602" glucose determination algorithm. The comparator method used during this study was the Yellow Springs Instruments 2300 glucose analyzer, abbreviated "YSI" in the tables below. The tables are organized by CGM system glucose ranges, and they tabulate the percent of CGM system measurements that were within a given range of paired YSI 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 on six different days of the PRECISION study: days 1, 7, 14, 30, 60, and 90 of sensor wear. The first table in this series includes data from all days pooled together. Each successive table has data from an individual day.

Table 1 - CGM System agreement to YSI organized by CGM glucose ranges; PRECISION study, **all days**, analyzed using SW-602 algorithm

CGM Glucose Range (mg/dL)	Number of Paired CGM and YSI Reference	Percent of CGM System Readings Within				
		Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference	Percent Greater than 40/40% of Reference
Overall	15170	85.4%	92.8%	98.1%	99.3%	0.7%
40 - 60	1236	91.9%	96.0%	98.4%	99.3%	0.7%
61 - 80	2003	87.3%	94.1%	99.1%	99.6%	0.4%
81 - 180	5786	80.5%	89.9%	97.2%	99.0%	1.0%
181 - 300	3566	84.8%	92.8%	98.1%	99.2%	0.8%
301 - 350	1628	92.8%	97.5%	99.1%	99.9%	0.1%
351 - 400	951	91.5%	95.8%	98.6%	99.8%	0.2%

Table 2 - CGM System agreement to YSI organized by CGM glucose ranges; PRECISION study, **day 1**, analyzed using SW-602 algorithm

CGM Glucose Range (mg/dL)	Number of Paired CGM and YSI Reference	Percent of CGM System Readings Within				
		Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference	Percent Greater than 40/40% of Reference
Overall	2665	79.1%	88.9%	95.8%	98.5%	1.5%
40 - 60	274	86.5%	91.2%	96.4%	97.8%	2.2%
61 - 80	378	81.7%	87.8%	97.1%	98.7%	1.3%
81 - 180	962	76.7%	87.8%	95.6%	98.9%	1.1%
181 - 300	585	80.3%	91.1%	96.1%	97.8%	2.2%
301 - 350	250	77.6%	90.4%	95.2%	99.2%	0.8%
351 - 400	216	74.5%	85.2%	94.0%	99.1%	0.9%

Table 3 - CGM System agreement to YSI organized by CGM glucose ranges; PRECISION study, **day 7**, analyzed using SW-602 algorithm

CGM Glucose Range (mg/dL)	Number of Paired CGM and YSI Reference	Percent of CGM System Readings Within				
		Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference	Percent Greater than 40/40% of Reference
Overall	2926	86.1%	93.3%	98.1%	99.0%	1.0%
40 - 60	214	93.0%	98.1%	99.5%	100.0%	0.0%
61 - 80	404	87.6%	94.3%	99.3%	99.8%	0.2%
81 - 180	1053	80.0%	89.3%	96.7%	97.9%	2.1%
181 - 300	630	84.6%	93.5%	97.5%	99.2%	0.8%
301 - 350	385	94.3%	97.4%	99.7%	100.0%	0.0%
351 - 400	240	95.0%	97.5%	100.0%	100.0%	0.0%

Table 4 - CGM System agreement to YSI organized by CGM glucose ranges; PRECISION study, **day 14**, analyzed using SW-602 algorithm

CGM Glucose Range (mg/dL)	Number of Paired CGM and YSI Reference	Percent of CGM System Readings Within				
		Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference	Percent Greater than 40/40% of Reference
Overall	2997	88.1%	94.6%	98.8%	99.6%	0.4%
40 - 60	269	87.0%	92.6%	96.7%	98.9%	1.1%
61 - 80	407	84.0%	93.4%	99.5%	100.0%	0.0%
81 - 180	999	82.0%	91.7%	98.0%	99.1%	0.9%
181 - 300	663	91.3%	95.9%	99.4%	99.8%	0.2%
301 - 350	383	97.1%	99.0%	99.5%	100.0%	0.0%
351 - 400	276	96.7%	99.6%	100.0%	100.0%	0.0%

Table 5 - CGM System agreement to YSI organized by CGM glucose ranges; PRECISION study, **day 30**, analyzed using SW-602 algorithm

CGM Glucose Range (mg/dL)	Number of Paired CGM and YSI Reference	Percent of CGM System Readings Within				
		Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference	Percent Greater than 40/40% of Reference
Overall	2284	88.0%	94.3%	98.9%	100.0%	0.0%
40 - 60	209	98.6%	99.5%	100.0%	100.0%	0.0%
61 - 80	416	92.8%	97.6%	100.0%	100.0%	0.0%
81 - 180	936	81.1%	90.0%	97.4%	100.0%	0.0%
181 - 300	492	87.4%	94.7%	99.8%	100.0%	0.0%
301 - 350	183	99.5%	100.0%	100.0%	100.0%	0.0%
351 - 400	48	100.0%	100.0%	100.0%	100.0%	0.0%

Table 6 - CGM System agreement to YSI organized by CGM glucose ranges; PRECISION study, **day 60**, analyzed using SW-602 algorithm

CGM Glucose Range (mg/dL)	Number of Paired CGM and YSI Reference	Percent of CGM System Readings Within				
		Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference	Percent Greater than 40/40% of Reference
Overall	2133	86.9%	93.7%	98.5%	99.6%	0.4%
40 - 60	165	98.2%	100.0%	100.0%	100.0%	0.0%
61 - 80	176	89.2%	96.6%	100.0%	100.0%	0.0%
81 - 180	880	85.9%	94.2%	98.3%	99.4%	0.6%
181 - 300	592	79.1%	86.8%	97.1%	99.5%	0.5%
301 - 350	239	96.7%	100.0%	100.0%	100.0%	0.0%
351 - 400	81	98.8%	100.0%	100.0%	100.0%	0.0%

Table 7 - CGM System agreement to YSI organized by CGM glucose ranges; PRECISION study, **day 90**, analyzed using SW-602 algorithm

CGM Glucose Range (mg/dL)	Number of Paired CGM and YSI Reference	Percent of CGM System Readings Within				
		Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference	Percent Greater than 40/40% of Reference
Overall	2165	83.9%	92.2%	98.5%	99.3%	0.7%
40 - 60	105	93.3%	100.0%	100.0%	100.0%	0.0%
61 - 80	222	90.5%	96.8%	99.1%	99.1%	0.9%
81 - 180	956	77.7%	86.7%	97.5%	99.2%	0.8%
181 - 300	604	85.9%	94.9%	98.8%	99.2%	0.8%
301 - 350	188	89.9%	98.9%	100.0%	100.0%	0.0%
351 - 400	90	95.6%	98.9%	100.0%	100.0%	0.0%

CGM System agreement to YSI comparator, organized by YSI ranges

These tables show the rate at which the Eversense CGM System agreed with a laboratory comparator method when using the new "SW-602" glucose determination algorithm. The comparator method used during this study was the Yellow Springs Instruments 2300 glucose analyzer, abbreviated "YSI" in the tables below. The tables are organized by YSI system glucose ranges, and they tabulate the percent of CGM system measurements that were within a given range of paired YSI measurements. The ranges included below are 15, 20, 30, 40, and greater than 40. For YSI 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 on six different days of the PRECISION study: days 1, 7, 14, 30, 60, and 90 of sensor wear. The first table in this series includes data from all days pooled together. Each successive table has data from an individual day.

Table 8 - CGM System agreement to YSI, organized by YSI glucose ranges; PRECISION study, **all days**, analyzed using SW-602 algorithm

YSI Glucose Range (mg/dL)	Number of Paired CGM and YSI Reference	Percent of CGM System Readings Within				
		Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference	Percent Greater than 40/40% of Reference
Overall	15170	85.4%	92.8%	98.1%	99.3%	0.7%
< 40	15	60.0%	73.3%	86.7%	100.0%	0.0%
40 - 60	1267	86.8%	92.6%	98.1%	99.1%	0.9%
61 - 80	2212	85.8%	93.0%	98.5%	99.3%	0.7%
81 - 180	5685	80.6%	89.4%	96.7%	98.8%	1.2%
181 - 300	3210	87.4%	94.9%	98.6%	99.8%	0.2%
301 - 350	1527	91.4%	97.8%	100.0%	100.0%	0.0%
351 - 400	1174	93.4%	97.5%	99.7%	100.0%	0.0%
> 400	80	81.3%	93.8%	97.5%	100.0%	0.0%

Table 9 - CGM System agreement to YSI, organized by YSI glucose ranges; PRECISION study, **day 1**, analyzed using SW-602 algorithm

YSI Glucose Range (mg/dL)	Number of Paired CGM and YSI Reference	Percent of CGM System Readings Within				
		Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference	Percent Greater than 40/40% of Reference
Overall	2665	79.1%	88.9%	95.8%	98.5%	1.5%
< 40	4	50.0%	75.0%	75.0%	100.0%	0.0%
40 - 60	222	86.5%	92.8%	96.8%	100.0%	0.0%
61 - 80	469	81.9%	90.0%	97.4%	98.9%	1.1%
81 - 180	974	74.3%	84.6%	93.4%	96.9%	3.1%
181 - 300	598	77.6%	89.0%	95.5%	99.3%	0.7%
301 - 350	234	82.9%	93.6%	100.0%	100.0%	0.0%
351 - 400	154	90.3%	100.0%	100.0%	100.0%	0.0%
> 400	10	100.0%	100.0%	100.0%	100.0%	0.0%

Table 10 - CGM System agreement to YSI, organized by YSI glucose ranges; PRECISION study, **day 7**, analyzed using SW-602 algorithm

YSI Glucose Range (mg/dL)	Number of Paired CGM and YSI Reference	Percent of CGM System Readings Within				
		Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference	Percent Greater than 40/40% of Reference
Overall	2926	86.1%	93.3%	98.1%	99.0%	1.0%
< 40	7	71.4%	85.7%	100.0%	100.0%	0.0%
40 - 60	213	77.5%	85.4%	94.8%	96.2%	3.8%
61 - 80	472	87.1%	93.4%	97.5%	98.1%	1.9%
81 - 180	1011	81.7%	91.2%	97.5%	99.0%	1.0%
181 - 300	580	84.7%	92.8%	98.6%	99.8%	0.2%
301 - 350	369	94.9%	99.2%	100.0%	100.0%	0.0%
351 - 400	272	98.9%	100.0%	100.0%	100.0%	0.0%
> 400	2	100.0%	100.0%	100.0%	100.0%	0.0%

Table 11 - CGM System agreement to YSI, organized by YSI glucose ranges; PRECISION study, **day 14**, analyzed using SW-602 algorithm

YSI Glucose Range (mg/dL)	Number of Paired CGM and YSI Reference	Percent of CGM System Readings Within				
		Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference	Percent Greater than 40/40% of Reference
Overall	2997	88.1%	94.6%	98.8%	99.6%	0.4%
< 40	4	50.0%	50.0%	75.0%	100.0%	0.0%
40 - 60	273	84.2%	90.5%	98.2%	99.3%	0.7%
61 - 80	423	85.8%	92.0%	98.8%	99.8%	0.2%
81 - 180	991	81.1%	92.2%	97.7%	99.0%	1.0%
181 - 300	610	92.3%	96.6%	99.5%	100.0%	0.0%
301 - 350	371	96.2%	99.5%	100.0%	100.0%	0.0%
351 - 400	307	98.4%	100.0%	100.0%	100.0%	0.0%
> 400	18	100.0%	100.0%	100.0%	100.0%	0.0%

Table 12 - CGM System agreement to YSI, organized by YSI glucose ranges; PRECISION study, **day 30**, analyzed using SW-602 algorithm

YSI Glucose Range (mg/dL)	Number of Paired CGM and YSI Reference	Percent of CGM System Readings Within				
		Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference	Percent Greater than 40/40% of Reference
Overall	2284	88.0%	94.3%	98.9%	100.0%	0.0%
< 40	0	--	--	--	--	--
40 - 60	262	92.0%	97.3%	100.0%	100.0%	0.0%
61 - 80	405	88.4%	95.6%	100.0%	100.0%	0.0%
81 - 180	921	82.4%	89.0%	97.4%	100.0%	0.0%
181 - 300	423	91.5%	98.8%	99.8%	100.0%	0.0%
301 - 350	156	95.5%	100.0%	100.0%	100.0%	0.0%
351 - 400	113	100.0%	100.0%	100.0%	100.0%	0.0%
> 400	4	100.0%	100.0%	100.0%	100.0%	0.0%

Table 13 - CGM System agreement to YSI, organized by YSI glucose ranges; PRECISION study, **day 60**, analyzed using SW-602 algorithm

YSI Glucose Range (mg/dL)	Number of Paired CGM and YSI Reference	Percent of CGM System Readings Within				
		Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference	Percent Greater than 40/40% of Reference
Overall	2133	86.9%	93.7%	98.5%	99.6%	0.4%
< 40	0	--	--	--	--	--
40 - 60	167	93.4%	95.8%	99.4%	99.4%	0.6%
61 - 80	186	89.8%	96.8%	98.4%	99.5%	0.5%
81 - 180	887	85.5%	92.4%	97.5%	99.3%	0.7%
181 - 300	484	89.0%	97.3%	99.8%	100.0%	0.0%
301 - 350	217	87.6%	94.9%	100.0%	100.0%	0.0%
351 - 400	180	80.6%	84.4%	98.3%	100.0%	0.0%
> 400	12	58.3%	75.0%	83.3%	100.0%	0.0%

Table 14 - S CGM System agreement to YSI, organized by YSI glucose ranges; PRECISION study, **day 90**, analyzed using SW-602 algorithm

YSI Glucose Range (mg/dL)	Number of Paired CGM and YSI Reference	Percent of CGM System Readings Within				
		Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference	Percent Greater than 40/40% of Reference
Overall	2165	83.9%	92.2%	98.5%	99.3%	0.7%
< 40	0	--	--	--	--	--
40 - 60	130	89.2%	94.6%	100.0%	100.0%	0.0%
61 - 80	257	83.3%	93.0%	99.6%	100.0%	0.0%
81 - 180	901	78.7%	86.8%	97.0%	98.6%	1.4%
181 - 300	515	90.9%	96.5%	99.0%	99.6%	0.4%
301 - 350	180	86.7%	98.3%	100.0%	100.0%	0.0%
351 - 400	148	87.2%	99.3%	100.0%	100.0%	0.0%
> 400	34	70.6%	94.1%	100.0%	100.0%	0.0%

CGM System concurrence to YSI comparator, organized by CGM ranges

These tables show the rate of concurrence between the Eversense CGM System and a laboratory comparator method when using the new "SW-602" glucose determination algorithm. The comparator method used during this study was the Yellow Springs Instruments 2300 glucose analyzer, abbreviated "YSI" in the tables below. The tables are organized by CGM system glucose ranges, and they tabulate the percent of paired YSI measurements that were in the identical range (shaded diagonal), as well as those YSI measurements that were in glucose ranges above and below the paired CGM readings.

The data which are tabulated in these tables was collected on six different days of the PRECISION study: days 1, 7, 14, 30, 60, and 90 of sensor wear. The first table in this series includes data from all days pooled together. Each successive table has data from an individual day.

Table 15 - CGM System concurrence to YSI, organized by CGM glucose ranges; PRECISION study, **all days**, analyzed using SW-602 algorithm

CGM (mg/dL)	Number of Paired CGM-YSI	Percent of Matched Pairs in Each YSI Glucose Range for Each CGM Glucose Range YSI (mg/dL)										
		<40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	>400
40-60	1236	1%	63%	34%	2%	--	--	--	--	--	--	--
61-80	2003	--	22%	67%	10%	--	--	--	--	--	--	--
81-120	2524	--	2%	17%	71%	10%	--	--	--	--	--	--
121-160	2342	--	--	--	18%	71%	11%	--	--	--	--	--
161-200	1727	--	--	--	1%	24%	59%	16%	--	--	--	--
201-250	1502	--	--	--	--	1%	19%	65%	14%	1%	--	--
251-300	1257	--	--	--	--	--	1%	18%	51%	27%	3%	--
301-350	1628	--	--	--	--	--	--	1%	10%	57%	32%	1%
351-400	951	--	--	--	--	--	--	--	2%	26%	65%	7%

Table 16 - CGM System concurrence to YSI, organized by CGM glucose ranges; PRECISION study, **day 1**, analyzed using SW-602 algorithm

CGM (mg/dL)	Number of Paired CGM-YSI	Percent of Matched Pairs in Each YSI Glucose Range for Each CGM Glucose Range YSI (mg/dL)										
		<40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	>400
40-60	274	1%	59%	36%	4%	--	--	--	--	--	--	--
61-80	378	--	14%	65%	19%	1%	--	--	--	--	--	--
81-120	516	--	1%	23%	63%	12%	--	--	--	--	--	--
121-160	332	--	--	--	17%	70%	12%	1%	--	--	--	--
161-200	226	--	--	--	1%	23%	58%	17%	--	--	--	--
201-250	268	--	--	--	--	4%	25%	55%	15%	--	--	--
251-300	205	--	--	--	--	--	2%	25%	57%	14%	1%	--
301-350	250	--	--	--	--	--	--	4%	27%	42%	26%	1%
351-400	216	--	--	--	--	--	--	1%	9%	46%	40%	4%

Table 17 - CGM System concurrence to YSI, organized by CGM glucose ranges; PRECISION study, **day 7**, analyzed using SW-602 algorithm

CGM (mg/dL)	Number of Paired CGM-YSI	Percent of Matched Pairs in Each YSI Glucose Range for Each CGM Glucose Range YSI (mg/dL)										
		<40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	>400
40-60	214	3%	56%	40%	--	--	--	--	--	--	--	--
61-80	404	--	18%	72%	10%	--	--	--	--	--	--	--
81-120	534	--	4%	16%	70%	10%	--	--	--	--	--	--
121-160	361	--	--	2%	15%	73%	9%	--	--	--	--	--
161-200	293	--	--	--	1%	24%	57%	18%	--	--	--	--
201-250	236	--	--	--	--	2%	21%	67%	10%	--	--	--
251-300	259	--	--	--	--	--	1%	25%	49%	24%	--	--
301-350	385	--	--	--	--	--	--	1%	10%	64%	25%	--
351-400	240	--	--	--	--	--	--	--	1%	25%	73%	1%

Table 18 - CGM System concurrence to YSI, organized by CGM glucose ranges; PRECISION study, **day 14**, analyzed using SW-602 algorithm

CGM (mg/dL)	Number of Paired CGM-YSI	Percent of Matched Pairs in Each YSI Glucose Range for Each CGM Glucose Range YSI (mg/dL)										
		<40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	>400
40-60	269	1%	62%	34%	3%	--	--	--	--	--	--	--
61-80	407	--	24%	65%	11%	--	--	--	--	--	--	--
81-120	426	--	2%	16%	72%	10%	--	--	--	--	--	--
121-160	428	--	--	--	13%	76%	10%	--	--	--	--	--
161-200	295	--	--	--	1%	21%	61%	17%	--	--	--	--
201-250	290	--	--	--	--	--	13%	72%	14%	--	--	--
251-300	223	--	--	--	--	--	--	13%	60%	26%	--	--
301-350	383	--	--	--	--	--	--	--	6%	67%	27%	--
351-400	276	--	--	--	--	--	--	--	--	20%	73%	7%

Table 19 - CGM System concurrence to YSI, organized by CGM glucose ranges; PRECISION study, **day 30**, analyzed using SW-602 algorithm

CGM (mg/dL)	Number of Paired CGM-YSI	Percent of Matched Pairs in Each YSI Glucose Range for Each CGM Glucose Range YSI (mg/dL)										
		<40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	>400
40-60	209	--	72%	28%	--	--	--	--	--	--	--	--
61-80	416	--	27%	67%	6%	--	--	--	--	--	--	--
81-120	417	--	--	16%	77%	6%	--	--	--	--	--	--
121-160	392	--	--	--	22%	65%	13%	--	--	--	--	--
161-200	243	--	--	--	--	19%	69%	12%	--	--	--	--
201-250	214	--	--	--	--	1%	24%	64%	11%	--	--	--
251-300	162	--	--	--	--	--	1%	15%	54%	30%	--	--
301-350	183	--	--	--	--	--	--	--	3%	58%	39%	--
351-400	48	--	--	--	--	--	--	--	--	4%	88%	8%

Table 20 - CGM System concurrence to YSI, organized by CGM glucose ranges; PRECISION study, **day 60**, analyzed using SW-602 algorithm

CGM (mg/dL)	Number of Paired CGM-YSI	Percent of Matched Pairs in Each YSI Glucose Range for Each CGM Glucose Range YSI (mg/dL)										
		<40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	>400
40-60	165	--	70%	30%	--	--	--	--	--	--	--	--
61-80	176	--	27%	65%	8%	--	--	--	--	--	--	--
81-120	308	--	1%	7%	78%	13%	--	--	--	--	--	--
121-160	378	--	--	--	17%	73%	10%	--	--	--	--	--
161-200	349	--	--	--	--	26%	56%	17%	--	--	--	--
201-250	213	--	--	--	--	1%	17%	64%	15%	2%	--	--
251-300	224	--	--	--	--	--	--	10%	45%	29%	15%	1%
301-350	239	--	--	--	--	--	--	--	7%	55%	37%	1%
351-400	81	--	--	--	--	--	--	--	--	20%	72%	9%

Table 21 - CGM System concurrence to YSI, organized by CGM glucose ranges; PRECISION study, **day 90**, analyzed using SW-602 algorithm

CGM (mg/dL)	Number of Paired CGM-YSI	Percent of Matched Pairs in Each YSI Glucose Range for Each CGM Glucose Range YSI (mg/dL)										
		<40	**40-60**	**61-80**	**81-120**	**121-160**	**161-200**	**201-250**	**251-300**	**301-350**	**351-400**	**>400**
40-60	105	--	63%	37%	--	--	--	--	--	--	--	--
61-80	222	--	27%	68%	5%	--	--	--	--	--	--	--
81-120	323	--	2%	21%	68%	8%	1%	--	--	--	--	--
121-160	451	--	--	--	21%	68%	11%	--	--	--	--	--
161-200	321	--	--	--	1%	31%	55%	14%	--	--	--	--
201-250	281	--	--	--	--	--	17%	67%	15%	--	--	--
251-300	184	--	--	--	--	--	--	14%	39%	43%	4%	--
301-350	188	--	--	--	--	--	--	--	2%	47%	47%	4%
351-400	90	--	--	--	--	--	--	--	--	12%	59%	29%

CGM System concurrence to YSI comparator, organized by YSI ranges

These tables show the rate of concurrence between the Eversense CGM System and a laboratory comparator method when using the new "SW-602" glucose determination algorithm. The comparator method used during this study was the Yellow Springs Instruments 2300 glucose analyzer, abbreviated "YSI" in the tables below. The tables are organized by YSI glucose ranges, and they tabulate the percent of paired CGM readings that were in the identical range (shaded diagonal), as well as those CGM readings that were in glucose ranges above and below the paired YSI measurements.

The data which are tabulated in these tables was collected on six different days of the PRECISION study: days 1, 7, 14, 30, 60, and 90 of sensor wear. The first table in this series includes data from all days pooled together. Each successive table has data from an individual day.

Table 22 - CGM System concurrence to YSI organized by YSI glucose ranges; PRECISION study data pooled from **days 1, 7, 14, 30, 60, and 90**, analyzed using SW-602 algorithm

YSI (mg/dL)	Number of Paired CGM-YSI	Percent of Matched Pairs in Each CGM System Glucose Range for Each YSI Glucose Range CGM (mg/dL)								
		40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400
<40	15	80%	20%	--	--	--	--	--	--	--
40-60	1267	62%	35%	3%	--	--	--	--	--	--
61-80	2212	19%	61%	20%	--	--	--	--	--	--
81-120	2440	1%	9%	73%	17%	--	--	--	--	--
121-160	2358	--	--	11%	70%	18%	1%	--	--	--
161-200	1577	--	--	--	16%	64%	18%	1%	--	--
201-250	1496	--	--	--	--	18%	65%	15%	1%	--
251-300	1024	--	--	--	--	--	20%	62%	15%	2%
301-350	1527	--	--	--	--	--	1%	23%	61%	16%
351-400	1174	--	--	--	--	--	--	4%	44%	53%
>400	80	--	--	--	--	--	--	4%	15%	81%

Table 23 - CGM System concurrence to YSI organized by YSI glucose ranges; PRECISION study data from **day 1**, analyzed using SW-602 algorithm

YSI (mg/dL)	Number of Paired CGM-YSI	Percent of Matched Pairs in Each CGM System Glucose Range for Each YSI Glucose Range CGM (mg/dL)								
		40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400
<40	4	75%	25%	--	--	--	--	--	--	--
40-60	222	73%	24%	3%	--	--	--	--	--	--
61-80	469	21%	52%	26%	--	--	--	--	--	--
81-120	470	2%	16%	70%	12%	--	--	--	--	--
121-160	361	--	1%	17%	64%	15%	3%	--	--	--
161-200	242	--	--	--	17%	54%	27%	2%	--	--
201-250	254	--	--	--	1%	15%	58%	20%	4%	1%
251-300	245	--	--	--	--	--	17%	48%	27%	8%
301-350	234	--	--	--	--	--	--	12%	45%	42%
351-400	154	--	--	--	--	--	--	1%	42%	56%
>400	10	--	--	--	--	--	--	--	20%	80%

Table 24 - CGM System concurrence to YSI organized by YSI glucose ranges; PRECISION study data from **day 7**, analyzed using SW-602 algorithm

YSI (mg/dL)	Number of Paired CGM-YSI	Percent of Matched Pairs in Each CGM System Glucose Range for Each YSI Glucose Range CGM (mg/dL)								
		40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400
<40	7	100%	--	--	--	--	--	--	--	--
40-60	213	56%	35%	9%	--	--	--	--	--	--
61-80	472	18%	61%	18%	2%	--	--	--	--	--
81-120	472	--	8%	79%	12%	--	--	--	--	--
121-160	391	--	--	14%	67%	18%	1%	--	--	--
161-200	253	--	--	--	13%	66%	19%	1%	--	--
201-250	281	--	--	--	--	19%	57%	23%	1%	--
251-300	194	--	--	--	--	--	12%	66%	21%	2%
301-350	369	--	--	--	--	--	--	17%	66%	16%
351-400	272	--	--	--	--	--	--	--	36%	64%
>400	2	--	--	--	--	--	--	--	--	100%

Table 25 - CGM System concurrence to YSI organized by YSI glucose ranges; PRECISION study data from **day 14**, analyzed using SW-602 algorithm

YSI (mg/dL)	Number of Paired CGM-YSI	Percent of Matched Pairs in Each CGM System Glucose Range for Each YSI Glucose Range CGM (mg/dL)								
		40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400
<40	4	50%	50%	--	--	--	--	--	--	--
40-60	273	61%	36%	3%	--	--	--	--	--	--
61-80	423	22%	62%	16%	--	--	--	--	--	--
81-120	416	2%	10%	73%	13%	1%	--	--	--	--
121-160	434	--	--	10%	75%	15%	--	--	--	--
161-200	262	--	--	--	17%	68%	15%	--	--	--
201-250	290	--	--	--	--	17%	72%	10%	--	--
251-300	199	--	--	--	--	1%	21%	67%	11%	--
301-350	371	--	--	--	--	--	--	16%	69%	15%
351-400	307	--	--	--	--	--	--	--	34%	66%
>400	18	--	--	--	--	--	--	--	--	100%

Table 26 - CGM System concurrence to YSI organized by YSI glucose ranges; PRECISION study data from **day 30**, analyzed using SW-602 algorithm

YSI (mg/dL)	Number of Paired CGM-YSI	Percent of Matched Pairs in Each CGM System Glucose Range for Each YSI Glucose Range CGM (mg/dL)								
		40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400
<40	0	--	--	--	--	--	--	--	--	--
40-60	262	57%	42%	--	--	--	--	--	--	--
61-80	405	15%	69%	17%	--	--	--	--	--	--
81-120	437	--	6%	74%	20%	--	--	--	--	--
121-160	326	--	--	8%	78%	14%	1%	--	--	--
161-200	272	--	--	--	19%	61%	19%	--	--	--
201-250	192	--	--	--	--	16%	71%	13%	--	--
251-300	117	--	--	--	--	--	20%	75%	5%	--
301-350	156	--	--	--	--	--	--	31%	68%	1%
351-400	113	--	--	--	--	--	--	--	63%	37%
>400	4	--	--	--	--	--	--	--	--	100%

Table 27 - CGM System concurrence to YSI organized by YSI glucose ranges; PRECISION study data from **day 60**, analyzed using SW-602 algorithm

YSI (mg/dL)	Number of Paired CGM-YSI	Percent of Matched Pairs in Each CGM System Glucose Range for Each YSI Glucose Range CGM (mg/dL)								
		40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400
<40	0	--	--	--	--	--	--	--	--	--
40-60	167	69%	28%	2%	--	--	--	--	--	--
61-80	186	26%	62%	12%	--	--	--	--	--	--
81-120	317	--	4%	76%	20%	--	--	--	--	--
121-160	413	--	--	10%	67%	22%	1%	--	--	--
161-200	271	--	--	--	14%	73%	13%	--	--	--
201-250	219	--	--	--	--	27%	63%	10%	--	--
251-300	151	--	--	--	--	1%	22%	66%	11%	--
301-350	217	--	--	--	--	--	2%	30%	60%	7%
351-400	180	--	--	--	--	--	--	18%	49%	32%
>400	12	--	--	--	--	--	--	25%	17%	58%

Table 28 - CGM System concurrence to YSI organized by YSI glucose ranges; PRECISION study data from **day 90**, analyzed using SW-602 algorithm

YSI (mg/dL)	Number of Paired CGM-YSI	Percent of Matched Pairs in Each CGM System Glucose Range for Each YSI Glucose Range CGM (mg/dL)								
		40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400
<40	0	--	--	--	--	--	--	--	--	--
40-60	130	51%	45%	4%	--	--	--	--	--	--
61-80	257	15%	58%	26%	--	--	--	--	--	--
81-120	328	--	4%	67%	29%	1%	--	--	--	--
121-160	433	--	--	6%	71%	23%	--	--	--	--
161-200	277	--	--	1%	18%	64%	18%	--	--	--
201-250	260	--	--	--	1%	17%	72%	10%	--	--
251-300	118	--	--	--	--	--	36%	60%	3%	--
301-350	180	--	--	--	--	--	1%	44%	49%	6%
351-400	148	--	--	--	--	--	--	5%	59%	36%
>400	34	--	--	--	--	--	--	--	24%	76%

CGM System threshold alarm performance

These tables show the rates at which the Eversense CGM System low glucose alerts and high glucose alerts correctly detected low and high glucose events (referred to as the event detection rate in the tables below) during the PRECISION study, as well as the rates at which alerts were found to be true alerts or false alerts (referred to as the true and false alert rate in these tables), when using the new "SW-602" glucose determination algorithm.

The confirmed event detection rate is the rate that the device alerted when it should have alerted. It is the ratio of the number of times an alert was sounded when blood glucose was below or above the alert threshold to the total number of times blood glucose went below the threshold. The Missed Event Detection Rate is the rate at which the device did not alert when it should have. It is the rate at which blood glucose, as measured by comparator method, was below or above the glucose alert threshold and the device did not sound an alert – this is the complement of the confirmed event detection rate.

The true alert rate is the ratio of the number of times an alert was sounded while blood glucose was below the alert threshold to the total number of times an alert was sounded (i.e. if 100 alerts were given saying "your glucose level is below 70," and for 90 of those alerts it was verified that blood glucose was indeed below 70, then the true alert rate would be 90%). The false alert rate is the complement of the true alert rate (i.e. if the true alert rate is 90%, the false alert rate would be 10%).

Table 29 - Hypoglycemia event detection, stratefied by in-clinic session, analyzed using SW-602 algorithm

Visit	Low Alert Setting (mg/dL)	Confirmed Event Detection Rate	Missed Event Detection Rate	True Alert Rate	False Alert Rate
Visit 3 (Day 1)	60	93%	7%	72%	28%
	70	95%	5%	84%	16%
	80	97%	3%	88%	12%
	90	99%	1%	90%	10%
Visit 4 (Day 7)	60	89%	11%	69%	31%
	70	94%	6%	91%	9%
	80	97%	3%	93%	7%
	90	97%	3%	93%	7%
Visit 5 (Day 14)	60	86%	14%	76%	24%
	70	97%	3%	92%	8%
	80	98%	2%	94%	6%
	90	99%	1%	91%	9%
Visit 6 (Day 30)	60	85%	15%	84%	16%
	70	96%	4%	97%	3%
	80	97%	3%	96%	4%
	90	97%	3%	96%	4%
Visit 7 (Day 60)	60	90%	10%	85%	15%
	70	98%	2%	98%	2%
	80	99%	1%	95%	5%
	90	97%	3%	92%	8%
Visit 8 (Day 90)	60	89%	11%	78%	22%
	70	94%	6%	95%	5%
	80	93%	7%	97%	3%
	90	96%	4%	96%	4%

Table 30 - Hyperglycemic event detection, stratified by in-clinic session, analyzed using SW-602 algorithm

Visit	High Alert Setting (mg/dL)	Confirmed Event Detection Rate	Missed Event Detection Rate	True Alert Rate	False Alert Rate
Visit 3 (Day 1)	120	99%	1%	95%	5%
	140	99%	1%	95%	5%
	180	99%	1%	92%	8%
	200	99%	1%	91%	9%
	220	99%	1%	92%	8%
	240	98%	2%	90%	10%
	300	99%	1%	80%	20%
Visit 4 (Day 7)	120	99%	1%	96%	4%
	140	100%	0%	95%	5%
	180	100%	0%	94%	6%
	200	99%	1%	95%	5%
	220	99%	1%	94%	6%
	240	100%	0%	94%	6%
	300	99%	1%	92%	8%
Visit 5 (Day 14)	120	100%	0%	97%	3%
	140	99%	1%	96%	4%
	180	100%	0%	96%	4%
	200	99%	1%	97%	3%
	220	99%	1%	96%	4%
	240	99%	1%	96%	4%
	300	99%	1%	97%	3%
Visit 6 (Day 30)	120	100%	0%	93%	7%
	140	100%	0%	94%	6%
	180	99%	1%	92%	8%
	200	99%	1%	90%	10%
	220	97%	3%	92%	8%
	240	98%	2%	94%	6%
	300	92%	8%	97%	3%
Visit 7 (Day 60)	120	100%	0%	96%	4%
	140	99%	1%	94%	6%
	180	98%	2%	91%	9%
	200	95%	5%	94%	6%
	220	98%	2%	96%	4%
	240	98%	2%	97%	3%

	300	87%	13%	95%	5%
Visit 8 (Day 90)	120	99%	1%	95%	5%
	140	99%	1%	92%	8%
	180	97%	3%	93%	7%
	200	98%	2%	94%	6%
	220	97%	3%	93%	7%
	240	98%	2%	93%	7%
	300	91%	9%	98%	2%