Appendix 2

PRECISION Study accuracy results using the original glucose determination algorithm ("Study-SW" 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. 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**

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	14161	78.9	87.9	95.9	98.5	1.5
40 - 60	775	89.7	94.8	98.	99.69)	0.4
61 - 80	1863	83.3	92.71)	98.2)	99.3	0.7
81 - 180	5734	71.5	82.3)	93.7	97.7	2.3
181 - 300	3429	78.8	87.4	96.0	98.4	1.6
301 - 350	1568	90.3	96.5	98.9	99.3	0.7
351 - 400	792	90.2	95.3	97.5	99.1	0.9

Table 2 - CGM System agreement to YSI organized by CGM glucose ranges; PRECISION study, **day 1**

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	2450	65.8	78.9	91.3	95.9	4.1
40 - 60	79	62.0	70.9	87.3	96.2	3.8
61 - 80	341	67.7	85.9	95.6	96.8	3.2
81 - 180	1004	58.6	73.4	90.4	96.4	3.6
181 - 300	533	66.4	77.5	88.2	93.6	6.4
301 - 350	224	77.2	85.7	93.8	95.5	4.5
351 - 400	269	80.7	90.0	94.8	97.4	2.6

Table 3 - CGM System agreement to YSI organized by CGM glucose ranges; PRECISION study, **day 7**

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	2470	69.0	80.2	92.9	97.4	2.6
40 - 60	97	87.6	96.9	99.0	100.0	0.0
61 - 80	356	80.9	90.4)	98.9	100.0	0.0
81 - 180	1031	52.3	68.7	86.7	94.9	5.1
181 - 300	597	73.0	80.6	95.5	98.5	1.5
301 - 350	254	91.7	97.2	99.2	99.6	0.4
351 - 400	135	91.1	94.8	96.3	100.0	0.0

Table 4 - CGM System agreement to YSI organized by CGM glucose ranges; PRECISION study, **day 14**

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	2879	84.2	91.0	96.8	99.1	0.9
40 - 60	140	85.7	92.1	97.1	100.0	0.0
61 - 80	418	83.0	93.3	98.6	100.0	0.0
81 - 180	1005	79.0	85.6	93.8	97.8	2.2
181 - 300	673	83.1	89.7	97.3	99.3	0.7
301 - 350	500	93.4	99.2	99.8	100.0	0.0
351 - 400	143	95.8	99.3	100.0	100.0	0.0

Table 5 - CGM System agreement to YSI organized by CGM glucose ranges; PRECISION study, **day 30**

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	2257	85.7	92.9	98.1	99.7	0.3
40 - 60	215	98.1	99.5	100.0	100.0	0.0
61 - 80	394	90.1	97.2	100.0	100.0	0.0
81 - 180	928	77.6	87.5	96.8	99.2	0.8
181 - 300	470	86.4	93.6	97.7	100.0	0.0
301 - 350	184	97.3	99.5	100.0	100.0	0.0
351 - 400	66	97.0	98.5	98.5	100.0	0.0

Table 6 - CGM System agreement to YSI organized by CGM glucose ranges; PRECISION study, **day 60**

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	2082	87.1	93.3	98.8	99.8	0.2
40 - 60	168	95.8	99.4	100.0	100.0	0.0
61 - 80	151	90.7	94.7	100.0	100.0	0.0
81 - 180	871	84.6	92.2	98.3	99.7	0.3
181 - 300	564	83.3	89.9	98.4	99.6	0.4
301 - 350	237	92.0	97.9	100.0	100.0	0.0
351 - 400	91	100.0	100.0	100.0	100.0	0.0

Table 7 - CGM System agreement to YSI organized by CGM glucose ranges; PRECISION study, **day 90**

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	2023	83.5	92.6	98.3	99.3	0.7
40 - 60	76	90.8	98.7	100.0	100.0	0.0
61 - 80	203	95.1	96.6	98.5	99.0	1.0
81 - 180	895	80.6	89.5	97.4	99.0	1.0
181 - 300	592	80.7	93.2	98.5	99.3	0.7
301 - 350	169	86.4	96.4	100.0	100.0	0.0
351 - 400	88	93.2	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. The comparator method used during this study was the Yellow Springs Instruments 2300 glucose analyzer, abbreviated "YSI" inpr 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**

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	14161	78.9	87.9 (	95.9	98.5	1.5
< 40	15	13.3	26.7	73.3	93.3	6.7
40 - 60	1176	72.8	83.6	95.0	98.3	1.7
61 - 80	2105	74.0	85.1	95.4	98.1	1.9
81 - 180	5274	74.7	84.1	93.5	97.4	2.6
181 - 300	2943	84.6	92.3	97.8	99.4	0.6
301 - 350	1402	89.2	96.0	99.9	100.0	0.0
351 - 400	1157	87.9	94.5	99.1	100.0	0.0
> 400	89	71.9	89.9	100.0	100.0	0.0

Table 9 – CGM System agreement to YSI, organized by YSI glucose ranges; PRECISION study, **day 1**

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	2450	65.8	78.9	91.3	95.9	4.1
< 40	4	0.0	0.0	50.0	75.0	25.0
40 - 60	196	48.0	71.9	92.9	98.0	2.0
61 - 80	426	57.5	75.1	92.7	96.0	4.0
81 - 180	898	60.2	72.0	85.7	92.9	7.1
181 - 300	527	70.0	82.4	93.0	97.2	2.8
301 - 350	222	83.8	96.4	100.0	100.0	0.0
351 - 400	170	100.0	100.0	100.0	100.0	0.0
> 400	7	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**

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	2470	69.0	80.2	92.9	97.4	2.6
< 40	7	28.6	57.1	85.7	100.0	0.0
40 - 60	203	53.2	67.5	85.2	93.6	6.4
61 - 80	469	64.0	76.8	91.0	95.5	4.5
81 - 180	835	62.6	76.3	90.2	96.6	3.4
181 - 300	453	79.2	88.3	97.8	99.8	0.2
301 - 350	267	82.8	88.0	99.6	100.0	0.0
351 - 400	225	80.0	87.1	95.6	100.0	0.0
> 400	11	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**

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	2879	84.2	91.0	96.8	99.1	0.9
< 40	4	0.0	0.0	75.0	100.0	0.0
40 - 60	252	71.4	83.3	94.8	99.2	0.8
61 - 80	406	79.1	87.7	94.8	99.8	0.2
81 - 180	942	80.0	86.4	94.7	97.5	2.5
181 - 300	575	88.7	94.8	99.0	100.0	0.0
301 - 350	360	96.9	99.4	100.0	100.0	0.0
351 - 400	321	92.8	99.7	100.0	100.0	0.0
> 400	19	63.2	94.7	100.0	100.0	0.0

Table 12 – CGM System agreement to YSI, organized by YSI glucose ranges; PRECISION study, **day 30**

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	2257	85.7	92.9	98.1	99.7	0.3
< 40	0	--	--	--	--	--
40 - 60	262	88.5	94.7	100.0	100.0	0.0
61 - 80	405	85.7	94.1	100.0	100.0	0.0
81 - 180	900	79.2	89.1	95.9	99.2	0.8
181 - 300	420	90.0	94.3	98.8	100.0	0.0
301 - 350	156	97.4	100.0	100.0	100.0	0.0
351 - 400	109	99.1	100.0	100.0	100.0	0.0
> 400	5	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**

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	2082	87.1	93.3	98.8	99.8	0.2
< 40	0	--	--	--	--	--
40 - 60	160	91.9	94.4	98.8	99.4	0.6
61 - 80	178	88.8	94.9	98.3	99.4	0.6
81 - 180	870	84.0	91.0	98.0	99.7	0.3
181 - 300	461	92.8	97.4	99.8	100.0	0.0
301 - 350	217	89.9	96.8	99.5	100.0	0.0
351 - 400	184	80.4	88.6	100.0	100.0	0.0
> 400	12	58.3	75.0	100.0	100.0	0.0

Table 14 – CGM System agreement to YSI, organized by YSI glucose ranges; PRECISION study, **day 90**

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	2023	83.5	92.6	98.3	99.3	0.7
< 40	0	--	--	--	--	--
40 - 60	103	92.2	93.2	100.0	100.0	0.0
61 - 80	221	84.6	93.2	100.0	100.0	0.0
81 - 180	829	81.7	89.6	96.5	98.4	1.6
181 - 300	507	88.2	96.8	98.8	99.6	0.4
301 - 350	180	82.2	96.1	100.0	100.0	0.0
351 - 400	148	76.4	91.2	100.0	100.0	0.0
> 400	35	62.9	85.7	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. 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**

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	775	1%	64%	33%	2%	--	--	--	--	--	--	--
61-80	1863	--	30%	61%	7%	1%	--	--	--	--	--	--
81-120	2593	--	4%	27%	62%	7%	--	--	--	--	--	--
121-160	2189	--	--	1%	24%	66%	9%	--	--	--	--	--
161-200	1667	--	--	--	2%	30%	55%	13%	1%	--	--	--
201-250	1468	--	--	--	--	2%	20%	63%	13%	2%	--	--
251-300	1246	--	--	--	--	--	1%	18%	45%	29%	6%	--
301-350	1568	--	--	--	--	--	--	1%	9%	52%	37%	1%
351-400	792	--	--	--	--	--	--	1%	3%	25%	63%	9%

Table 16 – CGM System concurrence to YSI, organized by CGM glucose ranges; PRECISION study, **day 1**

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	79	1%	47%	35%	16%	--	--	--	--	--	--	--
61-80	341	1%	38%	49%	9%	3%	--	--	--	--	--	--
81-120	560	--	5%	40%	50%	5%	--	--	--	--	--	--
121-160	315	--	--	1%	37%	55%	7%	--	--	--	--	--
161-200	217	--	--	--	3%	45%	44%	6%	2%	--	--	--
201-250	249	--	--	--	1%	6%	30%	55%	8%	--	--	--
251-300	196	--	--	1%	1%	3%	3%	33%	52%	9%	--	--
301-350	224	--	--	--	--	--	2%	3%	35%	44%	16%	--
351-400	269	--	--	--	--	--	--	1%	6%	39%	50%	3%

Table 17 – CGM System concurrence to YSI, organized by CGM glucose ranges; PRECISION study, **day 7**

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	97	4%	51%	44%	1%	--	--	--	--	--	--	--
61-80	356	1%	31%	61%	7%	--	--	--	--	--	--	--
81-120	565	--	8%	35%	51%	7%	--	--	--	--	--	--
121-160	313	--	--	3%	30%	54%	12%	--	--	--	--	--
161-200	248	--	--	1%	5%	34%	47%	12%	--	--	--	--
201-250	245	--	--	--	--	2%	18%	60%	11%	7%	2%	--
251-300	257	--	--	--	--	--	2%	19%	37%	32%	10%	--
301-350	254	--	--	--	--	--	--	1%	3%	56%	41%	--
351-400	135	--	--	--	--	--	--	--	4%	19%	69%	8%

Table 18 – CGM System concurrence to YSI, organized by CGM glucose ranges; PRECISION study, **day 14**

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	140	1%	67%	30%	1%	--	--	--	--	--	--	--
61-80	418	--	33%	60%	7%	--	--	--	--	--	--	--
81-120	436	--	5%	25%	66%	4%	--	--	--	--	--	--
121-160	414	--	--	--	18%	75%	6%	--	--	--	--	--
161-200	281	--	--	--	1%	30%	55%	13%	--	--	--	--
201-250	319	--	--	--	--	1%	19%	64%	16%	1%	--	--
251-300	228	--	--	--	--	--	--	14%	53%	32%	1%	
301-350	500	--	--	--	--	--	--	--	4%	53%	42%	2%
351-400	143	--	--	--	--	--	--	--	--	15%	78%	8%

Table 19 – CGM System concurrence to YSI, organized by CGM glucose ranges; PRECISION study, **day 30**

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	215	--	73%	27%	--	--	--	--	--	--	--	--
61-80	394	--	26%	68%	7%	--	--	--	--	--	--	--
81-120	413	--	1%	20%	73%	6%	--	--	--	--	--	--
121-160	371	--	--	--	29%	62%	9%	--	--	--	--	--
161-200	261	--	--	--	--	24%	66%	10%	--	--	--	--
201-250	201	--	--	--	--	1%	24%	67%	8%	--	--	--
251-300	152	--	--	--	--	--	1%	20%	56%	24%	--	--
301-350	184	--	--	--	--	--	--	1%	8%	60%	32%	--
351-400	66	--	--	--	--	--	--	--	2%	14%	77%	8%

Table 20 – CGM System concurrence to YSI, organized by CGM glucose ranges; PRECISION study, **day 60**

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	168	--	68%	32%	--	--	--	--	--	--	--	--
61-80	151	--	25%	65%	10%	--	--	--	--	--	--	--
81-120	321	--	2%	8%	72%	17%	--	--	--	--	--	--
121-160	354	--	--	--	17%	73%	10%	--	--	--	--	--
161-200	346	--	--	--	--	27%	58%	14%	1%	--	--	--
201-250	196	--	--	--	--	1%	15%	68%	14%	2%	--	--
251-300	218	--	--	--	--	--	--	9%	46%	32%	12%	1%
301-350	237	--	--	--	--	--	--	--	8%	50%	41%	1%
351-400	91	--	--	--	--	--	--	--	--	26%	66%	8%

Table 21 – CGM System concurrence to YSI, organized by CGM glucose ranges; PRECISION study, **day 90**

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	76	--	62%	38%	--	--	--	--	--	--	--	--
61-80	203	--	25%	70%	3%	1%	--	--	--	--	--	--
81-120	298	--	2%	16%	72%	9%	1%	--	--	--	--	--
121-160	422	--	--	--	18%	70%	12%	--	--	--	--	--
161-200	314	--	--	--	1%	25%	56%	19%	--	--	--	--
201-250	258	--	--	--	--	--	13%	67%	19%	1%	--	--
251-300	195	--	--	--	--	--	--	12%	33%	45%	10%	--
301-350	169	--	--	--	--	--	--	--	2%	47%	46%	5%
351-400	88	--	--	--	--	--	--	--	--	13%	57%	31%

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. 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; data pooled from accuracy assessments on **days 1, 7, 14, 30, 60, and 90** of the PRECISION clinical study.

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	47%	53%	--	--	--	--	--	--	--
40-60	1176	42%	48%	9%	--	--	--	--	--	--
61-80	2105	12%	54%	33%	1%	--	--	--	--	--
81-120	2303	1%	6%	69%	23%	1%	--	--	--	--
121-160	2173	--	1%	9%	66%	23%	1%	--	--	--
161-200	1429	--	--	--	14%	64%	20%	1%	--	--
201-250	1381	--	--	--	--	15%	67%	16%	1%	--
251-300	931	--	--	--	--	1%	21%	61%	15%	3%
301-350	1402	--	--	--	--	--	2%	26%	58%	14%
351-400	1157	--	--	--	--	--	--	6%	50%	43%
>400	89	--	--	--	--	--	--	2%	21%	76%

Table 23 – CGM System concurrence to YSI, organized by YSI glucose ranges; PRECISION study, **day 1**

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	25%	75%	--	--	--	--	--	--	--
40-60	196	19%	66%	15%	--	--	--	--	--	--
61-80	426	7%	39%	52%	1%	--	--	--	--	--
81-120	447	3%	7%	62%	26%	2%	--	--	--	--
121-160	328	--	3%	8%	53%	30%	5%	2%	--	--
161-200	202	--	--	--	11%	47%	37%	3%	2%	--
201-250	227	--	--	--	--	5%	60%	29%	3%	2%
251-300	221	--	--	--	--	2%	9%	46%	36%	8%
301-350	222	--	--	--	--	--	--	8%	44%	48%
351-400	170	--	--	--	--	--	--	--	21%	79%
>400	7	--	--	--	--	--	--	--	--	100

Table 24 – CGM System concurrence to YSI, organized by YSI glucose ranges; PRECISION study, **day 7**

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	57%	43%	--	--	--	--	--	--	--
40-60	203	24%	55%	21%	--	--	--	--	--	--
61-80	469	9%	46%	42%	2%	1%	--	--	--	--
81-120	420	--	6%	69%	22%	3%	--	--	--	--
121-160	297	--	--	12%	57%	29%	2%	--	--	--
161-200	204	--	--	--	19%	57%	22%	2%	--	--
201-250	230	--	--	--	--	13%	64%	22%	1%	--
251-300	137	--	--	--	--	1%	20%	69%	5%	4%
301-350	267	--	--	--	--	--	6%	31%	53%	9%
351-400	225	--	--	--	--	--	2%	11%	46%	41%
>400	11	--	--	--	--	--	--	--	--	100%

Table 25 – CGM System concurrence to YSI, organized by YSI glucose ranges; PRECISION study, **day 14**

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	252	37%	54%	9%	--	--	--	--	--	--
61-80	406	10%	62%	27%	--	--	--	--	--	--
81-120	396	1%	7%	72%	19%	1%	--	--	--	--
121-160	417	--	--	4%	75%	20%	1%	--	--	--
161-200	241	--	--	--	10%	64%	25%	--	--	--
201-250	273	--	--	--	--	13%	74%	12%	--	--
251-300	190	--	--	--	--	1%	26%	63%	10%	--
301-350	360	--	--	--	--	--	1%	20%	73%	6%
351-400	321	--	--	--	--	--	--	1%	65%	35%
>400	19	--	--	--	--	--	--	--	42%	58%

Table 26 – CGM System concurrence to YSI, organized by YSI glucose ranges; PRECISION study, **day 30**

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	60%	39%	2%	--	--	--	--	--	--
61-80	405	14%	66%	20%	--	--	--	--	--	--
81-120	436	--	6%	69%	24%	--	--	--	--	--
121-160	320	--	--	8%	72%	19%	1%	--	--	--
161-200	255	--	--	--	14%	67%	19%	--	--	--
201-250	192	--	--	--	--	14%	70%	16%	1%	--
251-300	117	--	--	--	--	--	15%	73%	12%	1%
301-350	156	--	--	--	--	--	--	23%	71%	6%
351-400	109	--	--	--	--	--	--	--	53%	47%
>400	5	--	--	--	--	--	--	--	--	100%

Table 27 – CGM System concurrence to YSI, organized by YSI glucose ranges; PRECISION study, **day 60**

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	160	72%	24%	4%	--	--	--	--	--	--
61-80	178	30%	55%	15%	--	--	--	--	--	--
81-120	307	--	5%	76%	20%	--	--	--	--	--
121-160	408	--	--	13%	63%	23%	--	--	--	--
161-200	267	--	--	--	13%	76%	11%	--	--	--
201-250	201	--	--	--	--	24%	66%	9%	--	--
251-300	148	--	--	--	--	1%	19%	68%	12%	--
301-350	217	--	--	--	--	--	2%	32%	55%	11%
351-400	184	--	--	--	--	--	--	15%	53%	33%
>400	12	--	--	--	--	--	--	17%	25%	58%

Table 28 – CGM System concurrence to YSI, organized by YSI glucose ranges; PRECISION study, **day 90**

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	103	46%	50%	5%	--	--	--	--	--	--
61-80	221	13%	65%	22%	--	--	--	--	--	--
81-120	297	--	2%	72%	25%	1%	--	--	--	--
121-160	403	--	--	6%	74%	19%	--	--	--	--
161-200	260	--	--	1%	19%	67%	13%	--	--	--
201-250	258	--	--	--	1%	23%	67%	9%	--	--
251-300	118	--	--	--	--	--	42%	55%	3%	--
301-350	180	--	--	--	--	--	1%	48%	44%	6%
351-400	148	--	--	--	--	--	--	14%	53%	34%
>400	35	--	--	--	--	--	--	--	23%	77%

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).

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 - Hypoglycemic event detection, stratefied by in-clinic session; PRECISION study

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	53%	48%	64%	36%
	70	69%	31%	88%	13%
	80	82%	18%	89%	11%
	90	92%	8%	91%	9%
Visit 4 (Day 7)	60	50%	50%	80%	20%
	70	73%	27%	95%	5%
	80	77%	23%	95%	5%
	90	88%	12%	94%	6%
Visit 5 (Day 14)	60	70%	30%	79%	21%
	70	87%	13%	96%	4%
	80	95%	5%	97%	3%
	90	94%	6%	98%	2%
Visit 6 (Day 30)	60	77%	23%	88%	12%
	70	92%	8%	98%	2%
	80	96%	4%	98%	2%
	90	96%	4%	98%	2%
Visit 7 (Day 60)	60	89%	11%	86%	14%
	70	97%	3%	99%	1%
	80	98%	2%	96%	4%
	90	97%	3%	93%	7%
Visit 8 (Day 90)	60	91%	9%	73%	27%
	70	94%	6%	96%	4%
	80	91%	9%	97%	3%
	90	96%	4%	94%	6%

Table 30 - Hyperglycemic event detection, stratefied by in-clinic session; PRECISION study

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	98%	2%	91%	9%
	140	100%	0%	90%	10%
	180	99%	1%	89%	11%
	200	99%	1%	89%	11%
	220	99%	1%	88%	12%
	240	98%	2%	85%	15%
	300	98%	2%	79%	21%
Visit 4 (Day 7)	120	99%	1%	92%	8%
	140	99%	1%	90%	10%
	180	98%	2%	92%	8%
	200	99%	1%	94%	6%
	220	99%	1%	92%	8%
	240	97%	3%	92%	8%
	300	84%	16%	96%	4%
Visit 5 (Day 14)	120	100%	0%	96%	4%
	140	100%	0%	96%	4%
	180	99%	1%	94%	6%
	200	99%	1%	95%	5%
	220	99%	1%	94%	6%
	240	98%	2%	95%	5%
	300	97%	3%	97%	3%
Visit 6 (Day 30)	120	100%	0%	92%	8%
	140	99%	1%	93%	7%
	180	99%	1%	91%	9%
	200	99%	1%	92%	8%
	220	98%	2%	91%	9%
	240	98%	2%	92%	8%
	300	94%	6%	92%	8%
Visit 7 (Day 60)	120	99%	1%	96%	4%
	140	99%	1%	95%	5%
	180	98%	2%	92%	8%
	200	97%	3%	95%	5%
	220	98%	2%	96%	4%
	240	98%	2%	97%	3%

	300	88%	12%	95%	5%
Visit 8 (Day 90)	120	99%	1%	95%	5%
	140	99%	1%	93%	7%
	180	97%	3%	94%	6%
	200	97%	3%	96%	4%
	220	97%	3%	94%	6%
	240	95%	5%	94%	6%
	300	89%	11%	99%	1%