Appendix 3

PRECISE II 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 2
CGM System agreement to YSI comparator, organized by YSI ranges 4
System concurrence to YSI, with CGM glucose ranges 7
System concurrence to YSI, with YSI glucose ranges 11
In-Clinic System Alarm Performance 15

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 four different days of the PRECISE II study: days 1, 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; data pooled from accuracy assessments on **days 1, 30, 60, and 90** of the PRECISE II clinical study, 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	15753	86.8	94.3	98.6	99.6	0.4
40 - 60	480	85.4	92.1	97.7	99.6	0.4
61 - 80	1111	83.3	90.7	97.4	99.1	0.9
81 - 180	7844	85.6	93.5	98.3	99.6	0.4
181 - 300	5377	88.3	95.6	99.1	99.7	0.3
301 - 350	692	90.8	98.0	99.7	99.9	0.1
351 - 400	249	96.8	99.2	100.0	100.0	0.0

Table 2 - CGM System agreement to YSI organized by CGM glucose ranges; PRECISE II 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	1708	76.8	87.1	96.3	98.5	1.5
40 - 60	39	59.0	76.9	87.2	94.9	5.1
61 - 80	107	59.8	67.3	83.2	91.6	8.4
81 - 180	1024	77.1	88.5	97.4	99.0	1.0
181 - 300	519	80.9	88.8	97.3	99.0	1.0
301 - 350	19	84.2	100.0	100.0	100.0	0.0
351 - 400	0	--	--	--	--	--

Table 3 - CGM System agreement to YSI organized by CGM glucose ranges; PRECISE II 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	5081	90.7	96.0	99.3	99.8	0.2
40 - 60	188	83.5	89.9	97.3	100.0	0.0
61 - 80	497	88.5	94.0	99.0	99.8	0.2
81 - 180	2851	89.1	95.6	99.1	99.6	0.4
181 - 300	1373	95.2	97.9	99.9	100.0	0.0
301 - 350	116	94.0	99.1	100.0	100.0	0.0
351 - 400	56	100.0	100.0	100.0	100.0	0.0

Table 4 - CGM System agreement to YSI organized by CGM glucose ranges; PRECISE II 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	4725	87.3	94.7	98.8	99.8	0.2
40 - 60	181	90.1	96.7	100.0	100.0	0.0
61 - 80	244	82.0	91.4	98.4	100.0	0.0
81 - 180	2092	87.3	94.1	98.2	99.6	0.4
181 - 300	1835	87.1	95.0	99.1	99.9	0.1
301 - 350	302	89.4	97.7	100.0	100.0	0.0
351 - 400	71	95.8	100.0	100.0	100.0	0.0

Table 5 - CGM System agreement to YSI organized by CGM glucose ranges; PRECISE II 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	4239	85.4	94.7	98.6	99.6	0.4
40 - 60	72	93.1	94.4	98.6	100.0	0.0
61 - 80	263	84.0	93.5	99.2	100.0	0.0
81 - 180	1877	83.1	92.6	97.9	99.7	0.3
181 - 300	1650	86.2	96.7	99.0	99.3	0.7
301 - 350	255	91.4	97.6	99.2	99.6	0.4
351 - 400	122	95.9	98.4	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 four different days of the PRECISE II study: days 1, 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 6 – CGM System agreement to YSI organized by YSI glucose ranges; data pooled from accuracy assessments on **days 1, 30, 60, and 90** of the PRECISE II clinical study, 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	15753	86.8	94.3	98.6	99.6	0.4
< 40	7	71.4	71.4	100.0	100.0	0.0
40 - 60	488	89.5	95.1	98.8	99.8	0.2
61 - 80	1159	84.5	92.0	97.7	99.1	0.9
81 - 180	7540	85.6	93.0	98.0	99.4	0.6
181 - 300	5378	88.4	95.9	99.4	99.9	0.1
301 - 350	820	88.4	97.4	99.8	100.0	0.0
351 - 400	326	86.5	96.6	98.5	100.0	0.0
> 400	35	91.4	100.0	100.0	100.0	0.0

Table 7 - CGM System agreement to YSI organized by YSI glucose ranges; PRECISE II 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	1708	76.8	87.1	96.3	98.5	1.5
< 40	1	100.0	100.0	100.0	100.0	0.0
40 - 60	27	96.3	100.0	100.0	100.0	0.0
61 - 80	82	78.0	91.5	98.8	100.0	0.0
81 - 180	1073	72.7	84.1	94.7	97.8	2.2
181 - 300	509	83.7	91.7	98.8	99.6	0.4
301 - 350	16	93.8	100.0	100.0	100.0	0.0
351 - 400	0	--	--	--	--	--
> 400	0	--	--	--	--	--

Table 8 - CGM System agreement to YSI organized by YSI glucose ranges; PRECISE II 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	5081	90.7	96.0	99.3	99.8	0.2
< 40	4	50.0	50.0	100.0	100.0	0.0
40 - 60	190	94.2	98.4	100.0	100.0	0.0
61 - 80	512	87.5	93.2	97.7	98.4	1.6
81 - 180	2746	88.7	95.0	99.1	99.9	0.1
181 - 300	1424	95.2	98.5	99.9	100.0	0.0
301 - 350	140	91.4	96.4	100.0	100.0	0.0
351 - 400	61	90.2	96.7	100.0	100.0	0.0
> 400	4	100.0	100.0	100.0	100.0	0.0

Table 9 - CGM System agreement to YSI organized by YSI glucose ranges; PRECISE II 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	4725	87.3	94.7	98.8	99.8	0.2
< 40	0	--	--	--	--	--
40 - 60	152	92.1	94.7	98.7	99.3	0.7
61 - 80	293	86.0	93.2	98.3	99.3	0.7
81 - 180	2006	88.1	94.9	98.7	99.7	0.3
181 - 300	1777	86.9	94.5	99.0	99.9	0.1
301 - 350	348	87.9	96.8	99.4	100.0	0.0
351 - 400	139	79.1	93.5	96.4	100.0	0.0
> 400	10	70.0	100.0	100.0	100.0	0.0

Table 10 - CGM System agreement to YSI organized by YSI glucose ranges; PRECISE II 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	4239	85.4	94.7	98.6	99.6	0.4
< 40	2	100.0	100.0	100.0	100.0	0.0
40 - 60	119	77.3	89.1	96.6	100.0	0.0
61 - 80	272	79.0	88.6	96.7	100.0	0.0
81 - 180	1715	85.5	93.4	97.6	99.2	0.8
181 - 300	1668	85.7	96.4	99.6	99.8	0.2
301 - 350	316	87.3	98.4	100.0	100.0	0.0
351 - 400	126	92.9	100.0	100.0	100.0	0.0
> 400	21	100.0	100.0	100.0	100.0	0.0

System concurrence to YSI, with CGM glucose 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 four different days of the PRECISE II study: days 1, 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 11 - CGM System concurrence to YSI organized by CGM glucose ranges; data pooled from accuracy assessments on **days 1, 30, 60, and 90** of the PRECISE II clinical study, 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	480	1%	63%	34%	3%	--	--	--	--	--	--	--
61-80	1111	--	16%	63%	20%	1%	--	--	--	--	--	--
81-120	3066	--	--	9%	76%	14%	--	--	--	--	--	--
121-160	3245	--	--	--	11%	73%	15%	--	--	--	--	--
161-200	2812	--	--	--	--	15%	64%	21%	--	--	--	--
201-250	2614	--	--	--	--	--	13%	68%	18%	--	--	--
251-300	1484	--	--	--	--	--	1%	17%	58%	23%	1%	--
301-350	692	--	--	--	--	--	--	1%	19%	59%	20%	--
351-400	249	--	--	--	--	--	--	--	--	20%	66%	13%

Table 12 - CGM System concurrence to YSI organized by CGM glucose ranges; PRECISE II 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	39	3%	44%	44%	10%	--	--	--	--	--	--	--
61-80	107	--	9%	44%	36%	10%	--	--	--	--	--	--
81-120	403	--	--	4%	69%	25%	1%	--	--	--	--	--
121-160	424	--	--	--	17%	66%	17%	--	--	--	--	--
161-200	343	--	--	--	--	22%	66%	11%	--	--	--	--
201-250	273	--	--	--	--	1%	29%	61%	9%	--	--	--
251-300	100	--	--	--	--	--	3%	38%	54%	5%	--	--
301-350	19	--	--	--	--	--	--	--	42%	58%	--	--
351-400	0	--	--	--	--	--	--	--	--	--	--	--

Table 13 - CGM System concurrence to YSI organized by CGM glucose ranges; PRECISE II 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	188	2%	62%	32%	4%	--	--	--	--	--	--	--
61-80	497	--	14%	69%	16%	--	--	--	--	--	--	--
81-120	1200	--	--	9%	79%	12%	--	--	--	--	--	--
121-160	1168	--	--	--	11%	77%	11%	--	--	--	--	--
161-200	860	--	--	--	--	13%	70%	17%	--	--	--	--
201-250	669	--	--	--	--	--	11%	77%	12%	1%	--	--
251-300	327	--	--	--	--	--	--	11%	72%	17%	1%	--
301-350	116	--	--	--	--	--	--	--	24%	61%	15%	--
351-400	56	--	--	--	--	--	--	--	--	20%	73%	7%

Table 14 - CGM System concurrence to YSI organized by CGM glucose ranges; PRECISE II 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	181	--	65%	35%	--	--	--	--	--	--	--	--
61-80	244	--	13%	62%	25%	--	--	--	--	--	--	--
81-120	827	--	--	9%	79%	11%	--	--	--	--	--	--
121-160	830	--	--	--	10%	73%	16%	--	--	--	--	--
161-200	787	--	--	--	--	16%	63%	20%	1%	--	--	--
201-250	885	--	--	--	--	--	14%	69%	16%	1%	--	--
251-300	598	--	--	--	--	--	--	19%	53%	25%	2%	--
301-350	302	--	--	--	--	--	--	1%	16%	60%	23%	1%
351-400	71	--	--	--	--	--	--	--	--	13%	76%	11%

Table 15 - CGM System concurrence to YSI organized by CGM glucose ranges; PRECISE II 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	72	3%	68%	28%	1%	--	--	--	--	--	--	--
61-80	263	--	24%	61%	15%	--	--	--	--	--	--	--
81-120	636	--	1%	14%	71%	14%	--	--	--	--	--	--
121-160	823	--	--	--	10%	70%	19%	1%	--	--	--	--
161-200	822	--	--	--	1%	13%	58%	28%	--	--	--	--
201-250	787	--	--	--	--	1%	9%	62%	28%	--	--	--
251-300	459	--	--	--	--	--	1%	12%	57%	29%	--	--
301-350	255	--	--	--	--	--	--	1%	19%	58%	22%	--
351-400	122	--	--	--	--	--	--	--	1%	25%	57%	16%

System concurrence to YSI, with YSI glucose 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 four different days of the PRECISE II study: days 1, 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 16 - CGM System concurrence to YSI organized by YSI glucose ranges; PRECISE II study data from **days 1, 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	7	86%	14%	--	--	--	--	--	--	--
40-60	488	61%	36%	2%	--	--	--	--	--	--
61-80	1159	14%	61%	25%	--	--	--	--	--	--
81-120	2935	--	7%	79%	13%	--	--	--	--	--
121-160	3227	--	--	13%	73%	13%	--	--	--	--
161-200	2661	--	--	--	19%	68%	13%	--	--	--
201-250	2619	--	--	--	--	22%	68%	9%	--	--
251-300	1476	--	--	--	--	1%	32%	59%	9%	--
301-350	820	--	--	--	--	--	2%	42%	50%	6%
351-400	326	--	--	--	--	--	1%	6%	43%	51%
>400	35	--	--	--	--	--	--	--	9%	91%

Table 17 – CGM System concurrence to YSI organized by YSI glucose ranges; PRECISE II 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	1	100%	--	--	--	--	--	--	--	--
40-60	27	63%	37%	--	--	--	--	--	--	--
61-80	82	21%	57%	22%	--	--	--	--	--	--
81-120	392	1%	10%	71%	18%	--	--	--	--	--
121-160	473	--	2%	22%	59%	16%	1%	--	--	--
161-200	385	--	--	1%	18%	59%	21%	1%	--	--
201-250	245	--	--	--	--	16%	68%	16%	--	--
251-300	87	--	--	--	--	1%	28%	62%	9%	--
301-350	16	--	--	--	--	--	--	31%	69%	--
351-400	0	--	--	--	--	--	--	--	--	--
>400	0	--	--	--	--	--	--	--	--	--

Table 18 - CGM System concurrence to YSI organized by YSI glucose ranges; PRECISE II 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	4	75%	25%	--	--	--	--	--	--	--
40-60	190	62%	38%	1%	--	--	--	--	--	--
61-80	512	12%	67%	20%	1%	--	--	--	--	--
81-120	1164	1%	7%	81%	11%	--	--	--	--	--
121-160	1157	--	--	13%	78%	10%	--	--	--	--
161-200	804	--	--	--	16%	74%	9%	--	--	--
201-250	703	--	--	--	--	21%	73%	5%	--	--
251-300	342	--	--	--	--	--	23%	69%	8%	--
301-350	140	--	--	--	--	--	3%	39%	51%	8%
351-400	61	--	--	--	--	--	--	5%	28%	67%
>400	4	--	--	--	--	--	--	--	--	100%

Table 19 - CGM System concurrence to YSI organized by YSI glucose ranges; PRECISE II 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	152	77%	20%	3%	--	--	--	--	--	--
61-80	293	22%	52%	26%	--	--	--	--	--	--
81-120	798	--	8%	82%	11%	--	--	--	--	--
121-160	827	--	--	11%	73%	15%	--	--	--	--
161-200	758	--	--	--	18%	66%	16%	--	--	--
201-250	889	--	--	--	--	18%	69%	13%	--	--
251-300	511	--	--	--	--	1%	28%	61%	9%	--
301-350	348	--	--	--	--	--	2%	44%	52%	3%
351-400	139	--	--	--	--	--	1%	10%	50%	39%
>400	10	--	--	--	--	--	--	--	20%	80%

Table 20 - CGM System concurrence to YSI organized by YSI glucose ranges; PRECISE II 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	2	100%	--	--	--	--	--	--	--	--
40-60	119	41%	53%	6%	--	--	--	--	--	--
61-80	272	7%	59%	33%	--	--	--	--	--	--
81-120	581	--	7%	78%	14%	1%	--	--	--	--
121-160	770	--	--	11%	75%	14%	1%	--	--	--
161-200	714	--	--	--	22%	67%	10%	1%	--	--
201-250	782	--	--	--	1%	30%	62%	7%	--	--
251-300	536	--	--	--	--	1%	41%	49%	9%	--
301-350	316	--	--	--	--	--	1%	43%	47%	10%
351-400	126	--	--	--	--	--	--	1%	44%	56%
>400	21	--	--	--	--	--	--	--	5%	95%

In-Clinic System 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 PRECISE II 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 21 - Hypoglycemia event detection, stratefied by in-clinic session

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	89%	11%	47%	53%
	70	98%	2%	61%	39%
	80	100%	0%	69%	31%
	90	98%	2%	66%	34%
Visit 4 (Day 30)	60	85%	15%	71%	29%
	70	97%	3%	87%	13%
	80	97%	3%	89%	11%
	90	98%	2%	89%	11%
Visit 5 (Day 60)	60	99%	1%	79%	21%
	70	99%	1%	87%	13%
	80	98%	2%	84%	16%
	90	97%	3%	85%	15%
Visit 6 (Day 90)	60	83%	17%	74%	26%
	70	92%	8%	84%	16%
	80	93%	7%	87%	13%
	90	97%	3%	85%	15%

Table 22 - Hyperglycemic event detection, stratified by in-clinic session

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	97%	3%	94%	6%
	140	97%	3%	91%	9%
	180	97%	3%	84%	16%
	200	98%	2%	79%	21%
	220	97%	3%	69%	31%
	240	97%	3%	65%	35%
	300	94%	6%	52%	48%
Visit 4 (Day 30)	120	99%	1%	96%	4%
	140	99%	1%	95%	5%
	180	98%	2%	94%	6%
	200	97%	3%	93%	7%
	220	98%	2%	92%	8%
	240	98%	2%	90%	10%
	300	86%	14%	85%	15%
Visit 5 (Day 60)	120	100%	0%	98%	2%
	140	99%	1%	97%	3%
	180	97%	3%	95%	5%
	200	97%	3%	94%	6%
	220	96%	4%	91%	9%
	240	94%	6%	89%	11%
	300	86%	14%	85%	15%
Visit 6 (Day 90)	120	99%	1%	97%	3%
	140	99%	1%	97%	3%
	180	98%	2%	94%	6%
	200	95%	5%	95%	5%
	220	93%	7%	93%	7%
	240	92%	8%	93%	7%
	300	88%	12%	87%	13%