

Appendix 1

PRECISE II 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	2
CGM System agreement to YSI comparator, organized by YSI ranges.....	4
CGM System concurrence to YSI comparator, organized by CGM ranges	7
CGM System concurrence to YSI comparator, organized by YSI ranges.....	11
CGM System threshold 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. 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.

CGM Glucose Range (mg/dL)	Number of Paired CGM and YSI	Percent of CGM System Readings Within				
		Percent 15/15% of YSI	Percent 20/20% of YSI	Percent 30/30% of YSI	Percent 40/40% of YSI	Percent Greater than 40/40% of YSI
Overall	15704	85.6	93.4	98.0	99.4	0.6
40 - 60	463	74.9	83.6	94.2	96.3	3.7
61 - 80	1149	82.5	89.1	95.7	98.5	1.5
81 - 180	7793	84.8	92.8	97.7	99.5	0.5
181 - 300	5338	87.4	95.6	99.2	99.6	0.4
301 - 350	711	89.3	94.1	98.6	99.9	0.1
351 - 400	250	94.8	99.2	99.6	100.0	0.0

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

CGM Glucose Range (mg/dL)	Number of Paired CGM and YSI	Percent of CGM System Readings Within				
		Percent 15/15% of YSI	Percent 20/20% of YSI	Percent 30/30% of YSI	Percent 40/40% of YSI	Percent Greater than 40/40% of YSI
Overall	1646	74.7	84.9	94.4	97.9	2.1
40 - 60	37	40.5	40.5	73.0	75.7	24.3
61 - 80	99	51.5	64.6	77.8	86.9	13.1
81 - 180	1013	73.4	85.2	95.1	99.1	0.9
181 - 300	485	85.2	92.0	98.1	99.2	0.8
301 - 350	12	58.3	83.3	91.7	100.0	0.0
351 - 400	0	--	--	--	--	--

Table 3 - CGM System agreement to YSI organized by CGM glucose ranges; PRECISE II study, day 30

CGM Glucose Range (mg/dL)	Number of Paired CGM and YSI	Percent of CGM System Readings Within					Percent Greater than 40/40% of YSI
		Percent 15/15% of YSI	Percent 20/20% of YSI	Percent 30/30% of YSI	Percent 40/40% of YSI	Percent 40/40% of YSI	
Overall	5086	89.8	95.2	98.8	99.6	0.4	
40 - 60	213	71.4	81.7	94.8	98.1	1.9	
61 - 80	518	86.9	92.1	98.1	99.4	0.6	
81 - 180	2799	89.1	95.2	98.7	99.6	0.4	
181 - 300	1383	94.7	97.8	99.8	100.0	0.0	
301 - 350	114	92.1	98.2	100.0	100.0	0.0	
351 - 400	59	96.6	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

CGM Glucose Range (mg/dL)	Number of Paired CGM and YSI	Percent of CGM System Readings Within					Percent Greater than 40/40% of YSI
		Percent 15/15% of YSI	Percent 20/20% of YSI	Percent 30/30% of YSI	Percent 40/40% of YSI	Percent 40/40% of YSI	
Overall	4711	87.5	94.7	98.7	99.7	0.3	
40 - 60	151	86.8	94.7	97.4	98.7	1.3	
61 - 80	274	84.7	90.9	96.0	99.6	0.4	
81 - 180	2062	87.4	94.4	98.3	99.5	0.5	
181 - 300	1838	86.9	95.4	99.5	99.9	0.1	
301 - 350	308	92.2	95.1	99.4	100.0	0.0	
351 - 400	78	94.9	98.7	100.0	100.0	0.0	

Table 5 - CGM System agreement to YSI organized by CGM glucose ranges; PRECISE II study, day 90

CGM Glucose Range (mg/dL)	Number of Paired CGM and YSI	Percent of CGM System Readings Within					Percent Greater than 40/40% of YSI
		Percent 15/15% of YSI	Percent 20/20% of YSI	Percent 30/30% of YSI	Percent 40/40% of YSI	Percent 40/40% of YSI	
Overall	4261	82.7	93.0	97.8	99.5	0.5	
40 - 60	62	79.0	88.7	96.8	96.8	3.2	
61 - 80	258	83.3	90.7	97.7	100.0	0.0	
81 - 180	191	81.9	91.5	96.9	99.7	0.3	
181 - 300	1632	82.4	95.1	98.8	99.1	0.9	
301 - 350	277	86.3	91.7	97.5	99.6	0.4	
351 - 400	113	93.8	99.1	99.1	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” 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.

YSI Glucose Range (mg/dL)	Number of Paired CGM and YSI	Percent of CGM System Readings Within				
		Percent 15/15% of YSI	Percent 20/20% of YSI	Percent 30/30% of YSI	Percent 40/40% of YSI	Percent Greater than 40/40% of YSI
Overall	15704	85.6	93.4	98.0	99.4	0.6
< 40	4	50.0	75.0	100.0	100.0	0.0
40 - 60	437	86.5	92.4	95.2	98.6	1.4
61 - 80	1153	83.3	91.0	97.1	99.1	0.9
81 - 180	7562	84.5	92.2	97.3	99.2	0.8
181 - 300	5360	87.0	94.7	99.1	99.8	0.2
301 - 350	828	86.8	97.8	99.8	100.0	0.0
351 - 400	329	90.3	97.3	99.7	100.0	0.0
> 400	31	96.8	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

YSI Glucose Range (mg/dL)	Number of Paired CGM and YSI	Percent of CGM System Readings Within				
		Percent 15/15% of YSI	Percent 20/20% of YSI	Percent 30/30% of YSI	Percent 40/40% of YSI	Percent Greater than 40/40% of YSI
Overall	1646	74.7	84.9	94.4	97.9	2.1
< 40	0	--	--	--	--	--
40 - 60	20	60.0	85.0	95.0	95.0	5.0
61 - 80	76	69.7	78.9	94.7	100.0	0.0
81 - 180	1048	71.6	82.7	92.8	97.2	2.8
181 - 300	486	82.3	90.1	97.5	99.0	1.0
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

YSI Glucose Range (mg/dL)	Number of Paired CGM and YSI	Percent of CGM System Readings Within				
		Percent 15/15% of YSI	Percent 20/20% of YSI	Percent 30/30% of YSI	Percent 40/40% of YSI	Percent Greater than 40/40% of YSI
Overall	5086	89.8	95.2	98.8	99.6	0.4
< 40	4	50.0	75.0	100.0	100.0	0.0
40 - 60	180	92.2	98.3	99.4	100.0	0.0
61 - 80	512	84.8	90.4	97.3	98.4	1.6
81 - 180	2760	87.7	94.1	98.5	99.6	0.4
181 - 300	1425	95.2	98.3	99.8	99.9	0.1
301 - 350	141	92.9	97.9	99.3	100.0	0.0
351 - 400	60	90.0	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

YSI Glucose Range (mg/dL)	Number of Paired CGM and YSI	Percent of CGM System Readings Within				
		Percent 15/15% of YSI	Percent 20/20% of YSI	Percent 30/30% of YSI	Percent 40/40% of YSI	Percent Greater than 40/40% of YSI
Overall	4711	87.5	94.7	98.7	99.7	0.3
< 40	0	--	--	--	--	--
40 - 60	139	87.8	90.6	94.2	96.4	3.6
61 - 80	291	88.0	95.9	98.6	100.0	0.0
81 - 180	2004	87.6	94.5	98.4	99.6	0.4
181 - 300	1781	87.1	94.3	99.1	99.9	0.1
301 - 350	348	88.5	98.0	99.7	100.0	0.0
351 - 400	139	86.3	95.7	99.3	100.0	0.0
> 400	9	88.9	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

YSI Glucose Range (mg/dL)	Number of Paired CGM and YSI	Percent of CGM System Readings Within				
		Percent 15/15% of YSI	Percent 20/20% of YSI	Percent 30/30% of YSI	Percent 40/40% of YSI	Percent Greater than 40/40% of YSI
Overall	4261	82.7	93.0	97.8	99.5	0.5
< 40	0	--	--	--	--	--
40 - 60	98	79.6	85.7	88.8	100.0	0.0
61 - 80	274	79.6	90.1	95.6	99.3	0.7
81 - 180	1750	83.8	92.1	96.9	99.1	0.9
181 - 300	1668	81.3	93.4	99.0	99.7	0.3
301 - 350	323	82.0	97.5	100.0	100.0	0.0
351 - 400	130	94.6	99.2	100.0	100.0	0.0
> 400	18	100.0	100.0	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 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.

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	463	1%	52%	41%	5%	1%	--	--	--	--	--	--
61-80	1149	--	15%	61%	22%	1%	--	--	--	--	--	--
81-120	3053	--	1%	8%	75%	15%	1%	--	--	--	--	--
121-160	3256	--	--	--	12%	71%	16%	1%	--	--	--	--
161-200	2751	--	--	--	--	15%	64%	20%	--	--	--	--
201-250	2617	--	--	--	--	--	13%	68%	19%	1%	--	--
251-300	1454	--	--	--	--	--	1%	16%	57%	24%	1%	--
301-350	711	--	--	--	--	--	--	2%	21%	56%	21%	--
351-400	250	--	--	--	--	--	--	--	1%	23%	63%	12%

Table 12 - CGM System concurrence to YSI organized by CGM glucose ranges; PRECISE II 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	37	--	22%	49%	19%	11%	--	--	--	--	--	--
61-80	99	--	11%	36%	39%	11%	1%	1%	--	--	--	--
81-120	404	--	--	5%	66%	27%	2%	--	--	--	--	--
121-160	434	--	--	--	17%	62%	20%	1%	--	--	--	--
161-200	328	--	--	--	--	20%	65%	15%	1%	--	--	--
201-250	250	--	--	--	--	1%	24%	60%	14%	--	--	--
251-300	82	--	--	--	--	--	4%	32%	55%	10%	--	--
301-350	12	--	--	--	--	--	--	17%	25%	58%	--	--
351-400	0	--	--	--	--	--	--	--	--	--	--	--

Table 13 - CGM System concurrence to YSI organized by CGM glucose ranges; PRECISE II 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	213	2%	52%	41%	6%	--	--	--	--	--	--	--
61-80	518	--	13%	66%	20%	--	--	--	--	--	--	--
81-120	1165	--	--	7%	79%	14%	--	--	--	--	--	--
121-160	1168	--	--	--	11%	77%	11%	--	--	--	--	--
161-200	842	--	--	--	--	12%	71%	16%	--	--	--	--
201-250	669	--	--	--	--	--	11%	77%	12%	--	--	--
251-300	338	--	--	--	--	--	--	14%	68%	17%	1%	--
301-350	114	--	--	--	--	--	--	--	26%	57%	17%	--
351-400	59	--	--	--	--	--	--	--	2%	27%	64%	7%

Table 14 - CGM System concurrence to YSI organized by CGM glucose ranges; PRECISE II 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	151	--	57%	41%	2%	--	--	--	--	--	--	--
61-80	274	--	17%	60%	23%	--	--	--	--	--	--	--
81-120	836	--	1%	8%	78%	13%	--	--	--	--	--	--
121-160	809	--	--	--	10%	73%	17%	--	--	--	--	--
161-200	761	--	--	--	--	16%	65%	18%	1%	--	--	--
201-250	911	--	--	--	--	--	14%	70%	16%	--	--	--
251-300	583	--	--	--	--	--	--	18%	55%	25%	3%	--
301-350	308	--	--	--	--	--	--	2%	16%	60%	22%	--
351-400	78	--	--	--	--	--	--	--	1%	17%	71%	12%

Table 15 - CGM System concurrence to YSI organized by CGM glucose ranges; PRECISE II 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	62	--	58%	39%	3%	--	--	--	--	--	--	--
61-80	258	--	20%	62%	17%	1%	--	--	--	--	--	--
81-120	648	--	2%	14%	70%	14%	1%	--	--	--	--	--
121-160	845	--	--	--	12%	67%	20%	1%	--	--	--	--
161-200	820	--	--	--	1%	14%	57%	28%	--	--	--	--
201-250	787	--	--	--	--	1%	9%	60%	29%	1%	--	--
251-300	451	--	--	--	--	--	2%	12%	53%	32%	1%	--
301-350	277	--	--	--	--	--	--	3%	23%	51%	22%	--
351-400	113	--	--	--	--	--	--	--	1%	26%	58%	16%

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 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; data pooled from accuracy assessments on **days 1, 30, 60, and 90** of the PRECISE II 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	4	100%	--	--	--	--	--	--	--	--
40-60	437	55%	41%	5%	--	--	--	--	--	--
61-80	1153	17%	61%	22%	--	--	--	--	--	--
81-120	2957	1%	9%	78%	13%	--	--	--	--	--
121-160	3227	--	--	14%	72%	12%	--	--	--	--
161-200	265	--	--	1%	20%	67%	12%	--	--	--
201-250	2603	--	--	--	1%	21%	68%	9%	1%	--
251-300	1480	--	--	--	--	1%	33%	56%	10%	--
301-350	828	--	--	--	--	--	2%	43%	48%	7%
351-400	329	--	--	--	--	--	--	6%	46%	48%
>400	31	--	--	--	--	--	--	--	--	100%

Table 17 - CGM System concurrence to YSI organized by YSI glucose ranges; PRECISE II 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	0	--	--	--	--	--	--	--	--	--
40-60	20	40%	55%	5%	--	--	--	--	--	--
61-80	76	24%	47%	29%	--	--	--	--	--	--
81-120	385	2%	10%	69%	19%	--	--	--	--	--
121-160	460	1%	2%	23%	59%	14%	--	--	--	--
161-200	372	--	--	2%	23	57%	16%	1%	--	--
201-250	231	--	--	--	1%	21%	65%	11%	1%	--
251-300	86	--	--	--	--	2%	42%	52%	3%	--
301-350	16	--	--	--	--	--	6%	50%	44%	--
351-400	0	--	--	--	--	--	--	--	--	--
>400	0	--	--	--	--	--	--	--	--	--

Table 18 - CGM System concurrence to YSI organized by YSI glucose ranges; PRECISE II 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	4	100%	--	--	--	--	--	--	--	--
40-60	180	61%	38%	1%	--	--	--	--	--	--
61-80	512	17%	67%	16%	1%	--	--	--	--	--
81-120	1169	1%	9%	79%	11%	--	--	--	--	--
121-160	1165	--	--	14%	77%	9%	--	--	--	--
161-200	804	--	--	--	16%	75%	9%	--	--	--
201-250	704	--	--	--	1%	20%	73%	7%	--	--
251-300	343	--	--	--	--	--	23%	67%	9%	--
301-350	141	--	--	--	--	--	1%	41%	46%	11%
351-400	60	--	--	--	--	--	--	5%	32%	63%
>400	4	--	--	--	--	--	--	--	--	100%

Table 19 - CGM System concurrence to YSI organized by YSI glucose ranges; PRECISE II 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	139	62%	33%	5%	--	--	--	--	--	--
61-80	291	21%	56%	22%	--	--	--	--	--	--
81-120	797	--	8%	82%	10%	--	--	--	--	--
121-160	826	--	--	13%	72%	15%	--	--	--	--
161-200	759	--	--	--	18%	65%	17%	--	--	--
201-250	889	--	--	--	--	16%	72%	12%	1%	--
251-300	514	--	--	--	--	1%	28%	62%	9%	--
301-350	348	--	--	--	--	--	1%	42%	53%	4%
351-400	139	--	--	--	--	--	--	11%	50%	40%
>400	9	--	--	--	--	--	--	--	--	100%

Table 20 - CGM System concurrence to YSI organized by YSI glucose ranges; PRECISE II 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	98	37%	52%	11%	--	--	--	--	--	--
61-80	274	9%	59%	32%	--	--	--	--	--	--
81-120	606	--	7%	75%	16%	1%	--	--	--	--
121-160	776	--	--	11%	73%	14%	1%	--	--	--
161-200	720	--	--	1%	24%	65%	10%	1%	--	--
201-250	779	--	--	--	1%	30%	61%	7%	1%	--
251-300	537	--	--	--	--	1%	43%	45%	12%	--
301-350	323	--	--	--	--	--	2%	45%	44%	9%
351-400	130	--	--	--	--	--	--	2%	48%	50%
>400	18	--	--	--	--	--	--	--	--	100%

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 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).

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, stratified 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	70%	30%	37%	63%
	70	94%	6%	60%	40%
	80	94%	6%	67%	33%
	90	90%	10%	62%	38%
Visit 4 (Day 30)	60	79%	21%	69%	31%
	70	94%	6%	88%	12%
	80	96%	4%	87%	13%
	90	98%	2%	88%	12%
Visit 5 (Day 60)	60	94%	6%	77%	23%
	70	97%	3%	92%	8%
	80	95%	5%	86%	14%
	90	96%	4%	85%	15%
Visit 6 (Day 90)	60	76%	24%	75%	25%
	70	86%	14%	89%	11%
	80	91%	9%	87%	13%
	90	94%	6%	86%	14%

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	93%	7%	94%	6%
	140	96%	4%	93%	7%
	180	95%	5%	87%	13%
	200	93%	7%	83%	17%
	220	91%	9%	76%	24%
	240	83%	17%	73%	27%
	300	94%	6%	67%	33%
Visit 4 (Day 30)	120	99%	1%	96%	4%
	140	99%	1%	95%	5%
	180	97%	3%	94%	6%
	200	96%	4%	93%	7%
	220	98%	2%	92%	8%
	240	97%	3%	90%	10%
	300	86%	14%	85%	15%
Visit 5 (Day 60)	120	99%	1%	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	84%	16%	87%	13%
Visit 6 (Day 90)	120	99%	1%	97%	3%
	140	99%	1%	97%	3%
	180	96%	4%	95%	5%
	200	93%	7%	95%	5%
	220	91%	9%	93%	7%
	240	90%	10%	93%	7%
	300	82%	18%	84%	16%