

## **Appendix 6**

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

### CGM System agreement to SMBG comparator, organized by SMBG ranges

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

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

|            |      | Percent of CGM System Readings within 15/15% of CM |       |       |       |        |        |        |
|------------|------|----------------------------------------------------|-------|-------|-------|--------|--------|--------|
|            |      | Day Ranges                                         |       |       |       |        |        |        |
| SMBG Range | N    | 1-7                                                | 8-14  | 15-29 | 30-44 | 45-59  | 60-74  | 75-90  |
| <40        | 5    | 0.0%                                               | --    | --    | --    | 100.0% | 100.0% | 100.0% |
| 40-60      | 433  | 77.2%                                              | 92.5% | 83.3% | 77.3% | 77.9%  | 89.8%  | 79.2%  |
| 61-80      | 1128 | 78.7%                                              | 78.6% | 84.8% | 76.2% | 72.8%  | 71.6%  | 73.4%  |
| 81-180     | 9586 | 62.9%                                              | 72.3% | 72.7% | 75.8% | 77.8%  | 77.9%  | 72.2%  |
| 181-300    | 5868 | 73.1%                                              | 77.8% | 78.0% | 79.8% | 83.0%  | 80.9%  | 74.1%  |
| 301-350    | 868  | 82.5%                                              | 82.1% | 78.7% | 82.0% | 68.8%  | 76.2%  | 76.3%  |
| 351-400    | 390  | 90.8%                                              | 89.8% | 79.7% | 76.9% | 79.4%  | 58.8%  | 79.5%  |
| >400       | 91   | 60.0%                                              | 80.0% | 35.7% | 37.5% | 60.0%  | 44.4%  | 57.1%  |

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

|            |      | Percent of CGM System Readings within 20/20% of CM |        |       |       |        |        |        |
|------------|------|----------------------------------------------------|--------|-------|-------|--------|--------|--------|
|            |      | Day Ranges                                         |        |       |       |        |        |        |
| SMBG Range | N    | 1-7                                                | 8-14   | 15-29 | 30-44 | 45-59  | 60-74  | 75-90  |
| <40        | 5    | 50.0%                                              | --     | --    | --    | 100.0% | 100.0% | 100.0% |
| 40-60      | 433  | 87.7%                                              | 98.1%  | 88.5% | 90.9% | 89.7%  | 91.8%  | 84.9%  |
| 61-80      | 1128 | 88.5%                                              | 90.6%  | 93.4% | 86.7% | 89.2%  | 83.7%  | 81.2%  |
| 81-180     | 9586 | 75.5%                                              | 83.2%  | 85.3% | 87.3% | 88.5%  | 87.7%  | 83.6%  |
| 181-300    | 5868 | 81.4%                                              | 89.8%  | 90.0% | 89.1% | 92.0%  | 93.4%  | 85.0%  |
| 301-350    | 868  | 94.2%                                              | 94.9%  | 90.2% | 93.7% | 89.9%  | 87.1%  | 84.2%  |
| 351-400    | 390  | 96.9%                                              | 94.9%  | 93.2% | 84.6% | 92.1%  | 78.4%  | 88.6%  |
| >400       | 91   | 80.0%                                              | 100.0% | 78.6% | 50.0% | 73.3%  | 63.0%  | 85.7%  |

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

|            |      | Percent of CGM System Readings within 30/30% of CM |        |        |       |        |        |        |
|------------|------|----------------------------------------------------|--------|--------|-------|--------|--------|--------|
|            |      | Day Ranges                                         |        |        |       |        |        |        |
| SMBG Range | N    | 1-7                                                | 8-14   | 15-29  | 30-44 | 45-59  | 60-74  | 75-90  |
| <40        | 5    | 100.0%                                             | --     | --     | --    | 100.0% | 100.0% | 100.0% |
| 40-60      | 433  | 93.0%                                              | 98.1%  | 98.7%  | 97.0% | 97.1%  | 95.9%  | 92.5%  |
| 61-80      | 1128 | 97.7%                                              | 97.4%  | 99.5%  | 99.3% | 97.5%  | 94.3%  | 89.6%  |
| 81-180     | 9586 | 89.7%                                              | 94.1%  | 95.9%  | 95.9% | 97.0%  | 95.4%  | 93.5%  |
| 181-300    | 5868 | 94.6%                                              | 97.3%  | 97.7%  | 97.9% | 98.2%  | 98.3%  | 93.0%  |
| 301-350    | 868  | 99.3%                                              | 100.0% | 97.0%  | 98.2% | 99.1%  | 99.0%  | 93.9%  |
| 351-400    | 390  | 98.5%                                              | 100.0% | 100.0% | 97.4% | 100.0% | 92.2%  | 97.7%  |
| >400       | 91   | 100.0%                                             | 100.0% | 92.9%  | 75.0% | 86.7%  | 88.9%  | 92.9%  |

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

|            |      | Percent of CGM System Readings within 40/40% of CM |        |        |        |        |        |        |
|------------|------|----------------------------------------------------|--------|--------|--------|--------|--------|--------|
|            |      | Day Ranges                                         |        |        |        |        |        |        |
| SMBG Range | N    | 1-7                                                | 8-14   | 15-29  | 30-44  | 45-59  | 60-74  | 75-90  |
| <40        | 5    | 100.0%                                             | --     | --     | --     | 100.0% | 100.0% | 100.0% |
| 40-60      | 433  | 93.0%                                              | 100.0% | 98.7%  | 98.5%  | 97.1%  | 98.0%  | 92.5%  |
| 61-80      | 1128 | 98.9%                                              | 98.3%  | 99.5%  | 100.0% | 99.4%  | 97.9%  | 92.9%  |
| 81-180     | 9586 | 96.1%                                              | 97.6%  | 98.5%  | 98.5%  | 99.0%  | 98.6%  | 96.5%  |
| 181-300    | 5868 | 98.8%                                              | 98.3%  | 99.1%  | 99.2%  | 99.8%  | 99.5%  | 96.3%  |
| 301-350    | 868  | 100.0%                                             | 100.0% | 98.8%  | 100.0% | 99.1%  | 100.0% | 94.7%  |
| 351-400    | 390  | 100.0%                                             | 100.0% | 100.0% | 97.4%  | 100.0% | 98.0%  | 100.0% |
| >400       | 91   | 100.0%                                             | 100.0% | 92.9%  | 75.0%  | 86.7%  | 92.6%  | 100.0% |

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

|            |      | Percent of CGM System Readings beyond 40/40% of CM |      |       |       |       |       |       |
|------------|------|----------------------------------------------------|------|-------|-------|-------|-------|-------|
|            |      | Day Ranges                                         |      |       |       |       |       |       |
| SMBG Range | N    | 1-7                                                | 8-14 | 15-29 | 30-44 | 45-59 | 60-74 | 75-90 |
| <40        | 5    | 0.0%                                               | --   | --    | --    | 0.0%  | 0.0%  | 0.0%  |
| 40-60      | 433  | 7.0%                                               | 0.0% | 1.3%  | 1.5%  | 2.9%  | 2.0%  | 7.5%  |
| 61-80      | 1128 | 1.1%                                               | 1.7% | 0.5%  | 0.0%  | 0.6%  | 2.1%  | 7.1%  |
| 81-180     | 9586 | 3.9%                                               | 2.4% | 1.5%  | 1.5%  | 1.0%  | 1.4%  | 3.5%  |
| 181-300    | 5868 | 1.2%                                               | 1.7% | 0.9%  | 0.8%  | 0.2%  | 0.5%  | 3.7%  |
| 301-350    | 868  | 0.0%                                               | 0.0% | 1.2%  | 0.0%  | 0.9%  | 0.0%  | 5.3%  |
| 351-400    | 390  | 0.0%                                               | 0.0% | 0.0%  | 2.6%  | 0.0%  | 2.0%  | 0.0%  |
| >400       | 91   | 0.0%                                               | 0.0% | 7.1%  | 25.0% | 13.3% | 7.4%  | 0.0%  |