device, which, in this case, is a home-monitoring BG meter. This error boundary for hypoglycemia is 70–85 mg/dl and 20% for hyperglycemia based on CLSI guidelines.[17] The charts illustrate the sensitivities reported previously, including the percentage of both threshold and predicted alerts for a 15-minute prediction horizon. Likewise, the specificities are shown for true and false threshold alerts. As the PRT algorithm does not include predictive alerts, but has the same calibration algorithm as the Revel and Guardian devices, its performance can be derived from **Figure 2** by only including threshold alerts in the calculations.

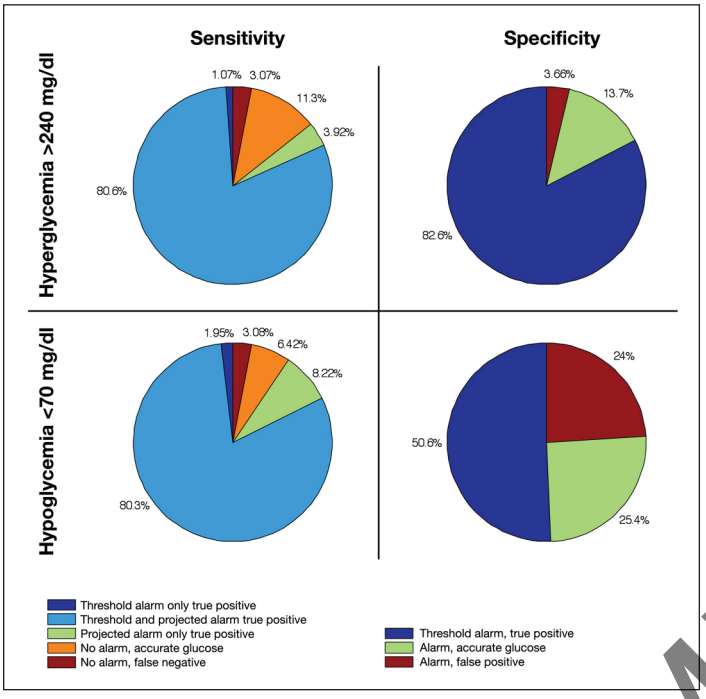

Figure 1. Veo algorithm sensitivity and specificity analyses for hypo- and hyperglycemic events.

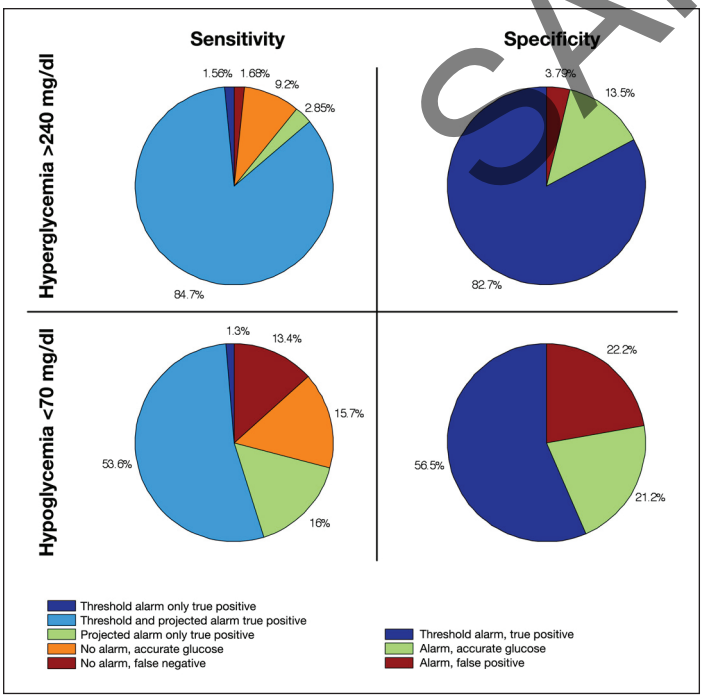

Figure 2. Revel and Guardian REAL-Time algorithm sensitivity and specificity analyses for hypo- and hyperglycemic events.

In the following alarm categories—threshold, threshold and projected, projected, no alarm accurate glucose, and false negative—when applying a 30-minute prediction horizon for hypoglycemia detection, the Veo algorithm generated accuracies of 2.62, 79.7, 11.4, 4.02, and 2.29%, respectively. Applying the same 30-minute prediction horizon to Guardian and Revel algorithms produced accuracies of 7.29, 47.6, 20.1, 13.8, and 11.3%, respectively.

Over 14 hours of data is illustrated in **Figure 3** for rates of change in excess of 1 mg/dl/min, and greater rates on the decline. The 330-mg/dl calibration sample before hour 28 resulted in the PRT algorithm overreading proceeding low glucose levels and consequently failing to detect the 59-mg/dl (PRT = 81 mg/dl) hypoglycemic event at hour 34, whereas the Veo algorithm detected the event several hours before the meter indicated a hypoglycemic episode.

Clarke and consensus error grid analyses are presented in **Tables 5** and **6**. Results are comparable—with greater than 97% of all readings in the A + B zones of the consensus error grid for both algorithms and in all ranges, with the exception of the PRT algorithm in the 40- to 80-mg/dl range. In this range, the new algorithm shows a 4% improvement. No points reside within the E zone of the consensus error grid for either algorithm. Similarly, results are comparable throughout most ranges for Clarke error grid analysis, with the exception of low

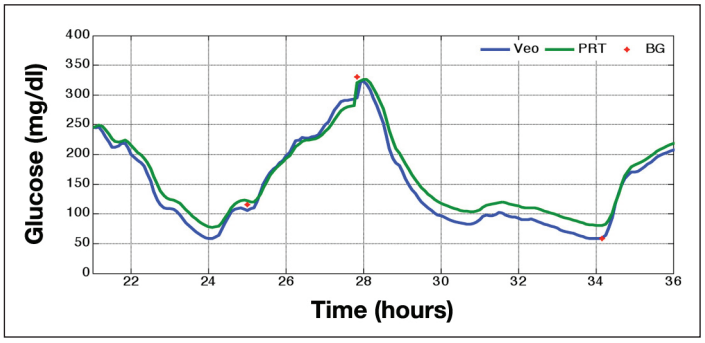

Figure 3. Sensor tracings for PRT and Veo calibration algorithms.