# Development and validation of a pattern recognition engine for visualization of glycemic patterns

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## Introduction

Review of self-monitoring blood glucose data (SMBG) is a key tool for structured assessment of mean blood glucose, hypoglycemia and hyperglycemia rates [1-3], and can play an important role in guiding therapeutic decisions. Furthermore, existing findings show that interventions including SMBG may reduce HbA1c more than interventions without SMBG [4].

Nevertheless, the use of SMBG in clinical practice could be improved. An analysis of SMBG data from over 13,000 patients with type 2 diabetes shows that the frequency of SMBG is suboptimal both in patients not treated with insulin (frequency less than once a day) and treated with insulin (frequency less than two times per day) [5]. On the other hand, healthcare professionals (HCP) struggle with time constraints, and do not have the time to download and review SMBG data in detail.

Interpretation of SMBG data patterns can shed light on the reasons for poor glycemic control and suggest possible management strategies [6]. It is essential to provide HCPs with tools that maximize the utility of SMBG data, by promptly highlighting and interpreting patterns that may otherwise remain unidentified. That will also help maintain patients' motivation to test regularly their BG levels.

We have developed a **Pattern Recognition Engine** (PRE) for visualizing hypoglycemic and hyperglycemic patterns to improve the utility of SMBG data.

## Methods

The Pattern recognition engine is part of MyStar Connect®, a diabetes data management software co-developed by Sanofi and Meteda, that allows systematic revision of SMBG data. [7]

The PRE focuses on the episodes of hypoglycemia and hyperglycemia, and evaluates all data as single points (overall averages may be influenced by outliers).

We leverage HCPs familiarity with the Modal day and Trend graphs, the reports most often used to review SMBG data. We then highlight the patterns on the reports: in red for hypoglycemic and in orange for hyperglycemic ones.

**Modal day (Figure 1)**: The patterns highlight the times of day when the patient had more frequent hypoglycemic (<70mg/dl) or hyperglycemic (>180 mg/dl) episodes, that may be linked to the patient's daily routine. The recurrence of these episodes is calculated over a period of up to 4 weeks. 2 or more hypo- or hyperglycemic values within 30 minutes are considered as a single episode. A pattern is detected when at least 2 hypo- or 3 hyperglycemic episodes are identified in a period of up to 3 hours (180 minutes), and their density is significantly higher in relation of the total of the glucose values done in the same period. The time period is up to 3 hours, with a rolling window of 1 minute, calculated by moving the window forward one observation at a time: the shorter the period, the greater the density of the data is in that time frame, suggesting a greater relevance of the pattern.

**Trend (Figure 2)**: The patterns highlight the weeks in which the patient had more frequent hypoglycemic (<70mg/dl) or hyperglycemic (>180 mg/dl) episodes, that may be linked to a change in the patient's treatment or lifestyle. The recurrence of the episodes is calculated over a period of up to 3 months. A pattern is detected when at least 2 hypo- or 3 hyperglycemic episodes are identified in a week, and the frequency of the episodes is significantly higher in that week than the average for the period.

## Results

Below are the preliminary results and visualizations of the PRE. The highlighted areas help identify the time of day or the weeks with clinically significant events.

**Figure 1: Modal Day**

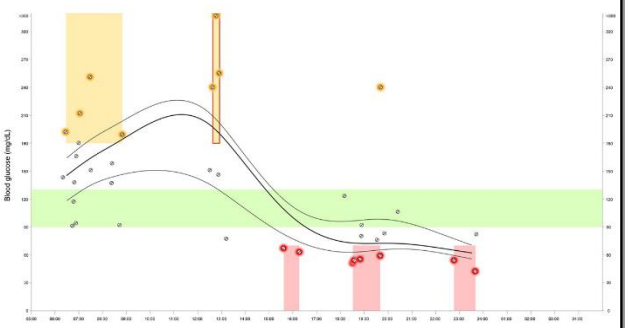
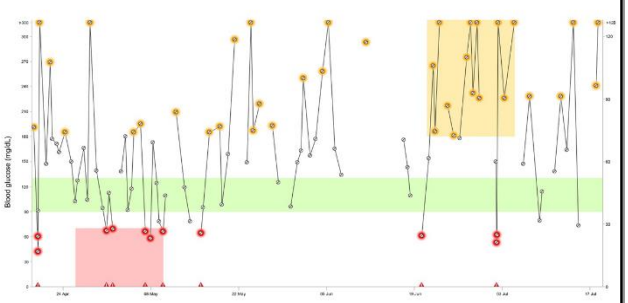



**Figure 2: Trend**




To confirm that all patterns identified by the PRE are clinically relevant, the system will undergo a validation process using 3-month SMBG data from 182 insulin and non-insulin treated patients. The process, which will be conducted separately for hypoglycemic and hyperglycemic patterns, is listed below:

- Available glycemic data will be independently evaluated by 3 expert assessors. The assessors are diabetologists with more than 15 years of clinical practice.
- Hypoglycemic and hyperglycemic patterns identified by each assessor will be compared to those identified by PRE.
- False-positive and false-negative rates will be considered and the rate of agreement between each assessor and PRE will be measured.
- In case of discrepancy, each assessor will be able to re-examine the case on the computer screen and decide, on the basis of more detailed information, whether to confirm the discrepancy or agree with the PRE.
- The 3 assessors will review together all cases in which discrepancy was identified and confirmed.
- When the assessors reach a joint agreement about any discrepancy with PRE, all required modifications will be implemented in the PRE system.

Finally, the PRE engine will be complemented by messages listing the possible causes for the glycemic patterns, to further facilitate the HCP in adjusting the patient's treatment.

## Conclusions

PRE is a user-friendly tool which allows the interpretation of SMBG data through simple and straightforward visualizations.

If the PRE proves to be effective in the identification of clinically relevant glycemic patterns, its implementation will represent a useful tool to guide treatment decisions and educate patients, thus minimizing the risk of hypoglycemia, hyperglycemia and excessive blood glucose fluctuations.

## References

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