Impact of Insulin and Carbohydrate Logging on the Performance of Glucose Prediction-The Accu-Chek® SmartGuide Predict App

Pau Herrero[1], Nils Babion[2], Hendericus Bos[3], Matthias Koehler[2], Yannick Klopfenstein[4], Eemeli Leppäaho[5], Patrick Lustenberger[4], Ajandek Peak[6], Christian Ringemann[2], Timor Glatzer[2]

[1]Roche Diabetes Care Spain, [2]Roche Diabetes Care GmbH, [3]IBM Client Innovation Center, [4]IBM Switzerland Ltd, [5]Oy IBM Finland Ab, [6]IBM Deutschland GmbH

Introduction & Objective

- Despite the significant increase in the utilization of continuous glucose monitoring (CGM) technology, the prevalence of diabetes distress and fear of hypoglycemia remains high, and many users continue to face challenges in achieving their glycemic targets. **[1]**
- While automated insulin delivery (AID) has been proven effective in improving glycemic outcomes, it is widely acknowledged that its suitability is significantly influenced by human factors and accessibility to the technology. **[2]**
- Most existing CGM digital companions only offer visualizations of past and present CGM values, which limits their utility to reactive management of glucose levels. Hence, it is crucial to provide users with CGM solutions that enable a more proactive and data-driven approach. **[3]**
- To address this gap, we propose the **Accu-Chek® SmartGuide Predict** app, an innovative CGM digital companion that incorporates a suite of advanced glucose predictive functionalities aiming to inform users earlier about acute glycemic situations.

Methods

- The **Accu-Chek® SmartGuide Predict** app, which is part of the **Accu-Chek® SmartGuide CGM solution*** (Figure 1), includes the following functionalities:

1. ***Glucose Predict (GP)***: a continuous forecast that visualizes glucose levels over the next 2 hours;
2. ***Low Glucose Predict (LGP)***: a notification system warning users up to 30-min before a low glucose event occurs;
3. ***Night Low Predict (NLP)***: a night guardian estimating the risk of hypoglycemia during the the upcoming night;
4. ***Glucose Patterns***: automatic detection and visualization of daily and weekly glucose patterns.

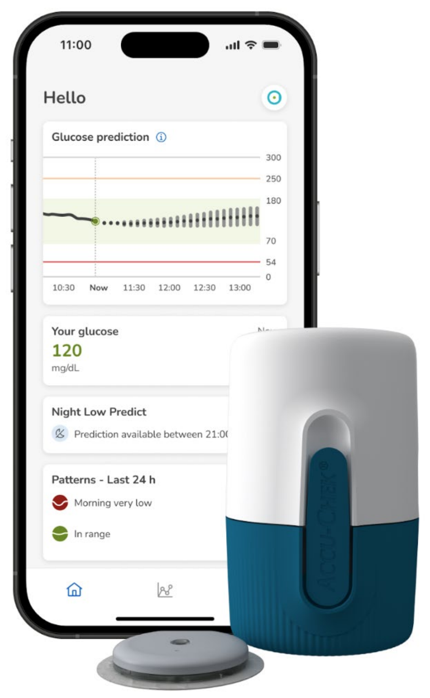

Figure 1. Accu-Chek® SmartGuide CGM solution*

*Accu-Chek® SmartGuide CGM solution is not FDA cleared or available for sale in the US.

Methods (continued)

- The three machine learning models powering the three predictive functionalities (***GP***, ***LGP***, ***NLP***) were developed using a proprietary dataset including 221 adult subjects with type 1 diabetes on multiple daily injections (MDI) therapy and CGM (PREDICT study).
- For training the three predictive models, 200 subjects were randomly selected from the PREDICT study, while the remaining 21 subjects were left for model validation. In addition, two external datasets were employed for validation purposes (Table 1).

Table 1. Data characteristics of the three employed validation datasets.

Dataset	n	Subject days	Diabetes	Therapy	Data type
PREDICT	21	~800	Type 1	CGM+MDI	Clinical Trial (Proprietary)
REPLACE-BG [4]	201	~51k	Type 1	CGM+Pump	Clinical Trial (Public)
MYSUGR	59	~12k	Type 2	CGM+MDI	Real-world (Proprietary)
TOTAL	281	~64k	–	–	–

- The development of the app relied on collecting objective user feedback through usability studies.

Results

Table 2. Performance of the ***GP*** model when evaluated on the three validations sets and pooled data for the prediction horizons of 30, 60, and 120 minutes. Metrics: percentage of data points in zones A&B of the Parkes Error Grid, root mean square error (RMSE), and mean absolute relative difference (MARD). The pooled data was generated by combining a balanced selection of data points from the three datasets. Results compare favorably, or at par, with the scientific literature. **[5,6,7,8].**

Dataset	Horizon [min]	A&B [%]	RMSE [mg/dL]	MARD [%]
PREDICT	30	99.7	18.5	8.4
	60	98.5	29.7	13.9
	120	95.7	42.3	21.3
REPLACE-BG*	30	99.6	17.6	8.6
	60	97.9	28.9	15.1
	120	94.2	42.2	23.5
MYSUGR	30	100.0	16.4	6.9
	60	99.7	26.2	11.1
	120	98.9	36.7	16.2
POOLED	30	99.8	17.5	7.9
	60	98.7	28.3	13.3
	120	96.3	40.4	20.3

*The source of the REPLACE-BG data set (NCT02258373) is Jaeb Center of Health Research. The analyses, content and conclusions presented herein are solely the responsibility of the authors and have not been reviewed or approved by Jaeb Center of Health Research.

Results (continued)

Table 3. Performance of the ***LGP*** model when evaluated on the three test datasets and pooled data. Results compare favorably, or at par, with the scientific literature. **[9,10, 1**

Dataset	Accuracy [%]	Sensitivity [%]	Specificity [%]	Lead Time [min]	ROC AUC [0.5-1]
PREDICT	98.6	95.3	98.6	16.2	0.951
REPL.-BG	98.6	95.3	98.7	16.4	0.951
MYSUGR	99.3	95.3	99.3	15.4	0.969
POOLED	98.9	95.2	98.9	16.2	0.958

Table 4. Performance of the ***NLP*** model when evaluated on the three test datasets and pooled data. Results compare favorably, or at par, with the scientific literature. **[12,13, 14,15]**

Dataset	Accuracy [%]	Sensitivity [%]	Specificity [%]	ROC AUC [0.5-1]
PREDICT	85.9	67.2	90.3	0.882
REPL.-BG	77.0	50.7	85.0	0.772
MYSUGR	93.8	32.1	97.0	0.851
POOLED	86.5	55.3	91.6	0.859

- Usability studies showed understanding of the app's functionalities and willingness to use its features. Task completion rate was 98.1%, indicating high success.

Conclusions

- The machine learning models powering the three predictive features within the **Accu-Chek® SmartGuide Predict** app underwent extensive testing using various clinical and real-world datasets, including data from individuals with type 1 and type 2 diabetes on MDI or pump therapy.
- The results from such evaluation provide reassurance that the demonstrated performance should translate into valuable real-world usage of the app, benefiting people with diabetes in their daily management.
- Usability studies suggest high user satisfaction, engagement, and retention with the app. However, verification is needed once the app is deployed and used over an extended duration.

References

1. Chatwin et al., J Diabetes Complications. 2023 1;37(11):108232. **DOI:** 10.1016/j.diabres.2021.108752
2. Marigliano et al., Journal of Personalized Medicine. 2023;13(7):1031. **DOI:** 10.3390/jpm13071031
3. Barnard-Kelly et al,. Diabet Med. 2024; 12:e15338. **DOI:** 10.1111/dme.15338.
4. Aleppo et al., Diabetes Care. 2017;40(4):538-545. **DOI:** 10.2337/dc16-2482
5. Georga et al., Med Biol Eng Comput. 2019;57:27-46. **DOI:** 10.1007/s11517-018-1859-3
6. Seo et al, Comput Methods Programs Biomed. 2021;211:106424. **DOI:** 10.1016/j.cmpb.2021.106424
7. Kushner et al., Diabetes Technol Ther. 2020;22(12):883-891. **DOI:** 10.1089/dia.2020.0061
8. Zhu et al., IEEE Trans Biomed Eng . 2023;70(1):193-204. **DOI:** 10.1109/TBME.2022.3187703.
9. Cichosz et al., J Diabetes Sci Technol. 2015 Jan; 9(1): 132–137. **DOI:** 10.1177/1932296814549830
10. Dave et al, JMIR Diabetes. 2021; 6(2): e26909. **DOI**: 10.2196/26909
11. Zhu et al. npj Digital Medicine, 5(1), 78. **DOI**: 10.1038/s41746-022-00626-5
12. Mosquera-Lopez et al,. Diabetes Technol Ther. 2020;22(11):801-811. **DOI**: 10.1089/dia.2019.0458.
13. Parcerisas et al., Sensors (Basel) . 2022 Feb 21;22(4):1665. **DOI**: 10.3390/s22041665.
14. Jensen et al. J Diabetes Sci Technol . 2020;14(2):250-256. **DOI:** 10.1177/1932296819868727.
15. Mosquera-Lopez et al., J Am Med Inform Assoc . 2023 Dec 22;31(1):109-118. **DOI:** 10.1093/jamia/ocad196.