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## **Glucose Monitoring Systems - general rules of use and chances in therapy of type 1 diabetes**

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## **ABSTRACT**

**Introduction:** Glycemic control and maintaining it within the desired range are essential for achieving therapeutic goals in patients with type 1 diabetes. Over the years, patients have gained access to advanced glycemic monitoring technologies that have revolutionized self-monitoring methods. These technologies provide data that was previously unavailable to glucometer users. They allow creating new goals to minimize the risk of diabetic complications.

**Purpose of the work:** The goal of this study was to answer the following questions: What additional information do glycemic monitoring systems offer to patients compared to glucometers? How should this information be utilized to make therapeutic decisions? Do these systems lead to improved glycemic management?

**Materials and Methods:** A literature review was made using PubMed, Springer Link and Google Scholar databases, searching for articles published in English and Polish up to May 2023, focusing on type 1 diabetes and glucose monitoring systems.

**Summary:** The use of glycemic monitoring systems provides additional information compared to relying only on glucometers. Patients equipped with a glucose monitoring system can make more accurate therapeutic decisions based on a larger volume of data. Some continuous glucose monitoring systems offer additional features compatible with personal insulin pumps, preventing or reducing the intensity and duration of hypoglycemia. Patients using glycemic monitoring systems can more frequently achieve therapeutic goals.

**Keywords:** type 1 diabetes, glucose monitoring systems, trends

## **Introduction.**

On January 1, 2023, the rules of public co-financing for the purchase of glycemic monitoring systems changed in Poland. [1] It allowed to significantly increase the target group of patients for whom such solutions were previously unattainable due to high costs. The data transferred from these systems allow for a more accurate observation of dynamically changing glycemic

levels, making more accurate therapeutic choices by patients, and making it easier for doctors to introduce changes in existing therapy.

### **General principles of operation of CGM/FGM systems.**

The most popular systems used by patients in Poland consist of a sensor placed in the subcutaneous tissue, which is replaced every few days and a transmitter. They connect wirelessly with the reader, which can be a dedicated device provided by the manufacturer, a mobile phone or an insulin pump. In FGM systems, the user obtains information about the current glycemic level after bringing the reader closer to the transmitter. In CGM systems, this process is automatic and does not require patient activity. The sensor takes readings every 1-5 minutes, which allows to obtain up to 1440 measurements per day. [2] Unlike glucometers, the measurement is performed not using capillary blood, but interstitial fluid in which the microfilament is immersed. This causes a time shift of the sensor readings (so-called lag time) in relation to the readings from the glucometer, up to several minutes. This is important in the case of dynamically changing blood glucose values, which may then be discrepant between the sensor and the glucometer. [3] However, this does not mean that the sensor does not work properly or is worse than traditional measurement methods. The patient's understanding of this basic operating principle helps to avoid frustration and loss of confidence in sensor readings.

### **Goals of therapy in type 1 diabetes.**

The goals of therapy for patients using glycemic monitoring systems and glucometers in terms of glycated hemoglobin (HbA1c) are the same. The Polish Diabetes Association (PTD) recommends  $HbA1c \leq 7\%$  as a general goal.

For individual groups of patients, this goal differs and amounts to:

$\leq 6.5\%$  for patients with type 1 diabetes, only if achieving this goal is not associated with an increased risk of hypoglycemia and reduced quality of life; in patients with type 2 diabetes, when the diagnosis was made no later than 5 years ago; and in children and adolescents regardless of the type of diabetes,

$\leq 8.0\%$  in elderly patients with a long diabetic history and significant macrovascular complications and/or other multiple comorbidities,

$\leq 6.5\%$  in patients with pre-gestational diabetes mellitus planning pregnancy, for whom the target is  $\leq 6.0\%$  during the 2nd and 3rd trimester of pregnancy, if it does not carry the risk of more frequent hypoglycaemia,

≤ 7.0% as the HbA1c target for patients elder than 65 years, who meet overall treatment goals and have a life expectancy greater than 10 years. [4]

Unfortunately, glycated hemoglobin is not an ideal parameter for assessing diabetes control. [5] Its value shows the average glycemic level over the last three months, while the last month's glycemic values have influence on 50% of the HbA1c value. In addition, its value varies depending on individual characteristics, which include e.g. the lifespan of the red blood cell, the presence of anemia, history of bleeding, or the concentration of urea. [6] A patient with large diurnal glycemic fluctuations with multiple hyper- and hypoglycaemia may have in-range glycated hemoglobin concentration, but will not be a well-controlled diabetic patient. [7] Thanks to glucose monitoring systems, we can obtain additional parameters such as TIR (Time In Range), TBR (Time Below Range) and TAR (Time Above Range). TIR is the percentage of time in a given period that sensor readings are in target range. TAR applies to readings above this range and TBR below. [8] According to the latest PTD guidelines, this parameter should be one of the basic parameters in assessing glycemic control. The authors of the guidelines have detailed the length of periods in which glycemic levels should be maintained, divided into five ranges for patients with type 1 diabetes and four ranges for pregnant women with type 1 diabetes. [4]

**Table 1.** Target values for TIR, TBR, TAR in patients with type 1 diabetes.

	TIR		TBR		TAR	
	percentage of readings (time)	Target value	percentage of readings (time)	Target value	percentage of readings (time)	Target value
Type 1 diabetes	>70%	70-180 mg/dL	<4% <1%	<70 mg/dL <54 mg/dL	<25% <5%	>180 mg/dL >250 mg/dL
Pregnant with type 1 diabetes	>70%	63-140 mg/dL	<4% <1%	<63 mg/dL <54 mg/dL	<25%	>140 mg/dL

### Daily use of FGM/CGM systems.

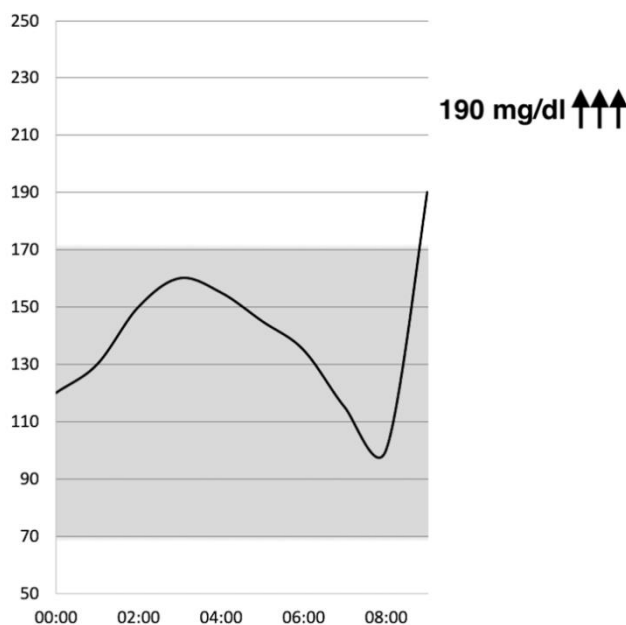
An important advantage of FGM/CGM is not only the number of available measurements, but also the so-called ‘trends’ informing the patient about the expected change in blood glucose levels in the future. Thanks to this, the patient knows what glycemia he had in the past, has currently and knows the expected reading in the future. [9] In the literature [10-12], there are suggestions for modifying the insulin dose, which would take into account not only the

current glycaemia, but also the above-mentioned trend. In this case, to calculate the required dose of insulin, in addition to information on the amount of carbohydrates consumed, correction for glycemia and planned physical activity, information about the trend can be included. The FGM/CGM systems distinguish several rates of change in blood glucose levels, expressed as a difference in mg/dL in one minute (mg/dL/min).

**Table 2.** Modification of insulin boluses depending on the trend.

Change in blood glucose (BG) value (trend)	Modification of the bolus (including mealtime and correction dose)
BG falls >2 mg/dL per minute	20% dose reduction
BG falls 1-2 mg/dL per minute	10% dose reduction
Blood glucose change < 1 mg/dL per minute	Dose unchanged
Increase in blood glucose 1-2 mg/dL per minute	Dose increase by 10%
Increase in blood glucose >2 mg/dL per minute	Dose increase by 20%

**Figure No. 1.** An example view of the current sensor reading along with the trend and data from the last hours



Trend information should also be used by patients to make therapeutic decisions following postprandial glucose control. Taking into account the trend can help to avoid hypoglycemia or prevent hyperglycemia and its worsening by reacting earlier. [13] The trend helps in the selection of the insulin dose, but it can also protect against hasty administration of corrective doses. Algorithms vary depending on the treatment method. It should be remembered that in each case factors affecting the dynamics of changes in postprandial glycemia should be taken into account: the size of the mealtime bolus, the time interval between insulin administration

and the start of the meal (additionally, the speed of eating this meal), glycemic index of eaten food and physical activity. [11]

**Table 3.** Proposed therapeutic decision in patients treated with multiple insulin injections + FGM/CGM. In the postprandial period >1–1.5 hours after rapid-acting insulin analog bolus / > 2.5 hours after a bolus of human insulin

Blood glucose (mg/dL)		<100	100-150	150-250	>250
1-2 mg/dL/min decrease in blood glucose		10-15g glucose	Trend verification in 15 min	Trend verification in 30 min	Correction bolus reduced by 10%
>2 mg/dL/min decrease in blood glucose		15-25g glucose	Consider 10g of glucose. Trend verification in 15 minutes.	Trend verification in 15 minutes.	Correction bolus reduced by 20%
Blood glucose (mg/dL)	<150	150-200	200-250	>250-300	
Increase in glycemic values 1–2 mg/dL/min.	Trend verification in 30-60 minutes.	Correction bolus should be considered	Correction bolus + possibly 10% dose increase	Correction bolus + 10% dose increase	
Increase in glycemic values >2 mg/dL/min.	Trend verification in 15-30 minutes.	Correction bolus should be considered	Correction bolus* + possibly 20% dose increase	Correction bolus* + 20% dose increase	

\*Glycemic verification using a glucometer

Patients treated with personal insulin pumps can additionally use the so-called ‘bolus calculator’. It is a tool that facilitates the calculation of the required dose of insulin, which bases its results on: meal size (the term ‘carbohydrate portion (CP)’ is most often used, which corresponds to 10g of available carbohydrates), current blood glucose, active insulin from previous boluses, insulin demand (how much units of insulin per 1 CP, or how many CP per 1 unit of insulin) and insulin sensitivity (what decrease in blood glucose can be expected in a patient after administering 1 unit of insulin). [14] In practice, a patient with an personal insulin pump when calculating the necessary mealtime dose of insulin, enters only the data on the current glycemia and the amount of CP that he plans to consume. The rest of the data is

pre-stored in the insulin pump memory. Insulin demand and sensitivity can be changed depending on individual needs. Trends informing about a decrease in glycemia should be additionally taken into account, e.g. in the postprandial period. [11]

**Table 4.** Suggested therapeutic decisions based on the trend of glycemic drop for patients treated with insulin pumps without automatic suspension of insulin supply in case of hypoglycemia (applies to FGM and CGM) in the postprandial period >1–1.5 hours after a bolus of rapid-acting insulin analog

Blood glucose	< 100 mg/dL	100-150 mg/dL	150-250 mg/dL	250 mg/dL
1-2 mg/dL/min decrease in blood glucose	10–15 g glucose. Suspension of the extended bolus. Temporary basal rates of 0% for 30 min*	Basal insulin rates of 0% for 30–60 min and trend verification within 30 min	Trend verification within 30 min	Correction* according to bolus calculator decreased by 10%
>2 mg/dL/min decrease in blood glucose	20 g glucose. Suspension of the extended bolus. Temporary basal rates of 0% for 30 min*	Basal insulin rate of 0% for 30–60 min. 10 g glucose and/or suspension of the extended bolus should be considered	Trend verification within 15 min	Correction* according to bolus calculator decreased by 20%

\*Glycemic verification using a glucometer

Some personal insulin pumps connect to CGM systems and form one larger system. Some of them have been equipped with additional functionality that allows to temporarily stop the supply of insulin. It makes it possible to shorten the duration of hypoglycaemia, reduce its severity and reduce the glucose intake. This feature affects not only the hypoglycemia, but also the hyperglycemia generated as a result of hypoglycemia treatment. [15] *MiniMedVEO - Medtronic* is a pump with the ability to automatically suspend insulin delivery in the event of hypoglycemia, and the suggestions for trends indicating a decrease in blood glucose differ from those for pumps not equipped with this function.

**Table 5.** Suggestions for therapeutic decisions based on the trend of glycemic drop for patients treated with insulin pumps with automatic suspension of insulin supply in case of hypoglycemia (*MiniMedVEO - Medtronic*) In the postprandial period > 1–1.5 hours after a bolus of rapid-acting insulin analog

Blood glucose	< 100 mg/dL	100-150 mg/dL	150-250 mg/dL	250 mg/dL
1-2 mg/dL/min decrease in blood glucose	5–10 g glucose. Suspension of the extended bolus. Temporary basal rates of 0% for 30 min*	Temporary basal rates of 0% for 30 min and trend verification within 30 min	Trend verification within 30 min	Correction* according to bolus calculator decreased by 10%
>2 mg/dL/min decrease in blood glucose	10–20 g glucose. Suspension of the extended bolus. Temporary basal rates of 0% for 30 min*	Temporary basal rates of 0% for 30 min. Consider 10 g glucose and/or suspension of the extended bolus should be considered	Trend verification within 15 min	Correction* according to bolus calculator decreased by 20%

\*Glycemic verification using a glucometer

The *MiniMed 640G - Medtronic* pump can automatically predict impending hypoglycemia and stop the insulin infusion before it occurs. This ability to predict the future and its automatic response requires a change in the patient's behavior. A pump user should remember that countermeasures to hypoglycaemia have already been taken by the device and it is not required to consume as much glucose as in the case of patients not using this type of insulin pumps. [11, 16]



**Table 6.** Proposals of therapeutic decisions based on the trend of glycemic drop for patients treated with insulin pumps with automatic suspension of insulin supply in the event of imminent hypoglycemia (*MiniMed 640G, Medtronic*) in the postprandial period >1-1.5 hours after a bolus of rapid-acting insulin analog

Blood glucose	< 100 mg/dL	100-150 mg/dL	150-250 mg/dL	>250 mg/dL
1-2 mg/dL/min decrease in blood glucose	Consider 5 g glucose	No reaction	No reaction	Correction* according to bolus calculator decreased by 10%
2-3 mg/dL/min decrease in blood glucose	5-10 g glucose	Consider 5 g glucose	No reaction	Correction* according to bolus calculator decreased by 20%
>3 mg/dL/min decrease in blood glucose	10-20 g glucose	5-10 g glucose	No reaction	Correction* according to bolus calculator decreased by 10%

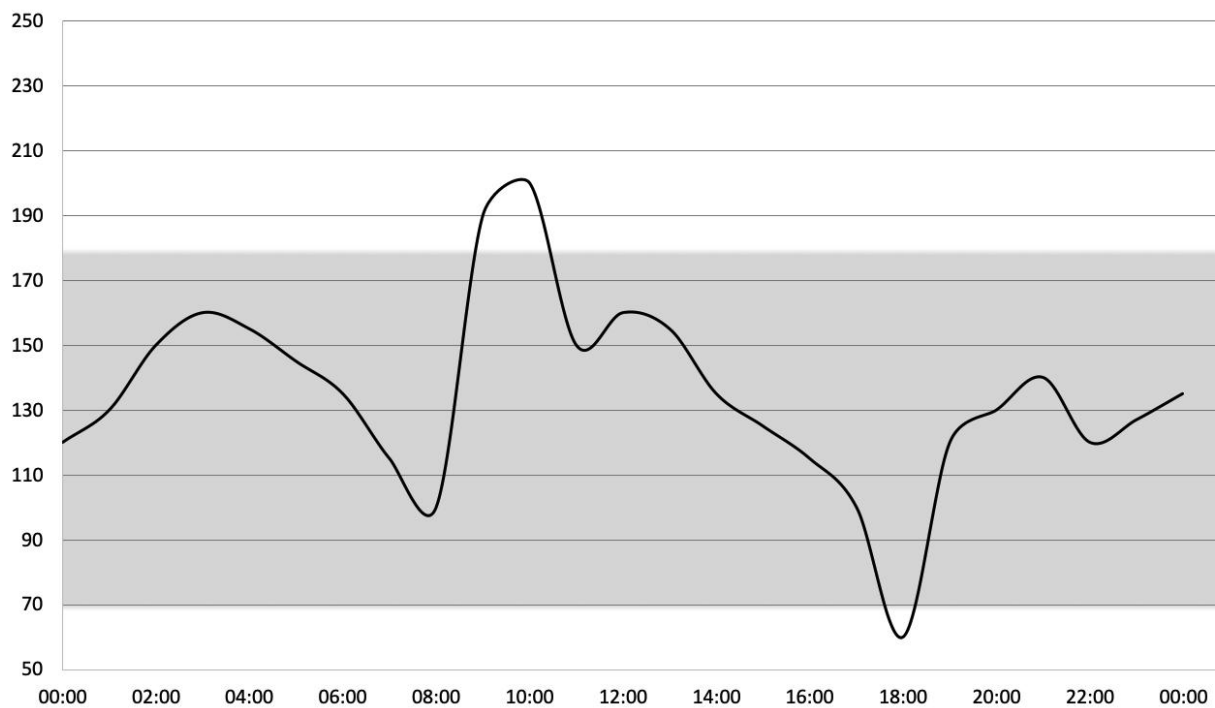
\*Glycemic verification using a glucometer

### Benefits.

A study by Champakanath et al. found that CGM users who started using the system within a year of their initial diagnosis of type 1 diabetes had significantly lower glycated hemoglobin scores compared to non-users during a seven-year follow-up. The positive effect of the therapy is also visible when the CGM system is started more than a year after the diagnosis date, but in this case the difference in the level of HbA1c is less. Patients participating in the study, using CGM systems within a year of diagnosis, recorded a decrease in HbA1c from an average of 11.5% at diagnosis to 7.6% 7 years after diagnosis. Patients not using CGM throughout the follow-up period in the study achieved a decrease from 11.6% to 9.8% at 7 years. In contrast, patients who initially did not use CGM but started after 3 years achieved an average score of 8.5% over the 7-year follow-up, an average improvement of 1.3 percentage points over those using only glucose meters. [16] Early implementation of CGM systems can have a positive impact on mean glycemic values and is recommended by the Polish Diabetes Association as the preferred method of self-management in type 1 diabetes. [4]

Manufacturers of glucose monitoring systems provide software that allows generating reports in which you can clearly see the history of measurements. Additionally, patients can enter data on meals eaten, insulin doses, physical exercise and other important events. When using a compatible personal insulin pump and a CGM system at the same time, some data is downloaded and matched automatically.

**Figure No. 2.** Example of a daily reading of a patient using a glucose monitoring system.



A patient using FGM/CGM has access to data that would be unavailable or would require extremely frequent measurements using only a glucometer. In addition to the multiplied number of readings, users can track how and how quickly the glycemic level changes depending on the type of meal eaten or the time that has elapsed since the administration of insulin to the beginning of the meal. The generated reports can automatically inform whether the patient meets the therapeutic goals and provide the expected level of glycated hemoglobin. [17]

### **Summary.**

Glucose monitoring systems have revolutionized the methods of self-monitoring in patients with type 1 diabetes. Thanks to the additional data coming from these systems, and in particular, the trends of glucose changes, patients can make more accurate therapeutic

decisions. These systems allow to track changing glycaemic levels on an ongoing basis, without the need for multiple punctures, and help achieve better metabolic control. This has the effect of reduced risk of hypoglycaemic episodes, hyperglycemia and late diabetic complications.

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