

# User Manual diafyt Guide, diafyt Guide Pro

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## 1. Meta-information

This user manual is intended for the products diafyt Guide and the variant diafyt Guide Pro.

This manual refers to version 1.0.0 of the apps diafyt Guide and diafyt Guide Pro.

The current version of the manual is in the Download area at <https://www.diafyt.de/english/diafyt-app/>

### 1.1. Information about the product

1. Name: diafyt Guide and diafyt Guide Pro
2. Identification: Version 1.0.0
3. Notes on variants:
  - a. **diafyt Guide** is an independent mobile application (app) for documenting everyday life as a diabetic. The basic version (diafyt Guide) of the diafyt app is functionally limited.
  - b. **diafyt Guide Pro** is the unrestricted full version. diafyt Guide Pro offers additional functions. The app supports the determination of the bolus insulin dose. diafyt Guide Pro is a paid subscription.
4. Notes on permitted accessories: diafyt Guide works in conjunction with a CGM. A list of supported CGMs can be found in chapter 6.1.
5. User interface: diafyt Guide is a smartphone app.

### 1.2. Manufacturer

pg40 Consulting Group GmbH  
Schwägrichenstr. 3  
04107 Leipzig

Germany

The current version of the imprint can be found in the Downloads area at <https://www.diafyt.de/english/diafyt-app/>

### 1.3 Publication date (date last changes)

Datum letzte Änderung	Kennnummer
16.9.2019	1.0.0

## 2. intended use

### 2.1 Overview

Individuals with an absolute insulin deficiency require insulin replacement therapy which is given through injections or an insulin pump. The main goal of a diabetes management system is, as far as possible, to restore glucose metabolism to a normal state.

*diafyt Guide* is a diabetes management decision support system for insulin dependent patients on an ICT (intensified conventional insulin therapy). **It helps patients who have difficulties finding the correct insulin dose.** It consists of 2 software components, a smartphone app and a cloud application. To support patients in their daily diabetes management procedure *diafyt Guide* can calculate a directing value that correlates with the individual patient's insulin demand. Thus *diafyt Guide* can assist in achieving effective bolus dosing.

Patients will use a smartphone app connected to a cloud service for calculation and optimization. The system adapts to the individual patient with machine learning.

Typical use-case situation: calculate insulin dose prior to meal

The patient

1. starts the app
2. reads the glucose sensor data
3. estimates the amount of carbohydrates in the meal and records the value in the app
4. runs the insulin demand calculation and receives a directing value
5. makes a qualified decision about the dosage amount taking the directing value into consideration and records the chosen dosage amount
6. injects the chosen amount of insulin (bolus)

### 2.1 Medical purpose

Diabetic patients need to calculate insulin dosages multiple times a day. *diafyt Guide* assists patients in their individual bolus calculation.

The principle of insulin dosage calculation is based on an algorithm that calculates a number that is correlating with the patient's individual insulin demand based on

- blood glucose levels
- insulin injections
- types of insulin used
- food intakes (carbohydrates)
- time of day
- parameter tuning functionality

- further body related parameters e.g. weight, age, other chronic illnesses

## 2.2 Other normal / Intended use

In addition the app can be used for glucose monitoring and diabetes management. Related records can be stored and transmitted.

## 3. Characterization of Users

Users are patients who

- can operate apps on a recent smartphone
- use a glucose monitoring sensor
- actively manage their diabetes e.g. record data, count carbohydrates

## 4 Characterization of Patients

### 4.1 Indications

The device is intended to be used by people having type 1 diabetes. Type 1 diabetes (T1D) is a form of diabetes in which very little or no insulin is produced by the pancreas. Before treatment this results in high blood sugar levels in the body. Injections of insulin – either via subcutaneous injection or insulin pump – are necessary for those living with type 1 diabetes. Insulin dosage is adjusted taking into account food intake, blood glucose levels and physical activity. People with type 1 diabetes always need to use insulin, but treatment can lead to low BG (hypoglycemia), i.e. BG less than 70 mg/dl (3.9 mmol/l). Hypoglycemia is a very common occurrence in people with diabetes, usually the result of a mismatch in the balance among insulin, food and physical activity.

### 4.2 Contraindications

The following contraindications for the use of the device are identified:

- patients with active tumor diseases, cortisone therapy, untreated thyroid dysfunction (hyperthyroidism), other pancreatic problems

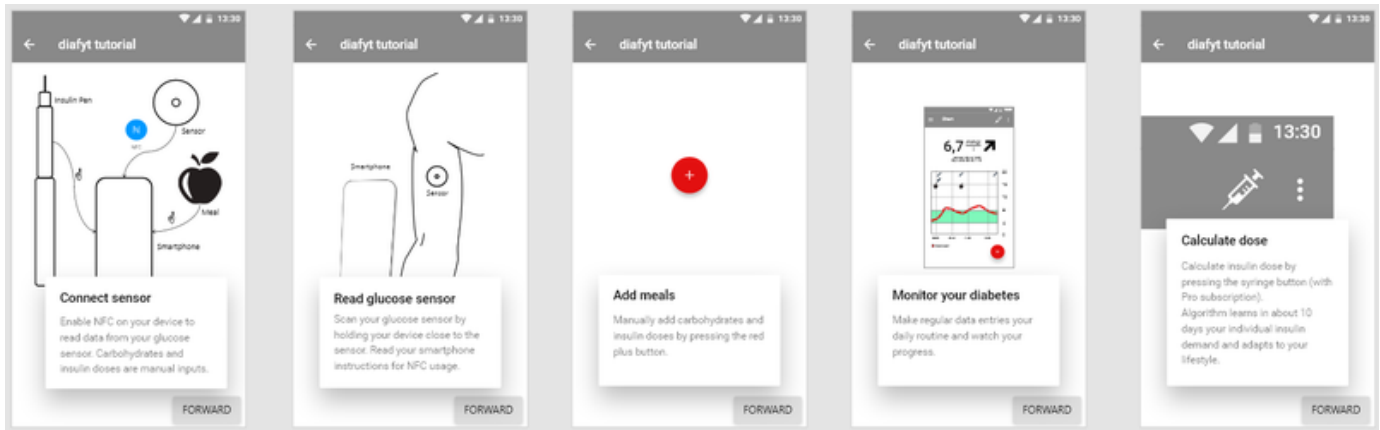
Further exclusions are:

- pregnant women
- children under age 14
- persons who use mixed insulin or only long-term insulin for their therapy,
- persons who are physically (e.g. with severely impaired vision) or psychologically unable to pursue their therapy independently.

## 5 Safety Instructions

### 5.1 Operation

The tutorial can be found in the app and in the download area at <https://www.diafyt.de/german/diafyt-app/>



## Tutorial

### 5.2 Place, duration, frequency of application

The values of the CGM sensor must be read into the app at least 3 times over the day via the smartphone. All meals and all insulin inputs have to be entered manually. The insulin dose is calculated as required, typically before each bolus insulin dose.

### 5.3 Usage environment

The app works depending on the allowed usage environment of the CGM and Smartphone.

### 5.4 Precautions and Warnings

**The decision on the time and amount of insulin dosage is made by the user.** The decision is based on the physician's recommendations. The value calculated by diafyt Guide Pro may deviate from the optimum dose.

The device helps patients having difficulties calculating their insulin dosage. To receive good results the patient has to input all and correct data e.g. Insulin taken, carbohydrates taken. However wrong inputs can lead to miss-calculations. Therefore the patient has to make the final decision about the insulin dosage.

diafyt Guide Pro is intended exclusively for type 1 diabetics who are over 14 years of age, require insulin and are trained in ICT therapy (or comparable programmes) (for minors aged 14 and over, see GTC 3.2.4) and who regularly undergo check-ups with doctors. Under no circumstances may diafyt Guide Pro be used by minors, or by persons who use mixed insulin or only long-term insulin for their therapy, or who are physically (e.g. with severely impaired vision) or psychologically unable to pursue their therapy independently.

The result determined by diafyt Guide Pro corresponds to a proposal to the user to use the calculated insulin dose. However, it is your sole responsibility to plausibilise the calculated value - based on your own experience, the medical specifications of your doctor and the package inserts of the medicines used - and to determine your insulin dose accordingly. We explicitly warn against following the suggestions of diafyt Guide Pro without own plausibility check. Under no circumstances can diafyt Guide Pro replace the medical expertise of a doctor or regular medical check-ups, administer insulin or other medications, measure blood sugar or calculate individual therapy parameters.

## 6 Further Safety Instructions

### 6.1 Combination with other products incl. Accessories

List of currently supported CGM:

1. FreeStyle Libre 1 (c)

### 6.2 Maintenance

The app is subject to updates and upgrades as part of the ongoing development and improvement process. Information about the respective updates and upgrades can be obtained via the mechanisms of your App Store or via the diafyt website.

### 6.3 Decommissioning

To uninstall the app, follow the relevant instructions of your smartphone manufacturer for uninstalling apps. Details on how to cancel the diafyt Guide Pro subscription can be found in the terms and conditions.




## 7 Performance data, measurement accuracies

The app uses the data of your CGM sensor. Find information about the performance data and the measuring accuracy at the manufacturer of your CGM.

## 8 Information about side effects and residual risks

There are no indications of side effects or residual risks when using the diafyt App.

## 9 Definition of symbols

symbol	title	explanantion
	apple	Meals, carbohydrates
	syringe	Bolus Insulin, short-acting insulin
	syruinge bold	Basal Insulin, long-acting insulin
	trend arrow	tendency blood sugar
	notepad	notes
	scale	body weight
	drop of blood	blood glucose level

## 10 CE-Identification



Council Directive 93/42/EEC concerning medical devices