How to calibrate in DiaBox

Restrictions

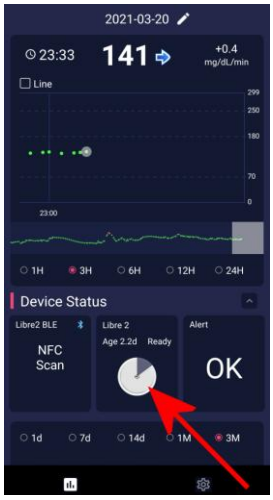
This document describes the calibration of Abbott's Freestyle Libre sensors in the DiaBox app for Android and iOS.

Calibration

The **calibration** serves to correct a deviation between a measured value and a reference value, here the sensor-specific deviation between the glucose measured value of the Freestyle Libre sensor and the reference value "finger prick value".

Enable the calibration

The calibration must be activated before the first use in DiaBox. To do this, tap on the "**Libre Info Panel**" (Libre Sensor symbol) in the **Device Status** area.

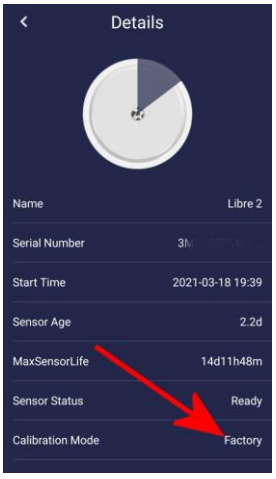


The details menu opens.

Quickly tap several times to the right of "**Calibration Mode**", then a dialog opens and the code word is requested once.

The "magic code" is:

"**GODMODE**"

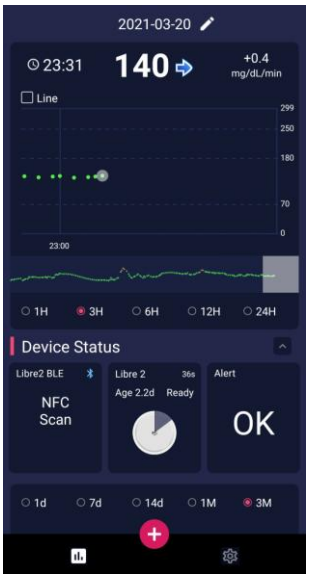


The calibration mode is now enabled, the entry changes to "**BG Calibration Mode**".

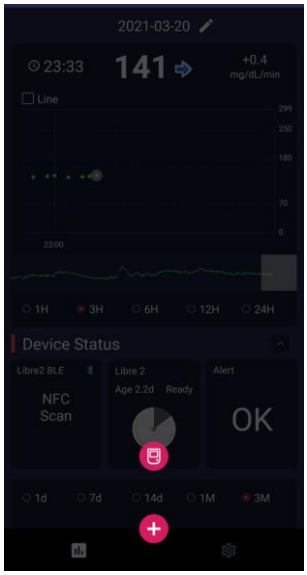
You can switch back to the factory calibration mode at any time: quickly tap several times on "**BG Calibration Mode**" in the details menu, the entry changes back to "**Factory Calibration Mode**" (previously entered calibration values are retained).

Enter calibration values

A red "+" button now appears at the bottom of the main screen.



If you tap on it, the red calibration button appears.



Pressing the red calibration button then opens the calibration dialog.

In this dialog you can set the finger prick measurement value with the slider and save the entry. The entry should be made promptly (within one minute after the finger prick measurement).

A calibration should only be carried out in a stable metabolic situation, i.e.

- there is no active residual insulin in the blood,
- one has just not eaten a meal,
- no exercise / sport was carried out

These are the same conditions as when carrying out comparative measurements. Put simply, a horizontal trend arrow must be displayed.

Initialization of the calibration

DiaBox requires the entry of 3 finger prick measured values ("calibration values", "calibration points") for the initialization of the calibration function. You have to wait at least 15 minutes between entering the respective values, but the intervals can also be selected longer.

It is recommended to spread the calibration points over the largest possible glucose measurement range. Calibration points can also be entered for low and high measured values, but always taking into account a stable metabolic situation.

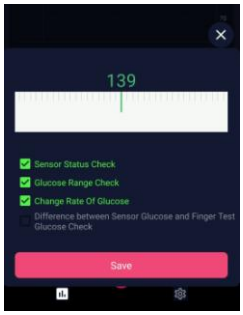
Calibrate

With the entry of the third calibration value the initialization is finished and DiaBox calculates the parameters of the calibration function. From now on, this function calculates the new, adjusted glucose value from the transmitted sensor value.

After the calibration has been initialized, you can enter further calibration values, but there must be an interval of at least 2 hours before a new calibration value can be entered.

If more than 3 calibration values are entered, the last 4 calibration points are used to update the parameters of the calibration function.

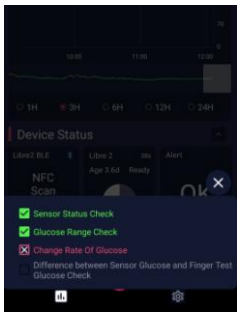
Calibration rules



The DiaBox app checks some rules ("**calibration rules**") before the calibration is even allowed; the green check marks in the calibration dialog indicate which rules are currently being satisfied.

The stable metabolic situation is ensured by rule 4: "**Change Rate of Glucose**":
Calibration is only allowed if the glucose level is stable and does not change too quickly. The change must be less than ± 2 mg/dL / min or ± 0.11 mmol/L / min.

The other green check marks represent the rules:



Rule 1: "**Sensor Status Check**".
The calibration can only take place when the sensor is in the "Ready" state. It does not work if the sensor state is "Warm-Up", "Sensor Error" or "Sensor End".

Rule 2: "**Glucose Range Check**".
Only a valid sensor value can be used for calibration. The sensor value must be in the range: 60 - 350 mg/dL or 3.3 - 19.4 mmol/L.

If one of the rules is violated, this is indicated by the missing green tick (in the example the rule "Change Rate Of Glucose"). The entry of a calibration value is then rejected.

Another rule is only applied when entering the finger prick measurement value:

Rule 3: "**Difference between Sensor Glucose and Finger Test Glucose Check**":
For safety reasons, calibration won't work when the deviation between the sensor value and the finger prick measurement value is too big, a difference of ± 90 mg/dL, or ± 5 mmol/L is permitted.

Calibration Function

A finger prick measured value ("**calibration value**") is assigned to a temporally associated sensor value after it has been entered and thus forms a "**calibration point**".

The calibration in DiaBox takes place with a linear function

y = ax + b with sensor glucose value x and calibrated glucose value y, **slope a** and **offset b**.

During the initializing of the calibration, after entering at least 3 calibration points, the parameters of the calibration function (ie slope and offset) are calculated ("line of best fit").

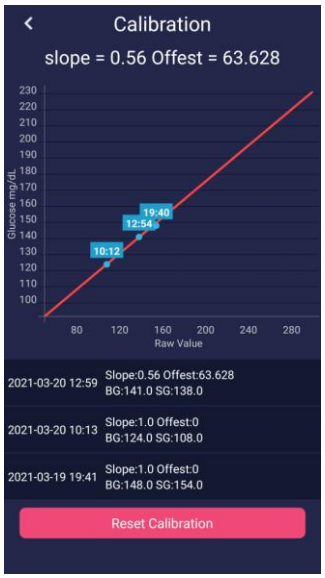
From now on, this function calculates the calibrated glucose value from the transmitted sensor value, which should now be closer to the bloody measured value.

It does not matter whether the sensor value was received via Bluetooth or was determined by scanning the sensor in NFC mode.

The calibration function and the calibration points entered so far can be viewed under **Settings / i-Algorithm / Calibration Graph**.

The currently used calibration function is also displayed, here e.g.

y = 0.56x + 63.628



Example: a sensor value of 120 mg/dL becomes a calibrated value of 131 mg/dL (see table).

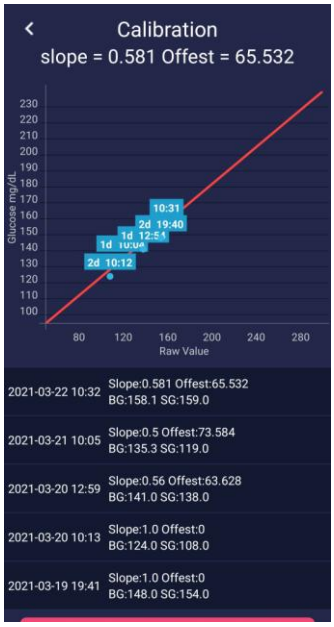
sensor value [mg/dL]		calibrated value [mg/dL]
80	→	108
120	→	131
160	→	153
200	→	176
240	→	198

It is possible to remove the calibration function data completely (e.g. if the calibration falsifies the values too much):
press the "**Reset Calibration**" button in **Settings / i-Algorithm / Calibration Graph**, then all old calibration points will be deleted.

You can then start with a new initialization of the calibration.

Activating a new sensor in DiaBox also resets the calibration and deletes all calibration points.

If more than 3 calibration values are entered, the last 4 (!) calibration points are used to update the parameters of the calibration function.



In the "Calibration Graph" diagram there are time stamps displayed at the calibration points, which indicate the length of time sincethe entry of the calibration values.

After entering a calibration value, the time stamp is highlighted in blue. After 4 days the color changes to gray.

Note: the color change only serves as an indication of the "age" of the calibration point, but does not mean that the calibration parameters have to be updated now.

The DiaBox DevTeam recommends not to calibrate Libre sensors very frequently, as the sensitivity of the Libre sensor is quite stable.

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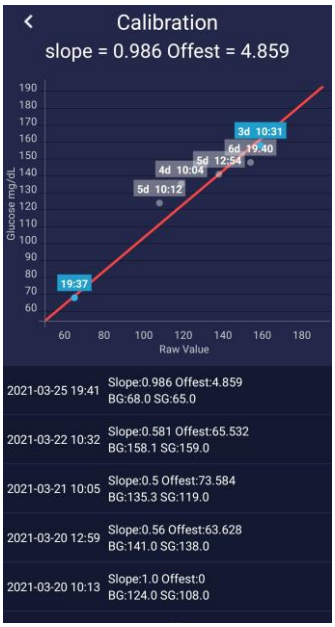
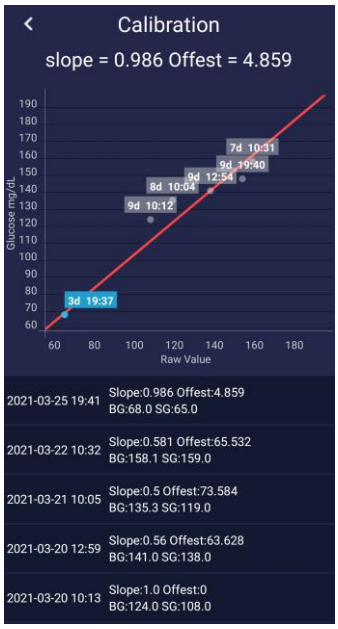
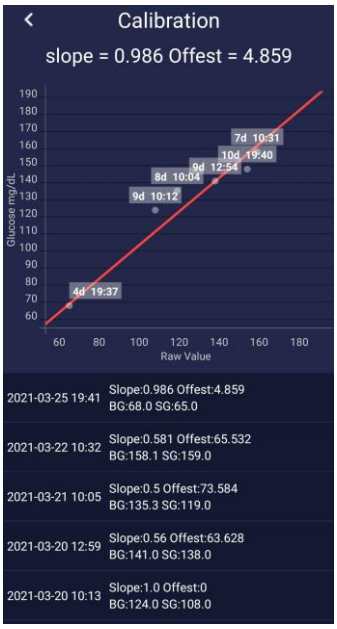






FAQ – Frequently Asked Questions

Which Libre Sensor versions can be calibrated ?

From the beginning, all Libre versions were supported in connection with the Bubble Transmitter, with the exception of the Libre 2 US version, for which there is no support, neither with Bubble nor via NFC scan.

NFC Mode:	Libre 1, Libre 2 EU, Libre US 10 days, Libre US 14 days, Libre Pro/H, Libre 1 Canada
Bubble Mode:	Libre 1, Libre 2 EU, Libre US 10 days, Libre US 14 days, Libre Pro/H
BT direct:	Libre 2 EU only, Libre 2 US unsupported, Libre 2 Canada (under development, as of April 2021)

Can I calibrate immediately after setting / activating a sensor ?

The calibration can be started when the sensor is in the "Ready" state, i.e. after the 60-minute start-up phase. However, a Freestyle Libre sensor needs up to 24 hours to run in and can measure more imprecisely during this time (e.g. due to defensive reactions of the human body against foreign substances). Abbott itself confirms the possible deviations in the first 24 hours [7].

Therefore, it does not make sense to calibrate the sensor in the first 24 hours if the sensor has been freshly set.

Many users therefore set the new sensor 12-24 hours before the old sensor expires, but only activate the new one when the old sensor expires.

Why do I have to calibrate at all, after all, the Libre sensor is factory calibrated ?

Factory-calibrated does not mean that every sensor always yields absolutely correct values for every user.

Due to production technology, the sensing elements of a lot show deviations from a reference element. By reprogramming the sensors, these deviations are compensated so that the measured values correspond again to the values of the reference element.

Thus the sensor is able to calculate halfway usable raw glucose measured values from the electrical values of the sensing element of this lot.

The data for the reference element were determined for the "average diabetic". But since everyone is different, the factory calibration works for many users (from good to tolerably), but not for everyone.

Why are there any differences between the sensor value and the finger prick reading and how large can the difference be?

Blood glucose meter strips and Libre sensors both measure with electrochemical methods, but at different sources. Test strips measure the glucose in the capillary blood, the sensor measures the glucose in interstitial fluid, the fluid that surrounds the cells of the tissue below the skin (tissue glucose).

Blood glucose and tissue glucose are not the same, but the tissue glucose reflects the blood glucose with a time delay, the time difference in the course between blood glucose and tissue glucose is about 10 min - 15 min.

The algorithms in the reader and the LibreLink app calculate a prediction value that lies in the "future" of tissue glucose, but still in the "past" of blood glucose, but usually approaches the blood glucose to within 5 minutes. Depending on the metabolic situation, it works sometimes better, sometimes worse.

Further error possibilities can occur with the sensor:

- The fluid balance influences the measurement in the interstitial fluid (e.g. not drinking enough).
- Lying on the sensor can displace the interstitial fluid and thus lead to incorrect measurements.
- Other medication ingested, such as pain medication, can affect the sensor reading.
- Higher temperatures (e.g. after showering or bathing) can also have an influence on the sensor value (even if the sensor can compensate for smaller temperature fluctuations).

In addition, all measuring devices may have a certain degree of inaccuracy.

Measurement accuracy

To put it simply, DIN EN ISO 15197: 2015 states: each measuring device may have ± 15% deviations from the actual value, i.e. up to 30% are allowed between 2 measuring devices. And in 5% of all measurements / users, these tolerance limits may even be exceeded.

Although this standard applies to blood glucose meters (in the EU), it can be assumed that sensors have similar tolerance limits.

A new study by Abbott showed that 93% of the sensor readings were within ± 20% of the bloody reference value (for a glucose value> 80 mg/dL) or within ± 20 mg/dL (for a glucose value <80 mg/dL) , ie in 7% of the measurements the deviations were even greater [6].

Many posts in the Facebook groups about large differences in sensor values and finger prick measurements confirm the frequency of deviations.

Can I still use the finger prick value for calibration if blood glucose meters are so inaccurate?

Despite the possible inaccuracies of blood glucose meters for household use described above, the finger prick measured values are considered to be more accurate compared to sensor measured values if the requirements are met.
"Official": Wash and dry your hands, no residues of creams, alcohol, fructose, impurities on the hands during the bloody measurement.

Therefore, finger prick measured values can be used for calibration or as a comparison measurement for checking a sensor.

When making a complaint to Abbott, the rules for comparative measurements must be observed: stable metabolic situation, i.e. scan first, do the finger prick measurement only when the trend arrow is horizontal, scan again after 5 minutes.

My sensor always measures 10 mg/dL too low, can't I just always add the deviation ?

Of course, you can use the "mental calibration" to calculate a known and constant deviation manually. When using the Libre reader or the LibreLink app, this is the only way to "calibrate off" a deviation in blood glucose and sensor values.

However, the deviations are usually not constant, but depend on the level of the glucose value. Therefore the calibration in DiaBox uses a linear function
$y = ax + b$,
with which the glucose level is also taken into account.

I only have slight deviations between the sensor value and the finger prick measurement, do I still have to calibrate ?

No, if the sensor value and the finger prick measured value differ only slightly from each other and you only use the value for display in a smartphone or smartwatch / fitness tracker, you do not have to calibrate. But you can just try it out, because you can easily switch between DiaBox calibration mode and factory calibration. When switching to the factory calibration, the previously entered calibration values, i.e. the calibration function, are retained.

Often it is not the accuracy of the measured value that is decisive for continuous tissue glucose measurement, but the course of the glucose, which makes the influence of food intake, insulin dose and exercise on one's own metabolism visible.

The situation is different when users apply the Freestyle Libre Sensor as part of a "closed-loop system" to automatically adjust the insulin delivery of a pump. Then it is advisable to calibrate even if there is only a slight deviation.

How often do I have to calibrate?

Studies have shown that the accuracy of a Freestyle Libre sensor changes over the life of the sensor. A study by Abbott found [7]:

Day of Wear	Day 1	Day 6	Day 11	Day 14
within ±20% of reference or within ±20 mg/dL (±1.11 mmol/L)	86.8%	92.9%	90.2%	91.4%
MARD[1]	10.9%	8.8%	9.3%	9.0%

[1] "MARD" is the abbreviation for "Mean Absolute Relative Difference", that the glucose values show in comparison to measurements with a reference method. It is calculated from the absolute difference between blood glucose measurements and tissue glucose measurements determined at the same time and is given as a percentage. In short: the lower the MARD, the more precisely a CGM system measures.

It is therefore advisable to carry out a comparison measurement every few days (or more frequently if the "sensed" and measured sensor values do not match). If necessary (the deviation has increased again) the finger prick measured value can then be used directly as a new calibration value.

The situation is different when users apply the Freestyle Libre Sensor as part of a "closed-loop system" to automatically adjust the insulin delivery of a pump. It can then be advisable to calibrate more frequently in order to obtain a sensor value that is as close as possible to the blood glucose.

In the diagram oft he calibation function in **Settings / i-Algorithm / Calibration Graph** the time stamps at the calibration points show the length of time since the calibration value was entered (blue: up to 4 days, gray: over 4 days).

Note: the color change only serves as an indication of the "age" of the calibration point, but does not mean that the calibration parameters have to be updated now.

The DiaBox DevTeam recommends not to calibrate Libre sensors very frequently, as the sensitivity of the Libre sensor is quite stable.

Can other reference values be used ?

There have been reports that users apply the reading from the Libre reader or the LibreLink app as a reference value for calibration, and allegedly have had good experiences with it.

This is very doubtful, since in this way the "sensor is calibrated with itself". The readings from the reader / LibreLink app are not raw tissue glucose values and no blood glucose values. The algorithms in both devices calculate a prediction value from a series of raw tissue glucose values and their changes, which is intended to compensate for the temporal offset of the tissue glucose value, but only reaches the blood glucose level up to approx. 5 minutes, so the value is somewhere in between.

In addition, the algorithms of the reader and the LibreLink app are now different (even with "simultaneous" scanning, different measured values are displayed).

In principle, these algorithms cannot compensate for a systematic deviation of the sensor measured value.

This calibration is as pointless as placing the two ends of the same folding meter stick on top of each other and comparing the centimeter marks. They match even if the centimeter marks are actually 11 mm apart due to an production error.

Can you also calibrate in NFC scan mode?

The calibration in NFC scan mode was implemented with the Android version 2021.03.08 and iOS DiaBoxMe version 1.5.0 and iOS DiaBox version 8.2.4.

The calibration procedure is the same as with the Bubble Transmitter:

First you scan the sensor with NFC, then you enter the finger prick value. When you press "Save Glucose", DiaBox asks for a new scan to check that the calibration rules are being checked.

What does the new calibration rule for "sensor threshold" mean?

The calibration rule "Calibration check for Sensor Threshold" was implemented with Android version 2021.03.08 and iOS DiaBoxMe version 1.5.0 and iOS DiaBox version 8.2.4.

This check concerns values that are used in connection with the OOP algorithm. DiaBox will not accept a calibration if the sensor glucose value is 39 mg/dL or 501 mg/ dL.

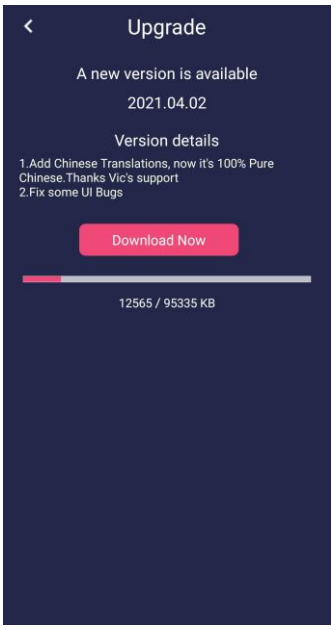
Details will be explained in a new version of the "Cakibeation Rules" document.

There is a new version of DiaBox, do I have to uninstall the old version or back up any data?

So far, new updates of DiaBox could be installed over an existing version. Data such as the settings, measured value history or calibration points, i.e. the calibration function, remained unchanged.

Note: DiaBox now searches for and informs about available updates.

You can then also download this new version in the app.



Sources, references

[1]	Calibration Rules in DiaBox	Directly in DiaBox App or here: https://docs.google.com/document/d/1UIe_UmxJo8SIgbl1G8xsnTDyCLPPtet-ARoL-1USazs/edit
[2]	DiaBoxDevTeam	diaboxapp@gmail.com
[3]	DiaBox Facebook Gruppe	https://www.facebook.com/groups/974278412920319
[4]	DiaBox D-A-CH Facebook Gruppe	https://www.facebook.com/groups/DiaBox.d.a.ch
[5]	Own experiences	Freestyle Libre 2 EU version, DiaBox for Android Wolfgang.Sander@t-online.de
[6]	Abbott	Accuracy of a 14-Day Factory-Calibrated Continuous Glucose Monitoring System With Advanced Algorithm in Pediatric and Adult Population With Diabetes, September 19, 2020
[7]	Abbott	FreeStyle Libre Flash Glucose Monitoring System Accuracy Study, Dezember 2018 https://freestyle.de/accuracy-of-freestyle-libre-2
	DiaBox Downloads	
[8]	DiaBox for iOS	https://testflight.apple.com/join/DVvR6GTM
[9]	DiaBoxMe for iOS	https://testflight.apple.com/join/Ynoo1pq7
[10]	DiaBox for Android	https://github.com/bubbledevteam/diabox/releases
[11]	DiaBox Translations	https://github.com/bubbledevteam/diabox/tree/master/language

Version Log

Version	Datum	Autor	Aktion
0.99	03/22/2021	Wolfgang Sander	initial version
0.995	02/25/2021	Wolfgang Sander	corrections, enhancements, legibility
1.0	03/26/2021	Wolfgang Sander	first release version in english
1.1	04/08/2021	Wolfgang Sander	additions and corrections, calibration in NFC mode, example calibration function, time stamp in "Calibration Graph"

Disclaimer

This calibration feature is highly experimental. It is provided as an information resource only, and is not to be used or relied on for any diagnostic or treatment purposes.

You do it at your own risk and you are fully responsible for any damages, loss, injury, or liability whatsoever suffered as a result of your reliance on this feature.