Can I use Extense as a stand alone device without connecting my smartphone?

No because Extense's Sugar Trend estimate is generated on an AI (Artificial Intelligence) Cloud platform. Your Extense connects to this platform via Bluetooth to your Android or iOS (iPhone or iPad) smartphone with a registered Extense app and a live Internet connection.

Does Extense require calibration using a blood sample?

If you use Extense in Wellness Mode, where your Sugar Trend estimation is presented on a color scale, then calibration is not required.

If you wish to use your Extense in Health Mode (only available on selected countries), then your Extense will require finger prick calibration. Your blood glucose calibration measurements can be obtained using a standard finger prick test using a blood glucose meter. The Extense app will require initial calibration measurements during the following periods:

i. Before breakfast in the morning.
ii. Approx 30-60 minutes after a main meal (e.g. lunch or dinner).
iii. At least 2 hours after this main meal.

How long does Extense take to estimate your Sugar Trend?

In total Extense takes about 45 seconds after you insert your finger in to your Extense for the sensors to calibrate, take a reading and communication the data to the AI Cloud and then feedback a result to you Extense app.

Does Extense require an Internet connection to perform the measurement ?

Yes, Extense requires an Internet connection which can be Wi-Fi, 3G or 4G on your connected SmartPhone. Extense also requires a Bluetooth (BLE 4.0) connection to the smartphone to connect to your smartphone so it can operate.

What does the Extense app display when users measure their Sugar Trend?

With each Extense scan, the Extense app displays the current glucose reading on a color scale where green colour is normal to red color, which indicates a very high glucose level. In Extense Health reading mode, the app presents the the exact value in mg/dl or mmol/L.

How accurate is the Extense estimation of Glucose ?

The value of Extense is that it measures your Sugar Trend rather than identifying your glucose as a specific point in time.

Extense accuracy is currently being refined during this "initial learning phase" [Link to video]. Extense performance is expected to be comparable to most common over the counter, home use glucose meters for self-monitoring by lay-users as defined by international or US standards.

The FDA guidance for glucose meters used by people at home ("over-the-counter") is that meters should meet the following accuracy standards:

- 95% of all measured blood glucose meter values must be within 15% of the true value (a lab measurement); and
- 99% of meter values must be within 20% of the true value.

By way of example, what this means is that a glucose meter is considered accurate if the true (lab-measured) glucose value is 100 mg/dl and the reading is between 80mg/dl and 120 mg/dl.

Is Extense FDA USA approved or approved in any other country ?

Extense is certified as Medical Device Class 1 for user safety in Europe, and preparation is under way to file a 510k submission to the FDA in USA.

What technology does Extense use to non-invasively estimate glucose levels?

Your Extense uses light spectroscopy. It shines light into your finger and then detects how this light is reflected. The optical absorption data is captured, encrypted and sent to the Cloud where it is processed using Artificial Intelligence.

The optical absorption spectrum of glucose has been known for years. However, its direct measurement has been recognized as challenging and problematic.
Extense uses specific light-emitting diodes in a defined configuration to shine light into your finger and photodetectors are then used to detect the spectrum absorption. This spectrum absorption data gathered from Extense is encrypted, sent to the Could where it is analyzed using a proprietary algorithm based on a non-linear mathematical approach together with dynamic chaos theory and is used to calculate glucose concentration on demand in Helo Extense.

Why is my PPG signal different to the PPG indicated on the Extense app?

Your Extense sensors may have problem scanning your finger tips due to external factors such as environmental temperature, humidity or your finger temperature. If you use your Extense below 20C (or 58F), your fingers may be too cold and Extense may not be able to accurately scan your finger and generate a reliable PPG because you may have insufficient blood flow in your finger. If this is the case, mover to a warmer environment, warm up your hands and try to massage your finger to help blood to flow to the tip of your finger, as as shown in the picture on the Extense app.

Is Extense patented technology ?

Yes, Extense technology has been filed in a Personal Healthcare Device patent US2018/0353137. This patent provides examples of the Near Field Infrared Light Emitting Diodes used in Extense, the wavelengths and configuration used to provide a flat inline sensor (FIS) and the Photo Diodes used for optical signal detection.

Why is the result of the Sugar Trend estimation different to the one displayed by an over the counter, home use, self-monitoring glucose meter?

First of all, there are many factors that may influence the result of the estimation produced by Extense. It is important that you submit a good PPG , as indicated on the Extense app so that an accurate Sugar Trend result is obtained.

If accurate PPGs are submitted and results are differ from your over the counter, home use, self-monitoring glucose meter, please reset the User calibration and perform a new calibration.

Can I use Extense to determinate my treatments or to decide my drugs and insulin intake ?

Absolutely Not.
Extense has been designed and is only indicated for use as a device that helps monitor your Sugar Trend with the objective of managing your diet and sugar intake. It has not been developed or is approved for use in evaluating or decision making regarding your treatment or determining your drugs or insulin intake.

You must contact your doctor or approved care giver for any changes or actions that you may choose to make regarding your current treatment.

Can I use Extense to estimate the glucose level for diabetes type 1 or type 2 ?

No.
Extense has been designed and is only indicated for use as a device that helps monitor your Sugar Trend with the objective of managing your diet and sugar intake. It has not been developed or is approved for use in estimating glucose levels for diabetes type 1 or 2.

You must contact your doctor or approved care giver for any changes or actions that you may choose to make regarding your current treatment.

In cases where Extense generates abnormal reading, please use an approved glucose meter to confirm the abnormal reading and contact your doctor.

Where can I download the latest SugarTrend App ?

The latest version of SugarTrend App is always available on HeloAppStore or on Google PlayStore or Apple AppStore. SugarTrend App is provided to the HeloAppStore by a third party partner. Check the About us section on the App for more information on the developer details.