



sugarBEAT[®]

Continuous Glucose Monitoring System

**Instructions For Use
(IFU)**

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Starting out with sugarBEAT®

sugarBEAT® is for people with Type 2 diabetes or prediabetes who wish to have assistance with monitoring their glucose levels throughout their day

sugarBEAT® also works well for people who wish to monitor their glucose as part of a healthy lifestyle.

This Instructions for Use covers your experience with the sugarBEAT® device. It covers what the sugarBEAT® device is and how to use it as well as how to download and use the sugarBEAT® App.

It is important to read all the Instructions for Use before you use sugarBEAT® as it contains important information about the device. You should keep your Instructions for Use somewhere safe as you may need to refer to it again in the future.



Your sugarBEAT[®] system

Below is a brief summary of what the **sugarBEAT[®]** system is and what it does. More detailed information is provided later in this guide.

sugarBEAT[®] is a non-invasive Continuous Glucose Monitoring (CGM) system for tracking glucose trends and patterns and is intended to help people with Type 2 diabetes and prediabetes better manage, reverse and prevent the onset of this condition. It can also be used by those who simply want to better understand the impact their lifestyle and diet is having on their glucose levels. sugarBEAT[®] is intended to be complimentary to Self-Monitoring Blood Glucose (SMBG) testing for those with diabetes although everyone will need to use blood glucose values from a Blood Glucose Meter (BGM) to calibrate their sugarBEAT[®] system.



This document contains important safety information. Read this document before using sugarBEAT[®]. Keep these instructions for use in a safe place as you may need to read them again.

The **sugarBEAT®** system is composed of the following:

Transmitter: The Transmitter records glucose levels and transmits data to the smart device application using Bluetooth. It is a small, rechargeable and reusable electronic device in a plastic casing.

Sensor Kit: The Sensor kit consists of a foil pouch containing a single use disposable glucose Sensor and a Guiding Frame that allows the correct and accurate placement of the Transmitter onto your arm.

Docking Station: The Docking Station connects to a USB cable and power supply and is used to charge the Transmitter.

Smart Device Application (App): The App connects to the Transmitter via Bluetooth and is used to download and present data on a smart device.

Once attached to your arm, the sugarBEAT® Transmitter provides glucose readings to the App on your smart device at 5 minute intervals and can be worn for up to 14 hours at a time.



Glossary of Terms

Acronym/ word	Definition
App	A software application on a smart device such as a mobile phone or tablet.
Type BF Applied Part	Not suitable for direct cardiac application.
Blood Glucose (BG) Value	BG is an abbreviation for Blood Glucose. Blood Glucose Value is the amount of glucose measured in the blood using a BGM.
Blood Glucose Meter / BG Meter / SMBG Meter	A medical device used to measure how much glucose is in the blood.
Calibration	The App needs a BGM reading to enable it to convert the Sensor signals into glucose readings. The more you calibrate the more accurate the App glucose reading will be.
CGM	Continuous Glucose Monitor. A device which determines glucose levels in your body and uses a transmitter to continuously send these values to an App which converts and then displays them.
Contra- indication	A situation where sugarBEAT® must not be used as the risk of use outweighs the benefit.
EMC	Electromagnetic Compatibility is the ability of electrical equipment and systems to work in the environment that they are being used in.

Acronym/ word	Definition
Fingerstick Testing / Test strip testing / SMBG	One way of determining your BG level. Using a BGM and test strips you can determine your BG level from a sample of blood from e.g. your fingertip.
Hyper-glycaemia	Medical term for high blood sugar (glucose) levels. Sometimes called a 'hyper' or 'high' and is typified by higher than average glucose levels in the bloodstream. It is a serious condition and if untreated can lead to complications such as Diabetic Ketoacidosis (DKA). The alert in sugarBEAT® for 'Glucose High' is set at 13.9 mmol/L and 22.2 mmol/L at for 'Glucose Urgent High' bearing in mind that sugarBEAT® is to be used alongside values from a BGM rather than as a replacement. Alerts are discussed in more detail later in this document.
Hypo-glycaemia	Medical term for low blood sugar (glucose) levels. Sometimes called a 'hypo' or 'low' and is typified by lower than average glucose levels in the bloodstream. It is a serious condition and if untreated can lead to serious complications such as unconsciousness. The alert in sugarBEAT® for 'Glucose Low' is set at 4.4 mmol/L and at 3.6 mmol/L for 'Glucose Urgent Low' bearing in mind that sugarBEAT® is to be used alongside values from a BGM rather than as a replacement. Alerts are discussed in more detail later in this document.
IEC	International Electrotechnical Commission is a recognised standards organisation for electrical / electronic technologies.



Acronym/ word	Definition
IFU	Instruction For Use.
Indication	A condition making a particular treatment or procedure advisable.
IP	The Ingress Protection (IP) marking is one of the IEC safety standards which classifies and rates how protected an electronic device is against water, dust, accidental contact etc. IP ratings are numerical with the number based on the conditions the device may come across.
MARD	Mean Absolute Relative Difference. Currently the most common way to assess the performance of a CGM system. MARD is the average of the absolute error between all CGM values and matched reference values. The smaller the percentage the closer the CGM readings are to the reference glucose value.
Precaution	A measure to be taken by you or your doctor to ensure the safe and effective use of sugarBEAT®.
RF	Radio frequency.
Safety Statement	A statement of the intended uses of sugarBEAT® and relevant warnings, precautions and contraindications.
Smart Device	A mobile device that can wirelessly connect to a network via Wi-Fi or a mobile data connection e.g. 3G, 4G, 5G. Smart phones and tablets are examples of smart devices.
SMBG	Self-Monitoring Blood Glucose. This is the method of determining your BG by use of a BGM and a blood sample applied to a BG test strip. Commonly called Fingerstick Testing.

Acronym/ word	Definition
Time-in-Range (TIR)	TIR is the percentage of time that a person spends with their glucose levels in a target range.
Warning	A type of safety statement which describes a feature and important information about the risks involved. Describes things to be aware of when using sugarBEAT®, their possible consequences and how to avoid them.
WEEE	Waste Electrical and Electronic Equipment should be disposed of in accordance with local requirements. This is discussed in more detail later in this document.



Intended Use

sugarBEAT® is a non-invasive Continuous Glucose Monitoring (CGM) system for tracking glucose patterns and is intended to help people with Type 2 diabetes and prediabetes better manage, reverse and prevent the onset of this condition.

It can also be used by those who simply want to better understand the impact their lifestyle and diet is having on their glucose levels. sugarBEAT® is intended to be complimentary to SMBG testing for those with diabetes although everyone will need to use blood glucose levels from a BGM to calibrate their system.

Remember that sugarBEAT® is not designed to replace SMBG testing and adjustments of your treatment e.g. insulin dose should **not** be made based on readings from it.

What do you need to know before using sugarBEAT®?

Not using sugarBEAT® and its components according to these instructions and safety information / warnings may result in you not getting the best from the system or it not working as it should.

Safety information appears throughout this document. This includes indications, relevant warnings, precautions and contraindications. Please read all of this information Instructions for Use to ensure you use the product safely and get the most from it. Information that is particularly relevant to the successful operation of sugarBEAT® is shown immediately below.

Contraindications

There are a small number of people who should not use sugarBEAT® and these are listed below:

- Persons with skin conditions which preclude the wearing of the Transmitter at the application site (e.g. recent burns / scalds, open wounds or skin lesions).
- Persons with known allergies to medical grade adhesives.
- Persons under 18 years of age*
- Persons over 70 years of age*
- Critically ill patients*
- Pregnant women*
- Persons undergoing dialysis*

* The accuracy of sugarBEAT® has not yet been tested in these groups and as such its use cannot be recommended as the accuracy of readings cannot be confirmed.

Persons with suspected allergies to skin adhesives should consult their healthcare professional before using sugarBEAT®. If skin irritation around or under the Sensor area is identified, use of the Transmitter should be stopped. If the irritation does not improve after 2-3 days, or worsens after 2 days, consult a doctor.

DO NOT USE sugarBEAT®:

- If the Sensor Kit or Sensor appear to be damaged or are already opened when you receive them.
- If the Transmitter's plastic case is or appears to be damaged.
- If any component has passed its use by date.
- If you plan to swim or take a shower / bath.
- Whilst you are in surgery.

During intense exercise, the Transmitter may loosen or come off due to sweat or movement. If this occurs, replace the Sensor and reapply the Transmitter.



Warnings

The following table gives advice / warnings to help ensure that you use your sugarBEAT® device safely and effectively:



Read this (IFU) before use. It is important to read and follow this information. Keep it safe so you can refer to it again.



Keep out of the sight and reach of children.



Explosion hazard. Do not place near to or use sugarBEAT® in the presence of any flammable substances, anesthetics or gases.



sugarBEAT® should only be used with the plug provided. Do not attempt to use alternative universal power supplies with the system as they may not meet the required standards.



Do not attempt to modify the equipment or system as this may cause injury. If you experience any unexpected events while using this device, please contact the manufacturer – details are provided at the end of this (IFU).



Do not immerse any part of the equipment in any liquid.



No user serviceable parts.



You should not ignore symptoms that may be due to low or high blood glucose. If you experience symptoms that are not consistent with the glucose readings from sugarBEAT®, confirm your blood glucose using a BGM and if necessary, consult a healthcare professional.

During conditions such as uncontrolled diabetes or rapidly changing blood glucose levels, you must confirm the sugarBEAT® readings with those from your BGM and / or recalibrate at regular intervals.



Do not ignore the 'High' or 'Low' alerts even if you feel fine. Check your blood glucose using a BGM and if necessary, recalibrate your sugarBEAT® Sensor.

Note: If the radio link between the Transmitter and your smart device becomes unavailable, the glucose "Alert" functions will not operate correctly.



Always check your glucose readings using a BGM. sugarBEAT® is intended to be used as an adjunct to a conventional BGM. The system does not intend to replace Self-Monitoring Blood Glucose (SMBG) devices.



Impaired awareness of Hypoglycaemia. sugarBEAT® has not been evaluated for use with patients that have impaired awareness of hypoglycaemia. Caution is advised with the use of this device in these patients.



Skin conditions, e.g. Psoriasis, Neurodermatitis. sugarBEAT® has not been evaluated for patients with these conditions (or similar). Consult your physician before using this device.



Choking hazard: sugarBEAT® contains small parts (including a Lithium-Ion battery) which may be dangerous if swallowed.



Transport / Flying: The Transmitter contains a Lithium-Ion battery. The device must either be attached to your arm and in use or placed in carry-on cabin baggage (recommended). Always check current airline rules prior to travel to an airport. Be aware that if the Transmitter is in use and you activate flight mode on your mobile device and Bluetooth connection is lost, the data transfer will automatically resume when you reconnect Bluetooth. No data will be lost.



Transport / Air Cargo: The battery cannot be shipped alone. It must be contained within sugarBEAT® or packed in the same primary container as sugarBEAT®. Contact your shipping agent BEFORE packing and shipping and check current International Air Transport Association (IATA) rules.



What to know before you apply your sugarBEAT® device

- Ensure the application site is clean, dry and free from moisturisers / lotions, excess sweat or dirt. If present, wipe them away with a standard alcohol wipe. It is recommended to change the application site after each use to prevent irritation. Leave a minimum of 24 hours before re-using an application site.
- Transmitter application is not approved for sites other than the upper arm. If placed on other sites, it may not function properly.
- Avoid skin areas with scars, moles, stretch marks, excessive hair, lumps, tattoos or insulin injection sites. Select a flat surface (no bent or folded skin) and one where muscle movement will be as little as possible. Choose a site that is at least 2.5 cm (1 inch) away from an insulin injection site.

Your blood glucose level compared with sugarBEAT® readings

There is a short lag period of, on average, 10-45 minutes from when sugarBEAT® measures your glucose level and it being displayed on the App. Differences in glucose readings between a BGM reading and sugarBEAT® may therefore be observed during times when blood glucose changes rapidly, such as after exercise, eating and insulin administration.

Cybersecurity Best Practice

Part of the sugarBEAT® system is an App which works on your smart device and displays the glucose readings detected by the Sensor. The App and the Transmitter are connected by Bluetooth technology and it is important that you take appropriate cybersecurity precautions in order to keep your data safe:

- The sugarBEAT® App should only be downloaded from official App locations (Google Play Store / App Store) to ensure only the official version is used.
- It is recommended that smart devices and associated accounts (i.e. Google Device) have user enabled passwords / pass codes / biometric identification i.e. fingerprint recognition enabled to prevent unauthorised access to the smart device and App data.
- It is recommended that a strong and unique password / pass code is used for smart devices and associated accounts.
- It is recommended that a lock-out timer is set to prevent unauthorised access to the smart device and App data.
- The rooting or jailbreaking of smart devices may prevent App security features from operating correctly and may give unauthorised access to the smart device and App data. It is not recommended to use sugarBEAT® with jailbroken or rooted smart devices.
- It is recommended that anti-virus and anti-malware software is installed on the smart device and security scans are enabled.



- It is recommended that App data backups are enabled and the Transmitter is periodically backed up and these backups are secured.
- It is recommended that the 'Scan device for Security Threats' feature is enabled (Android user only).
- Never give unauthorised access to the smart device and App.
- It is recommended to keep the software on your smart device and the App up to date by installing updates when prompted.
- Be aware that information e.g. your glucose readings sent over an unencrypted email are not secure and could be intercepted.

Smart Device Settings

It is important to ensure that the settings on your smart device are correct so that you do not miss an important alert when using sugarBEAT®. It's important to be aware that a smart device's internal settings or other accessory devices such as a smart watch or fitness tracker may interfere with or override the alerts in the sugarBEAT® App. To make sure this does not occur:

- Ensure that your smart device has a security password set.
- Make sure the notifications for the sugarBEAT® App are turned on in the settings menu of your smart device.
- Ensure sugarBEAT® has access to your smart device's location, even when running in the background.
- Ensure Bluetooth is enabled on your smart device.
- Turn off 'Do Not Disturb' on your smart device (if available).
- Always have the sugarBEAT® App running; do not close it down.
- Make sure any (new) devices you connect to your smart device do not interfere with or change the settings.
- Ensure the volume on your phone is set at a level that you can hear bearing in mind where you might be during the day.
- Ensure sugarBEAT® has permission to write to your smart device's storage.

The alert vibrations on the sugarBEAT® App are no different to other vibrating alerts on your smart device e.g. from a fitness tracker. As such the only way to see if a notification is from sugarBEAT® is to look at your smart device.



When to remove your device

- Remove your device after a maximum of 14 hours use.
- If you believe the reading from sugarBEAT® is incorrect or it is inconsistent, check it using your BGM. If the problem continues remove your device, charge your Transmitter and fit a new Sensor.
- Be aware that if the device becomes loose, you may get no or inconsistent readings.

Precautions

Performance with other (medical) devices

Performance of the sugarBEAT® system when used with other implanted medical devices, such as pacemakers or other CGMs, has not been evaluated.

The below table outlines things which could cause an issue with your device and how best to avoid them:

Effect	Precaution	Source
Can cause inaccurate Sensor readings	In order to maintain good general health you should always try to drink sufficient fluids to remain hydrated. Check with your healthcare professional if you are suffering from severe dehydration.	Severe dehydration / excess water loss
Lint and dust have little to no effect on the performance of sugarBEAT®. However, some users may have an allergic reaction to them.	Clean the Transmitter between use using a damp tissue or alcohol wipe. The Docking Station can also be cleaned as needed.	Lint & Dust



Effect	Precaution	Source
While direct sunlight may have minimal effect on the Transmitter and Docking Station, it can cause degradation of the Sensors and lead to incorrect or no readings being obtained.	Keep the Transmitter and Docking Station and in particular the Sensors, out of direct sunlight.	Sunlight
These substances may incorrectly raise reported sugarBEAT® glucose readings. The level of inaccuracy depends on the amount of substances active in the body and may be different for each user.	If taking these medications while using sugarBEAT®, be aware that the accuracy of the readings will need to be checked from time to time using a BGM.	Medications which contain Paracetamol, Aspirin or Ascorbic acid (Vitamin C)
Loose Sensors can cause incorrect or no glucose readings.	If a Sensor becomes loose during movement (e.g. intense exercise), replace the Sensor with a new one.	Loose Sensors
Degraded Sensors can cause incorrect glucose readings.	- Do not use Sensors if they appear damaged or the packaging is opened upon receipt. - Do not use Sensors which have passed their expiry date. - Do not re-use sensors.	Degraded Sensors

Effect	Precaution	Source
The sugarBEAT® system has not been tested with MRI or CT scans or with diathermy treatment. The associated magnetic fields and heat may damage the Transmitter, leading to glucose readings not being displayed. The effect of X-ray on sugarBEAT® performance has not been evaluated. Exposure to X-ray may damage the Sensor and may impact proper function of the Transmitter.	Remove sugarBEAT® before undergoing X-rays, MRIs, CT Scans, Diathermy treatments or any other procedures involving electrical currents.	Electrical equipment with strong interference (e.g. X-ray equipment, Magnetic Resonance (MRI) Scanners, CT Scanners, Diathermy Treatment)
Interference with the performance of sugarBEAT® which can lead to glucose readings not being displayed.	Do not use portable RF communication equipment closer than 12 inches to the Transmitter. This includes cables specified by the manufacturer.	Portable RF Communications Equipment (including peripherals such as antenna cables and external antennas)



Source	Effect	Precaution
Battery optimisations on your smart device	If the sugarBEAT® App is running in the background, it may be put to sleep by your smart device. This will cause the sugarBEAT® App to stop receiving data from the Transmitter. Android and iOS experiences may vary	Ensure sugarBEAT® is exempt from battery optimisations on your smart device.
Children and adolescents	sugarBEAT® has not been evaluated in persons below the age of 18 years. Children can choke on the components of sugarBEAT®.	• sugarBEAT® should not be used by anyone under the age of 18. • Keep sugarBEAT® out of the sight and reach of children.
Pests	Unwanted pests can cause contamination to parts of sugarBEAT®.	• Clean the Transmitter between use to avoid contamination from unwanted pests. • Store sugarBEAT® in a clean area.

Labelling & Packaging of sugarBEAT®

The following symbols may appear on sugarBEAT® components / labels and packaging.



Manufacturer



Date of Manufacture



Distributor



Use by / expiry date



Refer to Instructions for Use



Consult Instructions for Use



Warning



Do not reuse



Type BF Applied Part



Store between 2° C and 40° C



Do not use if the package is damaged



Do not throw sugarBEAT® out with household waste. The sugarBEAT® Transmitter and Docking Station should be disposed of in accordance with local regulations. The sugarBEAT® Transmitter contains a lithium battery, electronic parts and recyclable materials.



Batch number



Serial number



Keep dry



This product is a medical device



CE Mark - Manufacturer declaration that the product complies with the essential requirements of the relevant European legislation



Authorised Representative in the European Community for the Manufacturer



sugarBEAT®

What is in your sugarBEAT® Device Box?

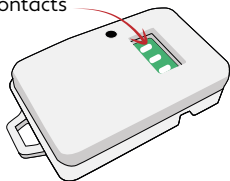
Transmitter

The Transmitter is the small rectangular shaped plastic unit. It consists of a non-disposable electronic module and a built-in Lithium-Ion rechargeable battery and is approximately 1.2" x 1.6".

The connection of the Sensor to the Transmitter allows our novel technology to measure the glucose that diffuses from the interstitial fluid into the skin. The fluid is analysed enzymatically by the Sensor and its signals are detected by the Transmitter and sent to the sugarBEAT® App using Bluetooth. This data is then correlated with blood glucose levels using an algorithm after calibration with a BGM reading and displayed in numerical and graphical formats on your smart device.

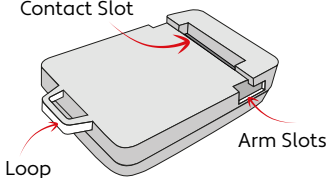
Transmitter - Front View

Gold Contacts



Transmitter - Back View

Contact Slot

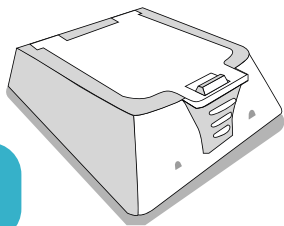


Docking Station

The Docking Station is used to charge the Transmitter.

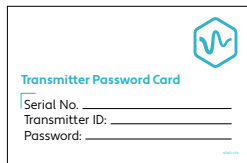


Note: The Docking Station does not function as a data link. It cannot be used as an interface to download data from the Transmitter.



Transmitter Password Card

Contains the Transmitter ID and case sensitive Password.



Charger

The Charger is comprised of USB to micro-USB Cable and a plug.

Quick Start Guide

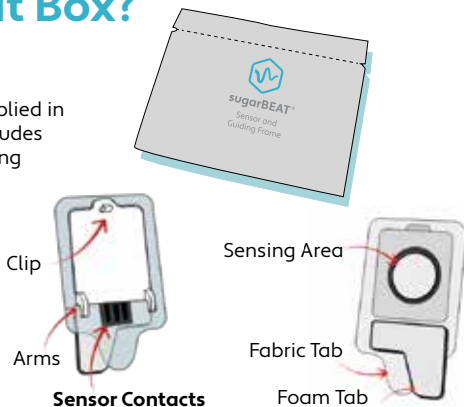
The Quick Start Guide (QSG) is provided in your sugarBEAT® Device Box.

What is in your sugarBEAT® Sensor Kit Box?

Sensor

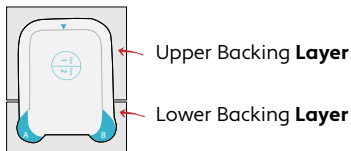
The Sensor Kit is supplied in a foil pouch. This includes a Sensor and a Guiding Frame.

The Sensor detects the glucose in the interstitial fluid.



Guiding Frame

The Guiding Frame is used to accurately position the Sensor on your arm and to prepare the skin.



The sugarBEAT® Smart Device App

The sugarBEAT® App is central to your entire sugarBEAT® experience. Processing information received from the Transmitter and presenting it in an easy to view and understandable format, helping you get to know your own glucose profile and how your lifestyle choices affect it.

The sugarBEAT® App has a whole host of easy to use features.

The sugarBEAT® App can be downloaded onto a smart device e.g. mobile phones and tablets, from either the Google Play (Android) or Apple App Store (iOS). The App requires a minimum software version of Android 7 or iOS 11.

If your smart device uses the iOS operating system you should be aware that the App is not intended for, nor does it support, deployment as part of a “Shared iPad” system.



We will talk through all the steps for using the App in detail later in this (IFU). We will now introduce the main screens and what you will see on them.



This is the main menu within the App which you can access by tapping the ‘hamburger’ symbol in the top left corner of the App. A quick summary of each of the items in the main menu is given below and is discussed in more detail later:

Dashboard – This is the ‘main’ screen and the one you will see and use most often. Its main elements are described in the next section.

Activity – Here you can enter any exercise you take such as walking, cycling, running etc. By logging this information regularly it will help you see what exercise does to your glucose levels.

Medication – Log when you take medication to see how this affects your glucose profile.

Food – Food can have a significant impact on your glucose level and this function allows you to log your food intake to view its effect on your glucose levels.

Wellbeing – You can enter how you feel and see if your mood affects your glucose profile or vice versa.

History – From here you can access stored data and generate reports which you can send to yourself, family members or healthcare professionals.

Transmitter – From this page you can access information on the Transmitter connected to the App.

Settings – There are a number of settings you can adjust to suit you and your lifestyle e.g. how you receive alerts.



The dashboard is the screen you will see most often when using the App and it consists of the following main elements:



Banner Message

Gives you key information and instructions during set-up. During use it will give the current status of your glucose level and will be where any alerts are shown.

Glucose Level

In this box we can see three things:

Time: The time of your latest glucose reading.

Trend: An arrow indicates in which direction your glucose level is heading.

Hexagon: Displays your most recent glucose reading and changes colour depending on your glucose level - this is explained in detail in the 'Alerts' section.



Today

In this box you will see an overview of the data collected for the current day as a glucose profile against time as well as circles displaying your average reading for each hour.

This Week

If you scroll down past 'Today' you will see the 'This Week' box which displays your daily high and low glucose values as well as your percentage of 'Time-in-Range' for the last 7 days. All of this information will be invaluable in helping you understand your glucose profile and how your lifestyle can affect / control it.

Your Device

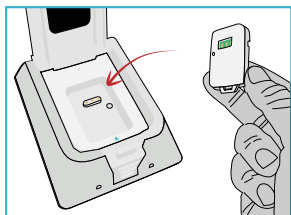
This last box includes the current status of your Transmitter, as well as a battery symbol which tells you how much charge is in your Transmitter. From here you can also click to e.g. recalibrate or disconnect your device.



Getting started with sugarBEAT®

In this section we will take you through all the steps to get the sugarBEAT® Transmitter charged and on your arm, ready to send your glucose data to the App. We will also see how to download, register and set the App up. Once you have finished this section, you will be ready to start using your device.

1. Charging the Transmitter



Charge the Transmitter for at least 6 hours immediately prior to first use.

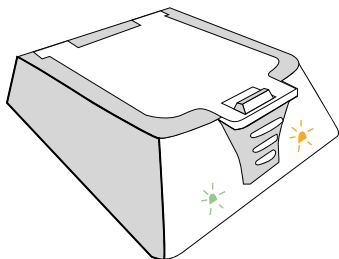
It should also be charged before each use. At room temperature, the Transmitter receives a full charge in approximately 6 hours and will then function for approximately 30 hours. However, it is recommended to charge your Transmitter the night before you use it.

To open the Docking Station press the button on the front of the Docking Station and open the lid.

Place the Transmitter onto the Docking Station with the three Gold Contacts facing down.

The arrow ▼ on the docking station and the Loop on the Transmitter should line up.

Close the lid. You will hear a 'click' confirming the lid is securely closed.



Connect the Charger to the Docking Station and a power supply.

The **GREEN LIGHT** indicates that the Docking Station has a power connection, and the **AMBER LIGHT** indicates that the Transmitter is charging. When first charging your Transmitter, charge for 24 hours. Subsequent charges should be for at least 6 hours.

When the Transmitter is fully charged, remove the Transmitter from the Docking Station.

2. Initial App Set-Up

While the Transmitter is charging it is a good idea to download and set the App up as this will be needed once the Transmitter is charged.

Before starting ensure that Bluetooth is activated on your smart device and in order to protect your data, it is recommended that your smart device has a security password set.



Download the sugarBEAT® App from the Google Play or Apple App Store.

Once done, tap on the sugarBEAT® App to launch it and it will initialise.

Android and iOS experiences may vary.



For first time use, a message will appear to remind you that sugarBEAT® **does not** replace a blood glucose meter (BGM).

Always use the values from your blood glucose meter for treatment decisions.

Tap 'I understand' to continue.



The App will ask you to create a 4-digit numerical PIN.

Create a 4-digit PIN. This PIN can be independent of the phone security PIN. Tap 'Confirm' when done.



For first time use, a message will appear to remind you that sugarBEAT® does not replace a blood glucose meter (BGM).

Always use the values from your blood glucose meter for treatment decisions.

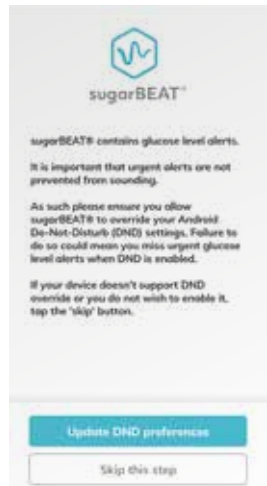
Tap 'I understand' to continue.

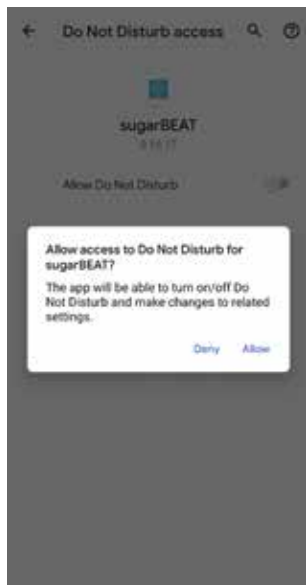
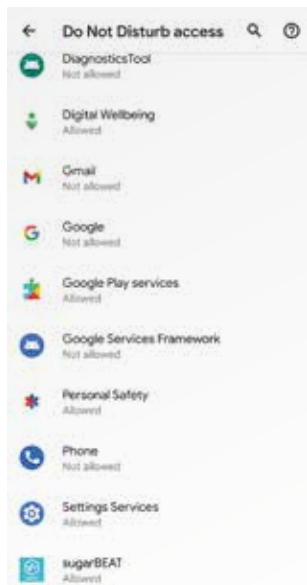
The App will then display a message about 'Do Not Disturb' (DND) preferences which you should read carefully.

As mentioned earlier, the sugarBEAT® App will alert you if your glucose levels are/or are moving towards going too high or low.

Tap '**Confirm**' when set so that your smart device does not override these alerts and stop you receiving them. As an example, on smart devices that use the Android operating system, you should select '**Update DND preferences**'.

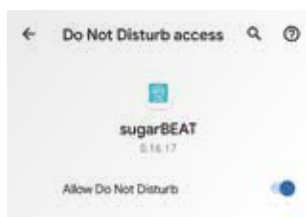
This will redirect you to the smart device's Do Not Disturb permissions. Select the toggle to allow sugarBEAT® DND permissions.





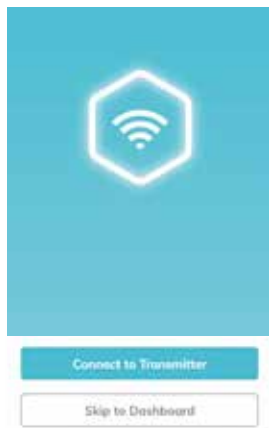
A pop up will be displayed to confirm sugarBEAT® can have access to your 'Do Not Disturb settings'. Tap '**Allow**'.

For phones which use other operating systems e.g. iOS please refer to your device's manual.



3. Connect the Transmitter to the sugarBEAT® App

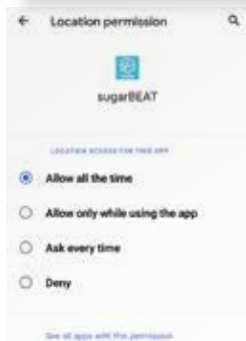
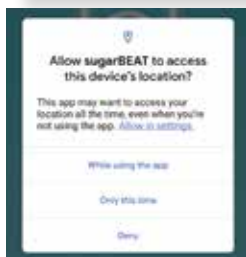
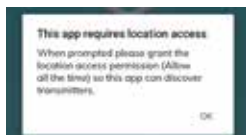
To connect your Transmitter to the App press '**Connect to Transmitter**'.

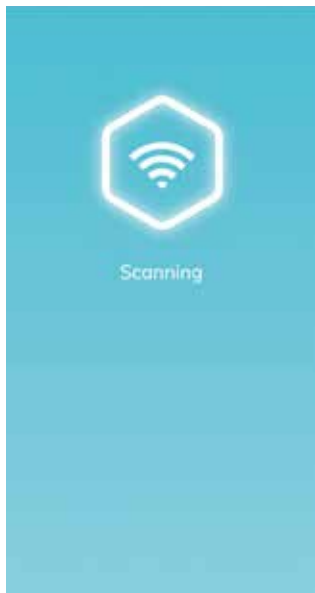


If the location permission window appears, choose the '**Allow all the time**' option (you may need to first choose '**Allow in settings**' to get to this option). This allows the App to connect to the Transmitter even while the sugarBEAT® App is in the background.

Tap the back button to continue using the app.

Ensure location is turned '**ON**' on your smart device.

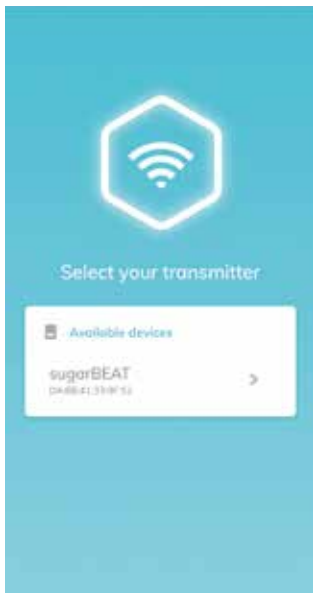




The App will then scan for your Transmitter.

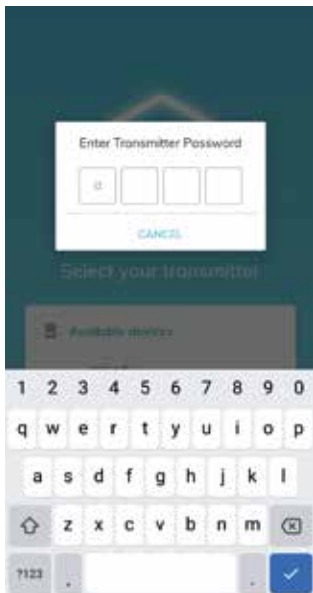
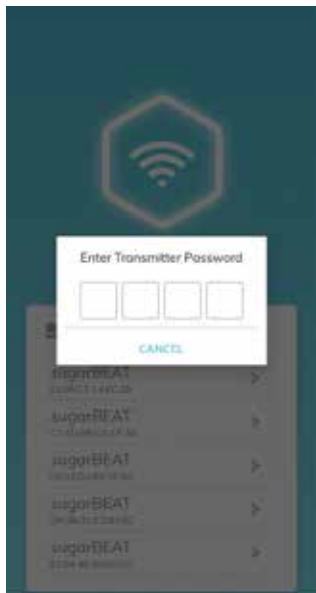
Note:

If you have more than one Transmitter, ensure you select the correct one.



Available Transmitters within range will be listed. The number for your Transmitter is located on the Transmitter and password card which is provided with your Starter Pack.

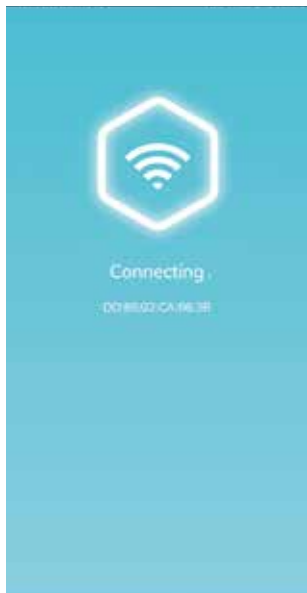
Press on the correct Transmitter number to select it.



When prompted, enter the password located on the card supplied with the device.

Note: The password is case sensitive.





Once done the App will start to connect to the Transmitter and you will see this screen.



Once the App verifies the password is the correct one for the Transmitter, you will see this screen.

You may have to accept a Bluetooth Pairing request on the very first connection to the Transmitter.

Connection to additional devices, may require separate requests to pair the devices.

4. Preparing your skin before attaching sugarBEAT®

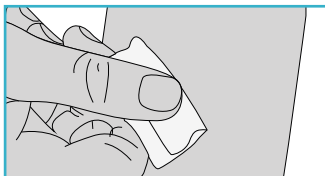
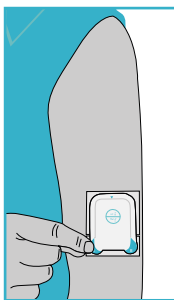
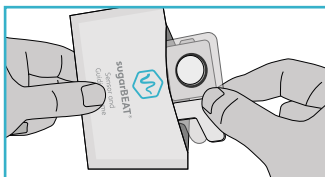
Remove the Sensor and Guiding Frame from the foil pouch and put to one side as you will need these later.

Select a clean, 'flat' and dry area on the outer side of your upper arm.

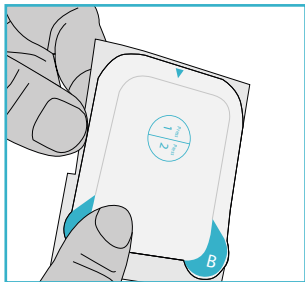
Avoid areas with scars, moles, stretch marks, lumps, excessive hair, tattoos and insulin injection sites. To reduce the chance of skin irritation, leave a minimum of 24 hours before re-using an application site.

Once you have chosen a spot, flex your arm to ensure you are not planning to place your device somewhere that is prone to lots of movement.

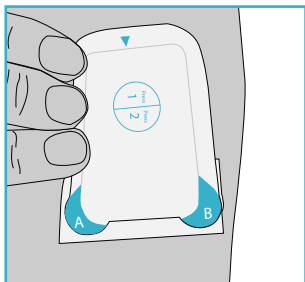
Once you are happy with the spot, if necessary, wipe it with an alcohol wipe to ensure it is free of sweat / dirt (not included).



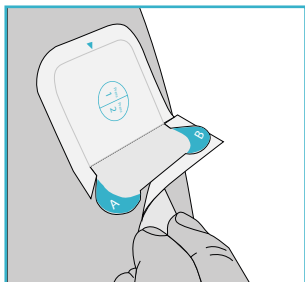
Remove the Upper Backing Layer from the Guiding Frame.



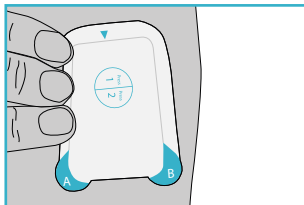
Firmly press the Guiding Frame onto your skin for 5 seconds.



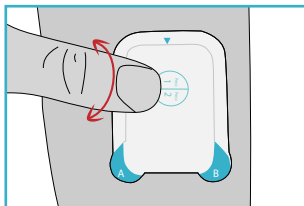
Remove the Lower Backing Layer from the Guiding Frame.



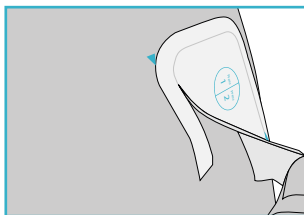
Firmly press onto your skin for an additional 5 seconds.



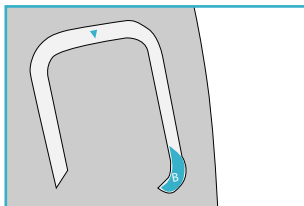
Press and roll the end of your thumb or finger over the area marked 'Press 1', for 10 seconds. Repeat for 'Press 2' for a further 10 seconds.



Peel off the part of the Guiding Frame labelled 'A' leaving part 'B' on your arm.



This frame will provide a visual aid of where to apply the Transmitter.



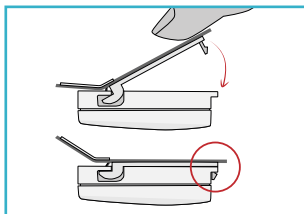
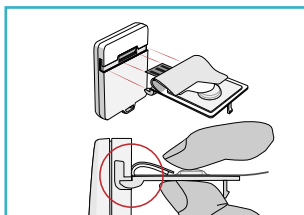
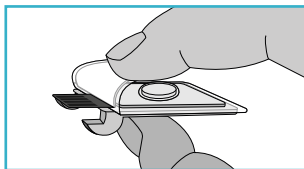
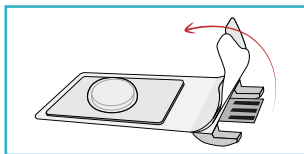
5. Attaching the Sensor

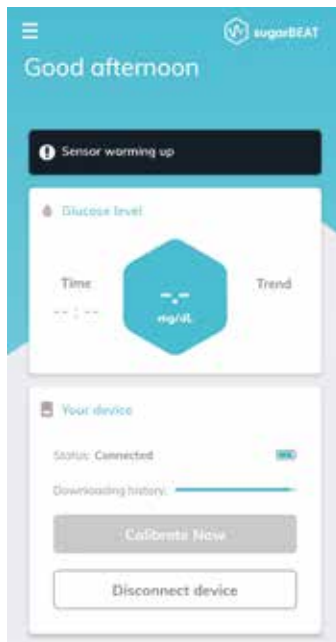
Gently fold back the Foam Tab to expose the Sensor Contacts.

Note: Do not remove the protective cover at this stage.

Gently insert the Sensor Contacts into the Contact Slot on the Transmitter until they cannot go any further. Ensure the Arms are fully in the Transmitter Arm Slots.

Push the Clip down towards the Loop to secure it in place on the Transmitter. Stop when you hear the click.





Once connected, the following screen will be displayed which indicates that the Sensor is warming up. It may take the Sensor on average 30-90 minutes to warm up.

At this time, the glucose level and overview boxes will not display any relevant information as the readings from your device will not yet be available.

If you have any issues with connecting the App and Sensor, please refer to the Troubleshooting section towards the end of this (IFU).

6. Placing the Transmitter on your Arm

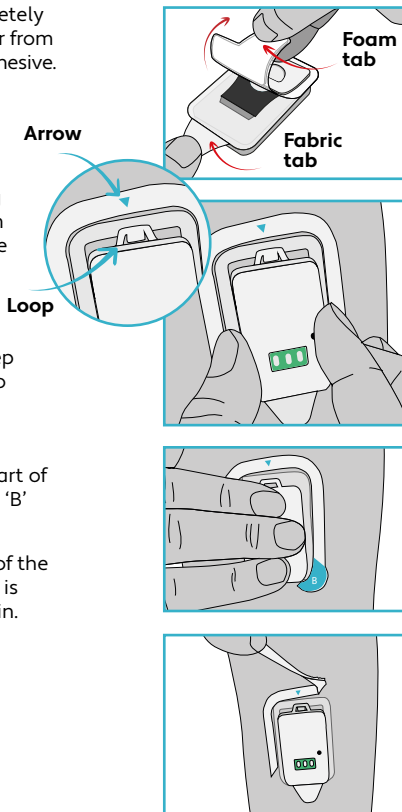
Using the Foam Tab, completely remove the protective cover from the Sensor to expose the adhesive. Now carefully pick up your Transmitter **avoiding the sticky surface**.

Place the Transmitter into the Guiding Frame aligning the **Loop** with the **Arrow** on the Guiding Frame. Press the Transmitter down at both the top and sides for 20 seconds.

Take your time with this step as it is not recommended to remove the Transmitter to realign it once it is stuck.

Peel away the remaining part of the Guiding Frame labelled 'B' to completely remove it.

Lightly press on the edges of the adhesive patch to ensure it is securely attached to the skin.



7. Calibrating the Transmitter

Now that the Transmitter is connected to the App and safely positioned on your arm, we are almost ready to start collecting the glucose readings.

We need to calibrate sugarBEAT® first and in this section we will show you how to do this so that you can get real-time glucose data every 5 minutes during your day.

You may calibrate more than once and it is recommended to calibrate twice a day - once on application of the Transmitter and again around halfway through the day. The App will automatically prompt you to **'calibrate'** when it's optimal to do so.



During the Sensor warm-up period (30 – 90 minutes) and before calibration, the App will display a glucose trend graph without any indication of your actual glucose levels. Actual glucose readings will only be available once your device is calibrated.

Once warm up is complete, the App will automatically prompt you to calibrate by entering a BG value from a BG meter e.g. a fingerstick test.

Once done you should follow these steps:

Tap 'Calibrate Now' to enter the BG value from your BGM.





Tap the box to enter your BG reading.



Note: Calibrate your device by using the values you obtain from your BGM. Any values on the diagrams are for illustration purposes only.

Press '**Calibrate**' to enter the readings

The App will ask you to confirm the blood glucose value.

If it is correct, tap '**Yes**' to accept the value entered.

If it is incorrect, tap '**No**' and enter the correct value.

In this example a BG value of 5.7 mmol/L has been entered for calibration.





Once your device is calibrated, the App will show all glucose values from the time the Transmitter was applied and will then report all future glucose values at 5 minute intervals from that point onwards.

The most recent glucose value will be displayed in the circle in the 'Glucose Level' section of the App and will automatically be added to the glucose trend graph in the 'Overview' section. In this way, the graph and glucose trend profile will gradually build up over the course of the day.

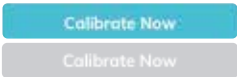
In the example shown, the hourly average was 10.2 mmol/L (recorded at 10 am) which changed to 6.9 mmol/L at 11 am, and is at 5.8 mmol/L at 12 pm. During this time, the Transmitter will have taken 28 readings.

Clinical studies have shown that the accuracy of sugarBEAT® based on a single calibration is 12.3 % MARD. This single point calibration can be made at any time of the day. In order to see actual glucose values, calibration needs to be performed soon after the '**Calibrate Now**' prompt appears on the screen.

Multiple calibrations can be performed, and it has been shown that a second calibration, approximately 7 hours after the first calibration improves the accuracy of the device with the MARD being 11.9 %.

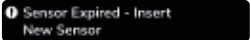
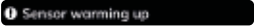
sugarBEAT® 'In-App' Symbols and Settings

The table below outlines the symbols you will see when using the sugarBEAT® App.

sugarBEAT® symbols	Meaning
	Wi-Fi connected
	Menu
	Whilst the Sensor is warming up the message asking you to calibrate will be grey / deactivated. Once the Sensor has warmed up it will turn blue.
	Banner message from main or home screen reminding you to calibrate your device.
	When App has loaded it will prompt you to connect it to your Transmitter. Tap the button to connect.
	This message appears in the 'Your Device' area of the dashboard if you are not connected to a Transmitter. You will see this message if you load the App to e.g. look at previous data without connecting your Transmitter.

sugarBEAT® symbols	Meaning
	You can disconnect your device by tapping this message although this will stop readings being shown although the Transmitter will continue to collect them. Disconnecting and reconnecting can sometimes solve minor issues – see the Troubleshooting section for more information.
	Banner message which will be displayed once your Transmitter has connected indicating that all previous readings are being synced ready for new readings to be added. This message will also show when your Transmitter reconnects after e.g. being out of range to show it is sending the readings it has collected in that time.
	Tapping this message provides you with the option to enter further readings from your BGM. It is recommended to calibrate at least twice a day. It will turn from grey to blue when re-calibration is possible.
	Banner message indicating that a new Sensor is required. You will see this when connecting your Transmitter for the first time, if you have removed an expired Sensor or if there is an issue with the Sensor you have inserted – see the Troubleshooting section at the end for more information.



sugarBEAT® symbols	Meaning
	Banner message indicating that the Sensor has expired and that a new one is required. You will see this message at the end of the 14-hour wear time.
	Banner message indicating that the Sensor is warming up. This will be displayed until the Sensor requires calibration.
	This message appears on initial start-up and allows you to access the App without connecting e.g. if you want to view previous data.
	Banner message indicating that your Transmitter is not connected to your smart device e.g. because they are not within Bluetooth range.
	This banner message will be displayed if the Transmitter is reconnecting to your smart device after being disconnected e.g. after temporarily being out of Bluetooth range.
	This banner message will be displayed if you input an incorrect 4-digit pin for the sugarBEAT® App.

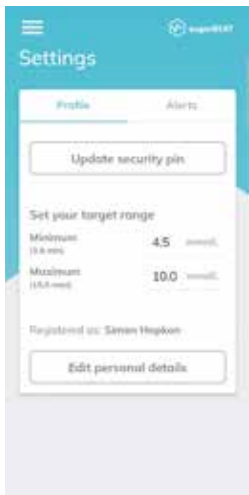
Battery Symbols

The App will display the estimated amount of power left in the Transmitter battery when you tap the battery symbol in the top right of the status bar. The different symbols are presented in the table below:

Battery symbols	Symbol Represents
	Over 14 hours battery life remaining
	Battery has ~12 hours remaining
	Battery has ~5 hours remaining
	Battery has < 2 hours remaining
	Battery is empty. At this point the Transmitter will not function and will need to be charged
	This symbol appears when the Transmitter is initially connected to the App and at that point it is not possible to determine the remaining battery life.



Review of Settings



Under the 'Settings' section of the App you can customise things to suit your needs.

Tap 'Menu' then 'Settings'.

Under the 'General' Tab you can do the following:

- Clear all user logs
- Clear all event logs
- Select all i.e. all user / event logs
- Decide if you want event logs to be included when you export.

Under the '**Profile**' Tab you can do the following:

- Update your security PIN, for example, if you are worried that someone has come to know it.
- Set your target range for your 'Time-in-Range'
- Register (if this step was skipped initially)



Under the '**Alerts**' Tab you can change how you receive the various alerts that the sugarBEAT® App can provide to suit your needs / daily routine i.e. silent, vibrate or audible depending if you are e.g. at work or not.

It is important to be aware that the alerts are provided for your benefit and therefore you should select the option most appropriate for you but also the one that ensures you will receive the alert in a timely way.

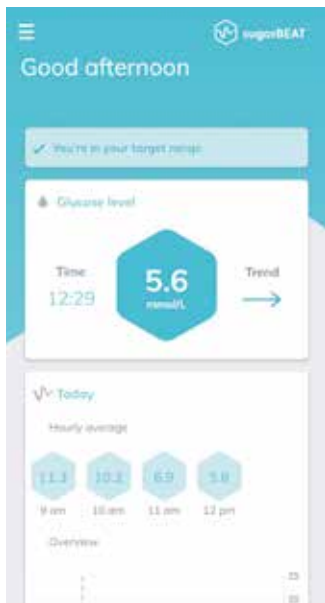
In this section it is also possible to turn off the alert for your glucose level increasing / decreasing quickly i.e. Glucose High Soon or Glucose Low Soon.



Alerts on the sugarBEAT[®] App

There are a number of alerts built in to the sugarBEAT[®] App to alert you if your glucose level is too high or too low or if is increasing / decreasing such that it might be high / low in the near future.

When you are wearing your Transmitter and it is connected and warmed up, you will see the following on the 'Home' page.



In the first small rectangular box called the 'Banner Message' you will see a short message describing your current glucose level. The possible messages, which are discussed in greater detail later, are as follows:

- Glucose Low Soon = Glucose predicted to be less than 4.4 mmol/L within 20 minutes
- Glucose Low = Glucose is 4.4 mmol/L or below
- Glucose Urgent Low = Glucose is 3.6 mmol/L or below
- Glucose High = Glucose is 13.9 mmol/L or above
- Glucose High Soon = Glucose predicted to be above 13.9 mmol/L within 20 minutes
- Glucose Urgent High = Glucose is 22.2 mmol/L or above
- You're in your target range = Glucose is between Low-High TIR targets

In the second box you will see the following:

- The time of your latest glucose reading.
- A circle which either depicts your most recent glucose reading or displays an 'Alert' indicating that your glucose level is high or low.
- A trend arrow which indicates the direction of your glucose level based on recent readings – this is discussed in more detail below.

In the third box you will see the following:

- A series of circles which indicate the hourly average of your glucose values for the current day.
- A graph which displays an overview of your glucose levels for the current day. This gives a visual representation of the information provided in the circles.



App Alerts: Low Limits

The App will display certain alerts if the readings from the Sensor indicate that your glucose level is getting or is too low as follows:

Glucose Low Soon

If based on recent readings, your glucose value is predicted to be less than 4.4 mmol/L within 20 minutes, the alert banner message will be **AMBER** in colour and will display the words '**Glucose Low Soon**'. This will also trigger an audible alert on your smart device to prompt you to look at the App.

The circle will also be amber and will display your most recent glucose value.



Glucose Low

If based on the most recent reading, your glucose value is less than 4.4 mmol/L, the alert banner message will be **RED** in colour and will display the words '**Glucose Low**'.

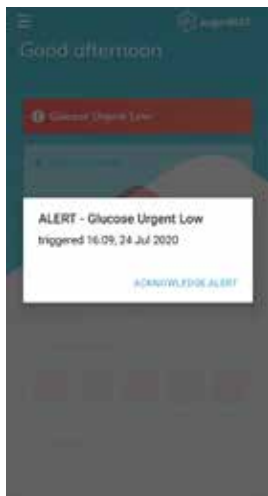
This will also trigger an audible alert on your smart device to prompt you to look at the App.

The circle will also be red and will display your most recent glucose value.

Glucose Urgent Low

If based on the most recent reading, your glucose value is less than 3.6 mmol/L, the alert banner message will be **RED** in colour and will display the words '**Glucose Urgent Low**'. The circle will also be red and will display 'LO' rather than your latest glucose value.

This will also trigger an audible alert on your smart device and a pop-up will appear stating '**ALERT - Glucose Urgent Low**'.



You can press '**Acknowledge Alert**' to dismiss the box / alert remembering that sugarBEAT® is to be used in conjunction with rather than as a replacement for SMBG testing by e.g. fingerstick. As such it is recommended that you confirm any alert from the system with a reading from your BGM.



App Alerts: High Limits

The App will display certain alerts if the readings from the Sensor indicate that your glucose level is getting or is too high as follows:

Glucose High Soon

If based on recent readings, your glucose value is predicted to be more than 13.9 mmol/L within 20 minutes, the alert banner message will be **AMBER** in colour and will display the words '**Glucose High Soon**'. This will also trigger an audible alert on your smart device to prompt you to look at the App.

The circle will also be amber and will display your most recent glucose value.



Glucose High

If based on the most recent reading, your glucose value is more than 13.9 mmol/L, the alert banner message will be **AMBER** in colour and will display the words '**Glucose High**'.

This will also trigger an audible alert on your smart device to prompt you to look at the App.

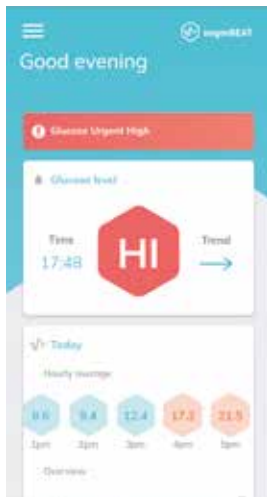
The circle will also be amber and will display your most recent glucose value.

Glucose Urgent High

If based on the most recent reading, your glucose value is more than 22.2 mmol/L, the alert banner message will be **RED** in colour and will display the words '**Glucose Urgent High**'. The circle will also be red and will display 'HI' rather than your latest glucose value.

This will also trigger an audible alert on your smart device and a pop-up will appear stating '**ALERT – Glucose Urgent High**'.

You can press '**Acknowledge Alert**' to dismiss the box / alert remembering that sugarBEAT® is to be used in conjunction with rather than as a replacement for SMBG testing by e.g. fingerstick. As such it is recommended that you confirm any alert from the system with a reading from your BGM.



Glucose Trend Arrows

The box which displays your current glucose level also includes an arrow which indicates the direction your glucose level is moving in. There are five possible arrows which are described below:



This arrow indicates that your glucose level is steady with it not having changed by more than 1 mmol/L in the last 15 minutes (3 readings).



This arrow indicates that your glucose level is rising with it having increased by 1 - 2 mmol/L in the last 15 minutes (3 readings).



This arrow indicates that your glucose level is falling with it having decreased by 1 - 2 mmol/L in the last 15 minutes (3 readings).



This arrow indicates that your glucose level is rising quickly with it having increased by more than 2 mmol/L in the last 15 minutes (3 readings).



This arrow indicates that your glucose level is falling quickly with it having decreased by more than 2 mmol/L in the last 15 minutes (3 readings).

Time-in-Range (TIR)

TIR is the percentage of time that a person spends with their glucose levels within a target range. Spending more TIR helps minimise both short and long-term health complications.

Time-in-Range goals are different for every person and may depend on medication, type of diabetes, diet, age, general health, and risk of hypoglycaemia. In general, people with diabetes should aim to spend as much Time-in-Range as possible, taking care to avoid low glucose levels.

Studies highlight that even a 5 % change in Time-in-Range is significant, which is equal to approximately one more hour per day spent in-range.

Experts recommend following target ranges for people with diabetes:

Type 1 diabetes	At least 70 % of the day in 3.9 - 10.0 mmol/L
Type 2 diabetes	At least 70 % of the day in 3.9 - 10.0 mmol/L
Gestational diabetes	At least 85 % of the day in 3.5 - 7.8 mmol/L
Those who are older or at high risk	At least 50 % of the day in 3.9 - 10.0 mmol/L
Those who are pregnant and have Type 1 diabetes	At least 85 % of the day in 3.5 - 7.8 mmol/L

As mentioned above the target range will vary depending on the person, but guidelines suggest starting with a range of **3.9 - 10.0 mmol/L** which is the default setting within the sugarBEAT® App. However, within the **'Settings/Profile'** tab of the App you can set you own target range as shown by the graphic.



As we know sugarBEAT® records your glucose levels every 5 minutes during wear time. For people with diabetes or prediabetes this allows you to build up and then visualise a data set of your glucose levels during the day and review the impact that lifestyle factors such as diet and exercise are having. For people using sugarBEAT® as a well-being device, TIR is less important but reviewing the daily profile can allow you to see what effect lifestyle factors are having on your glucose levels.

In the screenshot to the right you can see that the user has been within range from around 10am to 4pm:



On the **Dashboard** in the **'This week'** section of the App, you can see summary data for each day sugarBEAT® has been worn in the last 7 days as per the graphic to the left. You can see the percentage (%) of 'Time-in-Range' alongside the 'highest' and 'lowest' values for each day.

This data should enable you to spot trends or patterns associated with your lifestyle and so help you to better manage your glucose levels and hence your diabetes.

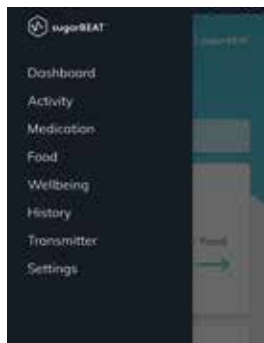
Viewing & Exporting Data

Data from any day on which your sugarBEAT® device is worn can be viewed and then exported via multiple methods including email, Bluetooth, messaging, Save to Google Drive and Android Beam. To export data, mobile data or Wi-Fi are required. If these are unavailable, the data will be sent when mobile data or Wi-Fi becomes available. (Android and iOS experiences may vary)

This shows an explanation of the circle icons below :

 = Days containing historical data

 = Current day



It is easy to view and export data if you follow these steps:
Pull up the main menu by tapping 

From there tap 'History'



To view the information for a particular date, tap on it. In this example the data is required from the 10th June 2021.





Create Reports

To export the data:
Tap on **'Create Reports'**

Two options will then be presented as you can either export data from a single day or for a period (multiple days).

To export data from a single day:

Tap **'Day'** and then scroll to the desired day.

Tap **'Create PDF'** to generate a data file for export.

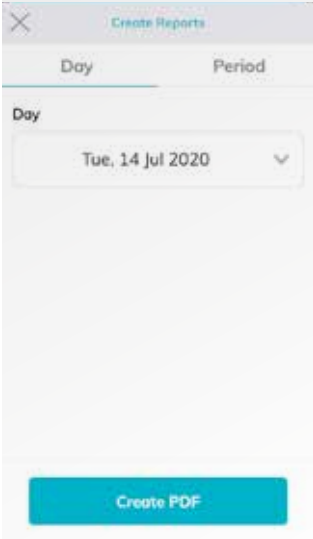
For a period:

Tap the **'Period'** tab

An option to change the **'From'** and **'To'** dates will be presented.

Scroll to the desired days for the period you would like the data from.

Tap **'Create PDF'** to export the data for that period.



Once you tap **'Create PDF'**, a prompt to enter a password will appear.

Tap above the line and enter a password of your choice. It can be the same password (but does not have to be) for connecting the App / Transmitter.

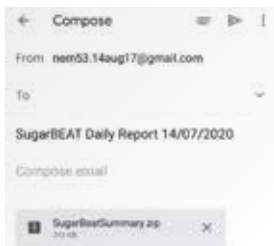
A password will be required each time data is exported. For the security of your data, the same password will be required to open the exported data.

Tap **'Create Reports'** to enter the password.



Depending on the operating system of your smart device, different options will appear to enable you to export the data. Choose the one that is most convenient for you. An example of one method (Gmail) is given but the others follow a similar process:

Exporting data using Gmail:
Tap on the Gmail icon

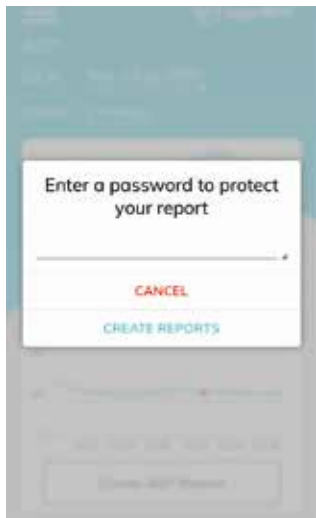


A window will appear to enter the recipient email details.

Enter the 'To' information and compose an email if required.

Tap ➤ to send the email. The email / data will be sent when there is mobile data or Wi-Fi connectivity.





Once you tap **'Create Report'**, a prompt to enter a password will appear.

Tap above the line and enter a password of your choice.

A password will be required each time data is exported. For the security of your data, the same password will be required to open the exported data.

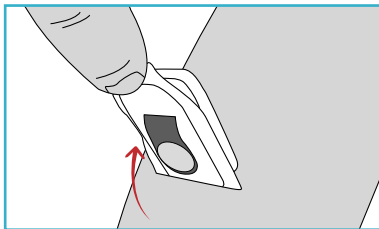
Tap **'Create Reports'** to enter the password.



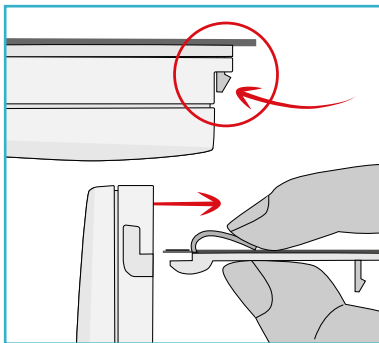
As before, different options will appear to enable export of the data. Choose the one that is most convenient for you.

Transmitter Removal + Storage

At the end of the day or if you have reached the end of the 14-hour wear time, remove the Transmitter by gently pulling the Fabric Tab away from your skin.



Remove the Sensor by unclipping it from the Transmitter. Remove the Arms from the Arm Slots on the side of the Transmitter.



The Sensor should be disposed of as general non-clinical waste. If you attempt to re-use the Sensor, the readings provided are unlikely to be accurate and cannot be relied upon. If you do try to re-use the Sensor, it is unlikely to connect or to warm-up, your App will likely display the following: **"Measurement Failure - Sensor Dry / Expired"**

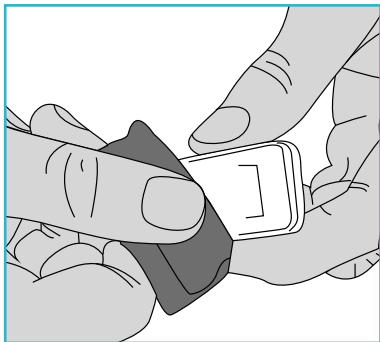


Do not reuse



Remove any dirt and moisture from the Transmitter by wiping with a damp cloth.

Store the Transmitter in the box or somewhere secure and away from moisture or excessive dust.



Everyday Use of the App / Transmitter

The following are things you might see and come across during everyday use of your sugarBEAT® device.



The App will prompt for a PIN, when it has not been used for a certain amount of time. Screen time out settings will be specific to your smart device.

If this happens simply enter your PIN to access the App.



During everyday use of the Transmitter, a reminder window may pop up during the warm-up phase stating:

'Always use your Blood Glucose Meter to check glucose readings and for your normal glucose measurement schedule.'

This is just to remind you that sugarBEAT® is designed to work alongside a BGM rather than replace it.





When you re-connect your Transmitter, the readings from previous days will also synchronise prior to use.

This is what you can see in the example shown i.e. **'History Sync'** is displayed in the banner message box.



It is possible to re-calibrate your device at any time. It is recommended to calibrate twice a day although once a day is adequate.

To re-calibrate, simply tap 'Re-calibrate', enter the BGM value obtained from a blood glucose meter, confirm that it is correct when prompted (or amend it if wrong) and you are done.

Diary Functions – Logging Food, Medication, Wellbeing and Activity

The sugarBEAT® App gives you the opportunity to enter what you eat, what medicine or exercise you take and how you are feeling during the time you are wearing your device. This gives you the chance to review how your glucose profile correlates with your lifestyle choices.

A. Activity

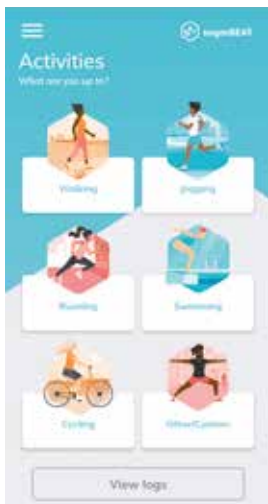
To log your activity, tap on the main menu and then **'Activity'**.

Once done select the type of activity you have just undertaken from the following by swiping across and then hitting 'next':

- Walking
- Jogging
- Running
- Swimming
- Cycling
- Other / Custom

If you select 'Other / Custom' you can input other kinds of exercise.

Note: The sugarBEAT® cannot be used during activities involving high moisture environments or direct contact with water, e.g. swimming, showering, bathing and saunas.



The App will then ask you to input the date and time that you performed the exercise, the duration and the approximate number of calories burned.

Once these are inputted, tap 'Save entry' and you're done.

This is a diary entry so can be done after you exercise or all in one go at the end of the day / week



The screenshot shows the 'Add activity' form. It has a title bar with a close button and the text 'Add activity'. Below the title bar is an illustration of a person walking. The form contains the following fields: 'When' (date and time), 'Duration' (hours and minutes), and 'Calories burned' (calories). The 'When' field is set to '10/6/2021' and '10:06'. The 'Duration' field is set to '0 hr' and '0 min'. The 'Calories burned' field is set to '0 kcal'. A 'Save entry' button is at the bottom.

In the screenshot (left) you can see that the following has been logged:

- Calibration at around 11:55 am
- Food at around midday
- Exercise just after 2 pm

B. Medication



Once done tap 'Save Entry' and you are done.

Again, this is a diary entry so can be done when you take your medicine or all in one go at the end of the day / week.

To log your medication, tap on the main menu and then **'Medication'**.

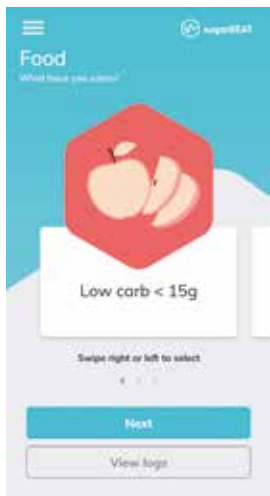
Then tap 'Add new medication' and input the following details:

- Date and time you took the medication
- The name of the medication
- The dose (with units) e.g. 50 mg



C. Food

By logging each meal and snack (in combination with when you exercise, take medication or just how you feel), you will be able to build a profile of your lifestyle against your glucose level.



To do this tap on the main menu and then **'Food'**.

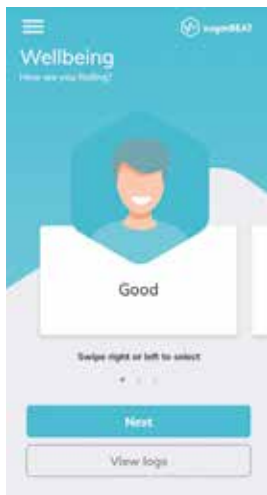
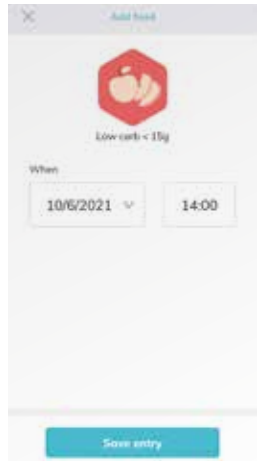
Once done select the type of meal / snack you have just eaten from the following by swiping across and then hitting 'next':

- Low carb < 15 g
- Medium carb < 30 g
- High carb > 30 g

The App will then ask you to input the date and time that you ate the food you are logging.

Once you have selected these, tap 'Save entry' and you are done.

As it is a diary function and has no impact on the functioning of sugarBEAT®, you can make these entries whenever you like i.e. you can enter all the food you have eaten that day in one go and it will be logged the same as if you do it after every meal.



D. Wellbeing

You can log your general mood / state of health to understand if this correlates with your glucose profile.

To do this tap on the main menu and then **'Wellbeing'**.

Once done select how you are feeling from the following by swiping across and then hitting 'next':

- Good
- OK
- Not well

×

Add wellbeing

Good

When

10/6/2021 ▾

10:04

Save entry

The App will then ask you to input the date and time for this wellbeing reading.

Once you have selected these, tap 'Save entry' and you are done.

Again this is a diary entry so can be done as many times as you like for any particular day and over the course of the day or all in one go.

The more entries you make the more accurate you will be able to track your glucose profile to your wellbeing.

Troubleshooting

We think that sugarBEAT® is easy to use but we know that sometimes things do not go to plan. We have created a handy troubleshooting section to cover the most common problems and most importantly their solutions:

A. Transmitter

Problem	Potential Cause(s)	Solution
Your Transmitter does not stick to your skin or is very loose.	The chosen area on your arm is not free from oil, dirt, excessive hair, sweat, scars, moles, stretch marks, lumps, lotions / moisturisers or tattoos. The chosen area is on the edge of a muscle and hence moves a lot during daily activities.	Ensure you select a clean, 'flat' and dry area on the outer side of your upper arm. Make sure you avoid areas with scars, moles, stretch marks, lumps, excessive hair, tattoos and insulin injection sites and ensure that the area is free of lotions / moisturisers. If necessary remove excess hair by shaving and if the selected area is sweaty or dirty, wipe it with an alcohol wipe or wash it with soap and water and allow to dry. Be sure to flex your arm to ensure you are not planning to place your device somewhere that is prone to lots of movement and avoid touching the adhesive before use as this can reduce its stickiness. If the Transmitter is loose or has fallen off, you will need to apply a new Sensor following the instructions to re-apply your Transmitter.



Problem	Potential Cause(s)	Solution
Skin irritation / discomfort including redness around the Transmitter application site.	Potential sensitivity to the skin adhesive	Re-apply your Transmitter to a new area of your skin. If the problem persists consult a healthcare professional.

B. Application

Problem	Potential Cause(s)	Solution
App does not start	The App does not have access to your location. On an Android device you must tap 'Allow all the time' when prompted or 'Allow' if there is no other option.	Go to the smart device settings and allow the App permission to your location. If the above does not solve the problem it is suggested to uninstall and reinstall the App and select 'Allow all the time' when prompted to share your location to allow the App to access the device's location during installation.
Following App alert appears: "Device authentication should be enabled. Enable a form of device authentication (e.g. use PIN authentication) to use this App."	There is no security preventing access to your smart device. As a security precaution and to keep your data safe, the App will not start on a device which does not have a PIN or passcode to prevent free entry.	This will be smart device specific. Please refer to the user manual of your smart device in order to set-up appropriate security such as a PIN or passcode.

Problem	Potential Cause(s)	Solution
App cannot find your Transmitter. 	• There is no Transmitter within Bluetooth range. • Bluetooth is turned off on your smart device. • The Transmitter has no battery life. • The Transmitter is connected to another smart device.	• Ensure a Transmitter is within Bluetooth range. • Ensure Bluetooth is enabled on your smart device. • Charge your Transmitter in your docking station for at least 2 hours and preferably for 3.5 hours. • Disconnect the Transmitter from any other smart device which may be connected to it. • If the problem persists, try disconnecting all other devices with a Bluetooth connection to your smart device and ensuring there are no other Bluetooth devices within range when trying to connect.
Transmitter not connecting / pairing with the App.	• Latest version of the App is not being used. • The battery in the Transmitter needs recharging. • The smart device is incompatible – the App works on smart devices with the more recent versions of the iOS and Android operating systems. • The Transmitter has lost the bond with the smart device. • You have not entered the password which came with your Transmitter correctly.	• Check for App / operating system updates. Ensure you have the latest versions. • Recharge the Transmitter for at least 2 and preferably for 3.5 hours and then try to re-establish a Bluetooth connection with the Transmitter. • Replace the Sensor and then re-apply the Transmitter. • Go to your smart device's Bluetooth settings and remove the Transmitter from the list of paired devices. • Ensure that you are typing the password correctly bearing in mind it is case sensitive.



Problem	Potential Cause(s)	Solution
After successful Bluetooth connection, the App screen states 'Sensor disconnected – Insert New Sensor!' 	• The Sensor may not have been inserted properly into the Transmitter or has become dislodged. • Transmitter has become loose / dislodged from the skin.	Replace the Sensor and re-apply the Transmitter. Be sure to: • Insert the Sensor the correct way. • Press and hold the Transmitter firmly when applying to your skin. • Prevent dust etc. from getting onto the adhesive before applying. • Avoid touching the adhesive before application. • Ensure you are using a new Sensor.
After successful Bluetooth connection, 'Measurement Failure – Sensor Dry / Expired' re-appears every 5 minutes in the 'Alert logs' section of the App. This is accessible when you Tap the main menu, then 'Transmitter' and scroll down to the 'Alert log'. 	• The Sensor may not have been inserted properly into the Transmitter or has become dislodged. • Transmitter has become loose / dislodged from the skin.	Replace the Sensor and re-apply the Transmitter. Be sure to: • Insert the Sensor the correct way. • Press and hold the Transmitter firmly when applying to your skin. • Prevent dust etc. from getting onto the adhesive before application. • Avoid touching the adhesive before application. • Ensure you are using a new Sensor

Problem	Potential Cause(s)	Solution
If the Sensor is not connected but the smart device is locked, a pop-up message will display 'Sensor Not Connected'. A repeating audible alert may also sound depending on the settings you have chosen. 	• The Sensor may not have been inserted properly into the Transmitter or has become dislodged. • Transmitter has become loose / dislodged from the skin.	Replace the Sensor and re-apply the Transmitter. Be sure to: • Insert the Sensor the correct way. • Press and hold the Transmitter firmly when applying to your skin. • Prevent dust etc. from getting onto the adhesive before application. • Avoid touching the adhesive before application.



Problem	Potential Cause(s)	Solution
If Bluetooth connection is lost – 'Bluetooth Disconnected' will be shown in the 'Alerts' window which is accessible when you tap the main menu then 'Transmitter' and scroll down to the 'Alert log'. The smart device App will blank out the current glucose level if no glucose reading has been received within the last 20 minutes, to avoid any misleading information. If the smart device is locked, a 'Push notification' will display 'Bluetooth Disconnected'. A repeating audible alert may also sound depending on your settings. 	• Transmitter / paired device are not within range of each other. • Bluetooth has been turned off on your smart device. • Transmitter has lost the bond with the smart device.	In order to maintain connection, keep your sugarBEAT® Transmitter within radio range (typically within the same room) of your smart device and ensure Bluetooth remains enabled. If the Transmitter is out of range with the paired device, it will stop sending readings to the App. Do not worry as the Transmitter will still continue to collect your glucose readings every 5 minutes and when it is back within range of the paired device, it will send all the stored data. As such if the paired smart device is away from the Transmitter, the data will not be lost. However you should be aware that as readings will not be received during this time there will be no opportunity for the App to alert you to high or low glucose levels. However it does give you the benefit of not having to carry your smart device with you all the time. In the screenshot, the Transmitter is reconnecting after it has returned within Bluetooth range. Go to your smart device's Bluetooth settings and remove the Transmitter from the list of paired devices.

Problem	Potential Cause(s)	Solution
App keeps crashing	• Latest version of the App is not being used. • Internal error on your smart device is causing the App to crash.	• Check for App updates. Ensure you have the latest version. • Restart your smart device. • Uninstall and reinstall the App.

C. Docking Station / Charging

Problem	Potential Cause(s)	Solution
Transmitter is not charging.	• Transmitter is not inserted correctly into the Docking Station. • USB cable is not inserted correctly / fully into the Docking Station / plug. • Power is not on or incorrect cable is being used.	• Ensure that you insert the Transmitter in the correct orientation with the three gold contacts facing down. Ensure the gold contacts are clean. • Check the cable is inserted fully into both the Docking Station and the plug. • Ensure the power is on and that you are only using the cables provided with your device.



Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Electrical Safety testing and compliance

EMC (Electromagnetic Compatibility) testing has been completed for the device according to EN 60601-1-2 with the following compliance levels:

EMISSION STANDARD FOR MEDICAL EQUIPMENT (EN60601-1-2)	
Conducted Emissions AC Port	EN55011, Class B
Radiated Emissions	EN55011, Class B
IMMUNITY STANDARD FOR MEDICAL EQUIPMENT (EN60601-1-2)	
Electrostatic Discharge	EN61000-4-2
Radiated Immunity	EN61000-4-3
Fast Transient Bursts	EN61000-4-4
Surges	EN61000-4-5
Conducted Immunity	EN61000-4-6
Voltage Dips	EN61000-4-11
Voltage Interruptions	EN61000-4-11
Magnetic Immunity	EN61000-4-8

Portable and mobile RF communications equipment can affect the readings made by sugarBEAT® so try to keep these kind of devices separate if possible.

The use of sugarBEAT® with other cables or accessories could increase the EMC emissions or decrease the EMC immunity of the system. Only use the cables and accessories provided in your Device Box.

IEC Classifications

Type of protection against electric shock:	Internally powered
Degree of protection against electric shock:	Type BF Applied Part 
Mode of operation:	Continuous
Degree of protection against ingress of liquids:	IP22
Degree of safety of application in the presence of a flammable anaesthetic:	Not suitable for use in the presence of a flammable anaesthetic mixture with air, oxygen or nitrous oxide.

Training

To ensure you use sugarBEAT® safely and get the most from it you should:

- Read and understand the contents of this document (the Instructions for Use, sometimes called IFU).
- Where available, watch the training video(s).
- Keep this Instructions for Use and the Quick Start Guide (QSG) in a safe place so you can refer back to them.

If after reviewing the Instructions for Use, QSG and training videos you still require assistance in setting up, using, or maintaining sugarBEAT®, please contact the manufacturer using the details at the end of this document.



Additional Information

Caring for and storing sugarBEAT®

sugarBEAT® is simple to use and easy to maintain. Follow the guidelines below to keep your system in top condition.

Keep it clean

Between each use or if the Transmitter has any visible dirt on it, use a damp tissue or alcohol wipe to clean it. The Docking Station and other accessories can be cleaned using the same method, as needed.

Store it Carefully

When sugarBEAT® is not in use, store in a cool, dry place at room temperature and without any exposure to liquid, moisture or direct sunlight. Keep the Sensor and Guiding Frame in the foil pouch until they are needed.

Reporting unexpected operations or events

If you experience any unexpected operations or events while setting up or using sugarBEAT®, please report these to the manufacturer.

Reporting Serious Incidents

Any serious incident that occurs in relation to the sugarBEAT® device should be reported to sugarBEAT® Ltd.

Specifications

A. sugarBEAT[®] Specifications

Blood glucose assay range	2.5 mmol/L to 25 mmol/L
Accuracy	MARD: 12.3 % (based on once a day calibration) MARD: 11.9 % (based on twice a day calibration)
Transmitter size	40 mm x 25 mm x 10 mm
Transmitter weight	10 g
Transmitter power source	Rechargeable Lithium polymer battery (LP-402025-1S-3, 3.7V DC, 155mAh)
Transmitter battery life	2 years
Transmitter memory	7 days of data
Transmitter operating temperature	2-40 ° C
Recommended Transmitter and Docking Station storage conditions	Ambient temperature and humidity
Operating and storage - altitude	Suitable for Hypobaric conditions (not affected by oxygen saturation levels)
Radio frequency (if applicable)	Bluetooth operates within the ISM 2.4 GHz frequency band (2.4 – 2.4835 GHz)
Data port	Wireless via Bluetooth
Expected service life	Transmitter & Docking Station: Minimum 1 year Charger: Minimum 3 years



USB cable	USB 2.0 type A to micro USB type B connector
Power adapter	USB Medical Approved (IEC 60601-1) Power Supply
Moisture Protection	IP22 - Protection against vertically falling water drops when enclosure tilted up to 15° and against hazardous materials. Do not submerge in water.
Protection against electrical shock	Type BF applied part

B. sugarBEAT® Sensor Specifications

Sensor glucose assay method	Enzyme based
Sensor glucose reading range	2.5 mmol/L to 25 mmol/L
Sensor size	2.5 cm x 1.5 cm
Sensor weight	Less than 1 g
Sensor life	Storage: 12 months from date of manufacture at ambient conditions In use: 14 hours
Sensor operating temperature	Between 2° C to 40 °C
Sensor storage	Store at room temperature (15 °C to 25 °C) Store in original sealed foil pouch to protect from moisture.
Guiding Frame and skin adhesive storage	Store at room temperature (15 °C to 25 °C) Store in original sealed foil pouch to protect from moisture.
Sensor water resistance	Sensor is damp in use and stored dry.
Operating and storage - altitude	Not affected by fluctuations in oxygen levels. Sensor is sealed against skin in use.

C. sugarBEAT® Accuracy Specifications



Accuracy based on calibrating once per day

Performance Metric	Adults (18-70 years)
Overall Accuracy MARD % - 2.5 to 25 mmol/L (% average absolute error versus reference across all glucose levels)	12.3 %
Performance Metric	Adults (18-70 years)
Clinical Accuracy % of readings which were in the Clarke Error Grid (CEG) Zone A [% CEG A+B Zone]	78.4 % [99.0 %]



Note: The reference device is the Abbott Architect (ARC) c8000 Laboratory Instrument



Accuracy based on calibrating twice per day

Performance Metric	Adults (18-70 years)
Overall Accuracy MARD % - 2.5 to 25 mmol/L (% average absolute error versus reference across all glucose levels)	11.9 %
Performance Metric	Adults (18-70 years)
Clinical Accuracy: % of readings that were in the Clarke Error Grid (CEG) Zone A [% CEG A+B Zone]	79.9 % [99.4 %]



Note: The reference device is the Abbott Architect (ARC) c8000 Laboratory Instrument.



Wireless Quality of Service Summary

The sugarBEAT® Transmitter communicates with your smart device via a radio link in the 2.4 GHz radio band which is shared with other radio technologies and users. Techniques are used to support shared access to the radio band with other users / devices but these cannot completely avoid the potential for lack of availability of the radio link due to its use by other users / devices.

To function as intended, the Transmitter needs to be connected and in proximity to your smart device. In an unobstructed outdoor environment, range tests have shown that the range can be up to 45 feet, but typically the smart device and Transmitter will need to be in the same room for reliable communication.

When connected, the Transmitter will then send measurements every 5 minutes to the smart device for display.

Although the radio link is normally reliable it could become unreliable or unavailable if, for example, the Transmitter is a long way from the smart device, the link between the Transmitter and smart device is obstructed or if there is significant interference in the 2.4 GHz radio band.

The following features are included to help protect against the above or assist you if the radio link is interrupted:

- The raw glucose readings are timestamped at the Transmitter when they are taken and this timestamp is transmitted as part of the glucose reading. As such even if a reading is delayed across the radio link, the App will display the time the reading was originally taken.
- If the radio link is unavailable or unreliable, the Transmitter will store the glucose readings (for up to the last 7 days). The data is transferred when the link re-connects; as a result, no data is lost.

- The smart device App will blank out the current glucose level if a glucose reading has not been received within the last 20 minutes so as to avoid any misleading information. The device will also indicate to the user if the radio link to the Transmitter is disconnected or not accessible.

If the link becomes unavailable or unreliable, this could lead to glucose readings being delayed (or temporarily lost). If this happens attempt the following (and reconnect if the link does not recover):

- Move your Transmitter closer to your smart device.
- Relocate your Transmitter and smart device away from any other radio devices that are in the vicinity.
- Manually disconnect the smart device from the Transmitter within the sugarBEAT® App and attempt to manually reconnect them.
- If the above steps are not successful, reset the Transmitter by placing it momentarily on a powered Docking Station. Wait up to 5 minutes before attempting to reconnect the smart device to the Transmitter.
- If the above steps are not successful, restart the smart device and attempt to reconnect to the Transmitter.



Wireless Security

The sugarBEAT® Transmitter broadcasts information (advertises) to allow you to pair it with a host mobile or tablet device (smart device). However, for your security you must provide a PIN associated with your specific Transmitter device in order to connect the two (see section 'Connect the Transmitter to the sugarBEAT® App'). Once your Transmitter is paired with your smart device, the radio link is encrypted and the sugarBEAT® Transmitter stops advertising and becomes unavailable for pairing with any other device.

If an unauthorised user were to attempt to pair with your Transmitter using the sugarBEAT® App and was able to supply the relevant PIN they would potentially be able to download information from your Transmitter device. However, to safeguard against loss of personal information this type of information e.g. name, age, address is never sent across the radio link between your Transmitter and smart device. In addition to this, the data sent across the radio link requires conversion by the algorithm within the App which in turn requires calibration from a blood glucose reading before it will display an accurate glucose reading. Therefore, any data sent across the link is not in itself interpretable by an unauthorised user.

Please also refer to the 'Cybersecurity Best Practice' section of this IFU for further information.

FCC Federal Communications Commission

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference, and
- (2) This device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to

No changes shall be made to the equipment without the manufacturer's permission as this may void the user's authority to operate the equipment. This equipment complies with the RF exposure limits in FCC § 1.1307.

Disposal of sugarBEAT® Device and Sensor

Each Sensor should be used **once** and should be disposed of as general non-clinical waste.

At the end of its shelf-life, take it to a local authorised recycling facility for safe disposal. Disposal should be carried out in line with local regulations.



Skin Care Tips

In the unlikely event that you experience some skin sensitivity such as mild erythema / redness, these symptoms should disappear within 1 day. To minimise the likelihood of experiencing these symptoms you should:

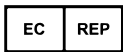
- Alternate application sites
- Keep your skin clean and moist when the Transmitter is not being worn
- Avoid scratching your skin

DECLARATION: There is no known hazard to the patient from the material used in sugarBEAT® and it does not contain natural latex rubber.

Manufacturer Contact Details



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