# SugoSure

# Phase A trial (June - July 2018)- Patient Case Study

## Background

### Clinical

Patient One is a 47 year old female accountant with a 5 year history of Type 2 diabetes mellitus, hypertension (diagnosed 2013) and dyslipidaemia (diagnosed 2014).

Her diabetic control has been variable and her most recent HbA1c on 23 Apr 2018 was 7.6%. Hypertension and Dyslipidamia are stable with BP recorded on 30th July 2018 at 124/80, total Cholesterol 3.72mmol/L, HDL-C 1.27mmol/L, LDL- C1.86 mmol/L and Triglycenides 1.33 mmol/L.

The patient's weight at start of the trial was 73.0 kg (BMI = 26.2) and while she had been trying to control her weight (and has been advised by the physician to restrict caloric intake to 1800 calories per day) she had not been set a clear weight target.

Patient One has a family history of Type 2 Diabetes: her mother and sister are both type 2 diabetics. Otherwise she has no other medical conditions of note.

Medication at start of trial: Diamicron MR 60mg morning, 30mg evening; Forxiga 10mg morning; Janumet 100mg/2000mg morning.

### Lifestyle

Since being diagnosed with Diabetes, the patient has made adjustments to her lifestyle by increasing activity levels and trying to control her diet.

For example, instead of taking the bus she now walks to the MRT to increase her step count.  She also goes on a brisk walk with a friend once or twice a week. However the patient finds it hard to stick to a regular exercise routine because of work.

The patient has found it hard to change her eating behaviours because she "loves carbs, bread... " and "big bowls of noodles", although she has been trying to eat more salad.

### Monitoring

The patient indicated that she did not regularly prick her finger to take blood glucose measurements (and was initially not comfortable doing do) and instead uses the Freestyle Libre flash glucose monitoring for the 2 weeks before she visits the physician (every 3-4 months), to provide a record of glycaemic control for discussion at the consultation.

She does not monitor her calorie intake at all, but uses a FitBit to count her steps.

## Trial approach

This was the very first time SugoSure was tested in patients and the main objective was to test clinical validity of the monitoring approach, as well as to identify and fix outstanding technical issues.  The version of SugoSure used was before a planned design upgrade and did not yet include full health coach functionality.  The trial was also conducted in a small number of patients: results were not subjected to detailed statistical analysis and should be interpreted in this light.

Using the SugoSure app, Patient One monitored her blood glucose levels three times a day (pre-breakfast, pre-lunch and pre-dinner) on 3 days a week ('Monitoring Days') for 4 weeks, reducing to 2 days a week for the final 2 weeks on the physician's instructions. In accordance with SugoSure's protocols, the patient also took photos of her food on Monitoring Days.  Food photos were analysed and assigned calories by ConnectedHealth's Advisor for Diabetes Lifestyle Plans (a trained dietician).

Remote patient data was shared with the physician through the SugoSure Physician Portal.  In his initial assessment the physician set a target HbA1c for the patient of 7.0% (Standard blood glucose control), a medium-term activity target of 10,000 steps per day (since the patient had no mobility issues) and basic diabetic, low cholesterol and low fat diets.

In accordance with SugoSure's Physician protocols the physician conducted a face-to-face initial SugoSure consultation and 2 remote reviews.

## Trial Findings

The patient's blood glucose control profile (Exhibit 1) showed a significant number of readings outside the target range (4-7 mmol/dl for pre-meal readings).  This was broadly consistent with the patient's HbA1c of 7.6% (albeit that HbA1c is a retrospective measure) - which was higher than target and shows scope for improvement through SugoSure intervention.

The patient's pattern of blood glucose readings (Exhibit 2) showed poorer control in mornings and evenings, with more clustered readings in the mornings and greater variance in evening readings.  In response to this the physician changed the patient's medication 4 weeks into the trial (increasing dosage of Diamicron MR from 30mg to 60mg pre-dinner) and initiated post-meal monitoring to evaluate the impact of diet on the patient's evening blood glucose readings (although the trial was terminated before any conclusions could be drawn from post-meal reading analysis).

# Exhibit 1: Pre meal Blood Glucose readings across the 6 week trial



Date of reading
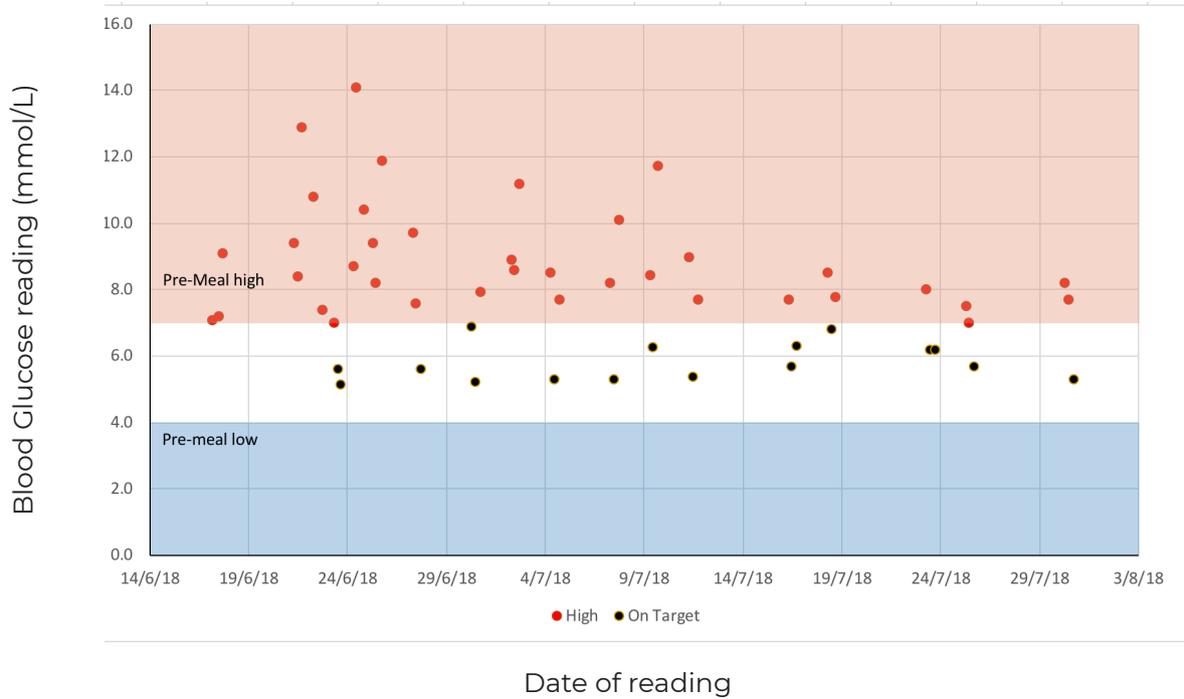
# Exhibit 2: Blood Glucose by time of day - Premeal readings across the 6 week trial



Time of reading

Pre-breakfast high BG cluster
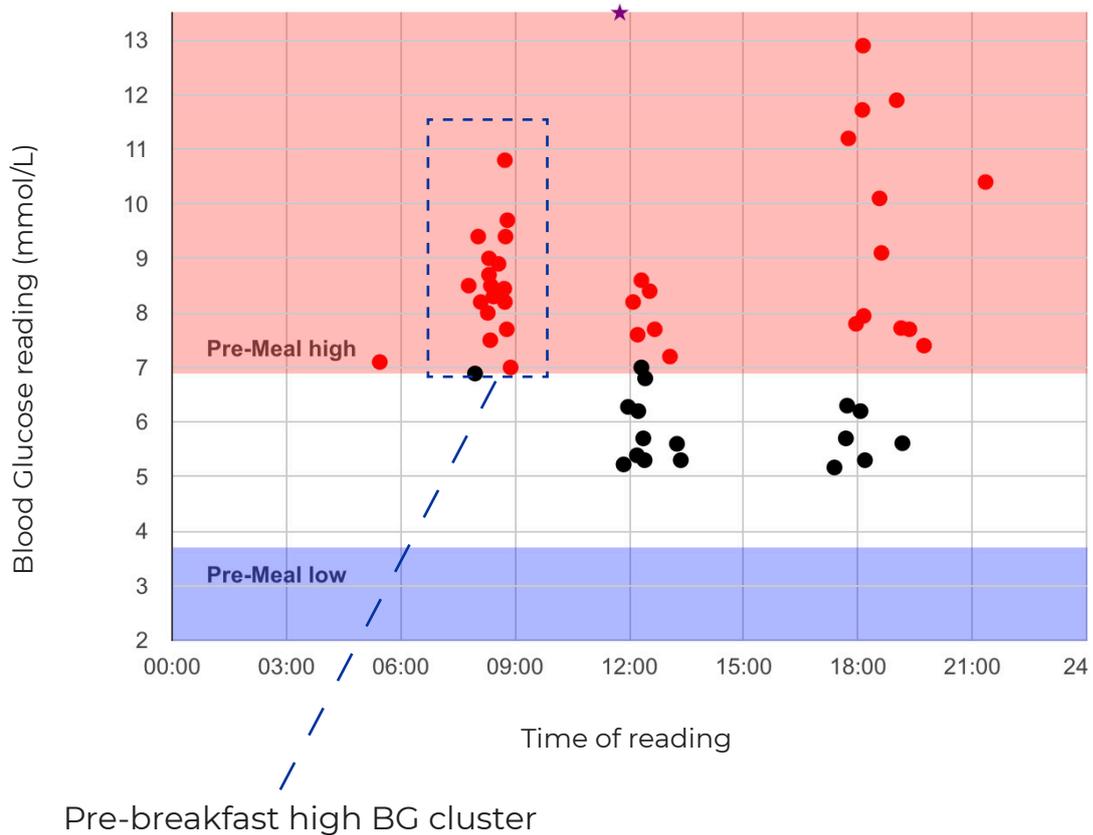
Data from activity and diet levels (Exhibits 3,4) was harder to interpret and was not a good representation of the impact of SugoSure on patient lifestyle in its eventual commercial launch format since these initial user trials did not include health coaching (This is an integral part of SugoSure's product offering).  However, based on patient records:

- Mean steps per day (based on days when this was recorded) was 6683 i.e. short of the 10,000 step per day target set by the physician (although practically quite a good result for a sedentary office worker).
- Mean daily caloric intake on Monitoring Days was 1589 calories i.e. within the 1800 calorie target set by the physician  It is possible that there may have been under-recording of calorie intake due to incompete food logging of snacks and sugared drinks (despite the patient's good compliance, logging 3 meals a day on Monitoring Days).  This is a limitation of any self-reported food logging approach.
- Net calorie balance was on average -465 on Monitoring Days, which should have generated some weight loss over the trial (although in practice a longer trial period would be needed to test this).  The patient's weight (Exhibit 5) however *increased* over the course of the trial – which would support our belief that food logging may have been incompete.

## Exhibit 3: Activity data (steps) across the 6 week trial



**Average:** 6683
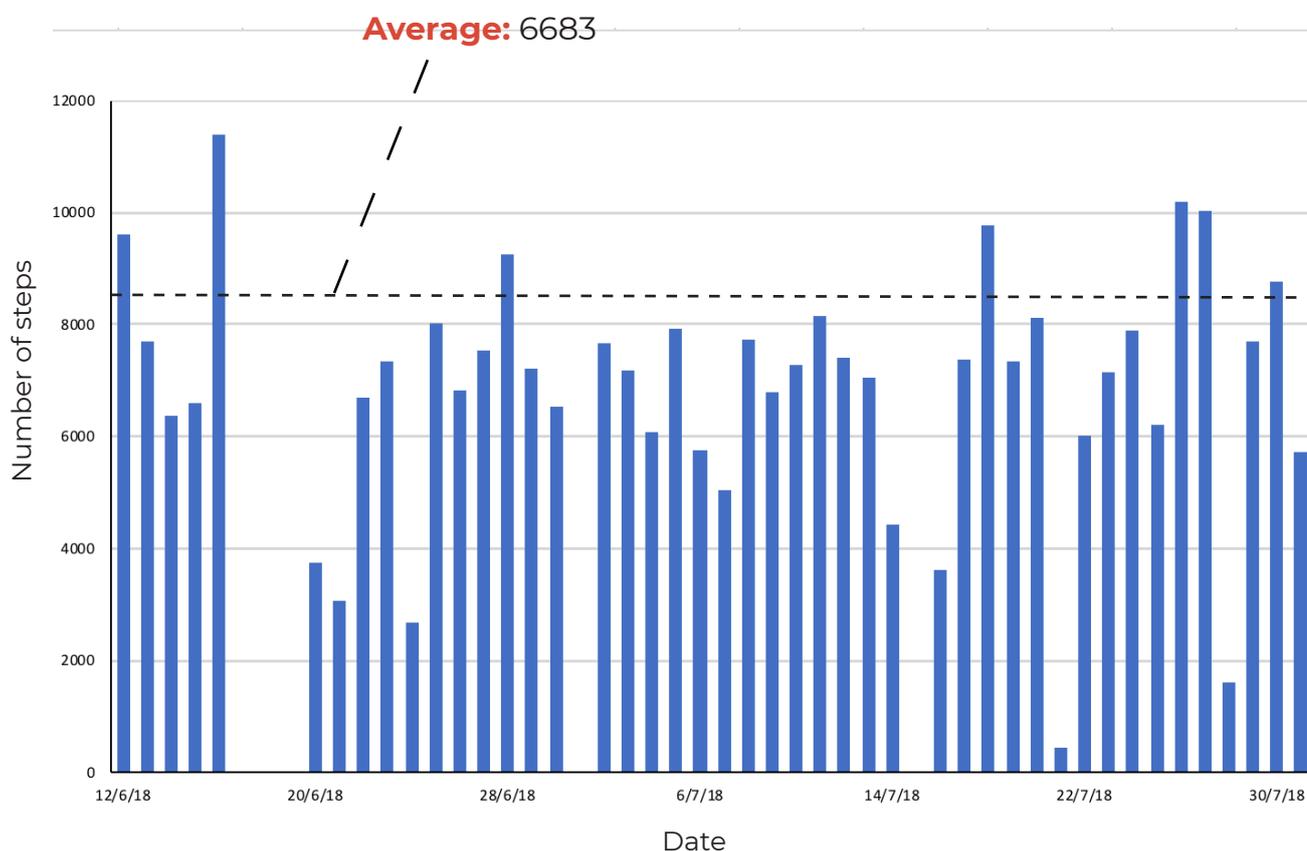
# Exhibit 4: Meals and daily calorie balance across 13 monitoring days during the trial

| Completed monitoring day | Meals eaten | Total calories consumed | Total steps taken | Calories burnt | Calorie balance |
|---|---|---|---|---|---|
| 22nd June | Kangkong Porkribs Wings<br>Nasi Padang Chicken<br>Maple and Margarin Pancake | 1168 | 6712 | 2067 | -899 |
| 23rd June | Rice Dumpling<br>Cesar Salad<br>Potato Gratin<br>Spicy Soup Tofu Mushroom(half)<br>Spicy Chicken Cashew Nut (half) | 1640 | 7357 | 2093 | -453 |
| 25th June | Tonkatsu<br>Bee Hoon Soup<br>BK Jam Sandwich Set | 1850 | 8046 | 2118 | -286 |
| 27th June | White Bread with Butter<br>Roast Chicken and Soba bowl<br>Braised Tofy and Sambal Fried Rice | 1700 | 7535 | 2098 | -398 |
| 30th June | White bread with Peanut Butter<br>Chashu Ramen<br>Mackerel Salad<br>Yoghurt | 1480 | 6529 | 2058 | -587 |
| 7th July | Bread with Peanut Butter<br>Fruits<br>Roasted Chicken and Egg<br>Fried Carrot Cake | 1570 | 5036 | 1997 | -427 |
| 9th July | Fried Rice, Veg, Chicken, Sting Ray (one bowl)<br>Fish Soup Vermicelli<br>Ham and Cheese Sandwich | 1720 | 3349 | 1931 | -211 |
| 11th July | Ham and Cheese Sandwich<br>Soya Soup dumpling noodles<br>Chicken rice set | 1590 | 8170 | 1728 | -138 |
| 16th July | Tuna Mayo and cheese sandwich<br>Yong Tao Fu with Bee Hoon<br>Soba with Terriyaki Chicken | 1220 | 3615 | 1554 | -334 |
| 18th July | Cranberry Bread<br>Vegetarian Tom Yam Noodles<br>Peking roast duck/Veg with mushroom/Black pepper beef | 1180 | 9792 | 1745 | -565 |
| 23rd July | White break with cheese<br>Been Hoon Soup<br>Fishball noodles | 900 | 7145 | 1689 | -789 |
| 25th July | Cheese sandwich<br>Roast Chicken and Quinoa bowl<br>Salad wrap with grilled chicken | 1320 | 6201 | 1656 | -336 |
| 30th July | Soft grain loaf with cheese<br>cup noodle black pepper<br>mcdonalds chicken burger and fries | 1690 | 8775 | 1892 | -202 |

**Exhibit 5: Weight readings across the 6 week trial**
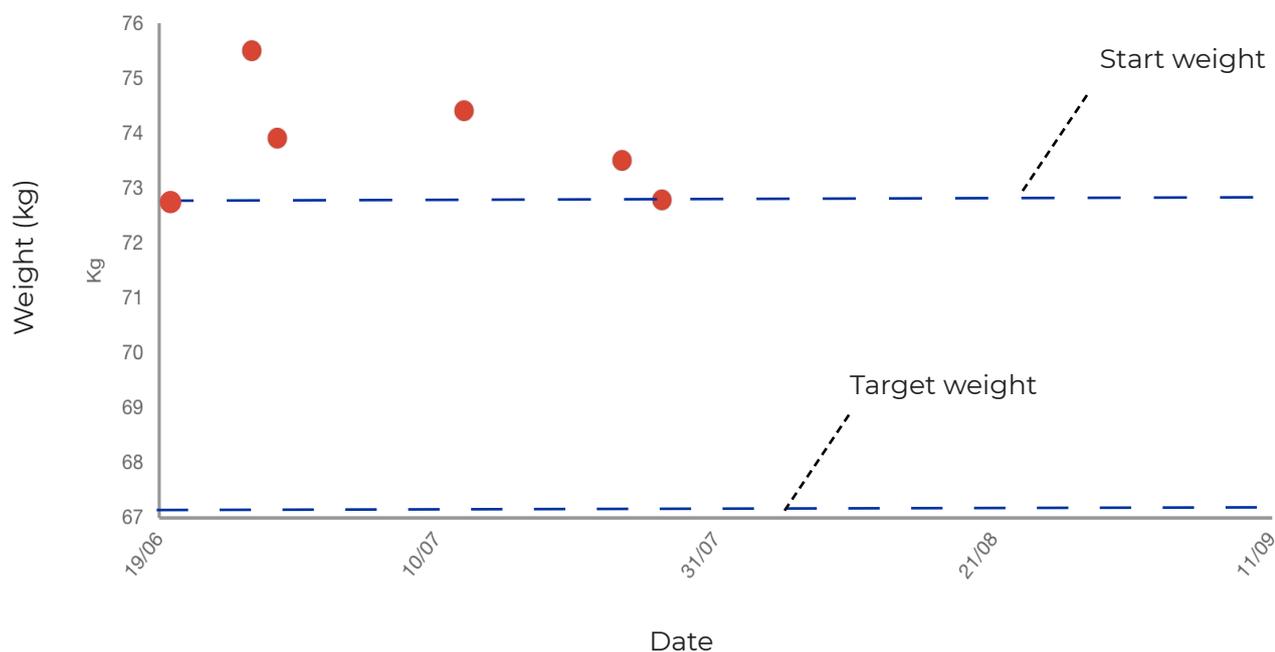
## Patient Benefits

Although in the form used for this trial SugoSure was incomplete (and did not fully reflect the product's use case when it will be launched commercially in early 2019), Patient One did note several benefits from the approach:

End of trial review:
*"Well, it was definitely helpful to me, because it was the information that I got from it. Because when I don't monitor, the motivation to work towards target, like (the physician) said to cut down my weight, it wears off after some time, until I see him again. So, this app actually helps, it's a constant reminder, a feedback that I actually consume so many calories in one meal".*

Mid trial feedback:
*"Knowing the readings and the calories of the food I consume, it actually helps me decide what to eat, and to be more disciplined in terms of food choice. So, it is actually a good reminder."*