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Accuracy and performance of the Yuwell Anytime CT3 continuous glucose monitoring device

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Abstract

Background: there have been many recent advances in diabetes technology, and continuous glucose monitoring (CGM) systems have grown in use and popularity. Aims: This study evaluated the accuracy and efficacy of the Yuwell Anytime CT3 CGM system in participants with type 2 diabetes. Methods: Forty participants were recruited to take part. They were asked to monitor their glucose levels for 10 days using two devices, a continuous glucose sensor (Yuwell Anytime) and an Accu-chek blood glucose finger-prick test. Findings: The overall mean absolute relative difference (MARD) between the two measurement systems was 6.9 % with a Pearson correlation coefficient of 0.92 ($P<0.0001$). The reliability of the sensor was preserved across the full observed range of glucose concentrations. Conclusions: The Yuwell Anytime had excellent agreement with a standard finger-prick blood test of glucose in free-living type-2 diabetics.

Keywords: accuracy; continuous glucose monitor; efficacy; diabetes; MARD.

Introduction

Diabetes mellitus is a disease that occurs when blood glucose is too high, raising the risk for damage to the blood vessels, eyes, kidneys, nerves, and heart [1]. Over time high blood sugar levels can damage these organs, leading to various complications. Diabetes therefore increases the risk of heart disease, stroke, high blood pressure and atherosclerosis. Taking steps to prevent or manage diabetes and manage blood glucose can lower the risk of developing related health problems [2].

Evidence indicates that diabetes prevalence is increasing worldwide, primarily due to a rise in obesity caused by multiple factors [3]. In 2021, there were 529 million people living with diabetes worldwide, and the global age-standardised total diabetes prevalence was 6·1% (5·8-6·5). Total diabetes prevalence, especially among older adults-primarily reflects type 2 diabetes, which in 2021 accounted for 96·0% of diabetes cases. By 2050, more than 1·31 billion (1·22-1·39) people are projected to have diabetes, with expected age-standardised

total diabetes prevalence rates greater than 10% in North Africa and the Middle East and 11·3% Latin America and Caribbean [4]. The incidence of diabetes mellitus is also rapidly increasing in the UK, there are currently 5.8 million people living with diabetes in the UK and 90% of those are Type 2. Diabetes is therefore a significant public health issue and it is clear that preventing and controlling type 2 diabetes remains an ongoing challenge. However, type 2 diabetes which makes up the bulk of diabetes cases is largely preventable and, in some cases, potentially reversible if identified and managed early [5].

Patients with diabetes may currently choose between two main methods for glucose measurement: blood glucose monitoring (BGM) systems measuring glucose within capillary blood, and continuous glucose monitoring (CGM) systems measuring glucose within interstitial fluid. However, for many patients taking capillary blood measurements on a regular basis is not popular due to it's invasive, potentially painful and conspicuous nature. Continuous glucose monitoring (CGM) can offer a transformative approach to early intervention in pre-diabetes adults by providing real-time, personalized feedback on glucose fluctuations, enabling individuals to understand how their behaviours—such as diet, exercise, and sleep impact their glucose levels [6]. There are a number of CGM devices on the market and research has shown that they can be valuable in providing support and information to individuals who are pre-diabetic or Type 2. Alsaif et al. [7] considered the impact of continuous glucose monitoring in individuals with Type 2 diabetes and concluded that CGM may reduce demand on secondary care services and GP time. Other studies have shown that using real-time continuous glucose monitoring (rtCGM) and intermittently scanned continuous glucose monitoring (isCGM) significantly improved HbA1c levels [8], encourage more active lifestyles [9] and improve glucose control and quality of life [10].

It is important to assess the accuracy of continuous glucose monitoring (CGM) systems and a number of studies have considered the accuracy of a number of devices that are currently available [11-15]. Mean absolute relative difference (MARD) is a key measure often considered, comparing any differences in measurement values between the new device and standard assessment from blood analysis. Devices that have a MARD that is less than 10% are considered suitable for use [16]. However, MARD values from laboratory studies should not be considered in isolation and further practical evaluation should be considered as well [17-18). Key features of CGM sensors, the frequency of the measurements, and how it performs across a range of glucose levels should also be evaluated. Some studies have also stressed the importance of testing the CGM sensor in free living conditions to evaluate its performance in the 'real world' context [19-20]. This study aimed to evaluate the accuracy

and efficacy of a recently developed continuous glucose monitor (Yuwell Anytime CT-3) in real world conditions for individuals with type 2 diabetes.

Methods

The study gained full ethical permission from the Faculty of Biological Sciences ethics committee (Application 2044). In addition, the study was registered with the Open Science Framework as a clinical trial (https://osf.io/5ywr9).

Participants

A total of n=40 participants were recruited for the 10-day study including n= 18 males and n= 22 females. One participant failed to return any data and was removed from the study and two participants failed to complete more than three days data collection and they were removed from the analysis. This gave a total number of 37 participants. All participants were aged between 32 and 87 years old with a mean age of 55.9 and a standard deviation of 12.1 years. The study population was made up of Type 2 diabetics n=40. 18% of the participants identified as minority ethnic. Body Mass Index (BMI) was also measured with participants ranging from 21.7 to 49.1 $kg.m^{-2}$ with a mean of 28.5 and a standard deviation of 6.0.

Pilot Test

All procedures were tested in a pilot study to ensure that participants were clear on how to: attach and connect the device, administer the finger prick test and record their results. We also operated workshops that demonstrated how to attach and use the device and checked instructions for use of the device were clear and appropriate. The pilot tests revealed that all procedures were clear and appropriate.

Equipment employed

- CT3 Yuwell Anytime (Continuous Glucose Monitoring Device (CGM device))

The device uses mobile Bluetooth and a phone app to report glucose levels that are continuously gathered by the sensor and sent to the phone via the transmitter. The device locally logs the data with a glucose reading logged every 3 minutes in internal memory storage, Bluetooth technology is used to synchronise the data directly to the participants' phone or tablet for visualisation and further analysis or sharing. The sensor can be placed on the skin of the arm or the stomach. The sensor is applied using a delivery device to ensure correct consistent depth of placement for the sensor and good contact adhesion with the skin. Once the sensor is in place the transmitter is then slotted onto this to provide the data logging and Bluetooth transmission link. The transmitter has an estimated overall lifespan of

two years with a capability to rapidly recharge it's internal battery. Each inserted glucose sensor lasts two weeks.

- Accu-Chek testing (Finger prick glucose testing equipment (SMBG device))

The Accu-Chek Instant is a blood glucose meter for self-monitoring of blood glucose for people with diabetes measuring glucose within capillary blood classically referred to as a self-monitoring blood glucose (SMBG) device. The device meets ISO 15197:2013/EN ISO 15197:2015 standards for accuracy and a number of studies have shown that it performs to a high level of accuracy [15 and 21]. Previous assessment of the accuracy of the Accu-Chek-Instant has been performed comparing results with laboratory calibrated hexokinase-based, and glucose-oxidase based glucose analysers [15]. This identified a MARD of 4.2 +/- 2.9 for the Accu-Chek-Instant with 98% of data points being within 10% of the values obtained using the laboratory analysers.

Before deployment the Accu-Chek devices used were checked using the manufacturer recommended control solution kit (Roche, Germany). The kit contained two control solutions, Control 1 and Control 2. A test strip was inserted into the Accu-Chek device and either Control 1 or Control 2 were applied to the strip. The device was subsequently instructed which control solution was being tested and the screen displayed 'OK' if the validation was correct. All devices used passed these quality control checks.

Procedures

At the start of the study participants were invited to the University of Leeds so that the use of the device could be demonstrated, consent taken and the participants given the opportunity to ask questions. It was made clear that participants have the right to withdraw from the study at any point without penalty or giving a reason.

The participants were asked to monitor and record their glucose levels for 10 days using two devices. One device was attached to the skin and remained in position for the duration of the study (CT3 Yuwell Anytime CGM). The second device was the Accu-Chek glucose finger prick test. The CGM sensor could be placed on the upper arm or stomach and participants were allowed to choose which site they would prefer. All participants chose to place the sensor on the upper arm. The correct placement of the sensor and the connection of the transmitter were demonstrated to all participants and the connection via Bluetooth from the transmitter to the phone app of the participant was checked by the researcher.

Participants were asked to take measurements on three occasions per day, before breakfast, before lunch, and before their evening meal. Participants were given a log book in which to record the glucose levels as measured by each device simultaneously at these time

points. Participants were instructed to carry on with their normal daily activities and it was made clear that the device could remain in place when showering, swimming, or exercising. No changes to the participant's normal daily routine was required. It should be noted that data collection therefore took place in **'free living conditions'** as this was considered to be the most realistic way of testing the device.

Logged data was returned electronically to the experimental team. Data was maintained as pairs of readings for each of the individual participants allowing collective and inter-individual comparison of data agreement. Data were initially processed in Microsoft Excel with GraphPad Prism 10.3 and RStudio 2024 used for subsequent statistical analysis. Retrospective power analysis was performed in G-Power 3.1.

Results

A full statistical analysis of the data has been undertaken to compare the ability of the CT3 Yuwell Anytime CGM device to monitor blood glucose over time as compared with evaluation of blood samples using a conventional finger prick test. In line with other studies evaluating such devices we have not only considered the absolute relative difference between measures (as defined by MARD) but also conducted correlational analysis, Bland-Altman assessment of agreement and a Clarke Error Grid Analysis [18].

Grouped comparison of all data points for paired measures using both devices

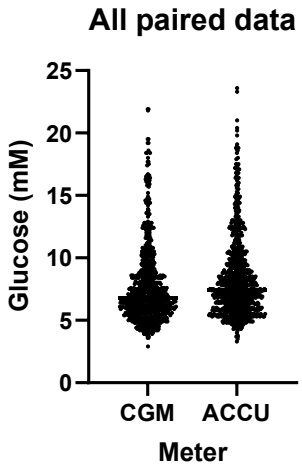

Figure 1. Complete set of blood glucose measures as obtained from the Yuwell Anytime CGM device (CGM) and directly-measured blood glucose (ACCU) evaluated.

Figure 1 shows the full individual set of glucose measurements using both the Yuwell Anytime CGM and from conventional finger-prick blood samples. The 1082 paired glucose sample points ranged in concentration from 2.9 to 23.6 mM. The mean pre-meal blood glucose was 7.7 mM for this population with type 2 diabetes. The data shows values covering an expected range and values for this population. Overall standard deviation for the data sets is 3.0 and 3.2 mM for the CGM and blood test respectively indicating comparable overall variance regardless of measurement approach. Given the n number of 37 and variance of the data using each approach this gives a statistical power of 84 % to identify discrepancies of 0.63 mM or greater in device vs. blood readings.

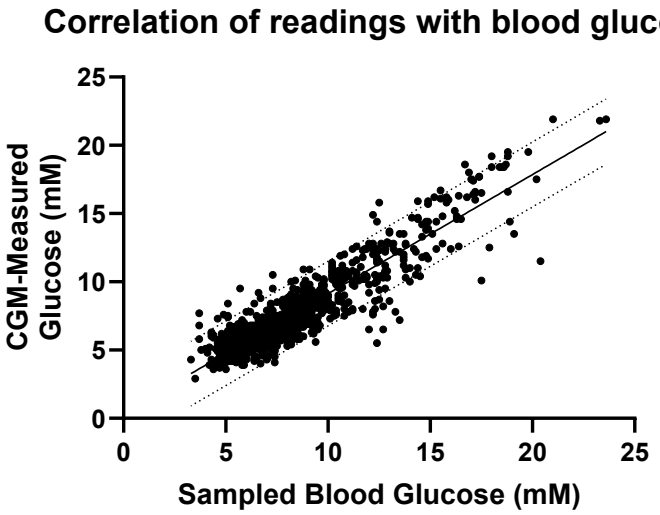

Figure 2. Linear correlation between pairs of CGM and blood measured glucose values. Solid line shows the linear regression to the data. Dashed lines show 95% confidence intervals of agreement.

Pearson correlation analysis of simultaneously obtained pairs of data values from the CGM and finger-prick blood sample yielded a correlation coefficient of **0.92** ($p<0.0001$) (Figure 2) showing very strong, significant agreement between measures. Across the full data range there was excellent linear agreement between the CGM values and measured blood glucose.

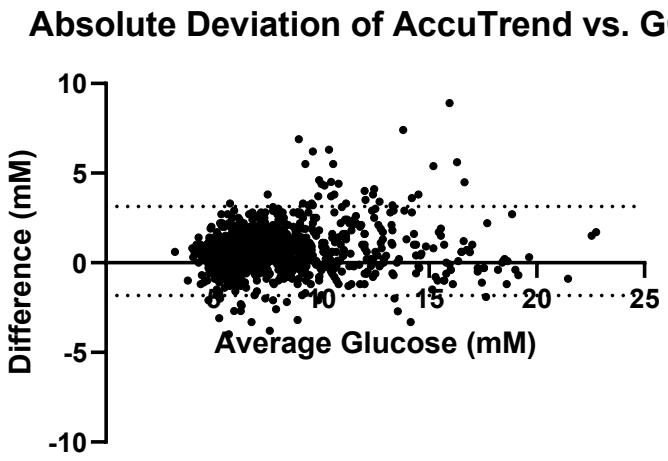

Figure 3. Bland-Altman analysis of agreement between the measurement approaches. Difference between CGM assessed and direct blood analysis of glucose mM.

A Bland-Altman analysis of agreement was used to identify any potential concentration-dependent or systematic difference between the two measurement approaches (Figure 3). There is no significant concentration-dependent gradient in variation or agreement. Reliability of the sensor is preserved across the typical range of blood glucose concentrations for this population. There is a very small non-significant bias between the two with an offset of 0.66±1.3 mM (n = 1082,mean ± S.D.).

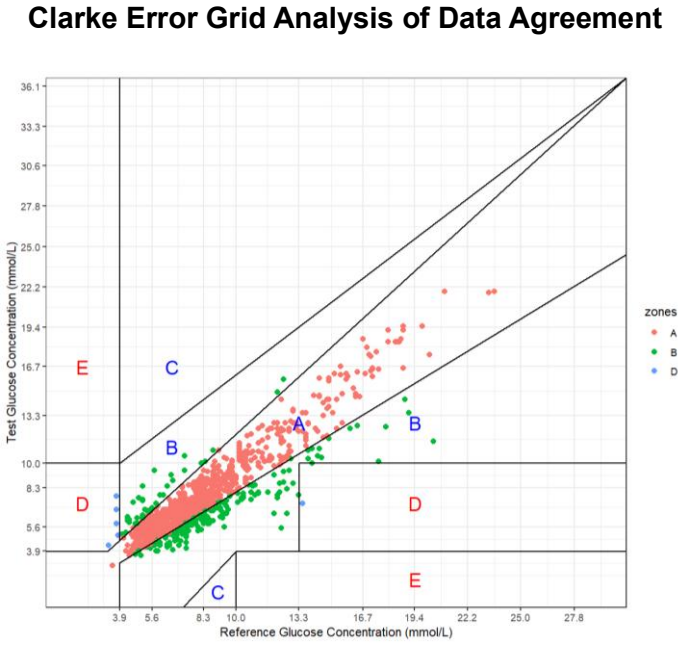

Figure 4. Plot of paired values on a color-coded error grid to identify agreement between values and resulting possible clinical impact of any discrepancies. Region A indicates points that agree within 20 %; B = outside 20 % but not of clinical relevance in impact; C indicates significant differences in actionable treatment may result; D indicates potential danger of

failing to recognize significant hypo or hyperglycemia; E are significant far misses which may lead to clinically concerning misinterpretations.

Table 1.

Distribution of data between regions (percentages):

A	B	C	D	E
79.2	20.2	0	0.6	0

Clarke error grid analysis for comparison of glucose measures between devices and as given by individuals was developed in 1987. This approach has since commonly been used in evaluation and comparison of glucose monitoring devices. Figure 4 shows the evaluation of discrepancies between data pairs using this approach. As indicated by the summary table (Table 1) 99.4 % of data pairs fall within categories A and B indicating differences of less than 20 % (A); or outside 20 % but of no significant clinical evaluative impact (B). No data points fall within error categories C or E, which is reassuring since E represents a zone where there is a danger of misidentifying serious clinical events in terms of blood sugar control and C also represents considerable discrepancy of values. 0.6 % of data points are significantly displaced in agreement. The discrepancies falling into zone D are a potential concern, although they are on the border-zone of these areas butrepresent a potential danger of failing to identify significant hypo or hyperglycemia.

Another common means used to compare and evaluate glucose measurements is the mean average relative difference (MARD) between measures. This analysis was conducted across all pairs of data values for each data set. Overall average MARD between the Anytime CGM and finger-prick blood sampling was 6.9% representing excellent agreement between measures across the period evaluated. There was significant inter-individual variation in MARD although 95% confidence intervals for this analysis across the cohort studied are 3.6 and 10.8 %. Sub-analysis of gender as an influencing factor failed to identify a significant difference between sexes ($p=0.35$ by nested t-test between sexes; males n= 17, females n=20). Equally no significant correlation between MARD and BMI was identified ($p=0.78$, by Spearman Rank Correlation analysis).

Discussion

Although it must be remembered that mean absolute relative difference (MARD) is not the only measure of accuracy that must be considered MARD is still an important indicator of accuracy [12-14]. Rodbard [16] indicated that only CGM devices with a MARD that is less

than 10% should be considered suitable for use. There are a number of devices currently available that meet this criteria and https://www.diabetesspecialistnurseforumuk.co.uk/ compares a number of devices and reports that MARD ranged between 7.8-10.6 across 12 devices including Freestyle Libre 3, Dexcom, Medtronic and GluoRx AiDEX. The Yuwell Anytime device tested in this study proved to be very accurate with a MARD of 6.9% which shows excellent agreement comparable with or exceeding performance of other devices. There are few studies that have directly compared between CGM devices although other studies have assessed the accuracy of devices in a range of populations, both diabetic and non-diabetic. [21 and 22]. Hanson et al [14] conducted one of the few studies that directly compares two devices and they found in their analysis that the Freestyle Libre 3 had a MARD of 7.9% compared with the Dexcom G7 which was 13.6%. Interestingly Garg et al [13] reported a MARD of 8.2% for the Dexcom G7. Alva et al [11] looked at the accuracy of the FreeStyle Libre® 3 continuous glucose monitoring system and found it had a MARD of 7.8%. It must be remembered that it is difficult to make comparisons due to the wide range of research methods that are employed and the diversity of the participants included in studies, this may account for different studies reporting different MARD. However, it is still important to consider the MARD and manufacturers should be encourage to aim for a MARD below 10% [12-14, 16]. It is perhaps not unexpected that devices based on the same core methodological approach may share similar reliability in terms of absolute measurements although adaptations to the internal algorithsm and filtering approaches can influence issues such as potential offsets and tracking kinetics. The new Yuwell Anytime device performs as expected in comparison with other glucose-monitoring devices based on this methodology.

We also examined individual sets of glucose measurements from across the 37 sets of data and the 1082 paired glucose sample points ranged in concentration from 2.9 to 23.6 mM which is an expected range and values for this population. This is comparable to other studies monitoring patients with type 2 diabetes where example average values of ~8-10 mM with ranges of 5 to 16 mM are typically observed (e.g. 23) even in treated patient cohorts where desirable target ranges are 4-8 mMol in advance of each meal (International Diabetes Federation, 24) As such the readings obtained cover the most frequently encountered range in this target population for the study.

A Bland-Altman analysis of agreement was used to identify any potential concentration-dependent or systematic difference between the two measurement approaches and there was no significant concentration dependent gradient in variation or agreement. The reliability of the Yuwell Anytime device was preserved across the typical range of glucose concentrations showing no significant systematic offset in terms of concentrations reported across the range observed. Barua et al [22] reported that the Freestyle Libre Pro CGM

underestimated the time spent in the 3.9-10 mM range (P = 0.002) and overestimated the time spent <3.9 mM (P < 0.0001) compared with the other 2 methods suggesting a bias of values in practical use. We identified in the Yuwel Anytime device a 0.66 mMol/litre offset but this was not significant. Jin et al [21] in assessing the accuracy of the Freestyle Libre2 also by Bland-Altman plot analysis found it to have an offset of 1.14 mM with a proportional bias showing increasing deviation with elevated concentrations even across the modest 3-9 mM range evaluated. A more recent study by Gu et al. [25] however found the Freestyle Libre to have an offset of 1.77 mMol/Litre compared with sampled venous glucose although identified no such concentration-dependent variation in reliability or bias. Systematic offsets and perhaps more importantly concentration-dependent variation in accuracy are a concern but one that can be potentially corrected by adjustment of the device algorithms that process the data. A degree of variation in potential offset may perhaps be expected due to differences in local skin environments but the low impact seen and lack of concentration dependency seen in the Yuwell Anytime is indicative that the device algorithms are ensuring good robustness and reliability. Evolution of such algorithms alongside our developing understanding of how factors may alter skin interstitial glucose evaluation can only improve the reliability of such devices.

Clarke error grid analysis for comparison of glucose measures between devices has been employed by several researchers [21, 22, 26]. For the Yuwell Anytime CGM 99.4 % of data pairs fell within categories A and B indicating differences of less than 20 % which is clinically acceptable. The discrepancies falling into zone D are a potential concern, although they are small in number (0.6 % of values) and are on the border-zone of these areas, they represent a potential concern for failing to identify significant hypo or hyperglycemia events. The data arecomparable with evaluation of other similar CGM sensors in a range of patient populations such as Narasaki et al [25] who demonstrated that nearly all CGM values were in clinically acceptable zones A (no harm) and B (unlikely to cause significant harm) using a Dexcom G5 device and Jin et al [21] or Gu et al. [25]who indicated 85.3% and 98.1 % of data points respectively for the Libre2 device were within Zones A + B (clinically acceptable) As such the Yuwell Anytime device performs in-line with other devices of this type for expected clinical performance.

Some studies have also stressed the importance of testing the CGM sensor in free living conditions to evaluate its performance in the ‘real world’ context [9, 19 and 27]. The current study adopted this method and it can be assumed that this gave the best opportunity to access the Anytime CGM in the conditions that it was going to be used in by individuals with type 2 diabetes. Other studies have shown that using real-time continuous glucose monitoring have significantly improved HbA1c levels [8] and encouraged more active

lifestyles and improve glucose control and [9 and 10]. Although we did not formally gather participants views on how using the Anytime CGM influenced their behavior many reported that they found it motivating, that they learnt about how different food affected them and they found it easier to control their glucose levels. Further work is clearly needed to determine the education value of wearing a CGM. Given the growing number of individuals with diabetes it is vital that a broader range of people are given access to an affordable CGM that enables them to accurately control their glucose levels

Limitations

As with many studies it would have been useful to have a larger number of participants and to assess the performance of the device for a longer period of time. Whilst we provisionally assessed any potential variance in reliability due to sex, age, ethnicity or BMI and found none, this element of the study is currently under-powered and does not fully reflect the full ethnic diversity that may be encountered in wider real-world deployment of such devices. Further data would establish if any variance perhaps associated with vascular and tissue composition differences may be present and of relevance in considering data obtained from this and similar devices. Equally future consideration must be given to evaluating the practical usability of the device in populations who are frequently elderly and may have additional issues concerning vision and mobility. We did not encounter such issues in our study but the ability to reliably deploy and use the device in such populations needs consideration [29].

A key contributor to the overall variance in this data and ability to resolve the dynamics of how the sensor responds to changes in blood glucose is the reliability of the blood glucose readings themselves and the potential kinetic differences between blood and interstitial fluid differences in terms of glucose concentrations. Use of laboratory conditions and laboratory-calibrated glucose measurement to further reduce potential for measurement variance would help in resolving any subtle differences in measures whilst a controlled glucose challenge under such conditions would allow us to establish the kinetics of response of the device, a key parameter that ideally should be investigated for other devices of this type too. It is in terms of kinetics of response that greater individual variance may be potentially observed as depending on vascular and tissue function, although this remains a hypothesis at this stage. Direct measurement of exchange rates of glucose between capillary glucose and interstitial fluid indicates an anticipated intrinsic differential response time of approximately 2.4 ± 0.8 minutes for the fluid to reflect capillary measures [28] but this is likely to change depending on local vascular performance which may be compromised in diabetic patients.

The study has focussed on a ‘real-world’ analysis and assessment of the potential value to type-2 diabetics in monitoring their glucose control. Further evaluation in insulin-controlled individuals and type-1 diabetics where risk of hypoglycaemia is greater will increase the lower range of critical glucose values investigated and is key for expanding use to this population. It is for this population though that kinetics of response are particularly key and future initial investigations of this aspect should be under clinical/laboratory conditions.

In conclusion the Yuwell Anytime device provided a reliable and accurate assessment of glucose concentrations, Performance was in-line with or exceeded performance characteristics of other CGM devices currently available. Further evaluation of the value of these devices in type-2 diabetics and the impact on their health outcomes is warranted as these devices become routinely integrated further into healthcare and promotion approaches.

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NDSS (National Diabetes Services Scheme), 2024. CGM Comparison Chart