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ORIGINAL ARTICLE

Performance of the Fifth Generation of a 16-Day Continuous Glucose Monitoring System in Adults with Diabetes

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Abstract

Background: This study evaluated the accuracy and safety of the Anytime 5Pro continuous glucose monitoring (CGM) system, a real-time, factory-calibrated device, over a 16-day period in adults with diabetes.
Methods: Adult participants with type 1 or type 2 diabetes were recruited from three clinical sites in China. Each participant was equipped with four sensors (one on each upper arm and two on the abdomen) for a period of up to 16 days. To evaluate sensor performance, participants were randomly assigned to one of three 7-hour clinic sessions on days 1 or 2, days 7, 8 or 9, and day 16. During the sessions, the real-time glucose values measured by Anytime 5Pro CGM system were compared with venous blood glucose values measured by the EKF blood glucose detector. Primary endpoints for assessment were the mean absolute relative difference (MARD), the proportion of CGM values within ± 20%/±20 mg/dL of reference values, and the percentage of paired points within Zones A and B of the consensus error grids.
Results: In the cohort of 72 participants (287 sensors), the CGM system exhibited an overall MARD of 8.58%, with 96.59% of values within the ± 20%/±20 mg/dL criteria. Comparative analysis revealed similar accuracy between arm (MARD: 8.58%; agreement: 97.03%) and abdomen (MARD: 8.58%; agreement: 96.16%) sensor placements. Throughout the 16-day wear period, the ± 20%/±20 mg/dL agreement rates remained above 95%, with MARDs ranging from 8.30%–8.88%. Consensus error grid analysis showed 99.99% of points in Zones A and B. No serious adverse events were reported.
Conclusions: The system demonstrated accurate glucose measurements across the 16-day wear period, irrespective of sensor placement site or glucose concentration.

Keywords: accuracy, Anytime 5Pro, continuous glucose monitoring, diabetes, factory calibration, MARD.

Introduction

In recent years, continuous glucose monitoring (CGM) system has become an effective complement to traditional methods of blood glucose monitoring and is being used with increasing frequency for the daily management of blood glucose in people with diabetes.[1–5] Multiple clinical studies have demonstrated that, compared with self-monitored plasma glucose,[6,7] the use of CGM devices can reduce HbA1c levels in children and adults with type 1 diabetes (T1D)[8–10] as well as in adults with type 2 diabetes (T2D) receiving either insulin or noninsulin therapies,[11–13] supporting its use in clinical therapeutic decision making. The early use of CGM is also recommended by the American Diabetes Association for people with diabetes.[14] Due to clear evidence for clinical benefits, many innovative devices are being developed.[15–19]

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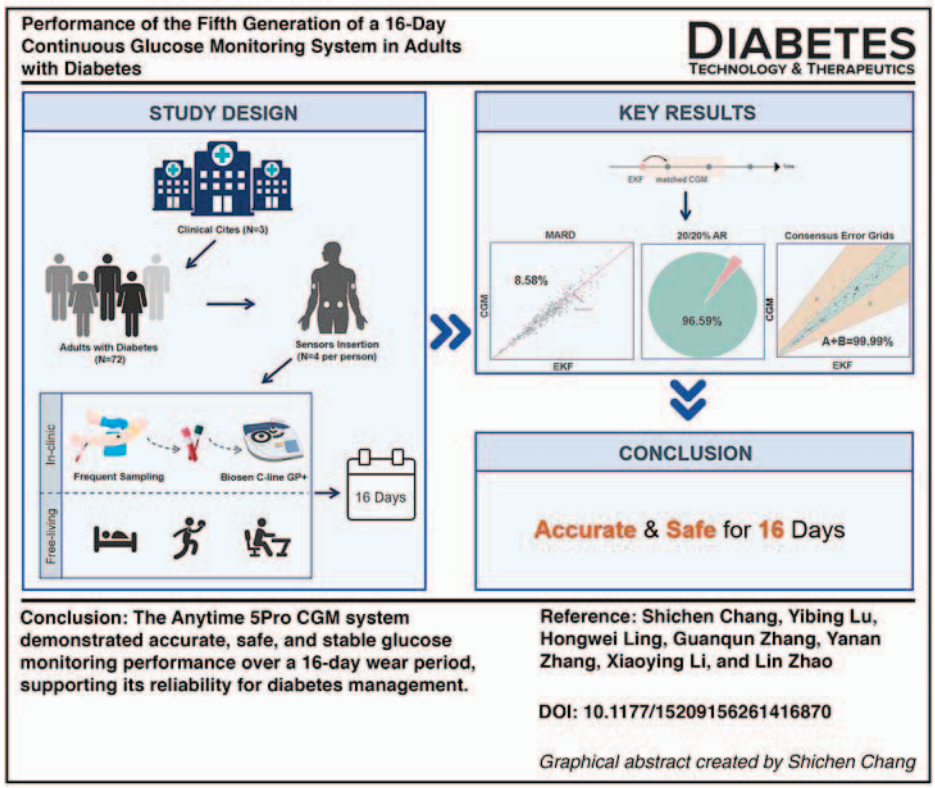


The CT2 CGM system (Jiangsu Yuwell POCTech Biotechnology Co., Ltd., Jiangsu, China) received market approval in 2021, with a wear time of up to 14 days in both clinical and home settings. The subsequent CT3 system further advanced the technology as a factory-calibrated device that maintained accuracy without user calibration. Building on the CT3 series, the Anytime 4 series CGM system introduced an optimized enzyme membrane formulation that further improved device performance and extended the wear time to 15 days. In addition, it incorporated an optional calibration mode while retaining the factory-calibrated option.

The Anytime 5Pro differs from the earlier Anytime 4 series by adopting an integrated design of the sensor and transmitter, reducing the assembly steps between the two components and thereby improving the user experience. The sensor can be worn for up to 16 days in both clinical and home-use settings with a warm-up time shortened to 45 min. It provides a broader reportable glucose range of 30–500 mg/dL (1.7–27.8 mmol/L) and automatically updates glucose readings every 3 min, yielding a data sampling frequency approximately 1.7 times higher than that of most commercially available systems, which typically update every 5 min. Given these design improvements and extended functional capabilities, we conducted a study to evaluate the accuracy and safety of the Anytime 5Pro system over 16 days in adult patients with diabetes.

The system components are depicted in Figure 1. The wearable sensor-transmitter unit measures $23 \times 23 \times 4$ mm and the applicator measures $52 \times 52 \times 73$ mm. The markings at the top of the display, shown in the companion mobile application, represent selectable time windows (3, 6, 12, 24 h), allowing users to choose the duration of data to view. The timeline at the bottom shows the actual time corresponding to the glucose data within the selected window, helping users track trends over time.

Methods

Study design

This prospective, self-controlled, single-arm, multicenter study was conducted between April and June 2024 at three clinical sites in China. The study protocol was approved by the institutional review board of each participating center, and the study was conducted in accordance with the principles of Guiding Principles for Design of Medical Device Clinical Trials, Good Clinical Practice for Medical Device Trials, and the Declaration of Helsinki. Written informed consent was obtained from all participants before study initiation. The study was registered with the Chinese Clinical Trial Registry (ChiCTR2400089452).

Study population

All participants underwent a screening visit, during which the required enrollment assessments were completed. Eligible participants were adults aged ≥ 18 years with a diagnosis of T1D or T2D, stable vital signs, established forearm venous access, and a hematocrit ≤ 70%. Key exclusion criteria included skin disorders at the prospective sensor insertion site, known allergies to alcohol-based disinfectants or medical adhesives, coagulation abnormalities, current pregnancy or lactation, a history of epilepsy or psychiatric disorders, and concurrent participation in another interventional device

FIG. 1. The Anytime 5Pro components (left to right) include the integrated sensor-transmitter with adhesive, the applicator, and the companion mobile application. The wearable sensor-transmitter unit measures 23 × 23 × 4 mm. The applicator measures 52 × 52 × 73 mm.

trial within the past 30 days. The complete eligibility criteria are detailed in Supplementary Table S1. Participants who met all inclusion criteria and none of the exclusion criteria were enrolled in the study.

Study procedures

Each participant concurrently wore four Anytime 5Pro sensors (one on the back of each upper arm and two on the abdomen) for up to 16 days. Sensor insertion and initialization were performed in the clinic by the participants themselves in accordance with the instructions for use and under the supervision of study staff. Over-patch tape was provided, and participants were instructed to apply it during the middle or later stages of wear.

Participants returned to the clinic for a single venous blood sampling session. They were randomly assigned in a 1:1:1 ratio to one of three groups, with the visit scheduled at different phases of the sensor wear period: (1) the beginning (day 1 or 2 after sensor initialization); (2) the middle (day 7, 8, or 9); and (3) the end (the final 24 h of the wear period). During each in-clinic session, venous blood was sampled frequently (every 15 ± 3 min for at least 7 h) via an intravenous catheter to obtain at least 20 paired measurements per session. Plasma glucose concentrations were assayed within 15 min of collection using a Biosen C-line GP+ analyzer (EKF-diagnostic GmbH, Germany). Each result was paired with a CGM value recorded within ± 5 min. When the reference glucose value was <4.4 mmol/L, an additional venous blood sample was obtained 10 ± 5 min after any scheduled draw.

Glucose manipulation was performed in participants with T1D who routinely used insulin injections. To induce hypoglycemia, a slightly higher premeal insulin dose than usual was administered, with the target of lowering glucose levels to ≤70 mg/dL (3.9 mmol/L). The duration of hypoglycemia was limited to 1 hour. All procedures were conducted under close supervision by clinical research staff. Hyperglycemia was not deliberately induced. Participants maintained their usual meal schedules and dietary habits during the intensive blood sampling period.

On day 16, participants returned to the study center for sensor removal by the study staff. At every clinic session, study staff evaluated insertion sites and adhesive areas and documented any participant-reported adverse events and device failure. During the removal visit, the skin assessment was repeated, and participants completed a usability questionnaire to assess satisfaction with the sensor. In cases of early sensor removal or unintentional dislodgement, the skin assessment and usability questionnaire were performed at that time and constituted the final visit.

Data analysis

A sample size of 60 participants was considered sufficient to provide >80% power at a two-sided significance level of 0.05 to meet the predefined accuracy endpoints, including a 20/20 agreement rate (AR) of 90% versus a threshold of 87%, MARD ≤ 15%, ≥90% of sensor values within Zones A and B of the Clarke/consensus error grid and a dropout rate of 20%. To satisfy regulatory requirements, the study also ensured at least 360 hyperglycemic pairs (≥200 mg/dL [11.1 mmol/L]) and 60 hypoglycemic pairs (≤70 mg/dL [3.9 mmol/L]); finally 72 participants were planned to be enrolled.

EKF measurements taken during the clinic sessions were matched with the first available CGM value from each sensor within the subsequent 5 min. Only those matched pairs where the sensor results were within the reportable range (30–500 mg/dL) with pairable comparator results were used for the performance evaluation.

Primary performance metrics included agreement within predefined error margins relative to the EKF reference values, the mean absolute relative difference (MARD), and the proportion of paired points falling within zones A and B of the consensus error grids. ARs were determined as the percentage of paired CGM and EKF values that fell within specified thresholds (±15 mg/dL for reference values ≤80 mg/dL or ± 15% for values > 80 mg/dL,[16] and analogously for ± 20/20 and ± 30/30). MARD was calculated as the mean of the absolute relative differences between paired CGM and EKF glucose values, expressed as a percentage. For low glucose concentrations (≤70 mg/dL), the mean absolute difference (MAD) in mg/dL was reported. Sensor accuracy was assessed across different glucose ranges, sensor wear periods, and diabetes types. Consensus error grid analysis was performed by plotting paired CGM-EKF values against reference values and determining the proportion of points located within clinically acceptable zones A and B. Clarke error grid analysis was also performed.

The rate of change (RoC) was calculated as the difference between consecutive glucose values per unit of time (units of milligrams per deciliter per minute). For analysis of consistency of the RoC between CGM and reference glucose measurements, the RoC values were grouped into the following ranges: <–2, –2 to <–1, –1 to <0, 0–1, >1–2, and >2, and the consistency percentage for each range was calculated. MARD and ± 20%/±20 mg/dL AR were also evaluated across these RoC categories.

The alert and detection performance were evaluated based on the true alert rate and the detection rate. The hypoglycemic and hyperglycemic alert thresholds were set at 70 mg/dL and 200 mg/dL, respectively. When the CGM value was below or above the corresponding threshold, a hypoglycemic or hyperglycemic alert would be triggered. A single alert or consecutive alerts were counted as one alert event. The true alert rate was defined as the proportion of times the CGM triggered an alert event and at least one EKF reference value was below or above the set thresholds within a ± 15-min window. When the EKF value was below or above the corresponding threshold, it was considered a hypoglycemic or hyperglycemic event, with the duration of the event being at least 15 min. The true detection rate was defined as the proportion of times a hypoglycemic or hyperglycemic event occurred and at least one CGM alert was triggered within a ± 15-min window.

Sensor repeatability was determined using the paired absolute relative difference (PARD) between two sensors worn simultaneously at symmetrical body sites. The 95% confidence intervals (CIs) for all proportion-based metrics were calculated using unclustered Wilson score intervals, based on a pooled analysis without adjustment for within-subject correlation.[20] Usability was assessed with structured participant questionnaires, focusing on ease of operation, readability, safety, and overall system usability. Sensor survival was estimated with Kaplan–Meier methods. Safety was assessed by monitoring vital signs and adverse events during the sensor use period.

All analyses were performed using SAS version 9.4 (SAS Institute Inc, Cary, NC, USA) and R version 4.3.1 (R Foundation for Statistical Computing, Vienna, Austria).

Results

Study population

A total of 73 participants were screened and 72 were included, resulting in the deployment of 288 sensors. All sensors were successfully initiated and provided at least one

Table 1. Demographic and Clinical Characteristics of the Participants at Baseline ($N = 72$)

Characteristic	*Value*
Age, years	
Mean (SD)	53.8 (14.0)
Median	55.5
Min, Max	22.0, 77.0
Gender, *n* (%)	
Female	38 (52.8%)
Male	34 (47.2%)
Weight, kg	
Mean (SD)	68.0 (14.0)
Median	67.5
Min, Max	44.0, 107.0
BMI, kg/m^2	
Mean (SD)	24.7 (4.2)
Median	24.1
Min, Max	16.9, 35.9
HbA1c, %	
Mean (SD)	7.4 (1.9)
Median	6.9
Min, Max	5.4, 14.5
Diabetes type, *n* (%)	
Type 1	24 (33.3%)
Type 2	48 (66.7%)
Duration of diabetes, years	
Mean (SD)	11.9 (9.9)
Median	9.5
Min, Max	1.0, 48.0
Medication, *n* (%)	
Oral medication	25 (34.7%)
Insulin	21 (29.2%)
Oral medication + Insulin	20 (27.8%)
None	6 (8.3%)

BMI, body mass index; SD, standard deviation.

Table 2. Sensor Accuracy Across CGM Glucose Ranges

Placement	Glucose range (mg/dL)	Matched pairs (n)	15/15[a] AR (%)	20/20[a] AR (%)	30/30[a] AR (%)	MAD[b] (mg/dL)	MARD (%)
Arm	30–500	4549	90.37	97.03	99.69	NA	8.58
	<54	130	86.92	93.08	100.00	7.14	NA
	54–70	522	93.87	98.85	100.00	7.45	NA
	71–180	2320	88.02	96.12	99.53	NA	8.90
	>181	1577	92.96	98.10	99.81	NA	7.28
Abdomen	30–500	4578	88.44	96.16	99.58	NA	8.58
	<54	130	88.46	93.08	100.00	7.29	NA
	54–70	522	93.68	98.66	99.81	6.89	NA
	71–180	2340	85.81	94.49	99.27	NA	9.30
	>181	1586	90.61	98.05	99.94	NA	7.22
Overall	30–500	9127	89.41	96.59	99.64	NA	8.58

[a]Accuracy results for glucose values ≤80 mg/dL are in mg/dL.
[b]Mean absolute difference (MAD) is provided for glucose values ≤ 70 mg/dL and mean absolute relative difference (MARD) is provided for glucose values > 70 mg/dL.
AR, agreement rate; CGM, continuous glucose monitoring; MAD, mean absolute difference; MARD, mean absolute relative difference; NA, not applicable.

valid reading. During the study, three sensors (one on the right arm and two on the left arm) fell off due to bathing or excessive sweating, with one occurring before the in-clinic session and two occurring after the in-clinic session. Consequently, data from 287 sensors (143 arm, 144 abdomen) were available for analysis. From these, 9127 matched CGM-reference pairs within the reportable range (30–500 mg/dL) were obtained, constituting the primary dataset for accuracy assessment (4549 from arm and 4578 from abdomen sensors).

Baseline participant characteristics are summarized in Table 1. The mean age was 53.8 (±14.0) years and 52.8% were female. The mean body weight and body mass index were 68.0 (±14.0) kg and 24.7 (±4.2) kg/m^2, with a mean HbA1c of 7.4%. Among the participants, 66.7% had T2D and the mean duration of diabetes was 11.9 years. Antidiabetic medication patterns were as follows: 34.7% were treated with oral antidiabetic drugs (OAD) only, 29.2% with insulin only, 27.8% with a combination of OAD and insulin, and 8.3% received no pharmacological treatment.

Accuracy evaluation

Sensor accuracy across different glucose ranges is summarized in Table 2, Supplementary Table S2, and Supplementary Table S3. Overall, the MARD was 8.58%. ARs within the ± 15%/±15 mg/dL, ± 20%/±20 mg/dL, and ± 30%/±30 mg/dL thresholds were 89.41%, 96.59%, and 99.64%, respectively. For arm-placed sensors, the MARD was 8.58% with ± 15%/±15 mg/dL, ± 20%/±20 mg/dL, and ± 30%/±30 mg/dL ARs of 90.37%, 97.03%, and 99.69%. For abdomen-placed sensors, the MARD was 8.58% and the corresponding ARs were 88.44%, 96.16%, and 99.58%. The ± 20%/±20 mg/dL ARs remained above 90% across various glucose ranges for both upper arm and abdominal sites.

Sensor accuracy across wear periods is summarized in Table 3. The ± 20%/±20 mg/dL ARs consistently exceeded 95%, whereas the MARDs were maintained within a narrow range of 8.30%–8.88%. Accuracy by diabetes type is summarized in Supplementary Table S4. For arm-placed sensors, the MARDs were 9.54% and 8.10% for individuals with T1D and T2D, respectively. The corresponding ± 20%/±20 mg/dL ARs were 96.47% and 97.40%. For abdomen-placed sensors, the MARDs were 8.96% and 8.39% for individuals with T1D and T2D, respectively. The corresponding ARs were 96.36% and 96.03%.

The performance of all 287 individual sensors is shown in Figure 2. The mean and median sensor-specific MARDs were 8.58% and 8.61%, respectively. The standard deviation was 2.16%, the standard error of the mean was 0.13%, and the interquartile range was 2.81%. The majority of sensors (75.69%) had a MARD of ≤10%, and only 0.69% exhibited a MARD of ≥14%.

Supplementary Table S5 summarizes the lower one-sided 95% confidence bounds for the Anytime 5Pro system across different glucose ranges, based on accuracy metrics used in integrated CGM (iCGM) assessments.[21]

Consensus error grid analysis (Fig. 3) showed that 99.99% of values were within zones A and B (zone A: 96.73%, zone B: 3.25%), and only 0.01% were in zone C. There were no values in zone D and E. Clarke error grid analysis (Supplementary Fig. S1) showed that 98.80% of values were within zones A and B (zone A: 95.25%,

Table 3. Sensor Accuracy Across Sensor Wear Periods

Sensor wear period	Study day(s)	Matched pairs (n)	15/15[a] AR (%)	20/20[a] AR (%)	30/30[a] AR (%)	MARD (%)
Beginning	1,2	2960	90.34	97.09	99.80	8.57
Middle	7,8,9	3080	89.29	96.95	99.68	8.30
End	16	3087	88.63	95.76	99.45	8.88

[a]Accuracy results for glucose values ≤ 80 mg/dL are in mg/dL.
AR, agreement rate; MARD, mean absolute relative difference.

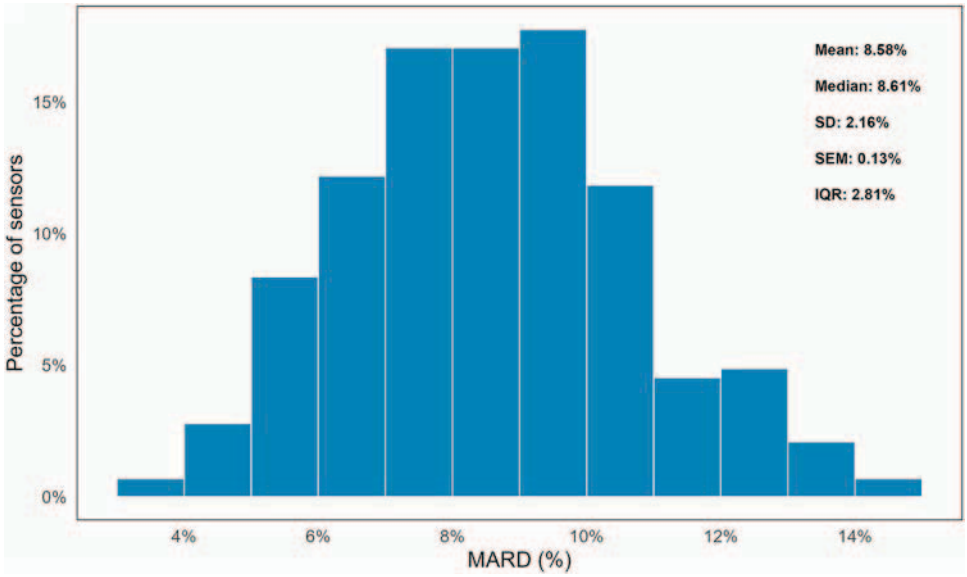


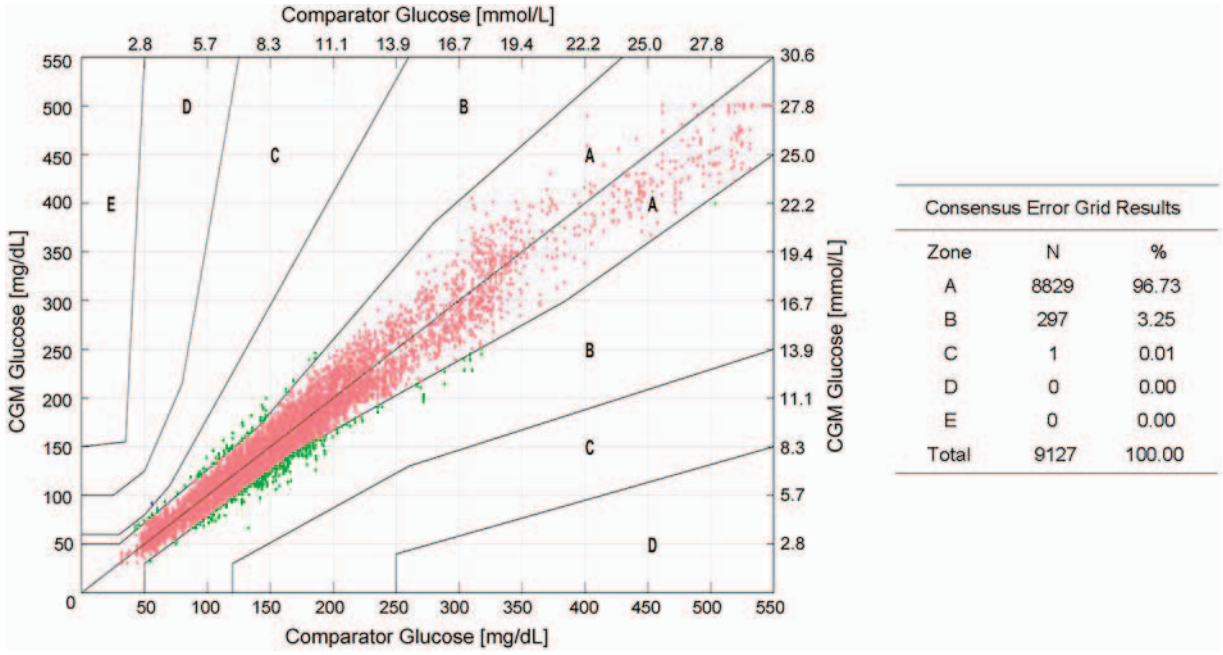
FIG. 2. Distribution of sensor-specific MARD values (n = 287). MARD, mean absolute relative difference.

zone B: 3.55%), with 1.20% in zone D. There were no values in zone C and E.

The consistency of the RoCs between paired CGM readings and EKF measurements across different intervals (Table 4) was as follows: 57.89% (<–2 mg/dL per minute), 53.58% [–2 to –1 mg/dL per minute), 65.98% [–1–0 mg/dL per minute), 52.95% [0–1 mg/dL per minute], 45.09% (1–2 mg/dL per minute], and 64.69% (>2 mg/dL per minute). When the corresponding venous blood glucose RoC was < –2 mg/(dL·min), 0.12% of CGM measurements indicated a positive RoC > 1 mg/(dL·min). When the corresponding venous blood glucose RoC was > 2 mg/(dL·min), 0% of CGM measurements indicated a negative RoC < –1 mg/(dL·min).

Sensor accuracy across various glucose concentration RoCs is shown in Supplementary Table S6. For arm-placed sensors, the MARDs at rapidly decreasing (RoC < –2 mg/dL per minute) or rapidly increasing (RoC > 2 mg/dL per minute) were 10.82% and 11.31%, respectively, and the ± 20%/±20 mg/dL ARs were 92.68% and 90.64%, respectively. Similarly, for abdomen-placed sensors, MARDs at rapidly decreasing or increasing RoCs were 11.25% and 12.02%, respectively, and ± 20%/±20 mg/dL ARs were 87.04% and 89.04%, respectively.

The alarm performance at different thresholds is summarized in Table 5. At the hypoglycemic threshold of 70 mg/dL, 106 alert events were generated, of which 100 (94.34%) were



Consensus Error Grid Results

Zone	N	%
A	8829	96.73
B	297	3.25
C	1	0.01
D	0	0.00
E	0	0.00
Total	9127	100.00

FIG. 3. Consensus error grid analysis plot for Anytime 5Pro CGM readings versus EKF reference values. Red, zone A; green, zone B; blue, zones C, D, or E. CGM, continuous glucose monitoring.

Table 4. Consistency in the Rate of Change Between Paired CGM Glucose Readings and Venous Blood Glucose Measurements

Change rate of CGM glucose reading, mg/(dL·min)	*Change rate of venous blood glucose measurement, mg/(dL·min)*						
	<–2	*–2 to < –1*	*–1 to < 0*	*0–1*	*>1–2*	*>2*	*Matched pairs (*n*)*
<–2	57.89%	23.16%	16.84%	2.11%	0.00%	0.00%	95
–2 to <–1	11.83%	53.58%	28.67%	5.91%	0.00%	0.00%	558
–1 to <0	1.90%	12.00%	65.98%	18.60%	1.25%	0.27%	3366
0–1	0.17%	2.71%	29.66%	52.95%	11.26%	3.25%	3543
>1–2	0.12%	0.23%	3.74%	28.39%	45.09%	22.43%	856
>2	0.00%	0.24%	1.66%	5.21%	28.20%	64.69%	422

CGM, continuous glucose monitoring.

true. A total of 1304 hypoglycemic events were recorded, with 1137 (87.19%) correctly detected within ± 15 min of the events. At the hyperglycemic threshold of 200 mg/dL, 288 alert events were generated, and 275 (95.49%) were true. Among 2283 hyperglycemic events, 2128 (93.21%) were successfully detected.

The PARDs at the arm and abdomen insertion sites were 9.39% and 11.19%, respectively (Supplementary Table S7).

Sensor survival

Of the 288 CGM sensors inserted during the study, 285 (98.96%) remained functional for the full 16-day wear period, while 2 (0.69%) terminated at day 14 and 1 (0.35%) at day 12. This yielded an estimated 16-day survival probability of 98.96% (Supplementary Fig. S2). The few sensors that did not complete the intended wear period were primarily attributed to accidental dislodgement during daily activities, such as bathing or sweating. No instances of insertion failure or technical malfunction were reported.

Safety and usability

The investigation demonstrated a favorable safety profile, with no serious adverse events reported. A total of 20 adverse events were documented among 18 participants, the majority (80%) of which were Grade 1 in severity. Only four events were considered possibly related to the investigational device (three cases of skin pruritus and one case of subcutaneous induration). These four skin reactions were observed during the sensor wearing period and none were recorded during implantation or removal (Supplementary Table S8 and Supplementary Table S9). All adverse events resolved or recovered without sequelae. All participants completed the usability questionnaire, and satisfaction ratings for ease of operation, readability, and perceived safety were above 95%. For the overall system evaluation, 76.39% of participants rated it as "excellent," 19.44% as "good," and 4.17% as "fair" (Table 6).

Discussion

This study demonstrated that the Anytime 5Pro CGM system provided accurate glucose measurements with an overall MARD of 8.58%, and 96.59% of readings falling within the ± 20%/±20 mg/dL agreement range. The system also maintained consistent performance across different glucose ranges, wear sites, and wear periods. In addition, 99.99% of CGM values fell within Zones A and B of the consensus error grid, indicating minimal potential impact on clinical decision-making. No safety concerns were identified, and participants reported high satisfaction with the system. These results suggest that Anytime 5Pro CGM may provide reliable glucose information for routine diabetes management.

Comparing the performance of different CGM systems is challenging due to the lack of comprehensive guidelines for clinical performance evaluations,[22] although the POCT05[23] guideline and FDA requirements for iCGM[24] systems address some aspects. Nevertheless, the overall MARD of the Anytime 5Pro CGM system (8.58%) appears to fall within the range reported for other CGM systems, including the 15-day Dexcom G7 (MARD 8.0%),[18] FreeStyle Libre 2 Plus/Libre 3 Plus (MARD 8.2% in adults, 8.1% in pediatric populations),[16] Accu-Chek SmartGuide (MARD 9.2%),[15] and CareSens Air (MARD 10.42%).[17]

Several functional features distinguish the Anytime 5Pro CGM system from currently available devices. It offers a 16-day wear duration, longer than most commercial CGMs, which typically last 10–15 days.[15–19,25–27] The system also has a reportable glucose range of 30–500 mg/dL, wider than that of many existing CGMs.[15–19,25,26] Furthermore, the Anytime 5Pro automatically updates glucose readings every 3 min, offering a data sampling frequency approximately 1.7 times higher than most systems, which typically update every 5 min.[17,19,26,27]

Additionally, the performance of the Anytime 5Pro system seems to align with the accuracy expectations outlined in the FDA special controls for iCGM systems,[21] suggesting

Table 5. Hypoglycemic and Hyperglycemic Alerts and Detections

Condition	*Threshold, mg/dL*	*No. of alert events*	*True alert rate,* N *(%)*	*No. of detections*	*True detection rate,* N *(%)*
Hypoglycemia	70 mg/dL	106	100 (94.34)	1304	1137 (87.19)
Hyperglycemia	200 mg/dL	288	275 (95.49)	2283	2128 (93.21)

Table 6. Participant Responses to Usability Questionnaire

Questions	*Satisfied,* N *(%)*	*Neutral,* N *(%)*	*Dissatisfied,* N *(%)*	*Total,* N
Was it easy to apply the sensor independently	72 (100.00)	0 (0.00)	0 (0.00)	72
Was it easy to attach the transmitter	72 (100.00)	0 (0.00)	0 (0.00)	72
Was the mobile application easy to operate (including initialization)	71 (98.61)	1 (1.39)	0 (0.00)	72
Was the screen size and visibility appropriate	72 (100.00)	0 (0.00)	0 (0.00)	72
Were the displayed glucose values and warning signals easy to read	72 (100.00)	0 (0.00)	0 (0.00)	72
Were the various alerts displayed on the device understandable	72 (100.00)	0 (0.00)	0 (0.00)	72
Was the menu display easy to navigate and comprehend	71 (98.61)	1 (1.39)	0 (0.00)	72
Was it easy to read glucose values independently	72 (100.00)	0 (0.00)	0 (0.00)	72
Was the monitoring system overall easy to use	72 (100.00)	0 (0.00)	0 (0.00)	72
Was it easy to enter calibration glucose values independently	71 (98.61)	1 (1.39)	0 (0.00)	72
How would you evaluate the product manual	71 (98.61)	1 (1.39)	0 (0.00)	72
How would you assess the safety of the product	72 (100.00)	0 (0.00)	0 (0.00)	72
How would you rate the overall performance of the entire system	Excellent 55 (76.39)	Good 14 (19.44)	Fairly good 3 (4.17)	72

that the system may have the potential to be used either independently or as part of digitally connected devices, including automated insulin dosing systems. However, certain aspects of the study design—such as the relatively small sample size and the use of multiple sensors worn at different sites—did not fully adhere to the methodological requirements specified for iCGM evaluation. Although the findings indicate a favorable trend, further validation is needed.

The MARDs for the upper arm (8.58%) and abdomen (8.58%) were similar. Several studies also compared the accuracy across different wearing sites. For example, Faccioli et al. evaluated Dexcom G5 in pediatric T1D subjects and found MARD values of 13.4% and 13.3% for the upper arm and abdomen, respectively.[28] Steineck et al. compared Dexcom G4 Platinum in adults and found MARD values of 12.0% for the upper arm and 12.3% for the abdomen.[29] Garg et al. reported a MARD of 8.2% for the upper arm and 9.1% for the abdomen using the Dexcom G7 in adults with diabetes.[26] The reasons for the differences between these studies remain unclear. Factors such as the CGM devices used, ethnicity, and subcutaneous fat thickness at the wearing sites may contribute to these differences.

Despite these findings, several limitations should be considered when interpreting the results of this study. First, the proportion of T2D participants (75%) was higher than the share for other CGM performance studies. Despite the promising accuracy observed in the T1D population, the small sample size remains a limitation. Further validation in a larger T1D cohort is needed. Second, the study did not include a structured hyperglycemic challenge. However, the collected hyperglycemic data points met the requirements for paired samples specified by the Chinese CGM guidelines[30] and the IFCC Working Group[31] (which requires ≥ 7.5% of comparator values > 300 mg/dL). But the evaluation of performance during rapid glucose changes was limited. More comprehensive glucose manipulations will be needed in future studies. Third, this study tested only a single batch of the product. Its stability across different batches and in large-scale commercial production remains unclear. Finally, pediatric and elderly populations were not represented. Future research should validate these findings in larger and more diverse populations.

Conclusions

In this prospective, multicenter study, the Anytime 5Pro CGM system demonstrated accurate, safe, and stable performance over a wear period of up to 16 days in individuals with diabetes, suggesting that the system may serve as a reliable tool for diabetes management.

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Author Disclosure Statement

G.Z. and Y.Z. are employees of Jiangsu Yuwell POCTech Biotechnology Co., Ltd. No other disclosures were reported.

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Supplementary Material

Supplementary Data

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